Systems of traceability and security features for tobacco products in the EU

Stakeholder manual

DG SANTE
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Introduction – Systems of traceability and security features for tobacco products in the EU

On 3 April 2014, the European Parliament and the Council adopted the Tobacco Products Directive 2014/40/EU (hereafter: TPD).[1] The overall objective of the TPD is to approximate the laws, regulations and administrative provisions of the Member States concerning rules governing the manufacture, presentation and sale of tobacco and related products.

It facilitates the smooth functioning of the internal market for tobacco and related products, protecting human health, especially for young people. In addition, Article 1 of the TPD explicitly refers to the obligations of the European Union (EU) under the WHO Framework Convention for Tobacco Control (FCTC).

Key provisions

Articles 15 and 16 of the TPD **aim to address illicit trade in tobacco products** by introducing **systems of traceability and security features** for these products. The systems will contribute to reducing the circulation of tobacco products not compliant with the TPD and other tobacco control legislation. They will also reduce artificially cheap supplies of illegal tobacco products that affect the uptake and general prevalence of smoking. The systems will therefore play an important role in protecting public health, state budgets and legal economic operators.

Traceability system

Under the **traceability system** (Article 15 TPD):

- All unit packets of tobacco products produced in, destined for, or placed on the EU market will need to display a unique identifier (with predefined information on location and date of manufacture, destination etc.).
- Their movements must be recorded throughout the supply chain (from the manufacturer to the last level before the first retail outlet).
- Information on recorded movements will be stored by independent data storage providers (with whom manufacturers and importers of tobacco products will need to sign contracts, to be approved by the Commission), and the data will be made accessible to authorities (Member States and the Commission) for enforcement purposes.

In this way, the traceability system will enable the movement of legal tobacco products to be monitored (tracking) and allow the public authorities to determine at which point a product was diverted into the illicit market, or vice versa (tracing).

[1] 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 (OJ L 127, 29.4.2014, p. 1), http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf

Security Features system

Under the **security features system** (Article 16 TPD) unit packets of tobacco products placed on the EU market must be marked with a tamper-proof security feature composed of visible and invisible elements. This will enable both consumers and authorities to determine if the product is genuine or illicit.

Secondary legislation

Articles 15 and 16 provide the basic framework for systems of traceability and security features. To complement them, the Commission has adopted three acts of secondary legislation with additional technical details:

- **Commission Implementing Regulation (EU) 2018/574** on technical standards for the establishment and operation of a traceability system for tobacco products;
- **Commission Delegated Regulation (EU) 2018/573** on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products;
- **Commission Implementing Decision (EU) 2018/576** on technical standards for security features applied to tobacco products.

The systems must be in place by **20 May 2019** for cigarettes and roll-your-own tobacco, and by **20 May 2024** for all other tobacco products.

I. Traceability system for tobacco products

Overview

The traceability system enables the monitoring of tobacco products across the supply chain (tracking) and, enables authorities to determine potential points of diversion from or into the supply chain (tracing).

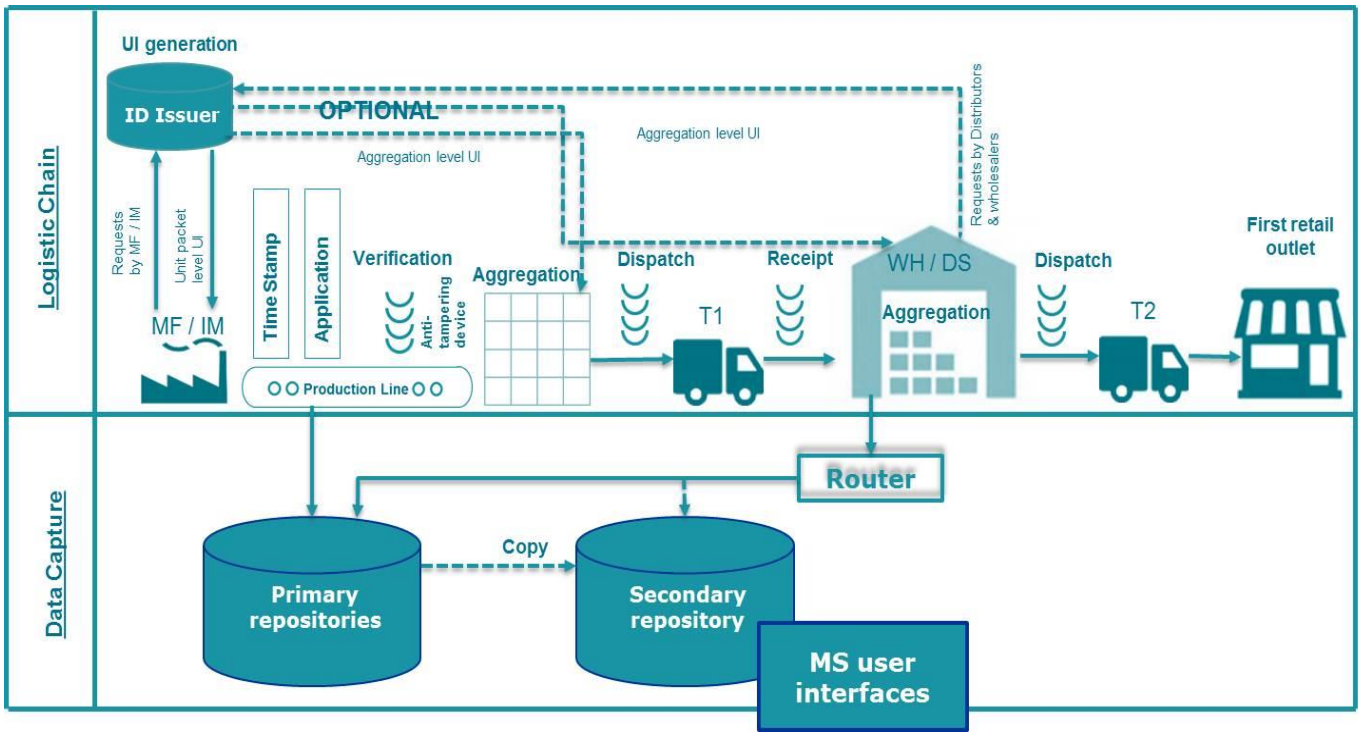
Traceability is only possible if tobacco products are marked with unique identifier (UI) codes (containing predefined information – such as origin and date of manufacture, destination etc.). This enables their identification, tracking and tracing throughout the supply chain, and the transmission of related information to a data storage facility.

The UI is an alphanumeric code, which is encoded in a data carrier for the purpose of machine readability (e.g. scanning). Data carriers often take the form of an optical (one or two-dimensional) barcode, which is irremovably applied to the product package.

The key requirements of the traceability system are set out in:

- **Article 15 TPD**;
- **Commission Implementing Regulation 2018/574** on technical standards for the establishment and operation of a traceability system for tobacco products; (including its Annexes I and II)
- **Commission Delegated Regulation 2018/573** on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products.

The figure below provides an overview of these key requirements (including key stages and events that will take place under the traceability system). For the purpose of clarity, a distinction is made between the logistic chain (where products physically move and where transactions are made) and data storage (where information on product movements and transactions will be processed).


Logistic Chain
UI generation
ID Issuer
OPTIONAL
Aggregation level UI
Aggregation level UI
Requests by Distributors & wholesalers
Requests by MF / IM
Unit packet level UI
MF / IM
Time Stamp
Application
Verification
Anti-tampering device
Aggregation
Production Line
Dispatch
T1
Receipt
WH / DS
Aggregation
Dispatch
T2
First retail outlet
Data Capture
Router
Primary repositories
Copy
Secondary repository
MS user interfaces

Detailed description of the system

Under the traceability system, the generation of UIs is entrusted to 'ID issuers' who are required to be financially and legally independent of the tobacco industry. Each Member State is responsible for the appointment of an ID issuer for its territory.

Once appointed, ID issuers will receive requests to generate the UIs from manufactures and importers of tobacco products, who will have to supply pre-defined information relating to the products. The ID issuers will then generate batches of UIs and deliver them to the ordering manufacturer or importer, for a fee. UIs that have been delivered but have not yet been applied to packets will remain valid for a period of six months. They will expire if they are not applied to packets within this time.

On the production line, manufacturers will complete the UI with a 'time stamp' (i.e. a marking indicating the date and time of manufacture of the tobacco product). The UI will then be applied to the unit packet, after being encoded in an authorised data carrier. Its application must be verified to ensure its readability. An anti-tampering device, capable of creating an unalterable independent record of this verification process, must previously have been installed. This record will be accessible to public authorities for potential investigations and inspections.

Note: In the case of importers, the above processes will need to take place before the products are imported into the Union (see Article 2(38) TPD) – i.e. in the third country of their production, or while under customs suspensive procedure.

Correctly marked unit packets can then be tracked and traced throughout the supply chain. In most cases, these will be added to bigger packages, such as cartons, master cases or pallets, known as 'aggregated packaging'. Tracking at aggregated packaging level is permitted, provided the unit packets remain track and traceable. This requires separate aggregated-level UIs, electronically linked to each lower-level UI. Recording product movements at aggregated packaging level is intended to alleviate the operational burden on economic operators (in particular wholesalers and distributors), who would otherwise need to scan each unit packet being handled. Aggregated-level UIs can either be requested from the competent ID issuer, or self-generated by the economic operator, based on prescribed international standards.

Transportation between different facilities is also subject to a clear set of rules: each dispatch and arrival will have to be recorded and reported to the repositories system, up to the point of dispatch to the first retail outlet, i.e. the first place where the products will be made available to consumers.

All recorded information must be submitted to the 'repositories system'. This is the general term used to describe the various primary repositories (contracted by each manufacturer and importer), the secondary repository (which will contain a copy of all traceability data stored in the primary repositories) and the router (a device established by the secondary repository that transfers data between different components of the repositories system).

Each manufacturer and importer will have to transmit the traceability information they have recorded to the primary repository contracted by them. All other economic operators (e.g. wholesalers and distributors) will transmit traceability information via the router.

The secondary repository will provide Member States and the Commission with an overview of tobacco product movements in the EU. This will enable checks and controls of the supply chain and assist their monitoring and enforcement activities.

Clear timeframes for the transmission of traceability data to the repositories system are laid down: in general it should take place 3 hours from the occurrence of an event, and 24 hours prior in the case of dispatch and transloading of tobacco products.

To ensure the correct transmission of traceability information, transmission messages must contain pre-defined information. This information is set out in Annex 2 of the Implementing Regulation.

Key stakeholder requirements for the establishment and operation of a traceability system for tobacco products

The following sections set out the key requirements of the tobacco traceability system, according to stakeholder category.

Unless otherwise stated, all articles referenced are those of **Implementing Regulation (EU) 2018/574 on technical standards for the establishment and operation of a traceability system for tobacco products** and its **Annex I** and **II**.

I. MANUFACTURERS AND IMPORTERS

The requirements for **manufacturers and importers** of tobacco products fall into three categories: **A)** Marking of packs with a unique identifier; **B)** Repositories system; **C)** Recording obligations.

A. Marking of packs with a unique identifier (UI)

Key requirements:

1. **Request identifier codes for economic operators, facilities and machines from relevant ID issuer:** Once Member States have completed the process of appointing ID issuers (*Art. 3*), one of the early tasks for **manufacturers and importers** of tobacco products is to apply to the relevant ID issuer (see below*) for identifier codes (for themselves, their facilities and the machines that they use in the production of tobacco products) *(Art.14; Art.16; Art.18).*

   Specific information should accompany the request for a code (set out in *Annex II, Chapter II, Section 1*). The ID issuer then supplies the identifier code, and establishes and maintains a registry of all identifier codes it has issued *(Art. 15; Art. 17; Art. 19).* Manufacturers and importers must be in possession of the relevant identifier codes in order to proceed to requesting UIs from ID issuers.

***Where to request IDENTIFIER CODES**

- Manufacturers and Importers -

To obtain **economic operator** identifier codes: **manufacturers** will need to apply to the ID issuer competent for each Member State in which they operate at least one facility. **Importers** will need to apply to the ID issuer competent for each Member State on whose market they place their products (*Art. 14*).

To obtain **facility** identifier codes: **manufacturers** will need to apply to the ID issuer competent for the Member State in which the facility is located. **Importers** are responsible for applying for codes for manufacturing facilities located outside the EU. They will need to apply to any ID issuer appointed by a Member State on whose market they place their products (*Art. 16*).

To obtain **machine** identifier codes: **manufacturers** will need to apply to the ID issuer competent for the Member State in which the machine is located. **Importers** are responsible for applying for codes for machines located outside the EU. They will need to apply to any ID issuer appointed by a Member State on whose market they place their products (*Art. 18*).

2. **Request UIs for tobacco packaging from relevant ID issuer**: Upon receipt of the relevant identifier codes (see above), manufacturers and importers can proceed to request UIs from ID issuers.

   To do so, they will have to send specific information (set out in *Annex II, Chapter II, Section II)* to a relevant ID issuer (see below*). Specific time limits apply for delivery of requested UIs (*Art. 9; Art. 13*). These may be sent electronically or, where applicable for unit packets, physically (*Art. 9*). UIs must be applied to packets within 6 months of receipt *(Art. 5.1).*

   For **unit packets**, manufacturers and importers must request UIs from a relevant ID issuer *(Art. 9)*. For **aggregated packaging** levels, UIs may **either** be requested from an ID issuer **or** generated directly by the manufacturer or importer, in accordance with ISO/IEC 15459-1:2014 or ISO/IEC 15459-4:2014 *(Art. 10)*.

***Where to request UNIQUE IDENTIFIERS**

- Manufacturers and Importers -

Manufacturers must apply for UIs from the ID issuer competent for the Member State in which the products are manufactured (*Art. 4.1*); **however**, by derogation, a Member State may designate its own ID issuer as responsible for generation of all UIs for all unit packets to be placed on its market *(Art. 4.1).* Manufacturers must inform themselves about any Member State making use of this derogation. **Importers** must apply to the ID issuer competent for the Member State in which the products will be placed on the market *(Art. 4.2)*.

Manufacturers and importers carrying out aggregation activities may choose to apply for UIs to the ID issuer competent for the Member State in which the aggregation takes place *(Art. 4.3)*. Alternatively, they may choose to generate aggregated-level UIs directly themselves, in accordance with ISO/IEC 15459-1:2014 or ISO/IEC 15459-4:2014 *(Art. 10)*.

Manufacturers and importers exporting tobacco products from the EU will need to apply to the ID issuer competent for the Member State in which the products are manufactured.

3. **Apply UIs on packs and verify:** Following receipt of UIs from ID issuers (or self-generation, in the case of aggregated level UIs), manufacturers and importers will apply these to packs (Art. 6; Art. 10). **Importers** will need to ensure that UIs are applied before the tobacco product is imported in the Union (Art. 6; *see also Art. 2.38 TPD*); In the case of all UIs generated by ID issuers, manufacturers and importers must add the time stamp in the prescribed format (*Art. 8.3; Art. 11.3*). The UIs must be encoded in one of the allowed data carriers (*Art. 21*).

   In the case of unit packets, the UI's readability will need to be verified for correct application and readability, and the verification process protected with an anti-tampering device supplied and installed by an independent third party *(Art.7)*. The record created by the anti-tampering device must be accessible to authorities upon request *(Art.7.5*).

   As set out in *Article 7.6*, certain economic operators will benefit from transitional periods or a full exemption from installing anti-tampering devices.

   Manufacturers and importers will also need to link the aggregated level UI to the list of all unit packet UIs that the aggregation contains (*Art. 12.1*), by transmitting the information listed under *Section 3, Chapter II, Annex II (point 3.2*) to the primary repository.

B. Repositories system

Manufacturers and importers are required to record all necessary information for the product events in which they are involved (*Art. 32; Art 33*). This data is then transmitted to, and stored in, a repositories system made up of three interoperable parts *(Art. 24)* – **1) primary repositories**; **2) a (single) secondary repository**; and **3) a router**.

Key requirements:

1. **Selection and establishment of the 'primary repositories':** Each manufacturer and importer must conclude a contract with an independent data storage provider, to set up a primary repository (*Art. 26.1*). The procedures governing this process (set out in Annex 1, letter A) require cigarette and roll-your-own tobacco manufacturers and importers to notify the Commission of the proposed storage provider (no later than 2 months following the entry into force of the **Delegated Regulation on key elements of data storage contracts to be concluded as part of a traceability system for tobacco products**). They must also provide a draft contract, with the key elements specified in the Delegated Regulation (as well as a table of correspondence and relevant written declarations) (see Annex I, Part A.1 and 2). The independence and technical suitability of the provider will be assessed by the European Commission and lists of approved providers will be published on its website (Annex I, Part A.8). Any subsequent amendment to contracts will be subject to approval (Annex I, Part A.9)

   Each primary repository will exclusively host information relating to the tobacco products of the manufacturer/importer that contracted it *(Art. 26.2).* All primary repositories must forward a copy of the data to the secondary repository *(Art. 26.3).* Data exchange modalities and a common data dictionary will be defined by the secondary repository *(Arts. 26.4; Art. 26.5).* Additional technical requirements *(Art. 25)* and procedures *(Annex 1, letters A + C)* apply to providers of primary repositories in order to ensure independence, functionality and interoperability of the system.

2. **Costs of the repositories system:** All costs related to the repositories system will be borne by manufacturers and importers of tobacco products. The costs of repository services must be fair, reasonable, and proportionate to the services rendered, and the amount of UIs requested (*Art. 30.1*).

   The costs of establishing and operating the secondary repository will be passed on to manufacturers and importers of tobacco products via the costs charged to them by the providers of primary repositories (*Art. 30.2*).

C. Recording obligations

Key requirements:

1. **Record product events**: The product events that must be recorded and transmitted are set out in Chapter VI of the Regulation. These include **product movement** events (such as the application of UIs on unit packets, or dispatch from a facility etc.) (*Art. 32.1*) and **transactional** events (such as the issuing of an invoice, the receipt of a payment etc.) (*Art. 33.1*). The responsibility for recording and transmitting the latter lies with the product vendor (*Art. 33.3*).

   In all cases, manufacturers and importers must transmit recorded information to their primary repository. The requisite information, as well as the format it should be transmitted in, are set out in Annex II, Chapter II, Sections 3 and 4. Successful transmission will be signalled by an acknowledgement message from their primary repository (*Art. 32.7; Art. 33.4*).

2. **Transmit required information within the necessary timeframe**: Manufacturers and importers must ensure information is transmitted within 3 hours from the occurrence of an event (*Art. 34.1*), e.g. 3 hours from the application of the UI to a unit packet. There are two exceptions: dispatch of products from facilities, and trans-loading of products. Information on these events should be transmitted 24 hours prior to the event occurrence (*Art. 34.3*).

   Certain derogations from the general 3 hour rule apply: SMEs (as defined in EU Recommendation 2003/361/EC), and manufacturers/importers who handled less than 120 million unit level UIs at Union level during the previous year, can transmit information up to 24 hours after an even has occurred *(Art. 34.4)*.

   Those that do not meet the above criteria will nonetheless benefit from a transitional period, applicable to all economic operators, until 20 May 2028. During this period, they may transmit information up to 24 hours after an event has occurred *(Art. 34.5)*.

   Derogations do not apply to dispatch and trans-loading events, for which prior reporting will always be required *(Art. 34.3)*.

3. **Ensure UI encoding using the correct data carriers**: Data carriers (i.e. barcodes) encode the UIs. The types of data carriers permitted have been strictly limited to three per level (*Art. 21.1; Art. 21.5)*: for unit packets, they are: **Data Matrix**, **QR Code** and **DotCode**; for aggregated packaging, they are: **Data Matrix**, **QR Code** and **Code 128.**

   Finally, there are specific rules on quality of the data carriers *(Art. 22)*, including that each data carrier must include a human-readable code to allow the information related to the UI to be accessed without the scanning device, if needed (*Art. 23*).

Table of main responsibilities – manufacturers and importers

The following table sets out the main responsibilities of manufacturers and importers under the traceability system. Please note, however, that it is not exhaustive and **Implementing Regulation (EU) 2018/574** and its accompanying **annexes**, as well as **Delegated Regulation, (EU) 2018/573** should be consulted for further details.

Actor	**Type of responsibility**
Manufacturers and importers of tobacco products	<u>Identifier codes</u> – Request an economic operator identifier code (Art. 14) – Request a facility identifier code (Art. 16) – Request a machine identifier code (Art. 18) <u>Unique Identifier (UI)</u> *For unit level UIs*: – Request unit level UIs from ID issuer (Art. 9) – Mark unit packets with UIs (Art. 6); add a timestamp (Art. 8.3) – Verification of unit level UIs (Art. 7) *For aggregated level UIs*: – Decision to request UIs from ID issuer or self-generate directly in accordance with relevant ISO standards (Art. 10) – If requesting from ID issuer: introduce request (Art. 13.). – If generating directly: generate UIs in accordance with relevant ISO standards (Art. 10). – Marking of aggregated packets with UIs (Art. 10); for UIs issued by ID issuers: adding a timestamp (Art. 11.3) <u>Data carriers</u> – Encoding of (electronically delivered) unit level UIs and aggregated level UIs (Art. 21) – Ensure quality of optical barcodes (Art. 22)

	– Inclusion of human-readable code into each data carrier (Art. 23) <u>Repositories system</u> – Establishment of a primary repository (Arts. 24 & 26) – Notify the Commission regarding the identity of the proposed repository provider together with all relevant documentation, including the draft contract (Annex 1, Part A.1 and 2) – Payment of all costs related to the repositories system via the costs charged by the providers of the primary repository (Art. 30) <u>Recording and transmitting of information</u> – Recording and transmission of information on product movements to the primary repository (Art. 32) within the permitted time frames (Art. 34) – Recording and transmission of transactional information to the primary repository (Art. 33) within the permitted time frames (Art. 34)

II. DISTRIBUTORS AND WHOLESALERS

The requirements for **distributors and wholesalers** can be grouped under the following headings: **A)** Marking of packs with a unique identifier; and **B)** Recording obligations.

A. Marking of packs with a unique identifier (UI)

Key requirements:

1. **Request identifier codes for economic operators, facilities and machines from relevant ID issuer**: Once Member States have appointed ID issuers (*Art. 3*), distributors and wholesalers must apply to these (see below*) for identifier codes (*Art. 14; Art. 16*). Requests must be made by supplying specific information (set out in Annex II, Chapter II, Section 1). The ID issuer will then be responsible for issuing identifier codes, as well as establishing and maintaining a registry of all codes issued (*Art. 15; Art. 17*).

*** Where to request IDENTIFIER CODES**

- Distributors and Wholesalers -

To obtain **economic operator** identifier codes: distributors and wholesalers will need to apply to the ID issuer competent for each Member State in which they operate at least one facility. (*Art. 14*).

To obtain **facility** identifier codes: distributors and wholesalers will need to apply to the ID issuer competent for the Member State in which the facility is located. (*Art. 16*)

2. **(*Where applicable*) Request UIs for aggregated-level tobacco packaging from relevant ID issuer:** Where aggregation or re-aggregation of tobacco products is carried out by distributors or wholesalers, aggregated-level UIs need to be applied to packaging (unless scanning of individual unit packets is preferred).

   Aggregated-level UIs may either be requested from a relevant ID issuer (see below*) by sending specific information (set out in *Annex II, Chapter II, Section II),* or generated directly by the wholesaler/distributor themselves, in accordance with ISO/IEC 15459-1:2014 or ISO/IEC 15459-4:2014 *(Art. 10).*

   Specific time limits apply for the electronic delivery of aggregated-level UIs by an ID issuer (*Art. 13*) (*Art. 13*), and these must be applied to packaging within 6 months of receipt *(Art. 5.1).*

***Where to request AGGREGATED-LEVEL UNIQUE IDENTIFIERS**

- Distributors and Wholesalers -

These should be requested from the ID issuer competent for the Member State in which the aggregation takes place (*Art. 4.3*).

(Alternatively, aggregated-level UIs may be generated directly by economic operators, in accordance with ISO/IEC 15459-1:2014 or ISO/IEC 15459-4:2014 *(Art. 10)*)

3. **(*Where applicable*) Application of aggregated-level UIs on packs:** Following receipt of the aggregated-level UIs from ID issuers (or self-generation), distributors and wholesalers must apply these to packs. In the case of aggregated-level UIs generated by ID issuers, distributors and wholesalers must add a time stamp *(Art. 11.3*). Before applying, the UIs must be encoded using one of the allowed data carriers (*Art. 21.5*) (see point B.3 below).

   An aggregated level UI must be linked to the list of all unit packet UIs that the aggregation contains (*Art. 12.1*). To do this, information listed under *Section 3, Chapter II, Annex II (point 3.2)* needs to be transmitted to the secondary repository, via the router.

B. Recording obligations

Key requirements:

1. **Record relevant events:** The product events that must be recorded and transmitted are set out in Chapter VI of the Regulation. These include product **movement** events (such as the application of UIs on unit packets, or dispatch from a facility etc.) (*Art. 32.1*) and **transactional** events (such as the issuing of an invoice, the receipt of a payment etc.) (*Art. 33.1*). In the case of transactional information, the responsibility for recording and transmitting will lie with the product vendor *(Art.33.3).*

   In the case of distributors and wholesalers, recorded information needs to be transmitted – to the secondary repository – via the **router** *(Art.32.2; Art.33.2).* The exact information to be transmitted, as well as the format that it should be transmitted in, is set out for each event in *Annex II, Chapter II, Sections 3 and 4.* Information will be deemed to have been successfully transmitted when the distributor or wholesaler receives an acknowledgement from the router *(Art. 32.7; Art. 33.4).*

2. **Transmit required information within the necessary timeframe:** Distributors and wholesalers must ensure that they transmit the information within 3 hours from the occurrence of an event *(Art. 34.1)*, e.g. 3 hours from the application of an aggregated-level UI, or from establishing a link between an invoice and the UI (invoicing can take place before or after dispatch). There are two exceptions: dispatch of products from facilities, and trans-loading of products. Information on these events should be transmitted 24 hours prior to their occurrence (*Art. 34.3*).

   Certain derogations from the 3 hour rule apply: SMEs (as defined in EU Recommendation 2003/361/EC), as well as those who handled less than 120 million unit level UIs at Union level during the previous year can transmit information up to 24 hours after an even has occurred *(Art. 34.4).*

   Those that do not meet the above criteria will nonetheless benefit from a transitional period, applicable to all economic operators, until 20 May 2028. During this period they may transmit required information up to 24 hours after an even has occurred *(Art.34.5).*

   These derogations do not apply to dispatch and trans-loading events, for which prior reporting will always be required *(Art.34.3).*

3. **Ensure UI encoding using the correct data carriers**: Data carriers (i.e. barcodes) encode the UIs. The types of data carriers permitted have been strictly limited to three per level (*Art. 21.1; Art. 21.5)*: for unit packets, they are: **Data Matrix**, **QR Code** and **DotCode**; for aggregated packaging, they are: **Data Matrix**, **QR Code** and **Code 128.**

   Finally, there are specific rules on quality of the data carriers *(Art.22)*, including that each data carrier must include a human-readable code to allow the information related to the UI to be accessed without the scanning device, if needed (*Art.23*).

Table of main responsibilities – distributions and wholesalers

The following table sets out the main responsibilities of distributions and wholesalers under the traceability system. Please note, however, that this is not exhaustive and the **Implementing Regulation (EU) 2018/574** and its accompanying **annexes** should be consulted for further details.

Actor	**Type of responsibility**
Distributors and wholesalers	<u>Identifier codes</u> – Request an economic operator identifier code (Art. 14) – Request a facility identifier code (Art. 16) – Request a machine identifier code (Art. 18) <u>Request aggregated level Unique Identifier</u> (if applicable) – Decision to request aggregated level UIs from ID issuer or self-generate in accordance with relevant ISO standards (Art. 10) – If requesting from ID issuer: introduce request (Art. 13.). – If generating directly: generate UIs in accordance with relevant ISO standards (Art. 10). <u>Apply aggregated level Unique Identifier to packs</u> (if applicable) – Marking of aggregated packets with UIs (Art. 10); for UIs issued by ID issuers: adding a timestamp (Art. 11.3) <u>Data carriers</u> (if applicable) – Encoding of aggregated level UIs (Art. 21) – Ensure quality of optical barcodes (Art. 22) – Inclusion of human-readable code into each data carrier (Art. 23) <u>Recording and transmitting of information</u> – Recording and transmission of information on product movements to the router (Art. 32) within the permitted time

	frames (Art. 34) – Recording and transmission of transactional information to the router (Art. 33) within the permitted time frames (Art. 34)

III. OPERATORS OF FIRST RETAIL OUTELTS

Under the traceability system, the movement of tobacco products must be recorded from the manufacturer to the last economic operator before the **first retail outlet**.

Article 2(3) of the Implementing Regulation defines the **first retail outlet** as the facility where products are placed on the market (i.e. made available to consumers located in the Union) for the first time, including vending machines used for the sale of tobacco products.

The only task under the traceability system for operators of **first retail outlets** is to ensure that they obtain **economic operator identifier codes and facility identifier codes**.

(Nb: *If your business functions as both a first retail outlet and a wholesaler/distributor to subsequent retail outlets, you will be required to ensure traceability of the products you handle until dispatch to the first retail outlet. For wholesale tobacco products, please follow the requirements for wholesalers/distributor set out in the previous section*.)

Application for economic operator and facility identifier codes

Key requirements:

1. Request identifier codes for economic operators and facilities from relevant ID issuer: The only task under the traceability system for operators of **first retail outlets** is to obtain **economic operator identifier codes and facility identifier codes** from the relevant ID issuer* (*Art. 14; Art. 16*). Obtaining these is required in order to ensure that other economic operators can deliver to the retail outlet whilst meeting their obligations under the system.

It is useful to remember that operators of first retail outlets can arrange to have their applications for identifier codes carried out by another (third party) economic operator (such as by one of their supplies, e.g. one of their distributors or wholesalers) (*Art. 14.3; Art. 16.3*). Such a third party must also be registered and have already obtained identifier codes. The registration by a third party must have the full consent of the operator of the first retail outlet, and the third party is required to communicate all details of the registration, including all codes which have been assigned, to the operator.

***Where to request IDENTIFIER CODES**

- Operators of first retail outlets -

To obtain **economic operator** identifier codes: **operators of first retail outlets** will either need to apply to the ID issuer competent for each Member State in which they operate. (*Art. 14.1*) or arrange for the application to be discharged by another registered third party economic operator (e.g. a registered distributor or wholesaler) (*Art. 14.3*)

To obtain **facility** identifier codes: **operators of first retail outlets** will either need to apply to the ID issuer competent for the Member State in which the facility is located (*Art. 16.1*) or arrange for the application to be discharged by another registered third party economic operator (e.g. a registered distributor or wholesaler) (*Art. 16.3*).

Table of main responsibilities – operators of first retail outlets

The following table sets out the main responsibilities of operators of first retail outlets under the traceability system. Please note, however, that it is not exhaustive and **Implementing Regulation (EU) 2018/574** and its accompanying **annexes** should be consulted for further details.

Actor	**Type of responsibility**
Operators of first retail outlets	Identifier codes – Apply for an economic operator identifier code (Art. 14) *or* arrange for the application to be carried out by a registered third party (such as by a registered distributor or wholesaler) – Request a facility identifier code (Art. 16) *or* arrange for the application to be carried out by a registered third party (such as by a registered distributor or wholesaler)

IV. MEMBER STATE AUTHORITIES

The requirements for **Member State authorities** can be grouped under the following headings: **A)** Appointment of an ID issuer; **B)** Access to recorded information.

A. Appointment of an ID issuer

Key requirements:

1. Appoint ID issuer: Unique identifiers (UIs) to be applied to unit packets (and, where applicable, aggregated packaging) must be generated by independent third parties – known as 'ID issuers' – appointed by each Member State *(Art. 3).* This appointment procedure will be one of the first technical steps in the establishment of the traceability system, and must be completed within 1 year from entry into force of the **Delegated Regulation** *(Art. 3.1).* Examples of entities that Member States may choose to appoint include state agencies, non-profit organisations or specialised IT providers. To assist Member States in the appointment process, the Regulation sets specific criteria, including on independence *(Art. 3; Art. 35),* that the ID issuer should fulfil. Each ID issuer shall be equipped with a unique identifier code *(Art. 3.4).* The same ID issuer can be appointed by more than one Member State, but must then be identifiable by the same code *(Art. 3.5).* ID issuers intending to engage in subcontracting will only be eligible for appointment if they have communicated the identity of the proposed subcontractors to Member States. (In addition, all subcontractors are subject to the independence criteria set out in Article 35).

2. Notify the Commission and ensure publication of information on ID issuer: Within one month of completing the appointment, each Member State must notify the Commission of the ID issuer it has appointed and of its identification code *(Art. 3.6).* It must also ensure that information on the appointed ID issuer is made publicly available *(Art. 3.7).*

B. Access to recorded information

Key requirements:

1. Designate national administrator(s): Authorities will need to designate a national administrator(s) who shall be responsible for creating, managing, withdrawing and granting subsequent access rights relating to the repositories system within the national administration concerned (*Art. 25.1.k*).

2. Access information via the surveillance tool: The secondary repository, which hosts a copy of all recorded data, will contain a surveillance tool (in the form of graphical and non-graphical user interfaces) that will allow Member States and the Commission to search and analyse tobacco product movements remotely in order to investigate and detect possible irregularities. In particular, the surveillance tool will need, first, to allow all data

stored in the repositories system to be accessed and queried *(Art. 27.2)* and, second, to make automatic alerts and periodic report requests possible *(Art. 27.3)*, based on individual risk-assessment rules that are linked to specific events (e.g. the appearance of duplicate UIs in the legal supply-chain). In this respect, it will be possible for authorities to request that automatic alerts and/or reports are sent to a specific external address, such as an e-mail address or IP address *(Art. 27.4)*.

3. Access recorded information via handheld devices (offline mode): Member State competent authorities will need to have the possibility to extract and read the information on unique identifiers anywhere on the spot using handheld scanning devices. In other words, they will need to be able to identify the information codified in the UI without accessing the repository system. This will be facilitated through so-called 'offline flat-files' that will be created by each ID issuer, and which competent authorities can download from the secondary repository onto handheld devices (e.g. smartphones or scanners) to be used by them *(Art. 20)*. By means of these 'flat-files', the handheld devices will then be able to extract the information from the UI and make it available to the user in offline mode.

4. Exchange of information with external systems: The traceability system will enable Member States and the Commission to feed information that is stored in the repositories system into other external systems that are used and managed by them. This will mainly be facilitated in the following ways. The repositories system should allow for the possibility to download full or selected sets of the data that it stores *(Art. 25.1. l)*. This data set can then be linked with other external systems. In particular, the traceability system will store product information using the Administrative Reference Code (ARC), which will ensure interoperability with EMCS. In a similar vein, information on the TP-ID of every recorded product will allow Member States to link supply-chain data to the relevant product reporting information stored in the EU Common Entry Gate (EU-CEG).

Table of main responsibilities – Member State authorities

The following table sets out the main responsibilities of Member State authorities under the traceability system. Please note, however, that it is not exhaustive and **Implementing Regulation (EU) 2018/574** and its accompanying **annexes** should be consulted for further details.

Actor	**Type of responsibility**
Member State authorities	<u>ID issuer</u> – Selection and appointment of an ID issuer (Art. 3.1) – Ensure the independence of ID issuers, providers of repository services and anti-tampering devices as well as, where applicable, their subcontractors (Art. 35) – Notify Commission of identity of ID issuer appointed and code; ensure publication of related information (Art. 3.6 and 3.7) <u>Repositories system</u> – Designation of national administrator managing access rights to surveillance tool (Art. 25.l.*k*.) – Access traceability information via the survey tool and handheld devices for the purposes of enforcement; exchange information with external systems where necessary.

V. EUROPEAN COMMISSION

The requirements for the **European Commission** relate mainly to the area of the **repositories system**.

Repositories system

Key requirements:

1. Approval of primary repository providers: The European Commission will be required to assess all proposed primary data storage providers and draft data storage contracts notified to it by manufacturers and importers – in particular as regards their independence and technical capacity – and to approve or reject them, within three months of the date of receipt of the notification. (*Annex I, Part A.3*)

2. Publication of lists of notified and approved primary repository providers: the European Commission will also be responsible for ensuring that lists of all notified and approved primary data storage providers are published on a website (*Annex 1, A.8*).

3. Appointment of the 'secondary repository': The Commission will be responsible for appointing, from amongst the approved providers of the primary repositories, the provider of the (single) secondary repository. The procedures governing this process are set out in Annex 1, letter B. The appointment will take place no later than 8 months following entry into force of the Delegated Regulation and the result will be published by the Commission. Thereafter, each primary provider will be obliged to enter into a contract with the provider of the secondary repository (and contracts will have to be signed and submitted to the Commission within one month of the date of the appointment of the secondary repository).

The secondary repository will host a global copy of all supply-chain events that have been recorded and stored in the primary repositories. Most importantly, it will provide for user interfaces that will allow Member States to run queries and define rules for automatic alerts and periodic reports related to the supply-chain data stored in the system. The provider of the secondary repository will be responsible for defining the data format and exchange modalities as well as a common data dictionary to be used by primary repositories and the router *(Art. 28).* In addition, there are a number of other general technical requirements *(Art. 25)* and procedural rules *(Annex 1, letters B + C)* that will apply to the provider of the secondary repository in order to ensure independence, functionality and interoperability of the system.

The provider of the secondary repository will also be responsible for establishing the router, which will provide a single entry-point for the reporting of data by economic operators other than manufacturers and importers *(Art. 29).* A copy of that data will be forwarded to the individual primary repositories concerned.

Table of main responsibilities – European Commission

The following table sets out the main responsibilities of the European Commission under the traceability system. Please note, however, that it is not exhaustive and **Implementing Regulation (EU) 2018/574** and its accompanying **annexes**, as well as **Delegated Regulation, (EU) 2018/573** should be consulted for further details.

Actor	**Type of responsibility**
European Commission	<u>Repositories system</u> – Approval of primary repository providers (Annex 1, A.3 and 4) – Publication of lists of notified and approved primary repository providers (Annex 1, A.8) – Appointment of a provider of the secondary repository (Annex 1, B.1) and publication of the identity of the provider (Annex 1, A.3)

II. System of security features for tobacco products

Overview

The aim of the system of security features is to enable competent authorities and consumers to identify legitimate tobacco products. Article 16 requires all unit packets of tobacco products placed on the EU market to carry a tamper proof security feature composed of visible and invisible elements.

The key requirements of the system of security features are set out in:

- **Article 16 TPD**;
- **Commission Implementing Decision (EU) 2018/576** on technical standards for security features applied to tobacco products (including its Annex I)

Detailed description of the system

Article 16(1) of the TPD requires all unit packets of tobacco products to carry a security feature that is:

- Tamper proof and composed of visible and invisible elements;
- irremovably printed or affixed (this includes a combination of printed and affixed);
- indelible;
- not hidden or interrupted in any form, including through tax stamps and price marks.

Key additional requirements on technical standards for security features are set out in detail in the **Commission Implementing Decision (EU) 2018/576 on technical standards for security features applied to tobacco products**.

Key stakeholder requirements under the system of security features for tobacco products

The following sections set out the key requirements of the system of security features, according to stakeholder.

Unless otherwise stated, all articles referenced are those of **Implementing Decision (EU) 2018/576 on technical standards for security features applied to tobacco products (including its Annex I)**.

I. MEMBER STATE AUTHORITIES & MANUFACTURERS AND IMPORTERS

The requirements for **Member State authorities** can be grouped under the following headings: **A**) Authentication elements and security features; **B**) Integrity and independence of security features; **C**) Verification of authenticity of security features.

The requirements for **manufacturers and importers** fall mainly under: **A**) Authentication elements and security features. They will be primarily responsible for ensuring compliance with the requirements laid down by the Member States in which they place their products on the market.

A) Authentication elements and security features

Key requirements

Member States:

1. **Ensure correct composition of security features**: Member States will have to ensure that each security feature applied to unit packets of tobacco products placed on their markets is composed of five or more different types of 'authentication elements'. It will also be necessary to ensure that, among these, at least one is overt[2], one semi-covert[3], and one covert[4] (*Art. 3.1*), and at least one provided by a third-party who meets the requirements of independence that are set out in Article 8 of the Decision (*Art. 3.2*).

2. **Communicate permitted combination(s) of authentication elements**: Each Member State will have to communicate to manufacturers and importers of tobacco products the combination, or combinations, of authentication elements that must be used for the security features applied to products placed on their market. The combination(s) may include any of the authentication elements set out in Annex 1 of the Decision, but Member States will also be free to choose alternative compliant authentication elements. The relevant combinations(s) must be communicated by Member States to all manufacturers and importers of tobacco products by **20 September 2018**. Any subsequent changes to combinations must be communicated by Member States 6 months prior to the date on which such changes should take effect (*Art. 3*).

[2] 'Overt' means directly perceptible by one or more of the human senses without recourse to external devices. The 'overt' category of authentication solutions referred to in ISO 12931:2012 shall be presumed to meet this definition.

[3] 'Semi-covert' means not directly perceptible by the human senses but detectable by those senses through the use of external devices, such as a UV torch or a special pen or marker, which do not require expert knowledge or specialist training. The 'covert' category of authentication solutions authenticated with off-the-shelf tools referred to in ISO 12931:2012 shall be presumed to meet this definition.

[4] 'Covert' means not directly perceptible by the human senses and detectable only through the use of purpose built tools or professional laboratory equipment. The 'covert' categories of authentication solutions requiring purpose built tools and forensic analysis referred to in ISO 12931:2012 shall be presumed to meet this definition.

3. **Decision and communication relating to use of tax stamps as security features**: Each Member State will have the possibility to decide whether its tax stamps (or national identification marks for fiscal purposes) can be used as the security feature. In this respect, they will have to verify whether their tax stamp or national identification mark complies with the requirements of Article 3 of the Decision and Article 16 of the TPD (*Art. 4.1*). In the case of partial compliance, Member States will have to inform manufacturers and importers of tobacco products by **20 September 2018** of the additional types of authentication elements to be used in conjunction with the tax stamp or national identification mark (*Art. 4.2*).

Key requirements

Manufacturers and importers:

1. **Ensure compliance with the security feature requirements laid down by each Member State in which their products are placed on the market**: Manufacturers and importers must ensure that they are fully informed of the individual security feature requirements of the Member State(s) in which their products are placed on the market, and that they are capable of complying with these rules.

B) Integrity and independence of security features

Key requirements

Member States:

1. **Ensure integrity of security features**: Competent authorities will be free to decide whether or not a rotation scheme for security features is implemented and how this should operate (*Art. 6.1*). An exception to this rule will exist for cases in which a Member State has reason to believe that the integrity of an authentication element of a security feature is compromised. In such cases it will have to ensure that this is replaced or modified. The manufacturers/importers and security feature providers concerned will have to be informed within five working days (*Art. 6.2*).

   Member States will also have to ensure that security features are applied to tobacco products in such a way that they cannot be replaced, reused or modified *(Art. 5.2.b).* Formal guidelines or requirements may apply at national level on the security of production and distribution procedures for security features *(Art. 6.3).*

2. **Require at least one authentication element to be provided by an independent third-party provider**: Each security feature will have to be composed of at least one authentication element that is provided by an independent third-party (*Art. 3.2*). To that end, Member States will have to ensure that the third-party providing the authentication element meets the relevant criteria on independence (*set out in Article 8*). This includes ensuring that the provider is independent from the tobacco industry both in legal terms (legal structure, organisation and decision-making processes, especially no direct or indirect control over it by the tobacco industry; Article 8.1(a)) and in financial terms (less than 10% of the annual turnover of the provider's undertakings – or group of undertakings – is generated by goods and services supplied to the tobacco industry over the past 2 calendar years before assuming its functions, and less than 20% for each subsequent calendar year; Article 8.1(b)).

   Member States will have to ensure that no conflict of interest with the tobacco industry exists among the persons responsible for the management of the provider (*Article 8.1(c)*). In the case of sub-contracting, the main provider will be responsible for ensuring compliance with the independence criteria (*Article 8.2*). Member States may request necessary documentation to assess compliance with the independence criteria (*Article 8.3*), and any change in circumstance lasting for 2 consecutive years must be communicated to Member States (*Article 8.4*).

C) Verification of authenticity of security features

Key requirements

Member States:

1. **Be in a position to verify the authenticity of tobacco products destined for a Member State's own national markets**: Based on the permitted combination(s) of authentication elements that they have been communicated to manufactures/importers, Member States will have to ensure that they possess the means and knowledge necessary to determine whether a product placed on their market is authentic (*Art. 7.1*). The authenticity will have to be determined by analysing the security feature, composed of permitted authentication elements, which is applied to the unit packet of the tobacco product concerned**.**

   To that end, Member States will have to require manufacturers and importers of tobacco products located on their territory to provide, upon written request, samples of unit packets, including the applied security feature *(Art. 7.2).* Member States may be requested to make these samples available to the Commission *(Art. 7.2)*.

2. **Offer assistance in verifying the authenticity of tobacco products destined for another national market:** Member States will be required to assist each other, upon

request, in verifying the authenticity of tobacco products destined for each other's national markets (*Art. 7.3*). This form of mutual assistance is crucial in light of the free movement of products and will further support competent authorities in their fight against illicit products. Assistance may take the form of sharing product samples (referred to above) or information on the security feature concerned.

Table of main responsibilities

The following table sets out the main responsibilities of the Member State authorities, as well as manufacturers and importers, under the security features system. Please note, however, that it is not exhaustive and **Implementing Decision (EU) 2018/576** and its accompanying **Annex I** should be consulted for further details.

Actor	**Type of responsibility**
Member States	<u>Composition of security features</u> – Ensure compliant composition of security features (Art. 3.1) – Communication of permitted combination(s) of authentication elements to manufacturers and importers (Arts. 3.3 / 3.4 / Annex 1) <u>Tax stamp / fiscal identification mark as the security feature</u> – If Member State wishes to allow existing tax stamp / fiscal identification mark to be used as the security feature: ensure that tax stamp / national identification mark is compliant with all legal requirements (Art. 4.1) – If tax stamp / fiscal identification mark intended for use as the security feature is not compliant with all legal requirements: inform manufacturers and importers of additional types of authentication elements required (Art. 4.2 / 4.3) <u>Integrity of security features</u> – Ensure the integrity of security features (Arts. 3.2 / 5.2.*b* / 6 / 8) <u>Independence</u> – Require at least one of the authentication elements used in a security features to be provided by an independent third-party meeting the criteria on independence (Arts. 3.2 / 8) <u>Verifying the authenticity of tobacco products</u> – Ensure it is possible to identify and verify the authenticity of

	tobacco products destined for one's own national market (Art. 7.1) – Ensure that manufactures and importers provide Member States with sample products upon request, and that samples are made available by Member States to the Commission upon request (Arts. 7.2) – Mutual assistance in supporting other Member States to verify the authenticity of tobacco products destined for their national markets (Art. 7.3)
Manufacturers and importers	<u>Authentication elements and security features</u> – Ensure information on the requirements of individual Member States in relation to security features is known; ensure compliant security features are applied to unit packets of tobacco products placed on the market of the various EU Member States.