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The EU Commission gives the green light to a genetically modified potato

On 2 March 2010, for the first time in 12 years, the European Commission authorised the placing on the market of a genetically modified crop, with Decisions (EU) No. 2010/135 and 2010/136. The 'Amflora' potato variety has been developed by the German company 'BASF' and is intended only for industrial use and animal feed.

Genetically modified (hereinafter, GM) food or feed are produced from, consist of, or contain genetically modified organisms (hereinafter, GMOs), *i.e.,* organisms, whose genetic characteristics have been subjected to artificial modifications, in order to acquire new properties. GMOs first made their appearance in the 1970s and their technological development, since, has been vast. Today, they are mostly employed in relation to crop plant series, such as maize and cotton, in order to enhance their resistance to pests and tolerance to herbicides.

With a view to ensuring that the use of GMOs is not compromising the high level of health and environmental protection to which the European Union is committed, the EU has adopted a comprehensive legal framework, mainly consisting of Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms and Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed. While Directive 2001/18/EC provides for an authorisation procedure pertaining to the release of GMOs into the environment for experimental reasons only or in connection with their marketing, Regulation (EC) No. 1829/2003 establishes an authorisation procedure for the placing on the market of food and feed made from them. However, for reasons of efficiency, there is the possibility for an applicant to file a request, both for environmental release of the GMO and its use in food and feed, exclusively under Regulation (EC) No. 1829/2003; the criteria established under Directive 2001/18/EC continue to apply, of course.

The centralised authorisation procedure established by Regulation (EC) No. 1829/2003, for the placing on the market of GM food and feed, is triggered by the submission of the application to the national competent authority of the EU Member State, where the product is first intended to be marketed. This authority, then, informs the European Food Safety Authority (hereinafter, EFSA), which carries out a risk assessment in relation to the environmental and health impact of the GMO. EFSA's conclusions are summarised in a publicly available opinion, which can be commented by all interested parties and that serves as a basis for the Commission's proposal on whether to grant or refuse the requested authorisation. If the Commission chooses not to abide by EFSA's opinion, it must state the reasons for doing so. The Commission's proposal can be adopted only after going through a comitology procedure. For the time being, this would be the regulatory procedure. However, the new Comitology Regulation, currently under preparation by the Commission, might bring about changes to the applicable decision-making regime.

Reports state that several EU Member States have already indicated their intention to have recourse to the safeguard clause of Article 23 of Directive 2001/18/EC, in order to ban the sale and/or use of the Amflora potato in their territories. If they proceed to doing so, they will have to present the relevant scientific information on which they base their respective measures. The Commission, after seeking the opinion of one or more of the EU Scientific Committees established by Commission Decision 97/579/EC, will adopt a decision on the safeguard measure, in accordance with the regulatory committee procedure. As already mentioned, the decision-making regime might soon be subject to changes, due to the ongoing reform of the Comitology Decision. If

the Commission finds that the national measure is not justified, the specific EU Member State will be obliged to remove it. In case of a failure to do so, affected private parties could claim compensation in national courts, ensuing from the Member State's failure to fulfill its EU obligations.

However, the fears expressed by some that complete segregation between GM and non-GM production is not practically feasible, cannot form the basis for adopting safeguard measures. The latter can only be adopted if grounded on sound scientific evidence, indicating that the authorised GMO can pose a threat from an environmental and/or a health perspective. Co-existence rules are developed by the Member States themselves, pursuant to the subsidiarity principle, as they are deemed to be better placed for formulating policies, which correspond to their respective local agricultural conditions. The last years have witnessed a significant progress in the development of national co-existence legislation. The role of the EU Commission is limited to monitoring the legislative evolution in the national spheres and producing guidelines to assist the development of co-existence policies.

The US requests the WTO to review India's export subsidies for textile and apparel

On 24 February 2010, the US made a request to the WTO Secretariat pursuant to Article 27.6 of the WTO Agreement on Subsidies and Countervailing Measures (hereinafter, the SCM Agreement) to undertake a computation for the purposes of the establishment of the status of 'export competitiveness' of Indian textiles and apparel exports.

India has been providing export subsidies to manufacturers of textiles and textile products, *inter alia*, in the form of discounts on the interest rate for loans. Such products are identified by the US as covered by chapters 50 to 63 of the Harmonised System Nomenclature (hereinafter, HSN) and include, *inter alia,* silk, wool, fine or coarse animal hair, cotton, other vegetable textile fibres, paper yarn and woven fabrics of paper yarn, man-made filaments, carpets and other textile floor coverings and articles of apparel and clothing accessories.

Export subsidies are prohibited by Article 3 of the SCM Agreement. However, specific flexibilities are provided in the SCM Agreement for Developing Countries. In particular, Article 27 of the SCM Agreement introduces a number of provisions concerning special and differential treatment for Developing Countries. In that respect, it recognises that export subsidies can play an important role in the economic development of such Countries in relation to market access. There are three categories of Countries identified under this provision: (i) Least Developed Countries, which are excluded from the prohibition of export subsidies; (ii) Developing Countries listed in Annex VII(b) of the SCM Agreement (*i.e.*, Bolivia, Cameroon, Congo, Côte d'Ivoire, Dominican Republic, Egypt, Ghana, Guatemala, Guyana, India, Indonesia, Kenya, Morocco, Nicaragua, Nigeria, Pakistan, Philippines, Senegal, Sri Lanka and Zimbabwe), that are excluded from the prohibition of export subsidies until the GNP per capita reaches 1,000 USD (in 1990 constant USD) for three consecutive years, subject to certain graduation and re-inclusion provisions; and (iii) a number of Developing Countries that are excluded from the prohibition on export subsidies for certain identified programmes, subject to notification, prior approval requirements and others, which might continue until, and in some cases even beyond, 2015.

India is among the WTO Members included in Annex VII(b) of the SCM Agreement. For such Countries, Article 27.5 of the SCM Agreement establishes that, if 'export competitiveness' is reached for any given product, the Country will have to phase out the related export subsidies over a period of eight years. Export competitiveness, in this respect, has been defined in Article 27.6 of the SCM Agreement as the situation in which exports of a product have reached a share of at least 3.25 per cent in world trade for that product for two consecutive calendar years. There are two ways to establish such status of export competitiveness. First, the Developing WTO Member could notify the WTO that it has reached such level. The other possibility, which the US is pursuing in this particular occasion, is for another WTO Member to request the WTO Secretariat to undertake a

computation exercise for certain products of the Developing WTO Member. The US requested that such computation be undertaken at both the section level (*i.e.*, section XI of the HSN concerning textiles and textile articles, *i.e.*, chapters 50-63 as a whole) and the heading level (*i.e.*, at the four digit level). The US did so because uncertainty exists concerning the correct legal interpretation of 'product', as the English version of Article 27.6 of the SCM Agreement refers to the section heading of the HSN, although the HSN itself contains headings at the four digit level. In should be noted that the Spanish and French versions, in this respect, mention *partidas* and *positions*, which refer to the headings at the four-digit level of the HSN.

If the WTO were to conclude that India has reached the level of export competitiveness for the indicated products as provided in the SCM Agreement, this could have severe consequences as India is a strongly export-oriented economy, especially in sectors such as textiles and apparel. Therefore, Indian exporters could be considerably hurt by such possible outcome. However, according to the SCM Agreement, the export subsidies would have to be phased out over a period of eight years, starting from the date export competitiveness exists. In this period, Indian exporters of textiles and apparel would have to contact the Indian Government in order to come to an agreed strategy that will facilitate the process of transition.

Draft Italian legislation on the use of substances other than vitamins and minerals in food supplements discussed at EU level

On 11 September 2009, the Italian Ministry of Labour, Health and Social Policies (Department of Public Veterinary Health, Nutrition and Food Safety) notified to the EU Commission under the so-called TRIS (Technical Regulation Information Service) procedure set up under Directive 1998/34/EC a draft decree in food supplements.

With the aim of providing transparency and avoiding unjustified barriers between EU Member States, the TRIS procedure imposes an obligation upon the EU Member States to notify to the EU Commission and to the other EU Member States all the draft technical regulations concerning products and information society services before they are adopted in national law. Italy argues that the draft decree on food supplements is necessary to protect consumers and to ensure that correct information regarding the use of substances other than vitamins and minerals in supplements is provided. It contains a positive list of herbal substances in Appendix 1, which specifies the botanical name, part used and reference to the effects of admitted vegetal extracts and labelling rules for some extracts. Attachment 1*bis* identifies the plants which cannot be used, for example *Piper Methysticum G. Forst* (Kava-Kava). Appendix 2 constitutes a non-exhaustive list of other substances with nutritional and physiological effects different from vegetable extracts, the use of which is permitted. It establishes, for example, that the daily intake of isoflavones (effect: woman's well-being and tropism of bones in menopause) should not exceed 80 mg per day. A mutual recognition clause provides that the sale of products not conforming to the provisions of this decree is permitted only if they originate in EU Member States where the same products are legally sold as food supplements.

In the meeting of the Standing Committee on the Food Chain and Animal Health - Section on General Food Law (hereinafter, SCFCAH) held on 22 February 2010, the representatives of the EU Member States exchanged views on the Italian notification, in particular with respect to additional warning labels. On 22 January 2010, the Italian authorities had submitted complementary information in support of the notified draft decree, as requested by the EU Commission.

Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of EU Member States relating to food supplements establishes harmonised rules for the labelling of food supplements and introduces specific rules on vitamins and minerals in the manufacture of food supplements. However, the use of substances other than vitamins or minerals in the manufacture of food supplements continues to be subject to national legislation, which applies within the framework of

the free movements of goods principle of the EU Treaty. Thus, the Italian initiative to regulate the use of substances other than vitamins or minerals in the manufacture of food supplements is, in principle, in line with EU law. Furthermore, as the EU Commission recognised in a recent report on the subject, unlike the market for food supplements containing vitamins and minerals, which appears to be relatively homogeneous, the market for food supplements containing other substances is characterised by its variety. Other substances with a nutritional or physiological effect in food supplements on the EU market may be categorised as amino-acids, enzymes, pre- and probiotics, essential fatty acids, botanicals and botanical extracts and miscellaneous bioactive substances.

Directive 2002/46/EC states that, in addition to general labelling requirements under Directive 2000/13/EC, the labelling of food supplements shall bear the following particulars: (a) the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances; (b) the portion of the product recommended for daily consumption; (c) a warning not to exceed the stated recommended daily dose; (d) a statement to the effect that food supplements should not be used as a substitute for a varied diet; and (e) a statement to the effect that the products should be stored out of the reach of young children. Contrary to the draft decree, the indication of nutritional or physiological effects is, therefore, not required under Directive 2002/46/EC. The Italian draft decree provides for the indication of warnings with respect to four herbal extracts (*i.e.*, Cimicifuga racemosa Nutt, Citrus aurantium L., Ginkgo Biloba L., Hypericum Perforatum L.) and five other substances (*i.e.*, Mixtures of Amino acids, Ramfied amino acids, Bioflavonoids, Creatine, Monascus purpureus (red yeast rice) monacolin).

The justification given in relation to some warning labels (*i.e.,* not to use in pregnancy or for children) is, for example, that the data in the literature is not sufficient to establish safety. Although food has to be safe according to general EU food law, a pre-marketing requirement establishing safety may be disproportionate. In principle, the warning messages contained in the draft may be justified provided that they are intended to ensure that consumers are correctly informed, and that there is a sufficient scientific justification. Italy only provided justifications. Whether the grounds can be deemed 'scientifically sufficient', it remains to be seen. Similarly, it may be argued whether warning messages could have been applied as a less distortive measure for the 'banned' herbal extracts, like in the case of kava-kava, which has been the target of such (arguably disproportionate) approach.

Furthermore, the draft decree providing for mandatory indication of the physiological or nutritional effects has to be seen in the context of Regulation (EC) No. 1924/2006 on nutrition and health claims, as the core principle of that regulation is that nutrition and health claims are made on a voluntary basis and are not imposed. Therefore, whether EU Member States are still allowed to introduce national measures imposing mandatory statements, which would amount to claims in the sense of Regulation (EC) No. 1924/2006, appears at least debatable as this may circumvent Regulation (EC) No. 1924/2006.

As to implications of international trade law, the TRIS notification states that the project will not be communicated in the context of the TBT Agreement (on technical barriers to trade) because it does not have a significant impact on international trade and that Italy will not ask that the project be communicated in the context of the SPS Agreement (on sanitary and phytosanitary measures) because the project is not a sanitary or phytosanitary measure according to appendix A of the SPS Agreement. While the 'significant impact on international trade' is subject to interpretation, it could well be argued that the prohibition of the use of certain plants or their parts in food supplements is an SPS measure.

The decree, if finally adopted, will have a significant impact on the Italian food supplements market, particularly with the labelling requirements, which always create additional costs, but also with the establishment of a list on prohibited herbal substances and the establishment of recommended daily intakes for certain substances with a nutritional or physiological effect. It remains to be seen

how the provision on mutual recognition will be applied in practice by the Italian authorities and whether products, which are legal in other Member States, can be marketed in Italy. Mutual recognition is not free from the risk that technical obstacles to the free movement of the products concerned can be maintained or created. The EU Commission has announced that it will express an opinion regarding the notification of the Italian Decree on food supplements by 23 April 2010, taking into consideration the exchange of views in the SCFCAH.

The EU and Singapore launch FTA talks

On 3 March 2010, Singapore and the EU announced that they would launch talks to come to a free trade agreement (hereinafter, FTA). The first round of talks was conducted from 8 to 12 March 2010.

The EU earlier pursued an FTA with ASEAN, the Association of Southeast Asian Nations, of which Singapore is part. The negotiating authorisation and directives were issued by the EU Council on April 2007 and the actual negotiations were launched in July 2007. However, those negotiations did not advance, *inter alia*, due to the diversified nature of the different members of ASEAN (*e.g.*, highly developed and industrialised Singapore *versus* least developed countries Cambodia, Laos and Myanmar) and the refusal of the EU to negotiate with Myanmar, due to its political situation. Therefore, the EU Member States agreed on 22 December 2009 that the EU Commission would pursue, in addition to an ASEAN FTA, FTA negotiations with the separate ASEAN Members on a bilateral level. In particular, the EU announced it will pursue an FTA with Singapore (the so-called EUSFTA) and two other separate ones with the Philippines and Vietnam. It was agreed that the mandate and the negotiating directives on the basis of which trade talks should be conducted for the potential Singapore FTA are the same as those issued for the ASEAN FTA.

Since the Lisbon Treaty entered into force on 1 December 2009, the procedure for negotiating and concluding international trade agreements has changed considerably (see also Trade Perspectives, Issue No. 21 of 13 November 2009). The European Parliament will play a much more active role throughout the entire process. Notably, besides being informed by the EU Commission throughout the negotiating process, it will also have to approve the final agreement. In particular, the negotiations of international trade agreements, including FTAs, are launched once the EU Council has decided on the negotiating mandate, on the basis of a recommendation from the EU Commission. In addition, the EU Council will provide a number of negotiating directives. The EU Commission will then conduct the negotiations in consultation with the Trade Policy Committee (*i.e.*, the former 133 Committee, composed of representatives of EU Member States and chaired by the EU Member State holding the EU presidency), while also reporting to the European Parliament about the progress of the free trade talks. If an agreement has been reached, the EU Commission initials it and presents the result to the EU Council. The EU Council then has to decide whether to sign the agreement. If it decides to do so, the agreement will have a provisional application. In the final stages of the procedure, it is for the European Parliament to consider whether to express consent with it. There are indications that, should the European Parliament object to certain parts of the agreement only, these will be exempted from the provisional application. This is intended to ensure that controversial issues will not hinder the provisional entry into force of the entire agreement. When the European Parliament has expressed full consent with it, the EU Council can conclude the agreement and it will enter into force.

The commercial implications for both trading partners are considerably high. The EU is the most important trading partner to Singapore. In 2008, trade between the two partners exceeded 55 billion EUR. In addition, 60 per cent of EU foreign direct investment in that region goes to Singapore, which, in turn, is the biggest trading partner to the EU from South-East Asia. Singapore could function as a hub to EU companies based in the Region (in fact, it already does). In particular, EU companies based there could use Singapore as an operating base to serve other Countries in the region, for example, within ASEAN, with which Singapore has preferential market access. The most significant area of interest to both partners is services liberalisation. In particular,

for Singapore, the insurance sector stands to gain the most. Singapore already has zero tariffs on a great range of goods, with, as an exception, *inter alia*, tobacco and alcoholic beverages.

Recently Adopted EU Legislation

- *Commission Regulation (EU) No. 196/2010 of 9 March 2010 amending Annex I to Regulation (EC) No. 689/2008 of the European Parliament and of the Council concerning the export and import of dangerous chemicals*

- *Commission Decision of 8 March 2010 concerning the draft Decree from Greece on the display of information of all manner of dairy products indicating the country of origin of the raw material (milk) used for the manufacture and sale of such products to the final consumer, and the obligations of retail sellers on how to display dairy products at points of sales within their stores (notified under document C(2010) 1195)*

- *Commission Decision of 2 March 2010 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch (notified under document C(2010) 1193)*

- *Commission Decision of 2 March 2010 authorising the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under Regulation (EC) No. 1829/2003 of the European Parliament and of the Council (notified under document C(2010) 1196)*

- *Implementing Regulation of the Council (EU) No. 195/2010 of 1 March 2010 amending Regulation (EU) No. 1202/2009 imposing a definitive anti-dumping duty on imports of furfuryl alcohol originating in the People's Republic of China following a 'new exporter' review pursuant to Article 11(4) of Regulation (EC) No. 1225/2009*

- *Council Directive 2010/12/EU of 16 February 2010 amending Directives 92/79/EEC, 92/80/EEC and 95/59/EC on the structure and rates of excise duty applied on manufactured tobacco and Directive 2008/118/EC*