

## I. GENERAL PROVISIONS

### MINISTRY OF FINANCE

**17604** *Order HAC/1365/2018, of 12 December, approving the technical standards regarding traceability and security features for tobacco products, for the development of articles 21 and 22 of Royal Decree 579/2017, of 9 June, regulating certain aspects related to the manufacture, presentation and sale of tobacco and related products.*

The illegal sale of tobacco products has a huge impact on public health and state functioning. It contributes to the failure to comply with health regulations on labelling, ingredients and emissions, hindering public control of market operators, facilitating its consumption by minors, subverting public income and favoring the trafficking of other illegal substances and the spreading of organized crime.

Along with efforts made by the competent authorities, various initiatives have been created on an international level, in Europe and in Spain, in order to fight against illegal trade. The World Health Organization Framework Convention on Tobacco Control from 2003, of which Spain and the European Union are part, expects a series of measures to be adopted by States to eliminate any type of illegal trade. In the creation of the Framework Convention, the Protocol for the Elimination of the Illegal Trade of Tobacco Products was adopted at the Party Conference of 2012. This is an international treaty that establishes diverse mechanisms to reinforce the control of the supply chain through licenses and authorizations, product tracking and traceability systems, public operator registries and sales control.

One of the main measures created in the European Union in the application of the Framework Convention and the Protocol, was the adoption of a traceability system and security features, in order to fight against illegal tobacco commerce and to ensure consumer security and compliance with healthcare, customs and fiscal regulations. Directive 2014/40/EU, on the approximation of laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products includes the implementation of a system to permit the follow-up and tracking of each unit of tobacco products across the entire Union in its article 15. This facilitates the control of the entire supply chain from the manufacturing or importation phases to the sale to the consumer, passing through the stages of distribution and storage, control of machines and facilities used or shipping routes, imposing obligations on the operators and the Member States. Along with this traceability system, article 16 establishes the obligation to include certain security features in all packaging units, so as to ensure the authenticity of the tobacco products.

The transposition of Directive 2014/40/EU to the Spanish regulation, with regards to traceability and security features, was carried out via Royal Decree – Law 17/2017, of 17 November, modifying Law 28/2005, of 26 December, on

healthcare measures on smoking and regulating the sale, supply, consumption and advertising of tobacco products, to transpose Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014 and Royal Decree 579/2017, of 9 June, regulating specific aspects related to the manufacture, presentation and sale of tobacco and related products. Royal Decree 579/2017, of 9 June, entrusting the Ministry of Public Finance and Public Service with the traceability and security features for tobacco products, attributes it with the regulatory competence, through a ministerial order, to issue the necessary development and implementation regulations.

Through the implementing acts of the 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, and the Commission Implementing Decision (EU) 2018/576, of 15 December 2017, on technical standards for security features applied to tobacco products, the necessary technical standards for the implementation of traceability and security features have been approved.

These implementing acts establish obligations for all of the operators and are directly applicable to all of their elements. However, technical standards of development and implantation should be issued regarding the traceability and security features of the tobacco products for their appropriate application in Spain.

This Order is issued in the exercising of the authorization detailed in articles 21.13 and 22.2 of Royal Decree 579/2017, of 9 June, regulating certain aspects regarding the manufacture, presentation and commercialization of tobacco and related products. Therefore, the technical standards regarding traceability and the security features of the tobacco products are approved. Therefore, according to the Council of State, I present:

## CHAPTER I

### **General provisions**

#### *Article 1. Objective.*

The objective of this order is to establish the technical standards of development and execution for the traceability and security features of tobacco products, in accordance with articles 21 and 22 of Royal Decree 579/2017, of 9 June, regulating certain aspects regarding the manufacture, presentation and sale of tobacco and related products, and in accordance with the Commission Implementing Regulation (EU) 2018/574, of 15 December 2017, on the technical standards for the establishment and functioning of a traceability system for tobacco products, and the Commission Implementing Decision (EU) 2018/576 of 15 December 2017 on technical standards for security features applied to tobacco products.

#### *Article 2. Definitions.*

For the purpose of this Order, the definitions appearing in article 2 of

Directive 2014/40/EU, in article 2 of the 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 and article 2 of the Commission Implementing Regulation (EU) 2018/576, of 15 December 2017, on the technical standards for security features applied to tobacco products.

*Article 3. Scope of application.*

1. Chapter II of this Order shall be applicable to tobacco products that are sold or added in any part of the country, including the peninsula, Balearic Islands, Canary Islands, Ceuta and Melilla, as well as those tobacco products that are manufactured in Spain, and are intended for exportation.

Chapter II of the Order also shall be applicable to economic operators and operators of retail outlets operating in at least one facility in the country.

2. Chapter III of this Order shall be applicable to tobacco products that are sold in any part of the country, including the peninsula, the Balearic Islands, the Canary Islands, Ceuta and Melilla.

## CHAPTER II

### **Traceability of tobacco products**

*Article 4. Designation of the identification (ID) Issuer.*

1. The National Stamp Factory and Spanish Mint Public Business Entity has been designated as the issuer of the relevant ID across the country, in accordance with article 3.1 of the Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on the technical standards for the establishment and functioning of a traceability system for tobacco products.

2. The Tobacco Market Commission shall notify the European Commission of the designation of the ID issuer and its identification code within a period of one month as of its designation.

Likewise, the Tobacco Market Commission guarantees that the identity of the ID issuer and its identification code shall be available to the public and may be accessed at the website of the Ministry of Public Finance.

*Article 5. Obligations of the ID issuer.*

1. The entity designated to issue the ID should ensure compliance with all requirements, conditions and obligations for the same, as established in article 15 of 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/CE, as well as those established in their developing provisions and, specifically, those detailed in the 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 and other applicable regulations.

2. In the case in which the entity designated as issuer of the ID intends to use a subcontractor to carry out its functions, it should previously inform the Tobacco Market Commission of the identity of the subcontractors and should sufficiently accredit compliance with the limits and requirements according to the law.

3. The entity that is designated as the ID issuer should accredit compliance with the criteria of independence and a lack of conflicts of interest before the Tobacco Market Commission, as detailed in article 35 of the Commission Implementing Regulation (EU) 2018/574 of 15 December 2017, on the technical standards for the establishment and operation of a traceability system for tobacco products.

Likewise, it should notify the Tobacco Market Commission regarding any real or potential threats or attempts to exercise undue influence that may undermine its independence.

4. In the case in which the entity designated as ID issuer seriously breaches its obligations, with the report of the Tobacco Market Commission accrediting said breach, another entity that complies with the requirements and conditions detailed in the applicable regulations may be designated as the relevant authority.

#### *Article 6. Competent issuer of ID for the creation and issue of unique identifiers for tobacco products manufactured in the Union.*

In compliance with article 4.1, second paragraph of Commission Implementing Regulation (EU) 2018/574 of 15 December 2017, all tobacco products that are sold in any part of the country should include their corresponding unique identifier, issued by the entity designated as the ID issuer in this Order.

#### *Article 7. Anti-tampering devices.*

1. In compliance with article 7 of Commission Implementing Regulation (UE) 2018/574 of 15 December 2017, anyone supplying and installing anti-tampering devices should provide a declaration to the Tobacco Market Commission that the device fulfils all requirements of this Regulation.

2. Anti-tampering device suppliers should accredit compliance with the criteria of independence and a lack of conflicts of interest before the Tobacco Market Commission, in accordance with article 35 of the 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.

Likewise, they should inform the Tobacco Market Commission of any potential threat or attempt to exercise undue influence, which may potentially jeopardize its independence.

#### *Article 8. Structure of the unique identifiers.*

In the case in which the ID issuers use encryption or compression techniques for the creation of unique identifiers on a unitary level, they should notify the Tobacco Market Commission of the algorithms used for this type of encryption/compression.

*Article 9. Identifier codes for operators, facilities and machines.*

1. The economic operators and operators of the first retail outlets should request an «economic operator identifier code» from the ID issuer designated in this Order when operating at least one facility in any part of the country.

2. According to that included in the Commission Implementing Regulation (EU) 2018/574 of 15 December 2017, any physical or legal entity that is involved in the sale of tobacco products, including their export, from the manufacturer to the last economic operator before the first retail outlet shall be considered an economic operator.

This includes, among others, state tobacco and stamp retailers when they carry out any commercial tobacco product activity distinct from making it available to consumers, including the supply and transport of tobacco products to vending machines used to sell tobacco products, authorized by applicable regulations.

3. According to that established in Commission Implementing Regulation (EU) 2018/574 of 15 December 2017, the following are considered first retail outlets:

a) State tobacco and stamp retailers in carrying out their activity of making tobacco and stamp products available to the consumer.

b) Vending machines used for the sale of tobacco products, authorized as set out on applicable regulations.

c) Duty free shops, defined in article 4, section 31 of Law 38/1992, of 28 December on Special Taxes, located in a port or airport area in Spain or the Balearic Islands.

d) Any others that, according to Commission Implementing Regulation (EU) 2018/574 of 15 December 2017, should have this consideration.

4. In cases established by sections 2, second paragraph, and 3.b) of the present article, economic operators and operators of the first retail outlets will have until 1 October 2019 to ensure full compliance with their obligations.

5. All facilities in any part of the country, from the manufacture to the first retail outlet, are identified via a «facility identifier code» generated by the ID issuer.

6. The machines located in any part of the country shall be identified by a «machine identifier code» generated by the ID issuer.

*Article 10. Deactivator of identifier code for operators, facilities and machines.*

1. If an economic operator or the operator of a first retail outlet, for any reason detailed in Law 13/1998, of 4 May on Regulation of the Tobacco Market and Fiscal Regulations, or in compliance with any other applicable provision,

loses or has its clearance, administrative concession or authorization removed, the issuer of the ID should deactivate or request the «economic operator identifier code » of the operator or, upon request of the Tobacco Market Commission or relevant authority.

In these cases, the Tobacco Market Commission or relevant authority should inform the economic operator or the first retail outlet operator of the deactivation, as well as the causes of the same.

The deactivation of an operator identifier code will lead to the automatic deactivation of the facility identifier codes and those of the corresponding machine.

2. In duly justified cases, upon request of the operator or prior requirement of the Tobacco Market Commission or relevant authority, the ID issuer shall deactivate any «facility identifier code».

In these cases, it is necessary to inform the economic operator or the operator of a first retail outlet regarding said deactivation, as well as the reasons for the same.

The deactivation of an identifier code of a facility shall lead to the automatic deactivation of the identification codes of the corresponding machine.

3. In duly justified cases, upon request of the operator or when required by the Tobacco Market Commission or the relevant authority, the ID issuer shall deactivate any «machine identifier code».

In these cases, the operator should be notified regarding the deactivation and the causes of the same.

#### *Article 11. Designation of national administrator.*

1. The State Tax Administration Agency has been designated as the national administrator, for all purposes detailed in article 25.1.k) of the Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on the technical standards for the establishment and functioning of a traceability system for tobacco products.

2. The designated national administrator will ensure that the Tobacco Market Commission and other public authorities, as requested, have all necessary accesses to exercise their functions.

#### *Article 12. Presentation of the annual audit report on data storage.*

The annual report established on article 21.8 of Royal Decree 579/2017 of 9 June, regulating certain aspects on the manufacture, presentation and sale of tobacco and related products will be presented to the Tobacco Market Commission.

## CHAPTER III

### **Tobacco product security features**

#### *Article 13. The use of fiscal markings as security features.*

1. In the fiscal markings of the tobacco products, all elements of authentication required in Spain shall be included as security features, according to the conditions determined by the Ministry of Public Finance, in compliance with the requirements of Commission Implementing Decision (EU) 2018/576 and article 16 of Directive 2014/40/EU.

2. The authentication elements shall be supplied across the country by the National Stamp Factory and Spanish Mint Public Business Entity, as issuer of all of the fiscal markings detailed in the governing regulations of the charges that shall specifically be placed on the diverse tobacco products.

#### *Article 14. Verification of the authenticity of the tobacco products.*

The Tobacco Market Commission shall demand that the manufacturers and importers of tobacco products located in the country provide, via written request, samples of the tobacco products sold in Spain. The samples shall be provided in a package unit format and shall include the security measures with all of the authentication elements demanded in Spain.

#### *Article 15. Independence of the providers of authentication elements.*

Upon request by the Tobacco Market Commission, the Public Business Entity National Stamp Factory and Royal Spanish Mint and its potential subcontractors, as providers of authentication elements, should provide the necessary documents to assess compliance with the criteria of independence detailed in article 8 of the Implementing Decision (EU) 2018/576.

#### *Additional unique provision. Special regime of the Autonomous Community of the Canary Islands.*

As established on the fourth additional unique provision of Law 28/2005, of 26 December, on health measures against tobacco addiction and regulating sales, supplies, consumption and advertising of tobacco products., the Autonomous Community of the Canary Islands shall be granted the competencies of monitoring, control and inspection of the manufacturers and sellers of tobacco on the islands, notwithstanding that established in the provisions of the Law of the European Union and applicable state laws and competencies.

#### *Transitional provision. Transitional regime.*

Cigarettes and rolling tobacco that have been manufactured in the European Union or imported to the Union prior to 20 May 2019 and that are not

marked with a unique identifier (UI) in the package unit in accordance with Implementing Regulation (EU) 2018/574 and that do not have a security feature in accordance with the Implementing Decision (EU) 2018/576, may remain in free circulation until 20 May 2020.

Tobacco products other than cigarettes and rolling tobacco that have been manufactured or imported to the European Union before 20 May 2024 and that are not marked with a unique identifier (UI) on the package unit, according to Implementing Regulation (EU) 2018/574 and that do not have a security feature in accordance with Implementing Decision (EU) 2018/576, may remain in free circulation until 20 May 2026.

Sole repeal provision. *Regulatory repeal.*

Upon entry into effect of this Order, all provisions of an equal or lower status that oppose that included in this document shall be repealed.

First final provision. *Powers used.*

This Order has been created under the scope of article 149.1.14.<sup>a</sup> of the Constitution, attributing the State with exclusive competence over the General Treasury.

Second final provision. *Entry into effect.*

This Order shall enter into effect on the day following its publication in the «Official State Bulletin».

However, chapters II and III of this Order shall be applied to cigarettes and rolling tobacco as of 20 May 2019 and to tobacco products other than cigarettes and rolling tobacco as of 20 May 2024.

Madrid, 12 December 2018.– The Minister of Finance, María Jesús Montero Cuadrado.