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Chile adopts warning statements in the form of a black STOP sign for ‘HFSS foods’ (i.e., foods high in fat, salt or sugar)**I. Introduction**

On 26 June 2015, the Chilean Official Journal published Decree No. 13 of 16 April 2015 (hereinafter Decree 13/2015) amending Decree 977/1996 *Reglamento sanitario de los alimentos* (hereinafter, the *Food Health Regulation*, as it is widely referred to in English, although the correct translation would be *Food Sanitary Regulation*). In particular, Decree 13/2015 requires warning messages in the shape of a black octagon in the form of a STOP sign to be placed on the front-of-pack with the text ‘*High in...*’ when food products exceed certain levels of energy, sodium, sugars or saturated fats. Although novel in the food sector, Chile’s measure is part of a trend of public policies aimed at tackling lifestyle risks by conveying certain information to the public. While warning messages that reduce the visual appeal of the packaging of products are ubiquitous in the tobacco sector, these types of messages are now also gradually being extended to the alcohol and food sectors.

II. Background

On 6 July 2012, Chile published Law No. 20,606, which is titled *Ley sobre Composición Nutricional de los Alimentos y su Publicidad* (i.e., Law on the Nutritional Composition of Food and its Advertising, hereinafter Law No. 20,606). Law No. 20,606 is justified by a public health objective and driven through Chile’s *Elige Vivir Sano* (i.e., Choose Healthy Living) programme, which aims at reducing consumption of so-called ‘critical’ nutrients. According to the Ministry of Health, through its policies, Chile seeks to respond to an increasing obesity rate and a widespread lack of consumer consciousness, caused, in part, by the fact that Chileans are moving to cities, consuming more processed food and leading lives that are more sedentary. In fact, Chile ranks among the top five OECD (i.e., Organisation for Economic Cooperation and Development) countries with the highest prevalence of diabetes and has the world’s sixth highest obesity rate, with 25% of Chileans being obese, and rising obesity in children, according to the Ministry of Health.

The most controversial point of Law No. 20,606 is its Article 5, which states that foods that “*have in their nutritional composition high levels of calories, fat, sugar, salt or other ingredients*” (to be eventually determined by implementing regulations) should be labelled

'*high in calories*', '*high in salt*', etc., or carry equivalent denominations. Under Article 5, the Ministry of Health must determine in regulations the limits of such ingredients, as well as the shape, size, colour, proportions, characteristics and content of the labels. Food manufacturers and importers must ensure that the information on the label of their products be complete and accurate and that the process of preparing the food complies with good manufacturing practices ensuring food safety. According to Article 6 of Law No. 20,606, foods bearing warning messages are prohibited from sale and promotion at elementary and high schools. This instrument also regulates food advertising and, in this sense, expressly prohibits advertising of products, referred to in Article 5, that are targeted at children under 14, as well as the use for such products of commercial hooks that attract children (such as gifts, contests or games, *inter alia*). Law 20,606 also requires that all food advertising in mass media be accompanied by a message (to be determined by the Ministry of Health) promoting a healthy lifestyle.

In recent years, measures implementing Law No. 20,606 have been discussed at the national level in Chile (in public consultations) and, at the international level, in the context of the WTO Committee on Technical Barriers to Trade (hereinafter, TBT Committee). On 16 January 2013, Chile notified members of the WTO TBT Committee of a proposed amendment to the *Food Health Regulation* implementing Law 20,606 under Article 2(10)(1) of the WTO Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement). This provision requires that WTO Members, upon adoption of a technical regulation, notify immediately other Members through the WTO Secretariat of the particular technical regulation and the products covered, with a brief indication of the objective and the rationale of the technical regulation, including the nature of the urgent problems. At the meeting of the TBT Committee of 5-7 March 2013, certain WTO Members (in particular the US, Mexico and the EU, but also Argentina, Guatemala, Peru, Canada and Colombia) expressed their support for Chile's public health objectives of reducing obesity and related non-communicable diseases (hereinafter, NCDs), but raised concerns regarding Chile's proposed amendments to its *Food Health Regulation*. The reason was that, according to the proposal, certain categories of food would need to bear labels informing and encouraging consumers to avoid excessive intake of certain nutrients that may lead to obesity and related NCDs. Moreover, products containing a critical amount of certain nutrients (e.g., fat, sugar and salt) would have to bear labels such as '*high in salt*', '*high in calories*' or equivalent warnings. According to the proposal, these warnings would need to be placed in the middle of an octagonal icon (*i.e.*, a STOP sign) occupying no less than 20% of the main surface of the package, be located in the upper right corner, and have a size of at least 4 square centimetres. WTO Members claimed that the amendment was not based on the relevant guidelines of the FAO/WHO Codex *Alimentarius* (hereinafter Codex); that WTO principles relating to the preparation of technical regulations, such as transparency, proportionality and scientific basis, had been breached; and that the measure would create unnecessary obstacles to international trade.

WTO Members use meetings of the TBT Committee to flag and discuss concerns about technical regulations affecting products and services that they believe hinder international trade and adversely impact competitive opportunities. Regulations concerning food and beverages (in particular, restrictive labelling and packaging measures, product standards, and marketing and sales restrictions) are often the subject of specific trade concerns at these meetings. WTO Members often question the evidence supporting the specific measures and inquire about the possibility of adopting less restrictive alternative measures to ensure, as required by the relevant WTO agreements, that technical regulations be not more trade restrictive than necessary. Only representatives of WTO Members attend TBT Committee meetings, which are, however, opportunities for the relevant industries (e.g., the food industry) to engage with their respective governments and provide supporting technical and factual information.

The concerns voiced by numerous WTO Members (*i.e.*, Brazil, Mexico, Guatemala, the EU, the US, Switzerland, Australia, Argentina, Canada, Colombia and Costa Rica) at the WTO TBT Committee meeting of 30-31 October 2013 appeared to be successful in '*watering down*' Chile's measure. On 17 December 2013, Chile published Decrees No. 12/2013 and 28/2013 of the Ministry of Public Health implementing Law 20,606. Decree No. 12/2013 amending the *Food Health Regulation* was the most remarkable, in that it set out the limits of critical nutrients for different food categories and defined the characteristics of the warning statements when these limits are exceeded. In turn, Decree No. 28/2013 approved the "*Manual of graphic standards of healthy living messages in food advertising*" (associated with the "*Choose Healthy Living*" educational campaign). Both decrees were to take effect six months after their publication, with one important exception, *i.e.*, the obligation to introduce warning statements on products exceeding the regulatory limits should gradually enter into force, according to the following deadlines: six months after publication for saturated fat, one year for sugar and eighteen months for sodium and calories. As compared to the Government's initial proposal, these amendments toned down the shape of the labels and reduced the number of covered products. In particular, the big black octagon became a smaller hexagon with the possibility for operators to choose among red, blue or green warning statements. In addition, the regulatory limits for calories, saturated fat, sugar and sodium were no longer called '*critical limits*' and they had to be indicated per portion and not per 100g.

However, a few days before Decrees No. 12/2013 and 28/2013 entered into force, on 14 June 2014, Chile's Official Journal published a modification of said decrees (by Decrees No. 102/2014 and No. 103/2014), which postponed their entry into force until 30 June 2015, citing a number of weaknesses in the published texts that required a comprehensive review. *Inter alia*, it was argued that the application in its current form could confuse consumers, including that a green label stating a product is '*high in sugar*' could appear to be a positive message.

The revisions were eventually implemented, first, with respect to Decree No. 12/2013, on 19 August 2014, through a new proposal amending the *Food and Health Regulation* and calling for public consultations. On 22 August 2014, Chile notified this proposal to the TBT Committee with 60 days for comments. The new proposal simplified the scope and the classification of food products for purposes of defining the limits of energy, saturated fat, sugars and sodium. The scope covers foods and food products, with a number of exceptions including foods when their content in certain nutrients is equivalent to the one contained in its 'natural' state. According to Chile's food industry sources, this will affect 90% of the food, while Chile's Government admits that it affects 60%. In regards to the classification, the proposal made only a distinction between solid and liquid foods. The limits were again indicated per 100g instead of per portion (*e.g.*, 4g/100g of saturated fats in solid food and 3g/100g of saturated fats in liquid foods). The rules on the graphic characteristics of the warning symbol were again modified, *i.e.*, a black octagon is prescribed with the wording '*excess in ...*' instead of '*high in ...*' for each relevant nutrient exceeding its respective limit (whereas, in the original version, two or more nutrients could be grouped in one symbol). Under the new proposal, the text '*Ministry of Health*' must appear underneath this wording. The provisions of the new draft were supposed to enter into force six months after its publication without exception (*i.e.*, thereby deleting the gradual escalation of the obligations to label the different nutrients). The proposal was assessed and discussed at the TBT Committee meetings on 5-6 November 2014 and 18-19 March 2015. In this context, WTO Members recalled the concerns voiced in previous meetings and noted the legal uncertainty created by Chile's successive modifications to its draft text.

At the TBT Committee meeting of 17-18 June 2015, Chile announced that, on 13 April 2015, its President and the Minister of Health had signed the relevant decree. Chile clarified that the decree had been subsequently transmitted to the office of the Comptroller General, with a view to assess its overall legality in light of Chile's legal framework. However, on 16 June 2015, the Ministry of Health withdrew the decree in order to make a number of amendments.

At the meeting, Chile noted that an amended decree would be notified to the TBT Committee by means of an *addendum* to the original notification and indicated that it expected that an amended decree be available by the end of June 2015.

Finally, on 26 June 2015 (*i.e.*, only a few days after the meeting), Chile's Official Journal published Decree No. 13/2015 of 16 April 2015 amending the *Food Health Regulation*. Decree No. 13/2015 repeals Decrees No. 12 and No. 28 of 2013, as modified by Decrees No. 102 and No. 103 of 2014, and its main provisions are set to enter into force on 27 June 2016. Decree No. 13/2015 provides, in particular, that the mention of '*high in ...*' be again incorporated (instead of '*excess in ...*') in an octagon with black background. The limits triggering the '*high in ...*' labels will be lowered (*i.e.*, made stricter) over time. For example, as of 27 June 2016, solid food with 22.5g/100g of sugar (and liquid foods with 6g/100g) will need to be labelled with a black octagon, which states '*high in sugar*', while as of 27 June 2017, this obligation will already apply to solid foods containing 15g/100g of sugars (and liquid foods containing 5g/100g). As of 27 June 2018, '*high in sugars*' labels will be required for solid foods containing 10g/100g of sugars (and liquid foods containing 5g/100g). In a similar way, the limits for energy, sodium and saturated fats in solid and liquid foods will be tightened over the same period. Decree No. 13/2015 foresees that the size of warning statements be proportional to the area of the main surface of the label (as opposed to the main surface of the packaging as originally foreseen) and be approximately within a range of 4 to 7.5% of it. Moreover, the use of stickers is expressly permitted to (apparently) facilitate the adjustment of foreign companies that export food products to the Chilean market. In these points, including the less restrictive size of the additional warnings and less burdensome placement requirements, Chile appears to have made some concessions to other WTO Members and their food industries. This clearly shows the importance for businesses to follow WTO developments and to assist their governments in discussing specific trade concerns within the WTO.

III. Comment

With the publication of Decree 15/2015, which is set to enter into force in 2016, the '*saga*' of the Chilean warning messages for foods exceeding certain levels of energy, sodium, sugars and saturated fats appears to have ended (at least, for the time being). Chile appears to have addressed some of the other WTO Members' concerns, such as those related to the size of the warning messages (which are considerably smaller than in the original proposals) and the possibility to use stickers. However, the matter still raises a number of procedural and substantive legal questions. In particular, Chile's different measures may run counter not only to certain provisions of the TBT Agreement, but also to the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter, TRIPs Agreement). In relation to the procedure, the Chilean Government appears to have failed to comply with the transparency obligation set out in Article 2.9 of the TBT Agreement, inasmuch as Law No. 20,606 (which is the legal base for the amendments to the *Food Health Regulation*) was never notified to the WTO Secretariat. Arguably, Law No. 20,606 presents the characteristics of a technical regulation, as provided for in Annex 1 to the TBT Agreement. This provision states that a technical regulation is a document that lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. A technical regulation may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. In US – Tuna II (Mexico), the WTO Appellate Body established three criteria for determining whether a measure was a '*technical regulation*' in the sense of paragraph 1 of Annex 1 of the TBT Agreement, *i.e.*, (i) that the measure apply to an identifiable product or a group of products; (ii) that it lay down one or more characteristics of the product; and (iii) that compliance with the product characteristics be mandatory. These criteria are arguably met by Law 20,606.

According to Article 2.2 of the TBT Agreement, Members must ensure that technical regulations do not create unnecessary obstacles to international trade. For this purpose, technical regulations must not be more trade-restrictive than necessary to fulfil a legitimate objective (e.g., the protection of human health). It appears that the Chilean measure's objective could be addressed by more effective and less trade-restrictive public policies. Article 2 of Law No. 20,606 already establishes an obligation to provide nutritional information, and the rationale for imposing additional warnings is not clear. Other less trade-restrictive information measures (such as launching campaigns to encourage the population to eat healthily and promoting physical activity programmes) also appear to be available for Chile's consideration.

Article 2.4 of the TBT Agreement provides that technical regulations must be based on the relevant international standards. Section 5 of the Codex Guidelines on Nutrition Labelling (CAC/GL2-1985) recommends in relation to supplementary nutrition information that it should intend to increase consumers' understanding of the nutritional value of their food and that it should assist in interpreting the nutrient declaration. The Codex Guidelines on Nutrition Labelling state that the information contained in the nutrient declaration "*should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product*". In addition, these guidelines provide that the use of supplementary nutrition information on food labels should be optional and should only be given in addition to (and not in place of) the nutrient declaration. There are alternative approaches under the Codex guidance, which provide consumers with information to make appropriate dietary choices and reduce their risk of diet-related NCDs. For example, the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and the Codex Guidelines on Nutrition Labelling establish conditions for voluntary 'low', 'free', or 'no added' claims in tandem with mandatory nutrition labelling for energy and the nutrients fat, saturated fat, cholesterol, sodium, sugars (and consideration of trans fatty acids in countries where this nutrient is a public health concern).

Section 3.5 of the Codex Guidelines on Nutrition Labelling, concerning '*tolerances and compliance*', may also be relevant. It does not establish nutrient thresholds for the nutrients targeted by the Chilean legislation. In spite of evidence of a positive association between the intake of certain nutrients and the risk of developing a disease or disorder, there is no scientific evidence suggesting that there is an identifiable threshold above which the risk exists. On this basis, considering that they set such specific nutrient thresholds, Chile's measures would arguably contradict Section 3.5 of the Codex Guidelines on Nutrition Labelling. Additionally, the manner through which Chile's measures pursue their legitimate public health objective appears to be incompatible with the list of prohibited claims under section 3 of the Codex General Guidelines on Claims (CAC/GL 1-1979). For instance, Section 3.5 of these guidelines prohibits "*claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer*". 'High in' warnings, such as those in the Chilean legislation, should be avoided, as they are not foreseen by the applicable Codex guidelines on Nutrition Labelling, and they risk demonizing some foods whose consumption in moderation can be part of a healthy diet. In a hypothetical comparison to EU law, Chile's warning measures would be classified as '*non-beneficial*' nutrition claims. It must be noted that nutrition claims are by nature '*beneficial*' claims since the operator who places them on its products intends to highlight something nutritionally '*positive*'. This is the reason why '*non-beneficial*' nutrition claims (like '*rich in fat*') do not fall under the scope of the EU's Nutrition and Health Claims Regulation (NHCR). Nutrient profiles, which are comparable to the nutrient limits under Chile's legislation, have been discussed in the EU for a number of years, but an agreement appears unlikely to be reached anytime soon.

Intellectual property rights may also be affected by Chile's measures. Article 20 of the TRIPs Agreement provides that the "*use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings*". It has been argued at the TBT Committee that Chile's measure prohibiting the labelling and advertising (involving, for example, children's characters, animations, cartoons, animals and toys) for some products could have an impact on protected existing and future trademarks. On another note, the EU appears to consider that Chile's new rules, which affect a large number of products, could have a strong impact on trade flows and could be contrary to provisions of the EU-Chile Association Agreement concluded in 2002. Indeed, Article 18(1) of part I of the Agreement requires cooperation on standards, technical regulations and conformity assessment as a key objective in order to avoid and reduce technical barriers to trade and to ensure the satisfactory functioning of trade liberalisation.

As Chile has announced, the introduction of warning statements is only the first step. In fact, a proposal before the Chilean Parliament to amend Article 5 of Law 20,606 suggests that no foods be marketed where they exceed certain thresholds of fats, saturated fats, sugars and salt (*inter alia*, more than 10g/100g and more than 7.5g/100ml of sugar). On 12 November 2014, Chile has also been proposed to add to the prohibition to advertise '*unhealthy*' food when targeted at children under 14, the prohibition that advertising or publicity campaigns for any kind of '*unhealthy*' food be made at sports events. In a further move that beggars belief, the draft proposes to add to the *Food Health Regulation* the provision that salt dispensers may not be placed permanently on restaurants' tables or counters (unless the customer expressly requires one). Finally, on 7 May 2015, Chile introduced a new proposal amending Law 20,606 requiring that the labelling must also state whether the food is genetically modified or is free of such process. A possible mandatory '*GM-free*' wording would, in fact, be difficult to defend on nutritional grounds.

IV. Conclusions

There is presently a trend in South and Central America to introduce food related measures with a public health objective. In 2013, Mexico approved a tax of one peso (*i.e.*, about EUR 5 cents) per litre of sugary drink sold, in an attempt to battle the country's obesity crisis. Reportedly, other countries in South and Central America have imposed taxes and banned fast food chains from using toys to promote meals for children. In this regard, Peru, Uruguay and Costa Rica excluded '*HFSS foods*' from public schools in 2012, while Ecuador imposed a traffic light system for purposes of food labelling. On the other hand, a number of initiatives at the state- and city-level have been established in the US, although there is no specific national food and health policy targeting NCDs. Notably, the City and County of San Francisco recently adopted legislation requiring adverts for sugar-sweetened beverages to include the warning "*Drinking beverages with added sugar(s) contributes to obesity, diabetes and tooth decay. This is a message from the City and County of San Francisco*". This measure was reportedly challenged on 24 July 2015 by the American Beverage Association (ABA), arguing that the rules violate the First Amendment of the US Constitution.

Traffic signs '*alerting*' consumers about HFSS foods appear to have become popular in some countries. In addition to '*traffic light labelling*', there are now "*STOP*" signs. In the next months, interested parties should continue to carefully assess measures that may, although pursuing a public health objective, hinder trade and discriminate against certain products. This applies to Chile's warning statements, but also to what other WTO Members may propose or introduce. The TBT Committee is the appropriate venue, where WTO Members can voice the concerns of their food industry. In the case of Chile's warning messages, some elements like the size, proportions and products covered appear to have been toned down. There is also the

possibility to use stickers. However, a black Stop sign with the text '*High in...*' the respective nutrient is nonetheless required for a number of products. Chile's measure may be inconsistent with provisions of the TRIPs Agreement and certain provisions of the TBT Agreement, in particular, Article 2.2 thereof, which provides that technical regulations need not create unnecessary obstacles to international trade and Article 2.4, which requires that technical regulations be based on the relevant international standards (*i.e.*, in this case the Codex Guidelines on Nutrition Labelling; Codex Guidelines for Use of Nutrition and Health Claims and Codex General Guidelines on Claims). Businesses and economic operators must monitor the results of the TBT Committee's discussions and systematically assist their governments and WTO representatives to ensure that adopted measures are fully within WTO law and minimally trade distortive.

Recent actions at the international and domestic levels to combat illegal, unreported and unregulated fishing practices

On 2 July 2015, Australia became the thirteenth State or regional economic integration organization to deposit an instrument ratifying, accepting, approving or acceding to (*i.e.*, implementing) the Agreement on Port State Measures to Prevent, Deter and Eliminate Illegal, Unreported and Unregulated Fishing (hereinafter, the Port State Measures Agreement) of the Food and Agriculture Organization (hereinafter, FAO) of the United Nations (hereinafter, UN). The ratification of the Port State Measures Agreement by Australia is just one of a number of recent developments that illustrate a growing effort to improve fisheries governance throughout the world.

The term illegal, unreported and unregulated (hereinafter, IUU) fishing refers to fishing that: (1) lacks authorisation, does not comply with conservation and management measures developed by regional fisheries management organisations (hereinafter, RFMOs), or violates national laws or international obligations (*i.e.*, is illegal); (2) is not properly reported under international, RFMO or national laws and regulations (*i.e.*, is unreported); and (3) is performed by vessels with no national flag or that jeopardise fish stocks (*i.e.*, is unregulated). The Port State Measures Agreement is part of the institutional framework on fisheries governance at the international level. Other treaties and agreements include the 1982 UN Convention on the Law of the Sea, the 1995 UN Fish Stocks Agreement and the 1995 FAO Code of Conduct for Responsible Fisheries. The Port State Measures Agreement is intended to build on these previous global instruments to add the first set of binding minimum standards specifically intended to combat IUU fishing. However, in order for the Port State Measures Agreement to enter into force, 25 signatories must implement its measures into their domestic legislation. Currently, only 13 signatories have done so, which, in addition to Australia, include Chile, the EU, Gabon, Iceland, Mozambique, Myanmar, New Zealand, Norway, Oman, the Seychelles, Sri Lanka and Uruguay.

Along with efforts at the multilateral level, it appears as though major importers of fishery products have also recently made efforts to combat IUU fishing at the domestic level. For example, on 17 June 2014, US President Barack Obama established the Presidential Task Force on Combating Illegal, Unreported, and Unregulated Fishing and Seafood Fraud. On 15 March 2015, said Task Force released an '*action plan*' that articulates the steps that US federal agencies will take to implement IUU fishing measures. The action plan includes 15 recommendations for the US Government to improve its governance of fishing practices, which address issues relating to international relationships, enforcement, partnerships and traceability in the following areas: (1) port state measures; (2) best practices; (3) maritime domain awareness; (4) free trade agreements; (5) fishery subsidies; (6) capacity building; (7) diplomatic priority; (8) information sharing; (9) customs mutual assistance agreements; (10) species name and code; (11) state and local enforcement; (12) enforcement authorities; (13) a partnerships forum; (14) seafood traceability; and (15) risk-based traceability.

The EU has arguably been more proactive, where *Council Regulation (EC) No. 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No. 2847/93, (EC) No. 1936/2001 and (EC) No. 601/2004 and repealing Regulations (EC) No. 1093/94 and (EC) No. 1447/1999* (hereinafter, the EU's IUU Fishing Regulation) has been in force since 1 January 2010. The EU's IUU Fishing Regulation was implemented under *Commission Regulation (EC) No. 1010/2009 of 22 October 2009 laying down detailed rules for the implementation of Council Regulation (EC) No. 1005/2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing* and aims at ensuring that no fishery products, which were caught illegally, enter the EU market. The EU's framework to combat IUU fishing, in part, requires flag States to certify the origin and legality of fishery products in order to fully trace all fishery products on the EU market, as a way to enforce the international institutional framework on the governance of fishery products. If a country is unable to conform to international rules, the EU Commission first attempts to cooperate and assist said country to improve its legal framework and practices, *via* a 'card' system. If a country exporting to the EU is unable to certify the legality of its fisheries products, the EU Commission will 'pre-identify' said country as non-cooperating and open a 6-month formal dialogue to assist the country to improve its situation. This is referred to as being given a 'yellow card' by the EU Commission. If said country improves its situation, the 6-month dialogue is extended and can eventually lead to the 'pre-identification' status being removed, which is referred to as being 'green-carded'. However, if the 'yellow-carded' country does not adequately improve its situation, the Council of the European Union may formally identify it as being non-cooperative, and issue a 'red card'. The issuance of a 'red-card' results in a prohibition of fishery products imported directly or indirectly from a non-cooperating country (*i.e.*, this includes fishery products that are processed in a different country, but were caught by a vessel flying the flag of a 'non-cooperating' country), and even triggers a fishing ban for EU vessels operating in that country's waters.

According to the EU Commission, as of April 2015, 91 countries have notified it that they have put in place the necessary legal instruments, dedicated procedures and appropriate administrative structures for the certification of catches by vessels flying their flag. Over 30 countries have improved their systems to combat IUU fishing due to cooperation with the EU under the 'card' system. Current countries that the EU Commission has pre-identified as non-cooperating (*i.e.*, are currently 'yellow-carded') include Curacao, Ghana, Papua New Guinea, the Solomon Islands, Thailand, Tuvalu, Saint Kitts and Nevis, and Saint Vincent and the Grenadines. The previously 'yellow-carded' countries of Fiji, Panama, the Philippines, South Korea, Togo and Vanuatu were recently 'green-carded' following significant reforms to their fishery management systems. Belize, who had been 'red-carded', had its trade ban lifted in October 2014 after it demonstrated a commitment to reforming its legal system and adopting new fisheries management rules. On the other hand, trade bans are still in place *vis-à-vis* fishery products from Cambodia, Guinea and Sri Lanka following 'red cards' in 2014.

Of the countries listed above, Thailand has received notable attention, especially following comments by Gabriel Mato, Member of the European Parliament and rapporteur on the negotiations for the EU-Thailand Free Trade Agreement, which were formally launched on 6 March 2013 and are currently ongoing. MEP Mato stated that he would support the issuance of a 'red card' to Thailand if its situation does not improve by October 2015, when the EU Commission is set to evaluate any progress made during the 6-month 'pre-identification' period. Although the EU Commission did not formally 'yellow card' Thailand until April 2015, its informal dialogue with Thailand dates back to 2011. *Commission Decision of 21 April 2015 on notifying a third country of the possibility of being identified as a non-cooperating third country in fighting illegal, unreported and unregulated fishing*, which served as formal notice to Thailand that it had been 'pre-identified' as non-cooperating under the EU's IUU Fishing Regulation, described in detail the EU Commission's issues with Thailand's fisheries

monitoring, control and surveillance, including: (1) the recurrence of IUU vessels and IUU trade flows; (2) failure to discharge its duties under international law with respect to cooperation and enforcement efforts; and (3) failure to implement international rules. In addition, the EU Commission found that no tangible evidence existed to correlate Thailand's shortcomings in fisheries monitoring, control and surveillance with its status as a developing country. In response to the 'yellow card' issued by the EU Commission, Thailand introduced rules that, in part, require all fishing vessels to have licenses, registered fishing equipment and navigation systems. In early July 2015, fishermen in over one-fourth of Thailand's provinces went on strike to protest against what they consider to be overly-burdensome regulations. However, if Thailand were to be unable to satisfy the EU Commission, the consequences could be significant for the continued export opportunities of its fishery industry. Statistics provided by the Directorate General for Trade of the EU Commission indicate that Thailand exported EUR 646 million in fishery products to the EU in 2014. Global exports of fishery products for Thailand, according to the Thai Frozen Foods Association, reached approximately USD 3 billion in 2014.

Efforts against IUU fishing are likely to continue to increase in the coming years, as IUU fishing still accounts for at least 15% of fish catches per year (*i.e.*, 11 to 26 million tonnes of fish caught). The global value of IUU fishing is estimated to be EUR 8-19 billion per year. Businesses and Governments that rely on the export of fishery products should continually monitor their legal frameworks and implementation efforts in order to ensure that they are not at risk of being listed as 'non-cooperating' by major markets, such as the EU. Cooperation with relevant authorities is key, and solutions require a comprehensive legal and technical strategy, continuous engagement with the authorities of the importing countries, and well-conducted negotiation to ensure that the legitimate IUU objective can also factor-in the needs and constraints of producing countries' fishery sectors.

The EU Commission issued its report on the public consultation for the definition of the criteria to identify endocrine disruptors

On 24 July 2015, the EU Commission released its report on the public consultation to define criteria for identifying endocrine disruptors. The public consultation was launched on 29 September 2014 as part of an impact assessment carried out by the EU Commission to analyse different options for defining such criteria (see Trade Perspectives, Issue No. 22 of 28 November 2014). These criteria will have a direct impact on the framework for the authorisation and use in the EU of plant protection and biocidal products. They will also affect other areas of EU legislation containing specific provisions on endocrine disruptors.

The WHO's International Programme on Chemical Safety (WHO/IPCS) defines an endocrine disruptor as an "exogenous substance or mixture that alters function(s) of the endocrine system and consequentially causes adverse health effects in an intact organism, or its progeny, or (sub)populations". Provisions on endocrine disruptors are present in various pieces of EU legislation, although formal criteria for the identification of such substances have not been established. In relevant part, the Plant Protection Products Regulation (*i.e.*, Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC) and the Biocidal Products Regulation (*i.e.*, Regulation (EU) No. 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products) establish rules for the approval of substances considered as endocrine disruptors and provide that, by December 2013, the EU Commission must establish scientific criteria for the determination of endocrine disrupting properties (pending the adoption of such criteria, *interim* criteria apply). Provisions on endocrine disruptors are also included in other EU legal instruments regulating the marketing and use of chemical substances (in the field of, *inter alia*, cosmetics, medical devices and water). These

provisions envisage, *inter alia*, a review of the regulation regarding endocrine disrupting properties (in the case of cosmetics); design, manufacture and labelling requirements (concerning medical devices); and the consideration of certain substances as main pollutants (with respect to water).

One of the key aspects of the ongoing process is determining whether the criteria for the identification of endocrine disruptors should be hazard-based or risk-based. These two drivers are broadly reflected in the four policy options that the EU Commission is considering, which are contained in a roadmap adopted in June 2014: 1) no specific criteria for endocrine disruptors (the *interim* criteria set in the Plant Protection Products Regulation and in the Biocidal Products Regulation would continue to apply); 2) use of the WHO/IPCS definition to identify endocrine disruptors; 3) use of the WHO/IPCS definition to identify endocrine disruptors and introduction of the additional categories of ‘*suspected endocrine disruptors*’ and ‘*endocrine active substances*’ based on the different strength of evidence for fulfilling the WHO/IPCS definition; and 4) use of the WHO/IPCS definition to identify endocrine disruptors and introduction of potency as an element of hazard characterisation.

In particular, a hazard-based approach appears to be specifically embraced in policy option 3. Under this option, the categories of ‘*suspected endocrine disruptors*’ and ‘*endocrine active substances*’ would cover, respectively: (i) substances for which there is some evidence for endocrine mediated adverse effects but such evidence is not sufficiently strong; and (ii) substances for which there is some *in vitro* or *in vivo* evidence indicating a potential for endocrine disruption mediated adverse effects in intact organisms and where evidence is not convincing for them to be classified as endocrine disruptors or suspected endocrine disruptors. Such approach would fail to include elements of hazard characterisation (e.g., potency, lead toxicity, severity and irreversibility), exposure assessment and risk characterisation, which, according to the European Food Safety Authority’s “*Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for the identification of endocrine disruptors and appropriateness of existing methods for assessing effects mediated by these substances on human health and the environment*”, issued in February 2013, should be taken into account in a risk assessment (see Trade Perspectives, Issue No. 22 of 28 November 2014), subjecting such substances to regulatory action even in the absence of strong or convincing evidence.

According to the EU Commission’s report, a total of 27,087 responses to the public consultation were received from a wide range of stakeholders, including individuals, public authorities, research institutions, private companies, health institutions, agricultural producers, trade associations and NGOs.

A number of stakeholders expressed concerns on the use of hazard-based criteria, and called for the use of a risk-based approach that would take into consideration hazard characterisation elements such as potency of the substance, severity and irreversibility of the adverse effects in light of exposure to the substance. Responses from non-EU governments (including Argentina, Australia, Canada, New Zealand and the US) and authorities, as well as private stakeholders, including exporters of agricultural products to the EU, indicated that a hazard-based approach would be contrary to WTO rules, in particular, the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) and the WTO TBT Agreement, which call for SPS measures and technical regulations to be based on science and on an assessment of the risks.

Indeed, the SPS Agreement requires that SPS measures adopted by WTO Members 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. Similarly, the TBT Agreement requires that measures not be more trade-restrictive than necessary to achieve a legitimate objective (e.g.,

human health or safety and environment protection), taking into account the risks that non-fulfilment would create. Concerns were raised that regulatory decisions based solely on the identification of a hazard would likely be more trade-restrictive than necessary to fulfil the legitimate objectives sought by the EU (*i.e.*, protection of human health and the environment) and would not be supported by scientific evidence.

The high number of responses to the consultation received serves as evidence of the huge impact that this regulatory process stands to have on several areas (human health, the environment, as well as trade and agricultural production, *inter alia*) and for a wide range of stakeholders. The criteria chosen will have an impact on the availability of a number of plant protection products in the EU market, affecting farmers' ability to control pests and diseases of their crops, especially where there are no or few alternative products. Imports of agricultural products into the EU will also be affected if the EU framework is to require exporters to comply with allowed levels of residues of substances based on default values, rather than an evaluation of the risks. Third-country exporters (represented by, *inter alia*, the Brazilian Confederation of Agriculture and Livestock, the Grape Growers' Federation of India, the Citrus Growers Association of South Africa, Pulse Canada, the Thai Mango Association and the Thai Chamber of Commerce) have voiced concerns about the impact that hazard-based criteria stand to have on their exports to the EU, and call for the EU to adopt measures having the least trade-restrictive impact on agricultural products.

While pursuing the legitimate objective of the protection of human health, the EU Commission may need to factor-in these views, together with scientific evidence and all other elements in its work to define criteria for endocrine disruptors. All interested parties should continue to follow closely this regulatory process and represent their views to the EU regulator.

Recently Adopted EU Legislation

Market Access

- *Decision No. 3/2015 of the Joint Implementation Committee set up by the Voluntary Partnership Agreement between the European Union, of the one part, and the Republic of Indonesia, of the other part of 8 July 2015 adopting amendments to the Annexes I, II, and V of the Agreement [2015/1382]*
- *Decision No. 1 of the EU-Korea Committee on Trade in Goods of 28 May 2015 on the adoption of the rules for Tariff Rate Quota administration and implementation [2015/1412]*

Trade Remedies

- *Commission Implementing Regulation (EU) 2015/1507 of 9 September 2015 amending Council Implementing Regulation (EU) No. 1371/2013 extending a definitive anti-dumping duty imposed on imports of certain open mesh fabrics of glass fibres originating in the People's Republic of China to imports consigned, *inter alia*, from India, whether declared as originating in India or not*
- *Commission Implementing Regulation (EU) 2015/1483 of 1 September 2015 amending Council Implementing Regulation (EU) No. 1106/2013 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain stainless steel wires originating in India following and absorption reinvestigation pursuant to Article 12 of Council Regulation (EC) No. 1225/2009*

- *Commission Implementing Regulation (EU) 2015/1429 of 26 August 2015 imposing a definitive anti-dumping duty on imports of stainless steel cold-rolled flat products originating in the People's Republic of China and Taiwan*
- *Commission Implementing Regulation (EU) 2015/1394 of 13 August 2015 amending Regulation (EU) No. 470/2014, as amended by Regulation (EU) 2015/588, imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of solar glass originating in the People's Republic of China following an absorption reinvestigation pursuant to Article 12 of Council Regulation (EC) No. 1225/2009*
- *Commission Implementing Regulation (EU) 2015/1361 of 6 August 2015 repealing the definitive anti-dumping duty imposed on imports of certain candles, tapers and the like originating in the People's Republic of China, following an expiry review pursuant to Article 11(2) of Council Regulation (EC) No. 1225/2009*
- *Commission Implementing Regulation (EU) 2015/1350 of 3 August 2015 amending Council Implementing Regulation (EU) No. 461/2013 imposing a definitive countervailing duty on imports of certain polyethylene terephthalate (PET) originating in India*

Food and Agricultural Law

- *Commission Recommendation (EU) 2015/1381 of 10 August 2015 on the monitoring of arsenic in food*
- *Commission Delegated Regulation (EU) 2015/1369 of 7 August 2015 amending Delegated Regulation (EU) No. 1031/2014 laying down further temporary exceptional support measures for producers of certain fruit and vegetables*

Other

- *Commission Implementing Regulation (EU) 2015/1296 of 28 July 2015 amending Regulation (EU) No. 468/2010 establishing the EU list of vessels engaged in illegal, unreported and unregulated fishing*
- *Commission Regulation (EU) 2015/1221 of 24 July 2015 amending Regulation (EC) No. 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, for the purposes of its adaptation to technical and scientific progress*

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