



Draft Royal Decree regulating the management of waste from wet wipes and balloons.

I

With a view to achieving United Nations Sustainable Development Goals 12 and 14, which form part of the 2030 Agenda for Sustainable Development adopted by the United Nations General Assembly on 25 September 2015, relating to the need to ensure sustainable consumption and production patterns and the conservation and sustainable use of the oceans, the seas and marine resources, respectively, the European Union adopted Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment.

This directive is part of the European Union's efforts to prevent and combat marine litter, considering that litter dispersed in the marine environment is inherently transboundary and is considered a growing global problem. At the same time, it adopts a circular approach that gives priority to reusable, sustainable and non-toxic products and reuse schemes over single-use products, with the primary objective of reducing the amount of waste generated.

To this end, Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019, focuses on the single-use plastic products most frequently found on beaches in the European Union, as well as fishing gear containing plastic and products made from oxo-degradable plastic. Different measures apply to these products, depending on various factors, such as the availability of suitable, more sustainable alternatives, the feasibility of changing consumption patterns, or the application of other existing European Union legislation.

These products include wet wipes and balloons, which are the fifth and ninth most commonly found single-use plastic items, respectively, on beaches across the European Union.

In order to mitigate the significant environmental impact resulting from the inappropriate disposal of wet wipes down the toilet and the release of balloons into the environment, especially in the marine ecosystem, this Directive establishes a number of measures, including mandatory marking for wet wipes containing plastic, the implementation of extended producer responsibility schemes for both products by 31 December 2024 and the development of awareness-raising initiatives. The Member States are responsible for applying these provisions and must ensure their effective implementation and enforcement.

II



Law 7/2022 of 8 April 2022 on waste and contaminated soils for a circular economy, which repeals Law 22/2011 of 28 July 2011 on waste and contaminated soils, transposes Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 into Spanish law, through Title V and includes specific provisions on wet wipes for personal hygiene and household purposes and on balloons.

In accordance with Article 58 of Law 7/2022 of 8 April, marking requirements are laid down for wet wipes containing plastic, in compliance with Commission Implementing Regulation (EU) 2020/2151 of 17 December 2020 laying down rules on harmonised marking specifications for single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904 of the European Parliament and of the Council on the reduction of the impact of certain plastic products on the environment. This Regulation lays down rules to harmonise the marking of single-use plastic products listed in Part D of the Annex to Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019, which aims to reduce the environmental impact of certain plastic products.

For its part, Article 60 of Law 7/2022 of 8 April 2022 provides for the Government to draw up regulations establishing an extended producer responsibility scheme for various products, including wet wipes containing plastic, and balloons, and which must specify the costs to be borne by the producers of those products. The development of the extended producer responsibility scheme will take into account the provisions set out in Title IV of the aforementioned Law, which lays down the mandatory minimum requirements to be applied in the field of extended producer responsibility.

Finally, Article 61 of Law 7/2022 of 8 April 2022 establishes the requirement for the competent authorities to carry out awareness-raising measures to inform consumers and encourage more responsible behaviour.

III

This Royal Decree applies to waste generated by single-use wet wipes and by single-use balloons containing plastic that are placed on the Spanish market. It should be noted that the products covered by this regulation are classified into two distinct categories, each with its own separate supply chain, which justifies the application of specific measures in each case.

In the case of wet wipes, this includes pre-moistened wipes intended for personal hygiene and domestic use. These products consist of non-woven textile material made from synthetic polymers, such as polyester; chemically modified natural polymers, such as polyhydroxyalkanoates (PHA); chemically



unmodified natural polymers, such as viscose and lyocell; or are made from mixtures of the above (mixed wet wipes).

This establishes two categories for wet wipes: those containing plastic and those that do not. The first category includes wipes made from synthetic polymers, chemically modified natural polymers and blended compositions containing any proportion, however small, of the aforementioned polymers, even if they are partly made from natural polymers that have not been chemically modified. Consequently, only wipes made entirely of natural polymers that are not chemically modified shall be considered plastic-free wipes.

In order to strengthen environmental legislation and reduce the environmental impact associated with wet wipes, in general, this Royal Decree applies to wet wipes containing plastic and wet wipes made entirely of chemically unmodified natural polymers that do not comply with the requirements of standard UNE 149002:2022, entitled *Acceptance criteria for products suitable for disposal through toilets*, which fall within the category of plastic-free wipes. This regulation is based on the seventh final provision, paragraph 2, of Law 7/2022 of 8 April 2022, which allows extended producer responsibility to be extended to other wet wipes not covered by Article 60(1) of that law, which refers exclusively to wet wipes containing plastic. Consequently, this Royal Decree extends its scope in relation to Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019, in accordance with the interpretation set out in the Commission's Guidelines on single-use plastic products pursuant to Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019. However, producers of these types of plastic-free products will be subject to less stringent financial obligations.

Wet wipes made of natural polymers that are not chemically modified and comply with UNE 149002:2022, as well as wet wipes for industrial and professional uses, such as medical or sanitary wipes, are excluded from the scope of this Royal Decree.

For the purposes of this Royal Decree, wet wipe means a small piece of pre-moistened or pre-wet material that has been conceived, designed and placed on the market for single use, i.e. is disposable after use for personal care or domestic use. In the field of personal care, wet wipes are used for hygienic purposes to cleanse and care for the skin, including products such as baby wipes, make-up remover wipes, and intimate care wipes, including moist toilet paper. As regards their domestic use, these wipes are designed for the cleaning of surfaces in kitchens and bathrooms, personal vehicles and glasses, among others. Pre-moistened wipes are usually impregnated with a liquid before being placed on the market and are normally presented in packs containing multiple single-use units, although they can also be sold in individual packs.



Furthermore, the point of purchase, the distribution channel and the type of end user are important factors that must be taken into account when determining whether the wet wipes are intended for domestic or professional use. For example, wet wipes sold through professional distribution channels (business-to-business) and used by healthcare professionals are considered to be intended for professional use and do not fall within the scope of Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019. However, wet wipes sold through business-to-consumer channels (i.e. those sold to members of the public in pharmacies and intended for use at home) are not considered to be for professional use; such products would, however, fall within the scope of this Royal Decree.

For balloons, this standard applies to those made from synthetic polymers, such as mylar or aluminium-coated nylon sheets, as well as those made from chemically modified natural polymers, such as latex. As for the latter, they fall within the scope of this Royal Decree as they do not break down completely due to unsuitable environmental conditions, even though in certain cases the balloons are classified as biodegradable.

However, balloons intended for industrial or professional uses and applications that are not marketed to the final consumer are excluded from the scope of this Royal Decree.

A balloon is a bag made of a lightweight, non-porous material that is inflated with air or gas. To be considered single-use and, therefore, to fall within the scope of this Royal Decree, it must meet two requirements: firstly, it must not have a valve or seals that allow it to be inflated and deflated on multiple occasions, as single-use products must be sealed by means of a knot, a cord or a ribbon – elements which, when untied and retied, cause them to deteriorate; and secondly, the balloons must not be capable of being refilled, as, if they were, they would be considered reusable. Consequently, the category of single-use balloons includes both those sold empty for the consumer to inflate – including self-inflating balloons fitted with a built-in inflation mechanism – and those already inflated with air or helium, as the consumer cannot reinflate them.

In addition, the point of purchase, the distribution channel and the type of end user are important in determining whether balloons are intended for domestic or professional use. Consequently, balloons sold through business channels to consumers or distributed to private individuals (for example, balloons that private individuals can purchase in a shop or that are distributed to them at a private event) are not considered to be for professional or industrial use or application, but rather for domestic use. These products should therefore be included in the scope of this Royal Decree. Furthermore, balloons for which, at the time of their placing on the market, it is not clear whether their intended use



is industrial or domestic must also be included within the scope of this Royal Decree in order to prevent any potential breaches of the applicable regulations.

Thus, the purpose of this Royal Decree is to prevent and minimise the impacts caused by the waste generated by wet wipes and balloons, in particular those resulting from their loss, abandonment or inappropriate disposal.

The impacts generated by these products have environmental, social and economic consequences. The extent of such effects will depend on both their use and the way in which they are disposed of.

Wet wipes, even those made from chemically unmodified natural polymers, have a negative environmental impact and significantly affect the functioning of sewerage and wastewater treatment systems. As they do not break down completely, they cause blockages in the sewerage system, which reduces its capacity to retain water and increases the risk of flooding, particularly during periods of heavy rain. This problem not only compromises urban infrastructure, but also generates direct waste discharges into rivers and other bodies of water, contributing to microfiber pollution and damaging ecosystems, especially aquatic ones. In addition, the difficulties of some municipalities in managing this waste can lead to penalties for administrative infractions or environmental crimes, which can ultimately generate significant economic losses.

Furthermore, it is important to note that, although some wet wipes are marketed as biodegradable, this does not mean they can be flushed down the toilet, as they degrade only to a limited extent in the environment, which thereby prolongs their polluting impact. Consequently, qualifying wet wipes as biodegradable may cause confusion for the consumer.

In Spain, the UNE 149002:2022 standard sets out guidelines for the disposal of certain products via the sewerage system. Its purpose is to define the requirements that must be met in order to be considered suitable for direct disposal down the toilet. Consequently, the aforementioned standard sets out rigorous tests on composition, ensuring that products must not contain synthetic materials, and tests for sedimentation and dispersion, whilst assessing the potential for disintegration and biodegradation under both aerobic and anaerobic conditions.

Consequently, this Royal Decree stipulates that wet wipe waste, regardless of whether it contains plastic or not, must be disposed of as residual waste fraction and emphasises that it must not be flushed down the toilet. Wet wipes that comply with the requirements of the UNE 149002:2022 standard are exempt from this restriction, as, as mentioned, they may be disposed of in this way. However, in accordance with the precautionary and preventive principles, it is recommended that these types of wet wipes should not be flushed down the



toilet, in order to minimise their impact on the sewerage infrastructure and the environment.

As far as balloons are concerned, their environmental impact is considerable. Their regular use in outdoor activities increases the risk of intentional release. This practice poses an environmental problem, aggravated by cultural trends that encourage its use in such contexts. Once released, the balloons frequently end up among marine litter and occupy prominent positions in the rankings of pollution on beaches in the European Union, causing serious damage to marine fauna. They also pose a risk to terrestrial fauna and can cause accidents due to collisions with electricity grids. Also, there are currently no viable design alternatives that significantly reduce their environmental impact.

Consequently, in order to prevent and minimise the aforementioned impacts, this Royal Decree establishes the legal framework for the management of waste from these products, as well as priority measures aimed at preventing the generation of this waste and improving its management, with the purpose of contributing to the transition towards a circular economy and promoting the development of more sustainable options.

With regard to the implementation of the extended producer responsibility scheme, and in accordance with the provisions of Article 60 of Law 7/2022 of 8 April 2022, producers of wet wipes and producers of balloons shall be obliged to bear, at a minimum, the costs of cleaning up litter generated by such products, including cleaning within sanitation and wastewater treatment infrastructure, as well as the subsequent transport and treatment thereof in accordance with the terms set out in Article 19; the costs of data and information collection, whether from regular collections or one-off operations due to sporadic dumping or littering, and the costs of awareness-raising measures. In this sense, Article 13(1)(f) of this Royal Decree establishes the obligation to cover the costs arising from the carrying out of economic analyses or audits. The latter obligation derives from Article 37(1)(g) of Law 7/2022 of 8 April 2022.

The costs incurred for litter clean-up shall be limited to activities regularly performed by or on behalf of the public authorities. The calculation methodology shall be developed in such a way as to ensure that the costs of cleaning up litter can be determined proportionately, in accordance with Annex IV.

The financial contribution paid by the producer shall not exceed the costs necessary to ensure that the provision of waste management services is cost-effective, and shall be determined in a transparent manner by the parties concerned; this shall be set out in the relevant agreements entered into with the public authorities. To minimise administrative costs, the financial contributions towards the costs of cleaning up litter may be determined by establishing



appropriate fixed multiannual amounts, which shall be set out in the corresponding agreements concluded with the public authorities.

In collective extended producer responsibility schemes, the financial contribution must be adjusted according to each category of wet wipes and each category of balloons, thereby ensuring that the contribution is tailored to the specific characteristics of each product. This modulation is a bonus granted by the collective scheme to the producer, when the product meets the efficiency criteria. Modulation levels shall be sufficiently high to provide an incentive and have a significant effect on the eco-design decisions of producers.

IV.

This Royal Decree consists of an explanatory part, preceded by its title, and an operative part. The explanatory part is divided into five sections. The operative part consists of twenty-six articles grouped into a preliminary title and four numbered titles, followed by three additional provisions, two transitional provisions, three final provisions and six annexes.

The preliminary title contains the general provisions and includes the subject matter, scope, definitions, planning instruments and economic instruments that may be applied by the competent authorities.

As regards definitions, these are set out in Article 2. First, the Commission Guidelines on single-use plastic products under Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 and Law 7/2022 of 8 April 2022 apply, including the definitions of 'natural polymers', 'non-chemically modified substance' or 'placing on the market'. Secondly, new concepts necessary for the implementation of extended producer responsibility are set out, such as the definitions of 'wet wipe', 'wet wipe made from synthetic polymers', 'wet wipe made from chemically modified natural polymers', 'wet wipe made from chemically unmodified natural polymers', 'mixed wet wipes', 'balloon' and that of 'producer of the product', which involves adapting the definition set out in Law 7/2022 of 8 April to the specific characteristics of these products.

Title I is entitled 'Prevention and Management of Waste from Wet Wipes and Balloons' and is divided into two chapters. Chapter I regulates the prevention of this waste, in application of the waste hierarchy principle contained in Article 8 of Law 7/2022 of 8 April, as the most appropriate way to improve the efficiency of the use of resources and reduce the environmental impact.

Finally, the requirement for the marking of wet wipes containing plastic in accordance with Commission Implementing Regulation (EU) 2020/2151 of 17 December 2020 is incorporated and, on a voluntary basis, the marking of wet wipes without plastic that do not comply with UNE 149002:2022 is



recommended to encourage proper disposal and appropriate management of the resulting waste.

Chapter II develops the management of this waste, establishing obligations for the initial producer of the waste or other waste holder. In order to ensure the proper management of waste for the protection of human health and the environment, in accordance with the principles set out in Article 7 of Law 7/2022 of 8 April 2022, the initial waste producer of wet wipes and/or balloons, or any other waste holder, is obliged to place waste derived from these types of products in the residual waste fraction bin, together with the other household waste collected in that bin. It is specified that under no circumstances may the initial waste producer abandon this waste in a manner that could generate litter. Furthermore, in the case of wet wipes, they should not be flushed down the toilet due to the environmental problems that this practice can cause, as mentioned above.

In implementation of Article 60 of Law 7/2022 of 8 April 2022, Title II of the Royal Decree develops the extended producer responsibility scheme in accordance with the provisions of Title IV of the Law. It is divided into two chapters; the first sets out the 'Obligations regarding information on placing products on the market', creating a specific section for each type of product in the Register of Product Producers, and requiring all producers to register and to submit annual information on the placing on the market of single-use wet wipes and balloons.

Chapter II is devoted to the 'Extended Producer Responsibility Scheme' and contains eight articles setting out the general obligations of producers, which must be fulfilled either individually or through the establishment of the relevant collective extended producer responsibility schemes. The following articles set out the provisions relating to the establishment and operation of extended producer responsibility schemes – both individual and collective – as well as the provisions governing the organisation and management of these schemes, specifying certain additional provisions for collective schemes and the agreements and arrangements that may be entered into. This chapter also contains provisions on the extent of producers' financial contributions to extended producer responsibility schemes, as well as the financial guarantee that these schemes must subscribe to in order to ensure the financing of waste management.

Title III sets out the obligations regarding information and awareness-raising, specifying, first of all, the information that extended producer responsibility schemes must provide annually to the autonomous communities and the Waste Coordination Commission. Transparency obligations are an essential part of the information that these schemes must provide to the public; the Royal Decree sets out the minimum requirements that must be met. Secondly, it sets out the



awareness-raising and education measures that public authorities, within their respective areas of competence, must adopt to inform consumers and encourage responsible behaviour, particularly amongst young people, with a view to reducing the littering of products covered by this Royal Decree. These awareness-raising measures will be financed by the extended producer responsibility schemes.

Finally, Title IV regulates inspection and control, and the applicable sanctioning regime, including actions to control and inspect the correct application of this Royal Decree by the competent authorities. It is envisaged that the monitoring of compliance with extended producer responsibility obligations will be carried out by the Waste Coordination Commission, which will be supported by a working group specialising in this area.

The provisions are supplemented by three additional provisions relating to the classification of this waste, which is to be carried out in accordance with the European Waste List (EWL), which has been developed using two general codes and one specific sub-code that will enable more effective management of this waste, another relating to the application of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations, and one concerning the application of data protection legislation, with two transitional provisions relating to the application of the financial contribution from the date of entry into force and to the reporting obligations for the year 2025; and finally, it includes three final provisions concerning the authorisation for regulatory development, the applicable legal bases and its entry into force, respectively. Finally, this Royal Decree is supplemented by six annexes which set out specific aspects of the provisions.

V

This rule is in line with the principles of good regulation of Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure for Public Administrations, and in particular those of necessity, effectiveness, proportionality, legal certainty, transparency and efficiency.

In this regard, and in accordance with the principles of necessity and effectiveness, this Royal Decree lays down the basic conditions required to protect human health and the environment by reducing waste generation from all single-use wet wipes and from single-use balloons containing plastic and, in particular, by minimising the litter generated by these products. It therefore promotes the prevention of this type of waste and improvements in its management, thereby ensuring a common basic framework throughout Spain.



In accordance with the principle of proportionality, this Royal Decree regulates only those aspects that are essential to achieving its objectives, setting out only those obligations on producers of wet wipes and balloons that are necessary to ensure the prevention and proper management of waste from these products. It also sets out the essential obligations of holders of this type of waste, which ensure compliance with the objectives of this Royal Decree.

In accordance with the principle of legal certainty, this Royal Decree brings Spanish legislation into line with European Union regulations on the reduction of certain plastic products in the environment, which focus, amongst other issues, on combating litter, particularly in the marine environment, where wet wipes and balloons are among the main threats. It also implements Law 7/2022 of 8 April 2022 on extended producer responsibility, is consistent with that law, and sets out specific details such as producers' financial contributions.

In accordance with the principle of transparency, all necessary steps have been taken to ensure the public participation of citizens and those affected by the regulation. Thus, prior to the drafting of the text of this Royal Decree, the prior public consultation, provided for in Article 133 of Law 39/2015 of 1 October 2015, in conjunction with Article 26(2) of Law 50/1997 of 27 November 1997, of the Government, has been carried out through the website of the Ministry for the Ecological Transition and the Demographic Challenge.

In drawing up this Royal Decree, the autonomous communities, the cities of Ceuta and Melilla, and the Spanish Federation of Municipalities and Provinces were consulted through the Waste Coordination Commission. Furthermore, the procedures relating to public consultation and public information have been completed. To this end, economic and social stakeholders and the most representative sectors potentially affected have been consulted. In addition, the draft was submitted to the Environmental Advisory Council and was also subject to a public consultation process, in accordance with the provisions of Law 27/2006 of 18 July 2006 regulating the rights of access to information, public participation and access to justice in environmental matters and with Law 50/1997 of 27 November.

This Royal Decree has undergone the procedure for the provision of information on technical standards specified in Royal Decree 1337/1999 of 31 July 1999, governing the provision of information in the field of technical regulations and standards and of rules on Information Society Services, to meet the provisions 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.



With regard to the principle of efficiency, this regulation aims to streamline the management of public resources, without imposing unnecessary or incidental administrative burdens on citizens and businesses.

Specifically, in accordance with the eighth additional provision of Law 7/2022 of 8 April 2022, all administrative procedures relating to this waste must be carried out electronically. The same applies to the reporting obligations set out in this Royal Decree, which must be fulfilled via the websites of the collective extended producer responsibility schemes.

Finally, this Royal Decree, in accordance with Article 25 of Law 50/1997 of 27 November 1997, is included in the 2026 Annual Regulatory Plan.

This Royal Decree is issued pursuant to Article 149(1)(13) and (23) of the Spanish Constitution, which confers exclusive competence on the State in respect of the basic rules and coordination of general economic planning and basic legislation on environmental protection, respectively, without prejudice to the powers of the autonomous communities to establish additional protective measures.

The power to adopt these implementing provisions is established in paragraph 1(b), (c) and (d) of the fourth final provision of Law 7/2022 of 8 April 2022, which empowers the Government, within the scope of its powers, to adopt the regulatory provisions necessary for the implementation and application of that Law and, in particular, to lay down rules for different categories of products in relation to the waste they generate, to lay down detailed rules governing extended producer responsibility, and to regulate waste by establishing specific provisions concerning its generation and management.

By virtue thereof, at the proposal of the Minister for the Ecological Transition and the Demographic Challenge, with the prior approval of the Minister for Digital Transformation and the Civil Service, in agreement with the Council of State and after deliberation by the Council of Ministers at its meeting on XXX.

THE FOLLOWING IS DECREED:

PRELIMINARY TITLE

General provisions

Article 1. Purpose

The purpose of this Royal Decree is to establish the legal regime applicable to waste generated by single-use wet wipes and balloons containing plastic that are single-use, with the aim of preventing and reducing their impact



on the environment and human health caused by their loss, abandonment or incorrect disposal.

To this end, measures are being introduced which are aimed, as a matter of priority, at preventing the generation of this waste and, subsequently, at improving its management, with a view to contributing to the transition towards a circular economy.

Article 2. Definitions

In addition to the definitions set out in Law 7/2022 of 8 April 2022 on waste and contaminated land for a circular economy, for the purposes of this Royal Decree, the following terms shall have the meanings set out below:

a) 'Wet wipe' means a small piece of pre-moistened or previously wetted material intended for personal hygiene and for domestic use. It is designed for single use.

Depending on the type of material of which they are composed, a distinction is made between:

1. 'Wet wipe made from synthetic polymers': a wet wipe containing fibres, either wholly or partly, obtained through industrial processes from synthetic polymers, such as polyester or polypropylene. These wipes belong to the category of wipes with plastic.

2. 'Wet wipe manufactured from chemically modified natural polymers' means a wipe containing fibres derived from polymers of natural origin that have undergone chemical processes that alter their molecular structure, such as polyhydroxyalkanoates (PHAs). These wipes belong to the category of wipes with plastic.

3. 'Wet wipe manufactured from chemically unmodified natural polymers' means a wipe containing exclusively fibres of natural origin that have not undergone chemical modification, such as viscose and 'lyocell' and which do not meet the requirements of standard UNE 149002:2022. These wipes belong to the category of plastic-free wipes.

4. 'Mixed wet wipe' means a wipe manufactured wholly or partly from synthetic polymers and/or chemically modified natural polymers, as well as those manufactured in part from chemically unmodified natural polymers. These wipes fall within the category of products containing plastic.



- b) 'Balloon' means a bag made from a lightweight, non-porous material that is inflated with air or gas and contains non-natural polymers, including, but not limited to, Mylar or aluminium-coated nylon film, and/or chemically modified natural polymers, such as latex. Only single-use balloons are included.
- c) 'Intentional release of balloons' means the deliberate act of releasing balloons into the air, generally in the context of events or celebrations, with potentially serious consequences, particularly marine, terrestrial and soil pollution.
- d) 'Places where litter typically accumulates': those areas within natural or urban environments where there is a significantly higher concentration of litter than in the immediate surroundings, as a result of habits or behaviour leading to the repeated dumping of litter in the same place.
- e) 'Producer of the product' means any natural or legal person who:
1. is established in Spain and produces and places on the market wet wipes or balloons under its own name or trademark in the Spanish territory; or
 2. is established in Spain and resells, under its own name or trademark, wet wipes or balloons manufactured by third parties. In this context, 'producer' shall mean any natural or legal person who commissions the design or manufacture of wet wipes or balloons bearing their own name or trademark, regardless of whether another trademark appears visibly on the product; or
 3. is established in Spain and is professionally engaged in the placing on the Spanish market of wet wipes or balloons from third countries or another Member State; or
 4. sells wet wipes or balloons via remote communication channels, such as post, the internet, telephone or fax, directly to private households or business customers in Spain, and is established in another Member State or in a third country.

Where wet wipes or balloons originating from outside Spain are placed on the market through e-commerce platforms and the producer has not appointed an authorised representative in accordance with Article 13(3), the platform shall act, on a subsidiary basis, as the producer of the product for the purposes of financial and information obligations and, where applicable, the organisational obligations laid down in this Royal Decree in respect of those products.



Article 3. *Scope of application*

1. This Royal Decree applies to single-use wet wipes and single-use balloons containing plastic that are placed on the market, as well as to the waste generated by the use of these products.

2. However, the following are excluded from this Royal Decree:

a) wet wipes manufactured from chemically unmodified natural polymers that comply with the requirements of the UNE 149002:2022 standard, and their waste,

b) wet wipes for industrial or professional use, including medical or sanitary wipes, and waste thereof;

c) balloons for industrial and/or professional uses and applications that are not distributed to consumers, such as hot air balloons or weather balloons, and their waste.

Article 4. *Planning instruments*

1. The State Waste Prevention Programme and the State Framework Plan for Waste Management, provided for in Articles 14 and 15 of Law 7/2022 of 8 April 2022, may include, within the scope of municipal waste, specific measures relating to wet wipes and/or balloons, as well as the waste they generate. These may include the setting of qualitative and quantitative targets and the necessary measures to achieve them.

2. In line with the instruments referred to above, the waste prevention and management plans and programmes of the autonomous communities and, where applicable, local authorities may also include specific measures concerning these products and the resulting waste.

Article 5. *Economic instruments*

The competent authorities may make use of economic instruments and other measures such as those provided for in Annex V of Law 7/2022 of 8 April 2022, in order to provide incentives for the application of the waste hierarchy and the fulfilment of the objectives set out in this Royal Decree. Specifically, amongst the examples set out in the aforementioned Annex V, those referred to in paragraphs 10, 11, 13, 14 and 15 are particularly relevant.



MINISTRY
FOR THE ECOLOGICAL TRANSITION
AND THE DEMOGRAPHIC CHALLENGE

STATE SECRETARIAT FOR THE
ENVIRONMENT

DIRECTORATE-GENERAL FOR
ENVIRONMENTAL QUALITY AND
ASSESSMENT



TITLE I
Waste prevention and management of wet wipes and balloons

CHAPTER I
Waste prevention of wet wipes and balloons

Article 6. Objectives and preventive measures.

1. In order to curb the generation of litter from wet wipes, producers of these products whose annual market share exceeds 2.5 % of the national total of products placed on the market must draw up and implement business plans for prevention and eco-design, with the aim of reducing the plastic content in such products, where appropriate, improving their biodegradability and reducing the amount of litter they generate. In addition, these plans shall help reduce the littering of wet wipes and promote the proper functioning of sewerage and wastewater treatment infrastructure by reducing the impact of wet wipes on that infrastructure.

Such plans may be drawn up individually by product producers or by collective extended producer responsibility schemes. However, responsibility for their implementation and compliance shall lie with the wet-wipe producers subject to the obligation laid down in the preceding paragraph.

These plans shall run for a period of five years. Within three months of their expiry, the wet-wipe producers concerned or the collective extended producer responsibility schemes shall submit a report evaluating their results to the autonomous community in which their registered office is located. That autonomous community shall forward the report to the other autonomous communities.

Wet-wipe producers or collective extended producer responsibility schemes shall make these reports available to the public via their websites, whilst ensuring, where appropriate, that any confidential information relevant to their activities is protected.

2. No later than five years after the entry into force of this Royal Decree, the Ministry for the Ecological Transition and the Demographic Challenge, through the Directorate-General for Environmental Quality and Assessment, shall evaluate the relevance of establishing prevention objectives in order to make progress in reducing the quantity and impact of waste from wet wipes and/or balloons on the environment.



3. With the same aim of reducing the generation of litter resulting from the use of wet wipes and balloons, and as provided for in Article 37(1)(a) and 37(2) of Law 7/2022 of 8 April 2022, certain criteria or conditions for the design of wet wipes and/or balloons may be laid down by Royal Decree of the Council of Ministers, on the initiative of the Ministry for Ecological Transition and the Demographic Challenge.

Article 7. Marking requirements for wet wipes.

In order to reduce the impact on the environment of waste wet wipes, and in compliance with Article 58 of Law 7/2022 of 8 April 2022, wet wipes containing plastic that are placed on the market shall be marked in compliance with the requirements of Commission Implementing Regulation (EU) 2020/2151 of 17 December 2020.

Wet wipes made from chemically unmodified natural polymers may voluntarily include the marking symbol corresponding to the appropriate waste management options of the product or the means of waste disposal to be avoided for that product, in line with the waste hierarchy, in accordance with Commission Implementing Regulation (EU) 2020/2151 of 17 December 2020.

CHAPTER II

Waste management of wet wipes and balloons

Article 8. Obligations of the original waste producer or other holder relating to the management of waste wet wipes and balloons.

1. In accordance with Article 20 of Law 7/2022 of 8 April 2022, the initial waste producer of waste wet wipes and/or balloons, or any other holder of such waste, is obliged to ensure the proper management of their waste in order to protect human health and the environment, in accordance with the principles set out in Article 7 of the aforementioned law. To this end, the initial waste producer or any other holder of wet wipe and/or balloon waste must place the waste in the residual waste fraction bin, together with the other household waste collected in that bin.

2. Under no circumstances may the initial waste producer or any other waste holder abandon this waste in a manner that could generate litter, particularly in places where such abandonment is common. In this respect:

- a) the deliberate release of balloons into the environment is prohibited.



- b) Wet wipes must not be flushed down the toilet, regardless of whether they contain plastic or not.

3. Likewise, in accordance with Article 20(1) of Law 7/2022 of 8 April 2022 and as provided for in Article 19(2)(b) of this Royal Decree, operators of sewerage and wastewater treatment infrastructure who are holders of waste shall be required to have at their disposal documentation attesting to the appropriate treatment carried out on their waste. This documentation shall include, as a minimum, information relating to the annual figures, expressed in tonnes and on a dry matter basis, for:

- a) the removed wet wipes waste, differentiating between wet wipes containing plastic and wet wipes without plastic.
- b) the discarded balloon waste.

4. The holders of waste referred to in the preceding paragraph shall send the aforementioned documentation annually to the Autonomous Community in whose territory the infrastructure is located. The first reporting year will be 2028, covering data from the previous financial year, and will be regarded as the base year.

5. The autonomous communities, for their part, shall submit annually, in aggregate form, information relating to wet wipe waste and balloon waste – broken down separately in each case – to the Directorate-General for Quality and Environmental Assessment of the Ministry for Ecological Transition and the Demographic Challenge.

The information for wet wipes residues must be submitted separately depending on whether they contain plastic or not.

Article 9. *Evaluation of the measures.*

The autonomous communities, in collaboration with local authorities, shall establish monitoring programmes to evaluate the implementation and degree of effectiveness of the measures provided for in this title and to advance the implementation of new measures. The first performance evaluation should be available by 2030 at the latest.

The autonomous communities shall inform the Ministry for the Ecological Transition and the Demographic Challenge, through the Waste Coordination Commission, of the establishment of such programmes and of the outcome of their evaluation. On the basis of these results, the Waste Coordination



Commission will draw up a summary report, which will be incorporated into the next National Waste Prevention Programme.

TITLE II **Extended Producer Responsibility**

CHAPTER I **Reporting obligations regarding the placing on the market of wet wipes and balloons**

Article 10. Creation of the sections of producers of wet wipes and balloons in the Register of Product Producers.

For the purpose of complying with reporting obligations relating to waste management and, in particular, collecting information on the placing on the market of wet wipes and balloons, a wet-wipes section (hereinafter the 'STH producer section') and a balloons section (hereinafter the 'SG producer section') are hereby established within the Register of Product Producers, in accordance with Article 7(2) of Royal Decree 293/2018 of 18 May 2018 on reducing the consumption of plastic bags and establishing the Register of Producers.

Article 11. Inscription in the Register of Product Producers.

1. Producers of products or, where appropriate, authorised representatives, shall be registered in the sections of STH or SG producers, as appropriate, within three months of the date of entry into force of this Royal Decree.
2. Producers of the product shall be required, at the time of registration, to provide the information set out in Annex I.A, which must be updated whenever any changes occur.

Similarly, if a collective scheme is chosen, proof of membership of the relevant extended producer responsibility scheme must be provided within one month of such schemes being established.

3. The information provided will be made public. The personal data will be protected by the current state legislation on the protection of personal data.
4. At the time of registration, a registration number will be assigned and must appear on the invoices.
5. In the event of definitive cessation of the activity, the product producer or their authorised representative shall notify the Register of Product



Producers within one month of the cessation of the activity and certify it, forwarding the corresponding document of cessation of activity of the undertaking.

Article 12. Annual reporting requirements regarding the placing on the market

1. Producers of prod registered in the STH and SG Producer Sections shall collect the information contained in Annex I.B, corresponding to the wet wipes or balloons they have placed on the national market in each calendar year.
2. This information shall be submitted to the Ministry for Ecological Transition and the Demographic Challenge by 31 March of the year following that to which it relates, in order to ascertain the quantities of these products placed on the market, to monitor compliance with the obligations laid down in this Royal Decree, and to assess the functioning of extended producer responsibility.
3. The information provided will not be made public and will only be accessible to the competent authorities for the purposes of inspection and monitoring, as well as for assessing and setting the prevention targets referred to in Article 6(2).

CHAPTER II
Extended producer responsibility scheme

Article 13. Producer obligations.

1. In accordance with the provisions of Article 60 of Law 7/2022 of 8 April , and pursuant to Article 37 thereof, in addition to any obligations set out in the preceding articles of this Royal Decree that may apply to them, producers of wet wipes or balloons shall be required to comply with the following obligations:

a) To place wet wipes and/or balloons on the market that comply with any ecodesign requirements that may be laid down by the Ministry for Ecological Transition and the Demographic Challenge, in accordance with the provisions of Article 6(3).

b) To achieve the prevention and management objectives that may be established in application of the provisions of this Royal Decree.



c) Financing the collection and treatment of waste wet wipes or balloons in accordance with Article 19.

d) Where that option is chosen, provide collective extended producer responsibility schemes with the information necessary to enable them to fulfil the information obligations laid down in this Royal Decree. In any case, collective schemes must safeguard the information they receive, in accordance with Article 48(2) of Law 7/2022 of 8 April 2022.

e) Ensure that the extended producer responsibility schemes in which they participate comply with the requirements laid down in this Royal Decree and that they have sufficient financial means to fulfil their obligations for the financing, collection and treatment of waste generated by their products within the territorial scope of the scheme.

f) Where the extended producer responsibility scheme deems it appropriate, carry out economic analyses or audits. These studies, both at the planning stage and once completed, must be submitted to the working group of the Waste Coordination Commission.

g) Respect the principles of the protection of human health, consumers and the environment, applying the waste hierarchy and safeguarding competition in relation to the placing on the market of these products and the management of the resulting waste.

2. In the specific case of wet wipes, and without prejudice to the obligations set out in the previous paragraph, producers of these products shall be subject to the following additional obligations:

- a) Develop and implement prevention and eco-design business plans in accordance with Article 6(1), with the aim of reducing the use of non-renewable resources and contributing to the fulfilment of the objectives of this Royal Decree.
- b) Label the product in accordance with Article 7.

3. Producers established in another Member State or in third countries and which place products on the market in Spain within the meaning of Article 2(e). 4. they must appoint a natural or legal person in Spanish territory as an authorised representative for the purpose of fulfilling the obligations of the producer of the product.

For the purposes of monitoring and verifying compliance with the obligations of the product producer in relation to extended producer responsibility, natural or legal persons designated as authorised representatives shall have the documentation attesting to the representation.



In the event that the producers of the product have not appointed an authorised representative in Spain, the first distributor or trader of the product based in Spain shall, in the alternative, be responsible for the obligations laid down for the producers of the product.

4. Producers shall comply with the obligations set out in points (b), (c) and (f) of paragraph 1 by establishing the relevant individual or collective extended producer responsibility schemes, ensuring that producers of wet wipes set up their own extended producer responsibility schemes independently and separately from the schemes which, in turn, must be established by producers of balloons.

The remaining obligations of producers of the product shall be fulfilled on an individual basis.

Producers of products shall submit the prior notification or application for authorisation, as provided for in Articles 14 and 15, within six months of the entry into force of this Royal Decree.

5. In accordance with the provisions of Article 54 of Law 7/2022 of 8 April 2022, the customs authorities and the competent environmental authorities may verify compliance with the obligations of producers of wet wipes and/or balloons, in particular, their registration in the relevant sections of the Register of Product Producers, whether they have provided the annual information to this Register as set out in Annex I to this Royal Decree, and their membership of an extended producer responsibility scheme, for the purposes of combating fraud involving wet wipes and/or balloons imported or resulting from an intra-Community acquisition subject to extended producer responsibility

Article 14. Constitution and operation of individual extended producer responsibility schemes.

1. In accordance with the provisions of Article 49(1) of Law 7/2022 of 8 April 2022, producers who opt for an individual scheme shall submit to the competent authority of the autonomous community in which their registered office is located a prior notification containing the information set out in Annex II.A, accompanied by the financial guarantee provided in accordance with Article 20. This communication shall be registered ex officio by the competent authority of the autonomous community in the



Waste Production and Management Register, taking into account the provisions of Article 49(2) of Law 7/2022 of 8 April 2022.

2.-Individual schemes shall submit each year to the Waste Coordination Commission their annual account, which shall reflect the financial resources allocated to fulfil the obligations of extended producer responsibility, without prejudice to the reporting obligations set out in Article 21.

3. From the moment the scheme is entered in the relevant register, the autonomous communities shall monitor compliance within their respective territories with the provisions set out in the notification.

Failure by individual schemes to comply with extended responsibility obligations may lead to the initiation of the corresponding penalty procedure. The competent authority to initiate the penalty proceedings shall be the Autonomous Community corresponding to the territory where the infringement is committed, which may suspend the activity of the individual scheme in its territory.

Without prejudice to the above, the competent authority may enforce the financial guarantee in whole or in part.

Where the non-compliance occurs in more than one autonomous community, the Waste Coordination Commission shall issue a report prior to assessing the relevance of the total revocation of the authorisation. The decision shall be issued and notified by the competent authority of the autonomous community in which the notification was submitted, which shall remove it from the Waste Production and Management Register. In all cases, revocation shall be subject to the interested party being given a prior opportunity to be heard.

Article 15. Constitution, authorisation and operation of collective extended producer responsibility schemes.

1. Producers that opt to fulfil the extended producer responsibility obligations laid down in this Royal Decree through a collective scheme shall act in accordance with Article 50 of Law 7/2022 of 8 April 2022. The collective scheme shall have as its sole purpose compliance with the extended producer responsibility obligations established in this Royal Decree.



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2. The application for authorisation prior to the start of its activity submitted by the collective scheme referred to in Article 50(2) of Law 7/2022 of 8 April 2022 shall be accompanied by the documentation relating to the financial guarantee that the collective scheme will subscribe in accordance with Article 20 of this Royal Decree. The application and the authorisation granted shall incorporate the information set out in Annex II.B.

3. The Waste Coordination Commission shall assess the content of the application in relation to the fulfilment of the obligations of extended responsibility. The following aspects will be analysed, inter alia:

a) Transparency and objectivity in the forms of incorporation of producers into the collective scheme, establishing agile and simple schemes, and without discrimination of any kind against producers of products.

b) The annual possibility for producers to change the manner in which their extended responsibility is fulfilled, either through another collective scheme or through the establishment of an individual scheme.

c) The internal decision-making process, to be carried out exclusively by the producers incorporated into the scheme, on the basis of objective criteria, without prejudice to the existence of executive bodies that must be chosen by all the members of the scheme or their representatives, and which will in any case follow the decisions taken by the producers that make up the scheme.

d) The rights to information of producers who are part of the scheme, to the formulation of claims and to their assessment.

e) The mechanisms for exchanging information among the members of the collective scheme and between the scheme and the other waste-management operators.

f) The application of objective, transparent and non-discriminatory conditions in relations between the schemes and other waste operators, as well as in agreements between collective schemes. Decision-making and the provision of information must not increase the risk of collusion among the producers participating in the scheme or between the scheme and other waste-management operators.

g) The absence of conflicts of interest between the members of the scheme, or those serving on its executive bodies, and other operators, particularly any waste-management operators with which the scheme contracts.

h) Compliance with the extended producer responsibility obligations laid down in this Royal Decree throughout the period of validity of the authorisation and during the procedure for its renewal.

4. Following a report from the Waste Coordination Commission on the application, the Autonomous Community shall, where appropriate, grant an authorisation setting out the technical, organisational, economic,



logistical and operational requirements and guarantees necessary for compliance with this Royal Decree throughout the territory of the State, in accordance with the content of Annex II.B.

In addition, the authorisation shall incorporate the points arising from the report of the Waste Coordination Commission and from compliance with the extended producer responsibility obligations, including, where appropriate, specifications for the performance of the collective scheme in the autonomous regions.

5. The maximum period for issuing and notifying the decision shall be six months from the date on which the application was entered in the electronic register of the competent authority of the autonomous community. This time limit may be extended for a further six months, subject to justification, on grounds relating to the complexity of the case; such an extension must be granted before the original time limit expires, in accordance with the provisions of Article 50.2 of Law 7/2022 of 8 April 2022.

If that period expires without an express decision having been notified, the application shall be deemed to have been rejected.

6. Once the documentation proving the validity of the corresponding financial guarantee has been submitted, the autonomous community will proceed to register the authorisation in the Register of Waste Production and Management, and the collective scheme may begin with its activity from this moment on. Once one month has elapsed following notification of the decision granting authorisation to the collective scheme, without the validity of the financial guarantee having been demonstrated, the authorisation shall cease to have effect.

7. The authorisation shall be valid for eight years, after which it shall be subject to renewal through a new procedure conducted in accordance with this Article. The existing authorisation shall remain valid until an express decision granting or refusing the renewal application has been notified. In each year during the validity of the authorisations, the autonomous communities shall monitor compliance with the conditions of the authorisation within their respective territories.

8. Failure to comply with the conditions of the authorisation may lead to the initiation of the corresponding penalty proceedings. The competent



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authority for initiating penalty proceedings shall be that of the autonomous community within whose territory the infringement was committed; that authority may order the suspension of the scheme's operations within that territorial area.

Without prejudice to the above, the competent authority may enforce the financial guarantee in whole or in part.

Where the non-compliance occurs in more than one autonomous community, the Waste Coordination Commission shall first issue a report assessing whether the authorisation should be revoked in full. The decision shall be issued and served by the competent authority of the autonomous community where the authorisation was granted within a maximum period of one year from the date of the decision to initiate proceedings, as provided for in Article 112(1) of Law 7/2022 of 8 April 2022. The competent authority of the autonomous community will then proceed to deregister the authorisation from the Waste Production and Management Register. In all cases, revocation shall be subject to the interested party being given a prior opportunity to be heard.

9. Any producer wishing to leave an extended producer responsibility scheme must notify the scheme they are leaving and the new scheme being established or which they are joining before the final quarter of the calendar year, and must notify the Waste Production and Management Register within the last three months of the year. In any event, the change from one responsibility scheme to another shall be conditional on the producer demonstrating that it is up to date with the financial obligations assumed towards the original extended producer responsibility scheme.

A change from one collective extended producer responsibility scheme to another shall entail the new scheme assuming in full the producer's obligations arising from its market share in the following year.

Article 16. General obligations of individual and collective extended producer responsibility schemes.

1. Individual and collective schemes shall be obliged to comply with the obligations conferred on them by producers in accordance with the provisions of Article 13(1). They shall also comply with the provisions included in the prior notification and authorisation of the extended producer responsibility schemes, as provided for in this Royal Decree.

2. In all cases, these schemes:



a) shall have the financial resources necessary to fulfil their extended producer responsibility obligations, which shall be exclusively intended for the fulfilment of those obligations.

b) shall conclude agreements with public administrations involved in the organisation of the management of wet wipes or balloon waste, to finance the management costs stipulated in Article 19.

c) shall draw up and send to all the autonomous communities in which they operate and to the Waste Coordination Commission the annual report provided for in Article 21(1).

d) shall provide, by 31 March each year, each local authority with which they have entered into an agreement with the data for the calendar year relating to the management of waste from wet wipes or balloons, as well as any other information agreed in the agreement, in accordance with the provisions of Article 18.

e) shall put in place an appropriate self-monitoring mechanism to assess:

1. Its financial management, including compliance with the requirements set out in Article 19, supported by regular independent audits, including studies of costs and economic and performance indicators of the scheme, both at State level, and disaggregated by each autonomous community.

2. The quality of the data collected and reported in accordance with paragraph (d), supported by independent audits.

f) They shall make available to the public the information provided for in Article 22(1), as well as the audits provided for in subparagraph (e) in relation to financial management and data quality.

Article 17. Additional provisions concerning the organisation and management of collective extended producer responsibility schemes.

1. Without prejudice to the provisions of the preceding Article, collective schemes shall:

a) Ensure equal treatment of producers of products irrespective of their origin or size.

b) Establish its internal operating rules by ensuring the participation of producers in decision-making, in accordance with Article 15. All members of the collective scheme shall have the right to receive information arising from compliance with the provisions of this Royal Decree, to submit comments and representations and to have them assessed and taken into account in the operation of the scheme.

c) Safeguard the confidentiality of the information provided by the members of the collective scheme for its operation, in particular information that may be



relevant to the economic activities of members of the scheme. Furthermore, where applicable, they shall ensure the confidentiality of the information provided by waste operators with whom they have concluded agreements.

d) Notify producers of the initiation of penalty proceedings for failure to comply with their obligations under the Royal Decree on extended producer responsibility.

e) Prepare and submit to all the autonomous communities in which they operate and to the Waste Coordination Commission the report provided for in Article 21(1).

f) Where a collective scheme ceases its activities, it shall notify all participating producers at least three months in advance, in order to ensure that they continue to fulfil their obligations. It shall also notify the administrative authority that granted its authorisation so that the authorisation may be revoked. Producers may form or be integrated into another extended responsibility scheme as provided for in this Royal Decree. The financial guarantees deposited shall be returned to the producers.

g) They shall make the updated information referred to in Article 22(2) available to the public.

2. Collective extended producer responsibility schemes may fulfil their obligations by themselves or may set up or contract an administering entity which shall have legal personality distinct from that of the collective scheme and which shall act under the direction of the collective scheme.

3. Collective extended producer responsibility schemes shall give all members of the scheme and the autonomous community that granted the authorisation three months' prior notice of any proposed change to the financial contributions associated with financing the obligations assumed by the collective scheme. The autonomous community shall forward that information to the relevant working group of the Waste Coordination Commission.

4. Without prejudice to paragraph 1(a), collective schemes may, on a voluntary basis and with the express consent of the producers who pay for it, allocate financial resources to carry out activities that complement the object of the collective scheme. The financing of these voluntary actions shall not come into conflict with the activities of waste operators, and competition rules shall apply to them.

Consent shall never appear as a mandatory clause in the contract for the incorporation of producers into the collective scheme, nor shall it be required for them to remain in the collective scheme.



Article 18. Agreements of the public administrations with the extended producer responsibility schemes.

1. Extended producer responsibility schemes must enter into agreements with public authorities to determine the financing of the costs of managing waste arising from their products, in accordance with the minimum requirements set out in Annex III.

The agreements shall provide for financing by the extended producer responsibility schemes of the public authorities involved in waste management, in accordance with Article 19. These contributions shall be treated as public-law revenues; therefore, in the event of non-payment, and without prejudice to any financial guarantees in place, the tax authorities of the public administrations that are parties to the agreements shall have the prerogatives established by law on the State Treasury, and shall act, where appropriate, in accordance with the relevant administrative procedures for the recovery of the amounts payable to the aforementioned schemes.

These agreements may take into account the measures resulting from the studies referred to in Article 13(1)(f) with the aim of reducing waste generation and promoting material recovery.

2. The agreements mentioned in the previous section will be signed with the corresponding autonomous community. However, the autonomous community shall ensure that the local authorities responsible for waste management and sanitation and wastewater treatment infrastructure are involved in the negotiation and monitoring of the agreement.
3. The agreements governed by this Article shall be concluded within a maximum period of twelve months from the authorisation or prior notification of the extended producer responsibility scheme.

In the event of disagreements between local authorities or autonomous communities and the extended producer responsibility schemes over the contents of the agreement, in particular those of an economic nature, that prevent the agreement from being concluded shall be resolved through the arbitration mechanism described in the following paragraph.

If there are indications of a possible practice contrary to Law 15/2007 of 3 July 2007 on the protection of competition, the competent authority shall transfer them to the National Commission for Markets and Competition.



4. The points at issue or disagreements that have occurred during the negotiation process of these agreements shall be settled by an arbitral award adopted in accordance with the proceedings and procedures established in Law 60/2003 of 23 December 2003, on Arbitration and according to the following specific rules:

a) The local entity or autonomous community and the extended producer responsibility scheme shall sign the corresponding arbitration agreement identifying the points at issue.

b) The arbitral award shall determine the financial terms under which the local authority or autonomous community, as the case may be, is to provide the services.

The arbitral award shall determine the corresponding financial compensation payable by the scheme as a fixed amount covering all the matters referred to in Article 19. That amount shall be calculated in accordance with the criteria and parameters set out in Annex IV and shall apply for the duration of the agreement or, failing that, for a maximum period of four years, although it shall be reviewed annually in accordance with the criteria that must be laid down in the arbitral award.

5. In the case referred to in paragraph 2(a), where it is established that the autonomous communities are to receive from the extended producer responsibility schemes the amounts provided for in Article 19, the autonomous communities shall transfer to the local authorities the amount of the costs actually incurred. This transfer shall be made within the time limit laid down in the agreement, which in no case shall be more than one month from the date of receipt of the said amounts.

6. The scope of the content of the agreements should make it possible to comply with transparency obligations. The agreements must be published in full, including their technical and economic annexes, in the official gazettes of the autonomous communities or, where appropriate, in the corresponding municipal official gazette. The publication of these agreements shall take place within one month from the day following that of their signature.

Article 19. Scope of the producers' financial contribution to extended producer responsibility schemes.

1. In accordance with the 'polluter pays' principle, the costs relating to the financing of waste management shall be borne by the producers,



2. In accordance with Articles 43 and 60(3) of Law 7/2022 of 8 April 2022, the financial contribution paid by the producer of the product in order to fulfil its extended producer responsibility obligations shall cover the following costs:

a) the clean-up of litter caused by wet wipes or balloons, including clean-up within sanitation and wastewater treatment infrastructure, and the subsequent transport and treatment of such waste.

In the case of the clean-up of litter scattered across sewerage and wastewater treatment infrastructure, and its subsequent transport and treatment, the costs shall be borne as follows:

1. Balloon producers will cover 100 % of the costs.
2. Producers of wet wipes made from synthetic polymers, wet wipes made from chemically modified natural polymers, and mixed wet wipes will cover 20 % of the costs upon the entry into force of this Royal Decree, with funding increasing to 40 % in 2029, 60 % in 2030, 80 % in 2031 and 100 % in 2032.
3. Producers of wet wipes made from chemically unmodified natural polymers will cover 10 % of the costs upon the entry into force of this Royal Decree, with this funding increasing to 20 % in 2029, 30 % in 2030, 40 % in 2031 and 50 % in 2032.

In the case of the clean-up of litter caused by wet wipes or balloons – as distinct from clean-up operations within sanitation and wastewater treatment infrastructure, and the subsequent transport and treatment of such waste – the producers of wet wipes and balloons shall fund 100 % of the costs.

b) the costs of data and information collection, whether for regular collection or ad-hoc collection for infrequent discharges or litter in the environment.

c) the costs of the awareness-raising measures referred to in Article 23 with regard to these products;

d) the costs associated with the provision of the financial guarantees provided for in Article 20.

e) those linked to the performance of the studies referred to in Article 13(1)
(f), in respect of the products that the producer places on the market.

4. The costs to be covered shall not exceed the costs necessary for the provision of such services in an economically efficient manner and shall be determined in a transparent manner between the actors involved in the agreements to be concluded.



Annex IV specifies the parameters and calculation operation that make it possible to identify the costs to be compensated to public administrations when they are involved in the organisation of waste management.

5. The costs arising from cleaning up litter, including cleaning within sewerage and wastewater treatment infrastructure, shall be limited to activities regularly undertaken by or on behalf of public authorities. The calculation methodology will be developed in such a way that these costs can be determined on a proportionate basis, as set out in Annex IV.

6. In order to minimise administrative costs, financial contributions towards the costs of clearing litter, including clean-up operations at sanitation and wastewater treatment facilities, may be determined by setting appropriate multi-annual fixed amounts, which shall be set out in the relevant agreements entered into in accordance with Article 18.

7. In extended producer responsibility schemes, the contribution must be tailored to each product category, taking into account, amongst other things, the nature and quantity of plastic used in its manufacture, the quantity of recycled plastic it contains, the presence of hazardous substances, or other factors affecting the ease with which the waste can be recycled.

Modulation is formed as a bonus granted by the collective scheme to the producer when the product meets the efficiency criteria. Bonuses should be established by collective schemes in a transparent and non-discriminatory manner, ensuring the participation of all stakeholders. Modulation may take into account the criteria set out in Annex V or similar criteria which apply to products belonging to those collective schemes and which achieve similar results.

Modulation levels shall be sufficiently high to provide an incentive and have a significant effect on the eco-design decisions of producers.

Within five years of the entry into force of this Royal Decree, the Ministry for the Ecological Transition and the Demographic Challenge, acting on a proposal from the Directorate-General for Quality and Environmental Assessment, shall analyse the effects of the modulation adopted by the collective schemes and shall review, where appropriate, Annex V. This review shall be carried out, where appropriate, by order of the holder of the Ministry for the Ecological Transition and the Demographic Challenge.

8. For the purposes of facilitating the monitoring and supervision of the financing obligations laid down in this Royal Decree, invoices issued by



producers for commercial transactions involving wet wipes and/or balloons placed on the market through collective extended producer responsibility schemes shall identify the contribution paid to those schemes clearly and separately from the other items included in the invoice. Producers may give product information to product at the request of customers.

In any event, where the amount of the contribution to the collective schemes is not shown on the invoice, it shall be presumed, unless proof to the contrary, that the contribution due for the products covered by it has not been paid.

Producers shall facilitate any checks and verification activities carried out by the entities managing collective extended producer responsibility schemes and by the competent authorities to verify the quantity and categories of wet wipes and/or balloons placed on the market by those producers through the schemes.

The entities managing collective schemes shall respect the confidentiality of commercial and industrial data in relation to any information obtained as a result of managing the waste of the undertakings participating in those schemes.

With respect to wet wipes or balloons placed on the market through collective extended producer responsibility schemes, producers shall retain, for a period of five years, information on the annual contribution paid to the scheme for each category of product placed on the market.

Article 20. *Financial guarantees*

1. In accordance with Article 51 of Law 7/2022 of 8 April 2022, extended producer responsibility schemes shall provide a financial guarantee and submit evidence of that guarantee to the competent authority of the autonomous community in which the prior notification is to be submitted or the application for authorisation of these schemes is to be made. This financial guarantee shall be in force throughout the period of operation of the extended producer responsibility scheme.
2. The term of the financial guarantee is annual, after this period shall be reviewed and a new one may be set up to bring its scope and amount into line with the provisions of the previous paragraph, or, where appropriate, be replenished during its period of activity.



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3. In all matters not specifically provided for in this Royal Decree, the financial guarantee shall be governed by the provisions of Royal Decree 208/2022 of 22 March 2022 on financial guarantees in the field of waste. In particular, the partial or total execution of the financial guarantee, as well as its replenishment, must be carried out in accordance with the aforementioned Royal Decree.

4. The producer who opts for an individual extended producer responsibility scheme must submit the accreditation of the subscription of the financial guarantee together with the prior communication, to the competent body of the autonomous community.

The competent body to which the communication was addressed shall supervise the documents submitted and the calculation of the amount of the guarantee in accordance with the provisions of the preceding article.

The guarantee must be valid at the start of the activity of the individual responsibility scheme.

5. Producers that opt for a collective extended producer responsibility scheme shall contribute to the provision of the scheme's financial guarantee in proportion to the wet wipes or balloons they place on the market. The application for authorisation of the collective scheme shall be accompanied by the documentation relating to the financial guarantee that the collective scheme will subscribe to so that it can be assessed by the competent administration.

The amount of the financial guarantee is integrated by the sum of the guarantees of the producers constituting the scheme. In turn, the amount of the financial guarantee for each producer shall be determined on the basis of the annual quantities of wet wipes and/or balloons placed on the market through the scheme and the estimated average costs of financing waste management in each product category in the year of compliance, on the basis of the actual costs incurred (awareness campaigns, data and information collection and average costs of financing waste management), in accordance with the formula set out in Annex VI.

The financial guarantee shall be in force when the collective scheme begins operating. The scheme shall have one month from notification of the decision granting its authorisation to establish the guarantee and submit it to the competent authority.



TITLE III Information and awareness-raising obligations

Article 21. Information to be provided by extended producer responsibility schemes on their management.

1. Individual and collective extended producer responsibility schemes shall submit, by 31 May of the year following the compliance period, to all the autonomous communities in which they operate and to the Waste Coordination Commission, the annual report containing the information set out in points (a) and (b) of Annex II.C. The report to be sent to the Waste Coordination Commission shall include information relating to the regional and national levels. The report to be sent to each autonomous community shall include data on the placing of the products on the market, broken down by territory.
2. In addition, the individual schemes shall include in that report their annual account provided for in paragraph d(1) of Annex II.C.

Similarly, collective extended producer responsibility schemes shall include in their report the information set out in Annex II.C(c) and (d)(2), duly audited and incorporating evidence of its authenticity, covering both the regional and national levels. If the report involves deviations from the forecasts submitted in the previous year by the collective scheme, the justification for this deviation must be provided.

The Waste Coordination Commission may request any additional information it deems necessary.

3. The annual report of the extended producer responsibility schemes provided for in paragraph 1 shall be assessed by each competent autonomous community authority within its territorial scope through the monitoring mechanisms it deems appropriate. In the case of the State-level report, it shall be reviewed by the Working Group of the Waste Coordination Commission referred to in Article 24.

Article 22. Transparency obligations.

1. Individual and collective extended producer responsibility schemes shall make publicly available through their websites, and update annually, information on the achievement of prevention and management targets,



where applicable; information on the occurrence of this waste as litter and on progress made in removing such litter; and the audits provided for in Article 16(2)(e) concerning financial management and data quality, including the amount allocated to financing awareness-raising measures and waste management.

2. Collective extended producer responsibility schemes must make the following information available to the public:

- a) The legal form chosen, indicating its structure and composition, as well as the producers participating in the collective scheme, including their method of participation in the decision-making of the scheme.
- b) The financial contributions paid by producers per tonne of product placed on the market, for each category, together with any other additional contribution to the scheme, indicating its purpose, including any modulation of producers' financial contributions to the scheme.

Without prejudice to these active-publicity obligations, which may be fulfilled through the websites of the collective schemes, end users or consumers of these products shall be entitled to receive a reasoned response, within a maximum of two months, to enquiries concerning how the collective scheme fulfils its extended producer responsibility obligations, including access to information on the amounts allocated to financing waste management.

- c) The agreements signed with local authorities or autonomous communities for waste management.

Article 23. Awareness-raising measures and their financing.

1. In accordance with Article 61 of Law 7/2022 of 8 April 2022, the State, the autonomous communities and local authorities shall, within the scope of their respective powers, adopt measures to inform consumers and to encourage responsible behaviour with a view to reducing the littering of waste from the products regulated by this Royal Decree.

2. The Minister for Ecological Transition and the Demographic Challenge, acting on a proposal from the Directorate-General for Environmental Quality and Assessment, may enter into agreements with extended producer responsibility schemes to define such campaigns at national level. Similarly, extended producer responsibility schemes may conclude agreements with the competent authorities of the autonomous



communities to supplement, extend or specify the scope of campaigns at regional level.

These campaigns may be carried out in collaboration with consumer, user and environmental organisations, as well as with any interested civil society organisation.

The campaigns shall promote individual and collective responsibility, emphasising that the improper disposal of these products leads to a significant increase in the maintenance costs of sewerage and wastewater treatment infrastructure, particularly in the case of wet wipes.

3. These awareness-raising measures shall be financed by the extended producer responsibility schemes as set out in Article 19.

The Waste Coordination Commission, through the working group set up for this purpose, shall establish, for guidance purposes, the minimum annual amount that extended producer responsibility schemes must guarantee.

Similarly, this Commission will, where appropriate, propose the allocation of the available budget for the various measures planned amongst the different public authorities, giving priority to national campaigns and those that reach the greatest number of consumers or users.

TITLE IV **Control, inspection and penalties scheme**

Article 24. Collaboration and monitoring of compliance with obligations.

1. The authorities responsible for the matters provided for in this Royal Decree, in particular those responsible for waste management at local, regional and state level, shall cooperate with each other to ensure the correct application of this Royal Decree, to ensure that the economic operators concerned comply with their obligations and to establish an adequate flow of information between public administrations.

This obligation to cooperate may be fulfilled through the Waste Coordination Commission and the specific working group responsible for monitoring the implementation of this Royal Decree.

2. Monitoring of compliance with the obligations under the extended producer responsibility scheme shall be carried out by the competent regional authorities in accordance with the criteria laid down by the Waste



Coordination Commission, on the proposal of the working group referred to in the previous paragraph. Other authorities of the autonomous communities and the General State Administration, which are not part of the Waste Coordination Commission, may cooperate in carrying out this supervisory task, especially when these tasks concern non-environmental matters, without prejudice to the competence of the competent authorities to carry out these tasks.

Article 25. Inspection and control.

1. The competent public administrations, including Law Enforcement Agencies, when, by reason of their duties, are required to carry out control, surveillance and inspection tasks, shall carry out appropriate checks and inspections to verify the correct application of this Royal Decree. Without prejudice to Article 106 of Law 7/2022 of 8 April 2022, these inspections shall include at least:

- a) the registration and information obligations provided for in Articles 11 and 12.
- b) information reported in the context of products placed on the market in the Register of Product Producers provided for in Articles 12 and 21;
- c) The information provided by waste operators and extended producer responsibility schemes in accordance with this Royal Decree, including aspects relating to financing.

2. Compliance with the obligations of the producer of the product may be verified by the customs authorities within the scope of their powers and in coordination with the relevant competent authorities, as provided for in customs legislation, for the purpose of combating fraud involving imported wet wipes or balloons subject to extended producer responsibility.

3. The competent authorities shall be responsible for the supervision and control of the exercise of operators in their territory as laid down in Article 21 of Law 20/2013 of 9 December 2013 on the guarantee of market unity.

4. The powers to inspect and monitor compliance with the obligations set out in Article 7 regarding the labelling, presentation and packaging of wet wipes shall lie with the autonomous communities, without prejudice to the powers vested in other public authorities.



Article 26. *Sanctions regime.*

Failure to comply with the provisions of this Royal Decree shall be penalised in accordance with Chapter II of Title IX of Law 7/2022 of 8 April 2022.

First additional provision. *Classification of waste.*

The classification of waste from wet wipes and balloons, irrespective of the place of accumulation of the dispersed waste that originates them, shall be carried out using the following codes in accordance with the European List of Wastes (LER):

- 19 08 01 Screening waste
- 20 03 01 Mixtures of municipal waste
- 20 03 06-02 Wet wipes residues present in sewer cleaning residues and in sewerage and wastewater treatment infrastructure

Second additional provision. *Application of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations.*

The provisions of this Royal Decree are without prejudice to the provisions contained in Law 39/2015 of 1 October, which shall apply to all procedures not expressly covered by this regulation and, in particular, those relating to registration in the Register of Product Producers, as regulated in Article 11, and the procedures for the imposition of penalties set out in Articles 14 and 15.

Third additional provision. *Application of the regulations on the protection of personal data.*

The activities governed by this Royal Decree shall be carried out in full compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (hereinafter, the 'General Data Protection Regulation'), Organic Law 3/2018 of 5 December 2018 on the Protection of Personal Data and Guarantee of Digital Rights, and all other applicable legislation in this field.

Furthermore, the processing of personal data carried out under this Royal Decree shall comply with the principles relating to processing set out in Article 5 of the General Data Protection Regulation, in particular those of lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, and integrity and confidentiality. Similarly, the data



controller shall implement the appropriate technical and organisational measures set out in Article 32 of the General Data Protection Regulation to ensure a level of security appropriate to the risk, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage.

First transitional provision. *Financial obligations of extended producer responsibility schemes.*

The financial responsibilities of the extended producer responsibility schemes regulated in this Royal Decree shall apply from their entry into force. These contributions shall be provided for retroactively in the agreements referred to in Article 18. For this purpose, the public authorities that conclude those agreements shall have documentation substantiating the costs to be financed.

Second transitional provision. *Start of the period for producers' reporting obligations.*

In relation to the reporting obligations of producers set out in Article 12(2), the first reporting year shall be 2025. Once registered in the STH and SG producer sections in accordance with Article 11, producers shall submit this information within the specified timeframe and with retroactive effect.

First final provision. *Authorisation of regulatory development.*

1. The head of the Ministry for the Ecological Transition and Demographic Challenge is authorised to issue, within the scope of his or her powers, all necessary provisions for the implementation and implementation of this royal decree.
2. The head of the Ministry for the Ecological Transition and the Demographic Challenge is empowered, on the same terms as in the preceding paragraph, to make any technical amendments to the annexes necessary to adapt them to technical developments and, in particular, to European Union legislation.



Second final provision. *Constitutional basis.*

This Royal Decree constitutes basic legislation and is issued in accordance with the provisions of Article 149(1)(13) and (23) of the Spanish Constitution, which confers exclusive competence on the State over the principles and coordination of the general planning of economic activity, and basic environmental protection legislation, without prejudice to the powers of the autonomous communities to lay down additional protection rules.

Third final provision. *Entry into force.*

This Royal Decree shall enter into force on the day after its publication in the 'Official State Gazette'.

However, Article 6(1) shall apply to producers of products whose volume exceeds an annual quota of 2.5 % of the national total of products placed on the market from 1 January 2031, such that the obligation laid down in that Article shall take effect from 1 July of the calendar year following that in which the producers of such products exceeded that annual quota.

ANNEX I

Registration and annual information to be provided to the Register of Product Producers

A. Data to be provided in the registration

- a) Name and address of the producer or its authorised representative, including post code, city, street and number, country, phone number, fax number, email and contact person. In cases of an authorised representative, contact details shall also be provided for the producer represented.
- b) European tax identification number or national tax identification number.
- c) Declaration of veracity of the information provided.
- d) A statement setting out the extended producer responsibility scheme or schemes through which they fulfil their obligations for each product category. A certificate confirming membership of the collective extended producer responsibility scheme must be provided within one month of the scheme's establishment.

B. Annual information on the quantities placed on the market by type and category of product



1. Categories of wet wipes placed on the market, according to the classification detailed below.

	Plastic-containing wet wipes for personal use	Plastic-free wet wipes for personal use	Plastic-containing wet wipes for domestic use	Plastic-free wet wipes for domestic use
Number of units placed on the market (in thousands of units)				
Weighted average weight of the wet wipe (in g)				
% (by weight) plastic over unit weight of wet wipe				
% of recycled material by weight per wet wipe				

2. Categories of balloons placed on the market, in accordance with the classification set out below.

	Balloons made of synthetic polymers	Balloons made from chemically modified natural polymers
Number of units placed on the market (in thousands of units)		
Weighted average weight of the balloon (in g)		
% (by weight) of plastic relative to the unit weight of the balloon		
% of recycled material by unit weight of the balloon		



ANNEX II

Establishment of extended producer responsibility schemes and annual report

A. Content of the prior notification for individual extended producer responsibility schemes

1. Identification data of the producer: registered office and NIF. Indication of whether this is an intra-Community manufacturer, importer or purchaser.
2. Territorial scope of action.
3. Identification (type and weight) of the products produced and placed on the market annually, and an estimate of the weight of waste on a dry weight basis that they expect to generate, in accordance with the specifications set out in Annex I.B.
4. A copy of the signed financial guarantee.
5. A copy of the agreements concluded for the financing of waste management.
6. Type of financing for activities.
7. Procedure for collecting data and providing information to public administrations.
8. Compliance with information obligations, and, in particular, the measures envisaged to ensure that holders of waste arising from these products are informed about measures to prevent waste and littering, as well as the mechanisms for exchanging information within the individual scheme and between that scheme and other waste management operators.

B. Content of applications for authorisation of collective extended producer responsibility schemes

1. Identification of the legal form.



2. Registered office of the collective scheme.
3. Description of the categories of products and waste on which it acts, as specified in Annex I.
4. Description of the geographical area of operation.
5. Identification of the producers forming the collective scheme, criteria for the incorporation of new members and description of the conditions for their incorporation.
6. Description of how the organisation operates (internal operating procedures and decision-making process).
7. Description of the measures for the fulfilment of the duties arising from the extended producer of the product responsibility, as laid down in the provisions of this Royal Decree.
8. Identification, where applicable, of the administering entity (legal form, registered office) and of the legal relationships and links to be established between this entity and the collective extended producer responsibility scheme and the producers participating in the scheme. Likewise, identification of the obligations assumed by the administering entity.
9. Legal relations and links or agreements to be established with public administrations for the financing of waste management in compliance with the obligations attributed to them.
10. Description of the financing of the scheme:
 - Cost estimation: costs arising from specific agreements signed with public administrations for the financing of waste management, information obligations, awareness campaigns, and administrative expenses of the collective scheme, including details of financial investments made by the scheme.
 - Estimated revenue. Details of the income and sources thereof. Producers' quotas and method of calculating the quota associated with covering the costs



referred to in the previous paragraph. Where applicable, the surcharge included in the cost of the product shall also be indicated.

- Where appropriate, differentiation in the disaggregated quotas by materials, or categories, indicating, where appropriate, the way in which the financial contributions are modulated.
- Method of collection of the quota.
- The conditions and modalities for the revision of the quotas according to the evolution of the fulfilment of the assumed obligations.

11. Proposal for funding criteria for public administrations.

12. Procedure for the collection of data from operators carrying out activities related to the exercise of the functions of the collective extended producer responsibility scheme and the provision of information to public administrations, according to the provisions of Article 21.

13. Proposal regarding the amount and form of the financial guarantee required.

14. An annual estimate, for the period of validity of the authorisation in each autonomous community, of the quantities of waste generated, expressed in tonnes on a dry basis, by category of waste to be generated.

C. Annual report on extended producer responsibility schemes

The report shall contain the following information supported by independent audits carried out by accredited undertakings:

a) General data on the placing on the market:

1) Identification of the extended producer responsibility scheme and number in the Register of Waste Production and Management.

2) Where applicable, and in the first reporting year, list of producers that make up this scheme, identifying the Register of Product Producers number of each of them. For successive years, a list of producers joining and leaving the extended producer responsibility scheme, as well as situations of non-compliance with financial obligations, also indicating their Register number.



3) Reporting period.

4) Quantity in weight (tonnes) and total number of units of products placed on the market by producers, differentiating the data by category.

b) Waste management data by weight (tonnes on dry basis) disaggregated by type of treatment (recycling, recovery and disposal), where applicable.

c) Economic data.

c.1) An annual account setting out the financial resources allocated to meeting the obligations under extended producer responsibility; in particular, it shall provide the information necessary for the verification referred to in Article 19 and, where applicable, the impact on the cost of the product.

c.2) The audit of the annual report of the schemes shall contain the economic data of the yearly activity carried out by the scheme as provided for in its authorisation.

The annual report shall include at least:

1) A justification for the costs of the scheme, and justification that these have been allocated exclusively to the fulfilment of the obligations arising from the extended producer responsibility that the scheme has assumed. The costs associated with each of the actions carried out by the scheme within the framework of its obligations should be specified.

2) A report on payments made to or income received from the public authorities responsible for waste management.

3) Financing of the scheme:

- Detailed information on the procedure for determining the contribution and the amount applied for each product category, together with a description of how modulation is applied, in accordance with Article 19.
- Financial contribution of producers to the scheme.
- Revenues received by the scheme from any other source, specifying those sources, as well as from arrangements with other extended liability



schemes, including other waste streams, providing information on the economic conditions of such agreements. It should be ensured that there is no double funding in the case of the application of different extended producer responsibility schemes.

4) Breakdown of costs relating to:

- The awareness-raising measures referred to in Article 23.
- The clean-up costs for litter generated by said products, including the cleaning of sanitation and water treatment infrastructure, and its subsequent transport and processing; and

5) Additional economic information on:

- Collaboration agreements signed with public administrations for collection, transport and treatment.
- Communication campaigns at state level, specifying, where appropriate, the costs of the campaigns of each autonomous community.
- Administrative costs of the scheme, distinguishing the costs of complying with the reporting obligations, in particular the costs associated with the development and maintenance of database schemes, the costs of obtaining the information and the costs associated with ensuring the traceability and reliability of the data. Where appropriate, the costs of carrying out economic analyses or audits, as well as on the impacts on the environment arising from the generation of the abandoned waste referred to in Article 13(1)(f).

6) List of companies audited and general summary of the audits carried out of the producers belonging to the scheme.

7) Assessment of the fees to be applied in the year following that of the compliance period, as well as their justification.

8) Revenue and expenditure forecasts for the year following the compliance period.



MINISTRY

FOR THE ECOLOGICAL TRANSITION
AND THE DEMOGRAPHIC CHALLENGE

STATE SECRETARIAT FOR THE
ENVIRONMENT

DIRECTORATE-GENERAL FOR
ENVIRONMENTAL QUALITY AND
ASSESSMENT



ANNEX III

Minimum requirements for agreements between public authorities and extended producer responsibility schemes

The minimum content shall be:

- a) Purpose and territorial scope.
- b) Form of accession by local authorities when the agreement is signed by the autonomous community.
- c) Financing of waste management, including the obligations and commitments of the parties.
- d) Provision of information to public administrations.
- e) Calculation methodology for financing by extended producer responsibility schemes of the public authorities involved in waste management, in accordance with Article 19.
- f) Billing and payment. In the event that the agreement is signed by the autonomous community, it must also specify the time limit for the transfer to the local authorities of the amount of the costs actually incurred in providing the service, which in no case may exceed one month from the date on which the said amounts are received by the autonomous community.
- g) Development of public information and awareness campaigns, to be carried out by the public administrations, with the funding of the schemes in the number and amount established. If public administrations decide to delegate the development of campaigns to extended producer responsibility schemes, it should be explicitly included in the agreement.
- h) Control and follow-up mechanisms. A plan shall be established to ensure that characterisation studies are carried out periodically at every stage of the waste-management process, enabling its traceability to be verified. In controls, characterisations and audits, the presence of local authorities, the Autonomous Community and the extended producer responsibility scheme must be ensured in good time and minutes must be drawn up. At least 50% of the characterisations shall be made where and when the competent body of the autonomous community determines, ensuring the representative characterisation of the management throughout its territory.
- i) Monitoring committee, which shall be composed of the extended producer responsibility schemes, the public administration undersigned to the agreement, and the local authorities where the agreement is signed by the autonomous community.
- j) Entry into force, duration and conditions for its extension, if any.
- k) Cases of resolution.



ANNEX IV

Criteria to be applied in the calculation of the financing of the cost of waste management.

The cost of managing waste from these products will be funded in four-year periods at the level of the autonomous community, in accordance with the criteria set out in this annex.

For funding purposes, only the proportionate share of the management cost corresponding to the percentage, by weight, of the waste contained in the total mass of waste collected and treated in accordance with the provisions of this Royal Decree shall be taken into account.

Financing costs shall be broken down into the following categories, without prejudice to any other costs which, within the framework of this Royal Decree, may be agreed in the relevant cooperation agreements.

1. The costs of financing waste management.

The financing of waste management shall cover the costs of cleaning up litter generated by these products, including cleaning within sewerage and wastewater treatment infrastructure, and the subsequent transport and treatment of that waste.

In accordance with Article 19, this funding may be provided either by reimbursing the costs incurred or by establishing a fixed multi-annual amount as provided for in Article 19(5).

The following items shall be taken into account when determining the costs:

a) Collection and transport.

The costs of waste collection and transport will be broken down into infrastructure costs (or fixed costs) and operating costs (or variable costs).

The costs associated with the infrastructure or fixed costs shall be those relating to the vehicles and equipment used in waste collection, covering the following items, which shall, in any event, be set out in detail in the agreements to be signed:

- a. Equipment purchase.
- b. Depreciation thereof.
- c. Replacement of the equipment.
- d. Maintenance, including cleaning and washing.
- e. Overheads and industrial profit of the company.



The operating or variable costs shall comprise the variable costs associated with waste collection and transport under the following headings:

- a. Depreciation of vehicles.
 - b. Expenditure on fuel for vehicles.
 - c. Cleaning and maintenance of vehicles.
 - d. Vehicle insurance and taxes.
 - e. Pick-up and transport staff.
 - f. Overheads and industrial profit of the company.
- a) Costs arising from the cleaning of scattered litter generated by wet wipes or balloons in sewerage and wastewater treatment infrastructure.
- b) Cost of waste treatment.

The costs associated with waste treatment, including the cost of landfill disposal, will also be taken into account.

2. Awareness-raising campaigns.

The costs of the awareness-raising and public awareness measures referred to in Article 23 shall include the costs of designing the campaign, the materials used, development costs and the management costs set out in the relevant agreements with public authorities.

3. Overheads incurred by local authorities or, where applicable, autonomous communities in monitoring and supervising management.

Account shall be taken of the expenditure incurred by local authorities or, where applicable, the autonomous communities, where so agreed in the agreement, in connection with the control and monitoring of the management of the extended producer responsibility scheme, including the cost of any characterisation work carried out. Similarly, account will be taken of the costs incurred by local authorities or autonomous communities in collecting data and compiling statistics, whether these relate to regular collections or one-off operations resulting from sporadic dumping or littering.



ANNEX V

Modulation of costs

The modulation criteria, by product category, may relate to:

- Reducing the weight of plastic components through eco-design.
- The amount of recycled plastic material incorporated into the product.
- The presence of hazardous substances in the product.
- The amount of material produced from chemically unmodified natural polymers.

ANNEX VI

Calculation of producers' financial guarantee

The amount of the financial guarantee to be provided by each producer shall be determined using the following formula:

Total scheme GF = $0.10 \times \Sigma (C \times \text{average waste management cost by category})$.

Where:

Total scheme GF: The amount of the producer's annual financial guarantee, based on the quantities of products and, where applicable, the categories they place on the market, in euros (€).

Q: Annual quantity of products placed on the market through the scheme, in tonnes (t).

AMC: Estimated average costs of financing waste management in each product category, taking into account the classification set out in Annex I.B, in the year of compliance, based on the actual costs incurred, in euros (€/t).