

PUBLIC CONSULTATION

PROJECT OF ROYAL DECREE MODIFYING ROYAL DECREE 579/2017, OF JUNE 9, WHICH REGULATES CERTAIN ASPECTS RELATED TO THE MANUFACTURE, PRESENTATION, AND MARKETING OF TOBACCO AND RELATED PRODUCTS.

In accordance with the provisions of Article 133 of Law 39/2015, of October 1, on the Common Administrative Procedure of Public Administrations, in relation to Article 26 of Law 50/1997, of November 27, on the Government, with the aim of improving citizen participation in the procedure for drafting regulations, a prior public consultation will be held through the portal of the website of the competent Administration, in which the opinion of the subjects and the most representative organizations potentially affected by the future regulation will be sought.

In compliance with the above and in accordance with the provisions of Order PRE/1590/2016, of October 3, which publishes the Agreement of the Council of Ministers of September 30, 2016, which gives instructions to enable public participation in the regulatory drafting process through the web portals of ministerial departments, information will be provided on the following aspects:

- a) The background of the regulation.
- b) The problems that the initiative aims to solve.
- c) The need and opportunity for its approval.
- d) The objectives of the regulation.
- e) Possible alternative regulatory and non-regulatory solutions.

Citizens, organizations, and associations who so wish may submit their opinions on the aspects raised in this questionnaire until April 24, 2023, through the following email address:

prevenciondeltabaquismo@sanidad.gob.es

Background of the regulation:

The first steps in tobacco-related legislation regarding general aspects were taken in the late 1980s and during the 1990s through royal decrees on limitations on the sale and use of tobacco, labelling, prohibition of oral use tobacco, and maximum nicotine, tar, and carbon monoxide contents of cigarettes. There was, therefore, a dispersed and unsystematic regulatory body that was replaced by Law 28/2005, of December 26, on sanitary measures against smoking and regulation of the sale, supply, consumption, and advertising of tobacco products. This law was subsequently modified twice, once in 2010, expanding smoke-free spaces, and another in 2017, to transpose Directive 2014/40/EU of the European Parliament and of the Council, of April 3, 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. In the development of Law 28/2005, Royal Decree 579/2017, of June 9, was promulgated, which regulates certain aspects relating to the manufacture, presentation, and marketing of tobacco and related products. The measures contemplated in this regulatory proposal must be in total harmony with the World Health Organization Framework Convention on Tobacco Control (hereinafter, WHO FCTC), made in Geneva on May 21, 2003, and ratified by Spain on December 30, 2004.

Problems to be solved by the new regulation:

In Spain, as in other developed countries, smoking is the leading preventable cause of mortality and morbidity. According to WHO data, tobacco consumption is responsible for 90% of lung cancer mortality, 95% of deaths from chronic obstructive pulmonary disease, 50% of cardiovascular mortality, and 30% of deaths from any type of cancer.

There is also scientific evidence that environmental tobacco smoke (passive or involuntary tobacco consumption) is a cause of mortality, illness, and disability. In addition to significant socio-sanitary problems, smoking is one of the main problems for public health. Hence, there is a need to implement measures aimed at prevention, protecting the population from exposure, limiting its supply and demand, and regulating its advertising, promotion, and sponsorship. The health protection provided by the regulation contained in Law 28/2005, as well as Royal Decree 579/2017, requires an urgent update of the text to address the problems that have arisen during this period, which can be summarized as follows:

- Stabilization in the reduction of tobacco product consumption and an increase in related product consumption.
- Exposure of the general population, particularly young people, to new forms of nicotine consumption.
- Inadequacy of current regulations for the greater supply of new related products present in the market.
- Loss of the effectiveness of combined health warnings and maintenance of the appeal of tobacco product packaging.
- Deficiencies in the regulation of nicotine-free electronic cigarettes and herbal smoking products.

Need and opportunity for approval:

The present Royal Decree project represents the first revision of the content of Royal Decree 579/2017, approved in strict compliance with Directive 2014/40/EU, and stems from the need to introduce different improvements identified during this period in which significant changes have occurred, both in terms of epidemiology and consumption patterns, and in the current configuration of the tobacco and related product market. In this sense, there is currently a variety of products with differentiated characteristics, with or without tobacco, with or without nicotine, with or without electronic components, and even with complex hybrid aspects that pose a challenge and for which it is necessary to provide an adequate technical response in order to guarantee the proper protection of people who consume these new unconventional products.

The project is in line with the document "Lines of Action 2019-20 in the Field of Smoking Prevention and Control," approved by the Public Health Committee of the National Health System Interterritorial Council (CISNS). Additionally, the project takes into account the joint experience of the European Union Tobacco Policy Expert Group regarding the orientation of the development of Directive 2014/40/EU and practical experience in each Member State. Also, at the European level, we must take into account the recent approval by the European Commission of the Delegated Directive on heated tobacco, which is expected to be transposed in the coming months. Finally, through this modification, it is intended to respond to the demands expressed both by scientific societies and by civil entities related to the subject, in order to contribute, ultimately, to the improvement of the health of citizens and to reduce the risk of entry into

nicotine consumption represented by related products, especially for the young population sector.

Objective of the regulation:

The objective is to introduce various measures into the existing regulation on the subject, such as:

- Improvements in the labeling and packaging of tobacco products by introducing plain packaging along with traceability and safety measures.
- Improvements in the proper categorization of emerging tobacco products and tobacco-related products.
- Prohibition of certain additives and components that distort the objectives set out in the Directive or that may be more attractive to consumers.

This regulatory initiative also aims to provide greater clarity, uniformity, and legal certainty in the tobacco and related products market, taking into account its development at the national and European levels.

Alternative regulatory and non-regulatory solutions

Alternative regulatory and non-regulatory solutions are not considered since the main objective is to adapt an existing regulation to the current context in order to protect the health of the Spanish population, which necessarily involves modifying a previously existing norm.