

April 12, 2023

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Submitted via Email to Standards Coordination Office (SCO) National Institute of Standards and Technology (NIST) at usatbtep@nist.gov

Subject: Comments on DOM/233, Draft Technical Regulation Governing the Marketing of Cosmetic, Personal Care and Household Care Products

The Household & Commercial Products Association¹ (HCPA) appreciates the opportunity to provide comments in response to the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Notification DOM/233, REGLAMENTO TÉCNICO QUE REGULA LA COMERCIALIZACIÓN DE PRODUCTOS COSMÉTICOS, DE HIGIENE PERSONAL Y DEL HOGAR (Technical regulation governing the marketing of cosmetic, personal care and household care products). Notification DOM/233 was submitted to the WTO to fulfill the Dominican Republic's obligations under the TBT Agreement.

HCPA would like to express our concerns, as it relates to household cleaning products, that this proposal would impede commerce between the Dominican Republic and other nations. HCPA supports the Dominican Republic in adopting regulations that align with international regulatory practices and that ensure safe and effective products enter the marketplace; however, the pre-market authorization and documentation requirements for the import of household cleaning products go beyond the requirements found in other countries and are unnecessary to protect public health or the environment.

HCPA is a voluntary, non-profit U.S. trade association representing approximately 240 companies engaged in the manufacture, formulation, distribution and sale of products for household, institutional, commercial and industrial use. HCPA member companies' wide range of products includes home, lawn and garden pesticides, antimicrobial products, air care products, automotive specialty products, detergents and cleaning products, polishes and floor maintenance products, and various types of aerosol products. Many members of HCPA

¹ The Household & Commercial Products Association (HCPA) is the premier trade association representing companies that manufacture and sell \$180 billion annually of trusted and familiar products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments. HCPA member companies employ 200,000 people in the U.S. whose work helps consumers and workers to create cleaner, healthier and more productive lives.

manufacture cleaning products intended for sale in the Dominican Republic and are affected by this proposal.

As proposed, before a household cleaning product can be imported and marketed in the Dominican Republic, a company would need to receive approval in the form of a Mandatory Sanitary Notification (NSO) from the General Directorate of Medicines, Food and Health Products (DIGEMAPS) after submitting information such as a product's formulation, label, certificate of analysis, copy of the good manufacturing practice (GMP) certificate, and a manufacturing/packaging contract in the event that the importer or marketer of a product is not the same as the manufacturer. HCPA is concerned with the disclosure of confidential information, such as the formulation, and the requirement of unique documentation in the Dominican Republic that is not common to cleaning products globally.

HCPA and our member companies have been a proponent of chemical transparency to consumers of cleaning products, as evidenced by our active engagement and support of the California Cleaning Right to Know Act of 2017.² However, without strong intellectual property protections, product formula disclosure can put confidential business information at risk. Loss of intellectual property to competition prevents a manufacturer from obtaining confidentiality protection for that formula anywhere else in the world and is very problematic for a company's overall global market strategy. Therefore, HCPA requests that DIGEMAPS follow the common practice to accept a Safety Data Sheet (SDS) presented according to the Globally Harmonized System (GHS).

Further, the request for documents such as a Certificate of Free Sale (CFS), a Good Manufacturing Practices (GMP) certificate, and an Official Technical Data Sheet are not customary for household cleaning products. The CFS only declares that a product is sold or may be sold in its country of origin and the document does not declare or certify that it complies with legal or regulatory requirements in most countries. With this in mind, it's also important to note that governments and other organizations, such as associations, are not set up to issue a CFS for cleaning products. This means that a CFS document does not offer much benefit for the consumers in the Dominican Republic and only adds unnecessary burden to obtain, maintain, and review for both regulators and companies. GMP protocols are not established or appropriate for household cleaning products, therefore, HCPA requests that the requirement for a GMP certificate be removed. Similarly, the concept of an official technical data sheet for a household cleaning product is unique and not common around the world. Therefore, it is unclear what information is expected.

HCPA believes that the responsibility for the quality, safety, and compliance of a household cleaning product belongs to the business that places a product on the market. Complex pre-market approval requirements that deviate from global practices will only add unnecessary administrative burdens for the regulatory authorities and industry without providing effective verification of compliance or assurance of safety. HCPA is concerned that this pre-market

² https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB258

approval process is likely to result in import delays or even decisions by some manufacturers to discontinue shipments to the Dominican Republic.

HCPA also has concerns with the date of manufacture requirement on the product label. Traceability is essential for consumer product manufacturers; many companies utilize a date code rather than the actual date of manufacture for a variety of reasons. Reasons to have a date code on the product include container or package size limitations, confusion with an expiration date, and additional information contained in a date code that aids in tracing a product globally. HCPA recommends that in addition to the date of manufacture, DIGEMAPS accept a date code which indicates when a product was manufactured. In the United States, many agencies only require an explanation of the date code upon request for when its needed rather than having companies submit it prior to conducting business. HCPA recommends that DIGEMAPS follows this path and only requires an explanation be submitted when necessary, so that a system to store and maintain such submissions is not required. Further, the date code should be allowed anywhere on the package, provided that it is clearly displayed, as in readily observable without irreversibly disassembling any portion of the product container or packaging, and not easily removed.

HCPA supports notifying consumers of fragrance allergens that may be present in household cleaning products. However, we recommend allowing the use of digital disclosure so that consumers have ready access to the information without having to read dense physical labels.

Lastly, HCPA requests a minimum of two years for the entry into force of the Technical Regulation, as well as sufficient time for the exhaustion of products already in inventory and on the market. Any product manufactured and imported prior to the effective date should be permitted to sell through without having to meet any labeling or notification requirements retroactively.

In conclusion, HCPA appreciates the opportunity to provide these comments. HCPA supports the use of international regulation and authorities as references and as the basis for a regulation in the Dominican Republic as a way to facilitate trade. Effective and less burdensome regulations can be developed using existing regulatory references to assure safety and the objectives of this proposal.

Respectfully submitted,



Nicholas B. Georges
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