MINISTRY FOR
HEALTH, SOCIAL SERVICES
AND EQUALITY
SECRETARY GENERAL
HEALTH AND CONSUMER
GENERAL MANAGEMENT
GENERAL MANAGEMENT
PUBLIC HEALTH AND QUALITY
INNOVATION
GENERAL BRANCH
HEALTH PROMOTION AND
Epidemiology

DRAFT ROYAL DECREE REGULATING THE MANUFACTURE, PRESENTATION AND SALE OF PRODUCTS AND PRODUCT SNUFF RELATED.

This Royal Decree transposes into Spanish law Directive 2014/40 / EU European Parliament and Council of April 3, 2014 on the approximation of the laws, regulations and administrative provisions of the Member States relating to manufacture, presentation and sale of snuff products and related products, and Directive 2001/37 / EC repealing, which aims to facilitate the smooth functioning the internal market for snuff and related products in the European Union, on the basis of a high level of protection of human health, particularly with regard to young, and to fulfill the obligations under the WHO Framework Convention for the Control with of Snuff ("FCTC").

Through this Royal Decree, the requirements are updated based on current knowledge and latest technological developments through a harmonized approach in all Member States, and It replaces the Royal Decree 1079/2002, of 18 October, by which regulates the contents maximum nicotine, tar and carbon monoxide in cigarettes, labeling snuff products, as well as measures relating to ingredients and denominations of snuff products, which is repealed.

The aim, therefore, of this Royal Decree is to develop certain aspects of manufacture, presentation and sale of snuff products while incorporating requirements specific tobacco-related products, such as devices capable of nicotine delivery products and herbal smoking.

The royal decree consists of forty two items, grouped in a preliminary title and three titles; an additional provision; a transitional provision; a rescinding provision four final provisions and three annexes.

The preliminary title establishes general provisions as are the subject of the royal decree and Definitions of terms expressed throughout its articles.

Title I deals with the products of snuff, which is most of it. Within of this title the requirements defined constituents and emissions, on methods for analysis on the test facilities. Communication of the list remains ingredients by manufacturers and importers but establishes for certain additives included on a priority list, including notification obligations reinforced the realization Extensive toxicological studies and evaluation by health authorities. Are prohibits the marketing of products with characteristic aroma, or supposedly additives health benefits, or stimulating compounds or to provide energy or vitality.

Second, requirements on labeling and packaging of products updated

snuff by compulsory health warnings on all combined
packaging units, and any outside packaging, products snuff smoking
plus other text warnings and informational messages. This measure is in line with the
Framework Convention of the World Health Organization Snuff Control (FCTC)
ratified by Spain on December 30, 2004, and which provides in its Article 11 that the
health warnings in the labeling of snuff products in the form of images or
pictograms are an appropriate instrument for reducing the demand for snuff.
In addition, progress in the use of the latest and new technologies to improve the
traceability and safety of snuff products by highlighting their dial
unique identifier. This identifier will facilitate the tracking and tracing of these products and
ensure the verification of their authenticity. This regulation is in line with the Protocol
elimination of illicit trade of snuff products FCTC having been adopted 12
November 2012 at the fifth meeting of the Conference of the Parties in Seoul that Spain has
signed on December 23, 2014.
the existing ban is maintained above about snuff for oral use.
As for sales of snuff products, the directive is limited to their competence framework
own to regulate only cross-border distance sales within the internal market
European Union. This type of sales with those made at national level are already prohibited
Spain as set out in Article 3.6 of Law 28/2005 of 28 December on measures
health against smoking and regulating the sale, supply, consumption and advertising
snuff products.
Finally, Title II introduces the novel concept of snuff products, forcing a
marketing notice should include the available scientific studies and
market research.
Title II incorporates the regulation of smoking-related products such as
devices capable of releasing nicotine and herbal products for smoking. This
incorporation is given by the growing importance of these due to recent
market developments at European level that has necessitated inclusion being products
related to smoking.
With respect to devices susceptible to nicotine delivery under this Royal Decree
regulate only those whose use provided by the manufacturer as not allude to features
defined under the scope of medicines, in which case they would apply the provisions of
Royal Decree 1345/2007, of 11 October, by which regulates the authorization procedure,
registration and conditions of supply of medicinal products for human use manufactured
industrially.
Following the provisions of Directive 2014/40 / EU, a notification system is implemented that
It provides, inter alia, the requirements that products must meet to be marketed in
Spain, among which are the maximum volumes, peak concentrations
nicotine, including information leaflets and warnings about the addictive power of this
substance. A surveillance system that will allow to obtain updated data is also set
adverse reaction, or safety aspects of use. Since surveillance is
competence of the autonomous communities, a network of coordinated surveillance is defined
by the
Directorate General of Public Health, Quality and Innovation. Similarly to product
the snuff, the obligation for manufacturers and importers to report to the authorities set
health, among other information, the list of ingredients used.
In addition, outside the competence of the European Union also regulate those
activities not included in this directive to be the responsibility of Member States, as
distribution, sales and market control. Sales can only be made in certain

establishments and as for snuff products, prohibit sales to and by
minors. A ban on distance sales include both nationally and
border with hawking, considering that this provision does not affect
activities among traders.
With regard to products herbal smoking, undergo certain requirements are the
including a general warning, or failure to include elements that encourage consumption, or
suggesting be less harmful, or which are similar to food or cosmetics.
It is communicating ingredients used in making such also requires
products.
Similarly in the devices susceptible to nicotine delivery are regulated
activities such as distribution, sales, market control and monitoring of reactions
adverse.
Finally, as part of the notification procedures, it has established a record of
responsible for marketing to enable them to have knowledge in order to
compliance notifications of lists of ingredients and other requirements applicable to the
products for both release devices susceptible to nicotine products
herbal smoking
Title III regulates the sanctions regime, establishing inspection and control measures
health as well as on violations and penalties, actors and administrations
competent.
Extensions transitional periods set out in the transitional provisions and derogations
marketing of products under the above conditions, whose terms have already been
set out in the directive and repealing Royal Decree 1079/2002, of 18 October, laying
regulate the maximum levels of nicotine, tar and carbon monoxide from cigarettes,
labeling of products of snuff, as well as measures relating to ingredients and
product designations of snuff, and any other provisions of equal or lower rank
contrary to the provisions of this Royal Decree.
Establishing the competence title in the final provisions, incorporating law
European Union and enable the Ministry of Health, Social Services and equality
transpose the directives that the European Commission has pursuant to delegated acts and
implementing acts, following the provisions of Directive 2014/40 / EU.
In the handling of this provision has been collected reports from the regions and
It has had the participation of business organizations, trade unions,
scientific societies and social organizations, also have been consulted in a hearing.
This Royal Decree has the status of basic standard and is issued pursuant to the provisions of
Article
149.1.16 of the Spanish Constitution and the implementation of Articles 24, 25.3, and 40.5 and 6
of Law
14/1986 of 25 April, General Health.
At its behest of the Minister of Health, Social Services and Equality, with the approval
after the Minister of Finance and Public Administration, according to the State Council
and after deliberation by the Cabinet in its meeting on XX XX XXXX,
ORDER:
PRELIMINARY TITLE
General disposition
Article 1. Purpose.
This Royal Decree aims to regulate:
a) the ingredients and emissions products snuff and obligations
related information, as well as emission levels of tar, nicotine

and carbon monoxide in cigarettes;
b) certain aspects of labeling and packaging of snuff products, including
health warnings to be printed on the packaging of products
snuff and any outside packaging and traceability and security measures
applicable to snuff products to ensure compliance with the provisions
of this Royal Decree;
c) prohibition of marketing of oral snuff;
d) cross-border distance sales of snuff products;
e) the obligation to submit a notification in relation to snuff innovative products;
f) the marketing and labeling of certain products related products
of snuff; devices particularly susceptible nicotine release and containers
recharge, and herbal products for smoking.
Article 2. Definitions.
For the purposes of this Royal Decree, the following definitions apply:
1. "additive" means a substance other than snuff leaves, added a snuff product, its
packaging unit or any outer packaging;
2. "health warning" warning on adverse effects on human health
products, or other unintended consequences of its consumption, including warnings
text, the combined health warnings, general warnings and messages
information;
3. "Combined health warning" health warning established in this royal decree,
giving notice combine text with a photograph or illustration;
4. "tar" condensate raw anhydrous nicotine-free smoke;
5. "characterizing flavor" clearly perceptible smell or taste different from snuff, because
an additive or combination of additives, including fruits, spices, herbs, alcohol,
candy, menthol and vanilla among others, can be felt before the consumption of the product
of snuff, or during such use;
6. "flavoring": an additive conferring odor and / or flavor;
7. "substantial change in circumstances": an increase of at least 10% of the volume
sales by product category in at least five Member States of the Union
European, based on the sales data transmitted under Article 5,
paragraph 4, or an increased level of prevalence in the consumer group less
25 years old, at least five percentage points in at least five states
members to the affected product category on the basis of the report of
Special Eurobarometer 385 of May 2012 or equivalent prevalence studies. In
any event, be deemed to have been a substantial change in circumstances if the
Sales volume by product category Retail does not exceed 2.5% of sales
Total of snuff products at the level of the European Union;
8. "cigarette" snuff roll that can be consumed by a combustion process,
whose detailed definition is contained in paragraphs 3 and 6 of Article 59 of the Law
38/1992 of 28 December on Excise;
9. "cigarette" pure small, completely defined in Article 8 paragraph 1 of the
Directive 2007/74 / EC of 20 December 2007 on the exemption from
value added tax and excise duty of imported goods
by travelers from third countries;
10. "cigar" snuff roll that can be consumed by a process of
combustion, whose detailed definition is contained in paragraphs 1 and 2
Article 59 of Law 38/1992, of 28 December;
11. "market": market products, regardless of their place of manufacture,

available to consumers residing in Spain, for payment or not of these
products, including through distance selling. In case of distance sales
border, the product must be marketed in Spain;
12. "consumer" means any natural person acting for purposes unrelated to his business activities,
business, occupational or professional;
13. "susceptible nicotine delivery device" means a product, or any of its
components, including a cartridge, a reservoir and the device without a cartridge or reservoir,
-usable steam consumption containing nicotine through a
nozzle. Devices capable of releasing nicotine may be disposable or
rechargeable by a charging container and a tank, or a rechargeable cartridges
only;
14. "outer packaging": any packaging used to market the products of snuff or
products and includes a packaging unit or group of units
packaging, transparent wrappers are not considered as the outer packaging;
15. "emission" means all substances released when the product is given snuff, or
related to it, the use for which it is intended, for example, substances
in smoke or chemicals released during consumption of products
the smokeless snuff;
16. "refill pack": a receptacle containing liquid nicotine turn, which can
susceptible used to recharge a nicotine delivery device;
17. "retail establishment" means any establishment in which products are marketed
of snuff, even by an individual;
18. "manufacturer" means any natural or legal person who manufactures a product, or designed or
manufacturing a product and markets it under his name or trademark;
19. "import snuff or related products" entry into the territory of the Union
European of such products unless those at the time of entry into the Union,
They are included in a procedure or suspensive procedure and the release for
consumption starting from a customs suspensive procedure or arrangement;
20. "importer or snuff products" means the owner or the person entitled to
snuff and disposal of products that have been introduced in the territory of
the Union;
21. "ingredient" snuff, an additive, and for any substance or item in the product
developed, including paper, filter, inks, and adhesives capsules;
22. "nicotine" means nicotinic alkaloids;
23. "peak" or "maximum emission": the maximum content or maximum emission
a substance in a product of snuff, in milligrams, including a zero value;
24. "pouch" means a packaging unit for rolling snuff, either in the form of rectangular bag
with a flap covering the opening or shaped flask stable base;
25. "power addictive": the pharmacological potential of a substance to cause addiction, a state
that affects an individual's ability to control the behavior, usually
offering a reward or relief of withdrawal symptoms, or both;
26. "product herbal smoking" product based on plants, herbs or fruits that do not
It contains snuff and can eat through a combustion process;
27. "snuff products" means products that can be consumed and consist in whole or
in part, by snuff, genetically modified or not;
28. "product of the novel snuff" snuff product that:
to. is not covered by any of the following categories: cigarettes, snuff for

liar, snuff pipe, snuff for hookah, cigars, cigarillos, snuff of
chew, use snuff or nasal snuff for oral use; and
b. It was sold after May 19, 2014;
29. "snuff products for smoking" products other than snuff snuff products
without combustion;
30. "smokeless snuff product": a product of snuff that does not involve a process of
combustion, including chewing snuff, snuff use of nasal and oral snuff use;
31. "system of age verification": a computer system, by electronic means,
unequivocally confirms the age of the consumer, according to the requirements
national;
32. "snuff" leaves and other natural parts, processed or not, snuff plant, including
expanded and reconstituted snuff;
33. "chewing snuff" snuff smokeless product, only to be chewed;
34. "snuff pipe" snuff can be consumed by the combustion process and
exclusively for use in a pipe;
35. "nasal snuff use" a product of snuff without combustion, which can be administered
through the nose;
36. "snuff for oral use" means all products for oral use, except
Products inhaled or chewed, made wholly or partly in the form of snuff
powder, fine or any combination of these forms particles, particularly
presented in sachet portions or porous sachets;
37. "snuff-rolling" snuff that consumers can use and establishments
retail for cigarettes;
38. "hookah snuff to" snuff a product that can be consumed by a pipe
of water. For the purposes of this Royal Decree, the snuff for hookah is considered a
smoking snuff product. If a product can be used both as
for hookah snuff and quality of snuff for rolling it shall be deemed to snuff liar.
39. "toxicity": the degree to which a substance may cause harmful effects on the body
human, including long-term effects, usually arising from the consumption or
Continuous exposure;
40. "packaging unit" means the smallest single package of a product or snuff
related product market;
41. "border distance sales" distance selling to consumers, when in the
when the product is responsible, the consumer is in a Member State
same as the Member State or third country where the establishment is set
retail; It is considered a retail establishment is set in a State
member:
to. if a natural person, if its center of business is in that
Member state;
b. in other cases, if it has its registered office, central administration or activity
business, including a branch, agency or other establishment in that
Member state.
TITLE I
Snuff products
CHAPTER I
Constituents and emissions
Article 3. emissions.
1. Cigarettes marketed or manufactured in Spain may not have emission levels
above:

a) 10 mg of tar per cigarette,
b) 1 mg nicotine per cigarette,
c) 10 mg of carbon monoxide per cigarette.
2. Any other emission levels that are set for other substances
other than those referred to in the preceding paragraph, issued by cigarettes, or other
snuff products other than cigarettes, should be notified to the European Commission.
Article 4. Methods of measurement.
1. Emissions of tar, nicotine and carbon monoxide in cigarettes is measured
according to ISO 4387, 10315 and 8454, respectively standards.
The accuracy of the information concerning the tar, nicotine and carbon monoxide
It verified in accordance with ISO 8243 standard.
2. The measurement methods used to measure emissions from different cigarettes
those referred to in Article 3.1 and to measure emissions snuff products
other than cigarettes, must be notified by manufacturers or importers to
Directorate General of Public Health, Quality and Innovation of the Ministry of Health,
Social Services and Equality, who in turn shall notify the European Commission.
Article 5. controls verification and quality.
1. Checks and measures referred to in Article 4.1 shall be made by
the test facilities approved and supervised by the authorities of the Ministry of
Health, Social Services and Equality.
The verification is carried out through annual audit plan to be developed
by the Directorate General of Public Health, Quality and innovation with the help of the
test facilities. The sampling plan shall include all products
market.
Those responsible for the marketing of products must snuff in Spain
provide requested samples of the products and, where applicable, of raw materials and
intermediate bulk products to the health authorities to carry out the
verification.
2. Regardless of the checks carried out by the health authorities, all
manufacturers are required to carry out inspections and tests as part of the control
product quality.
To make inspections and tests, manufacturers can use testing laboratories
own or require third-party testing. These testing laboratories shall have a
quality system implemented in the company to ensure technical competence to
carry them out.
3. may be required to manufacturers, importers or those responsible for marketing
to conduct studies to assess the effects of the ingredients on health,
taking into account, inter alia, of their toxicity or addictiveness.
4. All manufacturers or importers of snuff products sold in Spain
They must submit annually and before November 1 to the Directorate General of Health
Public, Quality and Innovation a report on the tests conducted in different
products, including sample sizes in respect of production and sampling data.
The report should include detailed analytical procedures or reference methods
ISO used, and data validation thereof.
The notification may be made by the responsible for the marketing of products
in Spain with the written consent of the manufacturer or importer.
5. The measurement methods used to measure emissions from different cigarettes
those referred to in Article 4.1 and to measure emissions snuff products
other than cigarettes, must be notified by manufacturers or importers to

Directorate General of Public Health, Quality and Innovation of the Ministry of Health, Social Services and Equality, who in turn shall notify the European Commission. The notification may be made by the responsible for the marketing of products in Spain with the written consent of the manufacturer or importer.

Article 6. Verification Laboratories.

1. The Ministry of Health, Social Services and Equality authorize laboratories They made the evidence in Article 5.1, and notify the European Commission. So same, the Ministry appoints the Research Center for Control and Quality Spanish Agency of Consumer Affairs, Food Security and Nutrition, as laboratory reference.

2. The entities applying to be test facilities may not be owned or controlled directly or indirectly by the industry snuff. Must submit the application to the Directorate General of Public Health, Quality and Innovation by letter and enclosing all documentation justifying compliance as defined in Annex I.

Approved laboratories verification shall be recorded and reported to the Commission European, specifying the criteria used for approval and the media supervision applied and updated every time a change occurs. The Commission shall publish the list of approved laboratories for the national authorities.

3. The applicant organizations must have a system in place to justify its quality technical competence to carry out appropriate measures on products snuff.

4. The Directorate General of Public Health, Quality and Innovation perform actions necessary to verify the ability of laboratories in order to take their permission out continuous monitoring to verify the maintenance of these skills in the laboratories authorized. To do this, it may require the assistance of the reference laboratory.

5. The Directorate General of Public Health, Quality and Innovation perform activities necessary to ensure that applicants laboratories meet the requirements, including accreditations that may arise. However, the act of authorization is independent of any certification or accreditation and is not bound by them. The results of the evaluation will be communicated to interested and entered in the Register Authorized national laboratories.

6. Once authorized, will be included in the mode or Testing Laboratory Laboratory Verification on the National Register of Laboratories and Test Verification. The authorization is issued for three years and may be renewed under the same conditions and with the same requirements as the initial authorization.

7. When you have authorized and make sure that laboratory no longer meets the requirements set out in Annex I, or has committed a breach of its obligations, the Ministry of Health, Social Services and Equality withdraw approval or limit its scope, after the administrative procedure, after hearing the interested party, and shall inform the European Commission.

8. In the event of termination of self-interest to a licensed laboratory verification it must notify the Department of Public Health, Quality and Innovation who adopt appropriate measures for removal from the National Registry and to ensure the management continuity test.

9. The Ministry of Health, Social Services and Equality notify the European Commission list of approved laboratories, and modifying every time occurs, specifying the criteria used for approval and the methods of monitoring applied.

10. The test facilities must submit annually to the Directorate General of Health

Public, Quality and Innovation analyzes reports and the management
economic prepared in accordance with accounting principles, in relation to the tests
emissions and product content of snuff.
11. The public authorities, without prejudice to existing provisions
professional secrecy shall ensure that all parties to the application of these concerns
provisions maintain the confidentiality of any information obtained in the exercise
functions. This does not affect the obligations of the competent authorities
regard to mutual information and the dissemination of warnings, nor the obligations of
information incumbent on those affected, both to the authorities and to the organs
jurisdictional.
Article 7. Notification procedure of ingredients and emissions.
1. All manufacturers and importers or responsible for the marketing of products
the snuff must file electronically on an annual basis and before 1
November before the Directorate General of Public Health, Quality and Innovation, the following
information in Castilian, by brand name and type: