

EXECUTIVE REPORT OF THE REGULATORY IMPACT ANALYSIS OF THE DRAFT DECREE OF THE GOVERNING COUNCIL ESTABLISHING THE REGISTER OF FOOD RETAIL COMPANIES FOR FOOD PRODUCTS OF THE COMMUNITY OF MADRID AND REGULATING THE COMMUNICATION PROCEDURE FOR THE ENTRY, AMENDMENT AND CANCELLATION IN THE REGISTER OF SUCH COMPANIES.

EXECUTIVE SUMMARY SHEET

Proposing Department / Body	Regional Ministry of Health Directorate-General for Public Health	Date	March 2025		
Title of the Regulation	Draft Decree of the Governing Council creating the Register of Food Businesses Retailing Food Products of the Community of Madrid and regulating the communication procedure for the registration, modification and cancellation in the Register of the same.				
Type of report	Extended	Executiv	ve		
	TIMELINESS OF THE PROPOS	SAL			
Subject	Royal Decree 191/2011 of 18 Februar Register of Food Businesses and Foods businesses that are subject to registration by final provision 1.1 of Royal Decree regulating certain hygiene requirements of foodstuffs in retail establishments, retail establishments, retail establishments of the corresponding official controls. All retail into the registers of the competent Communities established for that purpose notifies the competent authorities of the situated.	tuffs includes n. Following to 1021/2022 of or the product establishment cember 2022 Register, with establishme authorities e, after the fo	the activities of food he amendment made f 13 December 2022 tion and marketing of s as defined in Article have been excluded thout prejudice to the ents shall be entered of the Autonomous and business operator		



	The purpose of the approval of this Decree is to develop the provisions laid down in Royal Decree 191/2011 of 18 February 2007 on the General Health Register of Food Businesses and Foodstuffs, in order to meet the following objectives:
Objectives	 Create the General Register of Food Companies of Retail Trade in Food Products of the Community of Madrid as a food safety instrument, which contributes to protecting public health and the interests of consumers.
Objectives	 Regulate the procedure for notifying the start of operations of such food businesses for the purposes of their registration in the Register.
	 Elimination and reduction of administrative obstacles and costs for retailers of food products in the Community of Madrid, not being the presentation of the enabling communication for the start of the activity, in addition to being a free procedure that will not generate unnecessary costs for companies.
Main alternatives considered	The possibility of amending Order 1531/2005 of 6 October 2005 of the Department of Health and Consumer Affairs regulating the conditions and procedures for the authorisation of retail establishments for fresh meat and their derivatives in the Community of Madrid has not been considered as a favourable alternative, since a substantial modification of it would be necessary to adapt it to the new regulatory framework in this area.
Considered	 Nor does it raise the possibility of not carrying out this regulation, since Royal Decree 191/2011, of 18 February, establishes a mandate to the autonomous communities to create an autonomous registry in which retail establishments of food products are registered.



	CONTENT AND LEGAL ANALYSIS
Type of regulation	Decree
Structure of the regulation	 The Decree consists of a preamble and the following chapters: Chapter I (Articles 1, 2 and 3): General provisions. Chapter II (Articles 5, 6 and 7): From the Register of Food Companies of Retail Trade of Food Products of the Community of Madrid. Chapter III (Articles 8, 9, 10 and 11): Of the procedures of communication of start of activity, communication of modification of data of mandatory information contained in the communication or definitive cessation of the activity. Chapter 2, § 12. Penalty authority Sole transitional arrangement. Sole repealing provision. Two final provisions. An annex.
Reports to which the project is submitted	 Mandatory reports requested: Report on coordination and regulatory quality of the Technical Secretariat-General of the Regional Ministry of the Presidency, Justice and Local Administration. Gender impact report of the Directorate-General for Equality of the Ministry of Family, Youth and Social Affairs. Report on the impact on children, adolescents and families of the Directorate-General for Children, Family and Birth Promotion of the Ministry of Family, Youth and Social Affairs. of the General Technical Secretariats of the Regional Ministries; Report of the Consumer Council of the Community of Madrid. Budgetary impact report of the Directorate-General for Budget of the Regional Ministry of Economy, Finance and Employment. Report of the Directorate-General for Taxes of the Ministry of Economy, Finance and Employment. Report from the Directorate-General for Trade, Consumer Affairs and Services of the Ministry of Economy, Finance and Employment.



-	Report	of	the	Directorate-General	for	Citizen	Services	and
	Transpa	ren	cy of	the Ministry of the Pi	resid	ency, Ju	stice and	Local
	Adminis	trati	on.					
_	Report	of tl	ne Di	rectorate-General for	Coc	neration	with the	State

Report of the Directorate-General for Cooperation with the State and the European Union, of the Ministry of the Presidency, Justice and Local Administration.

Reports to be collected:

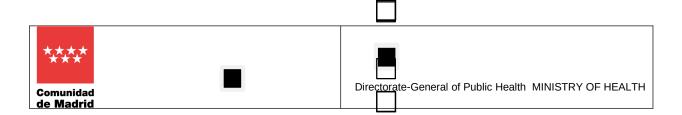
- Reports from the Technical Secretary-General of the Ministry of Health.
- The report of the General Advocacy of the Community of Madrid is necessary, in accordance with the provisions of Article 4.1.a) of Law 3/1999, of March 30, on the Regulation of the Legal Services of the Community of Madrid.

Procedures for prior public consultation and public information

• The public consultation procedure has been carried out in accordance with the provisions of Article 60(1) of Law 10/2019, of 10 April 2019, on Transparency and Participation of the Community of Madrid and Articles 4(2)(a) and 5(1) of Decree 52/2021, of 24 March 2021, of the Governing Council, regulating and simplifying the procedure for drawing up the general regulatory provisions in the Community of Madrid. The public consultation, authorised by the Agreement of the Governing Council of 8 May 2024, was completed with the publication of the draft Decree on the Transparency Portal of the Community of Madrid on 22 May 2024, with a deadline of 15 working days for submitting contributions (from 23 May to 13 June 2024).

• The procedure of hearing and public information referred to in Article 60.2 of Law 10/2019, of April 10, on Transparency and Participation of the Community of Madrid and in accordance with the provisions of Articles 4.2.d) and 9 of Decree 52/2021, of 24 March, of the Governing Council, regulating and simplifying the procedure for drawing up the general regulatory provisions in the Community of Madrid, from March 9 to March 30 2023 (period of fifteen working days) on the Transparency Portal of the Community of Madrid, having submitted eight contributions from different individuals and companies in the sector.

IMPACT ANALYSIS					
COMPLIANCE WITH THE DISTRIBUTION OF POWERS	This draft decree conforms to the order of distribution of competences established in Article 43 of the Spanish Constitution of 1978, and in Articles 27.4 and 22.1 of the Statute of Autonomy of the Community of Madrid, as well as to the competences attributed to the Ministry of Health, in accordance with the provisions of Decree 245/2023, of 4 October, of the Governing Council, establishing the organizational structure of the Ministry of Health.				
	General impact on the economy	There is no direct impact on the economy in general from the content of the project.			
	With regard to competition	The Regulation has no significant impact on competition. The regulation has positive effects on competition, although they are not relevant. The Regulation has negative effects on competition.			
ECONOMIC AND BUDGETARY IMPACT	With respect to administrative burdens	It reduces administrative burdens for retailers of fresh meat and meat products in the Community of Madrid. Estimated quantification of reduction in administrative burden: 5.600 € It introduces new administrative burdens for other food retailers. Estimated quantification: • Free of charge for retail businesses. • Initial administrative burden cost: 81.218 € It does not affect administrative burdens.			



	With respect to budgets, the Regulation: Affects the budgets of the Administration of the Community of Madrid Does not affect the budgets of the Administration of the Community of Madrid.	Implies an expense. Estimated quantification: € Implies an income. Estimated quantification: € It implies a reduction of the expected revenue. Estimated quantification: 8.576 €	
GENDER IMPACT	Gender impact	Negative None Positive	
IMPACT ON CHILDREN, ADOLESCENTS AND FAMILIES	Adolescence, childhood and family	Negative None Positive	
OTHER IMPACTS AND CONSIDERATIONS	It does not affect market unity, respecting the principles contained in Law 20/2013 of 9 December on market unit guarantees.		



1. INTRODUCTION.

This report of the regulatory impact analysis (hereinafter MAIN) is carried out in order to provide a comprehensive vision that facilitates the analysis and understanding of the proposal, in accordance with the provisions of Articles 4 and 6 of Decree 52/2021, of 24 March, of the Governing Council, which regulates and simplifies the procedure for preparing general regulatory provisions in the Community of Madrid.

In accordance with the provisions of Article 6.2 of the aforementioned Decree, an executive report is made since the proposed legislation does not result in any significant economic, budgetary or social impact on administrative burdens or any other analogous effect.

2. AIMS, OBJECTIVES, TIMELINESS AND LEGALITY OF THE STANDARD.

European legislation contains provisions relating to the registration by the competent authority of certain food businesses, in particular Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs requires food business operators to notify the appropriate competent authority of the businesses under their control in which any of the food production, processing and distribution operations are carried out in order to proceed with their registration.

At the state level, Article 25.1 of General Health Law 14/1986 of 25 April 1986 establishes that the obligation to submit companies or products to registration for health reasons shall be established by regulation, based on the provisions of that law and the General Public Health Law.

Law 33/2011, of October 4, General Public Health, in article 29.2 provides that health administrations may establish the obligation of responsible declaration or communication of start of activity for those facilities, establishments, services and industries that develop activities that may affect health, in accordance with the applicable sectoral regulations and taking into account the provisions of Law 17/2009, of November 23, on free access to service activities and their exercise.

On the other hand, Article 24(1) of Law 17/2011 of 5 July 2011 on Food Safety and Nutrition establishes that public administrations shall create or maintain the necessary registers for the knowledge of the different situations from which intervention actions in the field of food safety may be derived. The request for registration in the registers will not entail additional actions on the part of the interested parties, except those derived from the update of the declared information and the request for cancellation of registration when causing withdrawal.





Article 2.1 of Royal Decree 191/2011 of 18 February 2011 on the General Health Register of Food Businesses and Foodstuffs lists the food businesses and establishments subject to registration in that register. Article 2(2), as amended by Royal Decree 1021/2022 of 13 December 2022 regulating certain hygiene requirements for the production and marketing of foodstuffs in retail establishments, excludes retail establishments as defined in Article 2 of Royal Decree 1021/2022 of 13 December 2022 from the obligation to register. All retail establishments shall be entered into the registers of the competent authorities of the Autonomous Communities established for that purpose, after the food business operator notifies the competent authorities of the place where the establishment is situated.

Currently, in the Community of Madrid, only the Register of establishments for the retail trade in fresh meat and meat derivatives, regulated by Order 1531/2005 of 6 October of the Regional Ministry of Health and Consumer Affairs, regulating the conditions and procedure for the approval of establishments for the retail trade in fresh meat and its derivatives in the Community of Madrid, is authorised.

For the above reasons, it is appropriate to approve this decree, in order to develop the forecasts contemplated in Royal Decree 191/2011, of February 18, to meet the following objectives:

- a) Create the General Register of Food Companies of Retail Trade in Food Products of the Community of Madrid as a food safety instrument, which contributes to protecting public health and the interests of consumers. This register will allow the quantification, consultation and cataloguing of food businesses retailing food products in the territorial scope of the Community of Madrid, thus enabling, through the information provided by operators, a programming of official controls and, in cases of detection of a danger to public health, act quickly, effectively and efficiently.
- b) Regulate the procedure for notifying the start of operations of such food businesses for the purposes of their registration in the Register.
- c) Abolition and reduction of obstacles and administrative costs for retailers of food products in the Community of Madrid, this communication having no effect on the start of the activity, since these effects are achieved with the responsible declaration contained in Law 2/2012, of June 12, and also being a free procedure that will not generate unnecessary costs for companies. All of this will facilitate the installation of retail food businesses in the Community of Madrid, promoting competition and promoting economic growth in the region, without prejudice to the responsibility of operators to comply at all times with the applicable regulations and the powers of subsequent verification, control and inspection to be carried out by the Health Administration to ensure the protection of health in the field of food safety.



a) Alternatives.

The possibility of amending Order 1531/2005 of 6 October 2005 of the Department of Health and Consumer Affairs regulating the conditions and procedures for the authorisation of retail establishments for fresh meat and their derivatives in the Community of Madrid has not been considered as a favourable alternative, since a substantial modification of it would be necessary to adapt it to the new regulatory framework in this area.

Thus, it is considered more appropriate to adopt a new decree repealing the aforementioned Order 1531/2005, including in a single regulatory provision the regulation of a single general register for all food companies involved in the retail trade of food products in the Community of Madrid, and regulating a communication procedure as a single and sufficient requirement to start the activity.

Nor does it raise the possibility of not carrying out this regulation, since Royal Decree 191/2011, of 18 February, establishes a mandate to the autonomous communities to create an autonomous registry in which retail establishments of food products are registered, after notification of the food business operator to the competent authorities due to the place of location of the establishment.

3. COMPLIANCE WITH THE PRINCIPLES OF GOOD REGULATION

This decree complies with the principles of good regulation, in accordance with the provisions of Article 129 of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, and in Article 2 of the Decree 52/2021, of 24 March, of the Governing Council, regulating and simplifying the procedure for drawing up the general regulatory provisions in the Community of Madrid.

This standard complies with the principles of necessity and effectiveness, insofar as it implements the mandate established for the Autonomous Communities in Article 2(2) of Royal Decree 191/2011 of 18 February 2011, thus creating the regional register in which food retail companies operating in the Community of Madrid will be registered and establishing the procedure for communicating the start of their activity. All this will make it possible to carry out a programming of official controls, in order to attend to the general interest of protecting public health and the interests of consumers, with the approval of this Decree being the most appropriate legal instrument to guarantee its achievement.

Likewise, its adoption complies with the principle of proportionality, since it contains the minimum regulation essential for the achievement of the objectives pursued, that is, to have a



census of companies and retailers of food products in the Community of Madrid.

Likewise, its adoption guarantees the principle of legal certainty, being coherent with the rest of the legal system, national and of the European Union, its objectives being clearly defined, unifying the legal framework applicable to food retail companies in the Community of Madrid, thus creating a more favorable and transparent environment in this sector.

The principle of transparency is complied with, having carried out the procedures of public consultation, hearing and public information, in accordance with the provisions of Articles 60(2) of Law 10/2019, of 10 April 2019, on Transparency and Participation of the Community of Madrid, 5 and 9 of Decree 52/2021, of 24 March 2021, and, once the standard has been approved, it is published on the Transparency Portal.

Finally, in application of the principle of efficiency, the rule streamlines the management of public resources by entailing the elimination of several of the existing administrative burdens without imposing more new administrative burdens than those strictly necessary for the correct application of the rule.

4. identification of the prevailing competency title;

The present norm is adapted to the order of distribution of competences established in the Spanish Constitution of 1978 and in the Statute of Autonomy of the Community of Madrid.

Article 43 of the Spanish Constitution recognises the right to health protection and states that it is incumbent upon the public authorities to organise and safeguard public health by means of preventive measures and the necessary benefits and services.

Article 149.1.16.a of the Spanish Constitution confers on the State exclusive competence in matters of bases and general coordination of health and under this attribution Royal Decree 191/2011 of 18 February is approved, this rule provides that all establishments of retail trade of food products must be registered in the registers of the competent authorities of the autonomous communities, established for this purpose.

Article 27(4) of the Statute of Autonomy of the Community of Madrid, approved by Organic Law 3/1983 of 25 February 1983, confers on it the power to develop legislation, the regulatory power and the implementation of state legislation on health and hygiene.

This regulatory provision is approved by the Governing Council of the Community, which has generally and originally recognised the regulatory power under Article 22 (1) of the Statute of Autonomy of the Community of Madrid 'in matters not reserved in this Statute to the Assembly'. Article 21(g) of Law 1/1983 of 13 December 1983 on the Government and Administration of the



Community of Madrid includes within the powers of the Governing Council 'to approve by decree the regulations for the development and implementation of the laws emanating from the Assembly, as well as those of the laws of the State, when the execution of the competence corresponds to the Community of Madrid by virtue of the Statute of Autonomy, or by delegation or transfer, and to exercise in general the regulatory power in all cases in which it is not specifically attributed to the president or the directors'.

5. LEGAL ANALYSIS

The purpose of the draft Decree accompanying this report is to implement the mandate to the Autonomous Communities laid down in Royal Decree 191/2011 of 18 February, which lays down in Article 2 (2) the obligation for all food retail establishments to be entered in the registers of the competent authorities of those of the Autonomous Communities established for that purpose, subject to notification or self-declaration, which shall not be authorised, from the food business operator to the competent authorities of the place where the establishment is located.

As regards the formal status of the proposal, it must be a decree to implement the development of the provisions referred to in Royal Decree 191/2011 of 18 February 2011. In addition, Article 25.1 of General Health Law 14/1986 of 25 April 1986 provides that the obligation to submit companies or products to registration for health reasons shall be established by regulation, on the basis of the provisions thereof and the General Public Health Law.

a) Regulations that are repealed.

With the approval of this decree, Order 1531/2005 of 6 October 2005 of the Consejería de Sanidad y Consumo (Ministry of Health and Consumer Affairs) regulating the conditions and procedure for the approval of retail establishments selling fresh meat and its derivatives in the Community of Madrid is repealed.

6. ECONOMIC AND BUDGETARY IMPACT

a) Economic impact

This Decree does not identify negative effects on competition in the market, since the creation of the Register of Food Companies of Retail Trade in Food Products of the Community of Madrid will not restrict access to new retailers. On the contrary, this new regulation creates a more favorable and transparent environment for the owner of the food business since it clarifies the procedures to be carried out, not having this communication effects for the beginning of the activity, since these effects are reached with the responsible declaration contained in Law 2/2012, of June 12, and being also a free procedure that will not generate unnecessary costs for



the companies. This will facilitate the installation of retail food businesses in the Community of Madrid, promoting competition and ensuring legal certainty to promote economic growth in the region.

The adoption of this new decree does not impose obstacles to business activity and the free operation of markets, thus respecting the principles contained in Law 20/2013, of 9 December 2013, on guarantees of market unity.

With reference to the effects of the regulation on consumers, with the creation of a census of food retail companies in the Community of Madrid it will be possible to carry out a programming of official controls, which will revert to greater protection of public health and the interests of consumers.

b) Budgetary impact

Currently, in the Community of Madrid, only the register of establishments for the retail trade of fresh meat and meat products is authorised. The application for initial registration in said register, as well as applications for modification or cessation of activity, change of ownership or change of address of the establishment, are subject to the payment of a fee in the amount of EUR 10.72 per concession of administrative authorisation. This fee is applied in accordance with Legislative Decree 1/2002 of 24 October 2002 approving the consolidated text of the Law on Public Fees and Prices of the Community of Madrid, Chapter LVIII, point 58. The Ministry of Health processes approximately 800 authorisation files subject to a fee per year, which require registration in the Register of establishments for the retail trade in fresh meat and meat products.

With the entry into force of the decree accompanying this report, the Register of Food Retail Companies of the Community of Madrid will be created, and the current Register of retail establishments for fresh meat and derivatives will be terminated. Companies already registered in that Register shall be registered ex officio in the new Register of Food Retail Companies.

Registration in the Register of Food Retail Companies of the Community of Madrid shall be carried out ex officio once operators submit a start-of-activity communication, they shall also be obliged to communicate any changes to mandatory information data and the definitive cessation of activity, none of the aforementioned communications being subject to a fee.

In view of the above, the new system being designed will affect the General Budgets of the Community of Madrid, with a reduction of the economic rights to recognise and collect provided for in the General Budgets of the Community of Madrid for the financial year 2024, specifically in the subconcept of the revenue budget 30404 called inspection, audits and administrative



authorisations for public health, for an amount of EUR 8 576.



However, the implementation of the provisions of this Decree will not generate economic obligations for the Ministry of Health, since the cost of its operation will be charged to the budget of the Ministry of Health without entailing an increase in expenditure in any way, with the administrative management of the Register of Food Companies of Retail Trade being included in the operation of the Ministry of Health itself.

7. DETECTION AND MEASUREMENT OF ADMINISTRATIVE BURDENS

In order to detect and measure the administrative burdens involved in the adoption of this new decree, the analysis is carried out by dividing the food retail companies concerned into three main groups:

a) Retail establishments of meat products and derivatives that are registered in the current Register of meat establishments and retail derivatives of the Community of Madrid.

Currently, 8,500 retail establishments are registered in the Register of Meat and Retail Derivatives Establishments of the Community of Madrid. Entry in that register requires the payment of a fee for the granting of administrative authorisation.

With the entry into force of the new decree, this register will be terminated, and the establishments registered in it will be automatically incorporated into the Register of Food Companies of Retail Trade in Food Products of the Community of Madrid, therefore not having to submit a notification of the start of activity, or carry out any procedure to be included in the new register. This will prevent this new regulation from creating unnecessary and repetitive administrative burdens for them.

However, they will be obliged to communicate the changes produced in any of the mandatory information data they provided, as well as the cessation of activity. Under the current regulation, such communications are subject to a fee (except for the communication of cessation of activity of the establishment). Upon the entry into force of the decree accompanying this report, such communications shall be free of charge.

b) Retail companies of meat products and derivatives that will start activity in the Community of Madrid once the new Decree enters into force.

For future retail companies of meat products and derivatives that, with the decree accompanying this report in force, wish to start their activity in the Community of Madrid, administrative burdens are reduced, since with the new regulation, the authorisation regime provided for in Order 1531/2005, of 6 October, of the Ministry of Health and Consumer Affairs,



regulating the conditions and procedure for the authorisation of retail establishments for fresh meat and their derivatives in the Community of Madrid, which is also subject to a fee, is replaced by the notification of the start of activity, which will be free of charge.

Approximately 800 files of administrative authorisations for retail trade in fresh meat and derivatives are currently processed each year by the Directorate-General for Public Health.

Please find attached a comparative table of the burdens arising from the regulations now in force for retailers of fresh meat and meat products in the Community of Madrid and those provided for in the proposed legislation, taking into account the provisions of the Metodoological Guide approved by the Council of Ministers of 11 December 2009, the validity of which has been extended by paragraph 2 of the First Additional Provision of Royal Decree 931/2017 of 27 October regulating the report on regulatory impact analysis.

ADMINISTRATIVE BURDENS PROVIDED FOR IN ORDER 1531/2005, OF 6 OCTOBER, OF THE REGIONAL MINISTRY OF HEALTH AND CONSUMER AFFAIRS, REGULATING THE CONDITIONS AND PROCEDURE FOR THE AUTHORISATION OF RETAIL ESTABLISHMENTS FOR FRESH MEAT AND THEIR DERIVATIVES IN THE COMMUNITY OF MADRID.

		UNIT COST	FREQUENCY	TOTAL
Application for authorization of initial	Submit an online application	5 euros	800	4,000
registration, modification and cessation of activity.	Online submission of documents, invoices or requirements	4 euros	800	3,200
	TOTAL ADN		BURDEN COST	7.200 €

ADMINISTRATIVE BURDENS NEW DECREE					
Communication of initiation of activity, communications of modification of data and cessation of activity	2 euros	800	1,600		
TOTAL ADMINISTRATIVE BURDEN COST					
ref. Decree					
REDUCTION OF ADMINISTRATIVE BURDEN WITH APPROVAL					
ref. Decree					



c) Remaining food retail companies in the Community of Madrid.

For the other food retail companies in the Community of Madrid (those that do not trade meat and derivatives and therefore were not obliged to register in any regional register until the entry into force of this Decree), a new administrative burden is identified, which is only the submission of communication for registration in the Register.

In order to simplify this burden, the communication shall not be subject to a fee. It must contain only the following information: the business name of the food business establishment, the tax identification number, the registered office and the address of the premises where the activity or activities are carried out. The communication form shall be accompanied by a document certifying the tax identification number or foreigner identification number of the operator owning the facilities. With reference to the frequency of submission, it will be submitted before the start of activity, and its renewal is not necessary. Retail food business operators should only submit another communication when there is a change in the data they included in the notification of commencement of activity or they have definitively ceased the activity.

They will be submitted by electronic application, thus avoiding displacements and repetitions in the loads.

The presentation of communication will be free for all food retail companies in the Community of Madrid, avoiding an unnecessary cost for them. In addition, once the notification of the start of activity has been submitted, the registration in the Register of Food Companies of Retail Trade in Food Products of the Community of Madrid will be carried out ex officio by the Administration, thus avoiding duplication or repetition of burdens.

In order to calculate the cost of this new administrative burden, account has been taken of the forecasts contained in the Methodological Guide approved by the Council of Ministers on 11 December 2009, the validity of which has been extended by paragraph 2 of the First Additional Provision of Royal Decree 931/2017 of 27 October 2017 regulating the Regulatory Impact Assessment Report. The same estimates that the cost of submitting a communication is EUR 2.

There are approximately 40,609 food retailing companies in the Community of Madrid that are not registered in the Register of retailing establishments for fresh meat and its derivatives in the Community of Madrid and will therefore have to submit a notification of commencement of activity within one year of the entry into force of the new decree. The administrative burden in relation to these companies is shown in the following tables:



GLOBAL DATA	Census (%)	Font	REMARKS
Retail food companies in Comunidad de Madrid	9,329	Report of the Directorate- General for Trade, Consumer Affairs and Services ⁽¹⁾	According to the Autonomous Community register, as of September 2024 there are 6548 meat retail establishments in the territory of the Community of Madrid. ⁽²⁾
Merchants with non-fixed location, registered in Comunidad de Madrid	1,440	Report of the Directorate- General for Trade, Consumer Affairs and Services ⁽¹⁾	
Restaurants in the Community of Madrid	29,840	Information published by the Hotel and Catering Association of the Community of Madrid ⁽³⁾	
TOTAL ESTIMATED CENSUS	40,609		

⁽¹⁾ Report of the Directorate-General for Trade, Consumer Affairs and Services (https://www.comunidad.madrid/sites/default/files/el_comercio_de_madrid_en_cifras_16_mayo_2024_1.pdf)

⁽³⁾ Information published by the Association on its website: **Error! Hyperlink reference not valid.** de-hosteleria-desciende-en-2023-tanto-a-nivel-nacional-como-autonomico-en-la-comunidad-de-madrid-segun-el-dirce/

	Burden type	Unit cost	Frequency	Population	Total cost
Retail food companies of C. Madrid that do not trade in fresh meat and derivatives and are therefore NOT entered in the Register of establishments for the retail trade of fresh meat and derivatives in the Community of Madrid.	Submission Communication Not Subject to Fee	2	1	40,609	81.218 €
Initial adn	ninistrative burden				81.218 €

On the other hand, those new retail companies that start their activity, once the new decree enters into force, must communicate that start of activity. The following table shows the evolution of the number of food retailers in the Community of Madrid.

⁽²⁾ No of authorisations of retail establishments for meat issued by the DGSP, available on the open data portal (https://datos.comunidad.madrid/dataset/registro_establecimientos_comercio_por_menor_carne).



	2023	2024
Retail food companies in Comunidad de Madrid	11,570	10,724
Merchants with non-fixed location, registered in Comunidad de Madrid ⁽¹⁾	1,331	1,440
Restaurants in the Community of Madrid ⁽²⁾	32,005	29,840
TOTAL FOOD MINORIST COMPANIES	44,906	42,004

⁽¹⁾ Report from the Directorate-General for Trade, Consumer Affairs and Services.

⁽²⁾ Information published by the Association on its website: https://www.hosteleriamadrid.com/blog/el-numero-de-locales-de-hosteleria-desciende-en-2023-tanto-a-nivel-nacional-como-autonomico-en-la-comunidad-de-madrid-segun-el-dirce/

	Number of enterprises 2023	Number of enterprises 2024	Variation	Cost	Reduction of administrative burden
Total retail food businesses	44,906	42,004	- 2.902	2€	5.804 €

According to these data, the forecast of the administrative burden, with respect to companies that begin their activity, once the rule has entered into force, represents a reduction of the burden of € 5,804, given the evolution of the number of companies in the last two years.

It is important to note that the number of food retail businesses is very variable over time, making the administrative burden difficult to quantify.

This new administrative burden is justified and proportionate to the aim of developing the provisions laid down in Royal Decree 191/2011 of 18 February 2007, in order to have a census of businesses and retail outlets in the Community of Madrid, which makes it possible to carry out a programme of official controls, with the aim of protecting public health and the interests of consumers.

8. SOCIAL IMPACTS AND OTHER IMPACTS.

8.1 Gender impact

The gender impact report is requested from the Directorate-General for Equality of the Ministry of Family, Youth and Social Affairs, in accordance with Article 6(1)(e) of Decree 52/2021, of 24 March 2021, in conjunction with Article 19 of Organic Law 3/2007, of 22 March 2007, for the



effective equality of women and men, and Article 9(1)(b) of Decree 241/2023, of 20 September 2023, of the Governing Council, establishing the organic structure of the Ministry of Family, Youth and Social Affairs.

A report was received on 25 September 2024. The result of the gender impact analysis is included in section 9.2.c), in the section 'social impact reports'.

8.2 Impact on children and adolescents, and on the family

The report on the impact on children, adolescents and the family is requested from the Directorate-General for Children, the Family and the Promotion of Births of the Ministry of the Family, Youth and Social Affairs, in accordance with Article 6(1)(e) of Decree 52/2021 of 24 March 2021 in conjunction with Article 22d of Organic Law 1/1996 of 15 January 1996 on the Legal Protection of Minors, partially amending the Civil Code and the Law on Civil Procedure, in the tenth additional provision of Law 40/2003 of 18 November 2003 on the Protection of Large Families, Article 47 of Law 4/2003 of 22 March 2003 on the Rights, Guarantees and Comprehensive Protection of Children and Adolescents of the Community of Madrid and Article 7.15 of Decree 241/2023 of 20 September 2003.

Report received on 24 September 2024. The result of the gender impact analysis is included in section 9.2.c), in the section 'social impact reports'.

8.3 Other impacts.

No other impacts than those identified above are foreseen.

9. DESCRIPTION OF THE CONTENT AND PROCESSING.

9.1 Description of the content.

For the processing of this draft Decree, the provisions contained in Decree 52/2021 of 24 March regulating and simplifying the procedure for drawing up the general regulatory provisions in the Community of Madrid, which develops specific provisions contained, in particular, in Law 1/1983, of December 13, of the Government and Administration of the Community of Madrid, and in Law 10/2019, of April 10, on Transparency and Participation of the Community of Madrid.

Likewise, in so far as it does not oppose Decree 52/2021 of 24 March 2021, the Guide for the preparation and processing of general provisions in the Community of Madrid applies.

In this regard, the draft decree has been drawn up by the Directorate-General for Public Health, pursuant to the provisions of Article 25(m) of Decree 245/2023 of 4 October 2023 of the



Governing Council, establishing the organisational structure of the Ministry of Health, on the basis of the powers of health control, authorisation and registration of food businesses in the field of the safety of food products produced and marketed by them, excluding waste, by-products and waste resulting from their activity whose destination is not the human food chain.

The draft consists of an expository part containing the background, motivation and guiding principles of the standard and an operative part structured in thirty-six articles contained in eight chapters, two additional provisions, one derogatory provision and two final provisions. It also contains four annexes.

Chapter I sets out the subject matter, definitions, undertakings and establishments subject to registration and derogations (Articles 1, 2, 3 and 4 respectively).

Chapter II regulates the Register of Food Retail Establishments and Companies of the Community of Madrid, establishing in Article 5 the assignment and nature of the Register, in Article 6 its structure and in Article 7 its content.

Chapter III sets out the procedures for the notification of the commencement of activity, the communication of amendments to mandatory information contained in the communication or the definitive cessation of the activity, establishing the legal arrangements for the procedures in Article 8, the procedures for notifications for registration, amendment and cancellation in Article 9, the form and place of submission of the communications in Article 10, and non-compliance with the statements or declarations set out in Article 11.

Chapter IV regulates the power to impose penalties. Section 7 lays down the system of penalties.

The single transitional provision concerns the entry in the register of undertakings entered in the register of establishments for the retail trade of fresh meat and its derivatives.

The repeal provision determines the rules that will be repealed upon the entry into force of the decree.

Finally, the first final provision determines the development authorization and the second final provision establishes the entry into force of the decree.

As regards the annex, it contains the notification of registration, modification and cessation in the Register of Food Companies for Retail Trade in Food Products of the Community of Madrid.



9.2 Description of the procedure.

a) Public consultation:

The participation of agents and sectors representing interests is carried out in accordance with the provisions of Article 5.1 of Decree 52/2021, of 24 March, of the Governing Council, which regulates and simplifies the procedure for drawing up the general regulatory provisions in the Community of Madrid and in Article 60.1 of Law 10/2019, of 10 April, on Transparency and Participation of the Community of Madrid.

In accordance with the above, by Decision of the Governing Council of 8 May 2024, the Ministry of Health was authorised to publish, on the Transparency Portal of the Community of Madrid, the public consultation on the draft decree establishing the Register of Food Businesses Retailing Food Products of the Community of Madrid and regulating the procedure for notifying the start of their activity. In accordance with the above, the procedure for the public consultation has been evacuated by publishing the draft decree on the Transparency Portal of the Community of Madrid on May 5, 2022, with a period of 15 working days to submit contributions (from 6 May to 27 May 2022).

During this period, two submissions were received with the following proposals:



1. ADEPESCA Association proposes a solution to facilitate the registration process. Instead of limiting the exclusive use of the electronic certificate, traders should be allowed to authorise an entity or association that does have electronic certificates to carry out the procedure on their behalf or to manage registration in person or by means that are not exclusively digital. This would, according to the proposer, reduce the administrative burden for the self-employed and ensure that registration is carried out efficiently.

It is not appropriate to incorporate the solution proposed by the aforementioned Association into the regulatory text.

The subjection of the action of the public administrations to a certain procedural channel constitutes a requirement of constitutional scope with express mention in section c) of article 105 of the Spanish Constitution. This constitutional mandate is given effect preferentially in Law 39/2015, of October 1, on the Common Administrative Procedure of the Public Administrations (LPAC) approved under Article 149.1.18 of the Constitution that attributes to the State, among other aspects, the competence to dictate the bases of the legal regime of the Public Administrations and the common administrative procedure.

In Section 14: 2 of the same establishes that in any case, at least the following subjects shall be obliged to interact with the Public Administrations through electronic means in order to carry out any procedure of an administrative procedure:

- a) Legal persons.
- b) Entities without legal personality.
- c) Those who exercise a professional activity for which compulsory membership is required, for the procedures and actions they carry out with the Public Administrations in the exercise of said professional activity. In any case, within this group will be understood including notaries and registrars of property and commercial.
- d) Persons representing a data subject who is obliged to liaise electronically with the administration.
- e) Employees of public administrations for the procedures and actions they carry out with them due to their status as public employee, in the manner determined by regulation by each administration.



According to regulations, the Administrations may establish the obligation to relate to them through electronic means for certain procedures and for certain groups of individuals who, due to their financial or technical capacity, professional dedication or other reasons, can demonstrate that they have access to and availability of the necessary electronic means.

In addition, Article 68.4 of the aforementioned Law 39/2015, establishes that if any of the subjects referred to in Article 14.2 and 14.3 submits their application in person, the Public Administrations will require the interested party to correct it through their electronic presentation. In that regard, the date of submission of the notification shall be considered to be the date on which it has been remedied by being submitted electronically.

The Administration of the Community of Madrid, like the rest of the Public Administrations, has to act with full submission to the law and to the Law, as stated in article 103 of the Constitution, therefore, it will be obliged to process the administrative procedures following the legally established channel.

With reference to the electronic identification and signature systems necessary to use the electronic services of the Community of Madrid, the following are currently available: Electronic certificate/DNIe, the Cl@ve and Identify system

Identifies is a new digital identification and signature system created by the Community of Madrid, which will simplify and further facilitate access to digitized public services, thus expanding the options that the interested party had until now to carry out electronic procedures in the Community of Madrid. You will only need the DNI or NIE number, a password and a numeric code that will be sent to the mobile phone. It can be used on computers, as well as mobile and tablet computers, in any operating system and without the need to install anything, in accordance with the provisions of Article 9(3) of Law 39/2015 of 1 October 2015.

A processing guide is available on the website of the Community of Madrid, which explains how to take the steps and procedures of the administration of the Autonomous Community of Madrid online.

In the same vein, Article 5 of the aforementioned Law 39/2015 regulates the representation of the interested parties in the administrative procedures for the appropriate purposes.



2. CARNIMAD made several observations which are described below:

FIRST: 'First of all, and on a preliminary basis, we consider it positive that we can have an autonomous register of all retail establishments in the Community of Madrid, since until now only the autonomous register of retail outlets for meat and its derivatives was available.'

SECOND "From our organisation we have the experience of the years of the previous registration and our retail establishments already have a registration number in the regional register, so in order to avoid duplication, this circumstance should be taken into account so that not all establishments already registered in that regional register have to be registered again. Establishing a new registration system or a new regional numbering would create an unnecessary bureaucratic burden as well as new economic costs - both for businesses and for the public administration itself."

In response to this observation, we would like to inform you that, since it is a register of all the food retail trade, the system of registration of retail meat establishments, which distinguishes between Carnicería C, Carnicería-salchichería Cs and Carnicería-charcutería, is not valid.

It is thought that the new Registry will be unique for all activities, in this way, regardless of the changes in activity that occur, the number will be the same. (A single number for each company and industrial address).

On the other hand, the establishments that already have AECAME Registry, automatically, will be transferred to the new Registry of Food Retailers and will be assigned a new number, proceeding to notify the interested party of the change, without the need to make any request on their part.

THIRD 'Given that many of the establishments already registered in the Autonomous Community Register of Retail Trade in Meat and its derivatives have other activities or products that are the subject of the sale, we consider it appropriate, if necessary, to update it and request that this option be created as part of the application for registration itself. In this way, the extension, where appropriate, will not entail the modification of its registration number in the regional register. It must also be indicated that this number is used for signage and labelling, delivery notes, website, sales ticket, etc., and its modification would also generate a high economic cost.'



In response to this observation, we inform you that the application will be unique for all retail trade, and all the activities subject to registration are covered, so that, if any establishment registered with AECAME has any other retail activity, it would be sufficient to request the modification(s) that may apply, once the interested party has received notification of their Food Retailer Registry number.

As for the cost of modifying signage and labeling, delivery notes, website, sales ticket ... when a new registration number is assigned, we indicate that the draft standard does not contemplate the obligation to include this number in posters, labels or sales tickets.

Fourth. 'We also request the inclusion in the application for registration in the new regional register of a field dedicated to the 'tasting area', an activity complementary to all food shops as established in the new Royal Decree 1021/2022 of 13 December 2022 regulating certain hygiene requirements for the production and marketing of foodstuffs in retail establishments.'

In response to this, it is reported that it has been proposed in the decree that 'there may be tasting areas for the products that they market, without the need for additional registration annotation, since these activities will be in the establishment itself and, in any case, will be minority and marginal activities with respect to those registered in the establishment.'

Therefore, it will be a permitted activity without the need for separate registration annotation.

Five. 'Finally, it would also be of interest for this census to be public, as has been the case until now of establishments registered in the regional register of retail trade in meat and meat products. In the same vein, it would be desirable for the general interest and that of our companies for the register to be kept up to date with the greatest accuracy in order to be a useful tool. To this end, we propose that the new regional register of retail establishments be checked annually with the data available in other registers dependent on other bodies and referring to the census of economic activities, i.e. companies registered in the IAE for retail food trade equivalent to the regional registration in the Community of Madrid. In this way, withdrawals of activity (especially) could be detected, which in many cases are not notified to the register and continue to appear in the available censuses of public information, which does not convey a real situation of data of establishments active in the register.

We would like to inform you that it is not appropriate to incorporate this proposal into the legislative text.





The responsibility to maintain the veracity and accuracy of the information is the responsibility of the economic operator, and that of the administration to keep the registry updated based on it.

It is not feasible to cross-check the information with other records.

The amendment or cancellation of the registration shall be effected either by the notification of the economic operator or may be made ex officio where the particulars in the registration are found to be incorrect or the activity of undertakings and establishments definitively ceases.

In any event, any amendment made ex officio shall require that it be brought to the attention of the interested parties or, where appropriate, their representatives, in order to be able to plead and produce any supporting evidence and documents which they consider relevant.

b) Hearing and Public Information

The corresponding procedure of hearing and public information has been evacuated as it is a draft of a regulatory nature and general scope that affects the rights and legitimate interests of individuals for a period of 15 working days (from March 9 to March 30, 2023), in accordance with the provisions of Articles 4.2.d) and 9 of Decree 52/2021, of March 24, and in Article 60.2 of Law 10/2019, of 10 April, on Transparency and Participation of the Community of Madrid. The aforementioned procedure of hearing and public information has been published on the Transparency Portal of the Community of Madrid.

Within the period indicated, the following individuals or businesses in the sector have made observations or contributions, which have been examined and answered as follows:



1. BUSINESS ASSOCIATION OF HOSTELERIA IN THE COMMUNITY OF MADRID

Comments were received on 8 January 2025, on which the following is indicated:

DETECTION AND MEASUREMENT OF ADMINISTRATIVE BURDENS

Specifically, in its section 7 on the DETECTION AND MEASUREMENT OF ADMINISTRATIVE LOADS, it reasons that in order to detect and measure the administrative burdens involved in the approval of this new decree, the analysis is carried out by dividing the food retail companies affected into three large groups and, among them, those that affect those companies, the vast majority, that do not fall within the register of meat products already created:

"(c) Remaining food retail companies in the Community of Madrid. For the remaining food retail companies of the Community of Madrid (those that do not trade meat and derivatives and therefore were not obliged to register in any regional register until the entry into force of this Decree), a new administrative burden is identified, which is only the submission of communication for registration in the Register."

For this purpose, the report does identify a new normative burden created by this decree and that implies the registration in this register.

In response to this contribution, it is established that this new administrative burden is justified and is proportional to the purpose that is intended to be achieved, which is to develop the forecasts contemplated in Royal Decree 191/2011, of 18 February, in order to have a census of companies and retailers in the Community of Madrid that makes it possible to carry out a programming of official controls, in order to protect public health and the interests of consumers.

Proposal: Deletion of Article 3 (b). Scope and Article 6 (b). The structure:

Justification:

It is stated that catering establishments 'already have the obligation to declare to the Community of Madrid as tourism companies the start-up of our activity, in particular, in Article 12 of Law 1/1999 of 12 March 1999 on the Regulation of Tourism in the Community of Madrid.'

As a second argument, it is noted that 'it also has the obligation to obtain the municipal authorisation for the exercise of the activity. This permit constitutes the planning permission and covers operation in the premises, including aspects of safety, protection of people, environment and acoustics, but also the health authorisation that



is implicit in any municipal authorisation and that is granted by the revision of the facilities, equipment and their production that finally gives us the health security that the activities meet all the conditions necessary for their operation.'

Once assessed, the observation is not accepted. In this regard, it is noted that it has been necessary to create the regional register, which is the subject of this regulation, precisely because the minimum information required cannot be obtained from the currently existing registers, nor are they currently publicly accessible, including the Register of Tourism Companies, despite the indications of Law 1/1999, of 12 March, on the Management of Tourism of the Community of Madrid.

Moreover, as reflected in Article 23(2) of the aforementioned Law 1/1999 of 12 March 1999, set out in the written pleadings, '2. The Tourism Companies Register shall be managed by the Directorate-General responsible for tourism and shall be public and registered on a voluntary basis.' Since Royal Decree 191/2011 of 18 February 2011 requires the registration of all food retail trade, it does not seem possible for the aforementioned Tourism Companies Register, without entering the information associated with each entry in it, to provide the updated census of the catering sector.

Nor does the Register of Tourism Undertakings include 'collective social catering, understood as the provision of catering services in canteens of a care, institutional, social, employment nature and any other nature intended for private purposes and not for the general public'.

Furthermore, as stated in Article 2(1) of Royal Decree 191/2011 of 18 February 2011, 'all retail establishments shall be registered in the registers of the competent authorities of the Autonomous Communities established for that purpose'. The powers of the Directorate-General for Tourism and Hospitality¹¹, responsible for that register, do not include checking compliance with health regulations, which is why it is not appropriate for the proposed purpose.

As regards municipal licences or authorisations, it is indicated that the purpose of the regulation is not to grant operating authorisations, or to ensure compliance with the requirements of health regulations, but to create a register that complies with the provisions of Royal Decree 191/2011 of 18 February 2011, which includes the minimum relevant information, is kept up to date and is public in nature.

¹ See: https://www.comunidad.madrid/transparencia/unidad-organizativa-responsable/direccion-general-turismo-y-hosteleria



In addition, the creation of this register, associated with electronic processes of the Community of Madrid, will allow the automated annotation of a large part of the process of food companies, incorporating other functionalities of interest to economic operators, such as real-time consultation of their registration and public consultation, facilitating commercial activities between operators.

• Proposal: Deletion in article 6, subparagraph (a), of the following text:

'Establishments may have tasting areas for the products they place on the market, without the need for additional registration annotation and, in any case, they shall be minority and marginal activities with respect to those registered in the establishment.'

Justification:

'This draft in its current wording completely exceeds the regulatory capacity of this Decree to authorise the existence of product tasting areas in retail trade in the Community of Madrid, and from our point of view would be grounds for invalidity due to a lack of legal coverage and because this possibility is not contemplated within the framework established in the current Law 16/1999, of 29 April, on Internal Trade in Madrid.'

The observation made is not accepted, since this draft decree does not authorise the activity, which is provided for in Article 10 of Royal Decree 1021/2022 of 13 December, only exempts from creating an additional entry in the register for carrying out this activity.

2. ASSOCIATION OF SPANISH SUPERMARKET CHAINS

On 9 January 2025, a letter of comments was received proposing the following changes:

- Article 5. Woods and nature
 - 1. The Register shall be attached to the Directorate-General with responsibility for public health and shall be unique in the Community of Madrid.
 - 2. The register does not have an enabling character, shall be public and informative and shall be set up as a computerised database and does not include a registration fee.
 - 3. Entry in the Register does not exclude the full responsibility of the economic operator for compliance with food law.

<u>Justification:</u> The non-enabling nature and non-application of fees are reflected in the preamble of the standard itself.



Article 6. Structure.

The State Register is structured in the following sections:

- a) Section for retail food establishments: each establishment of undertakings with a fixed location in which the handling, preparation for sale, working or processing of foodstuffs and their storage at the point of sale or delivery to the final consumer, on site or at a distance, is carried out shall be registered. In the establishments there may be tasting areas for the products they market, without the need for additional registration and, in any case, they will be secondary, minority and marginal activities compared to those registered by the establishment.
- b) Section of retail catering establishments: each of the establishments of the companies with a fixed location in which prepared meals are produced and served for consumption on site or to take away shall be registered, except for establishments that are registered in accordance with paragraph (a). This section shall include establishments where beverages are served, as well as both packaged and canned food products that do not require cold or handling beyond the opening of the packaging with or without heating.

Justification:

The character of the tasting activity has to be assessed according to the main activity of the establishment, from this point of view it is considered clearer to include the term 'secondary' together with the rest.

The consideration relating to Article 6 (a) is accepted, incorporating the text provided.

The contribution relating to Article 6(b) is not accepted, since it considers that the acceptance of this claim may lead to interpretative errors. All activities (as listed in the application) carried out in retail food establishments shall be entered in the Register, so that sections (a) and (b), in particular, are not mutually exclusive. In order to avoid greater administrative burdens for the interested parties, a single registration has been provided for for company name and address of establishment, where all activities carried out in it will be registered. It is not difficult to find establishments that carry out activities in section (a) and (b); this is the case, for example, of pastry shops/bakers that have a cafeteria in the same premises, or restaurants that have a section for the retail sale of packaged foods.

Furthermore, the argument relating to the non-enabling nature of the registration is not upheld. Article 5 defines the public and informative nature of the register, which shall be constituted as a computerised database. It describes the informative function that enables health authorities,



through the information management of their data, to establish the programming of official controls to protect the public health of citizens.

With reference to fees, this suggestion is not accepted as what is not regulated cannot be imposed. Therefore, the reference to the fee would be included if it were to be imposed as mandatory.

Article 10. Form and place of submission of communications.

It is suggested to incorporate a paragraph 5 into Article 10, as follows:

5. The Community of Madrid will enable the models and systems for the communication and agile updating of companies that operate through networks of own establishments or under franchise, so that the registration obligation and its updating can be fulfilled through a single communication, periodically and telematically.

Justification:

For the purposes of efficiency and control, systems should be developed to allow for telematic communication and periodic updating for companies operating through networks of establishments.

This contribution is not accepted. The standard provides for the communication by telematic means of each food establishment, however, the Agency for Digital Administration of the Community of Madrid has been consulted on the feasibility and they have informed that it is not possible to notify by means of a single form all the establishments in a chain of establishments. This would require a manual record of each form in the file processing application, considerably increasing the possibility of errors and delaying the granting of the registration, as well as the subsequent management of the registration.

The enabled system will allow to automate in large part the creation and maintenance of the registry thanks to that individualized telematic notification and automatic synchronization with the application, generating direct communications to the interested party and allowing the agile update of the public information related to the registry. Although it will take more time for the economic operator at the time of notification, it will considerably speed up the granting of such registration, ultimately resulting in fewer disadvantages for economic operators.

Annex. 3. Type of activity

Justification:

In line with Article 6(a), the exercise of activities or tasting areas should also be



included in the Annex.

The contribution with regard to this section is not accepted, since it is not planned to create another activity, since the main activities will already be associated with the establishment, the tasting bar being a practice contained in Royal Decree 191/2011, of 18 February, and reflected in this regulation, and it is not considered appropriate to collect and record this practice, in cases where it is allowed and is carried out.

3. CEIM. BUSINESS CONFEDERATION OF MADRID-CEOE

Comments were received on 10 January 2025, on which the following is indicated:

 One: It is requested that a new burden be avoided, since registration will impose an administrative burden on companies and that the administration has sufficient information and means to know the data requested in the communication of registration.

The observation is not accepted, since it is found that there is currently no register, in the Community of Madrid, that includes all the information required by Royal Decree 191/2011, of 18 February 2011, for the different types of companies and retail establishments of foodstuffs, which is why this regulation has been developed.

- Two: It is proposed to amend point 2 of Article 5 by adding the underlined text:
 - '2. The Register is not of an enabling nature, shall be of a public and informative nature and shall be constituted as a computerised database with no registration fee attached."

The argument is not addressed both in the part referring to the non-enabling nature of the registration and to the fact that it does not entail a registration fee. Article 5 defines the public and informative nature of the register, which shall be constituted as a computerised database. It describes the information function, which enables health authorities, through the information management of their data, to establish the programming of official controls to protect the public health of citizens.

- Three: It is proposed to add the following point 5 to Article 10 by adding the underlined text:
 - "5. The Community of Madrid shall enable the models and systems for the swift communication and updating of companies operating through networks of own establishments or duty-free, so that the obligation of registration and its updating can



be fulfilled through a single communication, periodically and electronically.'

This contribution is not accepted, since, as previously reported in this report, in response to the Association of Supermarket Chains, communication by telematic means of each food establishment is planned. However, the Agency for Digital Administration of the Community of Madrid has been consulted on feasibility and informed that it is not possible to notify by means of a single form all establishments in a chain of establishments.

This possibility would require a manual census of each form in the file processing application, increasing the possibility of errors and delaying the granting of the registration, and the subsequent management of the same.

The authorised system will make it possible to automate to a large extent the creation and maintenance of the register thanks to this individualised telematic notification and automatic synchronisation with the application, generating direct communications to the interested party and enabling the agile updating of public information relating to the register. Although they will require more time from the economic operator at the time of notification, the granting of such registration will be considerably speeded up, resulting in less inconvenience for economic operators in the long run.

c) REPORTING

Article 8 of Decree 52/2021, of 24 March, establishes that the request for mandatory reports, including the report on regulatory coordination and quality, as well as the studies and consultations deemed appropriate, will be carried out simultaneously, except for the reports that, where appropriate, must be issued by the General Legal Counsel and the opinion of the Legal Advisory Commission of the Community of Madrid.

No opinion is requested from the Advisory Legal Commission, since, in accordance with Article 5 (3) (c) of Law 7/2015 of 28 December on the abolition of the Advisory Council, 'the Advisory Legal Commission shall be consulted by the Community of Madrid in the following matters: (c) draft regulations or general provisions adopted in implementation of the laws, and any amendments thereto'. As set out in the descriptive part of the text and in this MAIN, the regulation implements the mandate contained in Royal Decree 191/2011 of 18 February 2011, so that such consultation is not carried out.

Reports to be received

General Technical Secretariat of the Ministry of Health, in relation to the



adequacy of the processing and the content of the draft to the legality in force in accordance with Article 8.5 of Decree 52/2021, of 24 March 2021, which provides that draft drafts or draft regulations with the rank of law and draft regulatory provisions must be informed, in any case, after the procedure of public hearing and information has been carried out, and prior to the request, where appropriate, of the report to the Legal Service, by the Technical General Secretariat of the proposing department(s), unless the body promoting the standard is the Technical General Secretariat itself.

• Report of the Attorney General of the Community of Madrid, in accordance with the provisions of Article 4(1)(a) of Law 3/1999 of 30 March 1999 on the Regulation of the Legal Services of the Community of Madrid and Article 4(2)(f) of Decree 52/2021 of 24 March 2021.

• Mandatory reports collected:

- Social impact reports.
- Report, dated 24 September 2024, on the impact on children, adolescents and the family of the Directorate-General for Children, Family and Birth Promotion of the Ministry of Family, Youth and Social Affairs, in accordance with Article 6.1.e) of Decree 52/2021, of 24 March, in conjunction with Article 22d of Organic Law 1/1996, of 15 January, on the Legal Protection of Minors, partial amendment of the Civil Code and the Civil Procedure Law, and in the tenth additional provision of Law 40/2003, of 18 November, on the Protection of Large Families, Article 47 of Law 4/2023, of 22 March, on Rights, Guarantees and Integral Protection of Children and Adolescents of the Community of

From the aforementioned management center, examined the content of the norm, it is estimated that it does not generate any impact on the Family, Children and Adolescence.

• Report, dated 25 September 2024, of gender impact of the Directorate-General for Equality of the Ministry of Family, Youth and Social Affairs, in accordance with Article 6(1)(e) of Decree 52/2021, of 24 March 2021, in conjunction with Article 19 of Organic Law 3/2007, of 22 March 2007, for the effective equality of women and men, and Article 9(1)(b) of Decree 241/2023, of 20 September 2023, of the Governing Council, establishing the organic structure of the Ministry of Family,



Youth and Social Affairs.

The Directorate-General for Equality reports that there is a gender-neutral impact and that, therefore, it is not expected to have an impact on effective equality between women and men.

• Report on the impact on revenue of the Directorate-General for Taxation of the Regional Ministry of Economy, Finance and Employment.

Report dated 25 September 2024, in accordance with Article 9 (b) of Decree 230/2023 of 6 September of the Governing Council establishing the organisational structure of the Regional Ministry of Economy, Finance and Employment and the First Additional Provision of Law 15/2023 of 27 December on the General Budget of the Community of Madrid for 2024, which states in its first section 'All draft laws, administrative provisions, agreements or agreements. the approval and implementation of which could lead to an increase in public expenditure or a decrease in the revenue of the Autonomous Community of Madrid compared with that authorised and provided for in this Law, or which may commit funds from future financial years, must be submitted for a mandatory report to the Regional Ministry of Economy, Finance and Employment.'

The Directorate-General for Taxation of the Regional Ministry of Economy, Finance and Employment reports that, should it enter into force in the 2024 financial year, it would result in a reduction in revenue.

Budgetary impact report of the Directorate-General for Budget of the Regional Ministry of Economy, Finance and Employment.

Budgetary impact report of the Directorate-General for Budgets of 27 September 2024, in accordance with the provisions of Article 5(1)(k) of Decree 230/2023 of 6 September 2023 of the Governing Council establishing the organisational structure of the Ministry of Economy, Finance and Employment.

The Directorate-General for Budgets **reports favourably** the draft Decree of the Governing Council establishing the Register of Food Companies of Retail Trade in Food Products of the Community of Madrid and regulating the procedure for communicating the start of activity of such companies, noting that it will not entail a reduction of income in 2024.



Report from the Directorate-General for Trade, Consumer Affairs and Services.

We received a report dated 30 September 2024 from the Directorate-General for Trade, Consumer Affairs and Services, in accordance with Article 28 of Law 11/1998 of 9 July 1998 on the protection of consumers in the Community of Madrid.

The comments made have been taken into account, except for the following:

"... it is noted that the project, having included street vending in its scope of application, collides with Law 1/1997 of 8 January 1997 regulating street vending in the Community of Madrid. In accordance with Article 25 of Law 7/1985 of 2 April 1985 regulating the bases of the local regime, which confers on the municipalities, as their own competences, the matters of 'fairs, supplies, markets, auctions and street trade' and always 'under the terms of the legislation of the State and the Autonomous Communities', Law 1/1997 of 8 January 1997 makes the exercise of the activity subject to obtaining a municipal authorisation, and the provisions of the draft on prior communication and its character as a single document cannot be applied for the start of the exercise of the activity.

The requirements required for the exercise of the activity of itinerant commerce are regulated in Law 1/1997, of January 8, Law that would be modified by means of a decree, constituting a case of alteration of the principle of normative hierarchy.

In addition, based on the rules indicated in the previous paragraph, the inspection and sanction in the matter corresponds to the Municipalities, so that the provisions of the project in the field of street trade would not fit.

In this regard, indicate that it is a form of retail trade in food and is therefore explicitly included in Royal Decree 1021/2022 of 13 December 2022. Reiterate that the draft legislation does not duplicate the authorisations granted by the municipalities, since the operator's 'prior' communication has been eliminated and does not constitute an enabling requirement.

With regard to the regulations on street vending, Article 5 of Law 1/1997 (requirements for the exercise of activity) indicates that one of the requirements is 'to meet the conditions and requirements required by the regulations governing the



product or products subject to street vending', among them, they must comply with the provisions of Royal Decree 1021/2022 of 13 December 2022, including being registered.

Finally, the Directorate General of Public Health acknowledges, as indicated in the report, that the inspection and sanction in the field of street trade is the responsibility of the municipalities, and therefore the draft decree does not allude to these issues and is limited to complying with the regulatory requirement that the Community of Madrid has to establish an autonomous registry of food retail trade.

"For this reason, it is striking that the MAIN only establishes burdens for the Administration and that they are not contemplated instead for the recipients of the project, nor does it carry out a true analysis of the impact in terms of administrative burdens on them before the creation of the new register. This new administrative burden has an economic impact on companies, which the MAIN only quantifies for the Administration in EUR 103,000, which would in fact be assumed by the companies, and whose increase could end up being passed on to the consumer through its impact on prices, as indicated in the report of the Consumer Council, approved at its meeting on 27 September 2024."

In relation to this observation, it is estimated that the administrative burden corresponding to the initial communication amounting to EUR 2, in accordance with the Methodological Guide approved by the Council of Ministers of 11 December 2009, the validity of which has been extended by paragraph 2 of the First Additional Provision of Royal Decree 931/2017 of 27 October 2017 regulating the Report of the Regulatory Impact Analysis, is not significant and will therefore not have an impact on the final price of the products that are marketed and therefore on the final consumer.

Report of the Directorate-General for Citizen Services and Transparency of the Ministry of the Presidency, Justice and Local Administration

Pursuant to Decree 85/2002, of 23 May, regulating the Quality Assessment Systems of Public Services and approving the Quality Criteria for Administrative Action in the Community of Madrid, in its article 4.g) and criteria 12 and 14), and



Decree 229/2023, of 6 September, of the Governing Council, establishing the organizational structure of the Ministry of Presidency, Justice and Local Administration, in its article 9.2.f, the regulation of new administrative procedures or amendments to existing ones, as well as the preparation of standardized forms, must be informed by the general directorate responsible for quality of services, which may express its opinion on the need to simplify or rationalize the processing.

The comments received in the report dated 1 October 2024 were followed, with the exception of:

"there is no clear distinction between the persons required to register in the Register of Food Businesses for Retail Trade in Food Products of the Community of Madrid, between legal persons and natural persons, which allows the appropriate prior notification to be submitted for registration, either electronically or in person, as stated in the draft Decree. In other words, the references made to food businesses and establishments and their operators in Articles 2 and 8 of the draft Decree do not make clear the distinction between natural and legal persons and, therefore, the method laid down in Article 9 (3) of the draft Decree of submitting prior notification of the start of activities in person is not justified, given that they would appear to be legal persons that would be subject to the obligation to electronically liaise with the public administration, in accordance with Article 14 (2) of Law 39/2015 of 1 October."

This observation is not taken into account, since it is considered that the obligation to register food businesses is imposed by Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. Operators must communicate their activity and domicile to the relevant competent authority.

Furthermore, Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food takes into account the need to maintain an up-to-date register containing information concerning certain products and undertakings.

In Spain, food companies, depending on the food sector and the phase of the food chain in which they carry out their activity, after primary production, will be registered in one of the two registers established in Article 2 of Royal Decree 191/2011, of 18 February, as amended by Royal Decree 682/2014, of 1 August:

• Registers of regional scope that exist in the different Autonomous



Communities of Spain, in which those establishments in which, for the most part, food products are sold or served to the final consumer will be registered.

The establishments covered by this register are supermarkets, butchers, fish shops, fruit shops, bakeries, bars, restaurants, cafés, hotels, school canteens, company canteens, hospitals, celebrations houses, etc. Even those that facilitate home delivery to the final consumer.

These shall be registered in the registers of the competent authorities at regional level created for this purpose (see information and classification specific to each Autonomous Community in Annex IV).

• National registers: (RGSEAA – Registro General Sanitario de Empresas Alimentarias y Alimentos) Those other establishments linked to the food chain, (including companies that do not have an establishment under their ownership), at stages other than primary production, will be registered in the RGSEAA of a state nature: - either without prior operating authorisation - or prior operating authorisation in accordance with Article 4(2) of Regulation (EC) No 853/2004 by the competent authority.

By virtue of the general principles of law, the rule in question is subject to basic rules such as Law 39/2015, of 1 October, per se. This rule applies, as explained above, to undertakings and establishments irrespective of the legal and tax arrangements that the rules on this matter impose, as is the case for self-employed persons.

However, it is understood that the distinction is perfectly delimited by the amendment made to Articles 1, 2 and 3 of the regulation.

• Report of the Directorate-General for Cooperation with the State and the European Union of 8 March 2023.

In accordance with the content of 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 the information society, the draft is submitted to the Directorate-General for Cooperation with the State and the European Union of the Regional Ministry of the Presidency, Justice and Local Administration for a report on its possible classification as a technical regulation referred to in the Directive.



A report, dated 2 October 2024, is received communicating the need to forward, to that Directorate-General, the text of the draft Decree in final version for the issuance of the report and, where appropriate, the processing of the procedure for notifying the regulation to the European Commission. In the case of a technical regulation to be communicated to the Commission, a standstill period of three months shall be opened within which the draft decree may not be adopted until the Commission and the other Member States have given a decision on its content. At the end of this period and once the decree has been published, it must be notified again to the European Commission.

 Report on coordination and regulatory quality of the Technical Secretariat-General of the Regional Ministry of the Presidency, Justice and Local Administration.

In accordance with the provisions of Articles 34 of Law 11/2022, of 21 December 2022, on Urgent Measures for the Promotion of Economic Activity and the Modernisation of the Administration of the Community of Madrid, 4.2.c) and 8.4 of Decree 52/2021, of 24 March 2021, and 25.3.a) of Decree 229/2023, of 6 September 2023, of the Governing Council, establishing the organisational structure of the Ministry of Presidency, Justice and Local Administration.

A report was received dated 3 October 2024, in which the following comments were made:

'(iv) It is suggested, in general, to include in the MAIN a justification of the replacement of the authorisation by a prior communication, since this change of legal regime is not sufficiently explained, beyond the generic mentions made to the protection of the general interest related to public health.'

The observation is taken into account, noting that Royal Decree 191/2011 of 18 February 2011 includes the activities of food businesses that are subject to registration. Following the amendment implemented by final provision 1.1 of Royal Decree 1021/2022 of 13 December 2022, retail establishments as defined in Article 2 of Royal Decree 1021/2022 of 13 December 2022 have been excluded from the obligation to register, without prejudice to the corresponding official controls. All retail establishments shall be entered into the registers of the competent authorities of the Autonomous Communities established for that purpose, after the food business operator notifies the competent authorities of the



place where the establishment is situated.

Furthermore, Article 17(4) of Law 20/2013 of 9 December 2013 on the guarantee of market unity (hereinafter, Law 20/2013 of 9 December 2013): '[t]he competent authorities shall endeavour to minimise the administrative burdens borne by economic operators, so that, once the principle of necessity and proportionality has been applied in accordance with the preceding paragraphs, they shall choose a single means of intervention, either the submission of a communication, a responsible declaration or the application for an authorisation'.

Market unity is an essential economic principle for the competitive functioning of the Spanish economy. Article 139 of the Constitution sets out the principle of market unity, which expressly prohibits measures that directly or indirectly pose barriers to the freedom of movement and establishment of persons and the free movement of goods throughout Spain. In this regard, the principle of free economic initiative regulates the implementation of the principle of necessity and proportionality. The authorities may choose between a communication, a declaration of responsibility or an authorisation, depending on the general interest to be protected, the requirements that, where appropriate, are required for the protection of that general interest and taking into account the nature of the activity and whether the means of intervention is directed to the activity itself or to the physical infrastructure.

Authorisation is the means of intervention that most limits the access to and the exercise of an economic activity. The administrative authorisation implies that the interested party cannot carry out the activity without prior knowledge and approval by the public administration, which is responsible for verifying compliance with the applicable regulations.

The notification enables the person concerned to carry out the activity without prior approval by the public administration, although the undertakings are aware of the requirements that they must meet as they are defined in the applicable legislation.

In this line, this decree develops regulatory compliance with the provisions of Royal Decree 1021/2022, of December 13, specifying that it will not have effects for the beginning of the activity, since these effects are already achieved with the responsible declaration contemplated in the aforementioned Law 2/2012, of June 12.



'(...) it is suggested to assess the compatibility between the provisions of Law 2/2012, of 12 June 2012, Law 20/2013, of 9 December 2013, Royal Decree 191/2011, of 18 February 2011, and the provisions of the draft legislation, regarding the need to establish a prior communication as a requirement for the start of the activity of food retail trade.'

In relation to this consideration, it is specified that the "prior communication" has been eliminated, and only the communication has been included. This communication will have no effect on the start of the activity, as these effects are achieved with the responsible declaration contained in Law 2/2012, of June 12.

"(...) in accordance with Rule 7 of the Guidelines, the title of the standards must summarise their content and purpose, identify the standard and describe its essential content. Thus, in accordance with the provisions of Article 1(2), the draft decree includes the regulation not only of the procedure of prior notification of the start of the activity but also of the procedures of modification and cancellation of registration of food companies and establishments.

For all these reasons, we suggest adjusting the title of the project in order to adapt it properly to its object and content or, alternatively, simplifying the title; taking into account, in both cases, the provisions of observations (i) and (ii) of section 3.4.1 of this report".

The consideration is taken into account and the title is amended to reflect the content and subject matter of the provision.

'In relation to paragraph I of the MAIN, in general, and in accordance with the provisions of Articles 6 and 7 of Decree 52/2021 of 24 March 2021, it is suggested to assess the relevance of carrying out an extended MAIN, since there are impacts on administrative and budgetary burdens (however small) and there is a possible impact on market unity, in addition to taking into account the shift from an authorisation regime to a prior communication regime for the case of retail trade in the fresh meat and derivatives sector.'

This observation is not addressed by understanding that the MAIN is adapted to the requirements contained in Article 6 of Decree 52/2021, of 24 March 2021, since the proposed legislation does not result in significant economic and budgetary impacts on administrative burdens. In the same vein, in accordance with the provisions of Law 20/2013, of 9 December, on the guarantee of market unity, it



is guaranteed that the requirement of communication of the start of activity meets the principles of non-discrimination, cooperation and mutual trust, necessity and proportionality of its actions, simplification of burdens and transparency, required by the aforementioned Law 20/2013, of 9 December.

"(vii) It is suggested to assess the relevance of requesting the health impact report, in accordance with Article 35 of General Law 33/2011 of 4 October 2011 on Public Health, which requires the assessment of the impact on health, when, among others, the regulatory proposals may have a significant impact on health, in the terms provided for in that law."

In relation to this consideration, consideration is given to assessing the relevance of requesting the health impact report, although the main objectives of the draft regulation are to develop the provisions referred to in Royal Decree 191/2011 of 18 February 2011 by creating the General Register of Food Companies for Retail Trade in Food Products of the Community of Madrid as a food safety instrument, which contributes to protecting public health and the interests of consumers; to regulate the procedure for communicating the start of activity of such food companies for the purposes of their registration in that Register; to remove and reduce administrative obstacles and costs for retailers of food products in the Community of Madrid, not being the presentation of the notification of the start of activity for the start of the same, in addition to being a free procedure that will not generate unnecessary costs for companies.

All these objectives will provide the Community of Madrid with greater knowledge of the census of activities of food businesses in the retail trade of food products, so that, in case of risks to public health, action will be immediate, eliminating any possible impact that could occur. In view of the above, it is not considered appropriate to issue a health impact report.

• Reports from the Technical Secretariats of the various departments of the Community of Madrid.

In accordance with the provisions of Article 35 of Decree 210/2003 of 16 October approving the Regulations on the Internal Functioning of the Governing Council and its Commissions, a report has been requested from the Technical Secretariats of the various departments of the Community of Madrid, "for their knowledge and,



where appropriate, to make the necessary observations as to their suitability to the order of competence and of the powers established in the different decrees of structure", in accordance with the provisions of Article 4.3 of Decree 52/2021 of 24 March.

As of the date of preparation of this report, the following reports have been received:

- Technical General Secretariat of the Ministry of Transport and Infrastructure.

Report dated 9 December 2022 with no comments on the draft decree or Regulatory Impact Analysis Report

- Technical General Secretariat of the Ministry of Culture, Tourism and Sport.

Report dated 9 December 2022 with no comments on the draft decree or Regulatory Impact Analysis Report

- Technical Secretariat General of the Ministry of Economy, Employment and Finance.

Report dated 9 December 2022 with no comments on the draft decree or Regulatory Impact Analysis Report

- General Technical Secretariat of the Ministry of Presidency, Justice and Interior.

Report dated 9 December 2022 with no comments on the draft decree or Regulatory Impact Analysis Report

- General Technical Secretariat of the Ministry of Presidency, Justice and Interior.

Report dated 9 December 2022 with no comments on the draft decree or Regulatory Impact Analysis Report

 General Technical Secretariat of the Ministry of Family, Youth and Social Policy.

Report dated 9 December 2022 with no comments on the draft decree or Regulatory Impact Analysis Report

 General Technical Secretariat of the Ministry of Local Administration and Digitalisation.



Report dated 9 December 2022 with no comments on the draft decree or Regulatory Impact Analysis Report

- Technical Secretariat General of the Ministry of Economy, Employment and Finance.

Report dated 9 December 2022 with no comments on the draft decree or Regulatory Impact Analysis Report

Report of the Consumer Council of the Community of Madrid.

In accordance with Article 14(1)(a) of Decree 1/2010 of 14 January 2010 of the Governing Council approving the Regulation of Law 11/1998 of 9 July 1998 on consumer protection in the Community of Madrid and Article 28 of Law 11/1998 of 9 July 1998.

A favourable report was received on 27 September 2024.

The following observation is made:

'However, as an observation, it is considered that the costs associated with the incorporation of new administrative burdens in the food retail sector of the Community of Madrid, such as the presentation of prior notification for the start of activity, could to some extent increase the final prices of the products they market, which would have an impact on the final consumer.'

With regard to the consideration made, it is estimated that the administrative burden corresponding to the initial communication, which amounts to EUR 2, in accordance with the Metoological Guide approved by the Council of Ministers of 11 December 2009, the validity of which has been prolonged by paragraph 2 of the First Additional Provision of Royal Decree 931/2017 of 27 October regulating the Regulatory Impact Assessment Report, is not significant and will therefore not have an impact on the final price of the products that are marketed and therefore on the final consumer.

• Report of the Directorate-General for Cooperation with the State and the European Union of 8 March 2023.

This Decree was notified in accordance with 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.

The observations made in its report dated 5 March 2025 are taken into account.

10. LEGISLATURE REGULATORY PLAN.

The proposed draft Decree is included in the Regulatory Plan for the XIII Legislature (2023-2027), approved by Agreement of the Governing Council of 20 December 2023, under the name 'Decree establishing the Register of Food Businesses for Retail Trade in Food Products of the Community of Madrid and regulating the procedure for prior notification of the start of their activity'.

11. EX POST EVALUATION PROCEDURE.

Given the nature and content of the proposed standard, the proposing Directorate-General does not consider that the forecasts included in the project have any impact or effect that determine the obligation to carry out the ex post evaluation by its results, for the purposes of the provisions of Articles 3.3, 3.4 and 13.2 of Decree 52/2021 of 24 March, which currently regulates this matter for the Community of Madrid. All this without prejudice to any observations that may be made in its administrative procedure.

Madrid, on the date of signature

THE DIRECTOR-GENERAL FOR PUBLIC HEALTH

Digitally signed by: ANDRADAS ARAGONES ELENA Date. 2025.03.13 20:57

Signed: Elena Andradas Aragonés