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⁽¹⁾ Text with EEA relevance.

EN

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/444

of 16 December 2022

supplementing Directive (EU) 2018/1972 of the European Parliament and of the Council with measures to ensure effective access to emergency services through emergency communications to the single European emergency number '112'

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2018/1972 of the European Parliament and of the Council of 11 December 2018 establishing the European Electronic Communications Code ⁽¹⁾, and in particular Article 109(8) thereof,

Whereas:

- (1) Pursuant to Article 109(8) of Directive (EU) 2018/1972, in order to ensure effective access to emergency services through emergency communications to the single European emergency number '112' in the Member States, the Commission shall adopt delegated acts, with the first such act to be adopted by 21 December 2022. These delegated acts are to supplement paragraphs 2, 5 and 6 of Article 109 of the Directive on measures necessary to ensure the compatibility, interoperability, quality, reliability and continuity of emergency communications in the Union with regard to caller location information solutions, access for end-users with disabilities and routing to the most appropriate public safety answering point (PSAP).
- (2) Emergency communications are an important element for the pursuit of public safety, security and health. For more than 30 years, citizens of the Union have relied on access to emergency services using the single European Emergency number '112. They should continue to be able to do so in the digital world. Citizens should benefit from comprehensive and timely delivery of contextual information necessary for addressing an emergency situation. The high level of connectivity that is targeted by Europe's digital transformation, as reflected in the Decision establishing the Digital Decade Policy Programme 2030 ⁽²⁾, is bringing about a technological migration to all-IP technologies of electronic communication services used by citizens, in particular by persons with disabilities. The migration from circuit-switched to packet-switched technologies in electronic communication networks triggers the deployment of voice services through IP Multimedia Subsystem based fixed and mobile managed VoIP technologies such as Voice over Long Term Evolution (VoLTE), Voice over New Radio (VoNR in 5G) and Voice over Wi-Fi (VoWiFi). Packet-switched technologies also enable text and video-based services like real time text and total conversation services. Those IP-based communication services cannot be supported by the legacy circuit-switched networks, such as 2G and 3G networks that are in the process of being decommissioned. Therefore, there is a need to migrate emergency communications to packet-switched technologies as well. This Regulation aims to ensure that in this transformational process the quality and reliability of emergency communications are ensured.

⁽¹⁾ OJ L 321, 17.12.2018, p. 36.

⁽²⁾ Decision (EU) 2022/2481 of the European Parliament and of the Council of 14 December 2022 establishing the Digital Decade Policy Programme 2030 (OJ L 323, 19.12.2022, p. 4).

- (3) The goal of emergency services is to avoid, alleviate or manage the effects of emergency incidents through emergency intervention. The time necessary for emergency intervention has a fundamental impact on the outcome of emergency incidents. Effective emergency intervention requires rapid mobilisation of the intervention resources that could effectively address the emergency incident, and the fast arrival at the intervention scene.
- (4) The goal of emergency communications is to enable end-users to access emergency services to request and receive emergency relief from emergency services. While emergency communications are set up between the end-user and the PSAP, it should be the role of the most appropriate PSAP to process the information received and convey the request to the emergency services, hence ensuring access to emergency services. Depending on the national organisation of PSAP systems and emergency services systems, PSAPs and emergency services can be overlapping or autonomous entities.
- (5) In order to enable access to emergency services, effective emergency communications should ensure both the timely communication between the end-user and the most appropriate PSAP and the making available in a timely manner of contextual information, including caller location information. The contextual information contributes to the description of the emergency incident, for example, the physical environment, the condition and abilities of the persons involved, the localisation of the incident, etc. The availability and accuracy of contextual information enables the timely identification of the appropriate intervention resources and the quick arrival at the intervention scene, e.g. when an accurate caller location is available. This information may be conveyed to the emergency services through emergency communications by the end-user, or derived automatically from the device of the end-user or the network.
- (6) Caller location is one of the most important types of contextual information associated with emergency communications and it has a high impact on their effectiveness. The accuracy and reliability of caller location information influences the time necessary to identify the site of the emergency and the on-site arrival of emergency services.
- (7) Directive (EU) 2018/1972 requires competent regulatory authorities to establish the caller location accuracy and reliability criteria. Those criteria represent the minimum levels of accuracy and reliability of caller location information that have to be implemented on the territory of the Member State through network-based and handset-derived technologies. According to the case-law of the European Court of Justice ⁽³⁾, the criteria should ensure, within the limits of technical feasibility, that the end-user's position is located as reliably and accurately as is necessary to enable the emergency services to usefully come to the end-user's assistance. The mix of these technologies ensures that even where a handset-derived caller location solution fails to make the caller location information available to the most appropriate PSAP, emergency services can rely on network-based location to usefully come to the end-user's assistance, in line with the caller location accuracy and reliability criteria established by Member States. Caller location criteria, which do not allow the establishment of minimum levels of accuracy and reliability may lead to implementation that does not ensure that emergency services receive caller location information, which they can effectively use. It should be for the Member States to assess the combined effect of the technically feasible caller location solutions, and to establish minimum criteria for both accuracy and reliability of caller location, which, if implemented, would enable emergency services to usefully intervene. The usefulness of the accuracy of caller location information might vary depending on the area from which the emergency communication is originated (e.g. urban or rural) and could be reflected accordingly in the criteria set. In order to ensure a harmonised approach within the Union to the setting of the accuracy and reliability criteria which ensures a minimum level of contextual information, it is necessary to define the parameters that competent regulatory authorities should take into account when laying down such criteria. Moreover, it is important to recall that pursuant to the principle of sincere cooperation laid down in Article 4(3) of the Treaty on European Union, competent regulatory authorities are to cooperate among each other when laying down the criteria for the accuracy and reliability of the caller location information by consulting the Body of European Regulators for Electronic Communications (BEREC) or other relevant fora competent to provide guidance in this regard, in order to ensure the full effectiveness of Article 109(6) of Directive (EU) 2018/1972.

⁽³⁾ Case C 417/18; Judgment of the Court (Fourth Chamber) of 5 September 2019, *AW and Others v Lietuvos valstybė*.

- (8) The accuracy of caller location information may be expressed as a maximum radius of the search area for the intervention that is presented to the emergency services. Emergency intervention times could be significantly reduced when accurate and reliable network-based and handset-derived caller location information is available to the most appropriate PSAP, especially when end-users requesting emergency assistance are not able to specify their location. Therefore, for fixed networks, Member States should express the minimum levels of accuracy to be implemented on their territory as caller location information related to the physical address of the network termination point, for example by reference to the concrete street address, apartment, floor or similar information. For mobile networks the minimum levels of accuracy should be expressed in metres to indicate the maximum radius of the horizontal search area that is presented to the emergency services for intervention purposes. If applicable and technically feasible, the elevation or vertical accuracy criterion should be expressed in metres as well. Member States should assess whether these parameters are feasible to be applied to network independent providers of number-based interpersonal communication services when these are used in fixed or mobile networks.
- (9) The reliability of caller location should pertain to two aspects of the caller location information: the establishment and the transmission. The reliability of caller location information should be established according to the statistical measurements that indicate the success rate with which the actual location of the device originating the emergency communication matches the physical area indicated on the basis of the caller location information. An emergency communication should trigger both network-based and handset-derived caller location information, when the latter is available. The reliability of the caller location information for the emergency services should be established as a combined effect of these two technologies. The reliability of transmission of caller location information should be expressed as the success rate of the technical solution to transmit the caller location information to the most appropriate PSAP. The success rate is dependent on the capabilities of the network to convey the information, in case of network-based caller location, or the interoperability between the handset and the network resources to allow the transmission, in case of handset derived caller location, as well as the most appropriate PSAP capabilities to receive the information.
- (10) In order to enable the Commission to monitor the caller location criteria established in accordance with this Regulation, Member States should report on the adoption of the criteria and explain how they have taken into account the parameters established in this Regulation.
- (11) Directive (EU) 2018/1972 requires access to emergency services through emergency communications for end-users with disabilities to be equivalent to that enjoyed by other end-users. The principle of equivalence implies that end-users with disabilities should be able to access emergency services through emergency communications in a functionally equivalent manner to that in which other end-users access emergency services, in particular by calling the '112' number via voice-based services. Since there is no common understanding of the functional equivalence requirements, the requirements that replicate the functionalities of emergency communications enjoyed by other end-users, mainly voice-based services, should be established. If for technical reasons, Member States are not able to comply with the functional equivalence requirements established by this Regulation, they should inform the Commission of the specific reasons why this is not possible. Member States should inform the Commission when the technical design of the mandated means of access to emergency services does not require or allow the use of the single European emergency number '112' and how it is ensured that the same or higher awareness is reached amongst end-users with disabilities with regard to that means of access.
- (12) In order to enable the Commission to monitor the compatibility, quality, reliability, interoperability and continuity of the means of access to emergency services for end-users with disabilities, Member States should report the means of access to emergency services mandated in their jurisdiction for end-users with disabilities, including those using roaming services. The report should contain a first assessment of the compliance of the reported means of access with the functional equivalence requirements in accordance with this Regulation. The migration to all-IP networks will enable the implementation of new, accessible communication services like real time text and total conversation services. Member States should therefore report interoperability, compatibility or continuity issues encountered when deploying such services, in particular for roaming end-users. In order to fulfil their obligation under Article 16 of Regulation (EU) 2022/612 of the European Parliament and of the Council (*) to report to BEREC the means of access to emergency services that are mandated in their Member State and that are technically feasible to be used by roaming customers, national regulatory authorities or other competent authorities should establish, if applicable, the technical reasons for the lack of availability of the emergency communication service for roaming end-users where those services are available for domestic end-users. The first report, as well as information provided in the following years will enable the Commission to assess the necessity of adopting further measures, including standardisation mandates, to address such issues.

(*) Regulation (EU) 2022/612 of the European Parliament and of the Council of 6 April 2022 on roaming on public mobile communications networks within the Union (recast) (OJ L 115, 13.4.2022, p. 1).

- (13) Emergency communications and caller location information have to be routed to the most appropriate PSAP to enable the appropriate answering and handling of the emergency communications. Effective routing of emergency communications should be ensured also in the context of the technological migration from circuit-switched to packet-switched technologies. The most appropriate PSAP is normally determined by the Member State on the basis of a territorial competence to handle emergency communications or the competence to handle a certain type of communication, for example a PSAP equipped to handle real time text or sign-language communication. The interpersonal communication services provided through packet-switched technologies providing voice, text – including real time text –, and video may be routed in the public network domain or PSAP domain. Depending on the national organisation of PSAPs, while the emergency communication reaches PSAP system through the public networks, further routing may be necessary within the PSAP domain to reach the most appropriate PSAP. In order to guarantee the availability of effective emergency communications to the benefit of all end-users, Member States should ensure the timeliness of routing to the most appropriate PSAP of all types of emergency communications and of caller location information mandated on their territory.
- (14) The effectiveness of access to emergency services is dependent on the timeliness of the conveyance of the contextual information to the emergency services. Member States should ensure that the most appropriate PSAP to which the emergency communication is routed, is technically capable of transmitting in a timely manner the contextual information to the emergency services from the moment those services are alerted by that PSAP. According to the national organisation of PSAPs, the most appropriate PSAP may assess the usefulness of the contextual data and filter the information to be provided to emergency services.
- (15) In order to enable the monitoring by the Commission of the effectiveness of routing to the most appropriate PSAP, Member States should report on the performance of the routing of emergency communications to the most appropriate PSAP in terms of their timeliness, including when using voice, text, or video services.
- (16) Ensuring seamless access to emergency services, without pre-registration, for end-users, including end-users with disabilities, travelling in another Member State might not be under the sole control of a Member State and would require compliance with commonly agreed interoperability requirements. Without prejudice to the implementation of real time text and total conversation services pursuant to Directive (EU) 2019/882 of the European Parliament and of the Council ^(⁹), it should be possible to implement access to emergency services through voice, text or video services through emergency communications via mobile applications. Mobile applications may enable the transmission of rich contextual data to the most appropriate PSAP. Once a mobile application is downloaded and installed, the end-user may communicate with the most appropriate PSAP across the Union if the common interoperability requirements make that possible, and the mobile application providers and the national PSAP systems comply with those requirements. Member States should cooperate with the Commission in good faith to identify the common interoperability requirements the implementation of which would enable the use of such emergency communications to the most appropriate PSAP via mobile applications across the Union.
- (17) PSAP systems that were developed to answer and handle circuit-switched communications may not be able to answer, handle and process all features of emergency communications initiated through packet-switched technology. In order to ensure transparency with relevant stakeholders, in particular electronic communications services and network providers, as well as to ensure a coherent and timely upgrade of PSAPs systems within their territory, Member States should prepare a roadmap for the upgrade of the capabilities of their PSAP systems to answer, handle and process emergency communications provided through packet-switched technologies. The roadmap should contain the expected timeline and date of deployment of novel means of access to emergency services through emergency communications through packet-switched technologies, whether these are enabled in the core network as number-based interpersonal communication services or deployed via a mobile application. The roadmap should contain information on the timeline of the upgrade of the capabilities of the PSAP systems, taking account of the obligations set in Directive (EU) 2019/882 and the legal deadlines provided therein. This concerns in particular the appropriate answering by the most appropriate PSAP the emergency communications to the single European emergency number ‘112’, by using synchronised voice and text (including real time text), or, where video is provided, voice, text (including real time text) and video synchronised as total conversation. If applicable, the

⁽⁹⁾ Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70).

expected legal mandate to deploy emergency communications through packet-switched technologies under national legislation should be indicated. The roadmap should refer to the intermediary milestones, for example public and stakeholder consultations, legislative measures, interoperability, continuity and reliability testing, public procurement, etc. Member States should provide the roadmap to the Commission and provide updates on its implementation. Member States should also report the interoperability and continuity issues encountered with regard to the provision of electronic communication services used for accessing emergency services to enable the Commission to assess the necessity of adopting further measures, including standardisation mandates, that would address such bottlenecks.

- (18) A regular and structured gathering of information from Member States regarding several aspects pertaining to the effectiveness of emergency communications in the Union is necessary to enable the Commission to monitor their implementation and compliance with obligations set out in Article 109 of Directive (EU) 2018/1972, as supplemented by this Regulation. Following the first report as provided for in this Regulation, Member States should provide the Commission with updated information as requested in the context of each data gathering that the Commission initiates for the purposes of fulfilling its obligation to report to the European Parliament and the Council pursuant to Article 109(4) of Directive (EU) 2018/1972.
- (19) The Body of European Regulators for Electronic Communications was consulted in accordance with Article 109(8) of Directive (EU) 2018/1972 and delivered an opinion on 14 October 2022.
- (20) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽⁶⁾ and delivered an opinion on 15 November 2022,

HAS ADOPTED THIS REGULATION:

CHAPTER 1

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

This Regulation establishes measures to ensure effective access to emergency services through emergency communications with regard to caller location information solutions, access for end-users with disabilities and routing to the most appropriate PSAP.

Article 2

For the purposes of this Regulation, the following definitions apply:

- (1) 'effective emergency communication' means emergency communication as defined in Article 2, point (38) of Directive (EU) 2018/1972 that ensures:
- (a) timely communication between the end-user and the most appropriate PSAP, and
 - (b) the making available in a timely manner of contextual information, including caller location information;

⁽⁶⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

- (2) 'contextual information' means the information conveyed through an emergency communication by the end-user or derived and transmitted automatically from the device of the end-user or the relevant network in order to enable the timely identification of the intervention resources of the emergency services and the fast arrival of the emergency services at the intervention scene.

CHAPTER 2

CALLER LOCATION INFORMATION

Article 3

1. When laying down criteria for the accuracy and reliability of caller location information pursuant to Article 109(6) of Directive (EU) 2018/1972, competent regulatory authorities shall ensure, within the limits of technical feasibility, that the end-user's position is located as reliably and accurately as is necessary to enable the emergency services to come to the end-user's assistance. Competent regulatory authorities shall lay down the criteria taking into account the parameters specified in paragraphs 2 and 3 of this Article.
2. With respect to the fixed networks:
 - (a) the accuracy criterion for caller location information shall be expressed as information related to the physical address of the network termination point;
 - (b) the reliability criterion for caller location information shall be expressed as the success rate, in percentage, of the technical solution or mix of technical solutions to establish and transmit to the most appropriate PSAP a caller location information corresponding to the accuracy criterion.
3. With respect to the mobile networks:
 - (a) the accuracy criterion for caller location information shall be expressed in metres. If applicable, the elevation or vertical accuracy criterion shall be expressed in metres as well;
 - (b) the reliability criterion for caller location information shall be expressed as the success rate, in percentage, of the technical solution or mix of technical solutions to establish and transmit to the most appropriate PSAP a search area corresponding to the accuracy criterion.

CHAPTER 3

ACCESS TO EMERGENCY SERVICES FOR END-USERS WITH DISABILITIES

Article 4

When implementing means of access to emergency services through emergency communications for end-users with disabilities, Member States shall ensure that, subject to technical feasibility, the following functional equivalence requirements are met:

- (a) the emergency communication enables two-way interactive communication between the end-user with disabilities and the PSAP;
- (b) the emergency communication is available in a seamless way, without pre-registration, to end-users with disabilities travelling in another Member State;
- (c) the emergency communication is provided to end-users with disabilities free of charge;
- (d) the emergency communication is routed without delay to the most appropriate PSAP that is qualified and equipped to appropriately answer and process the emergency communication from end-users with disabilities;
- (e) equivalent levels of accuracy and reliability of caller location information are ensured for the emergency communication for end-users with disabilities as for emergency calls by other end-users;

- (f) the end-users with disabilities are enabled to reach at least the same level of awareness about the means of access to emergency services through emergency communications as other end-users about emergency calls to '112', either by the design of the means of access or through awareness raising measures.

CHAPTER 4

ROUTING TO THE MOST APPROPRIATE PUBLIC SAFETY ANSWERING POINT

Article 5

Member States shall ensure that emergency communications and caller location information are routed without delay to the most appropriate PSAP that is technically capable to convey the contextual information to the emergency services when alerting those services.

Article 6

For the purpose of ensuring the technical feasibility of the seamless access to emergency services as provided in Article 4(1), point (b) of this Regulation, without prejudice to the implementation of Directive (EU) 2019/882, Member States shall cooperate with the Commission to identify common interoperability requirements that enable the emergency communication to the most appropriate PSAP via a mobile application anywhere in the Union.

CHAPTER 5

REPORTING

Article 7

1. Member States shall regularly report to the Commission the performance of the routing to the most appropriate PSAP under Article 5, implemented for emergency communications and caller location information.
2. Member States shall prepare and report to the Commission no later than on 5 November 2023 a roadmap for upgrading the national PSAP system in order to be able to receive, answer and process emergency communications through packet-switched technology. The roadmap shall indicate the date of the expected deployment of voice, text or video based emergency communications through packet-switched technologies. The roadmap shall also include the indicative date by when PSAPs will be ready to receive such emergency communications. Member States shall provide updated information on the implementation of the intermediary milestones of the roadmap in accordance with Article 8.

Article 8

1. Member States shall report to the Commission no later than on 5 March 2024:
 - (a) the criteria for the accuracy and reliability of caller location information expressed according to the parameters referred to in Article 3,
 - (b) the means of access to emergency services through emergency communications to be used by end-users with disabilities, including those using roaming services, and the assessment of their compliance with the functional equivalence requirements in Article 5.
2. Member States shall provide the Commission with the information referred to in this article and Article 7 without prejudice to the initial deadlines provided therein, in the context of each data gathering that the Commission initiates for the purposes of fulfilling its obligation to report to the European Parliament and the Council pursuant to Article 109(4) of Directive (EU) 2018/1972.

CHAPTER 6

FINAL PROVISIONS*Article 9*

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/445**of 23 February 2023****approving amendments to the specification for a Protected Designation of Origin or a Protected Geographical Indication ('Colli Bolognesi Classico Pignoletto' (PDO))**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 99 thereof,

Whereas:

- (1) The Commission has examined the application for the approval of amendments to the specification for the Protected Designation of Origin 'Colli Bolognesi Classico Pignoletto', forwarded by Italy in accordance with Article 105 of Regulation (EU) No 1308/2013. The changes include a change of name from 'Colli Bolognesi Classico Pignoletto' to 'Colli Bolognesi Pignoletto'.
- (2) The Commission has published the application for the approval of the amendments to the specification in the *Official Journal of the European Union* ⁽²⁾, as required by Article 97(3) of Regulation (EU) No 1308/2013.
- (3) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (4) The amendments to the specification should therefore be approved in accordance with Article 99 of Regulation (EU) No 1308/2013.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

*Article 1*The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Colli Bolognesi Classico Pignoletto' (PDO) are hereby approved.*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.⁽¹⁾ OJ L 347, 20.12.2013, p. 671.⁽²⁾ OJ C 379, 3.10.2022, p. 41.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 February 2023.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

COMMISSION IMPLEMENTING REGULATION (EU) 2023/446**of 27 February 2023****amending Implementing Regulation (EU) 2018/2019 as regards certain plants for planting of *Ligustrum delavayanum* and *Ligustrum japonicum* originating in the United Kingdom and Implementing Regulation (EU) 2020/1213 as regards the phytosanitary measures for the introduction of those plants for planting into the Union territory**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ⁽¹⁾, and in particular Article 42(4), the third subparagraph, thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2018/2019 ⁽²⁾ establishes, on the basis of a preliminary risk assessment, a list of high risk plants, plant products and other objects.
- (2) Commission Implementing Regulation (EU) 2018/2018 ⁽³⁾ lays down specific rules concerning the procedure to be followed in order to carry out the risk assessment referred to in Article 42(4) of Regulation (EU) 2016/2031 for high risk plants, plant products and other objects.
- (3) Following a preliminary assessment, 34 genera and one species of plants for planting originating from third countries were provisionally listed in Implementing Regulation (EU) 2018/2019 as high risk plants. That list includes the genus *Ligustrum* L.
- (4) Commission Implementing Regulation (EU) 2020/1213 ⁽⁴⁾ sets out the phytosanitary measures for the introduction into the Union territory of certain plants, plant products and other objects, which have been removed from the Annex to Implementing Regulation (EU) 2018/2019, but for which phytosanitary risks are not yet fully assessed. This is because one or more pests hosted by those plants are not yet included in the list of Union quarantine pests of Commission Implementing Regulation (EU) 2019/2072 ⁽⁵⁾, but they may fulfil the conditions to be included following a further complete risk assessment.

⁽¹⁾ OJ L 317, 23.11.2016, p. 4.

⁽²⁾ Commission Implementing Regulation (EU) 2018/2019 of 18 December 2018 establishing a provisional list of high risk plants, plant products or other objects, within the meaning of Article 42 of Regulation (EU) 2016/2031 and a list of plants for which phytosanitary certificates are not required for introduction into the Union, within the meaning of Article 73 of that Regulation (OJ L 323, 19.12.2018, p. 10).

⁽³⁾ Commission Implementing Regulation (EU) 2018/2018 of 18 December 2018 laying down specific rules concerning the procedure to be followed in order to carry out the risk assessment of high risk plants, plant products and other objects within the meaning of Article 42(1) of Regulation (EU) 2016/2031 of the European Parliament and of the Council (OJ L 323, 19.12.2018, p. 7).

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/1213 of 21 August 2020 concerning the phytosanitary measures for the introduction into the Union of certain plants, plant products and other objects which have been removed from the Annex to Implementing Regulation (EU) 2018/2019 (OJ L 275, 24.8.2020, p. 5).

⁽⁵⁾ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and of the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

- (5) On 3 December 2021, the United Kingdom ⁽⁶⁾ submitted to the Commission, a request for export to the Union of large topiary evergreen plants of *Ligustrum delavayanum* grafted onto *Ligustrum japonicum* rootstocks grown in pots that are up to 20 years old and having a maximum diameter of 18 cm at the base of the stem. That request was supported by the relevant technical dossier.
- (6) On 28 September 2022, the European Food Safety Authority ('the Authority') adopted a scientific opinion covering the risk assessment of plants for planting of *Ligustrum delavayanum* and of plants for planting of *Ligustrum japonicum*, in growing medium, that are up to 20 years old and with a maximum diameter of 18 cm at the base of the stem, irrespective of whether they are grafted or not ('the relevant plants') ⁽⁷⁾. The Authority identified *Bemisia tabaci*, *Diaprepes abbreviatus*, *Epiphyas postvittana* and *Scirtothrips dorsalis* as pests relevant for those plants and estimated the likelihood of freedom of the commodity from the pests.
- (7) On the basis of that opinion, the phytosanitary risk from the introduction into the Union territory of the relevant plants is considered to be reduced to an acceptable level, provided that appropriate measures are applied to address the risk of pests related to those plants and the corresponding special requirements of Annex VII to Implementing Regulation (EU) 2019/2072 are complied with.
- (8) The measures described by the United Kingdom in the technical dossier are considered sufficient to reduce the risk from the introduction into the Union territory of the relevant plants to an acceptable level. Those measures should therefore be adopted as phytosanitary import requirements to ensure the phytosanitary protection of the Union territory from introduction of the relevant plants into it.
- (9) Consequently, the relevant plants should no longer be considered high risk plants.
- (10) Implementing Regulation (EU) 2018/2019 should therefore be amended accordingly.
- (11) *Bemisia tabaci* is listed as a protected zone quarantine pest in Annex III to Implementing Regulation (EU) 2019/2072 and *Scirtothrips dorsalis* is listed as a Union quarantine pest in Annex II to that Implementing Regulation.
- (12) *Diaprepes abbreviatus* is not yet included in the list of Union quarantine pests of Implementing Regulation (EU) 2019/2072, therefore the measures for that pest are based on those described by the United Kingdom in the dossier. When a complete risk assessment on that pest becomes available, it will be established if that pest fulfils the conditions to be listed in Annex II to Implementing Regulation (EU) 2019/2072 and the relevant plants in Annex VII to that Regulation, together with the respective measures.
- (13) Implementing Regulation (EU) 2020/1213 should therefore be amended accordingly.
- (14) *Epiphyas postvittana* is not included in the list of Union quarantine pests. The pest is present in a number of Member States and no official control measures are applied. Furthermore, the impact of the pest in the Union is not considered to be significant. For these reasons, no import requirements are necessary with respect to that pest.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for Plants, Animals, Food and Feed,

⁽⁶⁾ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this act, references to the United Kingdom do not include Northern Ireland.

⁽⁷⁾ EFSA PLH Panel (EFSA Panel on Plant Health), 2022. Scientific Opinion on the commodity risk assessment of *Ligustrum delavayanum* topiary plants grafted on *Ligustrum japonicum* from the UK. EFSA Journal 2022;20(11):7593.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2018/2019 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Implementing Regulation (EU) 2020/1213 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

In the Annex to Implementing Regulation (EU) 2018/2019, in the table in point 1, in the second column 'Description', the entry '*Ligustrum* L.' is replaced by the following:

'*Ligustrum* L., other than up to 20-year-old plants for planting of *Ligustrum delavayanum* and *Ligustrum japonicum* in growing medium, with a maximum diameter of 18 cm at the base of the stem, originating in the UK'.

ANNEX II

In the table in the Annex to Implementing Regulation (EU) 2020/1213, the following entry is inserted after '*Juglans regia* L., up to 2-year-old plants for planting which are bare-rooted, free of leaves, and with a maximum diameter of 2 cm at the base of the stem.':

Plants, plant products or other objects	CN Code	Third countries of origin	Measures
' <i>Ligustrum delavayanum</i> and <i>Ligustrum japonicum</i> , up to 20-year-old plants for planting in growing medium, with a maximum diameter of 18 cm at the base of the stem.	ex 0602 10 90	United Kingdom	(a) official statement that: <ul style="list-style-type: none"> (i) the plants are free from <i>Diaprepes abbreviatus</i>; (ii) the site of production has been found free from <i>Diaprepes abbreviatus</i> during official inspections carried out at appropriate times, since the beginning of the last growing season; and (iii) immediately prior to export, consignments of the plants have been subjected to an official inspection for the presence of <i>Diaprepes abbreviatus</i> with such a sample size as to enable at least the detection of 1 % level of infestation with a level of confidence of 99 %; (b) the phytosanitary certificates for those plants include under the heading "Additional Declaration": <ul style="list-style-type: none"> (i) the following statement: "The consignment complies with Commission Implementing Regulation (EU) 2020/1213"; and (ii) the specification of the registered sites of production.'

COMMISSION REGULATION (EU) 2023/447**of 1 March 2023****amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of glycosylated steviol glycosides as sweetener****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10(3) and Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012 ⁽³⁾ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) Those lists may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (4) In January 2019, an application was submitted for the authorisation of glycosylated steviol glycosides as a new food additive for use as a sweetener. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) Glycosylated steviol glycosides are produced via enzymatic bioconversion using a cyclomaltodextrin glucanotransferase that catalyses the transfer of glucose from starch to mixtures enriched in one or more individual steviol glycosides from purified *Stevia Rebaudiana* leaf extracts. They consist of a mixture of glycosylated steviol glycosides, containing 1–20 additional glucose units bound to the parent steviol glycosides. They have an improved sweetness profile as compared to the other authorised sweeteners including steviol glycosides from *Stevia* (E 960a).
- (6) The European Food Safety Authority ('the Authority') evaluated the safety of glycosylated steviol glycosides and expressed its opinion on 15 December 2021 ⁽⁴⁾. The Authority considered that the metabolism of glycosylated steviol glycosides is sufficiently similar to the already authorised steviol glycosides, and thus the toxicological data previously assessed by the Authority for steviol glycosides (E 960a) were considered to support their safety as a food additive. The enzyme cyclomaltodextrin glucanotransferase (EC 2.4.1.19) derived from a non-genetically modified strain of *Anoxybacillus caldiproteolyticus* and intended to be used in the manufacture of modified steviol glycosides does not give rise to safety concerns under the intended conditions of use based on the data provided to the Authority ⁽⁵⁾. The Authority concluded that there is no safety concern for the use of glycosylated steviol glycosides as a food additive for the same proposed uses and use levels as steviol glycosides (E 960a–960c) used as sweeteners.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁴⁾ EFSA Journal 2022;20(2):7066.

⁽⁵⁾ EFSA Journal 2022;20(1):7004.

- (7) Therefore, it is appropriate to authorise the food additive 'glucosylated steviol glycosides' (E 960d) as a sweetener in the food categories where steviol glycosides (E 960a–960c) are currently authorised and at the same the maximum levels.
- (8) The specifications for the food additive glucosylated steviol glycosides should be included in Regulation (EU) No 231/2012 as it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (9) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 1 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (a) In Part B, 2. Sweeteners, the following entry is inserted after the entry for E 960c:

E 960d	Glucosylated steviol glycosides';
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- (b) In Part C, (5) Other additives that may be regulated combined, point (v) is replaced by the following:

'(v) E 960a – 960d: Steviol glycosides

E-number	Name
E 960a	Steviol glycosides from Stevia
E 960c	Enzymatically produced steviol glycosides
E 960d	Glucosylated steviol glycosides';

- (c) Part E is amended as follows:

- (1) In category 01.4 (Flavoured fermented milk products including heat-treated products), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	100	(1) (60)	only energy-reduced products or with no added sugar';
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- (2) In category 03 (Edible ices), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced products or with no added sugar';
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- (3) In category 04.2.2 (Fruit and vegetables in vinegar, oil, or brine), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	100	(1) (60)	only sweet-sour preserves of fruit and vegetables';
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- (4) In category 04.2.4.1 (Fruit and vegetable preparations excluding compote), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced';
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- (5) In category 04.2.5.1 (Extra jam and extra jelly as defined by Directive 2001/113/EC), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

'E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced jams jellies and marmalades';
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- (6) In category 04.2.5.2 (Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced jams jellies and marmalades’;
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- (7) In category 04.2.5.3 (Other similar fruit or vegetable spreads), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	E 960a – 960d	Steviol glycosides	200	(1) (60)	only energy-reduced fruit or vegetable spreads and dried-fruit-based sandwich spreads, energy-reduced or with no added sugar’;
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- (8) In category 05.1 (Cocoa and Chocolate products as covered by Directive 2000/36/EC), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	E 960a – 960d	Steviol glycosides	270	(1) (60)	only energy-reduced or with no added sugars’;
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- (9) In category 05.2 (Other confectionery including breath freshening microsweets), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	E 960a – 960d	Steviol glycosides	270	(1) (60)	only cocoa or dried fruit based, energy reduced or with no added sugar
	E 960a – 960d	Steviol glycosides	330	(1) (60)	only cocoa, milk, dried fruit or fat based sandwich spreads, energy-reduced or with no added sugar
	E 960a – 960d	Steviol glycosides	350	(1) (60)	only confectionery with no added sugars only energy-reduced hard confectionery (candies and lollies) only energy-reduced soft confectionery (chewy candies, fruit gums and foam sugar products/marshmallows) only energy-reduced liquorice only energy-reduced nougat only energy-reduced marzipan
	E 960a – 960d	Steviol glycosides	2 000	(1) (60)	only breath-freshening micro-sweets, energy-reduced or with no added sugars
	E 960a – 960d	Steviol glycosides	670	(1) (60)	only strongly flavoured freshening throat pastilles, energy-reduced or with no added sugars’;

- (10) In category 05.3 (Chewing gum), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	3300	(1) (60)	only with no added sugar';
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- (11) In category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	'E 960a – 960d	Steviol glycosides	330	(1) (60)	only confectionary with no added sugar
	E 960a – 960d	Steviol glycosides	270	(1) (60)	only cocoa or dried fruit based, energy reduced or with no added sugar';

- (12) In category 06.3 (Breakfast cereals), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	330	(1) (60)	only breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy reduced or with no added sugar';
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- (13) In category 07.2 (Fine bakery wares), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	330	(1) (60)	only essoblaten – wafer paper';
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- (14) In category 09.2 (Processed fish and fishery products including molluscs and crustaceans), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	200	(1) (60)	only sweet-sour preserves and semi preserves of fish and marinades of fish, crustaceans and molluscs';
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- (15) In category 11.4.1 (Table-top sweeteners in liquid form), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	<i>quantum satis</i>	(1) (60);	
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- (16) In category 11.4.2 (Table-top sweeteners in powder form), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	<i>quantum satis</i>	(1) (60);	
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- (17) In category 11.4.3 (Table-top sweeteners in tablets), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	<i>quantum satis</i>	(1) (60);	
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- (18) In category 12.4 (Mustard), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	120	(1) (60);	
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- (19) In category 12.5 (Soups and broths), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	40	(1) (60)	only energy-reduced soups;
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- (20) In category 12.6 (Sauces), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	'E 960a – 960d	Steviol glycosides	120	(1) (60)	except soy-bean sauce (fermented and non-fermented)
	E 960a – 960d	Steviol glycosides	175	(1) (60)	Only soy-bean sauce (fermented and non-fermented);

- (21) In category 13.2 (Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	330	(1) (60);	
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- (22) In category 13.3 (Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	270	(1) (60);	
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- (23) In category 14.1.3 (Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar;
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- (24) In category 14.1.4 (Flavoured drinks), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	80	(1) (60)	only energy-reduced or with no added sugar;
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- (25) In category 14.1.5.2 (Other), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	'E 960a – 960d	Steviol glycosides	30	(1) (60) (93)	only coffee, tea and herbal infusion beverages, energy-reduced or with no added sugars
	E 960a – 960d	Steviol glycosides	30	(1) (60) (93)	only flavoured instant coffee and instant cappuccino products, energy-reduced or with no added sugars
	E 960a – 960d	Steviol glycosides	20	(1) (60) (93)	only malt-based and chocolate/ cappuccino flavoured drinks, energy-reduced or with no added sugars';

- (26) In category 14.2.1 (Beer and malt beverages), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	70	(1) (60)	only alcohol-free beer or with an alcohol content not exceeding 1,2 % vol.; 'Bière de table/Tafelbier/Table beer' (original wort content less than 6 %) except for 'Obergäriges Einfachbier'; beers with a minimum acidity of 30 milli-equivalents expressed as NaOH; Brown beers of the 'oud bruin' type';
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- (27) In category 14.2.8 (Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	150	(1)(60);	
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- (28) In category 15.1 (Potato-, cereal-, flour- or starch-based snacks), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	20	(1) (60);	
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- (29) In category 15.2 (Processed nuts), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	20	(1) (60);	
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- (30) In category 16 (Desserts excluding products covered in categories 1, 3 and 4), the entry for E 960a – 960c (Steviol glycosides) is replaced by the following:

	'E 960a – 960d	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar';
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- (31) In category 17.1 (Food supplements supplied in a solid form, excluding food supplements for infants and young children), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	E 960a – 960d	Steviol glycosides	670	(1) (60)	
	E 960a – 960d	Steviol glycosides	1800	(1) (60)	only food supplements in chewable form’;

- (32) In category 17.2 (Food supplements supplied in a liquid form, excluding food supplements for infants and young children), the entries for E 960a – 960c (Steviol glycosides) are replaced by the following:

	E 960a – 960d	Steviol glycosides	200	(1) (60)	
	E 960a – 960d	Steviol glycosides	1800	(1) (60)	only food supplements in syrup form’.

ANNEX II

In the Annex to Regulation (EU) No 231/2012 the following entry is inserted after the entry for food additive E 960c(iv):

E 960d GLUCOSYLATED STEVIOL GLYCOSIDES

Synonyms	
Definition	<p>Mixture of larger glycosides of steviol derived by glucosylation of steviol glycosides extracted from leaves of <i>Stevia rebaudiana</i> Bertoni plant. The mixture is composed of glucosylated steviol glycosides and residual parent steviol glycosides from Stevia leaf. Glucosylated steviol glycosides are produced by treating the steviol glycosides, extracted from Stevia leaf, and starch suitable for human consumption with Cyclomaltodextrin glucanotransferase (EC 2.4.1.19) derived from a non-GMO strain of <i>Anoxybacillus caldiproteolyticus</i> St-88. The enzyme transfers glucose units from the starch to the steviol glycosides. The resulting material is heated and treated with activated carbon to remove the enzyme, then passed through adsorption/desorption resin to remove residual hydrolysed starch (dextrin), followed by purification and preparation of the final product using processes that may include decolourisation, concentration and spray drying.</p>
Chemical name	<p>Steviolbioside: 13-[(2-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid Rubusoside: 13-β-D-glucopyranosyloxykaur-16-en-18-oic acid, β-D-glucopyranosyl ester Dulcoside A: 13-[(2-O-α-L-rhamnopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Stevioside: 13-[(2-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Rebaudioside B: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid Rebaudioside C: 13-[(2-O-α-L-rhamnopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Rebaudioside D: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester Rebaudioside E: 13-[(2-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester Rebaudioside F: 13-[(2-O-β-D-xylofuranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl)-β-D-glucopyranosyl]oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester And their glucosylated derivatives (1-20 added glucose units)</p>

Molecular formula	Trivial name	Formula	Conversion factor
	n-Glucosylated Steviolbioside	$C_{(32+n*6)}H_{(50+n*10)}O_{(13+n*5)}$	
	n-Glucosylated Rubusoside	$C_{(32+n*6)}H_{(50+n*10)}O_{(13+n*5)}$	
	n-Glucosylated Dulcoside A	$C_{(38+n*6)}H_{(60+n*10)}O_{(17+n*5)}$	
	n-Glucosylated Stevioside	$C_{(38+n*6)}H_{(60+n*10)}O_{(18+n*5)}$	
	n-Glucosylated Rebaudioside A	$C_{(44+n*6)}H_{(70+n*10)}O_{(23+n*5)}$	
	n-Glucosylated Rebaudioside B	$C_{(38+n*6)}H_{(60+n*10)}O_{(18+n*5)}$	
	n-Glucosylated Rebaudioside C	$C_{(44+n*6)}H_{(70+n*10)}O_{(22+n*5)}$	
	n-Glucosylated Rebaudioside D	$C_{(50+n*6)}H_{(80+n*10)}O_{(28+n*5)}$	
	n-Glucosylated Rebaudioside E	$C_{(44+n*6)}H_{(70+n*10)}O_{(23+n*5)}$	
	n-Glucosylated Rebaudioside F	$C_{(43+n*6)}H_{(68+n*10)}O_{(22+n*5)}$	
	n-Glucosylated Rebaudioside M	$C_{(56+n*6)}H_{(90+n*10)}O_{(33+n*5)}$	
	n: number of glucose units enzymatically added to the parent steviol glycoside (n = 1-20) Typical conversion factor for glucosylated steviol glycosides mixtures = 0,20 (on the dried, dextrin-free, basis)		
	Steviol	$C_{20}H_{30}O_3$	1,00
	Steviolbioside	$C_{32}H_{50}O_{13}$	0,50
	Rubusoside	$C_{32}H_{50}O_{13}$	0,50
	Dulcoside A	$C_{38}H_{60}O_{17}$	0,40
	Stevioside	$C_{38}H_{60}O_{18}$	0,40
	Rebaudioside A	$C_{44}H_{70}O_{23}$	0,33
	Rebaudioside B	$C_{38}H_{60}O_{18}$	0,40
	Rebaudioside C	$C_{44}H_{70}O_{22}$	0,34
	Rebaudioside D	$C_{50}H_{80}O_{28}$	0,29
	Rebaudioside E	$C_{44}H_{70}O_{23}$	0,33
	Rebaudioside F	$C_{43}H_{68}O_{22}$	0,34
	Rebaudioside M	$C_{56}H_{90}O_{33}$	0,25

Molecular weight and CAS No	Trivial name	CAS Number	Molecular weight (g/mol)
	n-Glucosylated Steviolbioside	Not available	642,73+n*162,15
	n-Glucosylated Rubusoside	Not available	642,73+n*162,15
	n-Glucosylated Dulcoside A	Not available	788,87+n*162,15
	n-Glucosylated Stevioside	Not available	804,88+n*162,15
	n-Glucosylated Rebaudioside A	Not available	967,01+n*162,15
	n-Glucosylated Rebaudioside B	Not available	804,88+n*162,15
	n-Glucosylated Rebaudioside C	Not available	951,02+n*162,15
	n-Glucosylated Rebaudioside D	Not available	1 129,15+n*162,15
	n-Glucosylated Rebaudioside E	Not available	967,01+n*162,15
	n-Glucosylated Rebaudioside F	Not available	936,99+n*162,15
	n-Glucosylated Rebaudioside M	Not available	1 291,30+n*162,15
	Steviol		318,46
	Steviolbioside	41093-60-1	642,73
	Rubusoside	64849-39-4	642,73
	Dulcoside A	64432-06-0	788,87
	Stevioside	57817-89-7	804,88
	Rebaudioside A	58543-16-1	967,01
	Rebaudioside B	58543-17-2	804,88
	Rebaudioside C	63550-99-2	951,02
	Rebaudioside D	63279-13-0	1 129,15
	Rebaudioside E	63279-14-1	967,01
	Rebaudioside F	438045-89-7	936,99
	Rebaudioside M	1220616-44-3	1 291,30
Assay	Not less than 95 % of total steviol glycosides, comprised of above mentioned steviol glycosides along with their glucosylated derivatives (1-20 added glucose units), on the dried, dextrin-free, basis.		
Description	White to light yellow powder, approximately between 100 and 200 times sweeter than sucrose (at 5 % sucrose equivalency).		

Identification	
Solubility	Soluble in water
pH	Between 4,5 and 7,0 (1 in 100 solution)
Purity	
Total ash	Not more than 1 %
Loss on drying	Not more than 6 % (105 °C, 2 h)
Residual solvent	Not more than 200 mg/kg methanol Not more than 3 000 mg/kg ethanol
Arsenic	Not more than 0,015 mg/kg
Lead	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Microbiological criteria	
Total (aerobic) plate count	Not more than 1 000 CFU/g
Yeast and moulds	Not more than 200 CFU/g
<i>E. coli</i>	Negative in 1 g
<i>Salmonella</i>	Negative in 25 g'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/448**of 1 March 2023****amending Implementing Regulation (EU) 2018/574 on technical standards for the establishment and operation of a traceability system for tobacco products**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC ⁽¹⁾, and in particular Article 15(11) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2018/574 ⁽²⁾ sets out the rules for the establishment and operation of a traceability system for tobacco products. The traceability system aims to provide Member States and the Commission with an effective tool that enables the tracking and tracing of tobacco products throughout the Union and the identification of fraudulent activities that result in illicit products being available to consumers.
- (2) In this regard, the operational rules of the traceability system play an important role in ensuring that the Commission and the Member States receive the data they need in order to ensure the proper functioning of the tobacco traceability system and control of the application of the tobacco traceability legislation as well as enforce this legislation respectively.
- (3) The traceability system established in accordance with Implementing Regulation (EU) 2018/574 started collecting data on tobacco products' movements and transactional data on 20 May 2019. Experience in its implementation has further demonstrated the importance of high quality, accuracy, completeness and comparability of the data that need to be recorded and transmitted to the system in a timely manner.
- (4) In its report on the application of Directive 2014/40/EU of 20 May 2021 ⁽³⁾, the Commission stressed that the Member States and the Commission had considerable problems with the quality of traceability data, for example in relation to value added tax numbers, information on production machines or information on last movements of products to retail outlets. In particular, the current definition of machines should be amended to reflect the various machines' configurations adopted in the sector and address the observed bad quality of information on machines. The report also concluded that data quality remains critical for enforcing the tobacco traceability legislation and for fully attaining the traceability system's objectives.
- (5) The discussions between the Commission and the Member States taking place on a regular basis in the framework of the Expert Subgroup on Traceability and Security Features have further demonstrated that only robust, complete and good-quality data can ensure a fully functional and successful traceability system. For the monitoring and use of these data, the Member States and the Commission need to be equipped with effective analytical tools and technical solutions, in particular necessary interfaces that enable them to access and query the data stored in the repositories system.

⁽¹⁾ OJ L 127, 29.4.2014, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a traceability system for tobacco products (OJ L 96, 16.4.2018, p. 7).

⁽³⁾ Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the application of Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products, COM(2021) 249 final.

- (6) Based on the gathered experience and knowledge, there is a need to amend certain technical rules laid down by Implementing Regulation (EU) 2018/574 in order to facilitate the reporting by all actors involved in the trade of tobacco products, reinforce the good practices in terms of data management and analysis, and consequently, improve the functioning of the traceability system for tobacco products. These technical rules concern the operation of the various components of the repositories system, the tasks of and the procedures to be followed by the ID issuers as well as the reporting activities of the economic operators and the technical tools available to the Member States in the context of their enforcement duties, in particular all access interfaces including for mobile inspections.
- (7) The amendments address a number of exceptions and special cases that were encountered after the launch of the traceability system, including the presence of economic operators solely involved in non-logistic trading operations, the involvement of non-EU entities in the EU supply chain, the existence of facilities combining non-retail and retail functions, cases of lost identifiers, cases of recovery of stolen goods, IT incidents necessitating data reprocessing, and the presence of atypical non-trade destinations such as laboratories or waste disposal centres. The actual operations of the traceability system also helped obtain a better picture of the size of data sets stored and processed in the repositories system, which in turn necessitates certain changes to the rules concerning the possibilities and characteristics of the repositories system and the tasks of the provider of the secondary repository.
- (8) Annex I to Implementing Regulation (EU) 2018/574 sets out the procedures for selecting the primary and secondary repositories' operators. To ensure consistency in the manner in which notifications of the identity of the proposed provider are submitted to the Commission by group of undertakings, and by importers and non-Union manufacturers, and the relevant data storage contracts are signed, it is appropriate to further clarify certain rules on the submission of notifications and the signature of data storage contracts. In addition, given the fact that the extension of the tobacco traceability system to all tobacco products that is foreseen by Article 15(13) of Directive 2014/40/EU, may increase the number of these notifications and data storage contracts, it is also necessary to lay down further details of the procedure for the approval of amendments to the key elements of data storage contracts, including the explicit possibility for the Commission to tacitly approve such amendments.
- (9) It is also appropriate to amend the period within which the contracts between each primary repository provider and the provider of the secondary repository shall be signed and submitted to the Commission to ensure that these entities have sufficient time to comply with their obligations. With regard to the requirements that apply to the procedure concerning the termination of the contractual relationship between the Commission and the provider of the secondary repository, it is necessary to lay down further details on the notice period that needs to be respected by the provider of the secondary repository, so that business continuity and an uninterrupted flow of data are fully ensured in the system.
- (10) The Protocol to Eliminate Illicit Trade in Tobacco Products to the World Health Organisation's Framework Convention on Tobacco Control (*), which provides for a package of measures to be taken by its Parties to eliminate the illicit trade in tobacco products entered into force on 25 September 2018. It is appropriate for the traceability system established in the EU to be up to date with the technical developments concerning the establishment of a global tracking and tracing regime.
- (11) Implementing Regulation (EU) 2018/574 should therefore be amended accordingly.
- (12) Some provisions of this Regulation should start to apply at a later date than its entry into force, in order to allow ID issuers as well as providers of repository services and of anti-tampering devices and other economic operators to prepare for the requirements introduced by these provisions.

(*) Protocol to Eliminate Illicit Trade in Tobacco Products to the World Health Organisation's Framework Convention on Tobacco Control (OJ L 268, 1.10.2016, p. 1).

- (13) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 25 of Directive 2014/40/EU,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2018/574 is amended as follows:

- (1) Article 2 is replaced by the following:

Article 2

Definitions

For the purposes of this Regulation, in addition to the definitions laid down in Article 2 of Directive 2014/40/EU, the following definitions shall apply:

- (1) “unique identifier” means the alphanumeric code enabling the identification of a unit pack or an aggregated packaging of tobacco products;
- (2) “economic operator” means any natural or legal person who is involved in the trade of tobacco products, including for export, from the manufacturer to the last economic operator before the first retail outlet;
- (3) “first retail outlet” means the facility where tobacco products are placed on the market for the first time, including vending machines used for the sale of tobacco products;
- (4) “export” means shipment from the Union to a third country;
- (5) “aggregated packaging” means any packaging containing more than one unit packet of tobacco products;
- (5a) “disaggregation of aggregated packaging” means any disassembly of aggregated packaging of tobacco products;
- (6) “facility” means any location, building, office or vending machine where tobacco products are manufactured, stored, logistically or financially handled or placed on the market;
- (7) “anti-tampering device” means the device allowing for the recording of the verification process following the application of each unit level unique identifier by means of a video or a log file, which once recorded cannot be further altered by an economic operator;
- (8) “offline flat-files” means the electronic files established and maintained by each ID issuer that contain data in a plain text format allowing for the extraction of information encoded in the unique identifiers (excluding the time stamp) used at the unit packet and aggregated packaging levels without accessing the repositories system;
- (9) “registry” means the record established and maintained by each ID issuer of all the identifier codes generated for economic operators, operators of first retail outlets, facilities and machines along with the corresponding information;
- (10) “data carrier” means a carrier representing data in a form readable with the aid of a device;
- (11) “machine” means assemblies of machinery that are used for the manufacture of tobacco products and are integral to the manufacturing process;
- (11a) “machine part” means any identifiable fixed or mobile part of a machine provided that such a part constitutes a complete module. A mobile part may be used for one or more machines simultaneously or interchangeably;

- (12) “time stamp” means the date and time of occurrence of a particular event recorded in UTC (Coordinated Universal Time) time in a prescribed format;
 - (13) “primary repository” means a repository storing traceability data relating exclusively to the products of a given manufacturer or importer;
 - (14) “secondary repository” means a repository containing a copy of all traceability data stored in the primary repositories;
 - (15) “router” means a device established within the secondary repository that transfers data between different components of the repositories system;
 - (16) “repositories system” means the system consisting of the primary repositories, the secondary repository and the router;
 - (17) “common data dictionary” means a set of information describing the contents, format, and structure of a database and the relationship between its elements, used to control access to and manipulation of the databases common for all primary and secondary repositories;
 - (18) “working day” means every day of work in the Member State for which the ID issuer is competent;
 - (19) “trans-loading” means any transfer of tobacco products from one vehicle to another during which tobacco products do not enter and exit a facility;
 - (20) “vending van” means a vehicle used for the delivery of tobacco products to multiple retail outlets in quantities that have not been predetermined in advance of the delivery;
 - (21) “IT service provider” means a service provider that is tasked by an economic operator with transmitting information on product movements and transactional information to the repositories system.;
- (2) in Article 3, paragraph 9 is replaced by the following:
- ‘9. The ID issuer may establish and charge fees to economic operators for generating and issuing unique identifiers. Fees are to be non-discriminatory, cost-based and proportionate to the number of unique identifiers generated and issued to economic operators taking into account the mode of delivery. Fees may reflect all fixed and variable costs incurred by the ID issuer in meeting its requirements under this Regulation.’;
- (3) in Article 7, paragraph 2 is replaced by the following:
- ‘2. The process referred to in paragraph 1 shall be protected with an anti-tampering device supplied and installed by an independent third party who shall provide a declaration to the relevant Member States and the Commission that the installed device meets the requirements of this Regulation. The record generated by the device shall provide proof of correct application and readability of each unit level unique identifier. The device shall ensure that any omission in the marking process referred to in Article 6 is recorded.’;
- (4) in Article 8, paragraph 2 is replaced by the following:
- ‘2. ID issuers shall be responsible for the generation of a code consisting of the elements listed in paragraph 1, points (a), (b), and (c).
- ID issuers shall prepare and make publicly available instructions for encoding and decoding unit level UIs in accordance with Annex III.’;
- (5) Article 9 is amended as follows:
- (a) paragraph 1 is replaced by the following:
- ‘1. Manufacturers and importers shall send a request to the competent ID issuer for unit level UIs referred to in Article 8 and the corresponding human-readable codes referred to in Article 23. Requests shall be introduced electronically, in accordance with Article 36.’;

(b) paragraph 3 is replaced by the following:

‘3. The ID issuer shall, within two working days from the receipt of the request and in the order indicated:

- (a) generate the codes referred to in Article 8(2) and the corresponding human-readable codes referred to in Article 23;
- (b) transmit both sets of codes along with the information referred to in paragraph 2 via the router to the primary repository of the requesting manufacturer or importer, as established under Article 26; and
- (c) electronically transmit both sets of codes to the requesting manufacturer or importer.’;

(c) paragraph 4 is replaced by the following:

‘4. However, a Member State may require ID issuers to offer physical delivery of unit level UIs as an alternative to electronic delivery. In cases where physical delivery of unit level UIs is offered, manufacturers and importers shall specify whether physical delivery is requested. In that case, the ID issuer shall within 10 working days from the receipt of the request, and in the following order:

- (a) generate the codes referred to in Article 8(2) and the corresponding human-readable codes referred to in Article 23;
- (b) transmit both sets of codes along with the information referred to in paragraph 2 via the router to the primary repository of the requesting manufacturer or importer, as established under Article 26;
- (c) electronically transmit both sets of codes to the requesting manufacturer or importer;
- (d) deliver both sets of codes to the requesting manufacturer or importer in the form of optical barcodes, compliant with Article 21, placed on physical carriers, such as adhesive labels.’;

(6) in Article 11, paragraph 2 is replaced by the following:

‘2. ID issuers shall be responsible for the generation of a code consisting of the elements listed in paragraph 1, points (a), (b), and (c).

ID issuers shall prepare and make publicly available instructions for encoding and decoding aggregated level UIs.’;

(7) Article 14 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Economic operators and operators of first retail outlets shall apply for a single code (‘economic operator identifier code’) from the ID issuer competent for each Member State in which they operate at least one facility. Importers shall also apply for an identifier code from the ID issuer competent for each Member State on whose market they place their products.

Economic operators managing standalone warehouses that are not based in the Union and that handle products manufactured in the Union and destined for the Union markets in transit through third countries may apply for an economic operator identifier code from the ID issuer competent for the Member State on whose market most of the products handled by these economic operators are placed.’;

(b) paragraph 5 is replaced by the following:

‘5. Any modification of the information submitted in the initial application form and any cessation of the operator activities shall be notified by the relevant operator to the ID issuer without delay, in the formats indicated in points 1.2 and 1.3 of Section 1 of Chapter II of Annex II accordingly. In case the operator ceases to exist, the ID issuer shall de-register the economic operator identifier code.

The de-registration of an economic operator identifier code shall lead to the automatic de-registration of related facility identifier codes and machine identifier codes by the ID issuer.’;

(8) Article 15 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. Within two working days, the ID issuer shall transmit the code to the requesting operator.

If the requesting operator is a manufacturer or an importer, it shall, within two working days from receiving the code, further transmit the code along with the information on its primary repository established in accordance with Article 26 to the operator of the secondary repository.’;

(b) paragraph 3 is replaced by the following:

‘3. All the information submitted to the ID issuer in accordance with Article 14(2), and the corresponding identifier codes, shall form part of a registry to be established, managed and kept up to date by the competent ID issuer. The competent ID issuer shall keep a record of the information stored in the register for as long as the traceability system is operational.’;

(9) Article 16 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. All facilities from manufacturing to the first retail outlet shall be identified by a single code (‘facility identifier code’) generated by the ID issuer competent for the territory in which the facility is located.

By way of derogation from the first subparagraph, a first retail outlet that is integrated into a non-retail type of facility shall be identified with a separate facility identifier code that corresponds to its function.’;

(b) paragraph 2 is replaced by the following:

‘2. Economic operators and operators of first retail outlets shall apply for a facility identifier code providing to the ID issuer the information listed in point 1.4 of Section 1 of Chapter II of Annex II, in the format indicated therein.

Economic operators managing standalone warehouses that are not based in the Union and that handle products manufactured in the Union and destined for the Union markets in transit through third countries may apply for a facility identifier code for a standalone warehouse that is located in a third country from the ID issuer competent for the Member State on whose market most of the products handled by these economic operators are placed. To this end, they shall provide to the ID issuer the information listed in point 1.4 of Section 1 of Chapter II of Annex II, in the format indicated therein.’;

(c) paragraph 5 is replaced by the following:

‘5. Any modification of the information submitted in the initial application form and any facility closure shall be notified by the economic operator to the ID issuer without delay, in the formats indicated in points 1.5 and 1.6 of Section 1 of Chapter II of Annex II.

The de-registration of a facility identifier code shall lead to the automatic de-registration of related machine identifier codes by the ID issuer.’;

(10) in Article 17, paragraph 3 is replaced by the following:

‘3. All the information submitted to the ID issuer in accordance with Article 16(2), and the corresponding identifier codes shall form part of a registry to be established, managed and kept up to date by the competent ID issuer. The competent ID issuer shall keep a record of the information stored in the register for as long as the traceability system is operational.’;

(11) Article 18 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Each machine and machine part shall be identified by a single code (‘machine identifier code’) generated by the ID issuer competent for the territory in which the machine is located.’;

(b) paragraph 3 is replaced by the following:

‘3. The obligation to apply for a machine identifier code related to machines and machine parts located in manufacturing facilities outside the Union shall lie with the importer established inside the Union. The importer shall apply to any ID issuer appointed by a Member State on whose market it places its products. The registration by the importer shall be subject to the consent of the entity responsible for the third country manufacturing facility. The importer shall inform the economic operator responsible for the third country manufacturing facility as to the full details of the registration, including the allocated machine identifier code.’;

(c) paragraph 4 is replaced by the following:

‘4. Any modification of the information submitted in the initial application form and any decommissioning of the registered machines and machine parts shall be notified by the manufacturer or the importer to the ID issuer without delay, in the formats indicated in points 1.8 and 1.9 of Section 1 of Chapter II of Annex II.

Manufacturers and importers shall carry out all necessary modifications of the information submitted in the initial application forms in order to provide the necessary information on machine parts which require a machine identifier code by 20 May 2024. The modifications shall take place in the format indicated in point 1.8 of Section 1 of Chapter II of Annex II. This requirement shall also apply to the information on machines containing no separately identifiable machine parts.’;

(12) in Article 19, paragraph 3 is replaced by the following:

‘3. All the information submitted to the ID issuer in accordance with Article 18(2), and the corresponding identifier codes shall form part of a registry to be established, managed and kept up to date by the competent ID issuer. The competent ID issuer shall keep a record of the information stored in the register for as long as the traceability system is operational.’;

(13) in Article 20, the following paragraph 5 is added:

‘5. ID issuers shall provide a secure online service for economic operators and operators of first retail outlets allowing them to consult the registries referred to in paragraph 1 as far as their own economic operator, facility and machine identifier codes are concerned. This service shall include a secure procedure for economic operators and operators of first retail outlets to reclaim their own economic operator identifier codes.’;

(14) Article 21 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. In the case of unit level UIs delivered electronically, manufacturers and importers are responsible for encoding unit level UIs in accordance with paragraph 1 and with Annex III.’;

(b) paragraph 3 is replaced by the following:

‘3. In the case of unit level UIs delivered physically, ID issuers are responsible for encoding the codes generated pursuant to Article 8(2), in accordance with paragraph 1 and with Annex III.’;

(c) paragraph 6 is replaced by the following:

‘6. In order to distinguish the data carriers referred to in paragraph 1 from any other data carrier placed on unit packets, economic operators may add the marking ‘TTT’ or ‘EU TTT’ next to such data carriers.

In order to distinguish the data carriers referred to in paragraph 5 from any other data carrier placed on aggregated packaging, economic operators shall add the marking ‘EU TTT’ next to such data carriers.’;

(15) Article 25(1), point (g), is replaced by the following:

‘(g) it shall allow for automatic validation of messages received from economic operators at each entry point to the system, including refusal of incorrect or incomplete messages, in particular reporting activities related to non-registered or duplicated unique identifiers, whereby the repositories system shall store the information concerning any refused message. Messages transmitted by the ID issuers and the primary repositories to the router and the secondary repository shall be validated again by the recipient.’;

(16) Article 27 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. The secondary repository shall provide for graphical and non-graphical interfaces, including an application programming interface, stationary and mobile user interfaces containing an inspection application for the leading mobile operating systems, that enable Member States and the Commission to access and query the data stored in the repositories system, using all commonly available database search functions, including Structured Query Language (SQL) or equivalent syntax for building custom queries, in particular by remotely carrying out the following operations:

- (a) retrieval of any information concerning one or multiple unique identifier(s), including the comparison and cross-checking of multiple unique identifiers and the related information, in particular their location in the supply chain;
- (b) creation of lists and statistics, such as product stocks and inflow/outflow numbers, associated with one or multiple elements of reporting information listed as Data Fields in Annex II;
- (c) identification of all tobacco products that have been reported by an economic operator to the system, including the products reported as recalled, withdrawn, stolen, missing or intended for destruction.’;

(b) paragraph 3 is replaced by the following:

‘3. The user interfaces referred to in paragraph 2 shall enable each Member State and the Commission to configure their own rules for:

- (a) automatic alerting based on exceptions and specific reporting events, such as abrupt fluctuations or irregularities in trade, attempts to introduce duplicate unique identifiers into the system, deactivation of the identifiers referred to in Articles 15(4), 17(4) and 19(4), or where a product is indicated by economic operators as stolen or missing;
- (b) the receipt of periodic reports based on any combination of the elements of reporting information listed as Data Field in Annex II;
- (c) tailor-made dashboards, for stationary interfaces.’;

(c) paragraph 5 is replaced by the following:

‘5. The user interfaces referred to in paragraph 2 shall enable Member States and the Commission to:

- (a) connect remotely to the data stored in the repositories system with the analytical software of their choice;
- (b) flag individual data points for analytical purposes, with flags and their values stored in the secondary repository and made visible to all or only selected users;
- (c) upload external data elements, such as brand normalisation patterns, that may be required for improvements in data analytical functionalities.’;

(d) paragraph 6 is replaced by the following:

‘6. The user interfaces referred to in paragraph 2 shall be provided in all official languages of the Union.’;

(e) paragraph 7 is replaced by the following:

‘7. The overall response time of the repository to any already established type of query or alert trigger, not considering the speed of the internet connection of the end user, shall be no more than 10 seconds for the data stored for less than 2 years and no more than 15 seconds for the data stored for 2 years or more, in at least 99 % of all types of already established queries and automatic alerts foreseen under paragraphs 2 and 3. The provider of the secondary repository shall prepare datasets necessary for responding, in line with the prescribed timelines, to any new query or alert trigger within 4 weeks from receiving a request from Member States or the Commission. After this period, the newly requested types of queries or alert triggers shall be deemed to be already established for the purpose of the response times stipulated in this paragraph.’;

- (f) paragraph 8 is replaced by the following:

‘8. As regards individual data points and messages, the overall time between the arrival of reporting activity data and its accessibility, via the graphical and non-graphical interfaces, in the primary and secondary repositories shall be no more than 60 seconds in at least 99 % of all data transfer activities. As regards pre-structured analytical datasets, the overall time between the arrival of reporting activity data and its accessibility, via the graphical interfaces, in the secondary repository shall be no more than 24 hours in at least 99 % of all data transfer activities.’;

- (g) paragraph 10 is replaced by the following:

‘10. The provider of the secondary repository shall establish and maintain a register of the information transferred to it in accordance with Article 20(3). The provider of the secondary repository shall keep a record of the information stored in the register for as long as the traceability system is operational.

ID issuers and providers of primary repositories may have access to the register referred to in the first subparagraph in order to validate the messages sent to them by manufacturers and importers.’;

- (h) the following paragraph 13 is added:

‘13. The provider of the secondary repository shall organise at least one full-day technical training session per year for the users from each Member State and from the Commission, on the use of the user interfaces referred to in paragraph 2. The provider of the secondary repository shall also develop and keep updated a full set of technical and user documentation for the competent authorities available in all official languages of the Union.’;

- (i) the following paragraph 14 is added:

‘14. The provider of the secondary repository shall provide an inspection application for the leading mobile operating systems that enables Member States and the Commission to connect to the secondary repository via the mobile user interfaces referred to paragraph 2.’.

- (17) Article 28 is amended as follows:

- (a) paragraph 1 is replaced by the following:

‘1. The provider operating the secondary repository shall communicate to providers operating primary repositories, ID issuers and economic operators, the list of specifications, including common validation rules, required for the data exchange with the secondary repository and the router. All specifications shall be based on non-proprietary open standards.

Any newly selected replacement provider operating the secondary repository shall rely on the latest version of the list of specifications communicated by its predecessor. Any updates to the list of specifications going beyond the change of the provider’s identity shall be made in accordance with the procedure laid down in paragraph 3.

The list referred to in the first subparagraph shall be communicated no later than 2 months following the date when the provider operating the secondary repository was selected.’;

- (b) paragraph 2 is replaced by the following:

‘2. On the basis of the information listed in Annex II, the provider operating the secondary repository shall establish a common data dictionary. The common data dictionary shall refer to labels of data fields in the human readable format.

Any newly selected replacement provider operating the secondary repository shall rely on the latest version of the data dictionary communicated by its predecessor. Any updates to the data dictionary going beyond the change of the provider’s identity shall be made in accordance with the procedure laid down in paragraph 3.

The common data dictionary shall be communicated to the providers operating primary repositories no later than 2 months following the date when the provider operating the secondary repository was selected.’;

- (c) paragraph 3 is replaced by the following:

‘3. Whenever necessary to ensure the effective operation of the repositories system in accordance with the requirements of this Regulation, the provider operating the secondary repository shall update the list referred to in paragraph 1 and the common data dictionary referred to in paragraph 2. Any such update shall be consulted on with providers operating primary repositories and ID issuers, and subsequently communicated to providers operating primary repositories, ID issuers and economic operators at least 2 months before the date of implementing the update into the system.’;

- (d) the following paragraphs 4, 5 and 6 are added:

‘4. Upon request from the provider of a primary repository, the provider of the secondary repository may carry out data reprocessing operations as far as they are necessary to eliminate consequences of past IT incidents and failures. Such operations shall be possible only to complete or correct the information stored in the secondary repository and be limited to the re-running of regular operations of the secondary repository. They shall exclude to the maximum extent possible negative consequences for any economic operators unrelated to the requesting primary repository.

5. The provider of the secondary repository shall establish a helpdesk service for the competent authorities of Member States, the Commission, ID issuers, providers of repository services, economic operators and IT service providers. The helpdesk service shall concern only the activities and functions of the router and the secondary repository and be available across all Member States for at least 8 hours on working days, with the exception of 1 January, 25 December and 26 December, and at least in English, French and German. The response times shall be no more than 2 working days in at least 75 % of all requests. The average monthly response time per request shall be no more than 4 working days. The provider of the secondary repository may regulate access to the helpdesk service for economic operators as a part of its fair use policy set out under the terms and conditions referred to in Article 29(6) and the contracts referred to in paragraph 4 of Part B of Annex I.

6. The provider of the secondary repository shall set up a test environment allowing ID issuers, providers operating primary repositories and economic operators to perform quality assurance of their technical solutions and routines before connecting to the repositories system. The test environment shall closely simulate the repositories system.

The provider of the secondary repository shall set up a user-acceptance-testing environment allowing ID issuers, providers operating primary repositories and economic operators to perform quality assurance of their technical solutions and routines in anticipation of the next version of the repositories system. The user-acceptance-testing environment shall reflect any planned changes to the repositories system upon their communication in accordance with paragraph 3.’.

- (18) In Article 29, the following paragraphs 5 and 6 are added:

‘5. Manufacturers and importers who doubt the correct functioning of their primary repositories shall have the possibility to verify against the router, by consulting the operator of the router, whether messages concerning the final dispatch of products out of their physical possession that are sent to the primary repositories, have been transmitted correctly. The operator of the router may set a daily limit on the use of this functionality.

6. The provider of the secondary repository shall establish and communicate to economic operators and IT service providers the terms and conditions, including the fair use policy, applicable to the use of the secondary repository and the router. The terms and conditions shall guarantee the right of economic operators to use the secondary repository and the router in line with their business needs and shall prevent repeated cases of negligent use.’.

(19) Article 30 is replaced by the following:

'Article 30

Costs of the repositories system

1. All ordinary costs related to the repositories system referred to in Article 24(1), including those that arise from its establishment, operation and maintenance, shall be borne by manufacturers and importers of tobacco products. Those costs shall be fair, reasonable, and proportionate:

(a) to the services rendered; and

(b) to the amount of unit level UIs requested over a given period of time.

2. The ordinary costs, as applicable, of establishing, operating and maintaining the secondary repository and the router shall be passed onto the manufacturers and importers of tobacco products through the costs charged to them by the providers of the primary repositories.

3. All extraordinary costs related to the reprocessing operations referred to in Article 28(4) charged by the provider of the secondary repository to the provider of the primary repository that made the request shall be fair, reasonable and proportionate to the services rendered. The provider of the secondary repository shall however itself bear any extraordinary costs of the reprocessing operations referred to in Article 28(4) to the extent that it is responsible for the causes leading to the reprocessing operations.'

(20) Article 32 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. Manufacturers and importers shall transmit the information listed in points 3.1 to 3.5 of Section 3 of Chapter II of Annex II, in the format indicated therein, to the primary repository contracted by them. All other economic operators shall transmit the information listed in points 3.1 to 3.5 of Section 3 of Chapter II of Annex II, in the format indicated therein, via the router.

For dispatch of tobacco products to laboratories, waste disposal centres, national authorities, international governmental organisations, embassies and military bases, manufacturers and importers shall transmit the information listed in point 3.8 of Section 3 of Chapter II of Annex II, in the format indicated therein, to the primary repository contracted by them. All other economic operators shall transmit the information listed in point 3.8 of Section 3 of Chapter II of Annex II, in the format indicated therein, via the router.;

(b) paragraphs 6 and 7 are replaced by the following:

'6. If, after the application of the unique identifier, tobacco products are destroyed or stolen, economic operators shall promptly transmit a deactivation request in accordance with the scope and format specified in point 2.3 of Section 2 of Chapter II of Annex II.

If tobacco products reported as stolen are recovered, economic operators may transmit a reactivation request in accordance with the scope and format specified in point 2.4 of Section 2 of Chapter II of Annex II.

7. The information concerning the event shall be deemed to have been transmitted correctly upon a positive acknowledgement by the primary repository or the router. The positive acknowledgement shall include the feedback information enabling the recipient to establish the correctness of its reporting activity, in particular the number of unit-level unique identifiers concerned by the event and in the case of disaggregation referred to in paragraph 3, the subordinate unique identifiers. The acknowledgement shall include a message recall code to be applied by the economic operator if the original message needs to be cancelled.;

(c) the following paragraph 8 is added:

‘8. The responsibility for recording and transmitting the information concerning the events referred to in paragraph 1 shall lie with the economic operator that is in possession of the tobacco products. To that end, all the reporting activities shall use the identifier code of this economic operator. IT service providers may also transmit this information on behalf of the economic operator that is in possession of the tobacco products.’.

(21) In Article 33, paragraph 3 is replaced by the following:

‘3. The responsibility for recording and transmitting the information referred to in paragraph 2 shall lie with the economic operator who is the vendor. To this end, all the reporting activities shall use the identifier code of this economic operator. IT service providers may also transmit this information on behalf of the economic operator who is the vendor of the tobacco products.’.

(22) Article 34 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Economic operators shall transmit the information referred to in Article 32(1), points (a), (b) and (d), Article 32(3) and (4), and Article 33(1), within 3 hours from the occurrence of the event.

The information referred to in Article 32 shall be transmitted in the order of the occurrence of the events.’;

(b) paragraph 5 is replaced by the following:

‘5. The first subparagraph of paragraph 1 shall apply from 20 May 2028. Until that date all economic operators may transmit the information referred to in paragraph 1 within 24 hours from the occurrence of the event.’.

(23) Article 36(1), point (a), is replaced by the following:

‘(a) the ID issuer for communications between the ID issuer, the operators of the first retail outlets and the economic operators registering with the ID issuer or requesting unique identifiers’.

(24) The following Article 36a is inserted:

‘Article 36a

Quality of data

1. The Member States may, issue reports on the inadequate quality of data reported by economic operators to the repositories system. These reports shall be addressed to the concerned economic operators and include examples of misreporting.

2. Member States shall require ID issuers to perform checks of addresses and other electronically verifiable data that are provided to the system by economic operators and operators of first retail outlets through ID issuers.’.

(25) Annexes I and II are amended in accordance with the Annex to this Regulation.

(26) Annex III is added in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 1 shall apply from 21 December 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 1 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Implementing Regulation (EU) 2018/574 is amended as follows:

(1) Annex I is amended as follows:

1.1. Part A is amended as follows:

(a) the following paragraph 1a is inserted:

‘1a. Where several legal persons constitute the same manufacturer or importer, the notification shall be submitted jointly by all legal persons.’

(b) the following paragraph 1b is inserted:

‘1b. In cases where the importer concerned cooperates with only one non-EU manufacturer or belongs to the same group of companies as the latter, the data storage contract may be co-signed by both the importer and the non-EU manufacturer. In cases where the importer concerned cooperates with several non-EU manufacturers or is also a Union manufacturer itself, the data storage contract shall be signed solely by the importer.’

(c) paragraph 9 is replaced by the following:

‘9. Any amendment to the key elements of the contract, as defined in Delegated Regulation (EU) 2018/573, shall be subject to approval by the Commission. In the absence of a reply by the Commission within three months of the date of notification of the amendment, the amendment shall be deemed to be approved. This deadline can be extended by the Commission once by a maximum of another three months, by means of a letter to the notifying operator. Any other amendment to the contract than to its key elements shall only require prior communication to the Commission.’

1.2. Part B is amended as follows:

(a) in paragraph 1, the words ‘within six months following the entry into force of Delegated Regulation (EU) 2018/573’ are deleted.

(b) paragraph 2 is replaced by the following:

‘2. The appointment of the operator of the secondary repository shall be based on an assessment of objective criteria and take place by means of a concession contract concluded in writing between the Commission and each successive operator of the secondary repository.’

(c) paragraph 5 is replaced by the following:

‘5. The contracts between each primary repository provider and the operator of the secondary repository shall be signed and submitted to the Commission within three months from the date of the appointment of each successive operator of the secondary repository.’

1.3. Part C is replaced by the following:

‘PART C

The following requirements shall apply in addition to the selection procedures outlined in Parts A and B:

1. Where the contractual relationship between a manufacturer or importer and the provider of a primary repository is terminated, or expected to be terminated, by any of the parties to the contract, for any reason, including the failure to comply with the criteria for independence laid down in Article 35, the manufacturer or importer shall immediately inform the Commission of such termination, or expected termination, and of the date of the notification of such termination to the provider, as well as the date at which the termination is or is expected to take effect. The manufacturer or importer shall propose and notify to the Commission a replacement provider at the latest three months prior to the termination date of the existing contract. The appointment of the replacement provider shall take place in accordance with Part A.

2. In the event that the operator of the secondary repository gives notice of its intention to cease operating that repository in accordance with the concession contract referred to in paragraph 2 of Part B, it shall immediately inform the Commission thereof and of the date at which the termination is to take effect. The notice period shall not be shorter than nine months. The contract shall provide for the Commission to be able to unilaterally extend it by up to six months if required for establishing and operationalising a replacement operator of the secondary repository. The Commission shall inform the competent authorities of the Member States about the notice period and its potential extension.
3. Where paragraph 1 applies, the contract referred to in paragraph 4 of Part B shall, in turn, be terminated by the parties immediately after the closure of the affected primary repository.'

(2) Annex II is amended as follows:

2.1. The introductory section 'Key messages to be sent by the economic operators' is replaced by the following:

'Key messages to be sent by the economic operators

The messages required for regulatory purposes shall contain at least the data fields listed in this Annex.

Member States and the Commission may require an extension of the address data to include exact geographic coordinates (latitude and longitude). Both ID issuers and providers of data repositories (including the router) may decide to extend the message content for strictly technical reasons to secure smooth functioning of the traceability system. ID issuers may also decide to extend the message content for non-technical reasons to secure smooth functioning of the tobacco products traceability system with other systems used for regulatory purposes. Before becoming effective, such extensions shall be reflected in the technical specifications updated in accordance with Article 28.

The messages listed in this Annex do not include the messages to be sent back by ID issuers and providers of data repositories (including the router) to the economic operators, such as acknowledgments of receipt.

All the messages generated within the traceability system shall contain the identification of the message originator and a timestamp up to the millisecond (see Data Type: Time(L)). This timestamp does not replace the time of the occurrence of a reported event, which shall be reported separately in accordance with the data fields prescribed in this Annex. The identification of the message originator, which may concern a third-party IT service provider, does not replace the identification of the economic operator responsible for the reporting activity (via an EOID to be indicated in the EO_ID field). The means of the identification of the message originator shall be specified in the technical specifications established and updated in accordance with Article 28.

ID issuers and providers of data repositories (including the router) shall timestamp each received message up to the millisecond.

In case of amendments to this Annex, any changes in the key messages listed herein become applicable to the economic operators as of the moment such changes are duly reflected in the technical specifications and the common data dictionary established and updated in accordance with Article 28.'

2.2. Section 1 in Chapter I is amended as follows:

(a) the table row for Data Type 'Country' is replaced by the following:

'Country	Country name coded with ISO-3166-1:2013 alpha-2 (or its latest equivalent). For overseas and autonomous regions, the country code of the relevant Member State is applicable. In case of Northern Ireland, the 'XI' code is applicable. In case of the international waters, the 'XZ' code is applicable.	'DE"
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(b) the table row for Data Type 'Text' is replaced by the following:

'Text	Set of characters coded with ISO8859-15:1999	'Abcde:12345'
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(c) the table row for Data Type 'Time(L)' is replaced by the following:

'Time(L)	UTC (Coordinated Universal Time) in the following format: YYYY-MM-DDTHH:mm:ss.SSSZ '2019-07-16T19:20:30.205Z'	
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(d) the table row for Data Type 'upUI(L)' is replaced by the following:

'upUI(L)	Unit packet level unique identifier coded with the invariant set of ISO646:1991 and composed of three blocks: (i) ID issuer's prefix in accordance with ISO15459-2:2015, (ii) middle block in the format established by the ID issuer and (iii) timestamp following the Data Type: Time(s)'	
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(e) the following table row is inserted after the table row for Data Type 'upUI(L)':

'upUI(i)	Unit packet level unique identifier coded with the invariant set of ISO646:1991 and composed of two blocks: (i) ID issuer's prefix in accordance with ISO15459-2:2015 and (ii) middle block in the format established by the ID issuer (i.e. upUI(i) is upUI(L) without the timestamp, a code to be generated by ID issuers in accordance with Article 8(2) of this Regulation)'	
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(f) the table row for Data Type 'upUI(s)' is replaced by the following:

'upUI(s)	Unit packet level unique identifier coded with the invariant set of ISO646:1991 and composed of two blocks: (i) ID issuer's prefix in accordance with ISO15459-2:2015 and (ii) serialisation element in the format established by the ID issuer (i.e. UI made visible in the human readable format on the unit packets in accordance with Article 23 of this Regulation) Whenever possible ID issuers are requested not to use upper-case letter 'O' (Oscar) and lower-case letter 'l' (lima) as well as upper-case letter 'I' (India) in order to avoid confusions with digits '0' (zero) and '1' (one), respectively.'	
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2.3. Section 1 in Chapter II is amended as follows:

(a) in point 1.1, the table row for Field 'EO_Address' is replaced by the following:

	'EO_street	Economic operator's street name and house number (or road number and kilometre)	Text	S	M	
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	EO_municipality	Economic operator's municipality (city, town or village)	Text	S	M	
	EO_postcode	Economic operator's postal code	Text	S	M	'n/a' is permitted value if no postal code has been assigned'
	EO_A_info	Additional information on economic operator's address (e.g. location in the shopping mall or industrial area)	Text	S	O	

(b) in point 1.2, the table row for Field 'EO_Address' is replaced by the following:

	'EO_street	Economic operator's street name and house number (or road number and kilometre)	Text	S	M	
	EO_municipality	Economic operator's municipality (city, town or village)	Text	S	M	
	EO_postcode	Economic operator's postal code	Text	S	M	'n/a' is permitted value if no postal code has been assigned'
	EO_A_info	Additional information on economic operator's address (e.g. location in the shopping mall or industrial area)	Text	S	O	

(c) in point 1.4, the table row for Field 'F_Address' is replaced by the following:

	'F_street	Facility's street name and house number (or road number and kilometre)	Text	S	M	
	F_municipality	Facility's municipality (city, town or village)	Text	S	M	
	F_postcode	Facility's postal code	Text	S	M	'n/a' is permitted value if no postal code has been assigned'
	F_A_info	Additional information on facility's address (e.g. location in the shopping mall or industrial area)	Text	S	O	

(d) in point 1.4, the following table rows are inserted after the table row for Field 'OtherFID_N':

'PrevFID_B	Indication if the facility was acquired from another operator and had already a facility identifier code	Boolean	S	M	0 – No (first time registration) 1 – Yes'
PrevFID_ID	Previous facility identifier used by the former operator of the facility	FID	S	M, if PrevFID_B = 1	

(e) in point 1.5, the table row for Field 'F_Address' is replaced by the following:

'F_street	Facility's street name and house number (or road number and kilometre)	Text	S	M	
F_municipality	Facility's municipality (city, town or village)	Text	S	M	
F_postcode	Facility's postal code	Text	S	M	'n/a' is permitted value if no postal code has been assigned'
F_A_info	Additional information on facility's address (e.g. location in the shopping mall or industrial area)	Text	S	O	

(f) in point 1.5, the following table rows are inserted after the table row for Field 'OtherFID_N':

'PrevFID_B	Indication if the facility was acquired from another operator and had already a facility identifier code	Boolean	S	M	0 – No (first time registration) 1 – Yes'
PrevFID_ID	Previous facility identifier used by the former operator of the facility	FID	S	M, if PrevFID_B = 1	

(g) point 1.7 is replaced by the following:

1.7. Request for a machine identifier code

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
	Message_Type	Identification of message type	Text	S	M	1-7

EO_ID	Economic operator identifier code	EOID	S	M	
EO_CODE	Economic operator's confirmation code provided in response to the registration of economic operator	Text	S	M	
F_ID	Facility identifier code	FID	S	M	
PrevMID_B	Indication if the object of this request was already registered, e.g. in relation to another facility identifier code	Boolean	S	M	0 – No (first time registration) 1 – Yes
PrevMID_ID	Previous machine identifier used for the object of this request	MID	S	M, if PrevMID_B = 1	
M_entirety	Indication if this request concerns the machine (v. a part of thereof)	Boolean	S	M	0 – No (machine part) 1 – Yes (machine)
P_Producer	Part's producer	Text	S	M, if M_entirety = 0	
P_Model	Part's model	Text	S	M, if M_entirety = 0	
P_Number	Part's serial number	Text	S	M, if M_entirety = 0	
P_Mobile	Indication if this part is intended to be used with multiple machines (fixed v. mobile part)	Boolean	S	M, if M_entirety = 0	0 – No (fixed part) 1 – Yes (mobile part)
P_ATD1	Indication if an anti-tampering device in the sense of Article 2(7) records the functioning of this part	Boolean	S	M, if M_entirety = 0	0 – No 1 – Yes

P_ATD2	Anti-tampering device's serial number	Text	S	M, if M_entirety = 0 and P_ATD1 = 1	
P_Description	Part's description explaining its technical function	Text	S	O	
M_Producer	Machine's producer	Text	S	M, if M_entirety = 1	
M_Model	Machine's model	Text	S	M, if M_entirety = 1	
M_Number	Machine's serial number	Text	S	M, if M_entirety = 1	
M_parts	Indication if the machine consists of multiple separately identifiable parts	Boolean	S	M, if M_entirety = 1	0 – No 1 – Yes'
M_plist	List of the identifiable parts	MID	M	M, if M_entirety = 1 and M_parts = 1	
M_ATD	Serial number of the anti-tampering device in the sense of Article 2(7)	Text	S	M, if M_entirety = 1 and M_parts = 0	
M_Capacity	Maximum capacity over 24-hour production cycle expressed in unit packets	Integer	S	M, if M_entirety = 1	

(h) point 1.8 is replaced by the following:

1.8. Correction of information concerning the machine identifier code

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
	Message_Type	Identification of message type	Text	S	M	1-8

EO_ID	Economic operator identifier code	EOID	S	M	
EO_CODE	Economic operator's confirmation code provided in response to the registration of economic operator	Text	S	M	
F_ID	Facility identifier code	FID	S	M	
M_ID	Machine identifier code (subject to the correction of information)	MID	S	M	
PrevMID_B	Indication if the object of this request was already registered, e.g. in relation to another facility identifier code	Boolean	S	M	0 – No (first time registration) 1 – Yes
PrevMID_ID	Previous machine identifier code used for the object of this request	MID	S	M, if PrevMID_B = 1	
M_entirety	Indication if this request concerns the machine (v. a part of thereof)	Boolean	S	M	0 – No (machine part) 1 – Yes (machine)
P_Producer	Part's producer	Text	S	M, if M_entirety = 0	
P_Model	Part's model	Text	S	M, if M_entirety = 0	
P_Number	Part's serial number	Text	S	M, if M_entirety = 0	
P_Mobile	Indication if this part is intended to be used with multiple machines (fixed v. mobile part)	Boolean	S	M, if M_entirety = 0	0 – No (fixed part) 1 – Yes (mobile part)

P_ATD1	Indication if an anti-tampering device in the sense of Article 2(7) records the functioning of this part	Boolean	S	M, if M_entirety = 0	0 – No 1 – Yes
P_ATD2	Anti-tampering device's serial number	Text	S	M, if M_entirety = 0 and P_ATD1 = 1	
P_Description	Part's description explaining its technical function	Text	S	O	
M_Producer	Machine's producer	Text	S	M, if M_entirety = 1	
M_Model	Machine's model	Text	S	M, if M_entirety = 1	
M_Number	Machine's serial number	Text	S	M, if M_entirety = 1	
M_parts	Indication if the machine consists of multiple separately identifiable parts	Boolean	S	M, if M_entirety = 1	0 – No 1 – Yes'
M_list	List of the identifiable parts	MID	M	M, if M_entirety = 1 and M_parts = 1	
M_ATD	Serial number of the anti-tampering device in the sense of Article 2(7)	Text	S	M, if M_entirety = 1 and M_parts = 0	
M_Capacity	Maximum capacity over 24-hour production cycle expressed in unit packets	Integer	S	M, if M_entirety = 1	

2.4. Section 2 in Chapter II is amended as follows:

(a) in point 2.1, the table row for Field 'P_Type' is replaced by the following:

'P_Type	Type of tobacco product	Integer	S	M	1 – Cigarette 2 – Cigar 3 – Cigarillo 4 – Roll your own tobacco 5 – Pipe tobacco 6 – Waterpipe tobacco 7 – Oral tobacco 8 – Nasal tobacco 9 – Chewing tobacco 11 – Novel tobacco product 12 – Other (product placed on the market before 19 May 2014, not covered by categories 1-9)
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(b) in point 2.1, the table row for Field 'P_Brand' is replaced by the following:

'P_Brand	Brand of tobacco product under which the product will be marketed on its intended market	Text	S	M	
P_SubType_Exist	Indicates if the product 'subtype name' exists. Subtype name provides further product identification beyond a product's brand name.	Boolean	S	M	0 – No 1 – Yes'
P_SubType_Name	The product 'subtype name' (if any) as marketed on its intended market	Text	S	M, if P_SubType_Exist = 1	
P_units	The number of individual units in the unit packet (number of sticks in the package).	Integer	S	M, if P_Type = 1 or 2 or 3	

(c) in point 2.1, the table row for Field 'TP_PN' is replaced by the following:

	'TP_PN	Tobacco product number used in the EU-CEG system (EAN or GTIN or SKU or UPC)	PN	S	M, if Intended_Market is a Member State O, if Intended_Market is a third country'	
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(d) in point 2.3, the table row for Field 'Deact_upUI' is replaced by the following:

	'Deact_upUI	List of unit packet level UIs to be deactivated	upUI(L) or upUI(i) or upUI(s)	M	M, if Deact_Type = 1'	
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(e) the following point 2.4 is added:

2.4. Request for reactivation of UIs for products reported as stolen but recovered (only permitted if in preceding message type 2-3, field Deact_Reason1 = 2)

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
	Message_Type	Identification of message type	Text	S	M	2-4
	EO_ID	Economic operator identifier code of the submitting entity	EOID	S	M	
	F_ID	Facility identifier code (facility of recovery)	FID	S	M	
	React_Type	Reactivation of unit packet or aggregated level UIs	Integer	S	M	1 – Unit packet level UIs 2 – Aggregated level UIs'
	React_Reason	Description of the context of reactivation	Text	S	O	
	React_upUI	List of unit packet level UIs to be reactivated	upUI(L) or upUI(i) or upUI(s)	M	M, if React_Type=1	

	React_aUI	List of aggregated level UIs to be reactivated	aUI	M	M, if React_Type=2	
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2.5. Section 3 in Chapter II is amended as follows:

(a) in point 3.3, the table row for Field 'Destination_ID5' is replaced by the following:

	'Destination_ID5	Destination facility's street name and house number (or road number and kilometre)	Text	S	M, if Destination_ID1 = 1	
	Destination_ID6	Destination facility's municipality (city, town or village)	Text	S	M, if Destination_ID1 = 1	
	Destination_ID7	Destination facility's postal code	Text	S	M, if Destination_ID1 = 1	'n/a' is permitted value if no postal code has been assigned'
	Destination_ID8	Destination facility's country	Country	S	M, if Destination_ID1 = 1	

(b) in point 3.5, the table row for Field 'Destination_ID3' is replaced by the following:

	'Destination_ID3	Destination facility's street name and house number (or road number and kilometre)	Text	S	M, if Destination_ID1 = 0	
	Destination_ID4	Destination facility's municipality (city, town or village)	Text	S	M, if Destination_ID1 = 0	
	Destination_ID5	Destination facility's postal code	Text	S	M, if Destination_ID1 = 0	'n/a' is permitted value if no postal code has been assigned'
	Destination_ID6	Destination facility's country	Country	S	M, if Destination_ID1 = 0	

(c) the following point 3.8 is added:

3.8. Dispatch of tobacco products from a facility to laboratories, waste disposal centres, national authorities, international governmental organisations, embassies and military bases

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
	Message_Type	Identification of message type	Text	S	M	3-8
	EO_ID	Economic operator identifier code of the submitting entity	EOID	S	M	
	Event_Time	Intended time of event occurrence	Time(s)	S	M	
	F_ID	Dispatch facility identifier code	FID	S	M	
	Destination_1	Indication of destination type	Integer	S	M	1 – Laboratory 2 – Waste disposal centre 3 – National authority 4 – International governmental organisation 5 – Embassy 6 – Military base
	Destination_2	Destination's street name and house number (or road number and kilometre)	Text	S	M	
	Destination_3	Destination's municipality (city, town or village)	Text	S	M	
	Destination_4	Destination's postal code	Text	S	M	'n/a' is permitted value if no postal code has been assigned
	Destination_5	Destination's country	Country	S	M	

	Transport_ mode	Mode of transport by which the product leaves the facility, see Annex II, Code List 7 of Regulation (EC) No 684/2009	Integer	S	M	0 – Other 1 – Sea Transport 2 – Rail transport 3 – Road transport 4 – Air transport 5 – Postal consignment 6 – Fixed transport installations 7 – Inland waterway transport
	Transport_ vehicle	Identification of the vehicle (i.e. number plates, train number, plane/flight number, ship name or other identification)	Text	S	M	'n/a' is permitted value if Transport_mode=0 and product movement takes place between adjacent facilities and is delivered manually
	Transport_ cont1	Indication if the transport is containerised and uses an individual transport unit code (e.g. SSCC)	Boolean	S	M	0 – No 1 – Yes
	Transport_ cont2	Individual transport unit code of the container	ITU	S	M, if Transport_ cont1 = 1	
	UI_Type	Identification of UI types in the dispatch (recorded at the highest level of available aggregation)	Integer	S	M	1 – only unit packet level UIs 2 – only aggregated level UIs 3 – both unit packet and aggregated level UIs'

	upUIs	List of unit packet level UIs subject to the dispatch	upUI(L)	M	M, if UI_Type = 1 or 3	
	aUIs	List of aggregated level UIs subject to the dispatch	aUI	M	M, if UI_Type = 2 or 3	
	S_Dispatch_comment	Comments by the reporting entity	Text	S	O	

2.6. Section 4 in Chapter II is amended as follows:

(a) in point 4.1, the table row for Field 'Buyer_Address' is replaced by the following:

	'Buyer_Address_1	Buyer's street name and house number (or road number and kilometre)	Text	S	M, if Invoice_Buyer1 = 0	
	Buyer_Address_2	Buyer's municipality (city, town or village)	Text	S	M, if Invoice_Buyer1 = 0	
	Buyer_Address_3	Buyer's postal code	Text	S	M, if Invoice_Buyer1 = 0	'n/a' is permitted value if no postal code has been assigned'

(b) in point 4.3, the table row for Field 'Payer_Address' is replaced by the following:

	'Payer_Address_1	Payer's street name and house number (or road number and kilometre)	Text	S	M, if Payment_Payer1 = 0	
	Payer_Address_2	Payer's municipality (city, town or village)	Text	S	M, if Payment_Payer1 = 0	
	Payer_Address_3	Payer's postal code	Text	S	M, if Payment_Payer1 = 0	'n/a' is permitted value if no postal code has been assigned'

2.7. Section 5 in Chapter II is replaced as follows:

'Recalls

5. **Recalls of requests, operational and transactional messages (possible for message types 2-1, 2-2, 2-3 (only within 24 hours from the original reporting of message 2-3, for Deact_Reason1 other than "2 - Product stolen"), 3-1 to 3-8, 4-1, 4-2 and 4-3)**

Item #	Field	Comments	Data Type	Cardinality	Prioritt	Values
	Message_Type	Identification of message type	Text	S	M	5
	EO_ID	Economic operator identifier code of the submitting entity	EOID	S	M	
	Recall_CODE	Message recall code provided to the message sender in the acknowledgement of the original message to be recalled	Text	S	M	Recall_CODE
	Recall_Reason1	Reason for recalling the original message	Integer	S	M	1 – reported event did not materialise (only for message types 3-3, 3-5 and 3-8) 2 – message contained erroneous information 3 – other
	Recall_Reason2	Description of the reason for recalling the original message	Text	S	M, if Recall_Reason1 = 3	
	Recall_Reason3	Any additional explanations on the reason for recalling the original message	Text	S	O	

Notice: A recall with respect to operational and logistic events results in flagging the recalled message as cancelled but does not lead to the deletion of the existing database record.'

(3) The following Annex III is added:

'ANNEX III

Structure of a unit-level unique identifier

	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
Element:	Symbol- ogy identifier	Manda- tory data qualifier	ID issuer's identifica- tion code	Optional data qualifier	Serial number	Optional data qualifier	Product code	Optional data qualifier	Time stamp
Type:	Qualifier	Qualifier	String (data element)	Qualifier	String (data element)	Qualifier	String (data element)	Qualifier	String (data element)

Position within the unique identifier:	Fixed	Fixed	Fixed	Non-fixed	Non-fixed	Non-fixed	Non-fixed	Fixed	Fixed
Regulated by:	Art. 21(1) and ID issuer's coding structure	Art.3(4), Art.8(1)(a), Art. 21(1) and ID issuer's coding structure	Art.3(4) and Art.8(1)(a)	Art. 21(1) and ID issuer's coding structure	Art.8(1)(b)	Art. 21(1) and ID issuer's coding structure	Art.8(1)(c)	Art. 21(1), Art. 21(4) and ID issuer's coding structure	Art.8(1)(d) and Art.21(4)
Applicable international standards:	ISO/IEC-16022:2-006, or ISO/IEC 18004:2015, or ISS DotCode Symbology Spec.	ISO 15459-2:2015 and ISO 15459-3:2014	ISO 15459-2:2015 and ISO 15459-3:2014						
Process:	Applied by economic operators	Applied by economic operators	Generated by ID issuers	Applied by economic operators	Generated by ID issuers	Applied by economic operators	Generated by ID issuers	Applied by economic operators	Applied by economic operators
Transmission to the repositories system:	No	No	Yes	No	Yes	No	Yes	No	Yes

Note: For the purpose of the above schema, group separators (/FNC1) are considered in the same manner as optional data qualifiers, i.e. their use depends on the ID issuer's coding structure.'

CORRIGENDA

Corrigendum to Commission Implementing Directive (EU) 2022/1647 of 23 September 2022 amending Directive 2003/90/EC as regards a derogation for organic varieties of agricultural plant species suitable for organic production

(Official Journal of the European Union L 248 of 26 September 2022)

On page 47, in Article 1, point (1)(b) (amending Article 1(3) of Directive 2003/90/EC), first subparagraph:

for: 'By way of derogation from the first subparagraph, as regards the value for cultivation or use, organic varieties suitable for organic production, which belong to the species listed in Annex IV, Part A, may, comply instead with the conditions laid down in Part B of that Annex.;

read: 'By way of derogation from the first subparagraph, as regards the value for cultivation or use, organic varieties suitable for organic production, which belong to the species listed in Annex V, Part A, may comply instead with the conditions laid down in Part B of that Annex.'

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