MINISTRY
OF HEALTH

REPORT ON THE REGULATORY IMPACT ANALYSIS OF DRAFT ROYAL DECREE XXXX/XXXX OF XX XXXXX AMENDING ROYAL DECREE 579/2017 OF 9 JUNE 2017 REGULATING CERTAIN ASPECTS RELATING TO THE MANUFACTURE, PRESENTATION AND MARKETING OF TOBACCO PRODUCTS AND RELATED PRODUCTS

Wednesday 22 January 2025

MINISTRY
OF HEALTH

EXECUTIVE SUMMARY

Proposing Ministries/Bodies	Ministry of Health Ministry of Finance	**Date**	22/01/2025
Regulation title	**ROYAL DECREE XXXX/XXXXX OF XX XXXXX AMENDING ROYAL DECREE 579/2017 OF 9 JUNE 2017 REGULATING CERTAIN ASPECTS RELATING TO THE MANUFACTURE, PRESENTATION AND MARKETING OF TOBACCO PRODUCTS AND RELATED PRODUCTS**		
Report type	Normal ■ Abbreviated ☐		
SCOPE OF THE PROPOSAL			
Subject	The aspects regulated by the draft Royal Decree involve the effective implementation of one of the main measures envisaged in the Comprehensive Plan for the Prevention and Control of Tobacco Use 2024-2027, and relate to the updating of health regulations on tobacco products and related products in aspects such as their content, quality and safety requirements or labelling. In addition, it should be noted regarding the current situation in our country that there is a variety of products with differentiated characteristics, with or without tobacco, with or without nicotine, with or without electronic components, and even with hybrid aspects that are complex to classify, which pose a challenge and for which it is necessary to provide the appropriate technical response in order to guarantee proper protection of people who consume these new unconventional products. Thus, the draft Royal Decree includes a Single Article with 16 Sections for the approval of the different proposed changes, some of which are innovative in regulating several categories of products for the first time. In addition, the Regulation incorporates an Additional Provision, a Transitional Provision and a Final Provision.		
Objectives pursued	Adopting all necessary measures to implement what is established in the Basic Axis of Regulatory Action envisaged in the aforementioned Plan. Thus, the Plan has identified the need to introduce various improvements, not yet envisaged in the harmonised regulation of the European Union, as a result of the significant changes experienced, both at the epidemiological level and in consumption patterns, as well as in the current configuration of the market for tobacco products and related products in our country. Therefore, the objectives to be achieved are, on the one hand, to improve the regulations applicable to tobacco		

	products and, on the other, to offer an innovative regulatory body for the wide range of related products currently lacking proper health regulations in order to effectively protect consumers.
Main alternatives considered	No alternative can be considered with regard to the regulation of new products currently on the market that lack any type of health regulation establishing minimum requirements for safety, control or limitation of content. The proposal made in Spain is in line with those also made by neighbouring Member States. Regarding the regulation of other tobacco products and related products, contradictory alternatives were raised in the public consultation process prior to the preparation of this draft, and those that provide a greater guarantee of public health protection were chosen.
CONTENT AND LEGAL ANALYSIS	
Type of standard	Royal Decree
Structure of the regulation	The draft Royal Decree consists of a Descriptive Part, a Single Article, an Additional Provision, a Transitional Provision and a Final Provision. Thus, the Single Article contains the following Sections: • Section 1 amends the subject matter of the Regulation to include nicotine-free e-cigarettes. • Section 2 amends and introduces definitions of the terms used throughout the Regulation. • Section 3 amends the regime of ingredients and additives to include heated products. • Sections 4 to 15 regulate nicotine-free e-cigarettes. Reporting obligations in relation to these products, testing, and control and verification requirements are regulated. • Section 7 amends certain quality and safety requirements for e-cigarettes. • Section 16 adds a new title to regulate related products other than e-cigarettes, nicotine-free e-cigarettes and herbal products for smoking. Two new product categories are introduced into our legal system: nicotine pouches and heated herbal products. • The Additional Provision defines competences in the classification of new products. • The Transitional Provision establishes an extension for manufacturing and placing on the market. • The Final Provision provides for entry into force on the day following its publication in the Official State Gazette.

Reports received	For the approval of the Royal Decree, it will be necessary to carry out the procedures described below. Reports from the proposing Department: • Report from the Budget Office of the Department, in accordance with Article 3(f) of Royal Decree 2855/1979 of 21 December 1979 establishing Budget Offices. • Report from the Ministerial Commission for Digital Administration, in accordance with the provisions of Article 7(4) of Royal Decree 806/2014 of 19 September 2014 on the organisation and operational instruments of information and communication technologies in the General State Administration and its Public Bodies. • Report from the Technical General Secretariat, in accordance with the provisions of Article 26(5)(4) of Law 50/1997 of 27 November 1997 on the Government. In accordance with the provisions of Article 26(5)(4) of Law 50/1997 of 27 November 1997: • Report from the Ministry of Finance. (Autonomous Body Commissioned for the Tobacco Market and State Tax Administration Agency) In accordance with the provisions of Article 26(5)(1) of Law 50/1997 of 27 November 1997: • Report from the Ministry of Social Rights, Consumer Affairs and 2030 Agenda. • Report from the Ministry of Agriculture, Fisheries and Food. • Report from the Ministry of Economy, Trade and Enterprise. • Report of the Ministry of Industry and Tourism. • Report from the Ministry of the Interior. • Report from the Ministry of Youth and Children. • Report from the National Institute of Toxicology and Forensic Sciences of the Ministry of the Presidency, Justice and Relations with the Parliament. Likewise, in compliance with the aforementioned Law 50/1997 of 27 November 1997: • Prior approval of the Ministry for Digital Transformation and the Civil Service, in accordance with the provisions of Article 26(5)(5) of Law 50/1997 of 27 November 1997. • Report from the Office of Coordination and Regulatory Quality of the Ministry of the Presidency, Justice and Relations with the Parliament, in accordance with Article 26(9) of Law 50/1997. • Report from the Ministry of Territorial Policy and Democratic Memory, in accordance with the provisions of Article 26(5)(6) of Law 50/1997 of

	27 November 1997. Report from the Autonomous Communities and Cities of Ceuta and Melilla, and the Spanish Federation of Municipalities and Provinces. Report from the Advisory Committee and the Interterritorial Council of the National Health System. Report from the Consumers and Users Council. Report from the National Commission on Markets and Competition. Notification to the European Commission pursuant 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. Opinion of the Council of State, in accordance with the provisions of Article 22(3) of Organic Law 3/1980 of 22 April 1980 on the Council of State.
Public consultation process	The public consultation process took place from 8 April to 23 April 2024.
Public information process	The public information process took place from 21 November to 22 December 2024.

IMPACT ANALYSIS		
COMPLIANCE WITH THE DISTRIBUTION OF POWERS	This Royal Decree is issued under Article 149(1)(16) of the Spanish Constitution, which confers on the State competence over the basic conditions and general coordination of health matters.	
ECONOMIC IMPACT	**Effects on the economy in general**	Has no effects.
	With regard to competition	**X** The Regulation has no significant effects on competition. ☐ The Regulation has positive effects on competition.

		☐ The Regulation has negative effects on competition.
	From the point of view of administrative burdens	☐ It entails a reduction in administrative burdens. Estimated quantification EUR_____ **X** It adds new administrative burdens. Estimated quantification EUR_____ ☐ It does not affect administrative burdens.
BUDGETARY IMPACT	With respect to budgets, the Regulation: ☐ Affects the budgets of the General State Administration. ☐ Affects the budgets of other Territorial Administrations.	☐ Implies an expense: _____€. ☐ Implies income
GENDER IMPACT	The law has a gender impact that is	Negative ☐ None Positive X
IMPACT ON CHILDHOOD AND ADOLESCENCE	Positive	
IMPACT ON FAMILIES	Positive	
IMPACT DUE TO CLIMATE CHANGE	None	
IMPACT ON HEALTH	Positive	

IMPACT ON LGBTI+ PEOPLE	Positive
EX-POST EVALUATION	Not applicable

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VIII.- EX-POST EVALUATION

I.- JUSTIFICATION OF THE REPORT

The purpose of the draft Royal Decree is to implement the provisions of the Comprehensive Plan for the Prevention and Control of Tobacco Use 2024-2027, specifically what is established in the Basic Axis of Regulatory Action. The Autonomous Communities, as well as other social and economic agents, together with non-governmental organisations and scientific societies, have duly participated in the preparation of the Plan, thus achieving a remarkable consensus regarding the measures envisaged in the Plan.

Therefore, as mentioned in the impact assessment section, the economic impact of the envisaged measures is limited, as the continued marketing of most tobacco products and related products is allowed.

The measures included in the draft legislation affect competition at the manufacturing level by prohibiting certain ingredients, and at the distribution level by imposing labelling requirements. However, given the multinational nature of the main companies in the tobacco sector in Spain, as well as the long tradition of applying this measure, its implementation by these market operators is currently facilitated by their manufacturing processes being adapted to these changes in the labelling and packaging regulations, with the sector having sufficient experience in this regard.

The measures envisaged correspond to the provisions included in the recently agreed and approved Comprehensive Plan and, from the perspective of the principles of good regulation, they appear adequate to protect health and prevent tobacco use.

In this sense, the changes proposed in the manufacture, presentation, and marketing of tobacco products and related products can be assumed by manufacturers and related sectors, and the observations presented during the prior public consultation process have been taken into account.

Finally, the application of the Regulation is expected to result in positive health impacts, although these cannot be considered appreciable or significant at present since they could only be measured, where applicable, in the medium to long term, and possibly focused on the population sector of adolescent and young women.

II.- SCOPE OF THE PROPOSAL

1. MOTIVATION

The purpose of the draft Royal Decree is to implement the provisions of the Comprehensive Plan for the Prevention and Control of Tobacco Use 2024-2027, specifically what is established in the Basic Axis of Regulatory Action within its Goal 1. Prevent the onset of tobacco and related product use, and more specifically with regard to Objective 1.3 '*Denormalise the use of tobacco and related products in public spaces and in the private sphere*' and Objective 1.5 '*Strengthen compliance with and monitoring of existing legislation*'. Thus, as a development of this Goal and its Objectives, the Plan envisages the following lines of action regarding the Legislative Strategy for that Goal:

'*Amend Royal Decree 579/2017 to introduce: -Prohibition of flavouring additives in tobacco products and related products*.'

Furthermore, the proposal is in line with the Sustainable Development Goals (SDGs), especially Target 3.4, to reduce by one third premature mortality from non-communicable diseases by 2030. In addition, it takes into account the recommendations established by the fourth edition of the European Code Against Cancer[1], in relation to avoiding the consumption of tobacco and related products, the maintenance of a home and workplace free of environmental tobacco smoke, as well as the objectives set by Europe's Beating Cancer Plan[2], submitted by the European Commission to the European Parliament and Council. This Plan sets the goal of achieving that, by 2040, less than 5 % of the population will consume tobacco, compared to the current average of 25 % in Europe.

The Plan also involves advancing the actions already undertaken in response to the challenge of emerging products that have appeared on the market and which, due to their attractiveness to young people, serve as a gateway to tobacco use. In this regard, reference should be made to the agreement adopted by the Interterritorial Council of the National Health System entitled '*Tobacco products and related products: implication of its consumption in Public Health*'[3].

Thus, the current situation of the market for tobacco products and related products requires an urgent update, as there is a variety of products with differentiated characteristics, with or without tobacco, with or without nicotine, with or without electronic components, and even with hybrid aspects that are complex to classify, which pose a challenge and for which it is necessary to provide

[1] European Code Against Cancer
https://www.sanidad.gob.es/ciudadanos/enfLesiones/enfNoTransmisibles/docs/Codigo_Cancer.pdf
[2] Communication from the Commission to the European Parliament and the Council. Europe's Beating Cancer Plan.
https://ec.europa.eu/health/sites/health/files/non_communicable_diseases/docs/eu_cancer-Plan_es.pdf
[3] Tobacco and related products: Implication of its consumption in public health
https://www.sanidad.gob.es/areas/promocionPrevencion/tabaco/legislacionAcuerdosDenuncia/docs/Acuerdo_Productos_Tabaco.pdf

the appropriate technical response in order to guarantee proper protection of people who consume these new unconventional products.

The proposal arises from and is based on this factual situation, and constitutes a response to it, establishing updated regulations regarding the conditions of manufacture, presentation and marketing of tobacco products and related products.

2. Objectives.

The main objective of the proposal is to provide a health-based response to the changes experienced, both at the epidemiological level and in consumption patterns, as well as in the current configuration of the market for tobacco products and related products in our country. Thus, the aim is to improve the information available to citizens regarding these products through changes in the labelling, as well as to protect the population from varieties with particularly attractive flavours and with clear public health repercussions in terms of their consumption, mainly among young people.

3. Alternatives.

No alternative can be considered with regard to the regulation of new products currently on the market that lack any type of health regulation establishing minimum requirements for safety, control or limitation of content. The proposal made in Spain is in line with those also made by neighbouring Member States. Therefore, countries such as France or the United Kingdom already have packaging with a uniform appearance in their markets, guaranteeing consumers a better perception of the product's special characteristics. Regarding the regulation of other tobacco products and related products, contradictory alternatives were raised in the public consultation process prior to the preparation of this draft, and those that provide a greater guarantee of public health protection were chosen.

4. Alignment with the principles of good regulation.

This Report complies with the principles of good regulation provided for in Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations and, in particular, with the principles of necessity and efficiency, since it is based on the general interest of protecting public health and is the most appropriate regulatory instrument to ensure its achievement.

In particular, as regards the principles of necessity and effectiveness, this Regulation is justified by a reason of general interest, such as the protection of the health of the population, through the implementation of measures aimed at its prevention and protection against exposure of the population. In addition, this Royal Decree constitutes the effective implementation of the provisions of the Comprehensive Plan for the Prevention and Control of Tobacco Use 2024-2027, specifically what is established in the Basic Axis of Regulatory Action within its Goal 1. Prevent the onset of tobacco and related product use. The Regulation entails the first exhaustive and comprehensive review of the content of Royal Decree 579/2017, approved in compliance with the strict transposition of Directive 2014/40/EU, and derives from the need to introduce various improvements identified during this period of time in which significant changes have occurred, both at the epidemiological level and in consumption patterns, as well as in the current configuration of the market for tobacco products and related products. The Regulation complies with the principle of proportionality, by including the essential provisions to address the aforementioned needs. It also complies with the principle of legal certainty, as it is fully consistent with the rest of the legal system. Likewise, during the procedure for drafting the Regulation, the prior public consultation process was formalised, as well as the public information process established by law in compliance with the principle of transparency, with wide participation of the different sectors affected, not only in business and health, but also among consumers, and the objectives of the Regulation were clearly described. Finally, the Royal Decree complies with the principle of efficiency, as the approval of the Regulation will not generate unnecessary administrative burdens.

5. Annual regulatory plan.

The amendment of Royal Decree 579/2017 of 9 June 2017 is planned and envisaged in the Ministry of Health's proposed annual regulatory plan for 2025.

III.- CONTENT

1. Structure.

The draft Royal Decree consists of a Descriptive Part or Preamble, a Single Article with 16 Sections, an Additional Provision, a Transitional Provision and a Final Provision.

2. Content.

The draft Royal Decree regulates:

- Section 1 amends the subject matter of the Regulation to include nicotine-free e-cigarettes.
- Section 2 amends and introduces definitions of the terms used throughout the Regulation.
- Section 3 amends the regime of ingredients and additives to include heated products.
- Sections 4 to 15 regulate nicotine-free e-cigarettes. Reporting obligations in relation to these products, testing, and control and verification requirements are regulated.
- Section 7 amends certain quality and safety requirements for e-cigarettes.
- Section 16 adds a new title to regulate related products other than e-cigarettes, nicotine-free e-cigarettes and herbal products for smoking. Two new product categories are introduced into our legal system: nicotine pouches and heated herbal products.
- The Additional Provision defines competences in the classification of new products.
- The Transitional Provision establishes an extension for manufacturing and placing on the market.
- The Final Provision provides for entry into force on the day following its publication in the Official State Gazette.

3. Main developments.

It restricts the presence of flavourings in e-cigarettes, with or without nicotine. Two new product categories are introduced into our legal system: nicotine pouches and heated herbal products.

IV.- LEGAL ANALYSIS

1. Legal basis and regulatory status

The draft finds its initial legal basis in the General Health Act 14/1986 of 25 April 1986 which established the obligation of public health administrations to direct their actions primarily towards the promotion of health and the prevention of diseases, to avoid activities and products that, directly or indirectly, may have negative consequences for health, and to regulate their advertising and commercial marketing.

For its part, Law 28/2005 of 26 December 2005 on health measures against smoking and regulating the sale, supply, consumption and advertising of tobacco products, empowers the Government, by means of a Royal Decree, to determine the contents and components of tobacco products, especially the addictive elements, as well as the labelling conditions that they must comply with. On the basis of this empowerment, Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and marketing of tobacco products and related products was issued and is now being amended.

Therefore, it is a proposal with the status of a Royal Decree, since it is intended to amend a Regulation of equal status.

2. Link between the Regulation and European Union law.

The Regulation is fully consistent with relevant European Union law, in particular 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, which was transposed into the national legal system by Royal Decree 579/2017 of 9 June 2017 regulating certain aspects relating to the manufacture, presentation and marketing of tobacco products and related products.

This Directive was amended by Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products, which is limited in scope due to its delegated status and was made in exercise of the empowerment contained in Articles 7(12) and 11(6) of Directive 2014/40/EU of 3 April 2014, in the event of a substantial change of circumstances. For this reason, it recently became necessary to carry out a limited and specific amendment to Royal Decree 579/2017 of 9 June 2017, insofar as it affects the withdrawal of said exemptions in respect of heated tobacco products. Thus, by means of Royal Decree 47/2024 of 16 January 2024 amending Royal Decree 579/2017 of 9 June 2017 regulating certain aspects

relating to the manufacture, presentation and marketing of tobacco products and related products, improvements were introduced with regard to the regulation of heated tobacco products in accordance with the changes experienced in the market for these products and their notable increases in sales.

These changes in the market for tobacco products and related products, together with the deficiencies that currently exist in European regulations, such as the lack of regulation of products like nicotine pouches and heated herbal products, are the reason for the presentation of this draft Royal Decree, the contents of which are consistent with what has already been put forward by other Member States and with the expected direction of the current process of revision of European regulations related to these products.

3. Repeal of Regulations.

There is no need to repeal any Regulations.

4. Entry into force and validity period.

The Single Final Provision establishes that the Regulation will enter into force the day following its publication in the Official State Gazette.

However, a transitional period is recognised through the extension of manufacturing and placing on the market, which responds to the need to allow manufacturers and marketers to adapt the products concerned to the new established requirements, as well as the exhaustion of available stocks.

Depending on the various changes made to the draft, a period of 10 to 12 months is recognised, which is considered sufficiently long to allow the sector to adapt without putting public health at risk.

V.- COMPLIANCE OF THE REGULATION WITH THE DISTRIBUTION OF COMPETENCES

This draft Royal Decree has the status of basic legislation and conforms to the constitutional order of distribution of competences, being issued in accordance with the provisions of Article 149(1)(16) of the Spanish Constitution,which confers on the State competence over the basic conditions and

general coordination of health matters, without prejudice to the Autonomous Communities establishing additional standards of protection, respectively.

VI.- DESCRIPTION OF THE PROCEDURE

Article 133 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations, concerning citizen participation in the procedure for drawing up laws and regulations, with the aim of improving citizen participation in the procedure for drawing up draft or preliminary draft laws or regulations, and Article 26(2) of Law 50/1997 of 27 November 1997 on the Government, concerning the procedure for drawing up laws and regulations, establish that prior to drawing up the text, a public consultation must be conducted through the Ministry of Health's website, in which the opinions of the most representative individuals and organisations potentially affected by the future regulation will be obtained. This was substantiated on the Ministry of Health's website, with a period from 8 April to 23 April 2024 to send comments or observations deemed appropriate via email. Contributions were received in this process from various companies distributing nicotine-releasing devices, scientific societies such as CNPT, SEMG, SEDET, SEE, CGCOF, SCATT and FAECAP, citizen organisations such as Nofumadores.org and AECC, and business organisations from different sectors. Thus, tobacconists' associations, agricultural organisations, trade union sections, duty-free shop operators, and advertising, design and telecommunication companies all expressed their views on the introduction of plain packaging.

For their part, there are also numerous personal experiences regarding the use of electronic cigarettes as a tool to quit smoking. This large number of responses is due to a campaign organised by various heated tobacco companies, the vaping sector and online content creators, and under the premise that the draft would mean the absolute prohibition of all flavoured vaping liquids. Thus, it should be noted that a total of 4114 responses to the public consultation were received, eight times the number of responses received to the last prior public consultation carried out on the occasion of the transposition of the Delegated Directive on heated tobacco. It is also worth mentioning the participation of responses received from outside Spain, a total of 33, the majority related to organisations defending harm reduction through heated tobacco products and related products.

In accordance with the provisions of Article 105(a) of the Spanish Constitution and Article 26(6) of Law 50/1997 of 27 November 1997, the mandatory public information process for the draft Royal Decree will be carried out by means of its publication on the Ministry of Health's website, during the period from 21 November 2024 to 22 December 2024.

It will be necessary to obtain the following reports from the proposing Department:

- Report from the Budget Office of the Department, in accordance with Article 3(f) of Royal Decree 2855/1979 of 21 December 1979 establishing Budget Offices.
- Report from the Ministerial Commission for Digital Administration, in accordance with the provisions of Article 7(4) of Royal Decree 806/2014 of 19 September 2014 on the organisation and operational instruments of information and communication technologies in the General State Administration and its Public Bodies.
- Report from the Technical General Secretariat, in accordance with the provisions of Article 26(5)(4) of Law 50/1997 of 27 November 1997 on the Government.

In accordance with the provisions of Article 26(5)(4) of Law 50/1997 of 27 November 1997, the report from the Ministry of Finance will be obtained.

In accordance with the provisions of Article 26(5)(1) of Law 50/1997 of 27 November 1997, reports will be obtained from the following Departments:

- Ministry of Social Rights, Consumer Affairs and 2030 Agenda.
- Ministry of Agriculture, Fisheries and Food.
- Ministry of Economy, Trade and Enterprise.
- Ministry of Industry and Tourism.
- Ministry of the Interior.
- Ministry of Youth and Children.
- National Institute of Toxicology and Forensic Sciences of the Ministry of the Presidency, Justice and Relations with the Parliament.

Likewise, in compliance with the aforementioned Law 50/1997 of 27 November 1997, the following reports must be obtained:

- Prior approval of the Ministry for Digital Transformation and the Civil Service, in accordance with the provisions of Article 26(5)(5) of Law 50/1997 of 27 November 1997.
- Report from the Office of Coordination and Regulatory Quality of the Ministry of the Presidency, Justice and Relations with the Parliament, in accordance with Article 26(9) of Law 50/1997.

- Report from the Ministry of Territorial Policy and Democratic Memory, in accordance with the provisions of Article 26(5)(6) of Law 50/1997 of 27 November 1997.

Likewise, the reports from the Autonomous Communities and Cities of Ceuta and Melilla, from the Spanish Federation of Municipalities and Provinces, as well as from the Advisory Committee and the Interterritorial Council of the National Health System will be obtained.

It will also be necessary to notify the European Commission in accordance with the provisions of Royal Decree 1337/1999 of 31 July 1999 regulating the transmission of information in the field of technical standards and regulations and of rules on Information Society services, and 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.

Likewise, the Consumers and Users Council, as well as the National Commission on Markets and Competition, must issue a report.

Finally, the Opinion of the Council of State will be obtained, in accordance with the provisions of Article 22(3) of Organic Law 3/1980 of 22 April 1980 on the Council of State.

Once all the formalities have been completed, the draft will be submitted to the General Commission of Secretaries of State and Undersecretaries, prior to its submission to the Council of Ministers for approval.

The result and reflection in the preliminary draft of the observations or proposals made will be included in an annex.

VII.- IMPACT ANALYSIS

1. Economic impact.

Regarding the consequences of its application on the sector and the effects on competition, market unity and competitiveness, it can be said that these are minimal. Thus, the economic impact of the envisaged measures is limited, as the continued marketing of most tobacco products and related products is allowed.

The measures included in the draft legislation affect competition at the manufacturing level by prohibiting certain ingredients, and at the distribution level by imposing labelling requirements.

However, given the multinational nature of the main companies in the tobacco sector in Spain, as well as the long tradition of applying this measure, its implementation by these market operators is currently facilitated by their manufacturing processes being adapted to these changes in the labelling and packaging regulations, with the sector having sufficient experience in this regard. These operators have significant resources at their disposal when dealing with any regulatory change, as well as a range of differentiated products together with commercial brands with a long tradition in the market, which in turn contribute to the turnover of the affected multinational companies.

Regarding the regulatory changes for e-cigarettes, the inclusion of those without nicotine in the scope of the Regulation does not entail a particularly notable impact, as much of the sector is familiar with and has adapted to the proposed communication obligations, even complying with such requirements without these being enforceable as part of their production processes, as these are just another variety of the different commercial brands and varieties they offer within their extensive product range. In the same vein, the restriction on the presence of flavourings can be compensated by shifting the consumption from some brand varieties to others within the same range.

Finally, it should be mentioned that the new regulation included in this Royal Decree regarding certain related products that have not been regulated until now has positive implications for the companies intending to market them, as it offers the necessary guarantee and legal certainty they previously lacked, facilitating their incorporation into the market while respecting proper protection of consumers.

2. Budgetary impact

As regards the impact on public expenditure, the application of the amendment laid down in this draft Royal Decree will not have a direct impact on the General State or Autonomous Community Budgets.

In relation to the General State Budgets, with respect to the Ministry of Health, for those activities that fall within the remit of the Directorate-General for Public Health and Health Equity, there are no direct or indirect associated costs, so it is not foreseeable that there will be an impact on public revenue or expenditure budgets.

With regard to the regional budgetary impact, there are no associated costs on the part of the competent authorities in the field of public health, so it is not foreseeable that there will be an impact on public revenue or expenditure budgets.

3. Analysis of administrative burdens

For tobacco products, e-cigarettes, and herbal products for smoking, which were previously regulated, it does not introduce new administrative burdens. In the case of nicotine-free e-cigarettes and new related products, new administrative burdens arising from marketing communications are introduced.

4. Gender impact.

The prevalence of tobacco use is higher in men (25.9 % in 2020) than in women (18.5 % in 2020), and although in both cases it is following a decreasing trend, the rate of decline is greater in men than in women. This has resulted in a narrowing of the difference in prevalence between women and men over the last 17 years (-7.4 pp in 2020 vs -12.9 pp in 2003).

More than half of students aged 14 to 18 admit to having used e-cigarettes at some point in their lives (54.6 %). This represents an increase of 10.3 percentage points compared to 2021, and places the use of these devices at the highest point in the historical series.

By sex, a greater increase in the prevalence of this substance is observed among female students (15.1 percentage points compared to 2021) than among male students (5.6 percentage points compared to 2021), marking the first time since this substance has been analysed that higher consumption has been recorded among girls than boys.

According to sex and age, it is observed that, in both groups, the prevalence of consumption increases with age, thus recording the highest proportion among those aged 18 (65.8 % in boys and 66.3 % in girls).

Regarding the content of e-cigarettes, more than half of those who have consumed e-cigarettes have done so without including either nicotine or cannabis. It is also observed that women consume more e-cigarettes with nicotine than men.

It is considered that the amendment has a positive impact on health for the general population, as the measures envisaged reduce addiction and therefore decrease the consumption of these products; however, this is not appreciable in the short term. Furthermore, it could be considered that the impact is greater for the female population as products with a characteristic flavour are more attractive to this sector of the population. This preference is supported by the scientific evidence available in different studies published internationally[4], as well as through recommendations made by the U.S. Centers for Disease Control and Prevention (CDC) regarding menthol tobacco products[5].

In view of the above, and taking into account the provisions of Article 26(3)(f) of Law 50/1997 of 27 November 1997 on the Government, it is considered that the proposed Regulation has a foreseeably positive gender impact, contributing to the elimination of inequalities between women and men and the fulfilment of the objectives of equality policies.

5. Impact on childhood and adolescence

More than half of students aged 14 to 18 admit to having used e-cigarettes at some point in their lives (54.6 %). This represents an increase of 10.3 percentage points compared to 2021, and places the use of these devices at the highest point in the historical series.

By sex, a greater increase in the prevalence of this substance is observed among female students (15.1 percentage points compared to 2021) than among male students (5.6 percentage points compared to 2021), marking the first time since this substance has been analysed that higher consumption has been recorded among girls than boys.

According to sex and age, it is observed that, in both groups, the prevalence of consumption increases with age, thus recording the highest proportion among those aged 18 (65.8 % in boys and 66.3 % in girls).

Regarding the content of e-cigarettes, more than half of those who have consumed e-cigarettes have done so without including either nicotine or cannabis. It is also observed that women consume more e-cigarettes with nicotine than men. This Regulation could have a positive impact on adolescents,

[4] Gilbert E, Ewald A. Fresher with flavour: young women smokers' constructions and experiences of menthol capsule cigarettes and regular cigarettes. BMC Women's Health. 2021 Apr 16;21(1):155. doi: 10.1186/s12905-021-01297-2. PMID: 33863322; PMCID: PMC8051088.
Hamadeh RR, Lee J, Abu-Rmeileh NME, Darawad M, Mostafa A, Kheirallah KA, Yusufali A, Thomas J, Salama M, Nakkash R, Salloum RG. Gender differences in waterpipe tobacco smoking among university students in four Eastern Mediterranean countries. Tob Induc Dis. 2020 Dec 2;18:100. doi: 10.18332/tid/129266. PMID: 33299390; PMCID: PMC7720794.

[5] Mentholated tobacco products
https://www.cdc.gov/tobacco/basic_information/menthol/spanish/index.html

but not a significant one in the short term, by prohibiting the presence on the market of products with a characteristic flavour that are more attractive to young people according to the scientific evidence available which is referenced in the previous Section.

6. Impact on the family

This Regulation is expected to have a positive impact on the health of the family, but not a significant one in the short term, as an aid in preventing the onset of smoking and nicotine addiction, preferably among the youngest members. In addition, as a consequence and indirectly, it would prevent the loss of the family's purchasing power by reducing the consumption of tobacco products and related products.

7. Impact due to climate change.

It is not considered to have an impact due to climate change.

8. Impact on health

This Regulation impacts health, as it establishes new rules for products such as nicotine pouches and nicotine-free e-cigarettes, which were not covered by the previous amendment to the Royal Decree. There has been an exponential increase in the consumption of said products, particularly among minors, who have experienced a significant rise in use, especially in the youngest age groups, with these products even being considered a gateway to nicotine addiction. With the measures envisaged, greater protection is being provided to the health of citizens, helping to reduce the onset of use.

By amending the labelling requirements, more information is provided to the general public.

9. Impact on LGBTI+ people.

Various studies[6] indicate that the prevalence of tobacco and related product use is higher in the LGBTI+ community compared to the general population. These differences are more pronounced in the age brackets for young people and adolescents[7].

Some studies also suggest that the LGBTI+ community is more exposed to the impact of advertising on social networks[8]. As social networks are precisely the main channels for advertising related products, this would mean greater vulnerability for this group.

VIII.- EX-POST EVALUATION

On the basis of the impact assessment carried out, no ex-post evaluation is considered necessary.

[6] Kann L, McManus T, Harris WA, et al. Youth Risk Behavior Surveillance — United States. (2017). MMWR Surveill Summ 2018;67(No. SS-8):1–114. DOI: http://dx.doi.org/10.15585/mmwr.ss6708a1External.
Soneji, S., Barrington-Trimis, J. L., Wills, T. A., Leventhal, A. M., Unger, J. B., Gibson, L. A., … Sargent, J. D. (2017). Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-analysis. JAMA Pediatrics, 171(8), 788–797. https://doi.org/10.1001/jamapediatrics.2017.1488
Emory, K. T., Scout, Kim, Y., Fagan, P., Vera, L. E., & Emery, S. (2017). Transgender Use of Cigarettes, Cigars, and E-Cigarettes in a National Study. American Journal of Preventive Medicine, 53(1), e1–e7. https://doi.org/10.1016/j.amepre.2016.11.022
Salloum, R. G., Thrasher, J. F., Kates, F. R., & Maziak, W. (2015). Water pipe tobacco smoking in the United States: Findings from the National Adult Tobacco Survey. Preventive Medicine, 71, 88–93. https://doi.org/10.1016/j.ypmed.2014.12.012

[7] https://www.cdc.gov/tobacco/basic_information/menthol/spanish/index.html

[8] Emory, K., Buchting, F. O., Trinidad, D. R., Vera, L., & Emery, S. L. (2018). Lesbian, Gay, Bisexual, and Transgender (LGBT) view it differently than non-LGBT: Exposure to Tobacco-related Couponing, E-cigarette Advertisements, and Anti-tobacco Messages on Social and Traditional Media. Nicotine & Tobacco Research, 21(4), 513–522.