by the Italian Government, which laid down the obligation to indicate the origin of poultry meat from other EU Member States in order to ensure the traceability of meat following the confirmation of outbreaks of bird flu in third countries. In its application, the EU Commission argued that the order was not justified by the public health considerations within the meaning of Article 18(2) of Directive 2000/13/EC, which the Italian Government relied on to justify the additional labelling requirement since the EU, in order to combat bird flu, had adopted a wide range of veterinary measures intended to ensure that only healthy poultry meat could enter the EU and be marketed there. However, there was no judgement issued in this case, as the Italian order was withdrawn.

IV. Conclusion

To avoid a further fragmentation of food labelling laws, the standard of review for the introduction of additional mandatory labelling particulars for specific types or categories of foods, justified on grounds of, respectively: the protection of public health; the protection of consumers; the prevention of fraud; and the protection of industrial and commercial property rights, should be set at a high level. Further, there should be stringent requirements in order to prove a link between certain qualities of the food and its origin or provenance, which would permit EU Member States to introduce measures concerning the mandatory indication of the country of origin or place of provenance. The commercial implications and costs of this national fragmentation are clear and would be severe to both free movement of goods on the internal market and to international trade.

EU and US Mutually Recognise their Respective Organic Standards and Control Systems as Equivalent

*Ignacio Carreño**

I. Introduction

On 15 February 2012, the EU Commission, the US Department of Agriculture (hereinafter, the USDA) and the US Trade Representative concluded in Nuremberg, Germany (at the BioFach World Organic Fair, the world's largest fair for organic products), a bilateral agreement recognising their respective standards and control systems for organic food as equivalent. The agreement was preceded by two years of negotiations, a review of each others' organic regulations and control programs, and on-the-spot missions in the US and the EU to evaluate the systems in place. In simple terms, as of 1 June 2012, the effective date of the agreement, organic products certified in the EU or in the US may be sold as organic in either region. Currently, operators deciding to trade products in the EU and the US must obtain separate certifications for two organic standards, and, consequently, encounter a double set of fees, inspections, and paperwork.

II. The procedure

The agreement was concluded by a formal exchange of letters.[1] The US has determined, pursuant to the *Organic Foods Production Act of 1990* (OFPA),[2] that agricultural products produced and handled in accordance with *Council Regulation (EC) No. 834/2007 on organic production and labelling of organic products*[3] and its implementing Commission *Regulations*

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1 Formal letters establishing the agreement were exchanged by Dacian Ciolos, European Commissioner for Agriculture and Rural Development for the European Commission; Kathleen Merrigan, US Agriculture Deputy Secretary for the the US Department of Agriculture; and for the Office of the US Trade Representative, Chief Agricultural Negotiator, Ambassador Islam Siddiqui.

2 7 U.S.C. Sec. 6501 *et sqq*.

3 OJ 2007, L 189/1, last amended by Council Regulation (EC) No. 967/2008 of 29 September 2008, OJ 2008, L 264/1.

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(EC) No. 889/2008[4] and *1235/2007*[5], are produced and handled under an organic certification program that provides safeguards and guidelines governing the production and handling of such products that are at least equivalent to the requirements of the OFPA. Until now, the US Government had only recognised the Canadian system as equivalent.[6]

As to the procedure followed on the EU side, the EU Commission examined a US request to be included in the list of equivalent countries, entertained discussions with the US authorities, and carried out an on-the spot-mission to the US.[7] This led to the conclusion that the US rules governing the production and controls of organic agricultural products are equivalent to those laid down in *Regulation (EC) No. 834/2007*. Consequently, the EU Commission adopted on 14 February 2012 *Commission Implementing Regulation (EU) No. 126/2012 amending Regulation (EC) No. 889/2008 as regards documentary evidence and amending Regulation (EC) No. 1235/2008 as regards the arrangements for imports of organic products from the United States of America*.[8] The US is now listed as an '*equivalent third country*' in Annex III of *Regulation (EC) No. 1235/2008 on imports of organic products from third countries*,[9] together with Argentina, Australia, Canada, Costa Rica, India, Israel, Japan, New Zealand, Switzerland, and Tunisia.

III. Comments

Certain agricultural products imported from the US are currently marketed in the EU pursuant to a different set of rules provided for in Article 19 of *Commission 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.* For countries that are not (or not yet) on the third country list, organic products can be exported to the EU when they are certified as organic by a certifier that is recognised by the EU Commission. On 6 December 2011, the EU Commission adopted the *Implementing Regulation (EU) No. 1267/2011 amending Regulation (EC) No. 1235/2008 laying down detailed rules for the arrangements for imports of organic products from third countries,*[10] which includes the long-awaited list of certification bodies that operate in third countries.

Although both parties individually determined the mutual equivalency of their programmes, an analysis of the details of the EU-US agreement nonetheless shows differences between the US and EU organic standards, which must be taken into account when organic products are traded between the two countries. The major difference concerns the use of antibiotics. The USDA organic regulations prohibit the use of antibiotics, except for the use of streptomycin to control invasive bacterial infections (*i.e.*, fire blight) in organic apple and pear orchards. EU organic standards do not provide for this exception. The EU organic regulations allow antibiotics only for the treatment of infected animals, which, on the other hand, is not permitted in the US. Therefore, US organic apples and pears on which antibiotics have been applied for fire blight control may not be exported to the EU as '*organic*', while EU organic agricultural products derived from animals treated with antibiotics may not be exported to the US. In addition, EU aquatic animals (*e.g.*, fish, shellfish) may not be exported to the US. In terms of labelling, a product must contain at least 95% organically produced products to be labelled as organic in both the US and the EU. In the US, a product that contains 70–95% organic ingredients may be labelled as '*made with organic*'.

4 Commission Regulation (EC) No. 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No. 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, OJ 2008, L 250/1, last amended by Commission Implementing Regulation (EU) No. 126/2012 of 14 February 2012, OJ 2012, L 41/5.

5 Commission Regulation (EC) No. 1235/2008 of 8 December 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, OJ 2008, L 334/25.

6 The Agreement between the US and Canada was concluded on 19 June 2009. The two letters determining equivalence and information on the details can be found on the US NOP website, available on the Internet at <www.ams.usda.gov/nop> (last accessed on 16 April 2012).

7 Mission of the European Commission to the US on organic products of plant and animal origin and organic processed products of plant and animal origin from 4–8 October 2010. The mission report is available on the Internet at <http://ec.europa.eu/agriculture/organic/files/news/mission_report_us.pdf> (last accessed on 16 April 2012).

8 Commission Implementing Regulation (EU) No. 126/2012 of 14 February 2012 amending Regulation (EC) No. 889/2008 as regards documentary evidence and amending Regulation (EC) No. 1235/2008 as regards the arrangements for imports of organic products from the United States of America, OJ 2012, L 41/5.

9 Commission Regulation (EC) No. 1235/2008 of 8 December 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, OJ 2008, L 334/25.

10 Commission Implementing Regulation (EU) No. 1267/2011 of 6 December 2011 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, OJ 2011, L 324/ .

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This option is not permitted in the EU. However, for products containing less than 95% organic ingredients, a percentage statement of organic content may be displayed in the EU. Different from the US organic legislation, which covers products for personal care, the EU organic legislation covers only food and feed products. Another difference between the two systems has been eliminated with the adoption of an EU Regulation on organic wine on 8 February 2012. With the new regulation, which will apply from the 2012 harvest onwards, EU organic wine growers will be allowed to use the term '*organic wine*' on their labels. Until then, the only statement allowed has been '*wine made from organic grapes*'. The permissible sulphite content in organic wine was the most controversial issue in drafting the regulation, with a maximum sulphite content finally set at 100 mg/l for organic red wine (150 mg/l for conventional wine) and 150 mg/l for organic white or rosé wine (200 mg/l for conventional), with a 30 mg/l differential where the residual sugar content is more than 2 g/l. The US and many other wine-producing countries, such as Australia, Chile and South Africa, have already established standards for organic wine. EU organic wines can now compete at the international level.

Prior to 1 June 2012, accredited certifiers will be trained on the terms of the EU-US agreement. The USDA and the EU Commission will conduct regular assessments of each others' organic regulatory systems to ensure that the terms of the arrangement are being met. They will also establish a joint working group to evaluate issues such as the use of veterinary drugs in organic production, and the exchange of information on organic production strategies on animal welfare, on antibiotic-free dairy, and methods to avoid contamination of organic products from genetically modified organisms and other activities to enhance the integrity of organic production systems. The EU-US working group will also establish cooperation arrangements on the recognition of new third country arrangements and initiate a common assessment exercise for third country evaluations.

IV. Conclusion

The combined organic products sector in the EU and the US is valued, according to the European Commission,[11] at around 40 billion EUR, and rising every year. The EU-US agreement is expected to generate additional trade and jobs in both the US and the EU. Third country operators and certifiers cannot directly benefit from the EU-US agreement. For example, third country organic products certified under the USDA organic regulations may not be shipped to the EU. These products must be certified under the EU organic regulation. Only products produced or which had final processing/packaging conducted within the US can be shipped to the EU under the EU-US organic agreement and *vice versa*.

11 See Commission Press Release (IP/12/138) of 15 February 2012.

Nanotechnology

This section is meant to give readers an insight into the emerging field of nanotechnologies and risk regulation. It informs and updates readers on the latest European and international developments in nanotechnologies and risk regulation across different sectors (e.g., chemicals, food, cosmetics, pharmaceuticals) and policy areas (e.g., environmental protection, occupational health and consumer product, food and drug safety). The section analyzes how existing regulatory systems deal with new kinds of risks and reviews recent regulatory developments with a focus on how best to combine scientific freedom and technological progress with a responsible development and commercialization of nanotechnologies.

The Drive Towards Nanotechnology Standardization: Shifting Roles in Governance and Key Challenges

*Evisa Kica**

I. Introduction

In recent decades, the development and the application of nanotechnology has been seen in various technological fields ranging from healthcare to food, agriculture, cosmetics and transportation. A number of disciplines, including electronics, biotechnology

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