**REPORT ON THE REGULATORY IMPACT ANALYSIS OF THE DRAFT ROYAL DECREE ON PROCESSING AIDS USED IN FOOD PROCESSING AND PRODUCTION PROCESSES**

**EXECUTIVE SUMMARY SHEET**

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| **Proposing Ministry/Body** | Ministry of Consumer Affairs and Ministry of Agriculture, Fisheries and Food. | | **Date** | 09/03/2023 |
| **Title of regulation** | Royal Decree on processing aids used in food processing and production processes. | | | |
| **Report type** | Normal Abridged | | | |
| **TIMELINESS OF THE PROPOSAL** | | | | |
| **Matter regulated** | The Royal Decree will identify the substances that are currently authorised in dispersed regulations for use as processing aids in the manufacture of foodstuffs, incorporating new substances that have not yet been authorised, and will establish a criterion for the use of processing aids in certain food sectors (those identified in Annex I) and for their authorisation. | | | |
| **Objectives pursued** | This measure seeks to facilitate the application of the provisions relating to the use of processing aids which are currently in force in a considerable number of national rules dispersed throughout the Spanish legal system. At the same time, it seeks to take advantage of the opportunity to regulate the use of processing aids in certain sectors which have been of particular interest to the industry. | | | |
| **Main alternatives considered** | The alternatives considered involve:  • Taking no action and maintaining the status quo. However, this was considered inappropriate as it has proved difficult both for the food industry and for the authorities responsible for official control to act in accordance with the legislation in force, which is not in all cases known.  • Regulating all types of processing aids regardless of the food sector in which they are used. However, this was considered inappropriate in the absence of regulations reflecting processing aids used in food of animal origin and which would serve as a starting point. | | | |
| **CONTENT AND LEGAL ANALYSIS** | | | | |
| **Type of regulation** | Royal Decree | | | |
| **Structure of the regulation** | A Preamble, five Articles, a Single Additional Provision, a Single Repealing Provision, three Final Provisions and two Annexes. | | | |
| **Process** | Ordinary | | | |
| **Reports to be collected** | - Report of the General Technical Secretariats of the proposing Ministries, in accordance with the provisions of Article 26(5)(4) of Law 50/1997 of 27 November 1997 on the Government: Ministry of Consumer Affairs; Ministry of Agriculture, Fisheries and Food.  - Report of the General Technical Secretariats of the Ministries concerned, in accordance with the provisions of Article 26(5)(1) of Law 50/1997 of 27 November 1997 on the Government.  - Report of the Ministry of Territorial Policy, on the alignment of the draft with the constitutional order of distribution of competences between the State and the Autonomous Communities, in accordance with Article 26(5)(6) of the aforementioned Law 50/1997 of 27 November 1997.  - Report of the Office of Coordination and Regulatory Quality of the Ministry of the Presidency, Relations with the Parliament and Democratic Memory, in accordance with Article 26(9) of Law 50/1997 of 27 November 1997.  - Report of the Interministerial Commission for Food Management.  - Report of the Council of Consumers and Users, in accordance with Article 39(2) of the consolidated text of the General Law on the Defence of Consumers and Users, approved by Royal Legislative Decree 1/2007 of 16 November 2007.  - Consultation and report of the Autonomous Communities and Autonomous Cities of Ceuta and Melilla.  - Communication to the European Commission pursuant to the procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015.  - Opinion of the Council of State. | | | |
| **Prior public consultation procedure** | Publication on the website of the Ministry of Consumer Affairs from 4 June to 25 June 2021, receiving comments from six national associations and five companies. | | | |
| **Hearing and**  **public information procedure** | Publication on the website of the Ministry of Consumer Affairs from 12 January to 3 February 2023. Input was received. | | | |
| **IMPACT ANALYSIS** | | | | |
| **Alignment with the order of distribution of competences** | This Royal Decree is issued under the provisions of Article 149(1)(13) and (16) of the Spanish Constitution, which grants the State exclusive competence in matters of the bases and general coordination of health. | | | |
| **Economic and budgetary impact** | General impact on the economy. | No economic impact associated with the publication of the Royal Decree is expected. | | |
| With regard to competition | The regulation has no significant impact on competition.  The regulation has a positive impact on competition.  The regulation has a negative impact on competition. | | |
| From the point of view of administrative burdens, the regulation | Entails a reduction in administrative burdens.  Incorporates new administrative burdens.  Does not affect administrative burdens. | | |
| From the point of view of the Recovery, Transformation and Resilience Plan, the regulation | Is not included in the plan.  Is included in the plan. | | |
| From the point of view of budgets, the regulation | Does not entail an increase in public spending. | | |
| **Impact on market competition** | In drafting this regulation, account was taken of the principles contained in Law 20/2013 of 9 December 2013 on guaranteeing market unity, including the necessity and proportionality of the regulation, not containing provisions that could be considered contrary to it. | | | |
| **Gender impact** | The regulation has an impact that is | Negative  Neutral  Positive | | |
| **Other impacts considered** | There are no impacts due to climate change, equal opportunities, discrimination or universal accessibility of persons with disabilities.  Likewise, the draft Royal Decree has no impact on children or adolescents, nor on the family. | | | |
| **Other considerations** | No additional considerations are considered necessary. | | | |

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# A) TIMELINESS OF THE PROPOSAL

## 1.- RATIONALE

The existence of an indeterminate but considerable number of national regulations (mainly royal decrees, but also resolutions), some of which date back to 1979, which regulate the use of certain substances as processing aids in certain foodstuffs, and the repeated amendment of those regulations or the exceedance of certain parts of them, due to subsequent publication of other higher regulations which partially repealed them de facto, has made it very difficult for both economic operators in the food sector and the authorities responsible for the official control of food businesses and foodstuffs to know which substances were actually authorised and what conditions of use should be considered.

With the publication of the Royal Decree, the aim is to facilitate the application of the legislation in force, noting the opportunity to extend the actions to other sectors that have justifiably been demanding this.

It was also considered appropriate to establish a procedure to ensure the protection of the safety of consumers who could be exposed to processing aids as a result of food ingested, applying to new substances which are not among those authorised and for which such status is desired.

## 2.- OBJECTIVES

The main objective to be achieved by the measure is to make it easier for both economic operators in the food sector and the authorities responsible for the official control of food businesses and foodstuffs to know which substances are actually authorised as processing aids in the foodstuffs listed in Part A of Annex I of the Royal Decree.

At the same time, it seeks to take advantage of the opportunity to incorporate new substances which have not yet been authorised as processing aids in any legislation and to regulate the procedure to be applied for amending the list of authorised substances.

## 3.- COMPLIANCE WITH THE PRINCIPLES OF GOOD REGULATION

This Royal Decree complies with the principles of good regulation referred to in Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations, which are the principles of necessity, effectiveness, proportionality, legal certainty, transparency and efficiency.

Thus, in relation to the principles of **necessity and effectiveness,** the Royal Decree meets an objective of general interest. General Law 14/1986 of 25 April 1986 on Health established the obligation of public health administrations to focus their actions primarily on the promotion of health and the prevention of diseases.

The aforementioned law provides that activities and products which, directly or indirectly, may have negative consequences for health, are subject to health control by the public administrations in such a way that consumers are prevented from the risks that could arise from food products.

Law 17/2011 of 5 July 2011 on food safety and nutrition aims to recognise and effectively protect the right to food safety, understood as the right to know the potential risks that may be associated with a food and/or any of its components; the right to know the impact of emerging risks on food safety and for the competent administrations to ensure the greatest possible protection against such risks. The recognition of this right results in the establishment of food safety standards, as a fundamental aspect of public health, in order to ensure a high level of protection of human health in relation to food. In addition, the specific purposes of this law include the establishment of instruments that contribute to generating a high level of food and feed safety and the contribution to the prevention of risks to human health arising from food consumption.

Furthermore, the envisaged regulation is considered to be **proportionate** in the fulfilment of this purpose, without affecting in any way the rights and duties of citizens.

It also contributes to greater **legal certainty** for economic operators by providing them with the identification, conditions of use and knowledge of the substances that are actually authorised as processing aids.

As regards the principle of **transparency**, the text underwent the procedures of prior public consultation and hearing and public information, as well as a Communication to the European Commission pursuant to the procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015, giving all interested parties the opportunity to submit any comments deemed appropriate.

Finally, in relation to the principle of **efficiency**, the regulation does not entail more administrative burdens than strictly necessary, avoiding unnecessary or ancillary administrative burdens.

## 4.- ALTERNATIVES

The alternative of taking no action and maintaining the status quo was considered inappropriate as it has proved difficult both for the food industry and for the authorities responsible for official control to act in accordance with the legislation in force, which is not in all cases known.

Furthermore, the alternative of regulating all types of processing aids, regardless of the food sector in which they are used, was also considered inappropriate in the absence of regulations reflecting processing aids used in food of animal origin and which would serve as a starting point.

Therefore, it is considered that the most appropriate option is to regulate the processing aids used by food sectors that already have substances authorised as such, and to incorporate those other sectors that have not been previously regulated but have been identified as necessary. At the same time, regulating the processing aid sector provides greater legal certainty for economic operators by providing them with the identification, conditions of use and knowledge of the substances.

## 5.- INCLUSION IN THE ANNUAL REGULATORY PLAN

This draft is included in the 2022 Annual Regulatory Plan.

# B) CONTENT AND LEGAL ANALYSIS

## 1.- CONTENT

The draft Royal Decree consists of a Preamble, five Articles, a Single Additional Provision, a Single Repealing Provision, three Final Provisions and two Annexes. Thus, its distribution addresses the following aspects:

**PREAMBLE**

The Preamble of the Royal Decree states that there is no harmonised regulation for processing aids in the European Union beyond the definition included in Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, which nevertheless excludes them from its scope of application.

It also states that in Spain there are numerous sectoral rules (technical and health regulations or quality standards) which regulate the use of processing aids. Many of these have been in force for more than 35 years and have undergone profound changes as a result of their age and the need to adapt them to the present day, or due to the application of European Union regulations on hygiene, food additives, materials in contact with food, etc. which regulate aspects contained therein.

All this justifies the need to draw up a Royal Decree so as to unify in a single regulation the set of processing aids which are, at the time of publication, authorised in a dispersed manner in an indeterminate number of national regulations, in order to facilitate their consideration and application by economic operators and control authorities in the development of their corresponding activities and thus to provide them with greater legal certainty.

**ARTICLES**

Article 1. Purpose and scope of application.

This Article states the purpose of the Royal Decree, which is to create a single list, set out in Part B of Annex I, of the processing aids currently authorised and those which, although not authorised as such in national regulations, have the favourable opinion of the AESAN Scientific Committee.

This Article also establishes the scope of application of the Royal Decree, which is processing aids used in the processes of producing and processing the foodstuffs identified in Part A of Annex I, whether used by food businesses, mass caterers or in the domestic sphere, without prejudice to other rules that may apply to the conditions for their use or labelling.

Article 2. Definitions.

This Article contains the definitions of processing aid, food business, mass caterer and domestic sphere.

Article 3. Conditions of use.

This Article establishes that the processing aids identified in Part B of Annex I of this Royal Decree may be used in the foodstuffs or production processes for foodstuffs listed in Part A of Annex I and this must be done in accordance with the identity and purity criteria set out in Annex II. It also provides that processing aids which are legally authorised in other Member States of the European Union may also be used, with the same restrictions and limitations as there and for the same purpose, as well as those substances that are authorised as food additives.

Article 4. Labelling of processing aids.

This Article establishes the information that must appear on the packaging or container in which processing aids are placed on the market, without prejudice to the indications provided for in other regulations that may apply.

Article 5. Conditions for companies engaged in manufacturing, packaging or distributing processing aids.

This Article establishes that companies engaged in manufacturing, packaging or distributing processing aids must comply with the provisions of Royal Decree 191/2011 of 18 February 2011 on the General Health Register of Food and Food Businesses, Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, and Regulation (EC) No. 852/2004 on the hygiene of foodstuffs.

**SINGLE ADDITIONAL PROVISION.** Mutual recognition clause.

**SINGLE REPEALING PROVISION.** Repeal of regulations.

**FIRST FINAL PROVISION.** Title of competence.

**SECOND FINAL PROVISION.** Development powers.

**THIRD FINAL PROVISION.** Entry into force.

**ANNEXES.**

Annex I Part A. List of foodstuffs.

Part A of Annex I sets out the list of foodstuffs falling within the scope of application of this Royal Decree, together with a reference, where this exists, to the legislation defining them.

Annex I Part B. List of processing aids.

Part B of Annex I sets out the list of processing aids falling within the scope of application of the Royal Decree.

Annex II. Criteria for the identity and purity of processing aids.

Annex II sets out the identity and purity criteria to be met by substances used as processing aids.

## 2.- LEGAL ANALYSIS

### Consistency with national law

Relationship to higher-ranking regulations: this Royal Decree emanates from the Spanish Constitution,

from Article 149(1) (13) and (16), and is in perfect harmony with what it stipulates about the competences of the State in matters of the bases and general coordination of health.

It is also in accordance with the provisions described in:

* General Law 14/1986 of 25 April 1986 on Health, specifically the technical requirements and minimum conditions for health control of the environment and the determination of the health requirements of technical and health regulations for services or products directly or indirectly related to human use and consumption.
* Law 17/2011 of 5 July 2011 on food safety and nutrition.

Consistency with the rest of the legal system: this provision is fully consistent with previous national legislation.

Legislation of the Autonomous Communities and Cities of Ceuta and Melilla: this regulation does not encroach on the competences of the Autonomous Communities or the two Autonomous Cities.

### Consistency with European law

The draft is consistent with European law, in particular with:

* Regulation (EC) No. 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
* Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
* Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

### Repealed regulations

The entry into force of this Royal Decree repeals a considerable number of rules or parts thereof authorising the use of processing aids in foodstuffs. In particular, the following:

1. Article 7(7) of Royal Decree 1798/2010 of 30 December 2010 regulating the exploitation and marketing of natural mineral waters and spring waters packaged for human consumption.
2. Article 6(4) of Royal Decree 1799/2010 of 30 December 2010 regulating the process of preparation and marketing of prepared waters packaged for human consumption.
3. Resolution of 2 December 1982 (rectified) of the Under-Secretariat for Health approving the positive list of additives and processing aids for use in the production of beer.
4. Article 6(5) and (6) and Article 8(6), (7) and (11) of Royal Decree 72/2017 of 10 February 2017 approving the quality standard for the different categories of natural cider and cider.
5. Article 3(12) of Royal Decree 650/2011 of 9 May 2011 approving technical and health regulations on soft drinks.
6. Article 6(4) of Royal Decree 1338/1988 of 28 October 1988 approving the technical and health regulations for the production and sale of Horchata de Chufa (tiger nut milk).
7. Article 4(1), (2), (5) and (8) of Royal Decree 661/2012 of 13 April 2012 establishing the quality standard for the production and marketing of vinegars.
8. Section 5 and Annex of Royal Decree 1052/2003 of 1 August 2003 approving technical and health regulations on certain sugars intended for human consumption.
9. Article 11 of Royal Decree 380/1984 of 25 January 1984 approving technical and health regulations for the production and sale of syrups.
10. Article 28(5)(b), 5(c) and 5(d) of Royal Decree 1011/1981 of 10 April 1981 approving technical and health regulations for the production, circulation and trade of edible fats (animal, vegetable and anhydrous), margarines, minarines and fatty preparations.
11. Article 12 of Royal Decree 308/2019 of 26 April 2019 approving the quality standard for bread.
12. Resolution of 1 August 1979 of the State Secretariat for Health approving the positive list of additives authorised for use in the production of confectionery, cakes, pastries, desserts and biscuits.
13. Resolution of 28 September 1983 of the Under-Secretariat approving the positive list of additives and processing aids for use in the production of table olives.
14. Annex I, Part B(3)(d) to (l) of Royal Decree 781/2013 of 11 October 2013 establishing rules on the production, composition, labelling, presentation and advertising of fruit juices and similar products intended for human consumption.
15. Resolution of 21 April 1983 of the Under-Secretariat approving the positive list of additives and processing aids for use in the production of fruit juices and other vegetable juices and their derivatives.
16. Article 2 of Royal Decree 1044/87 of 31 July 1987 regulating the production of grape juice in line with Community legislation.
17. Resolution of 18 October 1982 of the Under-Secretariat for Health approving the positive list of additives authorised for use in the production of compound spirits, liqueurs, aperitifs without base wine and other beverages derived from natural alcohols.
18. Resolution of 26 February 1981 of the State Secretariat for Health approving the organisation of positive lists of additives authorised for use in various foodstuffs intended for human consumption.
19. Resolution of the State Secretariat for Health approving the positive list of additives authorised for use in the production of canned and semi-preserved vegetables (‘BOE’, Official Estate Gazette, No. 249 of 17 October 1979).
20. Annex 1(2) of the Order of 21 November 1984 approving quality standards for canned vegetables.
21. Royal Decree 846/2011 of 17 June 2011 establishing conditions to be met by raw materials based on recycled polymeric materials for use in materials and articles intended to come into contact with food.

### Regulatory status

The regulatory status is Royal Decree.

### Entry into force

The Royal Decree shall enter into force on the day following its publication in the Official State Gazette. Since it does not impose new obligations on economic operators, a deferred entry into force in accordance with Article 23(1) of Law/1997 of 27 November 1997 is not considered necessary.

### Validity

This Royal Decree shall be valid indefinitely from the day of its entry into force.

# C) ALIGNMENT OF THE REGULATION WITH THE ORDER OF DISTRIBUTION OF COMPETENCES

The draft Royal Decree is issued under the provisions of Article 149(1)(13) and (16) of the Spanish Constitution, which grants the State exclusive competence in matters of the bases and general coordination of health.

In this regard, the constitutional order of distribution of competences is respected.

## D) PROCESSING AND CONSULTATIONS

In the processing of this Royal Decree, the following steps were foreseen:

* Prior public consultation in accordance with Article 26(2) of Law 50/1997 of 27 November 1997 on the Government, through the web portal of the Ministry of Consumer Affairs.
* Hearing and public information procedure in accordance with Article 26(6) of Law 50/1997 of 27 November 1997, through the web portal of the Ministry of Consumer Affairs.
* Consultation and report of the Autonomous Communities and Autonomous Cities of Ceuta and Melilla.
* Report of the General Technical Secretariats of the proposing Ministries, in accordance with the provisions of Article 26(5)(4) of Law 50/1997 of 27 November 1997 on the Government.
* Report of the General Technical Secretariats of the Ministries concerned, in accordance with the provisions of Article 26(5)(1) of Law 50/1997 of 27 November 1997 on the Government.
* Report of the Ministry of Territorial Policy, on the alignment of the draft with the constitutional order of distribution of competences between the State and the Autonomous Communities, in accordance with Article 26(5)(6) of the aforementioned Law 50/1997 of 27 November 1997.
* Report of the Council of Consumers and Users, in accordance with Article 39(2) of the consolidated text of the General Law on the Defence of Consumers and Users, approved by Royal Legislative Decree 1/2007 of 16 November 2007.
* Report of the Office of Coordination and Regulatory Quality of the Ministry of the Presidency, Relations with the Parliament and Democratic Memory, in accordance with Article 26(9) of Law 50/1997 of 27 November 1997.
* Report of the Interministerial Commission for Food Management.
* Communication to the European Commission pursuant to the procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.
* Opinion of the Council of State, in accordance with the provisions of Article 22 (2) of Organic Law 3/1980 of 22 April 1980 on the Council of State.

The following procedures were carried out:

#### Prior public consultation

In accordance with Article 26(2) of Law 50/1997 of 27 November 1997 on the Government, it was submitted for prior public consultation, through the website of the Ministry of Consumer Affairs, from 4 June to 25 June 2021, receiving comments from six national associations and five companies.

#### Hearing and public information

In accordance with Article 26(6) of Law 50/1997 of 27 November 1997, the draft was published for the knowledge and proposal of the general public, during the hearing and public information phase, on the website of the Ministry of Consumer Affairs, from 12 January to 3 February 2023.

The following comments were received during the hearing and public information period:

1. PROQUIMIA S.A. Report received on 20 January 2023.
2. Ms. MMMMM XXXXX YYYYY. Pharmacist EAP Plasencia I. Report received on 27 January 2023.
3. Spanish Association of Sea Salt Producers (ASOSALIMAR). Report received on 1 February 2023.
4. National Federation of Dairy Industries (FeNIL). Report received on 2 February 2023.
5. SANICITRUS S.L. Report received on 2 February 2023.
6. National Association of Extractive and Related Industries (AINDEX). Report received on 2 February 2023.
7. Spanish Federation of Food and Drink Industries (FIAB). Report received on 2 February 2023.
8. AGROFRESH. Report received on 2 February 2023.
9. Association of Table Olive Exporters (ASEMESA). Report received on 2 February 2023.
10. Spanish Confectionery Association (PRODULCE). Report received on 2 February 2023.
11. Juices and Gazpachos from Spain (Zumos y Gazpachos de España). Report received on 2 February 2023.
12. Clariant Ibérica Producción S.A. Report received on February 2, 2023.
13. TOLSA. Report received on 3 February 2023.
14. SEPIOLSA. Report received on 3 February 2023.
15. Mr EEEEE XXXXX YYYYY. Report received on 3 February 2023.
16. Brewers of Spain (Cerveceros de España). Report received on 3 February 2023.
17. Business Federation of the Spanish Chemical Industry (FEIQUE). Report received on 3 February 2023.
18. Association of Detergent and Cleaning, Maintenance and Related Product Companies (ADELMA). Report received on 3 February 2023.
19. Spanish Association of the Baking, Pastry and Cake Industries (ASEMAC). Report received on 3 February 2023.
20. Spanish Association of Manufacturers of Raw Materials and Improvers for the Baking, Cake and Related Industries (FEDIMA). Report received on 3 February 2023.
21. Official College of Veterinarians of Toledo (COLVETO). Report received on 3 February 2023.
22. Snacks Association (Asociación de Snacks). Report received on 3 February 2023.
23. Spanish Vinegar Association (AEVIN). Report received on 3 February 2023.

#### Report of the Autonomous Communities and Autonomous Cities of Ceuta and Melilla

The draft was submitted to these public administrations for consultation and reporting. A report was received from:

* The Autonomous Community of La Rioja Report received on 3 February 2023.

#### Report of the Council of Consumers and Users, in accordance with Article 39(2) of the consolidated text of the General Law on the Defence of Consumers and Users, approved by Royal Legislative Decree 1/2007 of 16 November 2007.

Favourable report, without any arguments, received on 1 February 2023.

#### Report of the General Technical Secretariats of the proposing Ministries.

In accordance with the provisions of Article 26(5)(4) of Law 50/1997 of 27 November 1997 on the Government, the mandatory reports of the General Technical Secretariats of the proposing Ministries were requested with the following being received:

* Report of the General Technical Secretariat of the Ministry of Agriculture, Fisheries and Food. Report received on 1 February 2023.

**Report of the General Technical Secretariats of the Ministries concerned.**

In accordance with the provisions of Article 26(5)(1) of Law 50/1997 of 27 November 1997 on the Government, the mandatory reports of the General Technical Secretariats were requested with the following being received:

* Report of the General Technical Secretariat of the Ministry of Industry, Trade and Tourism. Report received on 25 January 2023.
* Report of the General Technical Secretariat of the Ministry of Ecological Transition and Demographic Challenge. Report received on 6 February 2023.
* Report of the General Technical Secretariat of the Ministry of Health. Report received on 9 February 2023.
* Report of the General Technical Secretariat of the Ministry of Science and Technology. Report received on 15 February 2023.

**Report of the Ministry of Territorial Policy,** on the alignment of the draft with the constitutional order of distribution of competences between the State and the Autonomous Communities, in accordance with Article 26(5)(6) of the aforementioned Law 50/1997 of 27 November 1997.

The report, received on 25 January 2023, states that the content of the draft can be considered as a strict exercise of competences in matters of the bases and general coordination of health, granted to the State by Article 149(1)(16) of the Constitution, as expressed in the Final Provision of the draft. However, since some of the rules which are repealed in the Single Repealing Provision of the draft Royal Decree invoke the title of competence which grants the State exclusive competence over the bases and coordination of the general planning of economic activity under Article 149(1)(13) of the Spanish Constitution, it is appropriate to also invoke that title in the Final Provision of the draft in order to ensure adequate legal certainty.

**Report of the Interministerial Commission for Food Management.**

The draft received a favourable report at the ordinary session of the Interministerial Commission for Food Management on 9 March 2023.

**Report on the Communication to the European Commission pursuant to the procedure laid down in 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.**

PENDING

**Report of the Office of Coordination and Regulatory Quality of the Ministry of the Presidency, Relations with the Parliament and Democratic Memory, in accordance with Article 26(9) of Law 50/1997 of 27 November 1997.**

PENDING

**Report of the Council of State** **in accordance with the provisions of Article 22 (2) of Organic Law 3/1980 of 22 April 1980 on the Council of State.**

PENDING

# E) IMPACT ANALYSIS

## 1.- ECONOMIC AND BUDGETARY IMPACT

### Economic impact

The draft has no economic impact either for the Administration or for economic operators in the food sector, since it will not incorporate additional actions or requirements to those that already exist, beyond those relating to the information that must appear on the packaging or container in which processing aids are placed on the market.

### Budgetary impact

The application of the Royal Decree has no impact on the general budgets of the State or on the budgets of the Autonomous Communities or the Autonomous Cities of Ceuta and Melilla, since the official controls carried out by them already cover processing aids used in the manufacture of foodstuffs.

## 2.- IMPACT ON MARKET COMPETITION

The draft has no definite impact on market unity, it is not likely to introduce elements that distort competition in the market, since it applies to all companies that produce or use processing aids.

## 3.- IMPACT ON ADMINISTRATIVE BURDENS

Administrative burdens refer to all administrative tasks to be carried out by companies and citizens to meet the obligations under the Royal Decree.

In order to determine the possible generation of these burdens by the proposed regulatory draft, it must be subject to a ‘detection and measurement of these administrative burdens’, as established in Article 2(1)(e) of Royal Decree 931/2017 of 27 October 2017 regulating the regulatory impact analysis report.

In this sense, this draft Royal Decree does not generate new obligations for companies or citizens.

**4.- GENDER IMPACT**

The Royal Decree has zero gender impact, within the meaning of Article 26(3)(f) of Law 50/1997 of 27 November 1997 on the Government.

**5.- IMPACT IN RELATION TO THE FAMILY**

It has no impact on the family, in accordance with the provisions of the tenth additional provision of Law 40/2003 of 18 November 2003 on the protection of large families.

**6**.**-** **IMPACT IN RELATION TO CHILDREN AND ADOLESCENTS**

It has no impact on children and adolescents, as required by Article 22(d) of Organic Law 1/1996 of 15 January 1996 on the legal protection of minors.

**7.- IMPACT DUE TO CLIMATE CHANGE**

The impact due to climate change, the analysis of which is carried out under the provisions of Article 26(3)(h) of the Government Law, is considered to be zero.

**8.- OTHER IMPACTS**

There are no other significant impacts in terms of equal opportunities, non-discrimination in the development or use of digital administration media and services, or universal accessibility of persons with disabilities.

**F) EX-POST EVALUATION**

In view of the provisions of Articles 25(2) and 28(2) of Law 50/1997 of 27 November 1997 and of Article 3 of Royal Decree 286/2017 of 24 March 2017 regulating the Annual Regulatory Plan and the Annual Regulatory Evaluation Report of the General State Administration and establishing the Regulatory Planning and Evaluation Board, this Department considers that this Royal Decree does not meet the requirements that determine the need for its submission to the analysis of the results of its application, regulated in the aforementioned legislation, and therefore an ex-post evaluation is not required.