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EU Member States reach an agreement on the ILUC Proposal

On 13 June, Energy Ministers of the EU Member States, as gathered at the EU Council, endorsed an agreement on the draft directive amending the EU's regulatory framework on biofuels. The agreement, reached at COREPER, is the result of continued engagement by the EU Council's preparatory bodies, after EU Member States were not able to agree on the draft text put forward by the Lithuanian Presidency in December 2013.

The original proposal (*i.e.*, *Proposal for a Directive of the European Parliament and of the Council amending Directive 98/70/EC relating to the quality of petrol and diesel fuels and amending Directive 2009/28/EC on the promotion of the use of energy from renewable sources*) was tabled by the EU Commission in October 2012. It aims at amending the EU's *Fuel Quality Directive* and *Renewable Energy Directive* in order to minimise the impact of emissions arising from indirect land use change (hereinafter, ILUC) on greenhouse gas (hereinafter, GHG) emissions stemming from the production of biofuels (*i.e.*, emissions created as a result of increased land demand for the production of biofuels, where such land could have been used for food, feed or fibre production) and starting the transition from biofuels produced from food crops to biofuels obtained from non-food crops (for further background on the EU Commission's Proposal, see Trade Perspectives, Issue No. 15 of 26 July 2013 and Issue No. 17 of 20 September 2013).

In particular, the EU Commission's proposal envisages a primary distinction between '*first generation*' biofuels (also called '*conventional*' biofuels, originating from food crops) and '*advanced*' biofuels (originating from alternative sources, such as forest residues, *algae* or municipal waste). On this basis, the proposal suggests capping the contribution of '*first generation*' biofuels within the mandatory target of the *Renewable Energy Directive*, which requires that, by 2020, 10% of the energy used in the EU for the transport sector originate from renewable sources. *Inter alia*, the political agreement reached by EU Member States proposes that this cap be set at 7%, therefore raising it from the 5% initially proposed by the EU Commission and the 6% suggested by the EU Parliament.

The arrangement reached at the EU Council also encourages the transition from '*conventional*' biofuels to '*advanced*' biofuels by requiring EU Member States to set national targets for '*advanced*' biofuels, which each Member State "*shall endeavour to achieve*". This target is to be based on a '*reference value*' of 0.5 percentage points of the 10% target set forth in the *Renewable Energy Directive* for renewable energy in transport and is to be met

through the use of biofuels produced from feedstocks and other fuels listed in Part A of Annex IX of the agreed draft, which count twice their energy content towards the achievement of the target. 'Advanced' biofuels produced from feedstock not listed in Annex IX but used in existing installations prior to the adoption of the draft directive can also be counted towards the national target. EU Member States are allowed to set lower targets provided that this is justified by one of the three grounds foreseen in the draft (*i.e.*, objective factors such as the limited potential for sustainable production of certain biofuels or limited availability thereof; specific technical or climatic conditions of the national market for transport fuels; or the existence of national policies incentivising the use of electricity from renewable sources in transport).

As in previous drafts of the proposal, ILUC emissions resulting from biofuel consumption are relevant for the purposes of monitoring and reporting to the EU Commission. To further clarify ILUC-related issues (which have proven particularly controversial throughout the whole legislative procedure), the draft endorsed by the EU Council incorporates a recital emphasising the 'indirect' nature of these emissions, as well as the need for 'data and assumptions' to be reviewed in light of 'the latest available information on land conversion and deforestation'. The draft envisages unchanged provisional estimated ILUC emission factors for biofuels on the basis of feedstock used (which maintain the distinction between biofuels from (i) food crops (including categories for cereals and other starch-rich crops; sugars; and oil crops); and (ii) feedstocks other than those indicated above or whose production has led to direct land use change), although it is foreseen that they be adjusted in light of scientific developments. Further novelties in the EU Council's draft include the extension of the tool of statistical transfer of renewable energy between EU Member States to the targets in the *Renewable Energy Directive* and additional incentives to stimulate the use of electricity from renewable sources in the transport sector.

Although the agreement has been generally welcome as a sign of progress of the ILUC proposal, not all EU Member States appear to be entirely satisfied with its content. Reportedly, the Czech Republic, Estonia, France, Hungary, Poland, Romania, Slovakia and Spain stated that the 7% cap on 'conventional' biofuels is "the lowest acceptable level". The EU Council's position at first reading will now be considered by the newly-elected EU Parliament at second reading, a procedure which is expected to take place later in 2014 and where EU Institutions will be subjected to strict timeframes. It remains to be seen whether the EU Member States' position gathers sufficient support in the EU Parliament or if, on the contrary, the battle between EU Institutions, concerned industries and civil society on this controversial proposal is set to continue. Businesses with an interest in this dossier are highly recommended to continue to maintain active and fluent communications with the relevant authorities, in order to ensure that their interests are duly taken into account in the relevant instances.

German court repeals the withdrawal of marketing authorisation of kava-containing medicinal products

On 10 June 2014, in the matter of seven pharmaceutical companies representing a total of fourteen marketing authorisations of kava extract-containing herbal medicinal products against the Federal Republic of Germany, represented by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, hereinafter, BfArM), the Administrative Court of Cologne, Germany (*Verwaltungsgericht Köln*) repealed the BfArM decision of 21 December 2007 (in the form of the administrative appeal decision of 15 February 2012) in which the BfArM withdrew the marketing authorisations for kava extract-containing medicinal products.

Kava is an important crop in the South Pacific Island Countries. The major exporting producers of kava among the South Pacific Islands Countries are Fiji, Samoa, Tonga and Vanuatu. Kava, a social beverage prepared from the roots of *Piper methysticum*, is an essential part of South Pacific societies and culture. Kava is drunk in typical quantities of one to three cups per session, and has relaxing, stress-releasing and anti-aggressive effects without otherwise altering the state of mind of its consumers. High doses of kava drinks cause sleepiness, but have no known adverse effects. Due to the calming and relaxing properties of certain active ingredients of the plant, kava extracts have been used for the development of herbal medicinal products for the treatment of mostly situational anxiety, in particular in Europe. On the basis of the alleged liver toxicity of kava extracts, the BfArM, the German regulatory authority responsible for the monitoring of risks related to medicinal products, withdrew first the marketing authorisations for medicinal products containing kava-extracts in 2002 and, on appeal, suspended the marketing authorisations in 2005 and later withdrew them again in 2007.

In its decision of 10 June 2014, the Cologne Administrative Court ruled that the withdrawal of marketing authorisations for kava-containing medicinal products in Germany was unlawful. Essentially, the Court held that the BfArM could not withdraw the marketing authorisations merely on the basis of its undemonstrated doubts about the efficacy of such medicines and because clinical studies on kava extracts were outdated. In relevant part, the German Court ruled that, if risk cannot be clearly and scientifically corroborated, there is no justification for the withdrawal of marketing authorisations. In a benefit-risk-ratio, the risk must be assessed in context, especially if the therapeutic alternatives bear a greater risk. Here, the Court found that BfArM erred when it described benzodiazepines as a harmless alternative to kava.

As a result, kava has returned to the regulatory status it held in 2001 as a prescription-only medicinal product. However, the decision applies only in Germany. The fact that the withdrawal of marketing authorisations for kava-containing medicinal products in Germany has been repealed must yet become the regulatory context in all other EU countries that have similarly withdrawn their marketing authorisations for medicinal products containing kava. In 2000, approximately USD 200 million worth of kava was being exported from the South Pacific Island Countries per year. The 12-year *de facto* 'ban' has resulted in almost USD 3 billion of damages to the economies and communities of the Pacific Island Countries.

The safety concerns in relation to kava as an herbal medicine have a great influence on its status as a food. German legislation has not explicitly banned kava. However, the German Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV in its German acronym), in a press release on 23 October 2002, available on the website of its successor organisation, the Federal Institute for Risk Assessment (BfR in its German acronym), does not exclude damage to the liver as a consequence of consuming kava. Because it can be expected that such health damage can also occur after eating foods containing kava, the BgVV strongly warns consumers against the long-term consumption of such products. In legal terms, BfR's assessment of kava means that food including kava is not marketable under Article 5(1) of the German Food Law (LFGB), which refers to Article 14 of *Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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 basically provides that "food shall not be placed on the market if it is unsafe" and that "food shall be deemed to be unsafe if it is considered to be: (a) injurious to health; or (b) unfit for human consumption".

Across the UK, the Food Standards Agency (hereinafter, FSA) is responsible for food safety and food hygiene. According to the FSA, kava is banned in the UK because of concerns about its toxic effect on the liver. Therefore, according to the FSA, imports of kava food supplements or foods containing kava are prohibited. In fact, on 23 December 2002, the *Kava-kava in Food (England) Regulations 2002* were adopted under the *Food Safety Act*

1990. They came into force on 13 January 2003. Regulation 3 of the *Kava-kava in Food (England) Regulations 2002* provides that “no person shall (a) sell; or (b) possess for sale or offer, expose or advertise for sale; or (c) import into England from a country outside the United Kingdom, any food consisting of or containing Kava-kava”. Regulation 2 of the *Kava-kava in Food (England) Regulations 2002* defines “kava-kava” as a “plant, or any part of or an extract from a plant, belonging to the species *Piper methysticum*”. Under Regulation 3(1), any person who contravenes Regulation 3 shall be guilty of an offence and shall be liable on summary conviction to a fine.

In addition to these EU Member State measures, during the last years, there have been four notifications by EU Member States to the EU Commission under the Rapid Alert System for Food and Feed (RASFF) concerning kava and products containing kava. On 21 August 2009, the Maltese food authorities notified the Commission that “food supplements from the US containing the unauthorised novel food ingredient kava kava” were rejected at its borders. The UK authorities notified the EU Commission of “unauthorised novel food powdered kava” from Fiji on 25 May 2007, of “herbs and spices containing the unauthorised novel food kava kava” from Tonga on 1 August 2006 and of “unauthorised novel food ingredient kava kava in fruit concentrate” in non-alcoholic beverages from the US on 6 February 2006. It appears that kava is regarded by food authorities in certain EU Member States, including the UK’s FSA, as a novel food (*i.e.*, a food or food ingredient that has not been used for human consumption to a significant degree in the EU before 15 May 1997). Considering kava as a novel food, as certain EU Member State authorities appear to do, would imply a lengthy authorisation procedure under *Regulation (EC) No. 258/97 on novel foods*.

However, in this context it must be noted that, on 18 December 2013, the EU Commission adopted a proposal for a new Regulation on novel foods, which establishes the European Food Safety Authority (hereinafter, EFSA), and not the EU Member States’ authorities, as the competent risk assessment body. The proposal also streamlines the authorisation procedure for novel foods. The proposal intends to remove any barriers to trade caused by the lengthy authorisation process for traditional food from non-EU countries and introduces a new assessment procedure for food that is new to the EU. If the history of safe use of the food in a non-EU country is demonstrated, and there are no safety objections from EU Member States or the EFSA, the food will be allowed to be placed on the market on the basis of a notification from the food business operator in the non-EU country. This could be done for kava. It must be noted, however, that there are ‘non-noble’ kava cultivars called ‘two-day’ kava, which cause ‘hangovers’, due to their very long-lasting and strong effects. Trading in ‘non-noble’ ‘two-day’ kava is banned in Vanuatu through the *Vanuatu Kava Act No. 7 of 2002*. However, in practice, ‘non-noble’ varieties are still exported, to a very large extent due the lack of unambiguous specifications and laboratory equipment for testing. Traditional experience with the quality and safety of kava refers to ‘noble’ kava only, and specifically to roots, peeled rootstock chips and peeled stem parts unexposed to sunlight. Kava-exporting Pacific Island Countries are currently working to ensure that the production of kava meets safety and quality requirements and all other relevant standards set by the internationally-competent and recognised bodies (*e.g.*, the Codex Alimentarius). This includes the promotion of traceability systems, which will ensure that only kava extracts obtained through certain procedures and good agricultural practices are exported. Another very important step would be the establishment of a Codex Alimentarius standard for kava. Scientific work was started in 2012 to map all kava cultivars, so that an international Codex standard may be developed and become the worldwide guarantee of kava quality and safety. However, this work was not completed due to the lack of funding.

BfArM has already appealed the 10 June 2014 judgment to the competent higher administrative court and will try to delay the return of kava in any way possible. The judgment of 10 June 2014 was a major step, but it does not yet mark the definitive return of kava as

medicine or food in Europe. However, it can be argued that the decision taken in Germany must be the basis for all other countries to urgently review their own individual measures and stop discriminating against kava in an illegal and disproportionate manner. On the other hand, the South Pacific Island Countries must urgently resolve eventual quality issues with 'non-noble' kava cultivars.

Recent developments relating to illegal, unreported and unregulated fishing

In the last few weeks, a number of developments have occurred regarding illegal, unreported and unregulated (hereinafter, IUU) fishing. Through two decisions published on 17 June 2014, the EU Commission notified the Philippines and Papua New Guinea that they risk being identified as countries it considers non-cooperative in the fight against IUU fishing. On the other side of the Atlantic, the US President, on 17 June 2014, released a memorandum on a comprehensive framework to combat IUU fishing and seafood fraud.

The EU, which is the world's largest importer of fishery products, maintains a framework to ensure that no products obtained from IUU fishing practices are placed on the EU market. The EU's framework is based on two main instruments: the EU's IUU Regulation (*i.e.*, 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) and 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.

In relevant part, the EU's IUU Regulation establishes a system designed to ensure full traceability of all marine fishery products (with some exceptions, which include aquaculture products and certain species) traded with the EU through a catch certification scheme (for more details on the catch certification scheme see Trade Perspectives, Issue No. 23 of 13 December 2013). Through the operation of the scheme, the EU's framework substantially requires countries wishing to export their products to the EU to have in place measures to prevent, deter and eliminate IUU fishing and authorities responsible to enforce them. The EU's IUU Regulation further provides for the establishment of an 'IUU vessels' list and a list of non-cooperating third countries. Inclusion in this latter list entails the consequences envisaged in Article 38 of the EU's IUU Regulation, which notably include trade measures, such as a prohibition that fishery products caught by fishing vessels flying the flag of such countries be imported into the EU, as well as a denial of acceptance of catch certificates, *inter alia*. The EU Commission's recent action must be seen in light of its duty to identify and notify third countries that "[fail] to discharge the duties incumbent upon...[them] under international law as flag, port, coastal or market State, to take action to prevent, deter and eliminate IUU fishing".

In the cases of the Philippines and Papua New Guinea, the EU Commission initiated informal discussions with both countries over two years ago. The EU Commission considers that these countries' efforts to fight illegal fishing are not sufficient and it identified a number of shortcomings, such as lack of system of sanctions to deter IUU activities or lack of actions to address deficiencies in monitoring, controlling and surveillance of fisheries. As a result of the EU Commission's perceived lack of cooperation by the Philippines and Papua New Guinea, the EU Commission issued both countries 'yellow cards' (*i.e.*, warnings) by notifying these countries the risk of being identified as 'non-cooperating' countries. The warnings provide the Philippines and Papua New Guinea reasonable time to respond and take measures to rectify the situation, which will be incorporated into an action plan during formal discussions with the EU Commission. Should the Philippines and Papua New Guinea fail to effectively address

the EU Commission's concerns within the specified timeframe, they will be included in the list of non-cooperating third countries. In 2012, the EU Commission issued formal warnings to a number of countries, including Fiji, Panama, Sri Lanka, Togo and Vanuatu, and in 2013 Ghana, Curaçao and South Korea joined the list. Most of the countries that have received formal warning have developed new legislation and improved their monitoring, control and inspection systems. However, three countries (*i.e.*, Belize, Cambodia and Guinea) were placed, through a Council Implementing Decision issued on 27 March 2014, on the list of non-cooperating countries in fighting IUU fishing and, therefore, made subject to the consequences stated in Article 38 of the IUU Regulation.

In related news, a new comprehensive framework to combat IUU fishing was recently announced by the US administration. The US President ordered all relevant executive agencies and offices to implement and enforce policies, regulations and laws to ensure that seafood in the US is legally and sustainably caught and accurately labelled. Additionally, the executive order established a Presidential Task Force on Combating Illegal, Unreported, and Unregulated Fishing and Seafood Fraud, which will be co-chaired by the US Secretaries of State and Commerce, or their designees. The task force, over the next six months, will meet to create a set of recommendations for implementing the comprehensive framework to combat IUU fishing by the US.

Importers and exporters throughout the world should monitor developments in the EU and the US. The ten countries currently working with the EU to improve their domestic fishery policies still have the possibility of being listed as '*non-cooperating countries*' and, therefore, risk being unable to directly or indirectly export their fishery products to the EU, as it is the case with Belize, Cambodia and Guinea as of March 2014. Without undermining the importance of the environmental objective sought by the EU's IUU framework, the question may be raised as to whether the grave trade measures foreseen in the EU's IUU Regulation for non-cooperating countries are in line with the WTO requirements that measures adopted on environmental grounds (which would be otherwise inconsistent with the GATT) not result in arbitrary or unjustifiable discrimination nor in a disguised restriction to trade, as required by the *chapeau* of Article XX of the GATT.

Global losses attributable to sales of fishery products procured illegally are estimated to be over EUR 10 billion per year. Many businesses have an interest in ensuring that the policies adopted by the US are strong enough to have a positive impact in combating trade in illegal products, while some countries may need to monitor the developments to ensure that no policies are adopted that are unnecessarily burdensome and overly trade restrictive.

Recently Adopted EU Legislation

Food and Agricultural Law

- *Commission Regulation (EU) No. 696/2014 of 24 June 2014 amending Regulation (EC) No. 1881/2006 as regards maximum levels of erucic acid in vegetable oils and fats and foods containing vegetable oils and fats*
- *Commission Implementing Regulation (EU) No. 644/2014 of 16 June 2014 amending Regulation (EC) No. 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No. 834/2007 as regards the arrangements for imports of organic products from third countries*
- *Commission Implementing Regulation (EU) No. 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No. 1151/2012 of the European*

Parliament and of the Council on quality schemes for agricultural products and foodstuffs

- *Decision No. 1/2014 of the Joint Committee on Agriculture of 9 April 2014 on amending Annex 12 to the Agreement between the European Community and the Swiss Confederation on trade in agricultural products*

Other

- *Commission Implementing Regulation (EU) No. 718/2014 of 27 June 2014 amending Regulation (EC) No. 669/2009 implementing Regulation (EC) No. 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin*
- *Council Decision of 24 June 2014 establishing the position to be adopted on behalf of the European Union within the General Council of the World Trade Organization on the accession of the Islamic Republic of Afghanistan to the World Trade Organization*
- *Commission Implementing Decision of 23 June 2014 on additional historical aviation emissions and additional aviation allowances to take into consideration the accession of Croatia to the European Union*
- *Commission Implementing Decision of 11 June 2014 setting out the annual breakdown by Member State of the global resources of the European Maritime and Fisheries Fund available in the framework of shared management for the period 2014-2020*

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