WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures Original: English

RESPONSE OF THE EUROPEAN UNION TO G/SPS/GEN/1886 ON EU MRLS FOR CERTAIN PLANT PROTECTION PRODUCTS – (CONCERN NO. 448)

SUBMISSION BY THE EUROPEAN UNION

The following submission, received on 26 March 2021, is being circulated at the request of the Delegation of the European Union.

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1. Further to the European Union's assertion in point 1 of document G/SPS/GEN/1872:

(a) Could the European Union define the "lowest achievable level" in the setting of MRLs?

In accordance with the EU MRL Regulation (Regulation (EC) No 396/2005[1]), "Good Agricultural Practice" (GAP) is the nationally recommended, authorized or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed. It also implies the application of the principles of integrated pest control in a given climate zone, as well as using the minimum quantity of pesticides and setting MRLs/temporary MRLs at the lowest level which allows the desired effect to be obtained.

"Critical GAP" means the GAP, where there is more than one GAP for an active substance/product combination, which gives rise to the highest acceptable level of pesticide residue in a treated crop and is the basis for establishing the MRL.

As such, MRLs are set at the lowest level possible in achieving the desired effect, in line with the As Low As Reasonably Achievable (ALARA) principle.

(b) Could the European Union indicate whether "good agricultural practice(s)" can vary from country to country?

Yes, Good Agricultural Practices can vary from country to country and from crop to crop.

(c) Does the European Union accept "good agricultural practices authorized in third countries", even though they are different from those established in the European Union?

Yes, a third country can submit an application for an import tolerance in such cases with the required supporting evidence. The data are then evaluated first by a member State of the EU (the "Rapporteur member State") and then by the European Food Safety Authority (EFSA). If the outcome of this evaluation is favourable, an import tolerance can be established.

2. In light of the European Union's statements in point 2 of document G/SPS/GEN/1872:

(a) Does the European Union consider that, in cases where scientific evidence does not exist or is insufficient and the European Food Safety Authority (EFSA) is unable to conclude that an MRL is safe, Article 5.7 of the SPS Agreement is being applied?

[1] http://publications.europa.eu/resource/cellar/7deccc8e-5c03-11eb-b487-01aa75ed71a1.0006.02/DOC_1.

No, the precautionary principle allows risk managers to take SPS measures when scientific uncertainty persists, but the possibility of harmful effects on health has been identified based on available scientific evidence and such measures are necessary to ensure a high level of health protection in the European Union.

(b) Article 5.7 of the SPS Agreement indicates that in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information. Could the European Union indicate why it adopts definitive measures when EFSA studies do not deliver conclusive results?

In accordance with European Union law (Article 7(2) of Regulation 178/2002), food safety measures adopted under the conditions of scientific uncertainty are reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

(c) Does the European Union consider that the submission of reservations regarding MRLs adopted by the Codex Alimentarius (CXLs) releases it from its obligations under Article 3 of the SPS Agreement?

The purpose of raising reservations is to increase transparency and predictability in international trade. The EU is one of the very few or the only Codex member openly raising reservations and communicating to Codex membership every time when not in a position to adopt a new Codex MRL, providing scientific reasons for the reservations and consequent non-alignment. The EU encourages other Members to do likewise.

(d) The European Union has indicated that many CXLs are outdated and should therefore be reviewed again by EFSA. In this regard, could the European Union indicate how many CXLs have been reviewed since November 2017?

The European Union is currently carrying out a comprehensive review programme for existing MRLs. This review includes also the review of the existing CXLs of the active substance. The number of the reviewed CXLs is different for each active substance. Around 270 substances have been reviewed so far.

Details of the respective European Food Safety Authority (EFSA) risk assessments can be found on the EFSA website: https://www.efsa.europa.eu/en/publications. Using the search function and the name of the substance, the relevant risk assessment can be easily retrieved.

In addition, EFSA on a quarterly basis publishes the detailed work programme (progress report) and its indicative time schedule for the substances to be reviewed. The document is published on the EFSA website: https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf.

(e) We refer once again to the consultations on the degree of alignment between CXLs and European Union MRLs from November 2017 to date.

Relevant EU legislation requires that where international standards exist, they are to be taken into consideration in the development or adaptation of food law. More specifically, the MRL Regulation stipulates that pesticide MRLs set at international level by the Codex Alimentarius Commission should be considered when EU MRLs are being set, taking into account corresponding good agricultural practice.

As a consequence, EU MRLs are regularly and systematically aligned with Codex MRLs (CXLs), provided that these CXLs are higher than existing EU MRLs, are related to commodities for which the EU sets MRLs, and are acceptable in terms of consumer protection, supporting data and extrapolation rules.

For instance, between 2012 and 2019, a total of **2567** CXLs for food commodities were adopted by Codex. In that period, the EU has taken on board **1833** MRLs out of these 2567 CXLs. Taking into

account EU-MRLs that are set at the same or higher level than the CXLs for the same food products, the EU is aligned with more than **70%** of the CXLs established in this period.

However, at times the European Union deviates from international standards when justified for the protection of public health and on the basis of EFSA's scientific advice. In doing so the European Union acts in conformity with Article 3 SPS Agreement.

3. With regard to emergency authorizations granted by the European Union to its member States for plant protection products which are not already authorized in the European Union and whose MRLs have therefore been reduced to 0.01 mg/kg:

(a) Could the European Union indicate how many emergency authorizations have been granted since 2017, indicating the full list of products and member States where they have been granted?

In February 2020, the European Commission launched a public database containing information on the notifications made by member States on emergency authorizations. Users can search to identify emergency authorizations granted from June 2016 onwards.

According to this database, based on the information supplied by member States, 2604 emergency authorizations have been granted since 2017.

Third countries can search the database to obtain information on the substances, uses and member States in which the emergency use was authorized.

(b) Could the European Union indicate whether, when emergency authorizations are issued to member States, agricultural products that use these substances can be marketed within the European Union and also exported to third countries?

Emergency authorizations are not issued to member States; rather, they are issued by the member States – each member State is responsible individually for granting emergency authorizations. The European Commission does not issue emergency authorizations; nor are emergency authorizations issued at EU level.

Agricultural products that are treated with plant protection products whose use is permitted by an emergency authorization can be circulated within the European Union or exported outside of the European Union provided that they comply with the relevant MRL established in the EU or the importing country.

A member State of the EU may authorize the placing on the market **only within its territory** of treated food or feed **not complying with MRLs** established by the MRL Regulation in exceptional circumstances (and provided that there is no unacceptable risk to consumers). In such cases, in order for treated produce to be circulated within the EU, treated produce must be restricted to the territory of the member State granting the emergency authorization until such level is set at EU level.

Further details can be found in the EU guidance on emergency use, published in January 2021: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_aas_guidance_wd_emergency_authorizations_article53_post-210301.pdf.

(c) What criteria are taken into account to issue an emergency authorization for the use of prohibited substances? How many consecutive times can an emergency authorization be renewed for the use of substances above the MRLs in force established by European legislation?

Details can be found in the EU guidance on emergency use, published in January 2021: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_aas_guidance_wd_emergency_authorizations_article53_post-210301.pdf.

(d) Do emergency authorizations have any impact on import tolerances with regard to like or similar plant protection products?

There is no direct connection. However, agricultural products that are treated with plant protection products whose use is permitted by an emergency authorization can be circulated within the EU only provided that they comply with the relevant MRL. MRLs apply equally to all food/feed on the market regardless of whether it is produced domestically or imported. The MRL may have been based on an EU GAP, a GAP of a non-EU country (import tolerance) or a CXL.[2]

(e) How does the European Union reconcile the emergency authorizations granted to its member States with its obligations on national treatment under Article III of the GATT and Articles 2.3 and 5.5 of the SPS Agreement?

See reply to question 3(b) above.

Agricultural products that are treated with substances resulting from emergency use of plant protection products must comply with the applicable MRL in order for them to be traded.

In exceptional cases, a member State may authorize the placing on the market of treated food or feed **not complying with MRLs** established by the MRL Regulation, but such treated food or feed must remain within its territory.

4. With regard to the European Union's reply in point 4 of document G/SPS/GEN/1872:

(a) Could the European Union confirm that MRLs apply both to food and to feed?

Yes, MRLs apply to both food and feed, more precisely to the specific commodities set out in Annex 1 to Regulation (EC) No 396/2005.

(b) Do MRLs applied to feed have the purpose of protecting the life and health of animals?

(c) If so, does the European Union consider that MRLs applied to feed come within the scope of Article 5.3 of the SPS Agreement?

Rules for animal feed are laid down in specific EU legislation on feedstuffs. For certain products falling under the MRL Regulation it is not possible to determine whether they will be transformed into food or animal feed (e.g. cereals, oilseeds). Therefore, the MRL Regulation ensures that such products should be safe both for human and, where relevant, for animal consumption.

(d) Has the European Union conducted a regulatory impact analysis of the effects that would result from reducing the use of pesticides to 50% in the production of certain foods regarding which no alternative pest control substances are registered?

The Farm to Fork Strategy does not set any targets for third countries.

The EU pesticide targets have been established based on the extensive experience gained in the development of the existing Harmonised Risk Indicator, and with consideration on meeting the aim of a significant reduction in the overall use and risk of chemical pesticides.

An assessment of the impact of the Farm to Fork pesticide use and risk reduction targets will be specifically considered in an upcoming Better Regulation evaluation of the sustainable use of pesticides Directive and an impact assessment of its possible revision, including the aforementioned targets. This initiative is expected to conclude in the first quarter of 2022 with the publication of a staff working document including the outcome of the evaluation, impact assessment and the accompanying legislative proposal. This legislative proposal will aim to reduce the use and risk of chemical pesticides in line with the Green Deal and Farm to Fork Strategy objectives.

5. In point 5 of document G/SPS/GEN/1872, the European Union has indicated that it cannot provide an exhaustive list of "other legitimate factors" that could be taken into account when setting MRLs and cannot provide specific examples of the practice.

[2] The CXL itself may also have been based on an EU GAP or a GAP of a non-EU country.

However, it has observed that "societal, economic, traditional, ethical and environmental factors" should be taken into account in risk management decisions.

(a) Given that most of these factors are not strictly scientific in nature – but rather sociological or anthropological – and that SPS measures must be based on scientific principles, how would the consideration of these other factors be compatible with the European Union's obligations under Article 2.2 of the SPS Agreement?

Any measures capable of directly or indirectly affect international trade, which the EU justifies by the necessity to protect human, animal or plant life or health, are fully compliant with Article 2.2 SPS Agreement.

(b) Could the European Union indicate how these other factors are covered by the SPS Agreement?

The SPS Agreement applies to measures defined in Annex A to the SPS Agreement. Measures based on other grounds, e.g. environmental or ethical, fall outside the scope of the SPS Agreement, even if they apply to food products.

(c) Could weighting these other factors determine the setting of lower MRLs than those derived from strictly scientific or sanitary factors?

So far, the European Union has not resorted to the use of "other legitimate factors" when taking decisions on the setting of MRLs, including import tolerances.

As already explained, environmental concerns of global nature may be taken into account in setting import tolerances. Measures will be taken on a case-by-case basis and founded on the best available scientific evidence. For those specific cases, this may indeed result in lower MRLs.

6. We reiterate our request for specific examples that illustrate how comments by third countries have been taken into account by the European Union before taking a final decision.

As already explained, all the comments received in response to notifications are duly considered and taken into account before a final decision is taken. Detailed replies are sent to all trading partners that submit comments. The European Union always provides a reply to all the comments submitted by another WTO Member on an EU notification and explains in details the planned measures and their rationale.

7. The request for a single list containing all already reviewed substances and the status of those being revised was presented to the European Union in its TPR of February 2020 and reiterated in the subsequent SPS Committee meetings, but to date no copy of that list has been made available. The European Union has indicated, in point 7 of document G/SPS/GEN/1872, that the feasibility of the request is being considered. While the European Union is analysing this feasibility:

(a) Could the European Union confirm whether the informal list contained in document RD/SPS/131/Rev.1 and the information contained in that list are correct?

The EU would like to thank Paraguay for the preparation of the table distributed in document RD/SPS/131/Rev.1. We confirm that the sources used for retrieving the information were the correct ones.

8. With regard to the process of setting MRLs for specific substances:

(a) Could the European Union indicate whether account is taken in that process of the existence of alternative substances?

The main objective of the EU legislation on MRLs is consumer protection, which prevails over any economic considerations. An assessment of the economic impacts and alternative products available to farmers is not foreseen in this regulatory context. However, the EU supports a global move towards sustainable food systems through various programmes. Research, innovation and technologies are part of this support to increase farmers sustainability and competitiveness and this is in line with the Farm to Fork Strategy, EU's Common Agricultural Policy post 2020 proposal and the research programme Horizon Europe.

The EU funds several specific programmes that can help farmers in third countries to find suitable alternatives, and to comply with EU regulatory requirements, notably:

- The "Fit for market" programme (https://eservices.coleacp.org/en/fit-for-market-sps), by the Europe-Africa-Caribbean-Pacific Liaison Committee (COLEACP);
- The "Plantwise+" programme by the Centre for Agricultural Bioscience International (CABI) (https://www.cabi.org/); or
- The "Better Training for Safer Food" (BTSF) by the Directorate-General for Health and Food Safety of the European Commission (https://ec.europa.eu/food/safety/btsf_en).

(b) Does the European Union consider the possibility that, after the process of reviewing all substances and setting MRLs at the analytical detection limit, there will be no alternative plant protection products for specific crops?

The question seems to suggest that all MRLs are lowered to the limit of quantification after a review of MRLs. This is however not the case. MRLs are lowered to the limit of quantification only under the following circumstances:

- if there are no longer existing authorizations in the EU;
- if no information of authorized uses has been provided (neither for EU uses nor for uses in non-EU countries);
- if no or insufficient data have been submitted to support authorized uses;
- if a consumer risk has been identified; or
- if insufficient data have been submitted or there are concerns about toxicity of a substance.

As stated above the most important objective of the MRL Regulation is consumer protection, which prevails over any economic considerations and public health is therefore given clear priority over crop protection. Should one of the conditions above be fulfilled, this may indeed lead to the lowering of the respective MRL to the Limit of quantification for a given substance. To help farmers to find suitable alternatives, the EU funds several important programmes, explicitly targeted to farmers in non-EU countries (see the reply to question 8a).

(c) Has the European Union carried out an estimate of the total cost at European level that would result from the withdrawal of various plant protection products that are currently available for farmers?

Please see the reply to question 8a.

9. In point 9 of document G/SPS/GEN/1872, the European Union indicates that the burden of supplying scientific evidence is shifted onto applicants because they have a direct or indirect commercial interest in placing their product on the market. Moreover, in point 2 of document G/SPS/GEN/1872, the European Union indicates that, to establish an MRL, an EFSA risk assessment must show that the MRL is safe for consumers.

(a) Does the European Union consider that under the SPS Agreement it is for the Member that imposes a sanitary measure to undertake the risk assessment on which this measure is based?

Members should have access to high-quality, independent and efficient scientific and technical support.

In the European Union, the European Food Safety Authority has the role of an independent scientific point of reference in risk assessment and source of advice. The confidence of the Union institutions, the general public and interested parties in the European Food Safety Authority is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency.

(b) In the European Union's view, does the SPS Agreement provide for the burden of supplying scientific evidence to fall on an applicant third country? Could the European Union indicate where the legal basis for this is to be found in the text of the SPS Agreement?

The European Union has already replied to this question in document G/SPS/GEN/1872 (point 11). The SPS Agreement does not specify sources where data and information necessary for carrying out risk assessment must come from.

(c) What specific scientific evidence should applicants provide who have an interest in exporting to the European market?

Applicants that have an interest in exporting to the European market can make an application for an import tolerance request. A specific guideline with further information is available on the following website of the European Commission: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-setting-proc_v5-5.pdf.

(d) In cases where the European Union adopts MRLs lower than those established by the Codex Alimentarius and, in light of the provisions of Article 3.3 of the SPS Agreement, does the European Union consider that the burden of providing scientific evidence for stricter MRLs than those provided for in international standards also falls on applicants?

The burden of providing relevant information and data is shifted onto applicants if they have a direct or indirect commercial interest in placing the product on the market and – therefore – in actively contributing to risk assessment procedures. Risk assessment is carried out in an independent manner and applicants cannot influence its outcome.

10. At the seminar organized by the European Union on the weighting of environmental factors in setting MRLs, held online in Brussels on 20 January 2021, the European Union asserted that imported food that does not meet the relevant environmental standards of the European Union will not be allowed into the European market in order to avoid the transfer of non-sustainable practices. Moreover, the European Union indicated that environmental factors that will be taken into account are those that are of global concern and, as specific examples, the decline in the population of pollinators and the accumulation in the environment of persistent, bioaccumulative and/or toxic substances (PBTs and vPvBs) were mentioned.

(a) Could the European Union provide a definition of "sustainable practices" and the criteria taken into account to define them?

The EU remains committed to the 2030 Agenda. Sustainable practices must be understood as practices that are in line with the Sustainable Development Goals and its three dimensions: the economic, social and environmental.

(b) Could the European Union provide a definition of "global concern" and the criteria taken into account to define it?

Global concerns are those which are transboundary. Biodiversity loss is an example of a global concern.

(c) The Stockholm Convention of 2001 only refers to POPs (persistent organic pollutants). Could the European Union provide an exhaustive list of the substances that it considers to be PBTs and vPvBs?

Substances considered as PBT and vPvB are listed under the Candidate List of substances of very high concern for Authorization at the website of the European Chemicals Agency (ECHA): https://echa.europa.eu/candidate-list-table.

This list includes not only PBT and vPvB but also other substances of very high concern as substances classified as carcinogenic, mutagenic and toxic for reproduction (CMR) and Endocrine Disruptors (ED).

(d) Has the classification of substances as PBTs and vPvBs been undertaken by the European Union itself or is it based on some international standard?

The criteria of definition of PBT and vPvB are reported in Regulation 1907/2006 on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), notably its Annex XIII (Criteria for the identification of Persistent, Bioaccumulative And Toxic Substances, and Very Persistent and Very Bioaccumulative Substances):
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20140410.

It describes the information that must be considered for the purpose of assessing the persistent, bioaccumulative and toxic properties of a substance. For the identification of PBT substances and vPvB substances a weight-of-evidence determination using expert judgement shall be applied, by comparing all relevant and available information listed in Section 3.2 with the criteria set out in Section 1 of that Annex.

In the context of active substances used in plant protection products (pesticides), criteria to determine if a substance is considered to be PBT or vPvB are established in points 3.7.2 and 3.7.3 of Annex II to Regulation (EC) No 1007/2009: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1107-20191214&qid=1616159236649.

In the context of active substances used in biocides, criteria to determine if a substance is considered to be PBT or VPvB are established in Art 3 (f) of the Regulation (EC) No 528/2012: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0528-20191120&qid=1616159282520.

During the EU risk assessment of such substances these properties (persistence, bioaccumulation and toxicity) must be examined and a decision is taken based on the outcome of the evaluation of the available information.

(e) Can a pesticide be of "global concern", according to the European Union, in cases where a CXL exists for that pesticide?

This will be determined on a case-by-case basis and taking into account the best available scientific evidence.

11. At the same seminar referred to above, the European Union indicated that it considers the fact that current risk assessment tools do not correctly reflect the complex behaviour of these substances to be problematic. In these cases, would Article 5.7 of the SPS Agreement apply?

As already explained, the precautionary principle applies in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists. If these conditions are fulfilled, provisional risk management measures may be adopted if it is necessary to ensure the high level of health protection chosen in the European Union. Whether or not any decision can be referred to as "based on the precautionary principle" must be therefore verified taking into account these specific circumstances.