

**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 <sup>(1)</sup>, and in particular Article 15(11) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2018/574 <sup>(2)</sup> 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 <sup>(3)</sup>, 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.

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<sup>(1)</sup> OJ L 127, 29.4.2014, p. 1.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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.

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(\*) 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

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## 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.'