FRATINIVERGANO
EUROPEAN LAWYERS
TRADE PERSPECTIVES©

Issue No. 16 of 6 September 2019

The EU requests a WTO dispute settlement panel regarding measures concerning the production, importation, and marketing of pharmaceutical products by Turkey

On 2 August 2019, the EU requested the World Trade Organization (hereinafter, WTO) to establish a panel with respect to *Certain measures concerning the production, importation and marketing of pharmaceutical products* maintained by Turkey (WT/DS583/3). The request concerns certain measures on pharmaceuticals, introduced by Turkey in 2016, intended to promote the local production of pharmaceutical products, which are currently mostly imported. The EU considers the measures to be inconsistent with a number of Turkey's WTO obligations.

According to data from the *Pharmaceutical Manufacturers Association of Turkey* (*i.e.*, *İlaç Endüstrisi İşverenler Sendikası*, IEIS), the market size for pharmaceuticals in Turkey amounts to around USD 5.5 billion per year. According to the IEIS, there are currently 609 types of medicines that are being produced domestically, but many are imported. According to Turkey's Ministry of Health, around 54% of all pharmaceutical products used in Turkey are imported from a variety of third countries. After the general election on 1 November 2015, the President of Turkey *Recep Tayyip Erdoğan* made the development of the pharmaceutical and medical devices sectors a priority of the Government. Already in 2013, the Government of Turkey had published in its Official Gazette the '*Communique on Applying Industry Cooperation Program in Health and Services Areas*' (hereinafter, Communique). The Communique provides several rules and principles that require businesses, operating in the Turkish market for pharmaceutical products, to cooperate with the relevant administrative bodies and to increase domestic production. There are four categories of commitments: 1) Local support contribution; 2) Investment; 3) Technological cooperation; and 4) Export. Additionally, in 2013, the Government of Turkey introduced the *Tenth national Development Plan (2014-18)*, which, in point 1.2 thereof, sets the objective of reducing Turkey's overall import dependency. The majority of the relevant reforms took place in 2016, implementing the *2016 Action Plan of the 64th Government (Implementation and Reforms)*, which encouraged the increased domestic production of medicines. More specifically, it states that the reimbursement, pricing, and licensing processes of medical devices and of domestic medicines must be improved.

On 2 April 2019, the EU requested consultations with Turkey at the WTO (WT/DS583/1) and, on 18 April 2019, the US requested to join the consultations. In its request, the EU stated that it considers that certain measures introduced by Turkey, concerning the production, importation, and marketing of pharmaceutical products, are inconsistent with WTO disciplines.

The EU referred to four specific measures: 1) A localisation requirement; 2) A technology transfer requirement; 3) An import ban on localised products; and 4) A so-called prioritisation measure. Consultations between the parties to the dispute were held on 9 and 10 May 2019, but did not manage to settle the controversy. On 2 August 2019, the EU then requested the establishment of a panel, but only with respect to three of the four measures referred to in the submission for consultations. The complaint regarding the technology transfer requirement appears to have been left out. According to the European Commission (hereinafter, Commission), the estimated value of pharmaceutical exports that could be affected by Turkey's measures amounts to EUR 460 million.

In its submission requesting the establishment of a panel, the EU detailed its concerns regarding the three measures at issue. First, on the localisation requirement, the EU recalled that one of the objectives of the reforms taken by the Government of Turkey is to increase the local production of a substantial part of the pharmaceutical products consumed in Turkey. The EU's submission to the WTO states that the Government of Turkey requires foreign producers of pharmaceuticals "*to commit to localise in Turkey their production of certain pharmaceutical products*". The lack of such a commitment would automatically exclude the foreign producer's pharmaceutical product from Turkey's reimbursement scheme regarding pharmaceutical products sold by pharmacies to patients and operated by Turkey's social security system. According to the EU's submission, this scheme covers most sales of pharmaceutical products. The EU also notes that, when an imported pharmaceutical product is excluded from the reimbursement scheme, it is subject to an important competitive disadvantage vis-à-vis domestically produced '*like*' products. The EU goes on to note that the localisation requirement is periodically adapted, modified, updated, or extended with respect to, *inter alia*, the scope of products and/or *"the extent of localisation sought*". Finally, the EU maintains that the specific commitments are individually established for each foreign producer and in a non-transparent manner, differing from producer to producer.

The EU considers the localisation measure to be inconsistent with Article III:4 of the General Agreement on Tariffs and Trade (hereinafter, GATT) on '*National treatment*', which states that "*the products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use*". The EU notes that, by excluding imported pharmaceutical products, for which no localisation commitments have been made, accepted or fulfilled, from the reimbursement scheme, imported products are treated less favourable than '*like*' products of Turkish origin. The EU also claims that the reimbursement scheme operated by the Turkish social security system constitutes a subsidy within the meaning of Article 1.1 of the Agreement on Subsidies and Countervailing Measures (hereinafter, SCM), noting that "*the localisation requirement makes the granting of that subsidy contingent upon the use of domestic over imported goods, thereby violating Article 3.1(b) of the SCM Agreement*". Finally, the EU considers the localisation requirement to be inconsistent with Article X:1 of the GATT on the '*Publication and Administration of Trade Regulations*', because Turkey had failed to publish certain elements, terms, and conditions of general application of the measure in a way to enable other WTO Members and traders to become acquainted with them, as well as inconsistent with Article 2.1 of the Agreement on Trade-Related Investment Measures (hereinafter, TRIMs) on '*National Treatment and Quantitative Restrictions*', because the localisation requirement could be considered as an investment measure related to trade in goods, contrary to Article III:4 of the GATT.

Second, the EU refers to the import ban on localised products, noting that when the production of a pharmaceutical product has been localised in Turkey, in accordance with the localisation requirement, the importation of that particular pharmaceutical product is prohibited. The EU considers that this measure is inconsistent with Turkey's obligations under Article XI:1 of the GATT on '*General Elimination of Quantitative Restrictions*', which states that "*no prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party*

or on the exportation or sale for export of any product destined for the territory of any other contracting party". The EU notes that the fact that a product may no longer be imported into Turkey, because a foreign producer has localised production of a certain pharmaceutical product pursuant to the localisation requirement, means that Turkey institutes and maintains a prohibition or restriction, other than duties, taxes or other charges, on the importation of pharmaceutical products of the territory of other WTO Members.

Third, with respect to the prioritisation measure, the EU argues that, in certain cases where imported pharmaceutical products are not excluded from the social security's reimbursement scheme by virtue of the localisation requirement, Turkey prioritises the review of applications of domestic pharmaceutical products, over the review of the application of imported '*like'* products, to be included into the reimbursement system, as well as with respect to any pricing and licensing policies and processes. The EU considers this measure to be inconsistent with Article III:4 of the GATT on '*National treatment*'.

At the most recent meeting of the WTO's Dispute Settlement Body (hereinafter, DSB), on 15 August 2019, the EU presented its first request for a panel to rule on the various measures concerning the production, importation, and marketing of pharmaceutical products in Turkey. Turkey regretted the request by the EU, stating that the request was premature, and that it was not in a position to agree to the EU's request. Turkey noted that it was still fully engaged in consultations with the EU on the matter and that it hoped to continue such constructive discussions. Additionally, Turkey pointed out that the dispute concerned Turkey's social security system and Turkey's policies aimed at ensuring "*reliable and affordable access to medicines for its people*", and that its measures are consistent with its WTO obligations. Finally, Turkey underlined that matters concerning a WTO Member's healthcare and social security policies should not be subject to review by a WTO panel.

This is the first case that the EU brings to the WTO against Turkey, which is a candidate country for EU accession since 1999 and has been linked to the EU since 1995 by a Customs Union. However, it appears that the EU is concerned with the lack of implementation by Turkey of the Customs Union. In 2016, the Commission published a study on the '*EU-Turkey Bilateral Preferential Trade Framework, Including the Customs Union, and an Assessment of Its Possible Enhancement*'. The study showed that, even though the EU and Turkey are part of a Customs Union, various non-tariff barriers remain, such as administrative practices and import licensing requirements. The study noted that several measures and practices maintained by Turkey are considered trade-restrictive, constitute *de facto* bans, and infringe the rules of the Customs Union.

The EU is expected to present a second request for the establishment of a panel at the next meeting of the WTO DSB, which will take place on 10 September 2019. According to Article 6.1 of the WTO Dispute Settlement Understanding, a panel is to be established unless the DSB decides by consensus not to establish a panel. According to the Dispute Settlement Understanding, the panel should then be composed within 20 days. All interested stakeholders in the pharmaceutical sector should closely follow this case and engage with their respective Governments to contribute to the proceedings.

The EFSA finds that the pesticide *chlorpyrifos* does not meet the criteria for a renewal of its approval

On 2 August 2019, the European Food Safety Authority (hereinafter, EFSA) announced that the pesticides *chlorpyrifos* and *chlorpyrifos-methyl* do not meet certain criteria required by EU legislation for the renewal of its approval in the EU. According to the EFSA, increasing evidence links *chlorpyrifos* with serious health conditions, including impacts on children's brain development. The approval period for *chlorpyrifos* and *chlorpyrifos-methyl* will expire on 31 January 2020, and the manufacturers applied for a renewal, which is currently being evaluated under the EU's peer review system for the approval of pesticides. In parallel to the ongoing

process of whether to renew the present EU-approval of the pesticide or not, EU Member State Denmark is already evaluating to ban food treated with *chlorpyrifos* (see the next article in this issue of *Trade Perspectives*).

Chlorpyrifos and *chlorpyrifos-methyl* (the *methyl-derivate of chlorpyrifos*, *i.e.*, *chlorpyrifos-ethyl*) are typical broad-spectrum, chlorinated organophosphorus insecticides, mostly used to treat fruits and vegetables, which kill insects upon contact by affecting the functioning of the nervous system. Organophosphorus pesticides, including insecticides, such as *chlorpyrifos*, operate by blocking the functioning of an enzyme (*i.e.*, *acetylcholinesterase*) that breaks down a specific neurotransmitter (*i.e.*, *acetylcholine*). *Chlorpyrifos* is one of the most commonly used insecticides in Europe, launched for the first time as an insect repellent in 1965 by the US agrochemicals company *Dow Chemicals*, today *Corteva AgroScience*. According to the *Health and Environment Alliance* (HEAL) and *Pesticide Action Network Europe*, *chlorpyrifos* is among the 15 active substances most frequently found in unprocessed food and fruit in Europe. It is most often detected in citrus fruits, with more than one of three tested grapefruits and lemons and one of four tested oranges and mandarins containing *chlorpyrifos* residues.

The insecticide received its first EU approval under *Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances* and is currently listed in Part A of the Annex to *Commission Implementing Regulation (EU) No 540/2011*. *Council Directive 91/414/EEC* was replaced by *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*, which sets out the active substances that have been approved by the EU. On the basis of *Commission Implementing Regulation (EU) 2018/84*, the approval periods of *chlorpyrifos* and *chlorpyrifos-methyl* were scheduled to expire on 31 January 2019. However, *Commission Implementing Regulation (EU) 2018/1796 of 20 November 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, picloram, pyraclostrobin, pyriproxyfen and tritosulfuron*, extended the approval periods for *chlorpyrifos* and *chlorpyrifos-methyl* until 31 January 2020.

This extension of the approval periods of the active substances *chlorpyrifos* and *chlorpyrifos-methyl* to 31 January 2020 had become necessary since applications for the renewal of the approval of those substances were submitted in accordance with *Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market* and due to the fact that the assessment of those substances was delayed for reasons beyond the control of the applicants. Therefore, the approvals of those active substances were likely to expire before a decision had been taken on their renewal and it was decided to extend the approval period.

Since its first approval, eight EU Member States (*i.e.*, Denmark, Finland, Germany, Ireland, Latvia, Lithuania, Slovenia, and Sweden) have not renewed, or never authorised, plant protection products containing *chlorpyrifos*. Since 2016, France reportedly allows an exception for spinach. In Denmark, the insecticide was allowed in horticultural greenhouses until 2006, when *Corteva AgroScience* withdrew the product from the market because of Danish climate conditions. As a result of *Commission Implementing 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, chlorpyrifos* was not renewed in Denmark. In Denmark, residues of the insecticide are now only found in imported fruits and vegetables.

The renewal programme of all currently approved active ingredients in the EU is organised in batches and *chlorpyrifos* and *chlorpyrifos-methyl* are active substances covered by the third

batch of the renewal programme for pesticides (*i.e.*, active ingredient review 3 or AIR3) in accordance with *Commission Implementing Regulation (EU) No 844/2012*. Applications (in June 2013) and supplementary dossiers (in July 2015) for the renewal of approval were submitted, by a Task Force (comprising *Dow AgroSciences* and *Adama Agriculture B.V.*) and by *Sapec Agro SA,* for the active substance *chlorpyrifos,* and by *Dow AgroSciences* and by *Sapec Agro SA,* for the renewal of approval of the active substance *chlorpyrifos-methyl*.

Initial evaluations of the dossiers were provided by the *rapporteur* Member State (RMS) Spain in the respective Renewal Assessment Reports (RARs), which were submitted to the EFSA in July 2017. Subsequently, the EFSA initiated peer reviews of the pesticides risk assessment on the RMS evaluation in line with the provisions of *Commission Implementing Regulation (EU) No 844/2012*. The commenting period was completed and included public consultations on the reports.

The manufacturers' applications for renewal are currently still being evaluated under the EU's peer review system for approval of pesticides. Although the peer reviews are not yet fully completed, in July 2019, the European Commission asked the EFSA to provide statements on the available outcomes of the human health assessment in the context of the pesticides peer reviews for the renewal of approval of the active substances *chlorpyrifos* and *chlorpyrifos-methyl*, conducted in accordance with *Commission Implementing Regulation (EC) No 844/2012*.

According to Article 4(1) of *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*, an active substance shall only be approved if it may be expected, in the light of current scientific and technical knowledge, that plant protection products containing that active substance meet the requirements provided for in Article 4, paragraphs 2 and 3. Article 4(2) of *Regulation (EC) No 1107/2009* states that the residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements: 1) They shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the EFSA to assess such effects are available, or on groundwater; and 2) They shall not have any unacceptable effect on the environment. Under Article 4(3) of *Regulation (EC) No 1107/2009*, a plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements: 1) It shall be sufficiently effective; 2) It shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the EFSA to assess such effects are available; or on groundwater; 3) It shall not have any unacceptable effects on plants or plant products; 4) It shall not cause unnecessary suffering and pain to vertebrates to be controlled; and 5) It shall have no unacceptable effects on the environment.

The EFSA's statements on the active substances *chlorpyrifos* and *chlorpyrifos-methyl*, which were adopted on 31 July 2019 and published on 2 August 2019, contain a summary of the main findings of the assessment related to human health following the pesticides peer review expert discussions in mammalian toxicology, held between 1 and 5 April 2019. They also contain the EFSA's additional considerations, including whether the active substances could be expected to meet the approval criteria applicable to human health, as laid down in Article 4 of *Regulation (EC) No 1107/2009*.

The EFSA has identified concerns about possible genotoxic effects, as well as neurological effects during development, supported by epidemiological data indicating effects in children. According to the EFSA, the toxicological effects meet the criteria for classification as toxic for reproduction category 1B (regarding developmental toxicity). Based on those results, the

EFSA considers that the approval criteria, which are applicable to human health, as laid down in Article 4 of *Regulation (EC) No 1107/2009*, are not met. The approach taken by the EFSA in the hazard assessment of *chlorpyrifos-methyl* is largely based on the structural similarity with *chlorpyrifos*. This means that no safe exposure level, or toxicological reference value, can be set for *chlorpyrifos* and *chlorpyrifos-methyl*.

Also outside of the EU, concerns regarding *chlorpyrifos* are leading to the revocation or non-extension of approvals. In the US, the State of Hawaii decided to ban the use of pesticides containing *chlorpyrifos* by 2023. The State of New York banned all use of *chlorpyrifos* by 1 December 2021. Officials in the US State of California announced in May 2019 that the State would cancel the registration and ban *chlorpyrifos*, but no specific date was provided. At the Federal level, the registration of *chlorpyrifos* will be subject to a review by the US Environmental Protection Agency (EPA), which has a statutory deadline of October 2022. In 2017, then EPA Administrator Scott Pruitt reportedly denied requests to revoke tolerances or maximum residue levels for food and cancel all *chlorpyrifos* registrations. On 19 April 2019, the San Francisco Circuit Court of Appeals court ordered the EPA to decide, by mid-July 2019, if it intends to permanently ban the chemical. On 9 August 2018, the same Court had already ordered the EPA to finalise its proposed ban on *chlorpyrifos,* based on findings that the pesticide is unsafe for public health and particularly harmful to children and farmworkers, but the EPA was granted a rehearing. In March 2019, lawyers argued again in court that *chlorpyrifos* had no place near fruits or vegetables.

The European Commission reportedly appears supportive of a ban of *chlorpyrifos*, which civil society groups have urged the EU authorities and EU Member States' Governments to support. More than 212,000 people have signed a petition asking EU decision-makers not to approve the renewal of *chlorpyrifos*, which some say also has harmful effects on children's brain development. A coalition of NGOs, including *HEAL*, *SumOfUs*, *PAN Europe*, and *Générations Futures* welcomed the EFSA's statement, which they say is a first step to ban *chlorpyrifos* in the EU. At the end of August, it was reported that the European Commission had announced that it would propose to EU Member States not to renew the approval of pesticides *chlorpyrifos* and *chlorpyrifos-methyl*, following a recommendation from the EFSA.

The EFSA's statements only address the requirement for renewal of whether the active substances shall not have any harmful effects on human health, which is an exclusion *criterium* for the approval or renewal of an application. It appears that these statements from the EFSA could already mark the end of the peer review, which is in principle still ongoing. Interested stakeholders should closely monitor the developments and the possible forthcoming proposal from the Commission.

Denmark is considering a ban on the importing or placing on the market of food treated with the pesticide *chlorpyrifos*

In parallel to the ongoing process of whether or not to renew the current EU-approval of the pesticide *chlorpyrifos* (see the previous article), on 14 August 2014, *Mogens Jensen*, the Danish Minister for Food, Fisheries and Equal Opportunities, appointed on 27 June 2019, has reportedly instructed the Danish National Food Administration (*Fodevarestyrelsen*) to prepare a total ban on food treated with the pesticide *chlorpyrifos*. *Henrik Dammand Nielsen*, Head of Section for Chemistry and Food Quality at the *Fodevarestyrelsen*, reportedly stated that Denmark had informed the European Commission (hereinafter, Commission) about its plans to ban EU-wide the use of *chlorpyrifos* and expects a reply from Brussels within five to six weeks. If there were to be no reaction by the Commission, Denmark would go forward with preparing a national import ban.

Since *chlorpyrifos* received its first EU approval under *Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances*, eight EU Member States,

including Denmark, have reportedly not renewed, or never authorised products containing *chlorpyrifos*. In Denmark, the insecticide was allowed in horticultural greenhouses until 2006, when *Corteva AgroScience* withdrew the product from the market because of Danish climate conditions. As a result of *Commission Implementing 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, chlorpyrifos* was not renewed in Denmark. In Denmark, the insecticide is now only found in residues of imported fruits and vegetables.

The import ban announced by the Danish National Food Administration would be based on Article 54 of *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 addresses emergency measures for food of EU origin or imported from a third country. This regulation allows *interim* protective measures by EU Member States, if certain requirements are met: 1) It is evident that food or feed originating in the EU or imported from a third country is likely to constitute a serious risk to human health; 2) The EU Member State officially informs the Commission of the need to take emergency measures; and 3) The Commission has not acted in accordance with Article 53. If such *interim* protective measures are taken by an EU Member State, the EU Member State must immediately inform the other EU Member States and the Commission. Within 10 working days, the Commission must put the matter before the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) with a view to the extension, amendment, or abrogation of the national *interim* protective measures. The EU Member State may maintain its national *interim* protective measures any time until the EU measures have been adopted.

Where it is evident that food originating in the EU, or imported from a third country, is likely to constitute a serious risk to human health, animal health, or the environment, one or more of the following measures may be adopted according to Article 53 of *Regulation (EC) No 178/2002*, depending on the gravity of the situation, in the case of food of EU origin: 1) Suspension of the placing on the market or use of the food in question; 2) Laying down special conditions for the food in question; or 3) Any other appropriate *interim* measure. In the case of food or feed imported from a third country, the following measures may be adopted: 1) Suspension of imports of the food in question from all or part of the third country concerned and, where applicable, from the third country of transit; 2) Laying down special conditions for the food in question from all or part of the third country concerned; or 3) Any other appropriate *interim* measure.

A Danish measure banning the placing on the market or import of food treated with *chlorpyrifos* may only be maintained temporarily, as the Commission and other EU Member States have their say on it within 10 working days. The question is whether the emergency measures under *Regulation (EC) No 178/2002* can be used in those circumstances. Arguably, banning the placing on the market or import of food treated with an EU-approved active ingredient appears to result in a circumvention of the complex rules on approval of pesticides, notably when the pesticide, in this case *Chlorpyrifos*, has been approved for use in other EU Member States and the rules for accepted MRLs are respected.

According to the *Health and Environment Alliance* (HEAL) and *Pesticide Action Network Europe*, *chlorpyrifos* is among the top 15 active substances most frequently found in European unprocessed food and fruit. It is most often detected in citrus fruits, with more than one of three tested grapefruits and lemons, and one of four tested oranges and mandarins, containing *chlorpyrifos* residues.

The setting of maximum residue levels (hereinafter, MRLs) for *chlorpyrifos* and *chlorpyrifos-methyl* in different products is a separate matter from the approval of these active substances in pesticides in the EU. *Commission Regulation (EU) 2018/686 of 4 May 2018 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos, chlorpyrifos-methyl and triclopyr*

in or on certain products establishes, in particular, MRLs for *chlorpyrifos* and *chlorpyrifos-methyl* in a wide array of products: 1) Fruits and vegetables, including citrus fruits, apricots, sweet cherries, peaches, berries, dates, figs, table olives, kumquats, avocados, bananas, mangoes, papayas, pomegranates, pineapples, plums and tomatoes; 2) Fungi; 3) Pulses; 4) Oilseeds and oil products; 5) Cereals; 6) Teas, coffee, herbal infusions, cocoa and carobs; 7) Hops; 8) spices; 9) Sugar plants; and 10) Products of animal origin. For many of these products, the MRL is set at 0.01 mg/kg (*i.e.,* the default lowest limit of analytical determination or LOD), that is the MRL also for crops on which the pesticide has not been used or when its use has not left detectable residues.

On 27 March 2017, the European Food Safety Authority (hereinafter, EFSA) had published a *Review of the existing maximum residue levels for chlorpyrifos according to Article 12 of Regulation (EC) No 396/2005*. In that report, the EFSA reviewed the MRLs currently established at EU level for the pesticide active substance *chlorpyrifos*. To assess the occurrence of *chlorpyrifos* residues in plants, processed commodities, rotational crops and livestock, the EFSA considered the conclusions derived in the framework of *Directive 91/414/EEC*, the MRLs established by the *Codex Alimentarius Commission*, as well as the authorisations reported by EU Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was missing and possible chronic and acute risks to consumers were identified.

MRLs for *chlorpyrifos* have been subject to a number of specific trade concerns in the WTO Committee on Sanitary and Phytosanitary Measures (SPS Committee). For the first time in 2003, China expressed concerns over Japan's MRLs for several pesticide residues, in particular MRLs for *chlorpyrifos*. In March 2017, Israel expressed its concern regarding the United States' proposed rule to withdraw its food pesticide residue tolerances for *chlorpyrifos*. Israel explained that *chlorpyrifos* was produced in Israel, used on some 20 major crops exported to the US, and considered an efficient and cost-effective broad-spectrum pesticide. Israel noted that *chlorpyrifos* was less disruptive to beneficial insects than alternative pesticides and a good rotational option. Also, for several important pests, growers had limited or no viable alternatives to *chlorpyrifos*. Israel believed that the US' deviation from the existing international Codex MRLs was not scientifically justified. Israel argued that the US needed to develop individual risk assessments on the use of *chlorpyrifos* for each agricultural crop of concern, taking into account all available scientific evidence, as well as the objective to minimise negative trade effects. Ecuador supported Israel's concern, underlining that *chlorpyrifos* was broadly used worldwide and in Ecuador since 1989 on a variety of crops, including bananas, a major export product to the US. The US confirmed that all comments received would be considered by the Environmental Protection Agency (EPA) in finalising the proposed measure. While the US appreciated that many comments called on EPA to base its residue levels on Codex standards, it recalled the right of WTO Members, in line with the SPS Agreement, to carry out their own risk assessments.

In 2019, so far until the end of August, fruits and vegetables with residues of *chlorpyrifos* exceeding the respective MRL, have been detected at importation into the EU and have been notified to the EU's Rapid Alert System for Food and Feed (RASFF) network 27 times, more specifically 11 times concerning peppers, twice in pomegranates from Turkey, and once, respectively, in nashi pears from China, in frozen chillies and peppers from Viet Nam, in pomegranates from India, in pineapples from Colombia, in carrots from Serbia, in sweet peppers from Egypt, and in jackfruit from Thailand. During official controls on the market in the Czech Republic and Denmark, residues of *chlorpyrifos* exceeding the respective MRL were also detected and notified to the RASFF concerning head cabbage and apples from Poland. Most recently, official controls on the market in Denmark, at the end of August, revealed residues of *chlorpyrifos* exceeding the respective MRLs in coriander leaves and roots, in mangoes, and in pennywort (*Centella asiatica*) from Thailand. Finally, during a company's own check in Denmark, exceeding MRLs of *chlorpyrifos* were detected in black eyed beans from Turkey.

An eventual Danish or EU-wide ban on food treated with *chlorpyrifos* would have to be notified by the EU to the WTO SPS Committee. In case Denmark finally notified its measure to the Commission, within 10 working days, the Commission would have to put the matter before the PAFF Committee with a view to the extension, amendment or abrogation of the national *interim* protective measures. In the related matter (see previous article), in case the EU did not renew the approval of *chlorpyrifos*, further MRLs for chlorpyrifos might be set at the limit of analytical determination. Interested stakeholders should closely monitor these developments, as they may have important legal, commercial, and technical consequences.

Recently Adopted EU Legislation

Customs Law

- *Agreement in the form of an exchange of letters between the European Union and Ukraine amending the trade preferences for poultry meat and poultry meat preparations provided for by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part*

- *Council Decision (EU) 2019/1316 of 15 July 2019 on the signing, on behalf of the European Union, of the Agreement between the United States of America and the European Union on the Allocation to the United States of a Share in the Tariff Rate Quota for High Quality Beef referred to in the Revised Memorandum of Understanding Regarding the Importation of Beef from Animals Not Treated with Certain Growth-Promoting Hormones and Increased Duties Applied by the United States to Certain Products of the European Union (2014)*

Trade Remedies

- *Commission Implementing Regulation (EU) 2019/1382 of 2 September 2019 amending certain Regulations imposing anti-dumping or anti-subsidy measures on certain steel products subject to safeguard measures*

- *Commission Implementing Regulation (EU) 2019/1379 of 28 August 2019 imposing a definitive anti-dumping duty on imports of bicycles originating in the People's Republic of China as extended to imports of bicycles consigned from Indonesia, Malaysia, Sri Lanka, Tunisia, Cambodia, Pakistan and the Philippines, whether declared as originating in these countries or not, following an expiry review pursuant to Article 11(2) of Regulation (EU) No 2016/1036*

- *Commission Implementing Regulation (EU) 2019/1374 of 26 August 2019 reopening of the investigation following the judgment of 3 July 2019, in case C-644/17 Eurobolt, with regard to Council Implementing Regulation (EU) No 723/2011 of 18 July 2011 extending the definitive anti-dumping duty imposed by Regulation (EC) No 91/2009 on imports of certain iron or steel fasteners originating in the People's Republic of China to imports of certain iron or steel fasteners consigned from Malaysia, whether declared as originating in Malaysia or not*

- *Commission Implementing Regulation (EU) 2019/1344 of 12 August 2019 imposing a provisional countervailing duty on imports of biodiesel originating in Indonesia*

- *Commission Implementing Regulation (EU) 2019/1295 of 1 August 2019 amending Implementing Regulation (EU) 2018/1469 imposing a definitive anti-*

dumping duty on imports of certain seamless pipes and tubes, of iron or steel, originating in Russia and Ukraine, following a partial interim review pursuant to Article 11(3) of Regulation (EU) 2016/1036

Food and Agricultural Law

- *Commission Regulation (EU) 2019/1338 of 8 August 2019 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food*

- *Commission Implementing Regulation (EU) 2019/1324 of 5 August 2019 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by Bacillus subtilis LMG S-27588 as a feed additive for chickens for fattening or reared for laying, turkeys for fattening or reared for breeding, minor poultry species for fattening or reared for laying or for breeding, weaned piglets, pigs for fattening and minor porcine species (holder of authorisation Puratos)*

- *Commission Implementing Regulation (EU) 2019/1323 of 2 August 2019 on exceptional market support measures for the eggs and poultrymeat sectors in Italy*

- *Commission Implementing Regulation (EU) 2019/1294 of 1 August 2019 authorising the placing on the market of betaine as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470*

Other

- *Sustainable Fisheries Partnership Agreement between the European Union and the Republic of The Gambia*

- *Council Decision (EU) 2019/1317 of 18 July 2019 on the position to be adopted on behalf of the European Union within the Joint Committee established under the Agreement between the European Union and Japan for an Economic Partnership, as regards the establishment of the list of arbitrators*

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