

FRENCH REPUBLIC

Ministry of Health and Access to
Healthcare

Decree No ... of ...

on the prohibition of products for oral use containing nicotine

NOR: MSAP2430826D

Audiences concerned: *manufacturers, importers, distributors, and retailers of products containing nicotine, users.*

Subject: *implementation of the prohibition on products for oral use containing nicotine, with the exception of medicinal products and medical devices.*

Entry into force: *the text shall enter into force six months after its publication.*

Notice: *Because of its danger to human health, nicotine is classified under Article L. 5132-1 of the Public Health Code as a poisonous substance and may only be used or marketed under certain conditions, like products that are already regulated (tobacco products, vaping products and health products). Article L. 5132-8 of the same Code authorises the prohibition of any operation relating to poisonous substances by a decree of the Council of State. This Decree defines products for oral use containing nicotine, particularly in the form of portion sachets or porous sachets, paste, beads, liquids, chewing gum, lozenges, strips or any combination of these forms, which are subject to the prohibition, and specifies the conditions under which such products are prohibited. It also provides for derogations from this prohibition. Infringements of this prohibition shall be investigated and ascertained by officials working in competition, consumer affairs and fraud prevention, customs officials, and officials of the Directorate-General for Public Finance, on the basis of Article L. 5414-3 of the Public Health Code. The sanctions applicable in the event of failure to comply with this prohibition are those provided for in Chapter II of Title III of Book IV of Part Five of the same Code.*

References: *the Decree can be found on the website Légifrance (<https://www.legifrance.gouv.fr>).*

The Prime Minister,

The report of the Minister of Health and Access to Healthcare;

Having regard to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005, as amended, on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC;

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, as amended, laying down the general principles and requirements

of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;

Having regard to Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to the Public Health Code, in particular Articles L. 5132-1, L. 5132-7 and L. 5132-8 thereof;

Having regard to notification No XXXX/XXX/FR of XX XX XX to the European Commission,

Having heard the Council of State (social division),

Hereby decrees:

Article 1

Section II of Chapter II of Title III of Book I of Part Five of the Public Health Code is supplemented by a subsection worded as follows:

‘ Subsection 6

‘ Products containing toxic substances

‘ Art. R. 5132-96-1. – I. – The production, manufacture, transport, import, export, possession, offering, transfer, purchase, distribution, and use of products for oral use containing nicotine shall be prohibited on national territory.

‘ II. – Products for oral use containing nicotine are all manufactured products consisting wholly or partly of synthetic or natural nicotine, packaged for sale, regardless of their presentation, and intended for human consumption by ingestion or absorption.

‘ III. – This prohibition does not apply to:

1° Chewing tobacco referred to in Article L 3512-13

2° Medicinal products within the meaning of Articles L. 5111-1 and L. 5121-1-1, medical devices within the meaning of Articles L. 5211-1 and L. 5221-1, and raw materials for pharmaceutical use as defined in Article L. 5138-2;

3° Foodstuffs within the meaning of Regulation (EC) No 178/2002 of the European Parliament and of the Council naturally containing nicotine or complying with Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

‘ Art. R. 5132-96-2. – Derogations from the prohibition laid down in Article R. 5132-96-1 may be granted for research purposes by order of the Minister responsible for Health.

‘ The terms and conditions of these derogations shall be specified by order of the Minister responsible for Health and the Minister responsible for Research.’

Article 2

The title of Subsection 2 is replaced by the following title:

‘ *Subsection 2*
*‘ Substances and preparations other than those mentioned in Section I and Subsections 3, 4, 5
and 6’*

Article 3

Chapter I of Title II of Book V of Part Five of the Public Health Code is supplemented by the following provisions:

‘ *Article R. 5521-3.* – Articles R. 5132-96-1 and R. 5132-96-2 shall apply to Wallis and Futuna in their wording resulting from Decree No. of .’

Article 4

This Decree shall come into force six months after its publication.

Article 5

The Minister of Health and Access to Healthcare, the Minister of Higher Education and Research, and the Minister attached to the Prime Minister, responsible for Overseas Territories, shall be responsible, each insofar as they are concerned, for the implementation of this Decree, which shall be published in the *Official Journal* of the French Republic.

Done on:

By the Prime Minister:

The Minister of Health and Access to Healthcare

The Minister attached to the Prime
Minister,
responsible for Overseas Territories

The Minister of Higher
Education and Research