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RESPONSE OF THE EUROPEAN UNION TO G/SPS/GEN/2076 ON EU MAXIMUM RESIDUE LEVELS (MRLS) FOR CERTAIN PLANT PROTECTION PRODUCTS - STC NO. 448

SUBMISSION BY THE EUROPEAN UNION

The following document, received on 5 July 2023, is being circulated at the request of the Delegation of the European Union.

This document provides the European Union response to the questions raised in G/SPS/GEN/2076 regarding STC 448.

FOLLOW-UP TO: G/SPS/GEN/2076

1. Could each European Union member State please indicate:

   (a) How many emergency authorization applications it receives, on average, each year?

   (b) How many of these applications are approved?

   (c) How many are sent for mutual recognition to other European Union member States? Please indicate all the approved applications that have been sent for mutual recognition and to which member States.

   (d) How many emergency authorizations have been approved each year?

The European Union would like to thank the delegations of Colombia, Ecuador, Guatemala and Paraguay for the questions. The full list of emergency authorisations that have been granted by EU member States is publicly accessible via the EU emergency Authorisation Database (https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/screen/home). There is no information at EU level on the number of received or sent applications, only those approved by EU member States is presented in the database. Overall, over the last three years, there are on average around 650 emergency authorizations granted per year by all 27 EU member States. Figures vary by country (depending on sizes and agricultural production of the respective member States) and by year. The vast majority (approximately 80 %) of emergency authorisations concern Plant Protection Products containing approved active substances. Additionally, the EU would like to refer to the reply to question 8 with regards to the recent judgment by the European Court of Justice of 19 January 2023 in Case C-162/21.

2. Could each European Union member State please indicate how long, on average, it takes to approve an emergency authorization in its territory?

No specific data exist on the evaluation and approval times by member States for emergency authorisations. Data on average times for evaluations in the context of the regular approval/authorisation processes are available in the REFIT (Regulatory Fitness and Performance program) evaluation of the EU pesticides legislation conducted by the European Commission in 2020 in order to assess if the regulations meet the needs of citizens, businesses and public institutions in an efficient manner.

3. Could each European Union member State please indicate the disaggregated and total cost of active substance evaluations, including import tolerances, and emergency authorizations?

According to the findings of the REFIT evaluation[1], the overall annual costs for member States on approval and authorisation procedures for Plant Protection Products are estimated at 44 million euros, with around 930 full-time staff equivalents working as risk assessors and risk managers. Approvals and renewals of approval of active substances are estimated to account for 23 % of these resources, at a cost of 10 million euros (210 full-time staff equivalents). For MRL procedures, the estimated costs for member States are 5 million euros.

4. Could the European Union please provide a list of the active substances (in combination with the relevant product) for which it requires an MRL that is not harmonized with the Codex? With regard to these substances, could the European Union please indicate how many emergency authorizations and import tolerances have been granted?

The full list of MRLs that are established in the European Union is publicly accessible via the EU Pesticide Database (https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls). The database does not distinguish between MRLs based on CXLs and MRLs not based on CXLs, it also includes all import tolerances, but they are not flagged separately. In accordance with the WTO-SPS Agreement, the European Union communicates to its trading partners all of its intended measures lowering MRLs, including for cases when the newly proposed MRLs are not harmonised with existing Codex MRLs. In each session of the Codex Committee on Pesticides Residues it also transparently informs all delegations about which of the proposed Codex MRLs it can support. This is based on an EFSA scientific report[2] published each year and captured in the respective reports of the annual CCPR meetings. A specific overview table listing the import tolerances applications that were received and assessed at EU level during the period 2009-2020 is provided on the European Commission website (https://food.ec.europa.eu/system/files/2021-01/pesticides_mrl_guidelines_overview-it-table.pdf).

5. How many import tolerance applications have been submitted? How many have been rejected?

An overview table listing the import tolerances applications that were received and assessed at EU level during the period 2009-2020 is provided on the European Commission website (https://food.ec.europa.eu/system/files/2021-01/pesticides_mrl_guidelines_overview-it-table.pdf). The table also contain information concerning the number of import tolerance that were established in the European Union in that same period.

[1] COMMISSION STAFF WORKING DOCUMENT Accompanying the document REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides.

[2] https://www.efsa.europa.eu/en/publications.

6. Regarding the reply to question 9 in document G/SPS/GEN/2038:

(a) Could the European Union please explain what information is required from member States concerning the steps taken to confine to their territory products that have been treated with substances not authorized in the European Union and that have benefited from emergency authorizations?

(b) Could each European Union member State please explain what sort of information it provides to meet this requirement?

Article 18(4) of Regulation (EC) No 396/2005 sets the framework in case the granting of an emergency authorisation in an EU member States would require the setting of a national temporary MRL higher than the EU MRL. If the use of the plant protection product results in residues in food and feed above the EU MRLs, the authorising EU member State may exceptionally allow the placing on the market of food/feed in its own territory provided that the food or feed does not constitute an unacceptable risk. This provision has rarely been used in practice. In such cases, concerned products must stay on the territory of the EU member State. These products cannot be traded with other EU member States or non-EU countries. The control and enforcement actions are under the purview of each EU member States, not the Commission. The vast majority of emergency authorizations relate to plant protection products containing EU approved active substances, and to cases for which serious plant health risks relate to e.g. minor crops for which regular authorisations have not yet be granted.

7. Could the European Union please indicate which specific GATT articles are applicable for the establishment of MRLs under other specific factors?

The General Agreement on Tariffs and Trade (GATT) applies to international trade in goods, unless it is superseded by a more specific agreement, depending on the objective of the measure at stake.

8. We have searched through the EFSA publications on emergency authorization evaluations on the websites indicated by the European Union in document G/SPS/GEN/2038 and have only found 18 dossiers (eight for 2018 and 10 for 2021) on emergency approvals for neonicotinoids. Could the European Union please indicate:

(a) Whether these dossiers constitute all the emergency authorization evaluations conducted by EFSA?

If not, please provide copies of any other evaluations related to the products covered by this STC.

(b) In what circumstances might EFSA evaluate the need to grant or maintain an emergency authorization?

(c) How many times can a member State renew an emergency authorization? Is there a limit on the number of renewals?

(d) How does the European Union [the Commission?] use the technical information in the dossier provided by member States when granting an emergency authorization?

(e) Why does the evidence submitted by members States in their dossiers not provide sufficient justification for EFSA to re-evaluate MRLs?

(f) At what point does the EFSA evaluation take place? When an emergency authorization is being requested from a member State, or once a member State has already approved the emergency authorization?

(g) Could the European Union please explain why an emergency authorization is justified even in cases where highly effective alternatives (chemical or non-chemical) exist?

We refer to EFSA's evaluations, conducted in 2021, of the emergency authorizations granted by Belgium, Croatia, Denmark, Germany, Slovakia and Spain for the use of the active substances thiamethoxam, clothianidin and imidacloprid in sugar beet crops.

(h) Why are emergency authorizations for using certain active substances justified when EFSA notes that for certain crop/pest combinations their use is not/may not be necessary when the good agricultural practice of crop rotation is used?

We refer, by way of example, to EFSA's 2021 evaluations of the emergency authorizations for thiamethoxam, clothianidin and imidacloprid granted by Belgium (for the combination sugar beet/*Agriotes lineatus* and *Tipula sp.*); by Denmark (for the combination sugar, fodder and energy beet/*Atomaria linearis*, *Pegomya hyoscyami*, *Thrips angusticeps*); and by Slovakia (for the combination sugar beet/*Aphids*, *Atomaria linearis* and *Chaetocnema tibialis*).

(i) What consequences are there for a member State if EFSA considers the emergency authorization to be unjustified?

We note that, in Romania's case, the emergency authorization for the active substances thiamethoxam, clothianidin and imidacloprid, for the combination maize/Tany*mecus dilaticollis*, was considered unjustified by EFSA in 2018, and yet a new authorization was granted by Romania in January 2022.

(j) In cases where member States fail to provide EFSA with the information needed to determine whether the emergency authorization is justified, are there any consequences such as, for instance, greater scrutiny or a control system for the emergency authorizations granted by those member States following the EFSA evaluation?

For example, we note that in relation to the active substances thiamethoxam, clothianidin and imidacloprid, the required information was not submitted by Croatia in 2021 for sugar beet/*Alphididae*; by Bulgaria in 2018 for maize and sunflower/Tanymecus dilaticollis and Agriotes spp.; or by Hungary in 2018 for maize/*Tanymecus dilaticollis*, *Agriotes* spp. and *Melonthina melonthina* and sunflower/*Agriotes* spp.

a), b) and c) Article 53 of Regulation (EC) No 1107/2009 allows member States to grant authorisations for products containing active substances not approved in the European Union. These authorisations can only be granted for a period not exceeding 120 days, for a limited and controlled use provided such use is necessary because of a danger that cannot be contained by any other reasonable means and consumer safety must be ensured. Granting of emergency authorisations are the responsibility of the member States and do not need the European Commission's approval.

EFSA verified, on two requests of the European Commission, whether a limited number of emergency authorisations granted by a number of member States were justified. Based on the outcome of the assessment by EFSA and the reaction of the EU countries concerned, the European Commission adopted two decisions requiring two countries not to grant emergency authorisations in accordance with Article 53(3) for certain uses of these neonicotinoids for future seasons. For further information, please see the European Commission's website (https://food.ec.europa.eu/plants/pesticides/approval-active-substances/renewal-approval/neonicotinoids_en).

Please note that given the judgment by the European Court of Justice of 19 January 2023 in Case C-162/21(https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62021CJ0162), member States cannot grant any further emergency authorisations for products containing restricted neonicotinoids.

d) In the mandates on emergency authorisations, the Commission asked EFSA to consider the technical information provided by member States when verifying the justifications for these authorisations.

e) and f) So far, the European Commission has mandated EFSA after the emergency authorisation was granted by the member State as Article 53 of regulation (EU) No 1107/2009 does not foresee that member States notify the European Commission before issuing the authorisation. The European Commission however mandated the EFSA to develop fit-for-purpose protocols for evaluating emergency authorisations starting with a protocol for insecticides and acaricides by May 2025. Protocols for other types of pesticides will follow at a later date. Once available, these protocols will also help member States in their evaluations.

g) and h) The reasons why EFSA considered these emergency authorisations justified can be found in the respective technical reports on the EFSA website (https://www.efsa.europa.eu/en/news/neonicotinoids-efsa-assesses-emergency-uses-sugar-beet-202021).

i) The consequences for non-justified emergency authorisations are described in Article 53(3) of Regulation (EC) No 1107/2009. In 2020, the European Commission adopted two decisions requiring two EU member States not to grant emergency authorisations in accordance with Article 53(3) for certain uses of neonicotinoids for future seasons. Commission Implementing Decision (EU) 2020/152 of 3 February 2020 prohibited one of the member States to repeat only the granting of authorisation under Article 53(1) of Regulation (EC) No 1107/2009 for plant protection products containing the active substances clothianidin or imidacloprid for use on Brassica napus against the pests *Phyllotreta* spp. or *Psylliodes* spp. The emergency authorisations granted by that member State in 2022 were either for different active substances or different crops.

j) In such cases, the European Commission may ask the member State to provide further information or decide to ask EFSA for another opinion in case there is a specific need to do so (e.g. if there is further repetition of the measure). In the event that an emergency authorisation is not considered justified, the consequences outlined in point (i) above may apply. Independently of any mandate sent by the European Commission to EFSA, all member States need to include all relevant information, including justifications, in the online notification tool. Guidance on what information is needed for these notifications is given in the relevant guidance document. All member States are subject to periodical audits by the European Commission during which a check of the emergency authorisation process can be done. More info on the EU audit programme can be found on the European Commission's website (https://food.ec.europa.eu/horizontal-topics/official-controls-and-enforcement/health-and-food-audits-and-analysis_en).

9. We refer to notifications G/SPS/N/EU/394 – *Maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine*; G/SPS/N/EU/319 – *Maximum residue levels for imazalil*; and G/SPS/N/EU/264 – *Maximum residue levels for buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim*.

We note the following text in the "Description of content" section of the notification: "Lower MRLs are set after updating the limits of determination and/or deleting old uses which are not authorised any more in the European Union or for which a human health concern **may** not be excluded."

The active substances **carbon tetrachloride** and **omethoate** were never approved in the European Union for the use in plant protection products. Temporary MRLs were set for carbon tetrachloride in cereals by Commission Regulation (EC) No 149/2008 and omethoate (main metabolite of dimethoate) in several products by Commission Regulation (EU) 2017/1135.

In the context of the non-renewal of the approval of **chlorothalonil** the European Food Safety Authority (EFSA)[3] could not exclude a genotoxicity concern for residues to which consumers will be exposed. In addition, the assessment of consumer risk from dietary exposure could not be completed because of lack of data to confirm the definition of the residue in plants and the livestock exposure assessment, including the toxicological assessment of a metabolite.

In the context of the non-renewal of the approval of **chlorpropham**, EFSA[4] concluded that a final consumer risk assessment through dietary intake cannot be performed due to several data gaps and uncertainties identified for the food crop uses. Nevertheless, a critical area of concern for chlorpropham was identified regarding the results of an indicative consumer risk assessment where acute and chronic dietary risks for consumers have been identified both for chlorpropham and for its major metabolite 3-chloroaniline.

In the context of the non-renewal of the approval of **dimethoate**, EFSA[5] could not exclude a risk to consumers due to the exposure to residues of dimethoate, for which the genotoxic potential could not be excluded, and to its main metabolite omethoate which was concluded to be an in vivo mutagenic agent.

In the context of the non-renewal of the approval of **ethoprophos**, EFSA[6] was not possible to conclude on the genotoxic potential of ethoprophos and therefore health-based reference values could not be established. Consequently, the consumer and non-dietary risk assessments could not be conducted. In addition, several areas of the risk assessment could not be finalised including the consumer assessment with respect to residues in food of plant and animal origin, the assessment of developmental neurotoxicity. The endocrine disrupting potential of ethoprophos could not be concluded either.

In the context of the non-renewal of the approval of **fenamidone**, EFSA[7] was not possible to conclude on the genotoxic potential of fenamidone and no health-based reference values could be set. Consequently, the consumer and non-dietary risk assessments could not be conducted. The residue definitions for risk assessment in plant and livestock commodities were not finalised in terms of the inclusion of potentially relevant metabolites.

In the context of the non-renewal of the approval of **methiocarb**, EFSA[8] could not conduct the consumer risk assessment because the residue definition for risk assessment in plant commodities could not been finalised since the genotoxic potential of metabolite M01 could not be ruled out based on the available data.

In the context of the non-renewal of the approval of **propiconazole**, EFSA[9] concluded that Maximum Residue Levels (MRLs) in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council could not be confirmed for plant and animal products since data on the magnitude and toxicity of metabolites that are included in the residue definition for risk assessment was not available. In addition, several other aspects of the consumer risk assessment necessary to conclude on the risk to consumers through dietary intake could not be finalised based on the information available in the dossier.

In the context of the non-renewal of the approval of **pymetrozine**, EFSA[10] concluded that the toxicological profile of metabolites included in the plant residue definition for risk assessment could not be confirmed.

In conclusion, the approval of the active substances **chlorothalonil**, **chlorpropham**, **dimethoate**, **ethoprophos**, **fenamidone**, **methiocarb**, **propiconazole** and **pymetrozine** were not renewed by different Commission Implementing Regulations.[11] Consequently, for carbon tetrachloride, chlorothalonil, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine the MRLs were set at the limit of quantification (LOQ).

For chlorpropham, a temporary MRL has been set for potatoes, which is to be regularly reviewed, for the rest of the food/feed products MRLs are at the LOQ.

The approval of active substance **imazalil** was renewed by Commission Implementing Regulation (EU) No 705/2011. The existing MRLs for imazalil were reviewed in accordance with Article 12(1) of Regulation (EC) No 396/2005, based on EFSA's reasoned opinion[12], the MRLs which are safe for consumers in the European Union were considered for MRL setting.

The approval of the active substances **buprofezin** has been restricted to non-edible crops because confirmatory information required was not fully provided and that exposure of consumers to

[3] Conclusion on the peer review of the pesticide risk assessment of the active substance chlorothalonil. EFSA Journal2018;16(1):5126, 40 pp.; https://doi.org/10.2903/j.efsa.2018.5126.

[4] Conclusion on the peer review of the pesticide risk assessment of the active substance chlorpropham. EFSA Journal 2017;15(7):4903, 29 pp. doi:10.2903/j.efsa.2017.4903.

[5] EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance dimethoate EFSA Journal 2018;16(10):5454. https://www.efsa.europa.eu/en/efsajournal/pub/5454.

[6] Conclusion on the peer review of the pesticide risk assessment of the active substance ethoprophos. EFSA Journal 2018;16(10):5290, 34 pp. doi:10.2903/j.efsa.2018.5290.

[7] EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance fenamidone. EFSA Journal 2016;14(2):4406, 173 pp. doi:10.2903/j.efsa.2016.4406.

[8] EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance methiocarb EFSA Journal 2018;16(10):5429.

[9] EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance propiconazole. EFSA Journal 2017;15(7):4887, 28 pp. 10.2903/j.efsa.2017.4887.

[10] EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance pymetrozine. EFSA Journal 2014;12(9):3817, 102 pp. doi:10.2903/j.efsa.2014.3817.

[11] Commission Implementing Regulation (EU) 2019/677 of 29 April 2019 concerning the non-renewal of the approval of the active substance chlorothalonil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 114, 30.4.2019, p. 15).

Commission Implementing Regulation (EU) 2019/989 of 17 June 2019 concerning the non-renewal of approval of the active substance chlorpropham, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 160, 18.6.2019, p. 11).

Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 173, 27.6.2019, p. 39).

Commission Implementing Regulation (EU) 2019/344 of 28 February 2019 concerning the non-renewal of approval of the active substance ethoprophos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 62, 1.3.2019, p. 7).

Commission Implementing Regulation (EU) 2018/1043 of 24 July 2018 concerning the non-renewal of approval of the active substance fenamidone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 188, 25.7.2018, p. 9).

Commission Implementing Regulation (EU) 2019/1606 of 27 September 2019 concerning the non-renewal of the approval of the active substance methiocarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 250, 30.9.2019, p. 53).

Commission Implementing Regulation (EU) 2018/1865 of 28 November 2018 concerning the non-renewal of approval of the active substance propiconazole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 304, 29.11.2018, p. 6).

Commission Implementing Regulation (EU) 2018/1501 of 9 October 2018 concerning the non-renewal of approval of the active substance pymetrozine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 254, 10.10.2018, p. 4).

[12] European Food Safety Authority; Reasoned Opinion on the updated review of the existing maximum residue levels for imazalil according to Article 12 of Regulation (EC) No 396/2005 following new toxicological information. EFSA Journal 2018;16(10):5453.

aniline via consumption of processed crops cannot be excluded.[13] Therefore, the MRLs have been set at the LOQ.

At the time, the approval of the active substance **diflubenzuron** was restricted to non-edible crops as information submitted in the review process did not demonstrate that the risk from the potential exposure of consumers to metabolite 4-chloroaniline (PCA) as a residue is acceptable.[14] In particular, the presence of PCA in the metabolic pathway has been demonstrated in some plants and livestock and could not be excluded in others. Moreover, studies indicated a significant transformation of diflubenzuron residues into PCA under conditions similar or equal to food sterilisation processes, and such transformation could not be excluded for household processing practices. Given the genotoxic and carcinogenic properties of PCA and the absence of a threshold for acceptable exposure, it could not be established by EFSA that the exposure of consumers to PCA as a residue has no harmful effects. Since toxicological reference values for PCA cannot be set and as consequently no safe residue levels can be identified, any exposure of consumers to PCA should be prevented. Therefore, the MRLs have been set at the LOQ. In addition, the approval in the European Union expired on 31 December 2020.

In the context of the non-renewal of the approval of **picoxystrobin**, EFSA[15] considered it not possible to complete the assessment of genotoxicity for picoxystrobin and consequently health-based reference values for use in risk assessment could not be established and therefore consumer and non-dietary risk asessements could not be conducted. The dietary risk assessment from exposure to metabolites could not be finalised as further data were needed to define the toxicological profile of several metabolites; consequently, residue definitions for risk assessment purposes could not be derived. Consequently, the approval of the active substance picoxystrobin was not renewed by Commission Implementing Regulation (EU) 2017/1455[16] and the MRLs have been set at the LOQ.

The approval expired for active substance **ethoxysulfuron** on 31 March 2014, ioxynil on 28 February 2015, molinate on 31 July 2014 and **tepraloxydim** on 31 May 2015. No MRLs based on Codex maximum residue limits (CXLs) or import tolerance requests existed. All existing authorisations for plant protection products containing these active substances have been revoked. Therefore, the MRLs have been set at the LOQ.

Nevertheless, according to EU procedures, import tolerances can be requested for all those substances, according to Article 6 of Regulation (EC) 396/2005 and provided they receive a favourable assessment by EFSA, such import tolerances can be established

10. According to the replies previously received from the European Union regarding this STC, the European Union claims that its MRL measures do not fall within the scope of Article 5.7 of the SPS Agreement, despite the absence of categorical scientific evidence concerning health risks ("a human health concern may not be excluded"). Is this correct?

[13] European Food Safety Authority; Conclusion on the peer review on the review of the approval of the active substance buprofezin. EFSA Journal 2015; 13(8): 4207, 24 pp. doi: 10.2903/j.efsa.2015/420.

[14] European Food Safety Authority; Conclusion on the peer review on the review of the approval of the active substance diflubenzuron regarding the metabolite PCA. EFSA Journal 2015;13(8):4222. [30 pp.] doi:10.2903/j.efsa.2015.4222.

[15] EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance picoxystrobin. EFSA Journal 2016;14(6):4515, 26 pp. doi:10.2903/j.efsa.2016.4515.

[16] Commission Implementing Regulation (EU) 2017/1455 of 10 August 2017 concerning the non-renewal of approval of the active substance picoxystrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. (OJ L 208, 11.8.2017, p. 28.)

The measures covered by the SPS Agreement are those mentioned in Annex A(1) of the SPS Agreement. Under Article 5.7 of the SPS Agreement WTO Members are entitled to take provisional measures on the basis of available pertinent information. The EU MRLs are fully compliant with the provisions of the SPS Agreement.

A measure setting an MRL solely on the basis environmental risks falls outside the scope of the SPS Agreement and, therefore, such measures necessarily do not fall within the scope of Article 5.7 of the SPS Agreement. Such measures are notified under the TBT Agreement.