FRATINIVERGANO
EUROPEAN LAWYERS
TRADE PERSPECTIVES©

Issue No. 6 of 22 March 2013

The EU fails to approve a ban on neonicotinoid insecticides although EFSA's risk assessment concluded that their use implies risks for bees

In its meeting on 15 March 2013, the representatives of the 27 EU Member States in the Standing Committee on the Food Chain and Animal Health (Section Phytopharmaceuticals - Plant Protection Products, hereinafter SCFCAH) did not reach the necessary majority (in favour or against) in a vote on a draft *Commission Implementing Regulation amending Implementing Regulation (EU) No. 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances.* Except for two exceptions allowing the use of these three neonicotinoid insecticides to crops attractive to bees in greenhouses (at any time) and in open fields (only after flowering), the proposed measure would constitute a ban of neonicotinoids. Thirteen EU Member States (*i.e.*, Belgium, Cyprus, Denmark, France, Italy, Latvia, Luxembourg, Malta, the Netherlands, Poland, Slovenia, Spain, and Sweden) supported the proposal in the SCFCAH, nine EU Member States (*i.e.*, Austria, the Czech Republic, Hungary, Greece, Ireland, Lithuania, Portugal, Romania and Slovakia) voted against it, and five EU Member States (*i.e.*, Bulgaria, Estonia, Finland, Germany and the UK) abstained.

In recent years, beekeepers and environmental scientists have become more and more concerned at the mass die-offs of bees, including the phenomenon known as *Colony Collapse Disorder*. Neonicotinoids, a relatively new class of insecticides, that are chemically related to nicotine and with a common mode of action that affects the central nervous system of insects, causing paralysis and death, are blamed to be responsible for the adverse effects to bees' health. Neonicotinoids are not just present on the leaves and seeds, which pest insects might eat, but also in the pollen and nectar gathered by bees in the process of pollination.

On 31 January 2013, with the aim of protecting bees against the negative impact of the three marketed neonicotinoid insecticides, the EU Commission issued a proposal for a ban on their use on crops that are attractive to honey bees, such as barley, cotton, maize, oilseed rape, sunflowers and wheat. The active substances clothianidin, thiamethoxam and imidacloprid were previously included in Annex I to *Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market* by *Commission Directives 2006/41/EC, 2007/6/EC, 2008/116/EC* respectively. *Commission Directive 2010/21/EU* amended Annex I to *Directive 91/414/EEC* as regards the specific provisions relating to the three neonicotinoids. Active substances included in Annex I to *Directive 91/414/EEC* are deemed to be approved under *Regulation (EC) No. 1107/2009* and are listed in Part A of the Annex to *Commission Regulation (EU) No. 540/2011 of 25 May 2011 implementing Regulation (EC) No. 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances*.

When new scientific information concerning sub-lethal effects of neonicotinoids on bees was published in early 2012, the EU Commission, in accordance with Article 21(2) of *Regulation (EC) No. 1107/2009*, asked the European Food Safety Authority (hereinafter, EFSA) for scientific and technical assistance to assess this new information and to review the risk assessment of neonicotinoids as regards their impact on bees. On 16 January 2013, EFSA presented its conclusions on the risk assessment for bees in relation to clothianidin, thiamethoxam and imidacloprid (*i.e.*, the three neonicotinoid insecticides marketed in the EU), in which it identified for certain crops high acute risks for bees from plant protection products containing these active substances. EFSA identified, in particular, high acute risks for bees from exposure via dust as regards several crops, from consumption of residues in contaminated pollen and nectar as regards some crops and from exposure via guttation fluid as regards maize. In addition, EFSA stated that unacceptable risks, due to acute or chronic effects on colony survival and development, could not be excluded for several crops and identified a number of data gaps for each of the evaluated crops, in particular as regards long-term risk to honey bees from dust exposure, from residues in pollen and nectar and from exposure from guttation fluid.

In the light of the new scientific and technical knowledge assembled by EFSA, the EU Commission considered that there are indications that the approved uses of clothianidin, thiamethoxam and imidacloprid no longer satisfy the approval criteria provided for in Article 4 of *Regulation (EC) No. 1107/2009*, with respect to their impact on bees, and that the high risk for bees could not be excluded except by imposing further restrictions. The EU Commission's proposal put to the vote on 15 March 2013 restricts for two years the use of clothianidin, imidacloprid and thiamethoxam only to crops not attractive to bees and to winter cereals (as dust exposure during autumn is not considered a major issue), except for allowing the use in greenhouses at any time and in open fields only after flowering. It prohibits the sale and use of seeds treated with plant protection products containing these active substances. Both measures, according to the proposal, should be implemented at the latest by 1 July 2013 and should be reviewed by the EU Commission after two years.

The WTO Agreement on Sanitary and Phytosanitary Measures (hereinafter, SPS Agreement) provides that, while governments have the right to establish their own levels of protection and may adopt sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, these are only permissible where they can be proved to be science-based, proportional, non-discriminatory and/or based on international standards. There appears to be no international standard in relation to the application of neonicotinoids like clothianidin, thiamethoxam and imidacloprid. The measure that the EU Commission is proposing concerns the protection of bees (*i.e.*, animals). Bans on plant protection products and treated seeds containing clothianidin, thiamethoxam and imidacloprid would affect international trade and would fall under the scope of the SPS Agreement. It appears that a number of EU Member States, including Germany, that had abstained in the vote in the SCFCAH, argue that they would be willing to favour the ban when certain conditions were introduced, in particular exemptions on the basis that the neonicotinoids kill the bees only when mixed with airborne particles of dust. Germany has apparently developed a technique, treating the seeds with an adhesive agent, that '*glues*' the neonicotinoids onto the seeds and prevents them from going airborne. As a consequence of this technique, the seeds become dust-free and abrasion-resistant. Such approach could be a less restrictive measure than a complete ban on this type of insecticides. On 1 March 2013, the EU Commission notified the draft measure to the WTO Committee on Sanitary and Phytosanitary Measures. In view of the originally proposed date of entry into force (1 July 2013), WTO Members could make comments until 11 March 2013.

Environmental campaigners lobbying against the use of pesticides in the EU regretted the vote in the SCFCAH, while the pesticides industry welcomed the lack of support among EU Member States for the EU Commission's proposal. A recent study, which was commissioned

by EU think tank *Humboldt Forum for Food and Agriculture* (HFFA) and financed by *Syngenta* and *Bayer CropScience*, basically concluded that the withdrawal of neonicotinoids from the market would result in the loss of EU-wide agricultural revenues of 2.8 billion EUR (*i.e.*, 2.1 billion EUR crop market revenues and 0.7 billion EUR for lower production costs).

Under the current rules of procedure, set out in Article 291 TFEU and *Regulation (EU) No. 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers*, the EU Commission can now either refer the issue to the Appeals Committee (which also consists of representatives of the EU Member States), within two months, or amend the proposal. According to Article 6(3) of *Regulation (EU) No. 182/2011*, if there is a qualified majority in the Appeals Committee, the EU Commission must adopt the implementing Regulation. If there is no qualified majority in the Appeals Committee, the EU Commission may adopt the regulation. Only if there is a qualified majority against the proposal, the EU Commission cannot adopt the proposal. Third country governments and business operators should observe carefully any steps actually taken by the EU and consider addressing (or challenging) within the WTO the potentially indiscriminate use of disproportionate or unscientific SPS measures.

The EU plans to introduce a mandatory country of origin labelling requirement

On 13 February 2013, the EU Commission issued a package proposal for the establishment of a new framework on product safety and market surveillance. This package mainly consists of two proposals and a plan, *i.e.*, (i) the '*Proposal for a Regulation of the European Parliament and of the Council on consumer product safety' (*hereinafter, the '*Consumer Product Safety Proposal*'); (ii) the '*Proposal for a Regulation of the European Parliament and of the Council on market surveillance of products*'; and (iii) the '*Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. 20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU*'. The objectives of this new framework are, first, the simplification and unification of rules on product safety and market surveillance, which are currently spread over diverse instruments; and, second, the better coordination and enforcement of these rules.

The objective of simplifying and unifying the regulatory framework on product safety and market surveillance is achieved through the replacement of the existing legislation applicable to non-food products, where legislative instruments significantly overlapped with one another. In particular, the new '*Consumer Product Safety Proposal*' would replace the so-called '*General Product Safety Directive*' (*i.e.*, '*Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety*'), as well as '*Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers*'). The second objective is achieved through the introduction, via Article 7 of the '*Consumer Product Safety Proposal*', of a mandatory country of origin labelling requirement, which could entail significant controversy. In particular, the '*Consumer Product Safety Proposal*' requires manufacturers and importers to ensure that country of origin is indicated on products sold within the EU or, alternatively, if the size or nature of the product does not allow it, on the product's packaging or accompanying document. In particular, this labelling requirement would apply to all goods intended for consumers or with which consumers are likely to come into contact. Exceptions are provided for certain products, including, *inter alia*, medicinal products for human or veterinary use, food, and feed products. The application of the mandatory country of origin requirement to a vast category of goods is a novelty in the EU, as EU rules currently provide only for such

requirement for certain agricultural products (see Trade Perspectives, Issue No. 3 of 10 February 2011).

The EU has defined the country of origin of products according to the non-preferential rules of origin as set in Article 23 to 25 of *Council Regulation (EEC) No. 2913/92 of 12 October 1992 establishing the Community Customs Code*. Therefore, the country of origin is given by the place where the goods have been '*wholly obtained or produced*' or, if the production involved more than one country, by the place where the goods *'underwent their last, substantial, economically justified processing or working'*.

Under the proposed framework, EU manufacturers and importers bear an obligation to indicate either the EU Member State where the product originates from or, in the alternative, include a general reference to the EU origin, when the product originates from the EU. In order to further enhance consumers' protection and ensure a wide application of the requirement, the EU Commission has laid down broad definitions concerning the covered manufacturers and importers: manufacturers subject to the obligation to indicate the country of origin for all products placed on the EU market are *'any natural or legal person who manufactures a product or has a product designed or manufactured and markets that product under his name or trademark*'; importers under the same obligations are *'any natural or legal person established within the Union [who first makes available a product] from a third country on the Union market'*. In any case, it is provided that the mandatory country of origin labelling requirement would not be retroactive and that EU Member States must not impede the sale of products already placed on the market.

Upon implementation of this framework, EU legislation would be largely aligned with that of the US, which already provides for a country of origin labelling obligation on all products. However, this consideration does not affect the question of whether this framework would be consistent with EU's obligations under the WTO. Despite the recognition by the WTO's Appellate Body in the *United States - Certain Country of Origin Labelling (COOL) Requirements* of the right to regulate in order to enhance consumer information through labelling requirements, the administration of the requirement has to comply with the relevant WTO rules and obligations. Country of origin labelling requirements could have an impact *vis-à-vis* WTO rules, particularly Article 2.2 of the WTO Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement) and Article IX:4 of the WTO General Agreement on Tariffs and Trade (hereinafter, the GATT). The '*Consumer Product Safety Proposal*' may have an impact on the EU's obligation under Article 2.2 of the TBT Agreement, if it is established that other less trade-restrictive measures could have been put in place to ensure the product safety objective set by the EU. In addition, the mandatory country of origin labelling requirement may unreasonably increase the costs of the products, which would render the measure arguably inconsistent with Article IX:4 of the GATT.

In conclusion, the approval of the proposed framework on product safety and market surveillance looks poised to raise controversy as far as the country of origin labelling requirements are concerned, since they may impose heavy burdens on manufacturers and importers placing foreign goods on the EU market. While the harmonisation and simplification objectives of the EU would significantly lift the administrative burdens on manufacturers and importers, the specific design of the proposed country of origin labelling requirement appears to partly offset this enhancement. It remains to be seen whether the proposed EU framework will be consistent, *de facto* if not *de jure*, with the relevant WTO rules and obligations. This new framework on product safety and market surveillance is currently being reviewed by the European Parliament and the Council and is expected to enter into force in 2015. Companies operating in sectors eventually affected by the proposed framework are advised to stay abreast of these legislative and regulatory developments.

US compliance measure in the Country of Origin Labelling WTO case: is it the end of the story?

On 18 of March 2013, the US notified the WTO Committee on Technical Barriers to Trade of its amended Country of Origin Labelling (hereinafter, COOL) regulation. Such regulation is part of the US obligation to comply with the WTO Dispute Settlement Body's (hereinafter, DSB) ruling in the *US – COOL* dispute. This proposed rule is intended to amend the COOL regulation so that the labelling provisions for muscle cut meat meet the DSB ruling and achieve WTO consistency.

Following the panel's recommendations of 18 November 2011, Canada, Mexico and the US each appealed certain issues of law and legal interpretation developed in the WTO panel report. As a result of those appeals, the WTO Appellate Body upheld the most part of the panel's findings. In particular, the Appellate Body agreed with Canada and Mexico that the US COOL measure violated, *inter alia*, Articles 2.1 and 2.2 of the WTO TBT Agreement, inasmuch as they afforded Canadian and Mexican imports of livestock less favourable treatment than they accorded to domestic US livestock.

In its ruling, the Appellate Body found that, although the US had a right to adopt measures involving COOL requirements, the COOL measure at hand was administered in a manner that did not meet the policy objective. In particular, the Appellate Body found that the level of information conveyed to consumers through the mandatory labelling requirements was far less detailed and accurate than it should have been. The US welcomed the Appellate Body's finding confirming that the US had a right to adopt labelling requirements in order to provide information to American consumers about the meat they purchase. In this light, the US stated that it aimed at complying with the Appellate Body ruling by amending the COOL measure in a manner that addressed the ruling, particularly by introducing changes that would ensure that more thorough and detailed information was conveyed to consumers.

In particular, the US announced that it would amend its measure so that the label clearly indicates every country where a production stage has taken place. Under the proposed measure, products from animals born in Canada, but fed and slaughtered in the US, would carry a label stating such precise facts; while products from cattle strictly born, raised and slaughtered in the US would no longer be labelled as '*Product of the United States*' but as '*Born, raised and slaughtered in the United States*'. In its current drafting, prior to the adoption of the amendment at issue, the US COOL regulation defines the country of origin by classifying the muscle cut meat into categories depending on where the livestock was born, raised and slaughtered. Such labels stated either '*US origin*', '*Multiple countries of origin*', '*Imported for immediate slaughter*', '*Foreign country origin*', or '*Ground meat*'. The reasonable period of time for the US to bring its regulations in compliance with the DSB ruling amounted to 10 months, as established by the arbitrator under the Article 21.3 of the Understanding on the Rules and Procedures Governing the Settlement of Disputes (hereinafter, DSU) procedure.

Affected Canadian industries, as well as the Federal Government, reacted to the proposed amendments to the COOL regulation by stating that they would still not bring the mandatory measure into compliance with WTO law. According to Canada, the proposed amendments would increase discrimination against exports of cattle and hogs from Canada, therefore further injuring the Canadian industry, as well as entailing high financial costs, which would be eventually passed onto consumers, therefore hindering competition between Canadian and US industries. According to Canada, it appears that the proposed changes to the COOL regulation would not eliminate the less favourable treatment accorded to Canadian and Mexican livestock producers and, therefore, the violation of Article 2.1 of the TBT Agreement would continue to exist.

In case the US were to fail to adequately bring its measure into conformity with WTO law, in the sense of the Appellate Body's report, the DSU provides for a further mechanism to ensure that WTO Members' rights are respected. Pursuant to Article 22.2 of the DSU, a WTO Member may seek compensation or request the authorisation to suspend concessions or other obligations from the DSB within 20 days after the date of expiry of the reasonable period of time. In any case, and prior to requesting such authorisation, Canada and Mexico may, pursuant to Article 21.5 of the DSU, have recourse to the original Panel, to have it decide on whether the US has failed to bring its measure into compliance with the rulings of the Appellate Body.

Companies operating in the relevant industrial sectors in Canada and Mexico, but also in third countries exporting meat to the US, are advised to monitor the development of this dispute and, in particular, to closely examine the compliance measure that may be adopted by the US. Should they consider that the new measure infringes their commercial interest, they would have to liaise with their governments in order to address the matter in the appropriate *fora*.

Recently Adopted EU Legislation

Market Access

- *Commission Decision of 7 March 2013 on the safety requirements to be met by European standards for certain seats for children pursuant to Directive 2001/95/EC of the European Parliament and of the Council on general product safety*

Trade Remedies

- *Council Implementing Regulation (EU) No. 260/2013 of 18 March 2013 extending the definitive anti-dumping duty imposed by Regulation (EC) No 1458/2007 on imports of gas-fuelled, non-refillable pocket flint lighters originating in the People's Republic of China to imports of gas-fuelled, non-refillable pocket flint lighters consigned from the Socialist Republic of Vietnam, whether declared as originating in the Socialist Republic of Vietnam or not*

- *Council Implementing Regulation (EU) No. 217/2013 of 11 March 2013 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain aluminium foils in rolls originating in the People's Republic of China*

- *Council Implementing Regulation (EU) No. 214/2013 of 11 March 2013 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain organic coated steel products originating in the People's Republic of China*

- *Council Implementing Regulation (EU) No. 215/2013 of 11 March 2013 imposing a countervailing duty on imports of certain organic coated steel products originating in the People's Republic of China*

- *Council Implementing Regulation (EU) No. 205/2013 of 7 March 2013 extending the definitive anti-dumping duty imposed by Implementing Regulation (EU) No. 2/2012 on imports of certain stainless steel fasteners and parts thereof*

originating in the People's Republic of China to imports of certain stainless steel fasteners consigned from the Philippines, whether declared as originating in the Philippines or not and terminating the investigation concerning possible circumvention of anti-dumping measures imposed by that regulation by imports of certain stainless steel fasteners and parts thereof consigned from Malaysia and Thailand, whether declared as originating in Malaysia and Thailand or not.

Food and Agricultural Law

- *Regulation (EU) No. 228/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006*

- *Commission Regulation (EU) No. 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts*

- *Commission Implementing Regulation (EU) No. 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts*

- *Commission Implementing Regulation (EU) No. 202/2013 of 8 March 2013 amending Regulation (EC) No. 555/2008 as regards the submission of support programmes in the wine sector and trade with third countries*

Ignacio Carreño, Eugenia Laurenza, Nurhafia, Anna Martelloni, Blanca Salas, Victoria Simon and Paolo R. Vergano contributed to this issue.