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## Post-Brexit UK trade policy: the difficult undertaking of aligning EU and US approaches and expectations with UK policy objectives

From 2 to 5 March 2020, the EU and the UK held their first round of negotiations for the envisaged EU-UK partnership agreement. Also on 2 March 2020, the UK published its negotiating directives for the envisaged 'UK-US Free Trade Agreement'. While negotiations with the US are yet to be launched, negotiations with the EU have already started and the second round of negotiations was scheduled from 18 to 20 March 2020, but has been suspended due to the COVID-19 situation. Launching negotiations with the EU and the US at the same time, the UK will have to perform the balancing act of developing a trade policy approach that is able to reconcile the differing expectations of its two most important trading partners.

Following *Brexit* on 31 January 2020 at 24:00 CET, the EU and the UK entered into a transition period, which should end on 31 December 2020, during which further preparations and negotiations for the post-*Brexit* relationship between the two parties are to take place (see *Trade Perspectives*, Issue No. 2 of 31 January 2020). Most importantly, the EU and the UK intend to conclude a free trade agreement before the end of the year. Both the EU and the UK aim at concluding a preferential trade agreement with zero tariffs and zero quotas.

On 26 February 2020, the Council of the EU (hereinafter, Council) adopted a decision authorising the opening of negotiations for a new partnership with the UK and formally nominating the European Commission (hereinafter, Commission) as the EU negotiator. The Council also adopted negotiating directives, which constitute the Commission's mandate for the negotiations. The negotiating directives set the negotiation guideline for the future EU-UK partnership agreement and provide the "content of the envisaged partnership", which is divided into four parts: 1) "Initial provisions"; 2) "Economic part"; 3) "Security part"; and 4) "Institutional and other horizontal amendments". The negotiating directives envisage an ambitious partnership and state that the relationship should contain comprehensive arrangements including: 1) A free trade area; 2) Customs cooperation and trade facilitation; and 3) Regulatory aspects. Furthermore, the negotiating directives put particular emphasis on "robust commitments ensuring a level playing field for open and fair competition, as well as [...] effective management and supervision, dispute settlement and enforcement arrangements, including appropriate remedies".

On 27 February 2020, the UK published a document titled 'The Future Relationship with the EU, the UK's Approach to Negotiations'. The paper is divided into three parts: 1) "The Comprehensive free trade agreement" (hereinafter, FTA); 2) "Other agreements"; and 3) "Technical and other processes beyond the scope of the future relationship negotiations". The main element of the paper is its part 1 on 'the Comprehensive FTA', according to which the future FTA with the EU should substantially cover all trade. Notably, a sector that the UK includes in part 2 on 'Other agreements', is fisheries. In other words, the UK considers fisheries as falling outside of the scope of the main EU-UK FTA. The UK claims that a separate agreement on fisheries would allow the UK to "take back control" of its water and that its approach is based "on friendly cooperation between sovereign equals".

On 28 February 2020, the EU and the UK published the 'Terms of Reference' for their negotiations, which establish the structure of the EU-UK relationship negotiations, including indicative dates. Annex A of the 'Terms of Reference' establishes 11 negotiating groups, including, inter alia, groups on trade in goods, trade in services, transport, energy, mobility, as well as on social security coordination.

From 2 to 5 March 2020, the first round of trade negotiations was held in Brussels. According to Michel Barnier, the European Commission's Chief Negotiator for EU-UK relations, this first round was used to hold an exchange of views on the respective negotiating mandates, and to compare and clarify the respective positions. Following the conclusion of the first round of negotiations, Chief Negotiator Barnier stated that a number of convergences were noted, but that "serious divergences" existed. One of the divergences concerns the overall approach to the negotiations and the future agreement: While the EU prefers a single comprehensive agreement, the UK appears to prefer a multitude of sectoral agreements. Despite diverging interests on a number of aspects, Mr. Barnier considered the first negotiation round as productive. On the other side, the UK's Minister for the Cabinet Office, Michael Gove, reported that, during the first round of negotiations with the EU, "substantive discussions" had taken place "within eleven separate negotiating groups, as agreed between the parties and as set out in the Terms of Reference". According to Minister Gove, "discussions in some areas identified a degree of common understanding of the ground that future talks could cover". However, he recognised that, in other areas, "notably fisheries, governance and dispute settlement, and the so-called 'level playing field', there were, as expected, significant differences". The second round of negotiations was scheduled to take place from 18 to 20 March 2020 in London. However, due to the latest developments regarding the Covid-19, the negotiation round has been suspended. Both parties are currently exploring alternative ways to continue discussions, including the possibility of the use of video conferences.

Two issues that might lead to difficult negotiations are fisheries, as well as food and health standards. The EU's negotiating directives include fisheries as part of the EU-UK trade agreement. Notably, the EU's negotiating directives state that the agreement should include "provisions on fisheries setting out a framework for the management of shared fish stocks, as well as the conditions on access to waters and resources and common technical and conservation measures". The EU seeks to secure the continuation of EU Member States' rights to access UK waters. However, during an interview on 4 March 2020, the UK's Secretary of State for Environment, Food and Rural Affairs, George Eustice stated that the right to access UK waters for fishing was not to be part of the trade negotiations. The fact that, contrary to the EU mandate, the UK mandate does not include fisheries as part of the future EU-UK FTA is a key issue for a number of EU Member States, mainly for France, but also for Ireland, Spain and, to a lesser extent, Belgium and the Netherlands. There are concerns that these countries' fishery industries would be significantly affected without access to UK waters, as their main income comes from fish caught therein. France's Secretary of State for European Affairs, Amelie de Montchalin, stated that fishing rights were linked to the trade negotiations and warned that negotiations could turn into "a very nasty battle" if they were not included. However, Secretary of State George Eustice stated that there was no "precedent of linking a trade deal with sacrificing or forfeiting your right as an independent coastal state".

Another likely controversial issue appears to be food and health standards. The EU insists that it would not lower its standards on food and health. According to the EU's Chief Negotiator *Barnier*, the UK had already committed in the Withdrawal Agreement and the Political Declaration to maintain EU standards. However, on 11 March 2020, the UK's Prime Minister *Boris Johnson* stated that the UK should not accept EU rules in key areas. He stated that the UK would uphold or enhance its high standards, but that its approach would be "governed by science". This declaration appears to move away from the EU's 'precautionary approach', which is referenced in the EU's negotiating directives. According to the EU's negotiating directives, "the envisaged partnership should uphold the application of the precautionary principle in the Union as set out in the Treaty on the Functioning of the European Union". Currently, the UK regulatory system for food and agriculture is aligned to the EU approach of the precautionary principle, which, according to a report of the European Parliament on the precautionary principle enabled "decision-makers to adopt precautionary measures when scientific evidence about an environmental or human health hazard is uncertain and the stakes are high".

In addition to the negotiations for a preferential trade agreement with the EU, the UK published, on 2 March 2020, the document '*UK-US Free Trade Agreement*', in which the UK sets out its objectives for trade negotiations with the US. Already in February 2019, the US had published its '*Summary of Specific Negotiating Objectives*' with the UK. On a more general level, the UK Government announced that, by 2022, it intended to have 80% of total UK external trade covered by FTAs. Trade negotiations with the US are expected to be launched during this month and, during the week of 9 March 2020, the UK's Minister of State for Trade Policy, *Greg Hands*, visited the US to prepare them. In the best-case scenario, the UK Government expects the agreement to lead to a 0.16 % increase in the GDP over the next 15 years, which corresponds to a total of GBP 3.4 billion. The intended agreement is supposed to comprehensively cover both trade in goods and trade in services, also including a chapter on digital trade (see *Trade Perspectives*, Issue No. 4 of 28 February 2020). According to the UK Government, the agreement would particularly benefit manufacturers of ceramics, cars, food and beverages, as well as professional services, such as architects and lawyers.

Trade in agricultural goods and food products appears to emerge as one of the most contentious issues to be resolved during the UK-US negotiations. In its negotiating objectives of February 2019, the US points out its aim to "establish a mechanism to remove expeditiously unwarranted barriers that block the export of U.S. food and agricultural products in order to obtain more open, equitable, and reciprocal market access". Against the backdrop of the parallel negotiations between the UK and the EU, the US emphasis on market access for agricultural products may lead to a situation in which the UK finds itself pressured to adapt its future regulatory system to two fundamentally different approaches to agricultural and food regulation: While the EU follows the precautionary approach, the US emphasises the need for "science-based" measures that only apply in the case of "ascertainable risk", as opposed to potential hazards. In January 2020, US State Secretary of Agriculture Sonny Perdue underlined that "policy decisions [have to be] based on sound science when it comes to food". The chapter on sanitary and phytosanitary measures in the US negotiating objectives regarding a future agreement with the UK underlines this approach, stating that the agreement should aim at establishing "new and enforceable rules to ensure that science-based SPS measures are developed and implemented in a transparent, predictable, and nondiscriminatory manner". As long as the UK was part of the EU, its agro-food standards were in line with the precautionary principle. In its negotiating objectives for the UK-US negotiations, the UK states that, "without exception, imports into the UK will meet our stringent food safety standards - all food imports into the UK must be safe and this will not change in any future agreement'. However, the document avoids a clear commitment to the precautionary principle. Adding to that, in February 2020, UK Prime Minister Boris Johnson highlighted, in the context of his notions on food law, that UK free trade agreements would "be governed by science and not by mumbo-jumbo", understood by many as a statement of inclination towards the US approach. While US Secretary Perdue claimed that these different approaches on agricultural regulation would not present a 'deal breaker', from a UK perspective, the issue of agro-food standards will likely represent a sensitive point in negotiations with both the EU and the US.

Stakeholders and businesses in the EU, the UK, the US and trading partners around the world should diligently follow the developments and engage early in the game, so that their interests can be duly considered in the negotiations.

# Spain studies the introduction of a front-of-pack nutrition labelling scheme, looking at experience in Portugal, Chile and France, while Colombia announces a scheme with warning messages

On 28 February 2020, the Spanish Minister of Health, Consumption and Social Welfare, Alberto Garzón, announced during his appearance before the Committee on Health and Consumption of the Spanish Parliament (*Congreso de los Diputados*) that his cabinet was studying formulas to introduce a system of front-of-pack (hereinafter, FoP) nutrition labelling in Spain, taking into account the experiences in the FoP nutrition labelling schemes of France and Portugal, as well as of Chile. At the same time, Colombia has announced that it would introduce warning FoP nutrition labels.

Nutrition labelling is often presented as an important tool in the fight against obesity and other non-communicable diseases. As Minister Garzón explained, the Government of Spain seeks to "maximize efficiency" through a plan that will affect four areas: labelling, taxation, advertising and training and information to citizens. The minister advanced that, at this time, the Government of Spain was "evaluating the different degrees of effectiveness of the different existing systems, seeing which could be the most appropriate design". In that sense, Garzón outlined the experiences in the FoP nutrition labelling schemes of Chile, France or Portugal that "demonstrate the effectiveness of opting for labels, which are easy to understand, that help families" in making nutritional decisions. The Spanish Agency for Food Safety and Nutrition (Agencia Española de Seguridad Alimentaria y Nutrición, hereinafter, AESAN), under the authority of the Ministry of Health, Consumption and Social Welfare, will have key responsibilities in the development and deployment of this initiative for nutrition labelling, which already exists in a number of EU Member States.

At the end of 2018, Spain's Ministry of Health had announced its intention to promote the Nutri-Score model, a five-colour FoP model, which is the one used in France and Belgium, but it never materialised. Now, the new Ministry of Health, Consumption and Social Welfare takes over the competences of the AESAN (in coordination with the Ministry of Agriculture) to decide which system to choose and implement as soon as possible. Minister Garzón mentioned that the models of Portugal, France, and Chile had been studied. These three countries stand for three different systems of FoP labels: 1) Voluntary 'traffic light' labels in Portugal; 2) Voluntary 'Nutri-Score' colour code labels in France; and 3) Mandatory warning labels in Chile. Portugal has a diversity of 'traffic light' nutrition labelling models on the market, which offer information on the energy value, total fat content, saturated fat, sugar and salt per 100 grams of product and categorises each of the nutrients according to a colour code similar to a traffic light; red for a high level; and green for an optimal level. Portugal currently appears to be in the process of developing and implementing *Nutri-Score*, as well. Unlike 'traffic light' labels, which highlight key individual nutrients, the French Nutri-Score system provides a single score for the entire product, giving consumers an overall assessment of the product at a glance. *Nutri-Score* gives a rating to any food (except single-ingredient foods and water) ranging from a dark green A (best) to a red E (worst), by weighing the prevalence of nutrients categorised as 'good' and Belgium also recommends using the 'Nutri-Score' scheme Perspectives, Issue No. 16 of 7 September 2018) and other EU Member States, such as Austria, Germany, and the Netherlands, are considering officially doing so.

Spain appears to look a bit further than the voluntary Portuguese model and the increasingly popular French model with colour codes, including in its assessment Chile's mandatory model with warning labels. This was adopted in 2015 by the Government of Chile with Decree No. 13 of 16 April 2015 (hereinafter, Decree 13/2015) and requires warning messages in the shape

of a black octagon in the form of a 'STOP' sign to be placed on the FoP with the text 'High in...', when food products exceed certain levels of energy, sodium, sugars or saturated fats (see *Trade Perspectives*, Issue No. 16 of 11 September 2015). Peru and Uruguay followed Chile with their own warning labels, while heated discussions on implementing FoP schemes are ongoing in Brazil, Argentina, and Paraguay (see *Trade Perspectives*, Issue No. 16 of 7 September 2018).

At the end of February 2020, the President of Colombia Iván Duque Márquez announced that the Government of Colombia and food industry had agreed on warning nutrition labels that would become mandatory on "unhealthy" food and drink products. It took a year and a half to develop the warning label, during which stakeholders analysed graphic models and nutrient thresholds from around the world and other Latin American countries. According to the Government, the FoP warning logo would be black, circular in shape, and present a warning about products "high in" added sugars, salt, and saturated fats. Unlike the warning labels in use in Chile, Peru, and Uruguay, the Colombian model adds a visual representation of sugar, salt, and saturated fat. Sugar is represented by sugar cubes, saturated fats by a piece of butter or spread fats, and salt as a saltshaker. However, detailed information on specific nutrient thresholds, category exemptions or a copy of the draft regulation have not yet been made public. Reportedly, according to the National Business Association of Colombia (Asociación Nacional de Empresarios de Colombia, ANDI), the trade association that represents the interests of Colombian food manufacturers, food operators would also be allowed to add positive nutrition labels to the packaging of products that meet certain nutritional criteria, while the already existing nutrition contents table would be simplified.

In the EU, according to Article 35 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (hereinafter, FIR), in addition to the harmonised mandatory panel with 'nutrition information', the energy value and the amount of nutrients may be given by other forms of expression and/or may be presented using graphical forms or symbols in addition to words or numbers, provided that a number of requirements are met. It appears that, for example, the *Nutri-Score* scheme does not meet all the requirements (see Trade Perspectives, Issue No. 3 of 14 February 2020). Certain elements of a voluntary colour-coded FoP nutrition labelling scheme could also be classified as 'non-beneficial' nutrition claims. It must be noted that nutrition claims are, by nature, 'beneficial claims' since the FBO, which places them on its products, intends to highlight something nutritionally 'positive'. This is the reason why 'non-beneficial' nutrition claims (like 'high in sugar') do not fall under the scope of Regulation (EC) No. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods (NHCR), which states in recital 6 that "[n]on-beneficial nutrition claims are not covered by the scope of this Regulation: Member States intending to introduce national schemes relating to non-beneficial nutrition claims should notify such schemes to the Commission and to other Member States (...)". Importantly, the proliferation of different FoP schemes may become an obstacle to the free movement of goods within the EU and be contrary to EU law (see Trade Perspectives, Issue No. 21 of 20 November 2015 and Issue No. 6 of 24 March 2016).

Article 35(5) of the FIR requires the Commission to adopt, in light of the experience gained, a report to the European Parliament and the Council of the EU on the use of the additional forms of expression and presentation of the nutrition declaration, on their effect on the internal market, and on the advisability of further harmonisation. The Commission may accompany this report with proposals to modify the relevant EU provisions. For this purpose, EU Member States are required to provide the Commission with information concerning the use of such additional forms of expression or presentation on the market in their territory. The implementation of the national schemes has made the Commission's task to release a report on the topic more complex. The Commission is still in the process of preparing this report, originally foreseen by 13 December 2017, and the report is now scheduled to be released before the summer of 2020. The Commission further announced, as part of its Green Deal initiative, that the 'Farm to Fork Strategy', to be presented in spring 2020, would illustrate the objectives and actions necessary to secure a fair, healthy, and environmentally-friendly food

system. To promote sustainable food consumption, the Commission will, *inter alia*, propose actions to help consumers choose healthy and sustainable diets by providing better food information, such as the origin of the food and its nutritional value.

When it comes to the mandatory warning messages that are increasingly used in South America, the question arises whether the different measures imposing FoP nutrition labels, including warning messages on food, comply with international trade law. With respect to these measures, the different Governments are required to comply with the transparency obligation set out in Article 2.9 of the World Trade Organization's (hereinafter, WTO) Agreement on Technical Barriers to Trade (hereinafter, TBT Agreement) by notifying them to the WTO. According to Article 2.2 of the TBT Agreement, technical regulations must not be more traderestrictive than necessary to fulfil a legitimate objective. It would have to be determined if the different measures' objectives could be addressed and achieved by more effective and less trade-restrictive public policies, such as launching campaigns to encourage the population to eat healthily and promoting physical activity programmes or consistent voluntary labels. Article 2.4 of the TBT Agreement provides that technical regulations must be based on the relevant international standards, if they exist. Section 5 of the Codex Alimentarius Guidelines on Nutrition Labelling (CAC/GL2-1985) recommends, in relation to supplementary nutrition information, that it should intend to increase consumers' understanding of the nutritional value of their food and that it should assist in interpreting the nutrient declaration (see for more detail, Trade Perspectives, Issue No. 16 of 7 September 2018).

Additionally, the manner through which the measures pursue their legitimate public health objectives appears to be incompatible with the list of prohibited claims under section 3 of the *Codex General Guidelines on Claims* (CAC/GL 1-1979). For instance, Section 3.5 of these guidelines prohibits "claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer". 'High in' or even 'Excess in' warnings, such as those in Colombia's announced measure, and already existing in Chile's, Peru's and Uruguay's legislation, should be avoided, as they are not foreseen by the applicable *Codex Guidelines on Nutrition Labelling*, and they risk demonising some foods whose moderate consumption can be part of a healthy diet. It must be noted that, arguably, even a number of red 'traffic lights' on the FoP of a product could act as sort of 'non-beneficial' nutrition claim, inasmuch as the whole group of red traffic lights could be interpreted as a claim that this product is nutritionally disadvantageous.

Spain may add a layer of complexity to the situation in the EU and its Member States on voluntary FoP nutrition labelling. Minister *Garzón* announced that the future Spanish scheme would be supported by measures that seek to encourage the consumption of healthy products and discourage those with "certain harmfulness" to health. A further element that will be part of the comprehensive "healthy eating plan" is advertising and with it, the protection of minors. Minister *Garzón* pointed out that commercial information aimed at children, which stimulates the consumption of unhealthy products must, therefore, be regulated. Finally, the Minister announced that, in parallel to the implementation of such measures, his department would develop awareness and information campaigns "that allow our country to move towards healthy consumption".

With the forthcoming report on additional FoP nutrition labelling schemes, the Commission has a complex task. Stakeholders in the agri-food sector should monitor developments on FoP nutrition labelling in the EU and its Member States, but also in Latin America, and take action to ensure that their legitimate interests are voiced and represented within all relevant *fora*. In addition, given the unique situation of the EU Single Market, uniform legislation regarding FoP nutrition labelling should be adopted at the EU level, as piecemeal legislation across EU Member States would almost certainly have a negative impact on the free movement of goods. The release of the Commission's report in 2020 and of the 'Farm to Fork Strategy' in spring 2020, with proposed actions on better information on foods' nutritional value, will hopefully shed some light on this complex topic.

## The European Commission takes important measures for the restriction of Plant Protection Products that are considered harmful to biodiversity

On 3 February 2020, the European Commission (hereinafter, Commission) issued Commission Implementing Decision (EU) 2020/152 prohibiting Romania to repeat granting authorisations under Article 53(1) of Regulation (EC) No 1107/2009 for the plant protection products containing the active substance clothianidin or imidacloprid for use on Brassica napus against Phyllotreta spp. or Psylliodes spp and Commission Implementing Decision (EU) 2020/153 prohibiting Lithuania to repeat granting authorisations under Article 53(1) of Regulation (EC) No 1107/2009 for the plant protection products containing the active substance thiamethoxam for use on spring rape against Phyllotreta spp. and/or Psylliodes spp. Clothianidin, imidacloprid and thiamethoxam are active substances classed as neonicotinoids (i.e., pesticides, which are absorbed by plants and transported to leaves, roots and flowers, which are present in pollen and nectar). Neonicotinoids have the characteristic to be highly toxic for invertebrates and insects and are used in plant protection products (hereinafter, PPPs) to control insects harmful to plants. 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 establishes that PPPs may not be placed on the EU market or used unless they have been authorised by an EU Member State.

In 2013, the EU had authorised the following five neonicotinoids as active substances for the use in PPPs: acetamiprid, clothianidin, imidacloprid, thiacloprid, and thiamethoxam. In the same year, on the basis of risk assessments carried out by the European Food Safety Authority (hereinafter, EFSA) on clothianidin, imidacloprid and thiamethoxam, the Commission issued Commission Implementing Regulation (EU) 485/2013 amending Implementing Regulation (EU) 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, severely restricting the use of PPPs containing one of the three active substances. In simple terms, with the aim of protecting the honeybees population in the EU, the Regulation allowed the use of clothianidin, thiamethoxam and imidacloprid only on seeds destined for use in greenhouses, on the treatment of specific crops after flowering, and on winter cereals.

Following the issuance of Commission Implementing Regulation (EU) 485/2013 restricting the use of clothianidin, imidacloprid, and thiamethoxam, supplementary information was submitted in 2014 by the manufacturers of the three concerned active substances and, on that basis, a second assessment was carried out by the EFSA. The second set of opinions from the EFSA issued in 2016 on clothianidin, imidacloprid and thiamethoxam established that, even the outdoor uses previously authorised by Commission Implementing Regulation (EU) 485/2013. were no longer considered as safe. In 2015, the Commission requested the EFSA to organise an open call for data in order to collect new scientific information as regards the risk to bees from the neonicotinoids clothianidin, imidacloprid and thiamethoxam. In light of the EFSA's assessment, carried out on the basis of the collected data confirming the risk, the Commission completely prohibited the outdoor use of the three active substances through Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid, Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin and Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam. On 13 January 2020, the Commission, through Commission Implementing Regulation (EU) 2020/23 of 13 January 2020 concerning the nonrenewal of the approval of the active substance thiacloprid, prohibited the fourth of the five neonicotinoids authorised in 2013.

The progressively more restrictive measures regarding neonicotinoids are part of the Commission's strategy to address the decline of bee populations, which is laid down in the 2010 *Commission Communication on Honeybee Health*. Bees and other pollinators, such as birds, butterflies and beetles, are the key elements for crop reproduction and studies note that pesticides are one of the factors for their decrease across the EU. PPPs are pesticides primarily used in the agricultural sector that protect crops or plants by killing or controlling pests or weeds. They are chemical compounds containing at least one active substance and have one of the following functions: 1) Protecting plants or plant products against pests or diseases, before or after harvest; 2) Influencing the life processes of plants; 3) Preserving plant products; 4) Destroying or preventing the growth of undesired plants or parts of plants. An active substance for use in PPPs is a chemical, plant extract, pheromone, or micro-organism having an effect against pests or on plants or plant products. For an active substance to be used as a component of a PPP seeking authorisation for the placing on the EU market, it must be previously approved on the basis of an evaluation process carried out by the EU Member States and the EFSA.

In the EU, active substances are assessed through the pesticides peer-review system, which follows several phases in accordance with Regulation (EC) 1107/2009. Article 7 of Regulation (EC) 1107/2009 states that an application for the approval of an active substance is to be submitted to the competent authority of an EU Member State (the 'rapporteur' Member State) together with a complete dossier and a summary thereof. Within twelve months from the date of notification of the admissibility of the application, the designated 'Rapporteur' Member State prepares and submits to the Commission a draft assessment report, evaluating whether the active substance would meet the criteria established by Regulation (EC) 1107/2009 for approval. The draft assessment report is forwarded to the EFSA for peer-review, which circulates it to the applicant and to the other EU Member States. Finally, the EFSA adopts a conclusion on whether the active substance could be expected to meet the approval criteria established by Regulation (EC)1107/2009. Within six months from the receipt of the conclusion from the EFSA, the Commission is required to present a draft Regulation to the EU's Standing Committee on Plants, Animals, Food and Feed, taking into account the draft assessment report and the EFSA's conclusion. The adoption of the draft Regulation determines the conditions of use of the active substance in PPPs on the EU market. Article 14 of Regulation (EC) 1107/2009 states that the renewal of an approval shall be for a period not exceeding 15 years. According to Article 4(2) and (3) of Regulation (EC) 1107/2009, active substances and their residues must be proven to be safe for human and animal health and for the environment.

Article 53 of *Regulation (EC) 1107/2009* establishes a derogation for plant protection in emergency situations. On that basis, an EU Member State may authorise, in special circumstances and for a period not exceeding 120 days, the placing on the market of PPPs for limited and controlled use, where such a measure appears necessary because of a danger, which cannot be contained by any other reasonable means. According to a working document from the Commission's Directorate General for Health and Food Safety, authorising measures under Article 53 should be exceptional and, particularly in cases of repeated occurrence of a specific emergency situation, alternative acceptable approaches are to be preferred. In particular, emergency authorisations should not be used as routine replacements to standard authorisations. Emergency authorisations granted on the basis of Article 53 must be notified to the Commission and to the other EU Member States through the Plant Protection Products Application Management System (PPPAMS) and the Commission may ask the EFSA to deliver an opinion or to provide scientific or technical assistance. Additionally, the Commission may take, if necessary, a decision as to when and under what conditions an EU Member State may or may not extend the duration of the measure.

Following the restrictions of outdoor use of clothianidin, imidacloprid and thiamethoxam as active substances in PPPs, established by *Commission Implementing Regulation (EU)* 485/2013, several EU Member States used the derogation established by Article 53 of *Regulation (EC)*1107/2009 to grant emergency authorisations for some of the restricted uses. Importantly, on the basis of a scientific assessment carried out by the EFSA, which demonstrates that, for some of the products for which emergency authorisations were granted,

alternatives are available, the Commission requested the concerned EU Member States not to repeat the granting of the respective emergency authorisations. However, Romania and Lithuania, from 28 February 2014, repeatedly granted emergency authorisations covering the treatment of seeds, as well as the sale and the sowing of seeds treated with plant protection products containing clothianidin, imidacloprid and thiamethoxam and did not commit to cease doing so in accordance with the Commission's request. Therefore, on 3 February 2020, the Commission adopted official decisions obliging the two EU Member States to refrain from granting emergency authorisations for the use of clothianidin, imidacloprid, and thiamethoxam as active substances in PPPs.

Those actions, aimed at restricting the use of neonicotinoids and other pesticides considered harmful for human and animal health, come at a time when the Commission is reviewing EU rules on PPPs as part of its Regulatory Fitness Programme to assess the efficiency and effectiveness of EU legislation (i.e., REFIT) and while awaiting the publication of the EU's 'Farm to Fork Strategy for Sustainable Food'. A first step in the revision of EU rules on PPPs was achieved with the approval of Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain, and amending, inter alia, Regulation (EC) 1107/2009. Additionally, in September 2019, the EFSA had organised a stakeholders consultation for the review of its guidance on pesticides and bees. The European Commissioner for Health and Food Safety Stella Kyriakides affirmed, in a statement of 13 January 2020, that the restriction of the use of neonicotinoids was a demonstration of the Commission's commitment to protect the health of EU citizens and the environment. According to the Commission, one of the objectives of the 'Farm to Fork Strategy' would be to increase "the level of ambition to reduce" significantly the use and risk of chemical pesticides". In that respect, Commissioner Kyriakides announced the Commission's objective of reducing the use of synthetic chemical pesticides by 2030. Within the 'Farm to Fork Strategy', the Commission reportedly also plans to revise Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, improving provisions on integrated pest management and calling for greater use of alternative ways to protect harvests from pests and diseases.

Civil society organisations have been questioning the EU's pesticides authorisation system for several years, with protests culminating in an official manifesto launched in October 2018 by the Coalition 'Citizens for Science in Pesticide Regulation' and supported by more than one hundred organisations and institutions, requesting that "no pesticide should be authorised if it is found to have harmful effects on humans, animals, the environment, and the ecosystem".

Manufacturers of PPPs and farmers are advised to closely monitor the developments in this heavily regulated area in order to anticipate possible forthcoming changes in the authorisation mechanism that may arise from the finalisation of the Commission's REFIT exercise and from the priorities that will be established by the forthcoming 'Farm to Fork Strategy'.

#### **Recently Adopted EU Legislation**

#### **Trade Remedies**

Corrigendum to 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 (OJ L 204, 2.8.2019)

#### **Food and Agricultural Law**

 Publication of an application for approval of amendments, which are not minor, to a product specification pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

### **Trade-Related Intellectual Property Rights**

• <u>Commission Implementing Regulation (EU) 2020/395 of 6 March 2020 entering a name in the register of traditional specialities guaranteed 'Amatriciana Tradizionale' (TSG)</u>

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