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# The EU's Single Market for Green Products initiative and its possible implications on international *fora*

At the latest meeting of the WTO Committee on Trade and Environment (held on 23 October 2014), the EU updated WTO Members on the EU's Single Market for Green Products (hereinafter, SMGP) initiative, which was announced as part of the EU's Single Market Act of 2011, and in the 2012 Industrial Policy Communication Update. The SMGP initiative is presently being tested while, simultaneously, other initiatives, to which the EU is a part, are occurring. This is the case, for instance, of the WTO negotiations for the plurilateral Environmental Goods Agreement (hereinafter, EGA).

The SMGP initiative aims at creating a common, science-based, definition of what constitutes a 'green product' or what makes a 'green organisation', while addressing consumer distrust and confusion arising from the numerous initiatives and standards in place on environmental or sustainable products. According to EU Commission's studies, there are 80 leading methodologies and initiatives according to which GHG (i.e., greenhouse gas) emissions could be calculated and 62 methodologies and initiatives to calculate the carbon footprint of relevant products. Within the EU, Member States have different schemes that companies need to comply with, in order to show environmental performance, before marketing their products as 'green'. Companies also need to consider international standards, including Environmental Product Declarations (i.e., EPDs), of which there are six competing systems, all based on ISO 14025 (i.e., an international standard regarding environmental labels and declarations set by the International Organization for Standardization). On the other hand, consumers that are concerned with the environmental characteristics of products are exposed to over 400 environmental labels worldwide. According to Eurobarometer, 48% of consumers say that environmental standards are not clear and only 6% of EU citizens trust producers' claims regarding the environmental performance of their products.

On 9 April 2013, the EU Commission released its proposal for the SMGP through the Communication from the Commission to the European Parliament and the Council: Building the Single Market for Green Products – Facilitating better information on the environmental performance of products and organisations and the Commission Recommendation of 9 April 2013 on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations (for further background, see Trade Perspectives, Issue No. 8 of 19 April 2013). The proposal puts forward two methods to

measure environmental performance throughout a product's lifecycle, *i.e.*: (1) the Performance Environmental Footprint (*i.e.*, PEF); and (2) the Organisation Environmental Footprint (*i.e.*, OEF). The proposal also recommended the voluntary use of the two methods and announced a three-year testing period to develop product- and sector-specific rules. Following this period, a second phase is planned to build on the evaluation of the results of the testing period.

The SMGP initiative is undergoing its testing period while the EU is currently negotiating and involved with other international initiatives. In particular, the EU is a participant to the negotiations for a plurilateral EGA, together with 13 other WTO Members (*i.e.*, Australia, Canada, China, Chinese Taipei, Costa Rica, Hong Kong China, Japan, New Zealand, Norway, Singapore, the Republic of Korea, Switzerland and the US). The EGA intends to build upon the List of Environmental Goods agreed to by the Member Economies of the Asia-Pacific Economic Cooperation (hereinafter, APEC) in 2012, for which they would reduce the import tariffs to 5 percent *ad valorem* or less by 2015. The EGA will apply in accordance to the most-favoured nation (MFN) principle once a *'critical mass'* of WTO Members have agreed to participate. Therefore, all WTO Members, even those that did not participate in the negotiations and did not commit to the obligations, will eventually benefit from the reduced tariff rates. The types of goods covered by the APEC list include, *inter alia*, renewable bamboo-based products, parts and components for various *'green'* manufacturing items, products related to waste processing or disposal and instruments for testing and analysis of samples (for more information, see Trade Perspectives, Issue No. 14 of 11 July 2014).

Considering the lack of concrete indications of how exactly WTO Members are to 'build' upon the APEC list of environmental goods, the EU's SMGP initiative could not be more timely. The definition by the EU of the standards and criteria for the determination of what goods are to be considered 'green' in its domestic market raises the immediate question of whether these standards (or an equivalent thereof) are going to be put forward by the EU (or by other EGA participants) at the EGA's negotiating table. Although the EGA negotiations could arguably benefit from commonly agreed criteria for the consideration of 'green goods', this avenue could also become a double-edged sword susceptible of undermining the whole rationale and purpose of the EGA. As it appears, granting tariff preferences to products on the basis of specific criteria could lead to instances of discrimination, where products that are similarly environment-friendly (albeit on the basis of different criteria) would not benefit from the EGA's tariff reductions.

The concurrent EU's SMGP initiative and WTO EGA discussions create a potential conflict between two different approaches to the definition of 'green products' that businesses should monitor closely. From the perspective of trade, environmental performance standards and labelling requirements should lower obstacles encountered by companies attempting to market their products as 'green goods' in different markets throughout the world. In this light, and in order to ensure that trade negotiations do not actually lose sight of their objective of trade liberalisation, it is important that all interested parties make the necessary efforts to ensure that the agreed-upon standards and performance requirements be harmonised throughout the different systems.

# The final adoption of the WTO Agreement on Trade Facilitation appears to be within reach, at last

On 27 November 2014, WTO Members adopted a series of decisions to implement the 'Bali Package', including a separate decision to fully integrate the Agreement on Trade Facilitation (hereinafter, TFA) into the WTO framework. The TFA is a perfect example of how breaking down non-tariff barriers can create new opportunities for trade in both developed and developing countries.

The TFA was initially agreed as an essential part of the 'Bali Package' at the ninth WTO Ministerial Conference in Bali, Indonesia, on 7 December 2013 (see Trade Perspectives, Issue No. 23 of 13 December 2013). However, this year in July, India and a small group of countries threatened to block its final adoption in order to achieve a permanent solution with respect to certain food stock and security issues, which pushed the implementation of the whole 'Bali Package' into deadlock. Members had been negotiating on the TFA since 2004 "with a view to further expediting the movement, release and clearance of goods, including goods in transit". It will be the first new multilateral agreement of the WTO in the past 19 years since the WTO was established in 1994. It is estimated that the TFA may reduce the cost of trade by 10% for developed countries and up to 14% for developing countries. On 13 November 2014, the US and India reached an agreement to address India's concern and India therefore agreed to fully support the further implementation of the 'Bali Package', including not blocking the adoption of the TFA.

The TFA, as a multilateral trade agreement, will be binding on all 160 WTO Members. The agreement clarifies certain relevant provisions of the GATT (*i.e.*, Article V, on *Freedom of Transit*; Article VIII, concerning *Fees and Formalities connected with Importation and Exportation*; and Article X, on *Publication and Administration of Trade Regulations*) and sets out provisions for customs cooperation. The TFA is divided into two sections. Section I mainly addresses three issues: (1) transparency of customs procedures; (2) fees and formalities required by the customs authorities during the importation, exportation and transit of goods; and (3) freedom of transit. Section II provides rules on special and differential treatment to developing and least-developed country Members allowing flexibility in the implementation of the TFA.

Article 1 to Article 5 of the TFA address the issue of transparency. According to Article 1 of the TFA, WTO Members are required to publish relevant customs information in a nondiscriminatory and easily accessible manner (inter alia, procedures, forms and documents, applied duties, and any kind of taxes imposed on, or in connection with, import, export, and transit, customs classification and valuation rules, rules of origin and administration on tariff quotas). Article 1 specifically requires Members to make available certain information on the Internet, such as: a description of applicable import, export and transit procedures, including procedures for appeal or review; relevant forms and documents required for importation, exportation or transit; and contact information on their inquiry points. Additionally, Article 3 of the TFA requires WTO Members to issue an advance ruling with regard to the goods' tariff classification and origin in a reasonable, time-bound manner, as long as all necessary information is duly submitted. Reportedly, inconsistency of the decisions on tariff classification and origin among different customs offices or different officers in the same office is a major source of dispute between traders and the customs authorities. These may constitute de facto non-tariff barriers if wrong decisions are consistently made. The TFA aims at solving this problem by requiring WTO Members to guarantee the binding effect in a reasonable period of time, and prevent arbitrary modifications to the advance rulings. Article 4 further imposes obligations on Members to allow administrative or judicial appeal to be made on any administrative decisions issued by the customs authorities to the applicant. Besides the mandatory provisions discussed above, the TFA also includes provisions encouraging WTO Members to make better improvements. For example, WTO Members are encouraged not to require any payment for inquiry or providing the required forms and documents according to Article 3.3 of the TFA.

Furthermore, Article 5.1 imposes obligations on Members that adopt or maintain "a system, issuing notifications or guidance to its concerned authorities for enhancing the level of controls and inspections on the food, beverages and feedstuff for protecting human, animal or plant life or health within its territory". The provisions are closely related to the practice of the sanitary and phytosanitary (hereinafter, SPS) measures at the border. The TFA suggests that notifications or guidance be issued based on risk and applied uniformly only to the points of

entry where the SPS circumstances occur. It also requires Members to promptly terminate or suspend the notifications or guidance when circumstances are no longer existing, or address them in a less-restrictive manner if the circumstances are changed.

Articles 6 to 10 address the issues of fees and formalities required by the customs authorities during the import, export, and transit, for purposes of limiting or further decreasing the transaction cost of international trade. Article 6 stipulates that customs fees and charges "shall be limited in amount to the appropriate cost of the services rendered on or in connection with the specific import or export operation" (although not required to be linked to every import or export of goods). As for the release and clearance of goods, Article 7.1 requires WTO Members to adopt procedures to expedite the release of goods by allowing submission of relevant documents prior to the goods' arrival and separating the release of goods from the final determination of customs duties, taxes, fees and charges. In order to minimise the complexity of customs procedures, Article 10 of the TFA imposes an obligation on Members to maintain the formalities and document requirements in the least trade restrictive manner and to apply common customs procedures and uniform documentation requirements for release and clearance of goods within their territories. Article 10.6 also prohibits the mandatory use of customs brokers. Additionally, adoption of international standards, single window practice, and electronic customs system are also encouraged by the TFA.

As an expansion of Article V of the GATT, Article 11 of the TFA contains provisions on the freedom of transit. In relevant part, it stipulates that any regulations or formalities in connection with traffic in transit shall not be (1) maintained if the circumstances or objectives giving rise to their adoption no longer exist, or if the changed circumstances can be addressed in a reasonably available less trade-restrictive manner, and (2) applied in a manner that would constitute a disguised restriction on traffic in transit. Accordingly, Members shall further ensure that formalities, documentation requirements, and customs controls on traffic in transit are no more burdensome than necessary to identify the goods and ensure fulfilment of transit requirements. Once goods have been put under a transit procedure, they will not be subject to further customs controls until the transit has been concluded.

The TFA imposes obligations on WTO Members in order to expedite customs procedures and cut 'red tape'. Developed country Members shall implement the TFA immediately upon its entry into force. The TFA arguably demands more changes by developing and leastdeveloped country Members. Therefore, Section II of the TFA provides special and differential treatment to suit their implementation capacities. According to Article 14 of the TFA, developing and least-developed country Members are allowed to implement the TFA according to the timeframe established on the basis of a classification of provisions as Category A, B or C. Category A provisions are to be implemented immediately after the entry into force of the agreement, or, in the case of least-developed country Members, within one year after its entry into force. The implementation of provisions in Categories B and C is subject to an indication of the applicable transition periods and (for provisions in Category C only) whether technical assistance is needed. To date, there are 50 Members that have committed to implement the TFA immediately according to Category A requirements. However, these Members made reservations to various Articles in Section I of the TFA, which they are not able to implement upon entry into force. Consequently, the Category A commitments vary among Members.

WTO Members' authorities are now to commence the ratification process domestically. Ratification by two-thirds of the membership is required for the TFA to enter into force among those Members. The final adoption of the TFA is not only a significant step forward of the multilateral trading system, but it will also translate into real benefits for business operators in their day-to-day trading practices. Implementation activities at national level are expected to be launched soon and stakeholders are encouraged to actively engage in the process in order to maximise the benefits provided under the TFA.

# The EU Commission continues its work on the definition of criteria to identify endocrine disruptors

On 29 September 2014, the EU Commission launched a public consultation to define the criteria to identify endocrine disruptors. This consultation is part of the work carried-out by the EU Commission following actions by the EU Council and the EU Parliament in the past years, calling on the EU Commission to establish horizontal hazard-based scientific criteria to identify endocrine disruptors. Broadly speaking, endocrine disruptors (which may be natural or synthetic) are chemicals that interfere with the normal hormonal activity and cause adverse effects, including testicular, breast and prostate cancers, decline in sperm counts, pregnancy loss, puberty abnormalities, reproductive organ deformities, neurological problems, diabetes and obesity. 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 consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations".

Provisions on endocrine disruptors are in force in specific instruments of sectoral EU legislation, in spite of formal criteria for the identification thereof not having been established (although, pending their adoption, interim criteria apply). In particular, 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 (i.e., the Plant Protection Products Regulation) and 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 (i.e., the Biocidal Products Regulation) foresee that, by December 2013, the EU Commission must establish scientific criteria for the determination of endocrine disrupting properties. Additionally, a number of EU legal instruments regulating the marketing and use of chemical substances (in the field of, inter alia, cosmetics, medical devices and water) include provisions governing endocrine disruptors. These provisions envisage, inter alia, a review of the regulation regarding endocrine disrupting properties (in the case of cosmetics); design, manufacture and labelling requirements (with regards to medical devices); and the consideration of certain substances as main pollutants (with respect to water).

In order to address and remedy the lack of horizontal scientific criteria to identify endocrine disruptors, as early as 1999 the EU Commission adopted the 'Community strategy for endocrine disruptors' (which is currently under revision) and, in 2010, established expert groups to serve as open and transparent fora for discussions. The outcome of the work of one of these groups (i.e., the Endocrine Disruptors Expert Advisory Group), was submitted to the EU Commission and published in March 2013 and July 2014 in the form of reports. In addition, EFSA issued in February 2013 its 'Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment'.

Also in February 2013, the EU Commission circulated an *ad hoc* document containing a revised version of possible elements for the criteria for identification of endocrine disruptors. In relevant part, the paper endorses the WHO/IPCS definition of endocrine disruptors and establishes a categorisation between 'endocrine disruptors' and 'suspected endocrine disruptors'. The distinction is made on the basis of the strength of evidence and other considerations in weight of evidence. In particular, substances are considered 'endocrine disruptors' where they are known to cause endocrine mediated adverse effects, or where there is evidence of a strong presumption that they cause such effects. Conversely, substances fall within the scope of 'suspected endocrine disruptors' where there is some

evidence for endocrine mediated adverse effects, but such evidence is not sufficiently strong. This version appears to embrace hazard-based criteria, while explicitly rejecting certain additional considerations, including potency and lead toxicity of the substance, and severity and irreversibility of the adverse effects. Interestingly, EFSA's Scientific Opinion of February 2013 states, inter alia, that severity, irreversibility and potency should be evaluated in relation to the 'exposure' to a given substance, and accordingly affirms that "risk assessment (taking into account hazard and exposure data/predictions) makes best use of available information". EFSA's Scientific Committee goes on to conclude, inter alia, that "[e]ndocrine disruptors can therefore be treated like most other substances of concern for human health and the environment, i.e., be subject to risk assessment and not only to hazard assessment". It therefore appears, on the basis of EFSA's Scientific Opinion, that certain elements (i.e., severity, irreversibility and potency, as evaluated in relation to 'exposure') should be taken into account in the risk assessment, in addition to purely hazard-based criteria. This approach would arguably be in line with the EU's General Food Law (i.e., 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), which states that "hazard identification, hazard characterisation, exposure assessment and risk characterisation" are part of a "risk assessment".

The EU Commission's approach has already given rise to concerns on the potential and undesired effects that a policy based on such approach may have in a number of areas, especially agriculture. It appears that the categorisation between 'endocrine disruptors' and 'suspected endocrine disruptors', coupled with the failure to factor-in certain other elements for consideration, may render the identification of endocrine disruptors overly simplistic. In particular, concerns have been voiced that the determination of whether a substance constitutes an endocrine disruptor (and the legal consequences arising from such fact) would solely depend on the existence (or not) of a hazard, irrespective of additional (arguably, important) elements. This could lead to instances where substances that pose little or no concern to human health and the environment could be subject to severe restrictions in the EU market. Particularly in the field of agriculture, it is feared that the proposed approach could result in a wide number of plant protection products no longer being available, which could, in turn, lead to a significant reduction of the EU farmers' ability to control pests and diseases affecting their crops. The impact would likely be felt also on international trade, innovation and investment in the relevant areas.

Clearly, any potential measure adopted by the EU affecting, for example, agricultural products, on the basis of the use of endocrine disruptors throughout the products' supply chain (for instance, in the form of pesticides), would need to be aligned with the relevant provisions of the WTO Agreement on Sanitary and Phytosanitary Measures (*i.e.*, SPS Agreement). The SPS Agreement requires that SPS measures be based on a risk assessment (arguably, in line with EFSA's conclusions), 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 (*i.e.*, that measures not be more traderestrictive than necessary to achieve a legitimate objective, *e.g.*, human health or safety and environment protection), which could also be applicable.

The public consultation launched by the EU Commission in September 2014 is part of the impact assessment that is being conducted to evaluate the possible impacts of these proposed (and other) criteria for the identification of endocrine disruptors, and which is reportedly expected to be completed in 2015. The scope and policy options that are being assessed are set out in the impact assessment's roadmap, adopted in June 2014. All operators involved in the relevant sectors, and therefore with an interest in this matter, are encouraged to actively participate in the EU's consultation (which will be open until 16 January

2015). In addition to that, operators are advised to coordinate (among them and with the relevant authorities) in order to ensure that their interests are duly represented at all relevant decision-making instances.

### Uncertainties in relation to the labelling of fish and seafood in the EU

Less than a month before Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (hereinafter, the FIR) comes into effect on 13 December 2014, there are still a number of legal uncertainties and logistical problems in relation to the labelling of fish and seafood. First, there are different interpretations relating to the possible indication of both gross and net weight on glazed seafood packages. Second, under the FIR, the first freezing date has to be indicated for unprocessed fisheries products, while it is not always clear which date applies. Finally, Regulation (EU) No. 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products (hereinafter, the CMO fish regulation), which will apply in parallel to the FIR as of 13 December 2014, requires that consumers are provided with detail of the fishing gear used to catch the fish and seafood, and a more precise indication of the catch area for fish caught in some areas, which is a logistical challenge.

During frozen or cold storage, frozen seafood products can develop surface drying or dehydration. To prevent excessive drying leading to 'freezer burn', seafood products are typically glazed during frozen storage. Glazing is the application of a protective coating of ice (i.e., ice glaze) to frozen seafood products, whereby the ice layer excludes air from the surface of the product, reducing the rate of oxidation.

Article 23 of the FIR concerns the labelling of the net quantity of foodstuffs. In particular, it provides in its paragraph 3 that technical rules are laid down in its Annex IX. The second sentence of point 5 of Annex IX specifically addresses 'glazing' and provides that, where the food has been glazed, the declared net weight of the food must be 'exclusive of the glaze'. Under the first sentence of point 5 of Annex IX, where a solid food is presented in a liquid medium, the drained net weight of the food shall also be indicated. Sentence 3 of Annex IX defines 'liquid medium' as the following products, possibly in mixtures and also where frozen or quick-frozen, provided that the liquid is merely an adjunct to the essential elements of that preparation and is thus not a decisive factor for the purchase: water, aqueous solutions of salts, brine, aqueous solutions of food acids, vinegar, aqueous solutions of sugars, aqueous solutions of other sweetening substances, fruit or vegetable juices in the case of fruit or vegetables.

It is important to note that the 'glazing' of food was not specifically addressed in the respective provision of the FIR's predecessor, Directive 2000/13/EC of the European Parliament and of the Council of on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. Article 8(4) of Directive 2000/13/EC only stated that, where a solid foodstuff is presented in a liquid medium, the drained net weight of the foodstuff must also be indicated on the labelling and defined 'liquid medium' (i.e., only equivalent wording of the first and third sentence of point 5 of Annex IX of the FIR were contained in Article 8(4) of Directive 2000/13/EC).

Which weight or weights have to be declared on packages of glazed seafood under the FIR is subject to different interpretations. Reportedly, the association of the German fish processors and fish wholesalers (*Bundesverband der deutschen Fischindustrie und des Fischgroßhandels e.V.*, BV Fisch in its German acronym) argues that, where a solid food is presented in a liquid medium (the ice glaze being a liquid medium), the drained net weight of the food shall also be indicated. BV Fisch argues that the 'also' in the first sentence of point 5

of Annex IX indicates that more than one weight has to be declared: the weight with glaze (*i.e.*, the gross weight) and the net weight without the glaze. Reportedly, other national bodies, such as the French SNCE (*Syndicat National du Commerce Extérieur des produits congelés et surgelés*), the Danish Seafood Association or the Dutch Fish Federation, argue that the indication of the gross weight is not permitted. Their position is that, if consumers are already informed about the net weight, there is no added value of adding the gross weight. As the glaze is only there to protect the product, not to be consumed, the only information that gives consumers any value is the net weight.

The document of 31 January 2013 Questions and Answers on the application of the FIR by the EU Commission's Directorate General for Health and Consumer Affairs (DG SANCO) replies to question 2.12.2 (i.e., "The FIR provides that 'where the food has been glazed, the declared net weight of the food shall be exclusive of the glaze'. This means that in such cases the net weight of the food will be identical to the drained net weight. Do both 'net weight' and 'drained net weight' need to be indicated on the label?") as follows: "Where a solid food is presented in a liquid medium, the drained net weight must be indicated in addition to the net weight/quantity. For the purposes of this point, frozen or deep-frozen water is considered as a liquid medium which will entail the obligation to include in the label information about the net weight as well as about the drained weight. In addition, the FIR specifies that where a frozen food or quickfrozen food has been glazed, the net weight should not include the glaze itself (net weight without the glaze). As a consequence, the declared net weight of the glazed food is identical to its drained net weight. Taking this into account as well as the need to avoid misleading the consumer, the following net indications would be possible: a) Double indication: Net weight: 100g and Drained weight: 100g; b) Comparative indication: Net weight = drained weight = 100g; and c) single indication: Drained weight 100g or Net weight (without glaze) 100g".

This interpretation by the EU Commission does not resolve the confusion as to which weights need to be indicated where seafood has been glazed. However, a new draft of the EU Commission's questions and answers document on the FIR reportedly states that "in case of glazed foods it is not allowed, even on a voluntary basis, to declare the total weight of the product inclusive of the glaze".

It must be noted that the commercial background to the rules on glazed food is their increasing amounts on the market. Since these products are, in general, of high quality and therefore high-priced products (especially seafood), the visibility of the relationship between coating agent (usually water) and the 'pure' food is very important. To avoid any misleading of the consumer, the EU legislator has therefore decided that there should not be any information of the coating proportion. Ultimately, the coating liquid is probably no longer a liquid medium in terms of food law. The confusion appears to originate in that the EU Commission's guidance states that, in the context of glazed foods, frozen or deep-frozen water is considered as a liquid medium. In addition, the provision on glazed foods has been 'squeezed' between the first sentence of point 5 of Annex IX of the FIR, which provides that, where a solid food is presented in a liquid medium, the drained net weight of the food shall 'also' be indicated, and the third sentence of point 5 of Annex IX of the FIR, which defines liquid medium. Therefore, the question is to what weight the word 'also' refers to in the case of glazed foods, since it is not allowed, even on a voluntary basis, to declare the total weight of the product inclusive of the glaze.

In relation to the date of freezing, point 6.1 of Annex III of the FIR establishes that, for frozen unprocessed fishery products, the date of freezing or the date of first freezing, in cases where the product has been frozen more than once, must be declared. Therefore, the first freezing date has to be indicated for unprocessed fisheries products, for example for refrozen unprocessed fillets which are frozen more than once. However, EU Member States' authorities appear to differently interpret whether it is the date of the freezing of the headed and gutted

fish that has to be indicated or whether it is the date when the fillets were processed and then frozen. For headed and gutted fish frozen at sea, which is defrosted, filleted and refrozen, it has been argued that the date would be that of the freezing of the fillet. However, the latest draft of the EU Commission's questions and answers document on the FIR reportedly states that, where fish is refrozen, it is the 'original date of freezing' that has to be indicated. Filleting of fish may occur in other parts of the world and a lot of time may lapse between the first freezing at sea and freezing of the processed fillets on land. This is, therefore, a crucial decision for the industry, both in terms of quality and consumer perception.

The CMO fish regulation, which applies as of 13 December 2014, requires that consumers be provided with the details of the fishing gear used to catch the fish and seafood, and a more precise indication of the catch area for fish caught in some areas. This information must be evidence-based and verifiable. Cost of segregation of fish from different catch areas and methods must be incurred and the systems required as proofs are complex (see for more detail, Trade Perspectives Issue No. 14, 11 July 2014).

The amount and detail of information that has to be provided on the labelling of fishery products as of 13 December 2014 is a major challenge for the respective operators in the EU and third countries. There is an urgent need for better guidance, eventually clear implementing rules and possibly longer transition periods to allow the industry, which is making a huge effort, to comply with the new rules. Affected operators are encouraged to develop a solid understanding of the regulatory framework and, if need be, seek the necessary assistance from trusted advisors in order to achieve compliance.

# **Recently Adopted EU Legislation**

#### Market access

 Commission Implementing Regulation (EU) No. 1248/2014 of 20 November 2014 amending Implementing Regulation (EU) No. 776/2014 fixing the quantitative limit for the exports of out-of-quota sugar until the end of the 2014/2015 marketing year and repealing Implementing Regulation (EU) No. 1061/2014

# Food and Agricultural Law

- Commission Regulation (EU) No. 1226/2014 of 17 November 2014 on the authorisation of a health claim made on foods and referring to the reduction of disease risk
- Commission Regulation (EU) No. 1228/2014 of 17 November 2014 authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk
- Commission Regulation (EU) No. 1229/2014 of 17 November 2014 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 Implementing Regulation (EU) No. 1264/2014 of 26 November 2014 amending Regulation (EU) No. 408/2011 implementing Regulation (EC) No. 1185/2009 of the European Parliament and of the Council concerning statistics on pesticides, as regards transmission format

# **Trade-Related Intellectual Property Rights**

 Commission Implementing Regulation (EU) No. 1239/2014 of 19 November 2014 amending Regulation (EU) No. 716/2013 laying down rules for the application of Regulation (EC) No. 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks

### Other

 Commission Delegated Regulation (EU) No. 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use

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