



**REGULATORY IMPACT ASSESSMENT REPORT ON THE DRAFT ORDER
DECLARING CERTAIN SUBSTANCES AND ARTICLES AS BY-PRODUCTS UNDER
LAW 7/2022 OF 8 APRIL 2022 ON CONTAMINATED WASTE AND SOIL FOR A
CIRCULAR ECONOMY**

29 July 2024

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MINISTRY FOR THE ECOLOGICAL TRANSITION AND
THE DEMOGRAPHIC CHALLENGE

SECRETARY OF STATE FOR
THE ENVIRONMENT

DIRECTORATE-GENERAL
FOR ENVIRONMENTAL
QUALITY AND ASSESSMENT

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QUALITY
AND ASSESSMENT



EXECUTIVE SUMMARY SHEET

Proposing Ministry/Body	Ministry for the Ecological Transition and the Demographic Challenge Directorate-General for Environmental Quality and Assessment	Date	29/07/2024
Title of the Regulation	Draft order declaring certain substances and articles as by-products under Law 7/2022 of 8 April 2022 on contaminated waste and soil for a circular economy.		
Report type	Normal <input checked="" type="checkbox"/>		Abbreviated <input type="checkbox"/>
TIMELINESS OF THE PROPOSAL			
Matter regulated	Determine the conditions under which certain substances and articles resulting from a specific production process and intended for a specific purpose are by-products.		
Objectives pursued	<ul style="list-style-type: none">- Declare certain substances and articles as by-products, with application to the entire territory of the State in accordance with Article 4 of Law 7/2022 of 8 April 2022 on contaminated waste and soil for a circular economy.- Ensure greater legal certainty when determining in which cases such substances and articles may be considered as by-products.		
Main alternatives considered	<p>The main alternatives considered were the following:</p> <p>(a) Not to lay down the requirements for certain substances or articles to have the status of by-products rather than waste.</p> <p>(b) Establish the requirements that certain materials or articles must meet to be considered as a by-product.</p> <p>The second alternative has been chosen because, as discussed throughout the report, a number of benefits for the protection of the environment and human health can be derived from the declaration of these substances and articles.</p>		



	The result of not establishing any regulation would be that, given the same type of substance or article, its management could be approached differently depending on the autonomous community where the production facility is located.
CONTENT AND LEGAL ANALYSIS	
Type of regulation	Ministerial Order
Structure of the Regulation	It consists of a descriptive part and enacting terms with seven articles and two final provisions, supplemented by an annex.
Reports compiled	<ul style="list-style-type: none">- Ministry of Foreign Affairs, European Union and Cooperation (23/07/2024)- Ministry of Economy, Trade and Business, provided for in Article 26(5)(1) of Law 50/1997 of 27 November 1997 on the Government (pending).- Ministry of Social Rights, Consumer Affairs and 2030 Agenda, provided for in Article 26(5)(1) of Law 50/1997 of 27 November 1997 (pending).- Ministry of Industry and Tourism, provided for in Article 26(5)(1) of Law 50/1997 of 27 November 1997 (pending).- Ministry of Health, provided for in Article 26(5)(1) of Law 50/1997 of 27 November 1997 (09/07/2024).- Ministry of Agriculture, Fisheries and Food, provided for in Article 26(5)(1) of Law 50/1997 of 27 November 1997 (24/07/2024).- Ministry of Territorial Policy and Democratic Memory, on the distribution of powers, in accordance with Article 26(5) (6), of Law 50/1997 of 27 November (02/07/2024).- Ministerial Commission for Digital Administration of the Ministry for Ecological Transition and the Demographic Challenge CMAD-MITERD (pending).



	<ul style="list-style-type: none">- Environmental Advisory Council, provided for in Article 19 of Law 27/2006 of 18 July 2006 regulating the rights of access to information, public participation and access to justice in environmental matters (incorporates Directives 2003/4/EC and 2003/35/EC'. (03/07/2024).- Prior approval by the Ministry for the Digital Transformation and Civil Service, provided for in Article 26(5)(5) of Law 50/1997 of 27 November 1997 (pending).- General Technical Secretariat of the Ministry for the Ecological Transition and the Demographic Challenge, as the proposing department, as required by Article 26(5)(4) of Law 50/1997, 27 November (pending).- Opinion of the Council of State, pursuant to Article 22(3) of Organic Law 3/1980, of 22 April 1980, of the Council of State (pending).
Prior public consultation	In accordance with Article 26(2)(1) of Law 50/1997 of 27 November 1997, the prior public consultation procedure was available on the public participation section of the Ministry for the Ecological Transition and the Demographic Challenge internet portal from 30 March to 3 May 2023, inclusive.
Hearing and public information procedures	The following procedures have been completed: <ul style="list-style-type: none">■ Public information via the internet portal of the Ministry for the Ecological Transition and the Demographic Challenge (5 March to 5 April 2024).■ Hearing with autonomous communities and local authorities, via the Coordination on Waste (Comisión de Coordinación en materia de residuos), (5 March to 5 April 2024).■ Hearing of stakeholders (5 March to 5 April 2024).



	<ul style="list-style-type: none"> ■ Notification to the European Commission in the framework 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 Information Society services (pending). ■ Notification to the World Trade Organisation (WTO) (pending). 	
IMPACT ANALYSIS		
Compliance with the distribution of powers	The order is issued under Article 149(1) (23) of the Spanish Constitution, which confers exclusive competence on the State in matters of basic legislation on environmental protection, without prejudice to the powers of the autonomous regions to lay down additional rules of protection.	
Economic and budgetary impact	Overall economic impact	This draft ministerial order has positive effects on the economy.
	Impact on SMEs:	This draft ministerial order has a positive impact on SMEs.
	With regard to competition:	<input type="checkbox"/> the Regulation has no significant effects on competition <input checked="" type="checkbox"/> the Regulation has positive effects on competition <input type="checkbox"/> the Regulation has negative effects on competition
	From the point of view of administrative burdens	<input checked="" type="checkbox"/> implies a reduction in administrative burdens Estimated quantification: EUR 6 360/year. <input type="checkbox"/> it incorporates new administrative burdens.



		Estimated quantification: <input type="checkbox"/> it does not affect administrative burdens.
	From the point of view of budgets, the Regulation: <input type="checkbox"/> Affects State Administration budgets. <input type="checkbox"/> Affects the budgets of other regional administrations <input checked="" type="checkbox"/> Does not affect budgets	<input type="checkbox"/> entails an expense <input type="checkbox"/> entails revenue
Gender-based impact on childhood and adolescence and on the family	The Regulation has a gender impact:	Negative <input type="checkbox"/> None <input checked="" type="checkbox"/> Positive <input type="checkbox"/>
	The regulation has an impact on children and adolescents.	Negative <input type="checkbox"/> None Positive <input type="checkbox"/>
	This Regulation has an impact on the family.	Negative <input type="checkbox"/> None <input checked="" type="checkbox"/>



		Positive <input type="checkbox"/>
Impact on equal opportunities, non-discrimination and universal accessibility for persons with disabilities	Impact of the Regulation on equal opportunities, non-discrimination and universal accessibility for persons with disabilities	Negative <input type="checkbox"/> None <input checked="" type="checkbox"/> Positive <input type="checkbox"/>
Climate change impact	The Regulation has an impact due to climate change, which must be assessed in terms of mitigation and adaptation to it:	Negative <input type="checkbox"/> None <input checked="" type="checkbox"/> Positive <input type="checkbox"/>
Other impacts	The Regulation has an environmental impact:	Negative <input type="checkbox"/> None <input type="checkbox"/> Positive <input checked="" type="checkbox"/>
	The Regulation has an impact due to the development or use of the means and services of the digital government:	Negative <input type="checkbox"/> None <input checked="" type="checkbox"/> Positive <input type="checkbox"/>



INTRODUCTION.

This regulatory impact assessment report analyses the draft order declaring certain substances and articles, namely sodium hydroxide saturated in aluminium, artificial gypsum, 60 % nitric acid solution, vegetable substrate, dilute sulphuric acid, certain wood waste and certain paper rejects, as by-products in accordance with Law 7/2022 of 8 April on contaminated waste and soils for a circular economy.

This report is prepared in accordance with Article 26(3) of Law 50/1997 of 27 November of the Government. Also included in this report is the description of the procedure required under Law 27/2006 of 18 July 2006 regulating the rights of access to information, public participation and access to justice in environmental matters (incorporates Directives 2003/4/EC and 2003/35/EC).

I. TIMELINESS OF THE PROPOSAL.

1. Rationale

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (hereinafter the Waste Framework Directive) and its transposition into Spanish law through Law 22/2011 of 28 July 2011 on contaminated waste and soil introduced a set of requirements that must be met in order for a substance or article resulting from a production process whose primary purpose is not the production of that substance or article to be declared as a by-product and not as waste.

In accordance with Article 5 of the Waste Framework Directive, as amended by Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste, it is envisaged that the application of the legal concept of by-product may be at the level of the European Union or at the level of the Member State.

At the first level, the European Commission may adopt implementing acts to lay down detailed criteria on the uniform application of the four conditions to be met in order to achieve by-product status. At a second level, where criteria have not been defined at Union level, Member States may lay down criteria on the application of the four by-product conditions. At both levels, the requirements included in the directive are as follows: it is certain that the substance or article will be used at a later stage; That the substance or article can be used directly without having to undergo further processing other than normal industrial practice; the substance or article is produced as an integral part of a production process; and that the subsequent use is legal, i.e. the substance or article complies with all relevant requirements for the specific application relating to products and to environmental and health protection, and will not lead to overall adverse impacts on the environment or human health. In addition, the substances or articles must result from a production process whose primary purpose is not the production of that substance or article.

In accordance with the provisions of Article 4(1) of Law 7/2022 of 8 April 2022, substances or articles that are candidates for this procedure must always meet each and every one of the following conditions:

- (a) That there is certainty that the substance or article will be used at a later stage.
- (b) That the substance or article can be used directly without further processing other than normal industrial practice.
- (c) That the substance or article is produced as an integral part of a production process;



(d) That the subsequent use complies with all relevant product, human health and environmental protection requirements for the specific application, and does not result in overall adverse impacts on human health or the environment.

In accordance with the fourth final provision 2(a) of Law 7/2022 of 8 April 2022, the declaration of a substance or article as a by-product shall be made by Ministerial Order. Pursuant to this final provision, this order is made for the declaration of certain substances or articles resulting from a production process, the primary purpose of which is not the production of that substance or article as by-products.

Finally, in order to ensure adequate protection of human health and the environment in the use of certain substances and articles, and framing this regulation within the scope of European Union law, where it should be noted that there is no uniform regulation by means of European regulations, but that each Member State has developed the European provisions with particularities since, sometimes, there are different national approaches to the concept of by-product and the evaluation process, it has been considered appropriate to develop, for the whole territory of the State, an order determining when sodium hydroxide saturated in aluminium, artificial gypsum, 60 % nitric acid solution, vegetable substrate, dilute sulphuric acid, certain wood waste and certain paper rejects, with specific destinations, can be considered by-products in accordance with Law 7/2022, of 8 April 2022, and can be marketed as a product.

2. Objectives

The draft order establishes the requirements that certain substances and articles must meet to be declared as by-products with application to the entire territory of the State as established in Article 4 of Law 7/2022 of 8 April 2022. These substances and articles are:

- Sodium hydroxide saturated in aluminium, generated during the anodising and extruding processes of aluminium, for direct use in the manufacture of sodium aluminate.
- Artificial gypsum, obtained in electrolytic copper production facilities for direct use as a setting regulator in the manufacture of cement.
- 60 % nitric acid solution, generated in the manufacture of oxalic acid for direct use in the manufacture of nitrogenous fertilising products, in accordance with national regulations.
- Vegetable substrate, for use as a growing medium.
- Diluted sulphuric acid, obtained in the production of food maize for direct use in the manufacture of fertilising products, in accordance with national regulations.
- Chips, cuttings, sawdust, shavings, logs, cores, trimmings and virgin wood scraps from logging, sawdust or the manufacture of plywood and fruit and vegetable packaging bottoms, for use in the manufacture of particleboard and fibreboard.
- Paper rejects, from the 'converting' in the manufacture of tissue paper end products, for use in the preparation of tissue paper pulp.

Conversely, it should be understood that substances and articles that do not simultaneously comply with all the requirements established in this order will continue to be waste, and must be managed in accordance with the legal regime established in Law 7/2022 of 8 April 2022.



By means of this order, which defines and establishes the requirements that certain substances or articles must meet in order to be declared as by-products. In order to ensure greater legal certainty, it is intended to discern in which cases such substances and articles are covered by waste legislation and in which cases they are not, and therefore the legal regime for by-products would apply.

In addition to the above, there is a need to promote the circular economy in our country through, among others, the development of by-product requirements that guarantee the safe reuse of certain production waste. The direct benefits of having these by-product requirements at national level can be higher downstream utilisation and therefore lower landfill rates.

In addition, the by-product status for certain substances and articles will reduce the administrative burden for the shipment of waste, unlike in the area of waste, where waste control is essential.

3. Analysis of alternatives

The alternatives evaluated were the following:

- (a) Not to establish by regulation the requirements for the substances or articles indicated in the previous section to have the status of by-products rather than waste.
- (b) Establish the necessary regulatory framework determining the requirements to be met by the materials or articles mentioned in the previous paragraph in order to be considered as a by-product.

The second option has been chosen because, as explained above, a number of benefits can be derived from the establishment of by-product requirements both for the protection of the environment and for the protection of human health. In addition, through the second alternative, the by-product status for materials will be applied in a homogeneous manner throughout the territory of the State.

4. Adherence to the principles of sound regulation

This regulation meets the principles of sound regulation set out in Article 129 of Law 39/2015 of 1 October 2015 on Common Administrative Procedures in Public Administration. In accordance with the principles of necessity and effectiveness, this order is based on the adequate protection of human health and the environment, in which situations the substances or articles it regulates are considered by-products and in which situations they are not and have to comply with waste regulations. The declaration of certain substances or articles as by-products also ensures the protection of human health and the environment by setting criteria under which they can be used safely and by establishing traceability obligations during their use. Moreover, it is based on a clear identification of the objectives and given the highly technical nature of the requirements set, it is considered the appropriate instrument to achieve them.

This Regulation complies with the principle of proportionality, as it regulates the aspects that are essential for its purpose, which is to determine when certain substances or articles derived from different productive activities can be considered by-products in accordance with Law 7/2022 of 8 April 2022.

In accordance with the principle of legal certainty, the Regulation is consistent with the rest of the national and European Union legal system, as it makes it possible to clarify the status of by-product for certain substances and articles intended for specific uses with a general scope for the entire territory of the State, generating a stable, predictable, integrated and certain regulatory framework, which facilitates knowledge and



understanding and, consequently, the action and decision-making of the sectors affected.

It also complies with the principle of transparency since all the public information and hearing procedures have been scrupulously followed, which are described in detail in the 'description of the procedure' section of this report.

Finally, in application of the principle of efficiency, this Regulation ensures maximum efficiency in achieving its objectives at the lowest possible costs for its application.

II. CONTENTS.

Regarding the content and format of the Regulation, it should be noted that in order to achieve greater clarity and legal certainty, it has been decided to maintain the same structure in this order as in the orders on by-products previously approved and published in our country.

The draft order consists of a descriptive part, an operative part, and is supplemented by an annex, structured as follows:

- Descriptive part.
- Operative part, consisting of seven articles and two final provisions, which are detailed below:

Article 1: Purpose and scope of application. The object of the Regulation is defined, specifying to which specific substances and articles it applies, with a specific origin and destination. It is also specified that those substances and articles that do not comply with the provisions of this order must be managed as waste and in accordance with the provisions of Law 7/2022 of 8 April 2022.

Article 2: Terms and definitions A total of 12 terms are included, the definition of which has been assessed as essential within the scope of the Regulation.

Article 3: Requirements for substances or articles in this order to be declared as by-products. The requirements to be met by substances and articles in Article 1 in order to be declared as a by-product are laid down.

Article 4: Obligations of producers of substances or articles. The obligations that producers must comply with are determined, especially the obligation to submit a responsible declaration indicating that it complies with what is established in the Regulation.

Article 5: Obligations of by-product users. A number of obligations are established for users of by-products in order for them to maintain their status as by-products. Especially the obligations for those substances that are intended to be used in fertiliser products and as substrates for cultivation.

Article 6: Control of the autonomous communities. The verification checks that may be carried out by the competent authorities of the autonomous communities are determined.

Article 7. Transfer of by-products within the European Union. It lays down in which cases Regulation (EU) 2024/1157 of the European Parliament and of the Council of 11 April 2024 on shipments of waste, amending Regulations (EU) No 1257/2013 and (EU) 2020/1056 and repealing Regulation (EC) No 1013/2006 shall no longer apply.

First final provision. Attribution of powers: Relating to the title of competence under which the order is based, which is the exclusive competence of the State on basic



legislation on environmental protection.

Second final provision. Entry into force. It provides that the order shall enter into force on the twentieth day following its publication in the Official State Gazette.

Annex. Minimum content of the responsible declaration to be submitted by the producer: It contains a responsible declaration model to be completed by producers.

III. LEGAL ANALYSIS.

1. Legal basis and normative status

The regulatory status proposed for this draft legislation is that of a ministerial order because, in accordance with the provisions of Article 4(5) and the fourth final provision 2(a) of the aforementioned Law 7/2022 of 8 April 2022, the declaration of substances or articles resulting from a production process must be made by ministerial order of the Ministry for the Ecological Transition and the Demographic Challenge.

2. Conformity with national law

With the entry into force of Law 22/2011 of 28 July 2011, the concept of 'by-product' was incorporated into Spanish law, establishing, in Article 4, that 'A substance or article resulting from a production process, the primary purpose of which is not the production of that substance or article, may be considered as a by-product and not as waste, as defined in Article 3(a), when the following conditions are met:

- (a) That there is certainty that the substance or article will be used at a later stage.
- (b) That the substance or article can be used directly without further processing other than normal industrial practice.
- (c) That the substance or article is produced as an integral part of a production process;
and
- (d) That the subsequent use complies with all relevant product, human health and environmental protection requirements, and does not result in overall adverse impacts on human health or the environment.

Thus, Law 22/2011 of 28 July 2011 contained the four conditions laid down in Article 5 of the Waste Framework Directive, with some minor changes: in the second condition the law spoke of 'usual industrial practice' instead of 'normal industrial practice' and the fourth condition maintained the same criterion, although without making specific reference to the subsequent use being legal.

Subsequently, with the entry into force of Law 7/2022, of 8 April 2022, which repeals Law 22/2011, of 28 July 2011, the four conditions to be met to be able to consider a substance or article as a by-product are maintained, with small changes. Law 7/2022 of 8 April 2022 states that a substance or article 'may' be considered as a by-product instead of 'may be' as it was in the repealed law. In addition, the condition set out in subparagraph (d) determines that it is 'for the specific application'.

However, some important developments are introduced in relation to competition on the assessment and approval of by-product applications. Article 4(2) of the already repealed Law 22/2011 of 28 July 2011 attributed the assessment of substances or articles to the



Coordination on Waste and proposed their approval as a by-product to the then Ministry of the Environment, Rural and Marine Affairs, which was ultimately responsible for approval by order. By contrast, Article 4(3) of Law 7/2022 of 8 April 2022 now divides the competence to assess and approve applications for by-products between the Ministry for the Ecological Transition and the Demographic Challenge and the competent authorities of the autonomous communities.

Finally, as established in the final provision fourth 2(a) of Law 7/2022, of 8 April 2022, the declaration of substances or articles resulting from a production process will be made by ministerial order. Therefore, this order is in accordance with the provisions of Law 7/2022 of 8 April 2022.

3. Links with European Union law

The Waste Framework Directive was transposed into Spanish law by Law 22/2011 of 28 July 2011, which introduced a set of requirements that must be met in order for a substance or article resulting from a production process, the primary purpose of which is not the production of that substance or article, to be regarded as a by-product and not as waste.

Subsequently, Article 5 of the Waste Framework Directive was amended by Directive (EU) 2018/851 of the Parliament and of the Council of 30 May 2018, which finally lays down the specific requirements to be met for that change of legal status, which are the following: there is assurance that the substance or article will be used at a later stage; that the substance or article can be used directly without having to undergo further processing other than normal industrial practice; the substance or article is produced as an integral part of a production process; and that the subsequent use is legal, i.e. the substance or article complies with all relevant requirements for the specific application relating to products and to environmental and human health protection, and will not lead to overall adverse impacts on the environment or human health. In this way, after its amendment, the Waste Framework Directive maintains the wording of the four conditions to be met to achieve the status of by-product and introduces as a novelty the provision that the application of the concept of by-product can be at the level of the European Union or at the level of the Member State. At a first level, the European Commission may adopt implementing acts to lay down criteria on the uniform application of the conditions laid down to achieve by-product status. At a second level, where criteria have not been defined at Union level, those criteria may be established by the Member States.

Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 was transposed by means of Law 7/2022 of 8 April 2022, thus bringing national legislation into line with European Union legislation in this area.

4. Entry into effect

The Regulation shall enter into force on the twentieth day following that of its publication in the Official State Gazette.

This order does not impose new obligations on natural or legal persons who carry out an economic or professional activity, so in this case Article 23 of Law 50/1997 of 27 November 1997 does not apply.

5. Repeal of regulations

This order does not derogate from any other provision.

IV. COMPLIANCE OF THE STANDARD WITH THE DISTRIBUTION OF POWERS



This Regulation has the legal nature of basic legislation in accordance with the provisions of Article 149(1) (23) of the Spanish Constitution, which grants the State exclusive competence over basic legislation on environmental protection, without prejudice to the powers of the autonomous communities to establish additional protection Regulations.

V. DESCRIPTION OF THE PROCEDURE

The substances and articles that are intended to reach the status of by-product were evaluated in different Working Groups of by-products and end of waste status, some under the previous Law 22/2011, of 28 July 2011, and others under the new Law 7/2022, of 8 April 2022, resulting in a favourable report for each of the evaluated applications. Subsequently, it was submitted as a proposal for a favourable report to the Coordination on Waste, which issued a favourable report for each of the applications on compliance with the four conditions laid down in Article 4.1 of Law 7/2022 of 8 April 2022, proposing to the Ministry for the Ecological Transition and the Demographic Challenge that it be declared as a by-product by ministerial order.

The project has been processed in accordance with the provisions of Law 50/1997, of 27 November, and Law 27/2006, of 18 July 2006, as it is a standard with environmental impact.

1. Prior public consultation.

In accordance with Article 26.2 of Law 50/1997 of 27 November 1997, the prior public consultation was carried out on the internet portal of the Ministry for the Ecological Transition and the Demographic Challenge, from 30 March to 3 May 2023, inclusive.

In this process of prior public consultation, a response was received from the following entities:

- o Spanish Wood Trade and Industry Association (AEIM).
- o Forest Association of Cantabria (ASFORCAN).
- o Spanish Association of Pulp and Paper Manufacturers (ASPAPPEL).
- o Spanish Confederation of Business Organisations (CEOE)
- o Confederation of Spanish Forestry Owners (COSE).

All the arguments that were presented were in line with requesting an extension of the destinations that are collected for some of the substances and articles. However, they were not accepted, indicating that the by-product declarations are made with a specific origin and destination depending on the application submitted by the interested parties, since it is for that specific origin and destination for which the assessment has been made. The arguments relating to the prior public consultation procedure are detailed in Annex I.

2. Information procedure and public hearing

In compliance with the provisions of Article 26.6 of Law 50/1997, of 27 November 1997, as amended by Law 40/2015, of 1 October 2015, on the Legal Regime of the Public Sector, this draft order was made available to interested parties and potentially affected citizens, through the process of public information through its publication on



the department's internet portal. Stakeholders were heard during the same period. The text of the draft order together with MAIN was available on the department's website from 5 March to 5 April 2024.

In this public information procedure, a response was received from the following entities:

- o ATLANTIC COOPER
- o Carmen Callao Buatas, private individual.
- o FEIQUE (Spanish Chemical Industry Business Federation)

The comments received focused on clarifying some obligations when storing by-products, extending uses generically or requesting the application of Regulation (EU) 2019/515 of 19 March 2019. The claims received were not accepted.

3. Hearing procedure for the autonomous communities and local authorities.

The hearing procedure for the autonomous communities, the cities of Ceuta and Melilla and local authorities was carried out through the Coordination on Waste. Other ministerial departments were also consulted through the Working Group on by-products and end of waste status of this Coordination.

The text of the draft order together with MAIN was available on the department's website from 5 March to 5 April 2024.

In this public information procedure, only the following autonomous community replied:

- o Sub-Directorate-General for Waste, Director-General of Environmental Quality and Climate Change, Xunta de Galicia.

On the comment received, the Xunta de Galicia proposes that those agreed in the agreement of the Coordination on Waste regarding the scheme and design of the Register of By-products be included. In particular, the CPA code or certain information on the actors involved should be required. The claims received were accepted.

4. Reports from Ministries and Public Bodies.

The General Technical Secretariat of the Ministry for the Ecological Transition and the Demographic Challenge requested a report from the following ministries and public bodies:

- Ministry of Foreign Affairs, European Union and Cooperation, provided for in the first paragraph of Article 26(5) of Law 50/1997 of 27 November 1997 on the Government (23/07/2024). No comments were made.
- Ministry of Economy, Trade and Business, provided for in Article 26(5)(1) of Law 50/1997 of 27 November 1997 on the Government (pending).
- Ministry of Social Rights, Consumer Affairs and 2030 Agenda, provided for in Article 26(5)(1) of Law 50/1997 of 27 November 1997 (pending).
- Ministry of Industry and Tourism, provided for in the first paragraph of Article 26(5) of Law 50/1997 of 27 November 1997 (19/07/2024). It is proposed to replace the reference to European legislation on shipments of waste by its



current version, Regulation (EU) 2024/1157 of the European Parliament and of the Council of 11 April 2024.

- Ministry of Health, provided for in Article 26(5)(1) of Law 50/1997 of 27 November 1997 (09/07/2024). No comments are made in its report.
- Ministry of Agriculture, Fisheries and Food, provided for in Article 26(5)(1) of Law 50/1997 of 27 November 1997 (24/07/2024). Formal comments are made.
- Ministry of Territorial Policy and Democratic Memory, on the distribution of powers, in accordance with article 26(5)(6), of Law 50/1997 of 27 November (02/07/2024). The report states that no comments are made with regard to compliance with Law 20/2013 of 9 September 2013 on the guarantee of market unity. No observations of a jurisdictional nature are made either.
- Ministerial Commission for Digital Administration of the Ministry for the Ecological Transition and the Demographic Challenge (pending).

5. Report of the Environmental Advisory Board.

In accordance with the provisions of Article 19 of Law 27/2006 of 18 July 2006, the text of the draft order was sent for submission to the Advisory Council on the Environment and certified as having been submitted on 3 July 2024. During this process, comments were received from the CEOE (Spanish Confederation of Business Organizations), which were similar to those received from Atlantic Cooper and FEIQUE, during the Public Information process. The CEOE also received a comment from the CEOE requesting the extension of uses, which was not accepted.

6. Referral as a technical standard.

Since Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 introduces an amendment to Article 5 on by-products by providing for the provision that Member States notify the European Commission of the detailed criteria on by-products, 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, where that directive so requires, and given that the deadline for transposition of Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 has expired at the time of processing this order, it has been decided, in compliance with that provision, to submit this order to the procedure for the provision of information in the field of standards regulated by Royal Decree 1337/1999 of 31 July 1999, regulating the transmission of information in the field of technical standards and regulations and regulations relating to information society services, for the purposes of complying with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 (pending).

7. Notification to the World Trade Organization.

By virtue of the transparency commitments established in the Agreement on Technical Barriers to Trade to which the Kingdom of Spain is bound as a member of the World Trade Organization (pending).

8. Prior approval by the Ministry for Digital Transformation and the Civil Service.



As a result of the restructuring of the various ministerial departments, the Secretariat of State for the Civil Service of the Ministry for Digital Transformation and the Civil Service is responsible for processing the prior approval referred to in Article 26(5) of Law 50/1997 of 27 November 1997, in accordance with the provisions of Article 8(1)(v) of Royal Decree 210/2024 of 27 February 2024 establishing the basic organisational structure of the Ministry for Digital Transformation and the Civil Service (pending).

9. Report of the General Technical Secretariat of the Ministry for Ecological Transition and the Demographic Challenge. (Pending)

Requested on the basis of Article 26(5)(4), of Law 50/1997 of 27 November.

10. Opinion of the Council of State.

Pursuant to Article 22(3) of Organic Law 3/1980 of 22 April 1980 on the Council of State (pending).

VI. IMPACT ANALYSIS

1. Economic impact

- **General economic impact**

On the general economic impact and effects on productivity, this Regulation will allow progress to be made in promoting the circular economy, as it encourages the introduction of materials into production processes, thus reducing the consumption of virgin raw materials that are replaced by materials declared as by-products.

In turn, the promotion of the first stages of the waste hierarchy, which is one of the bets of the circular economy, leads to the emergence of new jobs associated with these first options (prevention, preparation for reuse and recycling), which are more job-seeking than the lowest options in the hierarchy (incineration and dumping).

- **Impact on SMEs**

Regarding the possible effects on SMEs, the draft order establishes a clear and homogeneous framework on how such companies should manage by-products and encourages their movement between companies, as it is expected that there will be greater demand for substances that have been declared by-product, as they are no longer considered waste. Given that most of the companies related to the waste sector are SMEs, it is considered that this regulatory project will have a positive impact on them.

- **Effects on market competition, market unity and competitiveness**

As regards compliance with Law 20/2013 of 9 December 2013 on the guarantee of market unity, the draft order takes account of the principles of that law, since no new economic requirements are imposed on operators. No new barriers or obstacles are established because no new authorisations, registrations or requirements are required for access to by-product status.

The draft order has a positive impact on competition by establishing for the entire territory of the State single criteria for considering certain substances and articles as by-products. This avoids situations of inequality between the different autonomous communities and ensures the same level of environmental protection for all of them.

In short, the draft legislation is consistent with the unity of the market, has a positive effect on competition and respects the principle of freedom of action throughout the territory of



the State, since no different economic requirements are required by reason of the territory.

2. Budgetary impact

The draft order does not generate economic obligations for public administrations, and has no budgetary impact on the General State Administration budgets, nor on the regional budgets.

Furthermore, the implementation of this order will not lead to changes in expenses or income, nor will there be any staff costs associated with it.

3. Analysis of administrative burdens

With regard to administrative burdens, it should be noted that this order will entail for producers wishing to manage any of the substances and articles listed in Article 1(1) as a by-product, the obligation to submit a signed responsible declaration to the competent environmental body of the autonomous community where they are generated, indicating that it complies with the provisions of this order, as specified in Article 4(1).

The quantification of this administrative burden is shown in the following table, for the calculation of which the Simplified Method of Estimating Administrative Burdens and their Reduction has been followed:



Draft order declaring certain substances and articles as by-products under Law 7/2022 of 8 April 2022 on contaminated waste and soil for a circular economy.

Administrative obligations	Article	Burden type	Unit cost	Frequency	Population	Annual cost
Responsible declaration	4.1	6	2	1	1 000 ¹	2,000
ANNUAL COST CHARGES						2,000

1. Estimated number of companies that, due to their activity, could benefit from the draft order.

Articles 4(5) and 5(d) of the draft order require producers to keep a chronological record of the quantities produced and managed as by-products, as well as their destination, and users to keep a chronological record of the quantities used and their origin, together with the keeping of both records and their availability to the competent authority for a period of 5 years. These charges were previously imposed by Law 7/2022 of 8 April 2022, so they are not new charges generated by this draft order.

The administrative burdens involved in this draft order (EUR 2 000 per year) must be compared with the burdens that would arise if the order declaring certain substances and articles as by-products did not apply to them. These charges would be those arising from the obligation to be authorised as waste managers, as set out in Law 7/2022 of 8 April 2022, and to apply accordingly, in national movements, Royal Decree 553/2020 of 2 June 2020 regulating the shipment of waste within the territory of the State, and in movements within the European Union and to third countries, Regulation (EC) No 1013/2006 of the Parliament and of the Council of 14 June 2006, which will be the following:

Law 7/2022 of 8 April 2022.						
Administrative obligations	Article	Burden type	Unit cost	Frequency	Population	Annual cost
Submission of waste treatment authorisation	33	7	4	0,44 ¹	1,000	1,760
ANNUAL COST CHARGES						1,760

1. According to Article 33(9) of Law 7/2022 of 8 April 2022, the authorisation for waste treatment facilities shall be incorporated into the integrated environmental authorisation, granted in accordance with Royal Legislative Decree 1/2016 of 16 December 2016 approving the revised text of the Law on integrated pollution prevention and control. In accordance with Article 26(2) of the revised text, the review of the authorisation shall be carried out every 4 years as a



general rule. Hence the value 0.44.

Royal Decree 553/2020 of 2 June.						
Administrative obligations	Article	Burden type	Unit cost	Frequency	Population	Annual cost
Retention of a copy of the identification document.	6.2	11	20	0.33 ¹	1,000	6,600
ANNUAL COST CHARGES						6,600

1. The value 0.33 derives from the obligation to keep the documentation for three years, as set out in Royal Decree 553/2020 of 2 June 2020.

Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006						
Administrative obligations	Article	Burden type	Unit cost	Frequency	Population	Annual cost
Information accompanying certain wastes	18	8	2	1 -	1,000	2,000
Preservation of documents and information	20	11	20	0.33 ^{Error! Marker not defined.}	1,000	6,600
ANNUAL COST CHARGES						8,600

1. In this case, frequency and population are not multiplied since both data coincide. It is considered that the indications on page 77 of the Methodological Guide for the elaboration of the MAIN would apply: 'when the obligation is fulfilled when an event occurs, for example when a company is set up, in the event of an accident at work or a dismissal, the only way to establish the frequency is to estimate the number of annual files. In this case it will NOT be multiplied by the population, since the frequency and the population are the same data'. In this case, the specific event is the shipment of certain waste that will be accompanied by the documentation to be signed by the person who organises the shipment before it begins. 2. The value 0.33 derives from the obligation to keep the documentation for three years, as set out in Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006.

According to the above, it can be concluded that for all those producers who take advantage of the future order, this will mean a reduction in administrative burdens of EUR 6 360/year; (6 600 + 1 760-2 000), in the event that they only carry out shipments at the national level. In addition, in the event that producers carry out shipments within the



European Union, the reduction will be even greater, amounting to EUR 14 690/year; (6 600+1 760+8 600-2 000). Although this last data must be taken with caution since it has not been possible to obtain, or even estimate, the number of shipments that are made for the materials or articles of this draft order at the European Union level and, therefore, it should be recalled that the data set out above are an estimate.

4. Gender impact

For the purposes of the provisions of Law 30/2003, of 13 October 2003, on measures to incorporate the gender impact assessment in the normative provisions prepared by the Government and in Article 19 of Organic Law 3/2007, of 22 March 2007, for effective equality of women and men, this draft order is considered to be based on a situation in which there are no inequalities of opportunity or treatment between men and women, and no modification of this situation is foreseen, so it can be said that the provisions contained in the order do not contain any aspect from which negative consequences or discrimination may arise and that it does not contain specific provisions related to gender, so the gender impact of this Regulation is zero.

The assessment of the gender impact in relation to the elimination of inequalities between women and men, as well as in relation to the fulfilment of the objectives of equality policies, is null, since they do not follow from the very purpose of the regulation or from its application in this area.

5. Impact on children and adolescents

Pursuant to the provisions of Article 22(d) of Organic Law 1/1996 of 15 January 1996 on the legal protection of minors, the partial amendment of the Civil Code and the code of civil procedure, as amended by Law 26/2015 of 28 July 2015 amending the system for the protection of children and adolescents, the draft legislation has no impact on children and adolescents, because it addresses technical issues and does not have direct legal effects on natural persons.

6. Family impact

Pursuant to the provisions of the tenth additional provision of Law 40/2003, of 18 November 2003, on the protection of large families, introduced by the fifth final provision of Law 26/2015, of 28 July 2015, amending the system of protection of children and adolescents, the draft legislation has no impact on the family, because it exclusively addresses technical issues and does not have direct legal effects on natural persons.

7. Impact on equal opportunities, non-discrimination and universal accessibility for persons with disabilities

Based on the provisions of the Consolidated Text of the General Law on the Rights of Persons with Disabilities and their Social Inclusion, approved by Royal Legislative Decree 1/2013 of 29 November 2013, this draft order has no impact on grounds of equal opportunities, non-discrimination and universal accessibility for persons with disabilities, because it deals exclusively with technical issues and does not have direct legal effects on natural persons.

8. Climate change impact



The study of this type of impact was included in the preparation of the MAIN from the entry into force of Law 7/2021, of 20 May 2021, on climate change and energy transition, whose fifth final provision amended Article 26.3 of Law 50/1997, of 27 November 1997, introducing a new point (h) that states that. 'The impact due to climate change, which shall be assessed in terms of mitigation and adaptation to it'. In this sense, it is considered that this draft order will have no impact due to climate change, since it has no effects on mitigation or adaptation.

9. Other impacts

Environmental impact.

A positive impact on the environment is expected since the substances and articles that intend to be recovered and reincorporated into the production process through the application of this order, replace virgin raw materials, which means a lower consumption of these, with the consequent reduction of the negative impacts associated with the extraction of raw materials from the environment and the foreseeable reduction of greenhouse gas emissions associated with these extractions. In this way the draft order will contribute to a prudent and rational use of natural resources from which benefits for the protection of the environment can be derived.

Impact due to the development or use of digital government media and services

A zero impact is expected in this section, since the digital obligations imposed by the order were already covered by other legislation in the past.

VII. EX-POST EVALUATION.

Having considered the provisions of Article 28(2) of Law 50/1997, of 27 November 1997, as well as Article 3 of Royal Decree 286/2017, of 24 March 2017, it is considered that the Regulation should not be evaluated for its results and, therefore, ex post evaluation mechanisms are not contemplated.



ANNEX I

Summary table of contributions in the process of Prior Public Consultation, hearing of autonomous communities and audience and Public Information.

Contributions to the Prior Public Consultation process

Adm./ Ag. Econ.	Name	Comment and Justification	Alternative proposal	Evaluation
1. Economic operator	Spanish Wood Trade and Industry Association (AEIM)	<p>The Timber sector considers of interest the list of by-product candidates, which would be raised by the Ministerial Order referring to the following: chips, cuttings, sawdust, shavings, logs, cores, trimmings, (cuts and scraps of virgin wood) from a holding, from sawmilling and from the manufacture of plywood boards and fruit and vegetable packaging bottoms for use in the manufacture of particle board and fibreboard.</p> <p>The destination of these by-products is not only for the manufacture of boards, as noted, since they have other industrial uses as by-products for the manufacture of briquettes, pellets and their use as fuel in biomass boilers, pulp manufacturing (cellulose and paper), among others. The following may also be cited: bark for binder in perfumes, gardening, compost (fertilisers) or decorative elements, and wood finishes and construction in the case of coastal areas.</p>	<p>ACEMM proposes as an alternative, in accordance with the principles of the circular economy of the wood industry and sustainability, that the destination of the by-products should reflect a generic destination, since it is currently used by several sectors, among others the biomass sector, the construction sector, the pulp-paper industry, the landscaping sector, etc. therefore: these by-products are for industrial processing use.</p>	<p>NOT ACCEPTED. By-product declarations are made with a specific origin and destination, depending on the application received. If another destination is desired, another request must be made.</p>



		Therefore, it is considered that it should not have an exclusive use for a single sector (manufacturing of boards) when used by different sectors not explained in the text.		
2. Economic operator	Forest Association of Cantabria (ASFORCAN)	From forest owners and managers in Cantabria are affected by the following candidate by-product materials and their specific destinations: 'Chips, cuttings, sawdust, shavings, logs, cores, trimmings and virgin wood scraps from logging, sawdust or the manufacture of plywood and fruit and vegetable packaging bottoms, for use in the manufacture of particleboard and fibreboard'. We believe that not only should their use be taken into account for the manufacture of particle board and fibreboard, but that their use is much broader. Our first concern is for the sustainability of our production and for the recycling of nutrients within the forest ecosystem, so its main use would be 'the recirculation of nutrients in the forest ecosystem itself'.	ASFORCAN proposes as an alternative, based on the principles of the circular bioeconomy, to take into account the use for the recirculation of nutrients in the same forest ecosystem and to also consider other industrial uses such as pellet manufacturing, fuel in biomass boilers, pulp manufacturing (cellulose and paper); gardening or decorative elements, wood finishes and construction and the production of electrical energy by combustion.	NOT ACCEPTED. By-product declarations are made with a specific origin and destination, depending on the application received. If another destination is desired, another request must be made.



		<p>It is necessary to consider that more than 70% of the nitrogen (N), calcium (Ca) and magnesium (Mg) contained in forest aerial biomass is found in this fraction (bark, branches and leaves) which is considered waste, which is actually the main way of returning nutrients to the soil, closing the cycle of them. The replacement of these extracted nutrients, in the event that they are considered waste, it is necessary to carry out it by means of fertilisers, with the consequent risk of contamination to the ecosystem. Therefore, its natural recycling in the forest ecosystem itself has a much smaller environmental footprint.</p> <p>In addition to this use as nutrient recycling is used for pellet manufacturing, as fuel in biomass boilers, pulp making (cellulose and paper); bark is also used for gardening or decorative elements, wood finishes and construction in the case of coastal areas and the production of electrical energy by combustion.</p>		
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3. Economic operator	Spanish Association of Pulp and Paper Manufacturers (ASPAPPEL)	The pulp and paper sector considers of interest the list of by-product candidates, which would be raised by the Ministerial Order referring to the following: chips, cuttings, sawdust, shavings, logs, cores, trimmings, (cuts and scraps of virgin wood) from a holding, from sawmilling and from the manufacture of plywood boards and fruit and vegetable packaging bottoms for use in the manufacture of particle board and fibreboard. The fate of these by-products also has another industrial use as by-products for pulp (cellulose and paper) production.	ASPAPPEL proposes as an alternative, in accordance with the circular economy of the pulp and paper industry, that the destination of the by-products should reflect another destination, since it is currently also used by the pulp-paper sector, therefore: these by-products are for industrial processing use.	NOT ACCEPTED. By-product declarations are made with a specific origin and destination, depending on the application received. If another destination is desired, another request must be made.
4. Economic operator	CEOE Confederación Española de Organizaciones Empresariales		The fate of these by-products as described in the consultation should be extended as there are many other industrial uses where they could be used. It should therefore be used not only 'for use in the manufacture of particle board and fibreboard', but also for other industrial uses. Justification: we consider that they comply with the requirements set out in Article 4(1) of Law 7/2022.	NOT ACCEPTED. By-product declarations are made with a specific origin and destination, depending on the application received. If another destination is desired, another request must be made.
5. Economic operator	Confederation of Spanish Forestry Owners (COSE).	Forest owners and managers in Cantabria are affected by the following candidate by-product materials and their specific destinations: 'Chips, cuttings, sawdust, shavings, logs, cores, trimmings and virgin wood scraps from logging, sawdust or the manufacture of plywood and fruit and vegetable packaging bottoms, for use in the manufacture of particleboard and fibreboard'.	The Consorci Forestal de Catalunya proposes as an alternative, based on the principles of the sustainable management of forest areas and the circular bioeconomy, requests that the role of cutting waste in soil improvement and nutrient recirculation in the forest ecosystem be taken into account and that other industrial uses also be considered in the case of products such as chips, cuttings, sawdust, shavings: manufacture of pellets, fuel in biomass boilers, manufacture of pulp (cellulose and paper); gardening or decorative elements, wood finishes and construction and the production of electrical energy by combustion.	NOT ACCEPTED. By-product declarations are made with a specific origin and destination, depending on the application received. If another destination is desired, another request must be made.



	<p>We believe that not only should their use be taken into account for the manufacture of particle board and fibreboard, but that their use is much broader. Our primary concern is the sustainability of forest management. The maintenance of the remains of the forest cut contributes to the improvement of the soil, the recirculation of nutrients in the forest ecosystem and the improvement of biodiversity as it is the habitat of numerous saproxylic organisms that contribute to the improvement of biodiversity.</p> <p>In addition to the fundamental role for the improvement of the forest ecosystem of cutting waste, products such as chips, shavings, cuttings, etc., are used for the manufacture of pellets, as fuel in biomass boilers, pulp making (cellulose and paper); bark is also used for gardening or decorative elements, wood finishes and construction in the case of coastal areas and the production of electrical energy by combustion.</p> <p>Key activities for the development of the bioeconomy in the forestry sector.</p>		
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Contributions in the hearing process to the autonomous communities

Administration/ Economic operator	Name	Comment and Justification	Alternative proposal	Evaluation
1. Administration	Sub-Directorate- General for Waste (Xunta de Galicia)	Article 1. We request that the CPA corresponding to each of the by-products be established in each of the sections of (a) to (g) in order to harmonise criteria between autonomous communities, bearing in mind that the CPA code is a field to be included in the Register of by-products, as established in the 'AGREEMENT OF THE COMMISSION FOR WASTE COORDINATION RELATING TO THE SCHEME AND DESIGN OF THE REGISTRATION OF BY-PRODUCTS IN ACCORDANCE WITH LAW 7/2022, OF 8 APRIL 2022, ON CONTAMINATED WASTE AND SOILS FOR A CIRCULAR ECONOMY'.	a) aluminium saturated sodium hydroxide (CPA:), generated during the anodising and extruding processes of aluminium, for direct use in the manufacture of sodium aluminate; b) artificial plaster (CPA:), obtained in electrolytic copper production facilities for direct use as a setting regulator in the manufacture of cement; 60 % nitric acid solution (CPA:), generated in the manufacture of oxalic acid for direct use in the manufacture of nitrogenous fertilising products, in accordance with national legislation; d) vegetable substrate (CPA:), for use as a growing medium; e) dilute sulphuric acid (CPA:), obtained in the production of food maize for direct use in the manufacture of fertilising products, in accordance with national rules; f) chips, cuttings, sawdust, shavings, logs, cores, trimmings, cuts and scraps of virgin wood from logging (CPA:), sawdust or the manufacture of plywood and fruit and vegetable packaging bottoms, for use in the manufacture of particle board and fibreboard; g) paper rejects resulting from converting in the manufacture of tissue final products (CPA:), for use in the preparation of pulp for the manufacture of tissue paper;	PARTLY ACCEPTED. The CPA codes shall be set out in the Annex.



<p>2. Administration</p>	<p>Sub-Directorate-General for Waste (Xunta de Galicia)</p>	<p>Annex. The information contained in the responsible declaration is not sufficient to fill in all the fields required in the Register of by-products, as established in the 'AGREEMENT OF THE COORDINATION ON WASTE COORDINATION REGARDING TO THE SCHEME AND DESIGN OF THE REGISTRATION OF SUB-PRODUCTS IN ACCORDANCE WITH LAW 7/2022, OF 8 APRIL, ON WASTE AND CONTAMINATED SOILS FOR A CIRCULAR ECONOMY'. In the responsible declaration there should be an option to collect the following cases:</p> <ul style="list-style-type: none"> • For each undertaking there may be one or more by-product production facilities. • For each by-product there may be one or more recipients • For each entity using a by-product, there may be 	<p>That is add in that responsible declaration the following fields:</p> <p>Details of the producing entity:</p> <ul style="list-style-type: none"> • Head office address. • Contact details: phone/email • CNAE (main economic activity). <p>Details of the installation producing by-products:</p> <ul style="list-style-type: none"> • NIMA. • Installation name. • Address: autonomous community, province, municipality, address, postal code. <p>Data of the user/s of the by-product receiving entity:</p> <ul style="list-style-type: none"> • Tax identification number. • Head office address: autonomous community, province, municipality, address, postal code. • CNAE. (Main economic activity). • Contact details: phone/email <p>Data of the User/s of the by-product installation/recipients:</p> <ul style="list-style-type: none"> • NIMA (if there is one). • Installation name. • Address of receiving facility: autonomous community, province, municipality, address, postcode. Indicate in the responsible declaration the options indicated, or indicate in the order that for each of these cases a separate responsible declaration must be submitted. 	<p>ACCEPTED</p>
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MINISTRY FOR THE ECOLOGICAL TRANSITION AND
THE DEMOGRAPHIC CHALLENGE

SECRETARY OF STATE FOR
THE ENVIRONMENT

DIRECTORATE-GENERAL
FOR ENVIRONMENTAL
QUALITY AND ASSESSMENT

		one or more facilities receiving that by-product.		
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3. Administration	Sub-Directorate-General for Waste (Xunta de Galicia)	Annex. In the responsible declaration there should be an option to collect the following cases: ·When each undertaking may have one or more by-product production facility. ·When each by-product there may be one or more recipients, for each entity using a by-product there may be one or more receiving facilities for that by-product.	Indicate in the responsible declaration the options indicated, or indicate in the order that for each of these cases a separate responsible declaration must be submitted.	PARTLY ACCEPTED.
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Contributions in the process of hearing and public information

Administration/econm. agent	Name	Comment and Justification	Alternative proposal	Evaluation
1. Economic operator	Atlantic Copper S.L.U. / FEIQUE/CEOE	<p>Amend the requirement in Article 3 that by-products <i>'shall be stored in appropriate facilities or containers, properly insulated, in order to avoid contact with the ground'</i>.</p> <p>Justification 1a: Several of the by-products do not meet the criteria for classification as hazardous substances under the Classification and Labelling of Chemicals (CLP) Regulation.</p> <p>Justification 2a: The requirement is stricter than that laid down in Article 21 of Law 7/2022 of 8 April 2022 on contaminated waste and soil for a circular economy. That article states that 'In the case of storage of hazardous waste these shall be weather-protected and with spill and spill retention systems'. That requirement does not apply to non-hazardous waste. Several of the substances covered by the</p>	<p>b) They shall be stored in appropriate facilities or containers, with the aim of avoiding, properly insulated according to their safety data sheet, in order to avoid contact with soil contamination and surface and groundwater bodies.</p>	<p>PARTLY ACCEPTED. Materials must be properly insulated, which should prevent contamination of soil and water.</p>



		<p>Ministerial Order, when they are not by-products, are non-hazardous waste and are not subject to the restriction of not being in direct contact with the soil.</p> <p>Justification 3a: The use of several of the by-products involves direct contact with the soil.</p> <p>Justification 4a: This requirement has not been included in previous ministerial orders concerning by-products not classified as hazardous (polyurethane foam trimmings, polymer production residues, production residues from the agri-food industry intended for animal feed).</p> <p>Therefore, taking into account the principles of good regulation established in Article 129 of Law 39/2015 and, in particular, those of necessity and effectiveness, proportionality and legal certainty, the requirement of Article 3 must be amended, inasmuch as the measure cannot be considered essential to comply with the objective pursued, when it is not established even for non-hazardous waste.</p>		
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<p>2. Economic operator</p>	<p>Atlantic Copper S.L.U. / FEIQUÉ/CEOE</p>	<p>Amend the requirement in Article 7 that '<i>Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste shall not apply in the following cases:</i> a) where by-products listed in Article 1(1) are sent to a user from the installation of a produce. from another Member State of the European Union, which is also declared as a by-product these substances or articles for the same subsequent use'. Justification 1a: It does not take into account the case where the substance is considered a product, and not a by-product/waste, in the receiving Member State. Justification 2a: The principle of mutual recognition implies that EU countries cannot prohibit the sale on their territory of goods lawfully marketed in another EU country, ensuring access to the market for goods that are not subject to EU harmonisation legislation or are partially subject to it. This principle is found laid down in</p>	<p>Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste shall not apply in the following cases: a) where the by-products listed in Article 1(1) are dispatched from a producer's installation to a user in another Member State of the European Union, who has also declared these substances or articles as by-products for the same subsequent use; or where the mutual recognition declaration has been delivered to the competent authority of the Member State of destination to carry out an assessment in accordance with Article 5 of REGULATION (EU) 2019/515 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008.</p>	<p>NOT ACCEPTED. Once the materials have been declared as by-products by this Order, interested parties may appeal to Regulation (EC) No 1013/2006, taking into account the limitations established therein when establishing mutual recognition.</p>
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		<p>Articles 34 to 36 TFEU and further developed by Regulation (EU) 2019/515 of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008, which establishes a procedure for the assessment of mutual recognition of goods, consisting of a prior authorisation procedure, whereby, at the request of an economic operator, the competent authority of a Member State must give its formal approval before the goods can be placed on the market of that Member State. By-products, as goods to be marketed under Regulation 2019/515, should be able to be freely marketed within the territory of the EU, by issuing the mutual recognition declaration. Restricting the access of these substances to other EU markets would violate the principle of mutual recognition and the free</p>		
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		movement of goods recognised in Articles 34 to 36 TFEU, as well as discouraging circular economy objectives.		
3. Economic operator	Carmen Callao Buatas	Article 5: As drafted, it appears that all substances in Article 1(1) must be used for the manufacture of fertilisers or substrates.	Article 5(b) When to be used... Article 5(c) When to use the vegetable substrate Add a section that clarifies what to do when they are not intended for fertiliser or substrate.	NOT ACCEPTED. Article 5 specifies that users who are going to use the substances or articles of the Order in a fertilising product must comply with certain rules: If the destination is not that, they must not meet that standard.



4. - economic operator	FEIQUE/CEOE	<p>Amend the requirement in Article 3(a) that by-products 'shall not be mixed with other materials, waste or other substances or articles'. Justification: The established criteria do not help many of the strategic circularity projects to be implemented. Depending on the production process, it should be possible to allow the subsequent mixing of a by-product, provided that the relevant risk analysis has been submitted and is used under certain conditions.</p>	<p>From the moment they are generated on the producer's premises, during transport, and until their final use on the users' premises, they shall not be mixed with other materials, waste or other substances or articles.. Mixing is permitted as long as a risk analysis is presented and used under certain permitted conditions.</p>	<p>NOT ACCEPTED. By-product declarations are for specific materials with specific characteristics. If it were allowed to be mixed with other materials, the material would no longer be the same and its characteristics could change, affecting the possibility of complying with the by-product conditions.</p>
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5. - economic operator	CEOE	<p>Amend Article 1(f) to include only specific uses, so that it also includes other industrial uses.</p> <p>Justification:</p> <p>The fate of these by-products as described in the consultation should be extended as there are many other industrial uses where they could be used. We consider that they comply with the requirements set out in Article 4(1) of Law 7/2022.</p>	<p>f) Chips, cuttings, sawdust, shavings, logs, cores, trimmings and virgin wood scraps from logging, sawdust or the manufacture of plywood and fruit and vegetable packaging bottoms, for use in the manufacture of particleboard and fibreboard, in addition to other industrial uses;</p>	<p>NOT ACCEPTED. The permitted uses are the uses that have been assessed on the basis of the application submitted. If new uses, which must be specific, are desired, a new application must be submitted to the autonomous community where the production facility is located.</p>
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