FRATINIVERGANO
EUROPEAN LAWYERS
TRADE PERSPECTIVES©

Issue No. 6 of 20 March 2015

New Zealand and the US file a request for the establishment of a WTO panel in *Indonesia – Importation of Horticultural Products, Animals and Animal Products*

On 18 March 2015, the Office of the United States Trade Representative (hereinafter, USTR) announced that New Zealand and the US filed requests for the establishment of a WTO panel in *Indonesia – Importation of Horticultural Products, Animals and Animal Products* (DS478). The US request (publicly available at the time of writing) challenges Indonesia's import measures under, in large part, two WTO agreements, namely, the General Agreement on Tariffs and Trade 1994 (hereinafter, GATT) and the Agreement on Agriculture (hereinafter, AoA).

The origin of the dispute actually dates back to 10 January 2013, when the US filed a request for WTO consultations in *Indonesia – Horticultural and Animal Products* (DS455). In that original dispute, the US complained against import measures on horticultural products, animals and animal products in Indonesia that, it alleged, violated the GATT, the AoA and the WTO Agreement on Import Licensing Procedures (hereinafter, IL Agreement). Two more separate requests for WTO consultations were filed by New Zealand and the US on 30 August 2013 (DS466 and DS465, respectively), where the complainants added claims under the WTO Agreement on Preshipment Inspection (hereinafter, PSI Agreement). Throughout the dispute, the Indonesian Government has remained receptive to the concerns raised by New Zealand and the US, going as far as voluntarily amending its laws and regulations to appease the complainants. However, Indonesia's efforts did not satisfy New Zealand and the US. The most recent request for the establishment of a WTO panel limits its substantive causes of action to Article XI:1 of the GATT and Article 4.2 of the AoA, though footnotes in the request also claim that Indonesia's import measures are inconsistent with Article III of that GATT and Articles 2 and 3 of the IL Agreement.

In the request for the establishment of a WTO panel published by the USTR, the US details its concerns with Indonesia's measures. With respect to horticulture products, the request takes issue with, *inter alia*: a six-month validity limit for imports, with limited periods of application prior to each import period; Indonesia's adherence to consistency requirements on importation documents and the associated type, quantity, country or origin and port of entry indications pertaining to relevant goods; prohibitions and restrictions on importation when the domestic market price of a good falls below a reference price set by a ministerial body; forms and applications that may limit the types and quantities of products specified for import; and potential restrictions on the post-entry use and sale of goods. With respect to animals and

animal products, the request lists similar concerns, including in part: limited validity periods for imports, with limited periods of application prior to each import cycle; Indonesia's adherence to consistency requirements on importation documents and the associated type, quantity, country or origin and port of entry indications pertaining to relevant goods; limits of certain types of animal products that may enter Indonesia; and prohibitions and restrictions on importation when the domestic market price of a good falls below a reference price set by a ministerial body.

According to Article XI:1 of the GATT, WTO Members may not institute or maintain any measures that act as "*prohibitions or restrictions other than duties, taxes or other charges*" on the importation of any product. In general, the term "*prohibitions and restrictions*" is interpreted relatively broadly, but the panel in *India – Autos* did note that the phrase suggests the need to identify not merely a condition placed on importation, but a condition that has a limiting effect. Article 4.2 of the AoA prohibits WTO Members from maintaining, resorting to, or reverting to any measures of the kind which have been required to be converted into ordinary customs duties. Types of measures that are required to be converted into ordinary customs duties include, *inter alia*, quantitative import restrictions, variable import levies, minimum import prices and discretionary import licensing. However, exceptions to both provisions can be found in Article XI:2 of the GATT and Article 5 of the AoA, respectively. Such exceptions include special safeguard provisions for designated products, and situations where restrictions are necessary for the purposes of applying international trade standards or where it is necessary to enforce certain government measures. In addition, at least with respect to the US claim that Indonesia's customs authorities are overly-restrictive regarding the consistency of import documentation relating to type, quantity, country of origin and port of entry characteristics of goods under Article XI:1 of the GATT, Indonesia may argue that such actions by its authorities are better characterised as allowable import formalities under Article VIII of the GATT.

The dispute, which has been ongoing for over two years, could have a sizable effect on the countries involved. The Indonesian market is one of the largest in Asia and its population continues to grow. New Zealand has a large beef and beef offal industry, and has much benefited from the Indonesian market. The US, on the other hand, appears interested in increasing its agricultural exports to Indonesia. Even though Indonesia has amended its laws and regulations following multiple WTO consultations with both New Zealand and the US, the complainants continue to seek additional modifications. Food and agricultural issues have been a continued source of debate and even disputes in light of conflicting perspectives from developed and developing countries. The record of protracted consultations is an indication that the parties to the dispute have long sought a mutually satisfactory solution and, also, that the allegations are not so clear cut and, presumably, legally strong to deliver through dispute settlement. Hopefully, a solution will be found without resorting to full-fledged WTO dispute settlement and to the protracted degree of uncertainty that operators face during the various stages of WTO litigation.

The EU continues its work under the biocidal products framework

On 11 March 2015, the EU Commission adopted two implementing regulations approving two active substances (*i.e.*, '*Bacillus thuringiensis subsp. israelensis serotype H14, strain SA3A*' and '*Propan-2-ol*') for biocidal products having specific uses. The EU Commission's approval means that business operators may now request an authorisation to market biocidal products containing such substances in the EU or any of its Member States.

Biocidal products (or biocides) are chemicals used to suppress organisms (such as pests and germs) that are harmful to human or animal health, or that cause damage to natural or manufactured materials. Because of their intrinsic properties and use patterns, biocides can

pose risks to humans, animals and the environment. For this reason, the placing on the market of biocidal products is regulated and subject to authorisation, and the active substances contained therein must be previously approved. Examples of biocidal products include insect repellents, disinfectants and industrial chemicals, such as anti-fouling paints for ships and material preservatives. Since September 2013, the placing of biocides on the EU's market is governed by *Regulation (EU) No. 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products* (hereinafter, the *Biocidal Products Regulation*). The *Biocidal Products Regulation* aims at improving the free movement of biocides in the EU's market, while ensuring a high level of protection for humans and the environment. With a view to remove obstacles to trade, but mindful of the precautionary principle, it lays down rules on the approval of active substances and the making available on the market and use of biocides.

In order to have an active substance approved, the concerned operator must submit an application before the competent authority in an EU Member State, which makes an initial evaluation of the form and substance of the submission and forwards the results to the European Chemicals Agency (hereinafter, ECHA). The ECHA prepares an opinion that, in turn, serves as a basis for the EU Commission to decide whether to approve the specific active substance. If the outcome is positive, the approval will be operative for a limited time period (no more than 10 years) and will be renewable. After an active substance is approved, businesses may file requests to market biocidal products containing such substance. The two recent implementing regulations mentioned above relate to the process of active substance approval. Following the submission of the relevant applications by the concerned private operators in Italy and Germany, the files were evaluated by the competent national authorities, which forwarded their assessment reports and recommendations to ECHA. ECHA's Biocidal Products Committee issued its opinions in June 2014 (in both cases, concluding that the relevant active substances may be approved) and, against the backdrop of those assessments and opinions, the EU Commission has now granted its approval.

For the approval and authorisation of active substances and biocides, the *Biocidal Products Regulation* relies, at least partly, on other pieces of EU legislation. In fact, together with the *Plant Protection Products Regulation* (*i.e.*, *Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC*), the *Biocidal Products Regulation* requires that, by December 2013, the EU Commission must have established scientific criteria for the determination of endocrine-disrupting properties. Active substances and biocides that, on the basis of such criteria, are considered to have endocrine-disrupting properties will be automatically excluded from approval and market authorisation, respectively. In addition, the identification of these criteria is set to produce effects on a number of other EU instruments (in the field of, *inter alia*, cosmetics, medical devices and water) that rely on the establishment of such scientific criteria for several purposes (see Trade Perspectives, Issue No. 22 of 28 November 2014).

These criteria have not yet been defined and, as of March 2015, the EU Commission is conducting an impact assessment for the definition of criteria to identify endocrine disruptors. Considering that these criteria stand to be ultimately used a basis to allow or prevent the marketability of biocides on the EU's market, it is clear that any approach will need to be in line with the EU's international trade obligations, including those under the WTO framework. In particular, the WTO Agreement on Sanitary and Phytosanitary Measures requires that measures be based on a risk assessment, that they be applied to the extent necessary to protect human, animal or plant life or health, that they be based on scientific principles and that they not be maintained without sufficient scientific evidence. Parallel obligations are in place under the WTO Agreement on Technical Barriers to Trade, which could also be applicable, in particular with respect to non-agricultural products.

The EU's failure to timely fulfil its obligations with regards to endocrine disruptors contrasts with the (apparently) smooth functioning of other aspects of the *Biocidal Products Regulation*, as evidenced by, *inter alia*, the two implementing regulations above. In addition, work is ongoing to ensure that, as required by the *Biocidal Products Regulation*, biocides only be made available on the market after 1 September 2015 if the relevant active substance is sourced from a supplier included in the relevant list. Diligent operators must adapt their practices to the legal requirements but, simultaneously, have a right to expect that authorities do the same. Considering the significant commercial impact of the definition of criteria to identify endocrine disruptors on (*inter alia*) the biocides sector, operators with an interest on the matter are encouraged to closely monitor all developments, and to coordinate with the relevant authorities in order to ensure that their interests are duly taken into account.

German '*probiotic*' baby food court battle over trademarks as '*health claims*' and transitional use of existing trademarks

On 26 February 2014, the German Federal Court of Justice (*Bundesgerichtshof*, hereinafter, BGH) held, in the case *Hipp* v. *Milupa* (I ZR 178/12), that trademarks can be health claims under *Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods* (hereinafter the Nutrition and Health Claims Regulation, NHCR). The BGH, therefore, confirmed the broad interpretation of the term '*health claim*'. Products bearing trademarks that existed before 1 January 2005 and that do not comply with the NHCR may continue to be marketed until 19 January 2022. On 15 January 2015, the Frankfurt/Main Higher Regional Court (hereinafter, OLG Frankfurt) handed down a new judgment in the proceedings between *Hipp* and *Milupa* (6 U 67/11), relating to the question as to whether a trademark had to be used with the identical and unchanged food product before January 2005 to fall under the transitional rule, or whether changes to the product were permissible.

Both parties of the litigation, *Milupa* (of the Danone Group) and *Hipp* (a German group present in over 50 countries), are major baby food manufacturers. Until 2012, Hipp sold products containing *Galactooligasaccharides* as a prebiotic component and the bacterium *Lactobacillus fermentum hereditum* as a probiotic component, with the label '*Praebiotik*® + *Probiotik*®'. Since 1999, *Praebiotik*® and *Probiotik*® are registered trademarks for *Hipp*, while *Milupa* or other producers of baby food are not permitted to use the terms Praebiotik and Probiotik for their products. On the products' labels, *Hipp* made the following statements (translated into English): '*Praebiotik*® + *Probiotik*® + *with natural lactic acid cultures* + *Praebiotik*® *for support of a healthy intestinal flora*'.

The NHCR defines a health claim in Article 2(2)(5) thereof as any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents, and health. Food business operators are not free to make any health claim for marketing their food products. Only those health claims are permitted, which are listed in an EU list adopted by the EU Commission based on generally accepted scientific evidence. If a food business operator desires to use an unlisted health claim, it may apply for the inclusion of the claim on the approved list. Article 1(3) of the NHCR states that a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food, which may be construed as a nutrition or health claim, may be used without undergoing the authorisation procedures required under the NHCR, provided that it is accompanied by a related nutrition or health claim, which complies with the NHCR.

Commission Regulation (EU) No. 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health provides for a positive list of so-called general function claims (see Trade Perspectives Issue No. 16 of 7 September 2012). After 14 December 2012, only health claims that are on this list are permitted. So far, not a single specific probiotic claim

has received a favourable opinion from EFSA and a formal approval by the EU Commission, even though arguably substantial scientific evidence is available supporting probiotics' benefits.

The '*probiotic*' baby food court battle started in 2010 with proceedings between the competitors *Milupa* and *Hipp* before the Frankfurt/Main Regional Court (Landgericht Frankfurt, LG Frankfurt). In the judgment of 23 March 2011 (6 O 568/10), *Milupa* succeeded and the claims '*Praebiotik*® + *Probiotik*®' were considered unlawful claims under the NHCR. However, in the judgment of 9 August 2012 (6 U 67/11), *Hipp*'s appeal before the OLG Frankfurt was successful in that the terms '*Praebiotik*® and *Probiotik*®' were considered permissible as mere references to ingredients of the baby food (and not as health claims).

In the revision of 26 February 2014, the BGH ruled that both declarations (*i.e*., the trademarks Praebiotik® and Probiotik®, as well as with the slogan '*Praebiotik*® + *Probiotik*® *with natural lactic acid cultures - Praebiotik*® *for the support of a healthy intestinal flora'*) are health claims. Regarding the use of the trademarks *Praebiotik*® and *Probiotik*®, the BGH held that an average consumer would not simply understand this labelling as an objective description of quality or contents, as had been assumed by the OLG Frankfurt. The average consumer would interpret it rather as a reference to the prebiotic and probiotic characteristics (*i.e.*, the ability to stimulate natural intestinal function and the body's own defence system). Therefore, the BGH concluded that the terms '*Praebiotik*® + *Probiotik*®' had to be considered as a health claims according to Article 2(2)(5) of the NHCR since they suggest that there is a relationship between the baby milk and a baby's health.

With this decision and its broad interpretation of the term '*health claim'*, the BGH confirmed previous decisions on this topic. On 6 September 2012, in case C-544/10 *Deutsches Weintor e.G.*, the Court of Justice of the European Union (hereinafter CJEU) ruled that it is apparent from the wording of Article 2(2)(5) of the NHCR that the starting-point for the definition of a '*health claim*' is the relationship that must exist between a food or one of its constituents and health. The CJEU noted that the definition provides no information as to whether that relationship must be direct or indirect, or as to its intensity or duration. In those circumstances, the CJEU concluded that the term '*relationship*' must be understood in a broad sense.

Concerning the entire statement '*Praebiotik*®*+Probiotik*® + *with natural lactic acid cultures* + *Praebiotik*® *for support of a healthy intestinal flora*', the BGH ruled that this claim was not permitted and ordered *Hipp* to stop using it. As regards the claim '*Praebiotik*® + *Probiotik*®', the BGH remanded the matter to the previous instance (OLG Frankfurt) in order to verify whether the claim was already in use before January 2005. According to Article 28(2) of the NHCR, products bearing trademarks or brand names existing before 1 January 2005, which do not comply with the NHCR, may continue to be marketed until 2022. As the CJEU stated on 18 July 2013 in its judgement in case C-299/12 '*Green-Swan Pharmaceuticals*', the trademark has to be used with the particular food product in question before January 2005 to justify the application of the transitional provision. It is not sufficient that the trademark only existed. The BGH also raised the additional question as to whether the trademark had to be in use with the identical and unchanged food product before January 2005, or whether changes to the product (*e.g.* changes corresponding to a normal life cycle management) were permissible. The BGH ruling also appears to be in line with the EU Commission's interpretation given in section III.1. of the '*Guidance on the implementation of Regulation (EC) No. 1924/2006*', where the statement '*contains probiotics/prebiotics*' is classified as a health claim in that the reference to '*probiotic*' and/or '*prebiotic*' implies a health benefit.

After revision and referral, on 15 January 2015, the OLG Frankfurt cancelled its previous judgment and ruled that the illegal health claims *Praebiotik*® and *Probiotik*® may not be exceptionally used for baby food as part of a continued use under Article 28(2) of the HCVO. For a continued use to exist, these designations needed to have been used before 1 January

2005 for a food that essentially corresponds to the product marketed today. This was not the case with food supplements for adults on the one hand and baby food on the other side. The OLG Frankfurt again permitted a revision to the BGH, which would be the fifth judicial instance in the case *Hipp* v. *Milupa*.

Besides the battle before German courts, the term '*probiotic*' could make a re-appearance on certain products, if Italy is successful in getting approval for its use as a '*generic descriptor'* according to its application of June 2014 to the EU Commission. Pursuant to Article 1(4) of the NHCR, specific generic descriptors that have traditionally been used to indicate a particular class of foods or beverages, which could imply an effect on health, may be exempted from the application of the NHCR following a request by the food business operators concerned. On 20 September 2013, the EU Commission adopted *Regulation (EU) No. 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations)* (see Trade Perspectives, Issue No. 20 of 31 October 2013). The Yoghurt & Live Fermented Milks Association (YLFA), together with the Italian Dairy Association (Assolatte) and the Italian Food Supplements Association (AIIPA), are behind the Italian application for approval of the term '*probiotic'* as a generic descriptor based on the fact that the general descriptive term '*probiotic*' had been used in Italy for over 20 years. The application involved discussions in the EU's Standing Committee on the Food Chain and Animal Health (SCoFCAH). There is no formal deadline for issuing a final opinion. The relation between generic descriptors and trademarks appears to be another potentially litigious matter.

Two main conclusions arise (so far) from the German *probiotic* baby food battle. For claims related to trademarks, a consistently broad interpretation of the term '*health claim*' appears to emerge in the courts of the EU and its Member States. Second, for a continued use of a trademark as health claim until January 2022, under Article 28(2) of the HCVO, these designations need to have been effectively in use before 1 January 2005 for a food that essentially corresponds to the product being marketed today. However, in relation to the second point, the OLG Frankfurt permitted an appeal to the BGH. It remains to be seen whether a revision against the judgment of the OLG Frankfurt has been filed in time (*i.e.*, one month after notification). Given the substantial commercial interests at stake, aside from the legal and systemic interpretative issues, interested operators should be actively involved in monitoring the state-of-play at EU and relevant Member States' level so as to timely take the appropriate administrative and industrial actions that may be required.

Recently Adopted EU Legislation

Trade Remedies

- *Commission Implementing Regulation (EU) 2015/409 of 11 March 2015 amending Council Implementing Regulation (EU) No. 917/2011 imposing a definitive anti-dumping duty and collecting definitely the provisional duty imposed on imports of ceramic tiles originating in the People's Republic of China*

- *Commission Implementing Regulation (EU) 2015/395 of 10 March 2015 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 slightly modified molybdenum wires, and making such imports subject to registration*

- *Commission Implementing Regulation (EU) 2015/392 of 9 March 2015 terminating a 'new exporter' review of Council Implementing Regulation (EU)*

No. 1389/2011 imposing a definitive anti-dumping duty on imports of trichloroisocyanuric acid originating in the People's Republic of China, re-imposing the duty with regard to imports from the exporter and terminating the registration of these imports

Customs Law

- *Commission Implementing Regulation (EU) 2015/428 of 10 March 2015 amending Regulation (EEC) No. 2454/93 and Regulation (EU) No. 1063/2010 as regards the rules of origin relating to the scheme of generalised tariff preferences and preferential tariff measures for certain countries or territories*

Food and Agricultural Law

- *Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory*

- *Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution*

- *Council Decision (EU) 2015/423 of 6 March 2015 establishing the position to be adopted on behalf of the European Union within the seventh meeting of the Conference of the Parties to the Rotterdam Convention as regards the amendments of Annex III to the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade*

Other

- *Commission Regulation (EU) 2015/402 of 11 March 2015 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health*

- *Commission Regulation (EU) 2015/391 of 9 March 2015 refusing to authorise certain health claims made on foods and referring to children's development and health*

- *Council Decision (EU) 2015/451 of 6 March 2015 concerning the accession of the European Union to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)*

Ignacio Carreño, Eugenia Laurenza, Anna Martelloni, Blanca Salas, Bruno G. Simões and Paolo R. Vergano contributed to this issue.

FratiniVergano specializes in European and international law, notably WTO and EU trade law, EU agricultural and food law, EU competition and internal market law, EU regulation and public affairs. For more information, please contact us at:

FRATINIVERGANO
EUROPEAN LAWYERS

Rue de Haerne 42, B-1040 Brussels, Belgium Tel.: +32 2 648 21 61 - Fax: +32 2 646 02 70
www.FratiniVergano.eu