IV. Costs of Misdiagnosis, Adverse Events, and Abuse

To date, relatively little analysis has been conducted regarding the costs of misdiagnosis, adverse drug reactions with OTC products, and abuse of OTC products. The reason these areas remain unexplored is due to the difficulty of obtaining data. Publicly available information on these areas is not sufficiently detailed to attribute these instances to OTC drug use.

The issue of physicians moving patients to different Rx products when there is an Rx to OTC switch needs to be further analyzed. Bae’s work describes what has occurred in the H2 antagonist market. By analyzing data on entire drug classes such as vaginal cremes or H2 antagonists before and after the switch would allow us to assess the significance and profitability of this prescribing pattern. It is possible that overall costs of treating patients for a specific health problem increase if physicians substitute more expensive Rx products for the reclassified OTC products.

Direct-to-consumer advertising is a growing cost in the marketing of both Rx and OTC products. Companies are able to promote their Rx products to both patients and physicians using direct-to-consumer advertising. An analysis of the expenses incurred by individual pharmaceutical companies to market their products before and after OTC status will help us to understand the costs that go into the switch.

A survey of physicians may be the best approach to quantify the prevalence of misdiagnosis and symptoms of more serious conditions left untreated. Asking physicians about their experiences or concerns with overdosing, misdiagnoses, or other problems would help to quantify the costs to patients of switching products to OTC status.

It would be useful to investigate whether the number of adverse events has increased significantly after the products have been placed OTC. Such categories as vaginal cremes, H2 antagonists, dextromethorphan, and acetaminophen are examples of products to examine for these experiences.

V. Conclusion

Switching pharmaceutical products from Rx to OTC will increasingly become an important public policy issue in the U.S. and elsewhere given improved access to information about health care alternatives, expanded roles of pharmacists in delivering health care, and identified policies to control health care costs. Changing the regulatory environment in the U.S. to accommodate switching broader classes of pharmaceutical products must balance the benefits and risks. Most prior discussions of switching have focused on the benefits. In terms of risks, the out of pocket costs to patients may increase, misdiagnosis of health problems may occur, adverse events may be unreported, and abuse may increase. Regulators should seek to quantify these risks when revising or modifying the process for switching products from Rx to OTC status to avoid adopting policies that may increase overall health care costs.

Trade, Investment and Risk

This section highlights the interface between international trade and investment law and municipal and international risk regulation. It is meant to cover cases and other legal developments in WTO law (SPS, TBT and TRIPS Agreements and the general exceptions in both GATT 1994 and GATS ), bilateral investment treaty arbitration and other free trade agreements such as NAFTA. Pertinent developments in international standardization bodies recognized by the SPS and TBT Agreement are also covered. Risk regulation refers broadly to regulation of health, environmental, financial or security risks.

Of recurrent interest in this area are questions of whether precautionary policies can be justified, the extent to which policy can and should influence risk regulation and the standard of review with which international judicial and quasi-judicial bodies assess scientific evidence.

Sustainability Requirements for Biofuels in the EU: A New Trade and Environment Concern for the WTO?

Eugenia Laurenza*

1. Introduction

At the meeting of the WTO Committee on Technical Barriers to Trade (hereinafter, TBT Committee) held...
on 13–14 June 2012, Argentina voiced its concerns over a measure adopted by Spain restricting imports of biodiesel products into its territory. These concerns were reiterated, jointly with Indonesia, at the meeting of the WTO Council for Trade in Goods of 22 June 2012. On 17 August 2012, Argentina filed a request for WTO consultations with the European Union (hereinafter, the EU) and Spain, targeting Spain’s restrictions.

The Spanish measure at issue is Ministerial Order IET/822/2012 (Orden IET/822/2012, de 20 de abril, por la que se regula la asignación de cantidades de producción de biodiesel para el cálculo del cumplimiento de los objetivos obligatorios de biocarburantes), which was published on 21 April 2012 and entered into force on 22 April 2012. This measure implements a system for the allocation of biodiesel production volumes for the computing of compliance with the targets put forward by Directive 2009/28/CE of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (hereinafter, Renewable Energy Directive). Argentina claims that the measure at stake has trade distortive effects by prohibiting de facto the importation of biodiesel from outside the EU, particularly from Argentina, which is the biggest exporter to Spain. According to Argentina, the measure is, in itself, discriminatory and targeted to its exports to Spain.

II. Background

The Renewable Energy Directive establishes a common framework for the promotion of energy from renewable sources in the EU by, inter alia, setting mandatory national overall targets and measures for the use of energy from renewable sources in order to reduce emissions and to achieve the EU’s climate change and energy policy objectives. It introduces sustainability criteria for biofuels (and bioliquids), based on the life cycle greenhouse gas emissions of biofuels and the characteristics of the land used to produce them. Biofuels that do not meet the sustainability requirements can still be imported and marketed in the EU, but cannot be counted for compliance with renewable energy national targets and are not entitled to financial support. Spain’s legislation lays down the necessary conditions to be met by plants in order to participate in the allocation procedure of biodiesel production volumes for the computation of the mandatory objectives laid down by the EU regime. It provides that the holder of a plant willing to have its biodiesel computed for the purposes of the Renewable Energy Directive’s targets may request the allocation of an annual biodiesel production volume, provided that the plant is duly licensed. However, the wording of the Spanish measure suggests that only plants located in Spain or in the EU are entitled to request the allocation of a biodiesel production volume.

III. Argentina’s complaint

At the TBT Committee meeting, Argentina argued that Ministerial Order IET/822/2012 has a trade distortive effect, in that it de facto prohibits the importation of biodiesel from outside the EU, and particularly from Argentina, which is the biggest exporter of biodiesel to Spain. Because it only applies to biodiesel, Argentina claimed the measure to be discriminatory and effectively targeted at its biodiesel products. Argentina reportedly stated that its biodiesel, which is derived from soybeans, complies with EU sustainability criteria and is a “like product” to Spanish and EU biodiesel. As a result, Argentina argued that Ministerial Order IET/822/2012 violates the most favoured nation (hereinafter, MFN) treatment and national treatment principles under Article 2.1 of the TBT Agreement. Argentina also claimed that the Spanish measure fails to take account of the special developmental, financial and trade needs of developing country Members by creating unnecessary obstacles for exports from Argentina, in violation of Article 12.3 of the TBT Agreement. According to Argentina, the measure could not be considered as environmental in nature and, as a result, it constitutes a disguised measure adopted in order to target and penalise Argentina’s biodiesel industry. Reportedly, the EU argued that Spain’s Ministerial Order IET/822/2012 did not fall within the scope of the TBT Agreement and, therefore, it should not be addressed within the TBT Committee.

Some of these claims were formalised by Argentina in its request for WTO consultations with the EU. In the document filed on 17 August 2012, Argentina
argued that Ministerial Order IET/822/2012 would constitute an infringement of a number of WTO obligations, including, *inter alia*, Articles III and XI of the General Agreement on Tariffs and Trade (hereinafter, the GATT) and Articles 2.1 and 2.2 of the Agreement on Trade-Related Investment Measures (hereinafter, TRIMS Agreement). Argentina did not mention the TBT Agreement in its request for consultations, but it did reserve the right to include other alleged violations, as well as to extend those specified in the request, during the consultations phase.

IV. Comments

The TBT Agreement continues to provide a relevant instrument for the examination of the measures adopted by Spain and the EU. In particular, it applies to technical regulations, standards, and conformity assessment procedures that are aimed at determining compliance with technical regulations and standards. In order for an instrument to be considered a technical regulation within the meaning of the TBT Agreement, the WTO Appellate Body in *EC – Sardines* clarified that the measure at stake must: (1) apply to an identifiable product or group of products; (2) lay down product characteristics; and (3) provide that compliance with the product’s characteristics must be mandatory.\(^3\) Ministerial Order IET/822/2012, as well as the Renewable Energy Directive apply, respectively, to an identifiable group of products (*i.e.*, biodiesel and biofuels/bioliquids respectively). Arguably, they lay down characteristics related to the product, inasmuch as they ascribe a “sustainability” value to biodiesel based on process and production methods. Lastly, they are mandatory, inasmuch as they prescribe the conditions that biodiesel needs to comply with for purposes of being eligible against the Renewable Energy Directive’s targets and financial support. As recently established by the Panel and the Appellate Body in *US – Tuna II (Mexico)*,\(^4\) an instrument may be mandatory in a “negative” way, *i.e.*, when it is legally enforceable and it prescribes in a binding manner the requirements for a product to obtain a given authorisation: in this case, to be eligible to request the allocation of a biodiesel production volume under the Renewable Energy Directive.

Should the Renewable Energy Directive and Spain’s Ministerial Order IET/822/2012 implementing it qualify as technical regulations, then a potential violation of Articles 2.1 and 2.2 of the TBT Agreement may be established. In making its determination under Article 2.1 of the TBT Agreement, the Appellate Body in *US – Clove Cigarettes*\(^5\) adopted an interpretative approach based on both the TBT Agreement and Article III:4 of the GATT, stressing that “*likeness*” under Article 2.1 of the TBT Agreement is a determination of the “*nature and extent of a competitive relationship*” between the two products at issue (*i.e.*, in the case at stake Argentine biodiesel and EU biodiesel). If less favourable treatment is found with regard to Argentina’s biodiesel, this EU legal framework may conflict with Article 2.1 of the TBT Agreement. Article 2.2 of the TBT Agreement requires WTO Members to ensure that technical regulations are not prepared, adopted, or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade.

The determination that Argentina’s biodiesel products concern are “*like*” biodiesel products produced in the EU is crucial to a finding of inconsistency with the national treatment obligation, under the TBT Agreement as well as the GATT, which is also applicable. As a matter of fact, Argentina did not base its request for consultations on the TBT Agreement, but on the GATT and the TRIMS Agreement. According to the relevant WTO case law, there are four criteria that reflect the categories of characteristics that potentially “*like*” biodiesel products of Argentina and EU origin might share. These include: 1) the physical properties of the biodiesel; 2) the extent to which Argentine and EU biodiesel are capable of serving the same or similar end use; 3) the extent to which consumers perceive and treat the biodiesel as an alternative means of performing particular functions in order to satisfy a particular want or demand; and 4) the international classification of biodiesel for tariff purposes. From a preliminary legal assessment, it appears that none of these criteria would allow Spain and the EU to put in place measures of the kind that are to be developed under Ministerial Or-

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and under the Renewable Energy Directive. Unless the EU can prove that Argentina’s biodiesels are, in fact, not “like” EU biodiesels, they may not be treated less favourably on the basis of the environmental effects connected to their production processes. Consequently, Article III:4 of the GATT will provide a powerful shield to prevent Spain from discriminating against Argentina’s (or any other imported) biodiesel in favour of the EU production of the “like” biofuel.

V. Conclusions

The concerns raised by Argentina with regard to Spain’s Ministerial Order IET/822/2012 highlight the increasing frictions between multilateral trade and environmental measures. When such frictions occur, the WTO is the appropriate forum for tackling these trade concerns.

Argentina’s concerns focus on the allegedly discriminatory and trade-restrictive nature of the measure imposed by Spain, which de facto singles out Argentina’s exports of biodiesel. In fact, some argue that Spain’s Ministerial Order IET/822/2012 was taken in order to retaliate against Argentina’s move to nationalise Spanish Repsol’s stakes in Yacimientos Petrolíferos Fiscales, an oil company. According to Argentina, the Spanish measure cannot be considered as environmental in nature (that is, even if it implements the requirements under the Renewable Energy Directive) and, as a result, it constitutes a disguised measure adopted in order to target and penalise Argentina’s biodiesel industry.

The sustainability requirements under the Renewable Energy Directive (and the Fuel Quality Directive, which contains corresponding sustainability criteria for biofuels used for road vehicles) are likely to pose concerns among exporters to the EU and result in WTO dispute settlement. A WTO complaint lodged against Spain’s measure may call on the WTO to decide whether the EU sustainability criteria, as applied by Spain in the case at stake, are arbitrary in nature, discriminatory, unnecessarily cumbersome, scientifically unjustified and, ultimately, disguised restrictions on trade. In that perspective, it is perhaps a pity that Argentina’s request for consultations has left out the arguments on the alleged violation of certain obligations under the TBT Agreement. These arguments may still be made in the request for the establishment of a panel, if the case is not settled during consultations and Argentina decides to commence panel proceedings.

Environmental protection and the pursuit of sustainable production practices are legitimate and sacrosanct objectives, which are recognised by the WTO and should be pursued through multilateral instruments, but they must not become intentional or unintentional forms of protection or trade distortion and should always be based on the least trade restrictive measures available. Governments and stakeholders must work together to identify these measures, if necessary through flexible and creative policy-making, and ensure that neither the environment nor world trade become victims to their unilateral approaches.

The Ractopamine Dispute in the Codex Alimentarius Commission

Michael Burkard*

The dispute over ractopamine in the Codex Alimentarius Commission (CAC) exemplifies changes in Codex proceedings. In its early days, the CAC resembled an honourable Club of senior food safety officials aiming at setting food standards in a consensual manner. However, with the WTO connexion established in 1995, CAC proceedings are overshadowed by looming trade disputes and increasingly decided by majority voting. The tendency towards majority voting in the CAC may ultimately undermine the universality of food safety standards and the legitimacy of the CAC as an international standard setting body.

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