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Calming troubled waters - Efforts to eliminate fishery subsidies and to combat IUU fishing for a more law-abiding, sustainable and balanced fisheries sector

The issue of fisheries and fisheries trade has recently received a considerable amount of attention. This comes as no surprise, given that fish is one of the world's most traded commodities and, at the same time, it is estimated that illegal, unreported and unregulated (hereinafter, IUU) fishing accounts for up to 50% of reported catches in some regions. On 15-16 September 2016, the third '*Our Ocean Conference*' took place in Washington, D.C., and set the stage for a number of announcements with respect to fisheries trade and IUU fishing.

According to recent statistics, IUU fishing likely accounts for annual catches of more than 26 million tonnes, worth more than USD 23 billion. Further to that, the Food and Agriculture Organization (hereinafter, FAO) estimates that more than 30% of commercial fish stocks (including commercially popular fish such as cod and tuna) are overfished and that 13% to 31%, and in some regions up to 50%, of reported catches are attributed to IUU fishing. During the course of this year, the Port State Measures Agreement, which is intended to build on previous global instruments, and which adds the first set of binding minimum standards specifically intended to combat IUU fishing, finally entered into force after its adoption in 2009. Notably, the EU and the US have continued their initiatives to combat IUU fishing. On 5 February 2016, the US National Oceanic and Atmospheric Administration (NOAA) published a proposal aimed at creating a seafood traceability programme. The programme intends to combat IUU fishing and prevent fraudulent trade (see *Trade Perspectives*, Issue No. 3 of 12 February 2016). A final version is expected shortly.

These further initiatives to combat IUU fishing, and the new momentum to eliminate certain fisheries subsidies, showcase a stronger focus on fisheries and sustainability. Apart from the economic importance of the fisheries sector, this recent focus can also be attributed to the '*United Nations Sustainable Development Goals*' (hereinafter, SDGs). Target 14.4 of the SDGs calls on UN Member States to "*effectively regulate harvesting and end overfishing, illegal, unreported and unregulated fishing and destructive fishing practices and implement science-based management plans, in order to restore fish stocks in the shortest time feasible*" by 2020, while Target 14.6 calls on UN Member States to "*prohibit certain forms of fisheries subsidies which contribute to overcapacity and overfishing, eliminate subsidies that contribute to illegal, unreported and unregulated fishing and refrain from introducing new*

such subsidies" by 2020. With 2016 drawing to an end, the timeframe to attain those goals is getting tighter by the day.

On 14 September 2016, on the occasion of the third '*Our Ocean Conference*', twelve countries (*i.e.*, Argentina, Australia, Canada, Chile, Colombia, New Zealand, Norway, Papua New Guinea, Peru, Singapore, Switzerland, Uruguay and the US) issued a '*Joint Statement Regarding Fisheries Subsidies*' aiming at the preparation for plurilateral "*negotiations in the WTO to prohibit harmful fisheries subsidies*". The proposal notes that, "*[f]isheries subsidies create significant distortions in global fish markets and are a major factor contributing to overfishing and overcapacity and the depletion of fisheries resources*". In order to address those issues, the countries then commit to take action and to aim at "*eliminating harmful subsidies, including those subsidies that contribute to overfishing and overcapacity, and subsidies linked to illegal, unreported and unregulated (IUU) fishing*". Additionally, the aim is to improve the reporting and transparency of fisheries subsidies. The specific format of those negotiations is still unclear. Recently, '*plurilateral*' negotiations have received more attention, while the overarching way forward within the WTO Doha Development Agenda remains unclear. Negotiations on environmental goods (*i.e.*, the Environmental Goods Agreement, or EGA), services (*i.e.*, the Trade in Services Agreement, or TiSA) and information technology (*i.e.*, the Information Technology Agreement, or ITA) have recently brought a stronger focus from certain groups of WTO Members. The twelve countries listed above announced that plurilateral negotiations among each other and other like-minded participants, to conclude an ambitious and high standard agreement, would be conducted in parallel to multilateral WTO negotiations. So far, no further countries have announced their intention to join. Important producers, exporters, importers and subsidisers, such as the EU, Japan and Russia, are currently not part of this initiative on fisheries subsidies. The initiative appears to be building on a provision in the Trans-Pacific Partnership Agreement (hereinafter, TPP). Article 20.16(5) of the TPP provides that Parties shall not maintain any: (1) subsidies for fishing that negatively affect fish stocks that are in an overfished condition; or (2) subsidies provided to any fishing vessel, while listed by the flag State or a relevant a Regional fisheries management organisation (RFMO) or Arrangement for IUU fishing. Seven of the twelve members of the coalition proposing this initiative are signatories of the TPP. It appears as no surprise that those countries, joined by a number of other countries, would aim at extending this ban on certain fisheries subsidies.

While those twelve countries appear to be pursuing a separate path, WTO Members are still '*reflecting*' on the best way forward. Within the WTO, the '*Negotiating Group on Rules*' is responsible for fisheries subsidies. With respect to fisheries, however, this negotiation group has been *de facto* paralysed. WTO Members, as recently as June 2016, affirmed their "*interest*" in reforming fisheries subsidies' rules, but continue to disagree on how to do so. New documents or proposals are sparse at the WTO and, therefore, this new approach put forth by the twelve countries in the wake of the TPP outcome might be a chance to revive the negotiations. Negotiations are likely to gain pace in the preparation for the next ministerial conference, scheduled to take place in Buenos Aires, Argentina, at the end of 2017. Reports already indicate that proposals can be expected from the group of African, Caribbean and Pacific (ACP) countries, as well as from Peru, in the near future. The possibility of achieving an agreement at next year's ministerial would also require beginning to negotiate actual text proposals. However, the eventual success of negotiations on fisheries subsidies within the *'Negotiating Group on Rules*' also depends on the general balance of rules negotiations, taking into account negotiations in other sectors, notably controversial negotiations relating to anti-dumping, horizontal subsidies and regional trade agreements. Already in 2016, several members of the twelve-country group responsible for the recent initiative circulated a paper with questions on subsidies policies within the WTO rules negotiations. Striving for an agreement outside of the '*Negotiating Group on Rules*', as proposed by the initiative, would '*decouple*' this process from the other trade issues being addressed by the group and considerably increase the chances for an agreement.

Meanwhile, the EU is continuing its initiatives against IUU fishing and in June 2016, awarded Indonesia with the '*green card*' status. This marked the end of the process of EU monitoring, after Indonesia had considerably and successfully stepped up its efforts against IUU fishing. As compared to other countries in the region, Indonesia is well ahead in terms of its initiatives against IUU fishing. Recently started negotiations between the EU and Indonesia for a Comprehensive Economic Partnership Agreement (CEPA) provide an opportunity to build on this achievement and to ensure that commercial advantages reward the achievements by Indonesia (see *Trade Perspectives*, Issue No. 17 of 23 September 2016). However, the EU's IUU framework is not without flaws and fishery products that do not meet IUU rules reportedly continue to reach the EU market from a number of other countries. In particular, the implementation of the IUU rules should be more thorough. A key shortcoming is the paper-based system for the documentation of imported seafood products, practically preventing effective information exchange and cross-checks. Additionally, more than 15,000 fishing vessels under flags of EU Member States are currently authorised to fish in '*distant waters*'. Reforms are supposed to take effect in 2017 to improve the transparency and the monitoring of this large EU fleet outside of Union waters. In general terms and as recently stressed by the EU, whether fishing is taking place inside or outside of the EU, it must be subject to the same rules and standards when the catch is then placed on the EU market. This non-discriminatory treatment must not only be underlined in theory, but also enforced in practice.

The combat against trade-distorting subsidies that contribute to overfishing and IUU fishing, as well as the various initiatives aimed at promoting more sustainable fisheries, can be lauded for their objectives. However, any proposed or applied measure must be non-discriminatory in nature and should not impose disproportionate burdens on third countries. Rather, countries must work together and not engage in implementing a piecemeal approach that sometimes appears to distort the conditions of competition among third countries. The WTO and the FAO should be and remain the preferred *fora* for any advancement of the rules in a multilateral setting. Stakeholders should be vigilant as this appears to be an area of increased (regulatory) activity, in particular leading up to the WTO Ministerial Conference in 2017 and the timelines set by the UN's SDGs. Additionally, countries, especially those with an important fishing sector, should make use of all available *fora*, in particular the WTO and bilateral or regional trade negotiations, in order to protect their interests and be active parts of the discussion.

Divergent views remain on the US Food and Drug Administration's Draft Guidance on biosimilar product labelling

On 31 March 2016, the US Food and Drug Administration (hereinafter, the FDA) issued its '*Draft Guidance on Labeling for Biosimilar Products*' (hereinafter, the Draft Guidance). From 4 April to 2 August 2016, interested stakeholders were invited to comment on the Draft Guidance. The FDA is currently assessing the comments received, in preparation of the final version of the Guidance, to be released by November 2016. Of particular note are the varying opinions of influential organisations and associations, which demonstrate the scope of the potential final Guidance.

A biosimilar, or follow-on biologic, is a biologic medical product, which is an almost identical version of a reference product that is manufactured by a different company. A biosimilar has no '*clinically meaningful differences from the reference product in terms of the safety, purity, and potency of the product*'. To address biosimilar labelling, the Draft Guidance provides detailed recommendations to stakeholders. Labelling provides key scientific information for the assessment of a therapeutic product's risk-benefit profile. The FDA recommends that biosimilar product labelling incorporate relevant data and information from the FDA-approved

labelling for the reference product, along with any appropriate modifications that are specific to the biosimilar product. For instance, the addition of a statement of biosimilarity, it may be necessary to describe the biosimilar product's relationship to its reference product. However, the FDA does not recommend that comparative data supporting the demonstration of biosimilarity be included in biosimilar product labelling. This aims at avoiding potential confusion or misinterpretation of the comparative data.

In its comments on the Draft Guidance, the General Pharmaceutical Association (hereinafter, GPhA), the sole association representing America's generic pharmaceutical sector in the US, supported the initiative of the FDA that biosimilar labelling reflect the scientific information necessary for health care providers to use a product safely and effectively. Nevertheless, the GPhA is concerned with the proposed biosimilarity statement because the latter is deemed unnecessary to the safe and effective use of biosimilars. According to the GPhA, the biosimilarity statement could confuse patients and healthcare providers as it may suggest that biosimilars have clinically meaningful differences from their reference products '*in terms of safety, purity, or potency*' when, in fact, they do not.

In its comments to the Draft Guidance, the International Generic and Biosimilar Medicines Association (hereinafter, IGBA) argues that the proposed '*same-label*' or '*reference label*' approach is consistent with "*the scientific concepts and principles underlying the biosimilar medicines development and the regulatory approval process*". Nonetheless, the IGBA is opposed to the naming policy, since it could trigger confusion and uncertainties among healthcare providers and other stakeholders. This confusion is arguably amplified by the introduction of three different types of names (*i.e.*, core name, proper name and proprietary names) in some sections of the label.

In its comments on the Draft Guidance, the Pharmaceutical Research and Manufactures of America (hereinafter, PhRMA) supports the proposed recommendation that biosimilar labelling should state that the product is a biosimilar. However, PhRMA would like the FDA to revise its Draft Guidance on certain issues. PhRMA advises that the FDA should ensure that biosimilar labelling provide healthcare professionals with appropriate regulatory transparency (including a statement of biosimilarity, a description of the nonclinical and clinical data supporting the biosimilar's approval, a description of the basis for approval of each indication, and a statement regarding whether or not the FDA has made a determination of interchangeability with the reference product and the result of that finding). PhRMA notes that this approach would facilitate informed prescribing, protect against inadvertent substitution, and promote consistency with domestic and international precedents.

In its comments on the Draft Guidance, the Association of Retired Persons (hereinafter, AARP) confirms its support for a "*workable biosimilar approval pathway that will provide consumers with access to safe and effective biosimilar products*". Nevertheless, it underlines that a biosimilar label should not mention that the product is a biosimilar. The AARP asserts that the requirement of a labelling statement that only applies to biosimilars could create confusion and discourage biosimilar adoption. According to the AARP, it is not necessary to differentiate between biosimilars and reference products. Otherwise, it could reduce the degree of comfort by prescribers and patients with respect to the biosimilar product. In its comments on the Draft Guidance, the Academy of Managed Care Pharmacy (AMCP) expressed exactly the same concerns.

As seen, the stakeholders disagree on what information should be included in biosimilar labelling. The GPhA, the IGBA and PhRMA agree that some labelling should be present on biosimilar products, inasmuch as they all consider labelling as a core element of communication for the safe and effective use of medicines. PhRMA also pushes for a label describing the relevant data from studies supporting a finding of biosimilarity. The GPhA is opposed to the proposed biosimilarity statement because the latter is deemed unnecessary

to the safe and effective use of biosimilars. The IGBA is not in favour of the introduction of three different types of names in some sections of the label. The IGBA emphasises that the use of labelling for biosimilars will increase acceptance of these new therapeutic options for more patients in the US and all over the world.

In the EU, such a statement does not exist because biosimilars have been used more widely and for a longer period of time. Since 2006, the EU has approved twenty biosimilars, while only two have been approved in the US. The Draft Guidance is generating an interesting debate between all relevant stakeholders around the world. There are still pending legal questions on biosimilars (*e.g.*, in competition law and concerning trade and intellectual property rights) that must be solved. Manufacturers of reference products are interested in delaying the development of biosimilars and ensuring their competitive position on the market. At the same time, the public should have access to competitive products such as biosimilars. The European Commission's new strategy, '*A Single Market Strategy for Europe – Analysis and Evidence*', also points out that the EU generic and biosimilar medicines industries will likely create up to 64,000 high tech jobs in the EU and dozens of new companies. This development could enhance pharmaceutical research and development in the EU, ultimately benefitting consumers. In this context, generics and biosimilars could represent 80% of the volume of medicines by 2020.

The FDA will need to assess the divergent views of the stakeholders on the Draft Guidance appropriately. This task is relatively demanding. The FDA will likely consider the negotiations of the Transatlantic Trade and Investment Partnership between the EU and the US, which reportedly aim at the harmonisation of labelling rules for biosimilars. This harmonisation would limit the number of diverging requirements to demonstrate the quality, safety and efficacy of these products and potentially facilitate the approval process for biosimilars in the US. The establishment of appropriate frameworks for regulatory cooperation in generic and biosimilar medicines in trade agreements will support the creation of collaborative approaches among regulators, reinforce the existing regulatory exchanges and foster a process of regulatory convergence that will, over time, reduce costs for businesses and consumers, together with facilitating trade in generic and biosimilar products. Interested stakeholders should continue to monitor this process as the FDA's Guidance on biosimilar product labelling is expected to be published shortly. The European Medicines Agency (EMA) will likely take into consideration the position of the FDA for the preparation of EU Guidance on the labelling of biosimilars.

A Swedish court rules that EFSA's reference values for vitamins and minerals cannot be used as upper limits in food

On 1 September 2016, the Administrative Court in Falun, Sweden, in proceedings between the food supplements manufacturer Great Earth Scandinavia AB and Samhällsbyggnadsnämnden i Gävle kommun (*i.e.*, the Municipality of Gävle), decided to lift the Municipality of Gävle's decision of 31 October 2013, which ordered that Great Earth Scandinavia AB reduce levels of vitamin B6 (pyridoxine) in all products, so that they are under the upper limit (hereinafter, UL) value of 25 mg per day set by the European Food Safety Authority (hereinafter, EFSA). It has also been reported that the Municipality of Gävle imposed a '*sales ban*' on vitamin B6 products produced by Great Earth Scandinavia AB. The court's judgment noted that, "*it is common ground that there are no statutory upper limits for vitamins and minerals in neither Swedish nor EU law*". The Administrative Court ruled that, in such a case, it is up to the food producer to take responsibility for ensuring that its products meet all safety requirements.

Excessive intakes of vitamins and minerals may result in adverse health effects and, therefore, *Regulation (EC) No 1925/2006 of the European Parliament and of the Council of*

20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (*i.e.*, the Fortified Foods Regulation) considers it necessary to set maximum amounts for them when they are added to foods, as the case may be. These amounts must ensure that the normal use of the products, under the instructions for use provided by the manufacturer and in the context of a diversified diet, will be safe for consumers. Therefore, those amounts act as the total maximum safe levels for the vitamins and minerals that are naturally present in the food and/or that are added to the food for whatever purpose, including for technological uses.

Article 6 of the Fortified Foods Regulation, titled "*Conditions for the addition of vitamins and minerals*", provides that, when a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold must not exceed maximum amounts. Measures setting those amounts will amend non-essential elements of the Fortified Foods Regulation by supplementing it and must be adopted by the Commission in accordance with the regulatory procedure with scrutiny. To this end, the Commission had to submit draft measures on the maximum amounts by 19 January 2009. *Article 5 of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements* also provides for the establishment of maximum and minimum amounts of vitamins and minerals.

In 2006, the Commission issued a *Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs*, which identified the main issues to be considered in this exercise. The public consultation closed on 30 September 2006 and received numerous responses. Although the Commission has, in past years, consulted extensively with EU Member States and interested stakeholders on the issue, no proposal has yet been presented due to the complex nature of the issue and the divergent views that were expressed by EU Member States, manufacturers and trade associations during the public consultation. The Commission suggests that it will take into account all available data on the potential effects on economic operators and consumers of the setting of maximum amounts of vitamins and minerals in foods, including food supplements, and that every effort will be made to ensure that the maximum amounts set will take into account the concerns expressed by all interested parties.

Therefore, not even a single legislative proposal on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs has been drafted yet. A common EU model for the setting of maximum amounts of vitamins and minerals in foods would, indeed, be useful. Such a model should be representative for the EU and flexible. Furthermore, it would have to take into account the variation of estimated intakes of micronutrients both from foods (including the contribution from fortified foods) and food supplements in different countries, in different social groupings, in different age groups, different genders, different physiological conditions, etc. This is the dilemma. EU-wide harmonisation of the law in this area is difficult, if not impossible. For example, someone living in Sweden, with the respective diet and exposure to the sun, has very different needs of vitamins and minerals than somebody living in Spain.

Under Article 17(3) of the Fortified Foods Regulation, EU Member States may, in compliance with the rules of the Treaty on the Functioning of the EU (TFEU), continue to apply existing national provisions on maximum and minimum amounts of vitamins and minerals listed in Annex I to the Regulation added to foods and on the conditions applicable to this addition until the adoption of corresponding EU measures.

Sweden is one the EU Member States without statutory ULs for vitamins and minerals. In the case at hand, the Municipality of Gävle, therefore, based its decision on a 2006 report produced by the EFSA on tolerable ULs for vitamins and minerals. The report recommended an UL of 25 mg of vitamin B6 per day for adults, but it also acknowledged the need for more

scientific evidence. In fact, a Tolerable Upper Intake Level of 25 mg per day for adults had already been established for vitamin B6 by EFSA's predecessor (*i.e.*, the Scientific Committee on Food, SCF) in an opinion of 19 October 2000.

The Administrative Court in Falun ruled that, since maximum permitted levels (MPLs) have not yet been mandated at the EU level, an EFSA recommendation is not binding. The Court cited a 2012 review where the EFSA examined scientific articles published between 1990 and 2012 indicating that ULs of 25 mg per day for adults originally recommended for vitamin B6 were too low. The Court held that the measures taken must be proportionate to the objective and must not be more trade-restrictive than necessary. A measure must be necessary to achieve the declared purpose and limited to cases in which the purpose cannot be achieved by less extensive prohibitions or restrictions. A more reasonable option could come in the form of appropriate labelling that provides consumers with information about the supplement. A suitable label, which provides consumers with information about the nature of the ingredients contained in the fortified foods and their properties, would allow consumers to decide for themselves whether they should consume such foods. The Court cited various cases of the Court of Justice of the EU (*i.e.*, Case C-192/01 Commission v Kingdom Denmark, Case C-41/02 European Commission v Kingdom of the Netherlands and C-24/00 European Commission v French Republic).

According to the judgment of the Administrative Court of Falun, where an EU Member State has not set statutory ULs for vitamins and minerals, local authorities cannot base decisions related to the maximum content of vitamins and minerals solely on recommendations of the EFSA. The EFSA is not an executive body. According to Article 27 of *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*, the EFSA shall provide scientific advice and technical support for EU legislation and policy in all fields that have a direct or indirect impact on food and feed safety. EFSA must provide independent information on all matters within these fields, communicate risks and cooperate with relevant EU Member States' authorities. The judgment of the Administrative Court of Falun can still be appealed, and the matter of ULs for vitamins and minerals should be carefully monitored by interested stakeholders as further litigation possibly unfolds.

Recently Adopted EU Legislation

Trade Remedies

- *Commission Implementing Regulation (EU) 2016/1777 of 6 October 2016 imposing a provisional anti-dumping duty on imports of certain heavy plate of non-alloy or other alloy steel originating in the People's Republic of China*

- *Commission Implementing Regulation (EU) 2016/1778 of 6 October 2016 imposing a provisional anti-dumping duty on imports of certain hot-rolled flat products of iron, non-alloy or other alloy steel originating in the People's Republic of China*

- *Commission Implementing Regulation (EU) 2016/1731 of 28 September 2016 reimposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain footwear with uppers of leather originating in the People's Republic of China and Vietnam and produced by General Footwear Ltd (China), Diamond Vietnam Co. Ltd and Ty Hung*

Footgearmex/Footwear Co. Ltd and implementing the judgment of the Court of Justice in Joined Cases C-659/13 and C-34/14

Customs Law

- *Commission Implementing Regulation (EU) 2016/1713 of 20 September 2016 fixing the quantitative limit for exports of out-of-quota sugar and isoglucose until the end of the 2016/2017 marketing year*

Other

- *Council Decision (EU) 2016/1749 of 17 June 2016 on the conclusion, on behalf of the European Union, of the Protocol to Eliminate Illicit Trade in Tobacco Products to the World Health Organisation's Framework Convention on Tobacco Control, with the exception of its provisions falling within the scope of Title V of Part Three of the Treaty on the Functioning of the European Union*

- *Council Decision (EU) 2016/1750 of 17 June 2016 on the conclusion, on behalf of the European Union, of the Protocol to Eliminate Illicit Trade in Tobacco Products to the World Health Organisation's Framework Convention on Tobacco Control, as regards its provisions on obligations related to judicial cooperation in criminal matters and the definition of criminal offences*

- *Protocol to Eliminate Illicit Trade in Tobacco Products*

- *Regulation (EU) 2016/1724 of the European Parliament and of the Council of 14 September 2016 amending Regulation (EC) No. 471/2009 on Community statistics relating to external trade with non-member countries as regards conferring of delegated and implementing powers upon the Commission for the adoption of certain measures*

- *Commission Implementing Decision (EU) 2016/1701 of 19 August 2016 laying down rules on the format for the submission of work plans for data collection in the fisheries and aquaculture sectors (notified under document C(2016) 5304)*

Laura Boschi, Ignacio Carreño, Tobias Dolle, David Leys, Bruno G. Simões and Paolo R. Vergano contributed to this issue.