DRAFT ROYAL DECREE REGULATING THE ACCESSIBLE LABELLING OF CONSUMER PRODUCTS

Industry comments on TRIS notification 2025/0311/ES (Spain)

1. Introduction

A.I.S.E., the European Detergents Association representing the European cleaning and maintenance products industry, would like to take the opportunity to provide input **on the Draft Royal Decree regulating the accessible labelling of consumer products** (hereafter "the draft Decree"), notified by Spain to the European Commission in June 2025.

The Spanish Royal Decree on Accessible Labelling, as notified through the TRIS system, introduces mandatory requirements to ensure that essential consumer products — listed in its Annex such as cosmetics, food, and hazardous substances and mixtures—are labelled in formats accessible to people with disabilities, particularly those with visual impairments. The regulation mandates the use of Braille, QR codes with tactile markers, or other accessible technologies to convey key product information clearly and comprehensibly. It applies to manufacturers, importers, and distributors placing products on the Spanish market, while excluding items for industrial use, bulk goods, and those packaged at the point of sale. The decree outlines specific labelling content requirements, including product identity, composition, usage instructions, and allergen information, with some of this information required to be in Spanish.

A.I.S.E. fully supports the ethical objective of the draft Decree to guarantee accessible labelling of consumer product that have specific relevance for the protection of the safety, integrity and quality of life of people with disabilities. Nevertheless, **we believe that such measures have to be proportionate and in line with the applicable legislative framework**, that is, at European level, **in a harmonised way and thus be able to meet the needs of the entire vulnerable population of the EU** and not cause distortions in the internal market.

2. Ensuring Safety off All Consumers Through the Detergents Regulation

The Detergents Regulation (EC) No 648/2004 provides a harmonised framework for the placing on the market and use of detergents and surfactants across the European Union, ensuring a high level of protection for both human health and the environment. In force since 2005, the Regulation has recently undergone a substantial revision with the aim of modernising its provisions. **The revised legislation is giving particular attention to the needs of the most vulnerable consumers as highlighted below:**

- The revised Detergents Regulation is introducing the use of digital labels to improve the communication of labelling information both by avoiding overcrowded physical labels and by allowing users to rely on various reading options available only for digital formats, such as increased font, automatic search, loudspeakers or translation into other languages**. The aim of these new provisions is to increase readability, ease of use and comprehension of labels for consumers, including vulnerable and visually impaired consumers.**

  Article 17(1)(e) of the Detergents Regulation setting out the requirements for digital labelling establishes that:
  "*The information on the digital label shall be presented in a way that **also** addresses **the needs of vulnerable groups, including persons with disabilities**, and supports, as relevant, the necessary adaptations to facilitate access to the information by those groups".*

- Such digital label, if provided, should be made available through the presence of a **data carriers (most probably a QR code)** for all detergents sold in the EU (Article 17(1)(i) of the new Detergents Regulation. The cleaning and maintenance products producers will therefore already have to perform label changes to include a data carrier either on the label, or the packaging of the product or on an accompanying document.

Provisions are therefore already foreseen to be integrated in the Detergents Regulation to ensure proper information access by the most vulnerable groups. In this context, digital solutions which are designed to be easily scannable and compatible with assistive technologies can offer a practical and scalable means of delivering accessible labelling content. By contrast, requiring physical modifications—such as embossing of packaging or the addition of tactile markers or special print to indicate the location of a data carrier—would entail significant technical challenges, including the need to refit production lines, adapt packaging materials, and redesign artwork. These changes would result in substantial cost increases and operational complexity for manufacturers, particularly for SMEs.

3. Harmonised labelling requirements across the EU regulatory framework

The labelling requirements for cleaning and maintenance products are governed by both the **Classification, Labelling and Packaging (CLP) Regulation** and the **Detergents Regulation**.

- **Detergents Regulation**
  While the new Detergents Regulation foresees to build digital labels with considerations for people with disabilities, it also empowers the European Commission to issue a delegated act by 30 months after Entry into Force (by approximately mid-2028) to determine specific requirements for digital labelling of detergents (Article 26(8)). Those requirements will establish the types of **IT solutions**, which economic operators may use, and the **alternative means for providing the information on the digital label as** referred to in the Detergents Regulation. The economic operators will need the legal clarity defined under the Delegated Act to start the implementation of digital labels. The new labelling requirements mandated by the revised Detergents Regulation will be applicable by **mid-2029.**

- **Classification, Labelling and Packaging Regulation (CLP)**
  The CLP Regulation was revised in 2024, with the majority of its general obligations becoming applicable as of **1 July 2026**. However, certain provisions—such as those concerning label formatting—will take effect from **1 January 2027**.
  As part of its sixth simplification omnibus initiative published in July 2025, the European Commission has introduced proposals aimed at streamlining regulatory requirements and procedures applicable to chemical products, including those regulated by the CLP) Regulation[1]. A central objective of this initiative is to simplify and introduce more flexibility in the formatting rules for the labelling of hazardous chemicals. Among other things, the omnibus broadens the use of digital labelling, thus allowing more pieces of information to be provided on the digital label, enabling multilingual information and reduce pressure on physical label space.

  The proposal to streamline and simplify the CLP requirements is coming as the European Commission recognises the technical limitation and costs implications coming from labels requirements as mandated by the revised CLP.

[1] Simplification of certain requirements and procedures for chemical products

The simplification omnibus is intended to alleviate the financial and administrative burden on economic operators, thereby enhancing the efficiency and competitiveness of businesses operating within the EU Internal Market.

As a result, economic operators will already be required to undertake label modifications to ensure compliance with both the revised CLP and the Detergents Regulation. This dual compliance process will necessitate careful planning and coordination to align with the respective implementation timelines and regulatory requirements.

Moreover, the introduction of additional tactile elements for purposes other than those mandated under CLP—such as the tactile warning of danger (TWD), which is strictly required for specific hazardous classifications—could generate confusion among visually impaired consumers. These individuals are accustomed to associating tactile warnings with specific safety hazards, and the use of similar tactile features for unrelated information could lead to misinterpretation or even underestimation of actual dangers

Having to perform label changes as proposed by the draft Decree in addition to already foreseen requirements mandated by the EU legislation, would lead to additional administrative and financial burden for the economic operators, as well as bringing legal unpredictability. Furthermore, should these requirements be adopted many businesses will not be able to adapt to the demands of Braille/tactile QR and therefore it **could be expected that the current product palette won't be available to the Spanish consumer.**

4. Practical repercussions for the detergents sector

- ***Technical challenges & sustainability implications***

  It should be noted that Braille labelling should not hinder the reading of product labels by people without visual disabilities. Currently, product labels already contain a lot of mandatory information, so that, on many occasions, Braille labelling will have to be included in such a way that it does not overlap with current texts, requiring, where possible, larger labels, leading to overpackaging and, therefore, to the likely increase in packaging waste.

  In recent years, the industry has made considerable advancements in optimising the use of ingredients and packaging, with a particular emphasis on product compaction. This innovation has played a pivotal role in reducing the environmental footprint by minimising packaging materials, lowering transportation volumes, and consequently decreasing CO_2 emissions. However, as explained in the annex of this paper, the mandatory inclusion of Braille labelling presents significant technical challenges. Specifically, it would necessitate larger packaging formats, thereby undermining both the objectives of the Packaging and Packaging Waste Regulation (PPWR) and the industry's ongoing efforts to reduce packaging size and environmental impact.

  Additionally, the requirement to include batch numbers and expiry dates in accessible formats, as outlined in Article 3.1(e) of the draft Decree, poses significant technical and financial challenges. This information is dynamic and not typically relevant for consumers unless in cases of product recalls or safety concerns. Adapting production lines to encode such data into QR codes or Braille would require costly investments, particularly burdensome for SMEs. Moreover, this is not a requirement under the upcoming Detergents Regulation, highlighting the disproportionate nature of the obligation.

- ***Costs repercussions***

Illustrative data of the costs entailed by label changes for the cleaning products sector are included in the Commission's staff working document[2] accompanying the chemical products omnibus, simplifying the CLP Regulation. The Commission concludes that for cleaning products label changes entailed by the CLP revision would lead to a **significant recuring increased costs per label between 22% and 200%.**

Moreover, if dynamic data such as batch numbers and expiry dates were to be required in accessible formats, the associated costs would be significantly multiplied. From June 2024 till February 2025, IKW (the German trade association of manufacturers and distributors of detergents and household cleaning products) has undertaken a project on the digital product passport to investigate the cost repercussions for its implementation. Based on feedback gathered through 8 IKW members an estimation is drawn about the final cost implication for 130 members operating in the German market. Among others, the project concludes that should the DPP be implemented at batch level – having a data carrier updated for each batch - would entail very frequent label changes. Consequently, the printing of the data carrier after filling would require **€ 65 million investment.**

Similar costs could be estimated as a result of the provisions proposed by the Spanish Royal Decree on Accessible Labelling.

5. Conclusions

In light of the foregoing, **we respectfully urge the European Commission to take the necessary measures to prevent the adoption of the proposed Royal Decree as currently notified, and to ensure its full alignment with European Union law.** We thank you for considering our observations and remain at your disposal should you require any further information or clarification.

Annex I – Joint industry statement

In addition to our specific sector concerns as highlighted above, A.I.S.E. is fully aligned with the joint industry statement supported by other 39 trade organisation across several industry sectors. The statement provides further details on the draft Decree conflicting requirements with the **Treaty on the Functioning of the European Union** (TFEU) and the **Packaging and Packaging Waste Regulation.** The final join industry statement can be found **HERE,** while below we summoned some of the key concerns addressed by the paper:

- The draft Decree obligations will create unjustified barriers to intra-EU trade and consequently amount to quantitative restrictions on imports or measures having equivalent effect, which are prohibited by **Article 34 of the Treaty on the Functioning of the European Union** (TFEU). Both embossing a tactile marker to indicate the location of digital labels and the use of a Braille labelling (requiring translation in Spanish language) entail technical and economic challenges, discriminating operators in Spain and creating barriers for non-Spanish companies to enter the Spanish market.
- Quantitative restrictions can only be justified by one of the public interest grounds set out in **Article 36 TFEU** or by one of the overriding and mandatory requirements developed by case-law in the EU Court of Justice. Such rules must be necessary in order to attain legitimate objectives and be in conformity with the principle of proportionality, which requires that the least restrictive measure be used. The proportionality of measures mandated by the draft

[2] SWD(2025)531 - Commission staff working document accompanying the COM(2025)526 and COM(2025)531 Proposals for Regulations (HERE)

Decree can be questioned and Spain has failed to provide adequate justification on the proportionality of the proposed obligations. Even if the intended objective to support visually impaired consumers is noble and would be considered legitimate, the suggested requirements are not proportionate as this objective can be achieved by less restrictive measures. As such, the provisions of the draft Decree will constitute disguised restrictions on trade between Member States, prohibited under Article 36 TFEU.

- The draft Decree is contrary to **Articles 4.2 and 4.3 of** the recently entered into force **Regulation (EU) 2025/40 on Packaging and Packaging Waste Regulation** (PPWR), which respectively establishes that:

  "Member States shall not prohibit, restrict or impede the placing on the market of packaging that complies with the sustainability, labelling and information requirements laid down in or pursuant to Articles 5 to 12."
  "If Member States choose to maintain or introduce national sustainability requirements, or information requirements additional to those laid down in this Regulation, those requirements shall not conflict with those laid down in this Regulation and the Member States shall not prohibit, restrict or impede the placing on the market of packaging that complies with this Regulation for reasons of non-compliance with those national requirements."
  It should be recalled that Article 114 TFEU is the PPWR legal basis.
- **Article 5 of Directive (EU) 2015/1535** on the Technical Regulations Information System, which provides for the obligation for Member States to notify to the Commission all draft technical regulations concerning products before they are adopted in national law. This obligation has not been fulfilled in relation to *Law 4/2022, of 25 February, on the protection of consumers and users in situations of social and economic vulnerability*, which is the legal basis for the draft Decree object of this submission.

Infringement of TFEU provisions on Single Market and EU legislation

The measures proposed by the Spanish Government infringe the following TFEU provisions on Single Market and applicable EU legislation, notably:

- **Articles 34 TFEU and 36 TFEU**, respectively prohibiting *"quantitative restrictions on imports and all measures having equivalent effect between Member States"*, and prohibitions or restrictions on imports that *"constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States"*. The establishment of a unilateral labelling requirement, not applicable elsewhere in the EU, will discriminate economic actors operating in Spain, requiring them to change artworks that are produced for the entire EU (or for a cluster of countries) to ensure compliance with the Spanish requirements. Since importers will also be required to comply with a national requirement, the imports into Spain of products in scope of the draft Decree will effectively be discouraged. As a result, the draft Decree creates obstacles to intra-EU trade, undermines the principle of mutual recognition, and imposes quantitative restrictions on imports[3].

[3] According to established case law, labelling requirements must be regarded as barriers to intra-EU trade in that they directly affect the product and thus trade within the EU. Several CJEU rulings on national labelling requirements confirmed that such measures have an equivalent effect to a quantitative restriction as prohibited under Article 34 of the TFEU, as it was ruled that these requirements impacted or were potentially liable to impact intra-community trade by adding to costs and complicating marketing and distribution. See as a reference, Judgment of December 14, 2004, Commission of the European Communities v Federal Republic of Germany, C-463/01, EU:C:2004:797 and judgement of October 14, 2004, Commission v. Italy, C-143/03, EU:C:2004:629. A similar rationale has also been employed by the European Commission when starting infringement procedures against the French Triman marking requirements, as well as the Spanish unilateral labelling set out in Royal Decree 1055/2022, see here and here.

Quantitative restrictions can only be justified by one of the public interest grounds set out in Article 36 TFEU or by one of the overriding and mandatory requirements developed by case-law in the EU Court of Justice[4]. Such rules must be necessary in order to attain legitimate objectives and be in conformity with the principle of proportionality, which requires that the least restrictive measure be used. The proportionality of measures mandated by the draft Decree, aimed at regulating the accessible labelling of consumer product that have specific relevance for the protection of the safety, integrity and quality of life of people with disabilities, can be questioned. Indeed, while the draft Decree is accompanied by an impact assessment, the latter clearly mentions from the outset that "[because] *Law 4/2022, of 25 February, on the protection of consumers and users in situations of social and economic vulnerability, urges the government to regulate labelling in Braille alphabet, as well as in other formats that guarantee the universal accessibility of those consumer goods and products of special relevance for the protection of safety, integrity and quality of life, especially for blind and visually impaired people as vulnerable consumers. This Royal Decree complies with the aforementioned additional provision. No other alternatives can be considered* […].[5]" It can therefore be concluded that Spain has failed to provide adequate justification on the need and proportionality of the proposed measures, falling short of evaluating alternative measures. Even if the intended objective to provide accessible information to people with disability would be considered legitimate, the measures are not proportionate as this objective can be achieved by less restrictive measures, such as for instance the use of digital labelling without embossing a tactile marker. The implementation of solutions fully based on digital technologies such as QR codes, NaviLens codes or other technologies with no tactile markers are being widely used by businesses, as well as by consumers, allowing companies to export to different markets and quickly adapt to the specificities of local customers - including those related to accessibility - without having to graphically or structurally alter the label[6]. This approach aims to overcome language and technical barriers, offering a flexible and inclusive digital solution which cannot be provided by the use of tactile markers or the Braille system[7]. Indeed, the latter is known or used by a low percentage of visually impaired people[8] and is a system that is expressed in different languages, so unsuitable to companies and consumers operating in the Single Market.

Further on proportionality, the draft Decree does not provide any transition period for economic operators to adapt to the proposed requirements. Although a 2-year sell-off period is foreseen for products already labelled, it requires all other products to be compliant the day

[4] See, in relation to this, case law codifying the need for the purported risks to be well found, serious and real and supported by evidence: C-270/02; C319/05; C-148/15; C-270/02; C-319/05; C-421/09.

[5] This is also confirmed by the text of the draft Decree, foreseeing an ex-post evaluation of its provision, under the paragraph "Disposición final segunda. Evaluación de la norma."

[6] These mechanisms lead to web environments whose contents can be viewed and listened to by using standard default functions already installed in current mobile phones such as screen readers. These mobile phone features can be widely used by people with disabilities.
In addition, there are also free and freely accessible solutions on the market to provide consumers with practically all the mandatory mentions contained in the labels of consumer products, such as: product name, list of ingredients, net weight, allergens, nutritional information, etc. The barcodes already exist on all products, the consumer is presented with all the details of the product information. Likewise, the screen reader of Smartphones clearly and accurately announces these contents.

[7] It is interesting to note that Commission itself has indicated in response to a p[arliamentary question that a request for labelling in Braille did not emerge from the stakeholder consultation preceding the adoption of Regulation (EU) No 1169/2011. In the same response, the Commission also suggests that there are potentially new ways to provide consumers with better information via digital means , see E-000215/2020.

[8] See, as a reference, data published by the UK Royal National Institute of Blind People, revealing that the use of Braille by blind and partially or severely sight impaired people varies between around 8% and 15% in the UK. See, here.

after publication of the final Decree in the BOE. This means that, to ensure compliance, businesses effectively need to start applying today the requirements of a law that is not yet adopted and is still subject to change. This adds to the costs already incurred by operators marketing packaging in Spain, who have been obliged to rework their artworks following the entry into force of unilateral sorting instructions under Royal Decree 1055/2022, on which an infringement procedure is ongoing.

- **Articles 4.2 and 4.3 of the PPWR,** respectively mandating that *"Member States shall not prohibit, restrict or impede the placing on the market of packaging that complies with the sustainability, labelling and information requirements laid down in or pursuant to Articles 5 to 12."* and that *"If Member States choose to maintain or introduce national sustainability requirements, or information requirements additional to those laid down in this Regulation […] the Member States shall not prohibit, restrict or impede the placing on the market of packaging that complies with this Regulation for reasons of non-compliance with those national requirements."*

  Article 1.3 of the draft Decree clarifies that the proposed marking obligations apply to manufacturers, as well as their legal representatives, and to importers, when placing products on the Spanish market. It further specifies that distributors shall not place products on the market until they comply with accessible labelling requirements. Considering this, all economic actors operating in Spain, including importers, will no longer be allowed to place on the Spanish market packaging which is fully compliant with the requirement of the PPWR, unless the packaging of the products in scope of the draft Decree will also be labelled in accordance with its requirements. This represents a clear violation of Article 4.2. and 4.3 of PPWR, which is a directly applicable Regulation with an internal market legal basis. Article 114 being the legal basis of the PPWR further limits the discretion of Spain vis-à-vis imposing additional requirements on packaging in contradiction to Article 4 of the Regulation.
- **Article 5 of Directive (EU) 2015/1535** on the Technical Regulations Information System, which provides for the procedure for Member States to notify to the Commission all draft technical regulations concerning products before they are adopted in national law. *Law 44/2022, of 25 February, on the protection of consumers and users in situations of social and economic vulnerability*, establishing the obligation to develop a Braille labelling, has never been notified to the TRIS portal. According to established case law[9], a breach of the notification obligation by Member States constitutes a procedural defect in the adoption of the technical regulations concerned and renders those technical regulations inapplicable.

Technical constraints and economic impacts

Rigorous implementation and enforcement of the Single Market principles are key to ensure harmonised legal requirements facilitating economies of scale, long-term investments and strengthening the business case for innovative products and technologies. As recognised by the recently published Single Market Strategy[10], rules on labelling must balance the need to be clearly understood by consumers with the need to reduce market barriers and burden for industry

We detail below the technical constraints and economic impacts derived from the draft Decree.

[9] See here.
[10] See, COM(2025) 500 final, page 10.

Technical constraints

- There are inherent **space limitations** for the amount of Braille information that can fit on a pack. The Braille standard requires that each character be at least 6.2 to 6.6 mm wide, and that the lines be 1 cm high. Even large containers would not fit all of the required information. For small packs, it would be impossible. By way of illustration, see below the text in Spanish “Agua mineral natural 500 ml”, meaning "Natural mineral water 500 ml”, consisting of 28 characters and requiring between 17.3 and 18.4 cm in length to represent it in Braille.

Only 160 characters can fit 100 cm2 (10 x 10 cm). Very few consumer products reach this size. Further to this, it should be considered that Article 10 of the PPWR establishes clear minimisation obligations, to be fulfilled by all packaging in the future as market access requirements.

- **If other EU countries adopt similar measures**, there will be space limitations for how much Braille information can actually fit on packs that may be sold in multiple countries. Therefore, multiple languages would have to fit on the pack. The need to include information on pack as Braille could become a barrier to the Single Market if the pack size doesn’t fit the amount of Braille that would be required for countries to be grouped together. This further justifies the need for alternative digital technologies to be used instead.
- Braille and tactile markers are **technically challenging for some packaging formats**, such as flexible formats. There would need to be a full impact assessment to ascertain whether Braille can actually be embossed on all packaging materials and whether the embossing is not flattened during the production cycle. For instance, during label printing in some cases, the labels are wound and rewound onto rolls under tension and applied with a water-based adhesive under tension. The wet conditions, tension and rolling would result in most or all of the braille embossing being flattened.
- Braille would **require entire production lines to be refitted**. Even when it might be possible for some rigid materials, the way that products move through production lines can flatten the embossing so entire production lines would need to be refitted with different equipment requiring significant capital investments and it would increase production costs due to increased complexity.
- The level of complexity is high given that **the implementation processes**, which often go beyond the processing industry and depend on material suppliers, would need to be accompanied by planning, development and execution projects with durations at least 36 months. There are suppliers with potential solutions to project reliefs in primary/secondary packaging, but they are very new technological innovations and without scalability for such a short period of time. It would also mean a disproportionate increase in the costs to undertake these investments. For example: it would be necessary to carry out die changes and mould changes in all production lines that manufacture primary or secondary packaging, which would obviously increase the direct production costs of companies.
- Embossing Braille on packaging with a sticker or by increasing the thickness of packaging conflicts with Article 43 of the PPWR on the Prevention of Packaging Waste as it creates an obligation for producers to use more packaging materials.

- It should also be noted that, if digital labels are used instead of Braille, the draft Spanish decree would require a tactile marker to indicate the digital label. The technical challenges, costs and complexity described above would still be applicable to add a tactile marker to packaging.

Economic impacts

- **The obligation for additional labelling** on all packaged goods marketed in Spain is highly problematic to industry as many companies operating within the internal market use only one type of packaging execution for the EU as a whole or for a group of several neighbouring EU countries. The proposed measures will impede the use of a single packaging execution and consequently requires the redesign of all packaging across the entire internal market destined for Spain or the production of separate variants for the Spanish market. In relation to national labelling requirements already introduced in several Member States, the estimated cost for a change to an artwork (printing) file would amount to approximately €1,500 which include evaluation by a regulatory specialist to ensure veracity of all other mandatory labelling requirements (CLP etc). When a few thousands Stock Keeping Unit (SKUs) are put on the market, this can represent a potential one-off cost of a few million Euros for a single company, even before any ongoing costs for separate production of packaging executions for Spain. The magnitude of the costs for Braille in Spain will be much higher than such costs. This is because Braille requires embossed dots. As an example, for plastic packaging this could require adaptation of new packaging moulds for all such products; for cardboard packaging, it would necessitate the use of a moulded roller. Another alternative is the use of an embossed transparent label. In all cases, this is significantly more expensive than printing costs alone. Increases in costs for such adaptations as communicated by members of an impacted industry association in Spain are in the range of 5% to 15% per product with feasible lead times up 36 months and always greater than what foreseen by the Spanish measure, which will apply with no transition period.
- The costs for artwork change derived from the draft Decree would **add to those economic operators already assumed to comply with Article 13 of Royal Decree 1055/2022**, establishing unilateral sorting instructions in Spain as of 1 January 2025. Further to that, the draft Decree requirements will have an implementation period out of step with the measures introduced by the PPWR, introducing harmonised labelling and sustainability requirements for all packaging, making the whole process even more complex and costly, forcing the packaging of products to be redesigned again, without the opportunity to amortise costs already assumed.
- Higher production costs or the cost derived from stickering products during the 2-year sell-off period foreseen under the draft Decree will potentially result in **higher prices for Spanish consumers** if those costs are passed on.

About A.I.S.E.

A.I.S.E. represents the detergents and maintenance products industry in Europe. Based in Brussels, A.I.S.E. has been the voice of the industry to EU regulators since 1952. Membership consists of 30 national associations across Europe, 19 corporate members and 23 value chain partners. Through this extensive network, A.I.S.E. represents over 900 companies supplying household and professional cleaning products and services across Europe.

Committed to promoting sustainable practices and innovation, A.I.S.E. collaborates closely with European institutions, industry stakeholders, and the public to enhance the sector's environmental protection, consumer safety, and regulatory compliance efforts.

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