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*(Information)*INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES
AND AGENCIES

EUROPEAN COMMISSION

COMMISSION NOTICE

**on information related to risks and non-compliance in the context of periodic reviews of
Commission Implementing Regulation (EU) 2019/1793**

(2022/C 265/01)

1. Introduction

This Commission Notice explains the relevant criteria and considerations, in the context of periodic reviews under Article 12 of Commission Implementing Regulation (EU) 2019/1793 ⁽¹⁾. The purpose of this Notice is to make the process transparent for citizens, business operators, and national competent authorities, both in the Union and in territories and third countries from where food and feed of non-animal origin subject to Implementing Regulation (EU) 2019/1793 are imported into the Union.

This Notice is intended to assist citizens, business operators and national competent authorities to better understand the application of Article 12 of Implementing Regulation (EU) 2019/1793. Only the Court of Justice of the Union is competent to interpret Union law. The views expressed in this Notice do not prejudice the position that the Commission might take before the Union and national Courts.

2. Scope of Implementing Regulation (EU) 2019/1793

Implementing Regulation (EU) 2019/1793 lays down rules concerning the temporary increase of official controls and emergency measures governing the entry into the Union of certain food and feed of non-animal origin from certain third countries, based on the empowerments provided in Article 47(2) (b) and Article 54(4) (a) and (b) of Regulation (EU) 2017/625 of the European Parliament and of Council ⁽²⁾, as well as Article 53(1)(b) of Regulation (EU) No 178/2002 of the European Parliament and of Council ⁽³⁾.

⁽¹⁾ Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council (OJ L 277, 29.10.2019, p. 89).

⁽²⁾ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

⁽³⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

The objective of Implementing Regulation (EU) 2019/1793 is to protect Union consumers from known or emerging health risks, or because there is evidence of widespread serious non-compliance with the Union agri-food chain legislation (see Article 1(2) (a) and (c) of Regulation (EU) 2017/625 for food and feed of non-animal origin). Implementing Regulation (EU) 2019/1793 provides for a harmonised approach to official controls on certain food and feed of non-animal origin entering the Union and is intended to ensure the application of Union agri-food chain legislation to such commodities.

Commodities originating in third countries and subject to a temporary increase of controls, emergency measures or a suspension of entry into the Union are listed in the Annexes to Implementing Regulation (EU) 2019/1793. The frequency of identity checks and physical checks on commodities subject to a temporary increase of controls and emergency measures is established taking into account in particular the level of risk associated with the hazard under consideration, non-compliances detected during official controls by competent authorities in the internal market, and the actual frequency of border rejections. Depending on the specific hazard, different criteria will need to be taken into account and the relative weight of the criterion will also differ (see, sections 3.1 and 3.2.2, below).

The Annexes to Implementing Regulation (EU) 2019/1793 list food and feed of non-animal origin from certain third countries and the corresponding measures, as follows:

Annex I to Implementing Regulation (EU) 2019/1793 lists food and feed of non-animal origin from certain third countries subject to a temporary increase of official controls at their entry into the Union.

Annex II to Implementing Regulation (EU) 2019/1793 lists food and feed subject to special conditions, e.g., the requirement to provide an official certificate and results of laboratory analysis, governing their entry into the Union due to the risk of contamination by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins, and of microbiological contamination.

Annex IIa to Implementing Regulation (EU) 2019/1793 lists food and feed of non-animal origin for which the import into the Union is suspended.

Annexes II and IIa constitute emergency measures within the meaning of Article 53 of Regulation (EC) No 178/2002.

Commodities are listed on the basis of their third country of origin, the description of the commodity, the combination of Combined Nomenclature (CN) code and Integrated Tariff of the European Union (TARIC) classification, and the hazard. Commodities from a third country may be simultaneously subject to temporary increase of official controls and/or emergency measures (save for suspension of entry into the Union) for more than one hazard.

Article 12 of Implementing Regulation (EU) 2019/1793 requires the Commission to review the lists set out in the Annexes on a regular basis, and not exceeding six months, in light of new information related to risks and non-compliance. In addition, in case of an emerging risk, or where there is evidence of a widespread serious non-compliance with the Union agri-food chain legislation, a safeguard measure ranging from special import conditions (listing of the commodity in Annex I or Annex II) to suspension of entry into the Union (listing in Annex IIa) may be imposed at any moment in response to imminent risks, regardless of the regular reviews

The necessary amendments to Implementing Regulation (EU) 2019/1793 are adopted in accordance with the examination procedure referred to in Article 58(2) of Regulation (EC) No 178/2002 and Article 145(2) of Regulation (EU) 2017/625.

Transitional periods may be necessary to allow for the entry into the Union of consignments of commodities that are dispatched from the country of origin before an amendment to the Regulation enters into force. Such periods allow operators and third countries to adapt to the requirements established in the Regulation that amends the listed commodities in the Annexes, and, where required, for the competent authorities of third countries to organise a certification system. In certain situations, based on the level of risk there may be no transitional period provided.

3. Steps of the review in accordance with Article 12 of Implementing Regulation (EU) 2019/1793

3.1. Hazards included in Implementing Regulation (EU) 2019/1793

Commodities are listed on the basis of the origin/CN code/hazard combination.

The list of hazards which may be the basis for increasing official controls or emergency measures in Implementing Regulation (EU) 2019/1793 is not exhaustive. At the moment the Implementing Regulation currently includes, among others the following hazards:

- (a) Microbiological: *Salmonella*;
- (b) Chemical:
 - (i) Contaminants: aflatoxins, pentachlorophenol and dioxins;
 - (ii) Residues of pesticides: residues of pesticides listed in the coordinated multiannual Community control programme adopted by the Commission in accordance with Article 29(2) of Regulation (EC) No 396/2005 ^(*), and other residues of pesticides, for example amitraz, nicotine, tolfenpyrad, diafenthiuron, dicofol, dithiocarbamates, dinotefuran, folpet, prochloraz, thiophanate-methyl, triforine, acephate, phenthoate, chlorbufam, formetanate, prothiofos, quinalphos, carbofuran, metrafenone;
 - (iii) Other hazards: Sudan dyes, rhodamine B, sulphites, cyanide, ethylene oxide.

The above list of hazards may be extended at a certain stage where there is a need to introduce certain commodities from certain countries for a particular hazard, therefore the list provided is not exhaustive, only current hazards are mentioned in this Notice.

3.2. **Information collection**

The sources of information, information retrieved and reference period for collection of information for each commodity described below.

3.2.1. *Sources of information*

Several sources of information are used to collect the information necessary in the context of the assessment of possible amendments of Regulation (EU) 2019/1793:

- (a) Information exchanged between the Commission and Member States – proposals for new listings of product/hazard combinations, comments, requests for amendments;
- (b) Information received from third countries, actions taken by third countries to ensure compliance with relevant Union requirements;
- (c) Information on the controls carried out by the Commission in third countries in accordance with Article 120 of Regulation (EU) 2017/625 – audit reports;
- (d) Information from the European Food Safety Authority (EFSA);
- (e) Records of results of official controls in the TRACES-NT system.

3.2.2. *Information retrieved for each commodity*

- (a) Outcome of official controls carried out by the Member States on listed commodities, recorded in TRACES-NT:
 - (i) Total number of consignments of food and feed of non-animal origin imported into the Union;
 - (ii) Total number of identity and physical checks carried out by the Member States' competent authorities on consignments of food and feed of non-animal origin imported into the Union;
 - (iii) Total number of unfavourable control results detected during physical checks (laboratory analysis) for the specific hazard for which the commodity is listed;
 - (iv) Percentage of unfavourable control results relative to the number of identity and physical checks on consignments for the hazard for which the commodity is listed;

^(*) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

- (b) Notifications submitted in the Rapid Alert System for Food and Feed (RASFF) and the Administrative Assistance and Cooperation System (AAC) non-compliance and the AAC food fraud systems: number of RASFF border rejection notifications and AAC non-compliance and AAC food fraud notifications for origin/product/hazard combinations;
- (c) Trade volumes for concerned commodities as provided by EUROSTAT.

3.2.3. *Reference period for information collection*

The reference period for the Commission to collect the information described in point 3.2.2. for each commodity corresponds to the full semester (in the year before or during the same year) before a new review process is started. The reference period (semester) goes from January to June, and from July to December of a given year. More recent developments and trends are considered where they are relevant in the context of assessing specific trends, in order to ensure a fully informed decision. For commodities to be newly listed in the Annexes, information from several semesters may be taken into consideration.

3.3. **Information analysis**

3.3.1. *Steps of the information analyses process*

The process of regular review start with collection of relevant information as described in point 3.2.3 and analysis of information available. Results of analysis, a review of origin/commodity/hazard combination and proposed amendments for Annexes are discussed with Member States in a working group of the Standing Committee on Plants, Animals, Food and Feed (PAFF). Results agreed with Member States are submitted to the Standing Committee on Plants, Animals, Food and Feed (PAFF) ⁽⁹⁾ for the opinion of Member States.

3.3.2. *Considerations for information analysis*

Several factors are taken into consideration during the assessment of information collected for possible amendments of Regulation (EU) 2019/1793.

Analysis is based on all information collected as mentioned in point 3.2.2. concerning a certain commodity. However, a case-by-case assessment is made depending on the origin /commodity/hazard combination. In particular, measures may be maintained even if actual trade has stopped, where there is no evidence of an improvement in risk management, concerning the relevant hazard, hazard at the place of origin of the commodity and therefore, with the available information, the risk of unsafe commodities being exported to the Union remains.

Seasonal trade patterns, trends in time and trade volumes are amongst the factors considered.

Where a potentially systemic issue in a third country is detected, which goes beyond findings relating to the responsibility of individual operators for the compliance of their exports with the Union rules and where Member States report non-compliance levels that do not significantly improve, a harmonised, gradual response, depending on the scope of the problem and the foreseeable management, is introduced:

- (a) listing in Annex I/ increase in the frequency of checks for products already listed in Annex I (as a measure affecting operators importing consignments of food and feed of non-animal origin into the Union and indirectly the third countries);
- (b) listing in Annex II/ special import conditions are introduced where specific responsibility is placed upon the competent authorities of exporting third countries, via an obligation for them to test at origin and certify compliance of consignments with the Union rules;
- (c) listing in Annex IIa/ where food or feed of non- animal origin imported into the Union constitutes a serious risk to human health, animal health or the environment, suspension of entry into the Union of certain commodities may be imposed as the most stringent measure, due to serious/recurrent health issues and/or unresolved systemic issues.

⁽⁹⁾ PAFF committees (europa.eu)

3.4. *Possible amendments resulting from information analysis*

The decisions for each individual commodity are based on information analyses and on discussion with Member States during Working Group meetings on temporary measures for the import of food and feed of non-animal origin. The decision is taken on a case by case basis for each individual commodity, taking into account a multifactorial combination of hazard, frequency of non-compliance, trade volumes, scope of the problem and the forecast for its satisfactory management.

Possible decisions regarding amendment of Annexes of Regulation (EU) 2019/1793 are as follows:

- (a) Inclusion of a commodity in an Annex;
- (b) Deletion of a commodity from an Annex;
- (c) Deletion of a commodity from one Annex and movement to another Annex;
- (d) Changes to the frequency of identity and physical checks required upon entry into the Union: increase or decrease. Frequencies are set at 5 %, 10 %, 20 %, 30 %, and 50 %.

The frequency of identity and physical checks may vary on a case by case basis on a combination of multiple factors described in points 3.1 and 3.2, above, and in agreement with Member States' during Working Group meetings.

3.5. *Procedure*

The draft amending act, prepared on the basis of the information analysis and outcome of discussions with Member States during Working Group meetings, is submitted for the opinion of the Standing Committee on Plants, Animals, Food and Feed (PAFF). The draft amending act, after receiving a favourable opinion in the vote of the PAFF Committee, is adopted by the Commission and published in the *Official Journal of the European Union* (OJEU). In the period between receiving a favourable opinion of the PAFF Committee and before adoption by the Commission, the Commission informs the third country concerned by letter of the envisaged changes (e.g., inclusion/delisting from Annexes, changes to the frequency identity and physical checks) for the commodities listed in Annexes of the draft amending act. After publication in the OJEU a sanitary and phytosanitary (SPS) notification is submitted by the Union to the World Trade Organization (WTO).

4. **Glossary**

AAC	The Administrative Assistance and Cooperation (AAC) System is a system developed and managed by the Commission where members of the Union Food Fraud Network exchange information. Member State can contact the competent authorities of another Member State and share information in a secure manner, which can lead to administrative actions, administrative sanctions or judicial proceedings. It was fully integrated into the Rapid Alert System for Food and Feed (iRASFF) in 2020.
Compliance	Compliance with the rules as referred to in Article 1(2) of Regulation (EU) 2017/625.
CN code	The Combined Nomenclature code (CN code) is a tool for classifying goods set up to meet the requirements both of the Common Customs Tariff and of the Union external trade statistics. It is used mainly when the goods are declared to customs in the Union, and determines which rate of customs duty applies. It corresponds to the goods nomenclature, as laid down in Annex I to Council Regulation (EEC) No 2658/87. It comprises the harmonized system nomenclature.
TARIC classification	It corresponds to an integrated tariff of the Union, based on the combined nomenclature. It comprises <i>inter alia</i> additional subdivisions, referred to as 'Taric' subheadings', which are needed for the description of goods subject to the specific Union measures, and the rates of customs duty and other charges applicable, as defined in Article 2 of Council Regulation (EEC) No 2658/87.

Consignment	It corresponds to the quantity of goods covered by the same official certificate, official attestation or any other document, conveyed by the same means of transport and coming from the same territory or third country, and, except for goods subject to the rules referred to in point (g) of Article 1(2) of Regulation (EU) 2017/625, being of the same type, class or description, as defined in Article 3(37) of Regulation (EU) 2017/625.
EFSA	The European Food Safety Authority (EFSA) is a European agency set up in 2002 by the Union under Regulation (EC) No 178/2002. It is responsible for assessing risks throughout the food chain, and providing independent scientific advice to the decision makers who regulate food safety in the Union. It operates independently from the European legislative and executive institutions (Commission, Council, and Parliament) and the Union Member States.
Entry into the Union	The action of bringing goods into one of the territories that are listed in Annex I to Regulation (EU) 2017/625 from outside these territories, as defined in Article 3(40) of this Regulation.
EU	European Union
EUROSTAT	Eurostat is the statistical office of the Union. It coordinates statistical activities at Union level and provides high quality statistics and data on the Union.
Food and feed of non-animal origin	The words 'food and feed of non-animal origin' refer to 'food' meaning any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans as defined in Article 2 of Regulation (EC) No 178/2002; and 'feed' meaning any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals, as defined in article 3(4) of Regulation (EC) No 178/2002, which are of plant origin (e.g. fruits and vegetables, spices, tea), or of any other non-animal origin, such as minerals (salt).
Hazard	Any agent or condition with the potential to have an adverse effect on human, animal or plant health, animal welfare or the environment, as defined in Article 3(23) of Regulation (EU) 2017/625.
Import of food and feed	Import of food and feed refers to non-Union food and feed of non-animal origin intended to be placed on the Union market or intended for private use or consumption within the customs territory of the Union.
Official controls	Official controls are defined in Article 2(1) of Regulation (EU) 2017/625 as activities performed by the competent authorities, or by the delegated bodies or the natural persons to which certain official control tasks have been delegated in accordance with Regulation (EU) 2017/625, in order to verify (a) compliance by the operators with that Regulation and with the rules referred to in Article 1(2); and (b) that animals or goods meet the requirements laid down in the rules referred to in Article 1(2), including for the issuance of an official certificate or official attestation.
OJEU	The <i>Official Journal of the European Union</i> (OJEU) is the gazette of record for the European Union.
PAFF	The Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) is composed by representatives of all Member States and presided by a Commission representative, and plays a key role in ensuring that Union measures on food and feed safety, animal health & welfare as well as plant health are practical and effective. It delivers opinions on draft measures that the Commission intends to adopt. The PAFF Committee's mandate covers the entire food supply chain -from animal health issues on the farm to the product on the consumer's table - helping the Union deal effectively with health risks at every stage of the production chain.

Placing on the market	Placing on the market is defined in point (8) of Article 3 of Regulation (EC) No 178/2002 as the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.
RASFF	The Rapid Alert System for Food and Feed (RASFF) is established by Article 50 of Regulation (EC) No 178/2002 as a rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed and corresponds to a network involving the Union Member States, the Commission as member and manager of the system, EFSA. It also involves the European Free Trade Association (EFTA) states and the EFTA Surveillance Authority. The different types of notifications are defined in Article 2 of Commission Implementing Regulation (EU) 2019/1715. That Regulation also lays down implementing measures for the efficient operation of the RASFF. The RASFF notifications classified as border rejections concern consignments of food, feed or food contact material for which entry into the Union was refused by a competent authority at a border post within the Union due to a risk to human health, animal health or to the environment.
Risk	A function of the probability of an adverse effect on human, animal or plant health, animal welfare or the environment and of the severity of that effect, consequential to a hazard, as defined in Article 3(24) of Regulation (EU) 2017/625.
SPS	Sanitary and phytosanitary (SPS)
TRACES-NT	The TRAdE Control and Expert System (TRACES) is the Commission's multilingual online sanitary and phytosanitary certification platform supporting the importation of animals, animal products, food and feed of non-animal origin and plants into the Union, and the intra-Union trade and the Union exports of animals and certain animal products. The new release of the tool called TRACES New Technology (TRACES-NT) features electronic certification practices by enabling both Union and third country competent authorities to stamp digitally official documents and certificates or to sign a decision taken on a consignment, thus, making the use of paper certification obsolete.
WTO	<p>The World Trade Organization (WTO) deals with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible.</p> <p>Under the WTO, the SPS Agreement states that countries should notify changes to their SPS measures. SPS measures are any measure applied (i) to protect human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (ii) to protect human life or health from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; (iii) to protect animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; or (iv) to prevent or limit other damage from the entry, establishment or spread of pests.</p> <p>The agreement states that: <i>'Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.'</i></p> <p>The SPS Agreement requires countries to notify the WTO of proposed new sanitary and phytosanitary regulations or modifications to existing regulations whenever: (i) either an international standard, guideline or recommendation does not exist, or; (ii) the content of a proposed SPS regulation is not substantially the same as the content of an international standard, guideline or recommendation, and, in both cases, if; (iii) the regulation may have a significant effect on trade of other countries.</p>