UNIVERSIDAD DEL AZUAY

Faculty of Legal Sciences

School of International Studies

Cosmetics Regulation in Ecuador (2020-2024): ARCSA-SENAE Impact

Project prior to obtaining a Bachelor's Degree in International Studies

Author:
María Paula Piña Juela

Advisor:
Claudia Inés Campoverde Cárdenas

Cuenca – Ecuador
2026

To my parents, for being my rock and my
unconditional support every step of the way.
To my brother, for being my engine and my greatest
motivation to achieve this dream.
This achievement is as much his as mine.

ACKNOWLEDGEMENTS

Thanks to my parents for their patient love, for believing in me even on days when I couldn't find reasons to do so. To my brother, for being the engine of my resistance and the support that prevented me from taking a single step back. To my grandparents and my family, for their silent but invaluable presence. And to my friends and companions on this path, thank you for making this journey, although difficult, totally worthwhile, your friendship is the best complement to my training.

Table of Contents

List of Figures, Tables and Appendices

List of Figures

List of Tables

List of Appendices

COSMETICS REGULATION IN ECUADOR 2020-2024: ARCSA-SENAE IMPACT

ABSTRACT

The central axis of this research work refers to the import regime 10 for the consumption of cosmetics in Ecuador, in the period 2020-2024, in order to find the different changes that have occurred in the regulations to which this tariff heading 3304 is governed, the presumption of knowledge of non-tariff barriers and the impact of these on import values and volumes of the main subheadings of these goods. Where the guide of this analysis is the national and supranational regulations in force in the established period of time, which is of support for the qualitative analysis, while, for the quantitative analysis, the main source is the database obtained from Trade Map. Complementing the analysis, with the knowledge and experience of experts in the area such as a Customs Agent and a Customs Agent Assistant. This information has been key to meeting the problem, objectives and answering the research question. The research work evidenced a series of modifications in the regulatory evolution, a significant impact in terms of values and volume of imports of the main subheadings. In addition, the importance of know-how in this process.

Keywords: tariff, trade, control, cosmetics, import.

REGULACIÓN DE COSMÉTICOS EN ECUADOR 2020-2024: IMPACTO ARCSA-SENAE

RESUMEN

El eje central de este trabajo de investigación hace referencia al régimen 10 de importación para el consumo de cosméticos en Ecuador, en el periodo 2020-2024, con la finalidad de encontrar los diferentes cambios que se han dado en las regulaciones a las que se rige esta partida arancelaria 3304, la presunción de conocimiento de barreras no arancelarias y el impacto de estas sobre valores y volúmenes de importación de las principales subpartidas de estas mercancías. Donde la guía de este análisis es la normativa vigente nacional y supranacional en el periodo de tiempo establecido, la cual es de apoyo para el análisis cualitativo, mientras que, para el análisis cuantitativo, la fuente principal es la base de datos obtenida de Trade Map. Complementando el análisis, con el conocimiento y experiencia de expertos en el área como lo son un Agente de Aduana y un Auxiliar de Agente de Aduana. Esta información ha sido clave para cumplir con la problemática, objetivos y responder a la pregunta de investigación. El trabajo de investigación evidenció una serie de modificaciones en la evolución regulatoria, un impacto significativo en cuanto a valores y volumen de importaciones de las principales subpartidas. Además, de la importancia del know-how en este proceso.

Palabras clave: arancel, comercio, control, cosméticos, importación.

INTRODUCTION

After the COVID-19 pandemic, the world of foreign trade changed completely. For the import sector, this meant cataloguing goods into essential and non-essential products, to give preference to those that could not be stopped from being imported. Therefore, among the non-essential were cosmetics. However, this was no reason to exclude the rules and regulations that govern these products from being modified. Due to this event, changes were made in order to make certain rules more flexible to facilitate foreign trade that had deteriorated during this period of time, so that within the period 2020-2024 a variety of adjustments were presented to the regulations to which these processes are subject, both in necessary pre-shipment documents, clearance, release and post-importation of goods, in this case cosmetic products.

This directly affected the import values and volumes of tariff heading 3304, pertaining to: "Beauty or make-up preparations and skin care preparations (except medicines), including anti-sun preparations and tanning creams; preparations for manicures or pedicures". Evidenced in the 2020 Trade Balance Evolution Report of the Central Bank of Ecuador (2021), where it was found that the category of consumer goods, which includes cosmetics, was affected with a 16.2% decrease in FOB value during this year, as those products took a back seat during the pandemic.

It is important to note that the process of importing cosmetics must be executed meticulously, since to implement it is necessary to comply with a series of previous, accompanying and post-import requirements, for which it is necessary to remain alert to any modification that is made, since, sometimes, the repeatability of the processes generates that it is assumed that the process or that the requirements will remain the same, which can lead to sanctions or even reshipment of the goods.

By virtue of the above, the import process encompasses legal, logistical and financial aspects, which must be correctly developed to achieve optimal and effective import management. For this, it begins with the search for suppliers, where the quality, prices, times are fundamental. A very important point is to verify the veracity of the information prior to shipment; otherwise, there is a risk that transport costs will be generated and that in the end a mandatory reshipment will be caused for not complying with the requirements. After this, it is essential to know all the conditions that national regulations have to import the product you are looking to obtain. Therefore, for those new importers who do not have full

knowledge of the requirements, the advice of experts in the area such as Customs Agents is essential.

In this research work, through the chapters we will develop the regulatory evolution that the regulations involved in the import process of tariff heading 3304 in Ecuador have undergone, the non-tariff barriers, the presumption of knowledge of different standards and the importance of know-how in these processes, based on information provided by experts in the area.

CHAPTER 1
THEORETICAL FRAMEWORK AND STATE OF THE ART

1.1 Theoretical Framework

1.1.1 Cosmetics Health Regulation and Life Cycle

For the comparative review, the cosmetic product is related to its external use and for hygiene, perfumery or aesthetic purposes, which implies that there is a health document, a labeling, an ingredient control, and a definition of the owner's responsibilities. During importation, checkpoints are distributed between the health authority and customs, particularly with regard to traceability and document verification. Sanitary control extends to the marketing and post-marketing phase, in which the technical rigor of the dossier and the accuracy of the formulation are decisive in institutional control and response (Ferreira et al., 2022; Morel et al., 2023; Nayak et al., 2021; Vieira et al., 2024).

1.1.2 Post-marketing security, evidence and surveillance

Post-marketing surveillance and safety assessment of cosmetics are based on traceability, technical evidence and documentary quality. Cosmetovigilance allows adverse events to be identified, although problems of underreporting and incomplete identification of the product or batch persist. Therefore, the labelling, the local manager and the technical file strengthen traceability and allow corrective measures to be taken. In imported products, the authority requires valid, reproducible and traceable evidence on ingredients and intended use, so that the declared properties have a direct correlation with specific import batches and have scientific validation of their content. This requirement relates to recent trends that reinforce testing and safety standards in regulated consumer products, including cosmetics (Barthe et al., 2021; Lucca et al., 2020; Nayak et al., 2021; Silva & Tamburic, 2022; Vieira et al., 2024).

The study of the regulations in the cosmetics trade in different parts of the world allows us to observe differences in the examination of regulatory notifications, the figure of the local manager, the language of the labels and the documentation of the composition. In the Andes, the coexistence of Community rules and national provisions reinforces the inter-institutional nature of imports, and makes more evident the need to harmonize sanitary requirements and customs formalities (Ferreira et al., 2022; Morel et al., 2023).

1.1.3 Non-Tariff Measures, Compliance Costs, and Control Performance

Non-tariff measures applied to cosmetics include technical requirements, conformity assessment, and restrictions associated with safety and health, the effects of which depend on their design and application at the border. In these products, these requirements cover prohibited ingredients, concentration limits, purity and labelling obligations, compliance with which is supported by technical and safety files. During importation, this file becomes a documentary chain that crosses several dependencies, which increases the risk of inconsistencies due to changes in formula or supplier. Therefore, the analysis must distinguish between sanitary purpose and administrative burden, since both have an impact on compliance costs, inspections, rejections and corrections (Ghodsi, 2023; Morel et al., 2023; Vieira et al., 2024).

Border control depends on coordination between customs and health authorities, especially when verification is supported by a single window and interoperability between systems. Standardizing data and identifiers can reduce duplication and document burdens, while articulation failures lead to cross-validations, traceability issues, and automatic rejects. These mismatches increase compliance costs, turnaround times, and revision variability. In addition, risk management must concentrate controls on operations with a higher probability of non-compliance, preventing profiles built with incomplete information from multiplying unnecessary reviews on compliant importers and on goods subject to technical restrictions (Heijmann et al., 2020; Kuo & Chou, 2021).

Ingredient control, labelling and conformity assessment depend on current technical documentation, regulatory lists and the operator's ability to maintain consistent dossiers. Regulatory differences between countries may require reformulation or relabeling for the destination market, even if the product is compliant in its country of origin, which directly impacts border controls. The label is a document that centralizes composition, warnings, country of origin, responsible, batch number, and the conformity assessment can include quality, free sale and technical validation documents. This documentary heterogeneity is what explains the observations, the retentions, and the greatest sacrifice for verification by the authority (Barthe et al., 2021; Ferreira et al., 2022; Morel et al., 2023; Vieira et al., 2024).

The increase in online commerce and the number of small shipments generates more customs declarations, with limited information and makes traditional controls difficult, as well as requiring more coordination between health and customs authorities. In this sense, risk management focuses on the quality of information, the capacity for integration and

interoperability, institutional capacity and document traceability. In the case of cosmetics, the system is improved when customs information can be sorted by product type, batch number, and person of the trade, so that controls at country boundaries can be more effectively connected to alerts, recalls, and other corrective actions. Hence, performance evaluations must consider not only the findings, but also the time of dispatches, the operator's experience, and the inter-institutional experience. (Heijmann et al., 2020; Karklina-Admine et al., 2024; Lucca et al., 2020).

The importation of cosmetics requires a clear distribution of responsibilities between the health holder and the customs declarant, since the lack of coordination can delay files, corrections and transmission of data to the customs system. At the same time, the risk assessment must distinguish between administrative time and time associated with health requirements, tests and document reprocessing. This analysis allows us to observe how regulatory changes can increase administrative burdens without altering their health purpose. In addition, the description of the use and exposure of the product influences labeling, classification and required evidence, especially when the good approaches therapeutic or antiseptic categories (Barthe et al., 2021; Ferreira et al., 2022; Ghodsi, 2023; Karklina-Admine et al., 2024; Morel et al., 2023).

The framework can be structured in three blocks: cosmetic security, inter-institutional governance at the border and the continuity of the trade flow. Security translates into marketing instruments, governance in risk management, selection and interoperability, and continuity in the friction that may exist between substantive requirements and operational demands. Based on this articulation, it is possible to operationalize indicators for measuring the impact of the ARCSA-SENAE coupling during the period 2020–2024, avoiding an analysis that is reduced to a single regulatory component (Ghodsi, 2023; Karklina-Admine et al., 2024; Vieira et al., 2024).

1.1.4 ARCSA: Sanitary Requirements and Procedures Associated with NSO

The National Agency for Health Regulation, Control and Surveillance (ARCSA) is responsible for the sanitary control of cosmetics and requires the Mandatory Health Notification (NSO) for the marketing and import of products. The NSO identifies the person responsible for control in the country and establishes traceability, at least, per batch, links the labelling commitment, information on the composition and surveillance of the product in the market. In operation, the NSO is integrated into the customs formalities in the prior control and is incorporated as an accompanying document of the clearance (Resolution No.

ARCSA-DE-006-2017-CFMR: Technical Sanitary Regulations for the Manufacture, Importation, Conditioning, Storage, Distribution, Transport and Marketing of Cosmetic Products., 2017).

Between 2020 and 2021, the sanitary regulation of cosmetics transitioned from a national technical regulation, based on documentation on the product, manufacturer, local responsible, formula, labeling and payments, to a substitute regulation aligned with Decision 833. This change incorporated recognition of the NSO, communication of changes and obligations related to operating permits and Good Manufacturing Practices. In operational terms, the transformation implied moving from a more national and administrative scheme to one with greater community harmonization and greater requirements for document consistency before clearance (Andean Community [CAN], 2018).

The operationalization of the Andean framework is reflected in the guidance issued in 2022 that is still in force to this day, where ARCSA explains the use of Transitory System 833 (ST 833) for obtaining, renewing, recognizing CAN members and modifying outdated NSO data, as well as the treatment of the parallel importer. The instruction mentions the minimum information provided for in Article 9 of Decision 833 of the CAN, which includes product identification, manufacturer data, qualitative and quantitative composition, label design, warnings and safety evidence. Field standardization helps with subsequent verification and decreasing ambiguities. This scheme must be interpreted in a complementary manner to the set of standards and instructions in force published by ARCSA for the sanitary management of cosmetics and related products (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022).

Together with ST 833, ARCSA published technical criteria for the classification of the level of health risk of cosmetic products. The classification guides the type of documentary evaluation and the intensity of supervision, differentiating the lowest risk cosmetics from the categories with the highest exposure. The document provides criteria based on the route of use, target population, area of application and the nature of the ingredients. For imports, classification influences subsequent controls and consistency between the trade description and the declared category (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022).

The Andean Community framework has strengthened the regulation of cosmetics with the incorporation of the Guidelines on Good Manufacturing Practices (GMP) established in Resolution 2206, of June 17, 2021, and labeling found in Chapter V of Decision 833;

establishing harmonized requirements on manufacturing, traceability and mandatory information on packaging. Mandatory information includes product name, country of origin, net content, applicable precautions, lot number, registration code, INCI (International Nomenclature of Cosmetic Ingredients) list, expiration date, and there are restrictions on the use of additional labeling. For imports, these regulations increase the burden of obligation for the responsible health authority and increase the need for consistency between the technical file, the traceability provided by the manufacturer and the verified documents (General Secretariat of the Andean Community, 2021; General Secretariat of the Andean Community, 2022; General Secretariat of the Andean Community, 2024).

The years 2020-2024 indicate a shift from an earlier national NTS to a more refined community architecture, supported by accompanying processing platforms and technical specifications. The most visible change lies in the information content required for NSOs, in the formalization of recognitions and in the obligations related to GMP documents and labelling. For analysis, these changes capture compliance variables in relation to documents, notifications, and processing times.

1.1.5 SENAE: Customs Formalities, Prior Control and Release for Consumption

Ecuador's National Customs Service (SENAE) manages import clearance and applies selective controls based on risk profiles. For entry into consumption, the importer registers the declaration in the ECUAPASS and attaches accompanying documents, while prior control documents are required when sectoral authorities intervene. In regulated goods, the prior control articulates SENAE with ARCSA, because customs verifies the existence of the sanitary permit and its correspondence with the declared merchandise (National Customs Service of Ecuador [SENAE], 2025).

Between 2020 and 2022, SENAE adjusted its procedures by transferring them to electronic channels, intensive use of ECUAPASS, and transitory mechanisms to submit prior control documents when the Ecuadorian Single Window (VUE) did not fully integrate them. Subsequently, it updated the process of the delivery of goods and the coordination of inspections, assigning operational responsibilities to temporary warehouses and applicants for the service, while incomplete coverage of the one-stop shop in matters subject to inspection persisted. In cosmetics, these changes had an impact on document logistics, capacity scheduling and coordination with external entities for sample collection (National Customs Service of Ecuador [SENAE], 2020; National Customs Service of Ecuador [SENAE], 2020; National Customs Service of Ecuador [SENAE], 2022).

In 2024, operational management will be maintained under the logic of electronic declaration, risk-based selectivity and document control, with an emphasis on data consistency. The rise of e-commerce and low-volume shipments challenges traditional control, as it increases the number of declarations and reduces the scope for extensive inspections. This scenario maintains the need for coordination with health authorities and clear rules on the evidence required in each channel (Heijmann et al., 2020; Morini et al., 2024).

From 2020 to 2024, the most evident procedural change in SENAE focuses on the modes of attention and document management during the health emergency, while the flow of declaration and selectivity remains. For cosmetic products, the sensitive element continues to be the management of the control document and the coordination of inspection with the ARCSA, since both impact release times, logistics costs and exposure to returns due to documentary inconsistencies.

1.1.6 ARCSA–SENAE Interface: Documentary Sequence and Control Points

The interaction between ARCSA and SENAE can be understood as a chain of documentary compliance that begins with the NSO and the construction of evidence of composition, labeling and manufacture, and ends in classification, logistics and customs declaration. Between 2020 and 2024, this chain evolved from records of national regulations and previous forms to documents that have standardized fields under ST 833 and recognition and modification criteria. While standardization decreases discretion, it increases the need for consistency in labeling, declared composition, and classification, impacting observations, amendments, timing, and costs of (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022; National Agency for Health Regulation, Control and Surveillance [ARCSA], 2018).

Under this scheme of inter-institutional collaboration, the Ecuadorian Single Window (VUE), being one of the modules of ECUAPASS, arises as: "an electronic tool through which all users of customs services and, in general, all foreign trade operators, will present the requirements, procedures and documents necessary to carry out foreign trade operations" (Presidency of the Republic of Ecuador, 2010, p.5). Therefore, in this case it works as a prior control channel, although its partial integration during part of the period forced certain documents to be sent by mail, generating traceability problems and longer response times. In the import of cosmetics, this situation is aggravated because customs must verify consistency between commercial description, subheading, origin, quantity and sanitary

evidence, in addition to reviewing requirements derived from Andean labeling and GMP, such as warnings, lots, INCI list and data of the NSO holder. Therefore, the ARCSA-SENAE interface can be measured by sanitary process times, frequency of inspections, observations and reasons for document retention (General Secretariat of the Andean Community, 2022; National Customs Service of Ecuador [SENAE], 2022).

1.1.7 Comparison 2020-2024: Matrix of Changes in Requirements and Processes

The comparison highlights change in substantive requirements (security, composition, labelling) and modifications in procedures (platforms, forms, timeline, coordination). The matrix captures the intersections between sanitary and customs regulation and highlights legal changes that impact required documents, method of filing, and validations. It helps to identify discontinuities between 2020 and 2024 and relate them to operational indicators in the Ecuadorian case.

Table 1

ARCSA Comparative Matrix of Sanitary Requirements for Cosmetics Imports (2020 vs 2024)

Dimension	2020	2024
Applicable technical health standard	NTS prior to the 2021 replacement version; NSO routines in previous scheme.	substitute NTS ARCSA-DE-2021-016-AKRG and alignment with Decision 833; instructions in force.
Procedure scheme	NSO processing with previous formats; emphasis on file and payment.	Procedure by ST 833 for obtaining, renewing, recognizing and modifying NSO.
NSO Informational Content	Identification of the product and the local manager; proposed labeling; Formulation information in the file.	Standardized fields (art. 9 Decision 833), with qualitative and quantitative composition and draft label.
Parallel importer	Mainly administrative treatment, with less standardization of requirements.	Explicit rules for taking advantage of an existing NSO in the instruction by ST 833.
Risk Classification	Less formalized criteria for grading subsequent surveillance.	Formalized technical criteria for health risk level and selective surveillance.
Good Manufacturing Practices	General references to quality and manufacturer responsibility.	Andean Technical Regulation of GMP (Res. 2206) and harmonized verification tools.
Labelling	Previous rules and national adjustments; emphasis on minimal information and traceability.	Andean Technical Labeling Regulation (Res. 2310) approved; modification of validity (Res. 2458).
Relationship with border control	NSO is presented as a pre-clearance document in the office.	NSO with standardized fields and recognition rules; more consistent validation in prior control.

Table 2

Comparative Matrix of SENAE Processes Linked to Cosmetics Imports (2020 vs 2024)

Dimension	2020	2024
Statement Platform	ECUAPASS as the axis of dispatch and interaction with the user.	ECUAPASS is maintained; greater reliance on electronic flows and digital traceability.
User service and procedures	Exclusive attention through electronic channels for health emergency resolutions.	Standardized digital care; improvements are aimed at predictability and traceability.
Prior Control Documents (PRDs)	DCPs required for regulated goods; mailings when DCP was not available in VUE.	DCP using EUVs and electronic records; interagency interoperability dependency.
Coordination of inspections	Coordination with external entities; Programming may depend on operating agreements.	Manual 2022 maintains coordination by applicant until VUE coverage of inspections; Persistence of friction.
Selectivity and risk management	Channeling by profiles; documentary or physical inspection according to risk.	Growing pressure for e-commerce and small shipments; need for analytics and interagency coordination.
Hardware management	Rules for the subsequent delivery of physical support during a health emergency.	More widespread digitization, with archiving requirements and validation of consistency.
Point of contact with ARCSA	NSO validation and document coherence as a condition for release.	NSO validation with standardized fields; emphasis on consistency of sanitary and customs data.

1.2 State of the Art

1.2.1 Evidence 2020-2024 on Trade Facilitation and Digitalization

Modernization in trade facilitation and more recent processes in digitalization show that the effects of modernization depend less on the existence of platforms and more on their potential to accelerate, consolidate, and reduce transaction costs and coordination. In this sense, the literature distinguishes infrastructure improvements and changes in procedures, and concludes that digitalization only operates to eliminate frictions in the presence of standards, interoperability, and institutional robustness for the management of information flows. This perspective serves for the analysis of the articulation of sanitary control and customs control in the import of cosmetics, and for the analysis of its effects on process variables, instead of purely formal changes (Ouyang & Park, 2024).

This research analyzes general effects of digitalization and trade facilitation on time, costs, and coordination, but does not address in detail the interaction between the health authority and customs in the import of cosmetic products. Therefore, in the Ecuadorian case, its application is found in the elaboration of types of analysis on interoperability, standardization and performance, but they do not explain how these elements are articulated

in the coordination between ARCSA and SENAE in prior control and dispatch (Ouyang & Park, 2024).

1.2.2 Technical Measures, Regulatory Convergence and Effects on Quality

The literature on non-tariff measures, technical barriers, and regulatory convergence provides tools to quantify regulatory intensity, compare regulatory frameworks, and link those changes to delivery times, compliance costs, and changes in the trade portfolio. In cosmetics, these approaches allow us to analyze how restrictions on formulation, labeling, and documentation requirements can lead to reformulations, brand segmentation, or supplier substitution. In addition, they show that greater regulatory convergence is likely to decrease adaptation costs and frictions at the border, while overlapping regional and national standards may increase control, reprocessing, and documentation requirements on importers and logistics operators (Fell & Duver, 2024).

The literature on technical barriers and regulatory convergence allows us to understand how ingredient, labeling, and documentation requirements affect adaptation costs, document quality, and dispatch times. However, these studies do not precisely examine the operational coordination between health and customs entities in a specific national case. Consequently, the study of the Ecuadorian case provides a more precise institutional reading of how these regulatory changes translate into validations, observations, reprocesses and documentary control during the importation of cosmetics (Fell & Duver, 2024).

1.2.3 Customs inspections, classification and technological adoption

The latest research on customs inspections also presents quantitative evidence on elements that increase the probability of red carcass. In analysis for the Argentine case, it is established that tariff dispersion for "similar" goods is related to a greater probability of being classified in the red channel, and, therefore, to a measurable increase in the probability of being inspected. The author relates the tariff structure to delays and opens the way to how classification and subheading decisions impact control. In the importation of cosmetics, where the classification is articulated with permits and technical standards, this type of evidence suggests that the impact of changes in the classification criteria and on the consistency of the declaration should be measured (Domínguez Prost & Scattolo, 2024).

During the years 2020 to 2024, tariff classification studies have included tools such as the use of web applications and the use of artificial intelligence. One paper establishes the guidelines for the classification of goods under import tariffs and export tariffs, mentioning

the costs that can arise due to erroneous classifications, litigation and redoing the procedures. The author mentions assistive technologies such as notes and resolution finders, so-called code recommendation systems, and presents some criteria for assessing where these systems focus on their performance and coverage. This job deals with the importation of beauty products, because incorrect classification can lead to the application for permits, and/or inspections unnecessarily, which affects customs clearance time (Grainger, 2024).

The adoption of new inspection technologies also translates into the transformation of inspection systems. A case study from China on the practice of automated assessment through AI presents areas for improvement for shipment detection and addresses the issues of control and facilitation in inspection. The study argues that the effectiveness of an inspection system speaks volumes in relation to the quality of the training data and the depth with which the inspection system is integrated with the thaw decision system and the management of resistance to organizational change. In the case of regulated inputs, it is argued that the integration of the signals of the filters of the sanitary and technical permit criteria in the inspection system should not shift risks to enclaves of lower control (Cao and Zheng, 2024).

1.2.4 Cross-Border E-commerce, Small Shipments, and De Minimis Policies

Part of the research in *e-commerce*, cross-border electronic network and its logistical challenges has been concerned with the impact of logistical uncertainty on risk management. The literature on cross-border e-commerce has been able to establish connections on different types of uncertainty and different management strategies, such as excess inventory, the choice of logistics providers and supplier management. These situations can be associated with the shipment of cosmetic products, where information uncertainty is aggravated by the requirement for content and health labeling. While evidence suggests that some logistics techniques can be efficient, at the same time, the sacrifice of such efficiency is the increased documentary complexity that results from strategically dividing shipments to meet de minimis limits (Giuffrida et al., 2021).

Another B2C e-commerce study with China investigates the logistics of uncertainty and different dispatch configurations based on costs, times, and the risk of disruptions. The analysis focuses on a priori channel logistics decisions, in relation to the availability of information and control over returns, aspects related to compliance with consumer goods regulations. With respect to imported cosmetics, logistics solutions are offered and parameters are evaluated that show how companies adjust their routes based on border and

permit control, as well as the effect that their routing decisions have on the diversion of volume to modes of transport with greater or lesser verification control (Giuffrida et al., 2019).

The evidence of low-value and de minimis shipments has increased because this regime can facilitate consumption and at the same time could facilitate under-reporting. A study for Kazakhstan analyzes the impact of changes in the minimis thresholds and finds partial and negative effects on the *e-commerce* and the under-reported value of products, as well as restrictions due to the lack of statistical evidence. The study mentions that measuring this is difficult and supervised monitoring of flows is offered. As for the *e-commerce* of cosmetic products, these results inform how thresholds and messaging systems affect each other's health control capacity, particularly when volumes are fragmented into multiple shipments with insufficient data (Yeleussizova et al., 2024).

A study conducted in Latin America on changes in regulations around small parcel shipping describes what it calls a 'paradigm shift' in relation to the implementation of cross-border e-commerce in Brazil, compared to unprecedented volumes of parcel traffic and the rise of spam in compliance management. This study suggests that the quality and availability of 'prior information' limit traditional control and implies that enforcement frameworks control and close gaps in claims. For Ecuador, this evidence suggests the need to evaluate the performance of sanitary and customs control compared to traditional shipments compared to small packages, and whether specialized tools are necessary for cosmetics given the profile of safe, but highly risky counterfeits (Morini et al., 2024).

1.2.5 Compliance, SMEs and Reducing Corruption Risks

The literature on trade facilitation has also paid attention to SMEs, as they face greater difficulties in adapting to technical requirements, procedural changes and learning burdens linked to new platforms or document rules. In the import of cosmetics, this situation is reflected in an uneven capacity to manage technical files, respond to observations and maintain regulatory compliance. In turn, digitalization has been examined for its relationship with discretion, transparency and corruption risks when institutional integration is incomplete, which makes it pertinent to analyze whether coordination between health and customs reduces contacts, times and spaces of arbitrariness (Mavlonov, 2023; Thu Hien & Quang, 2022).

1.2.6 Recent Trends in Cosmetics Regulatory Safety

Recent developments in international cosmetic regulations show a trend towards stricter demands in the areas of safety, traceability, documentation, reporting and the impacts on imports, supplier selections and challenges in compliance costs. The literature suggests that digitalization and regulatory convergence, when combined with appropriate coding of non-tariff measures, reduce friction, transcription errors, and reporting costs in the presence of data standardization and system interoperability, and frictionless exposure. For Ecuador, this debate allows us to examine how regulatory changes from 2020 to 2024 impacted ARCSA and SENAE in terms of turnaround times, reprocessing and validation controls, and documentation controls and articulation of turnaround, reprocessing and validation times (Fell & Duver, 2024; Ouyang & Park, 2024).

The literature on tariff classification, assistive technologies, artificial intelligence and cross-border e-commerce warns that customs risk management depends on the quality of information and the consistency between declaration, sanitary permits and inspected goods. Tariff dispersion, incorrect coding and automated systems with incomplete data can increase observations, inspections and retentions, while AI demands precise delineation between automated decisions and human review. In small shipments, the low quality of pre-information and operational fragmentation make monitoring difficult, especially in cosmetics due to their traceability per batch, risk of counterfeiting and sanitary control (Dominguez Prost & Scattolo, 2024; Grainger, 2024; Morini et al., 2024; Yeleussizova et al., 2024).

The combination of the trends analyzed indicates that the approach of cosmetic regulations in the context of sanitary requirements must be disaggregated and looked at in the perspective of standards, classifications, documentary controls, interoperability, border risk management and others. Despite this, the literature continues with the same approach and in the general, or comparative, planes, without paying sufficient attention to the evolution of regulations and practice on a certain binomial of health coordination A-1. This limitation would frame the relevance of the analysis of the Ecuadorian case as an area where technical regulation, prior control and operational effects on the dispatch are articulated (Cao & Zheng, 2024; Grainger, 2024; Morini et al., 2024).

CHAPTER 2
REGULATORY REQUIREMENTS AND PROCESSES

2.1 ARCSA-SENAE on Cosmetics Imports

2.1.1 Cosmetics Regulatory Framework in Ecuador

The importation of cosmetics is governed by a regulatory articulation of Community scope and national application. At the Andean level, CAN decisions harmonize sanitary requirements and define responsibilities of the product holder for its marketing in member countries. Internally, ARCSA acts as the National Competent Authority and administers Mandatory Health Notification (NSO) and related authorizations. SENAE, for its part, carries out customs control at the border through the Customs Import Declaration (DAI), verifying commercial documents and documents required by control authorities. The relationship between the two institutions is materialized in the documentary evidence that accompanies the DAI and in the selectivity criteria applied during the capacity (National Customs Service of Ecuador [SENAE], 2024).

The category "cosmetic product" is defined as a formulation intended for contact with superficial parts of the human body or with teeth and oral mucosa, for hygiene, perfume or aesthetic care purposes. For its first commercialization in the Andean subregion, Decision 833 requires an NSO code, processed by means of an affidavit with minimum standardized information. In Ecuador, ARCSA manages the obtaining of the NSO through an automated system and requests data on the owner, manufacturer, technical manager, formula, specifications and label project. The code is used for subsequent customs verification. The reported validity for the NSO is seven years, with the possibility of renewal for equal periods (Andean Community [CAN], 2021).

The typical import flow combines a pre-sanitary stage and a customs clearance stage. First, the operator defines whether the product requires NSO, recognition, modification, parallel importer or a specific authorization, and processes the administrative act in the ARCSA. Then it prepares the commercial operation, logistics and the support file required for the DAI. In the clearance, SENAE requires a transport document, invoice and, when applicable, additional documents required by the competent authority. After transmission, the system assigns a gauging channel (automatic, documentary, physical or non-intrusive physical), according to risk profiles. Subsequent health checks may include surveillance and

actions on labelling and market safety (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022).

The digitalization of health and customs compliance is supported by the use of one-stop shops, where the operator submits information through one point of entry for multiple authorities. The World Trade Organization's Trade Facilitation Agreement promotes the one-stop shop for import documentation and data to be sent only once and distributed to participating entities (World Trade Organization [WTO], 2017, Art.10.4). In Ecuador, the Ecuadorian Single Window is linked to sanitary procedures and the customs computer ecosystem, reducing transfers and document redundancies. This approach is also associated with risk management practices and data analysis in customs (World Customs Organization, 2021).

2.2. Regulatory Evolution of the Applicable Regime between 2020 and 2024

To respond to the requirement for precision, each modification is set forth with three elements: the rule applicable before the change, the amending act with its article, and the practical effect on the evidence that the ARCSA issues or accepts and that SENAE reviews during the dispatch. Priority is given to regulations with a direct impact on imports: entry into force of Decision 833 of the CAN, temporary flexibility of copies in recognition, extensions for stock-outs and adoption of the RTA labelling. The period 2020–2024 is presented by milestones: Decision 857 of the CAN (May 2020), Resolution 2161 of the General Secretariat of the CAN (August 2020), Decision 868 of the CAN (September 2020), validity of Decision 833 of the CAN (March 2021) and Resolution 2310 of the General Secretariat of the CAN (December 2022) with entry scheduled after 24 months.

2.2.1. Background to the Community Regime and Transition to Decision 833

Before 2020, community control of cosmetics was supported by CAN Decision 516 and derived national regulations, with an emphasis on labelling and documentary support of the file. In 2018, CAN Decision 833 was approved with a model aimed at harmonizing information, assigning an NSO code and reinforcing the responsibility of the owner over the technical file (Andean Community [CAN], 2021). During 2020, CAN Decision 833 was not yet fully operational at the border, because its entry depended on transitional provisions and the issuance of the implementing regulation. At that stage, ARCSA maintained national procedures with documentary support and SENAE continued to verify prior control

documents according to the declared operation. This coexistence raised the need to interpret validities and transitions.

2.2.2. Content and Scope of CAN Decision 833

Decision 833 redefines access to the Andean market through a notification procedure, based on minimum information and the responsibility of the holder. Article 9 of the Code provides that the application to issue the NSO code is submitted by means of an affidavit on the Community form (Andean Community [CAN], 2021). Before its entry into force, control was supported by certified copies and formal verifications of the file in each country. With Decision 833, the technical file is in the custody of the owner and can be required in control actions, while the code functions as an identifier (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022). In customs, the consistency between code, description, origin and label is reviewed in the primary zone according to the gauging channel assigned according to the risk profile.

Decision 833 is operationalized by the Community Regulation approved by the General Secretariat of the Andean Community in Resolution 2108 of November 14, 2019, which establishes formats and criteria for the issuance, renewal, recognition and modification of the NSO code (General Secretariat of the Andean Community, 2021). Before its application, operators faced procedural differences between member countries, especially in legalizations and copies. With the Regulation, the information is organized in standardized annexes and the code is consolidated as a reference for inter-institutional verification. In Ecuador, the ARCSA links the procedure to the Transitory System 833 and the Ecuadorian Single Window, which consolidates electronic files (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022). For SENAE, standardization facilitates comparisons between the NSO and the DAI within the ECUAPASS during capacity.

2.2.3. Temporary Regulatory Adjustments during 2020 and 2021

CAN Decision 857 marked the first temporary adjustment of Decision 833. Prior to the change, the fifth final provision of Decision 833 contained the date scheduled for its entry into force. Article 4 of Decision 857 replaced that provision and set March 1, 2021 as its effective date (Andean Community [CAN], 2020). The variation postponed the transition during 2020. At ARCSA, the postponement involved maintaining national procedures while platforms and instructions for the system based on the code were adjusted. At SENAE, the customs operation continued under prior references and with documentary review according

to the risk profiles and the gauging channel, with the requirement of coherence between supports and the DAI, especially for imported cosmetics.

CAN Decision 857 adjusted labeling during the transition to Decision 833. Prior to the amendment, the control practice was based on the presence of the notification number printed on the packaging, which is useful in inspections. Article 3 of Decision 857 incorporated Article 33 into CAN Decision 516 and stated that the printing of the NSO number obtained under Decision 833 on labels shall not be required (Andean Community [CAN], 2018, Art.3). At ARCSA, the move decreased etiquette observations and shifted control to the file and code. In SENAE, visual verification lost a direct piece of data, so that the dependence on documentary comparison between DAI, invoice, description and health code increased (SENAE, n.d.).

In 2020, the General Secretariat of the Andean Community of Nations issued a documentary relaxation for the recognition of the NSO code. Prior to August 2020, the procedure required certified copies of NSO-related documents. CAN Resolution 2161 temporarily authorized the submission of simple copies, physical or digital, for the recognition of the NSO code for cosmetics, managed under Decision 833, effective until December 31, 2020 (General Secretariat of the Andean Community, 2020, Art. sole). For ARCSA, the provision reduced legalization barriers and facilitated continuity during mobility restrictions. For SENAE, the effect was expressed in electronic media annexed to the DAI, without changing the obligation to keep documentation, which is always verifiable for subsequent controls (SENAE, n.d.).

The documentary flexibility was extended beyond 2020. Prior to February 2021, the authorization of plain copies had ended on December 31, 2020, in accordance with CAN Resolution 2161. CAN Decision 873 extended the acceptance of plain copies, physical or digital, for the recognition of the NSO code of cosmetics until December 31, 2021 (Andean Community [CAN], 2021, Art.1). In the ARCSA, the extension maintained recognitions without legalization costs in the institutional reopening. In SENAE, the effect was reflected in electronic supports of the DAI and in non-intrusive documentary or physical gauging, with verification of coherence between documents and declaration (National Customs Service of Ecuador [SENAE], 2024). The measure was temporary and required the preservation of evidence that was always verifiable.

2.2.4. Exceptional Regime for Stock-Out

Stock-out became a central issue during the transition. Prior to September 2020, the regulatory change could require relabeling or withdrawal of products under the previous regime. CAN Decision 868 approved an exceptional provision to allow stock-outs and authorized the sale of products with previous conditions until June 30, 2021, with an additional period to deplete inventories (Andean Community [CAN], 2020, Art.1). In the ARCSA, the rule was applied through authorizations and verifications on batches and dates of entry. In SENAE, the impact was reflected in the review of documents attached to the DAI, because goods could be imported with transition labels, requiring a comparison between authorization, commercial description and declared quantity (National Customs Service of Ecuador [SENAE], 2024).

The stock-out policy was adjusted in 2021. Before February 2021, CAN Decision 868 set June 30, 2021 as the deadline for selling products with previous conditions. CAN Decision 872 amended Article 1 of Decision 868 and extended the measure until December 31, 2021 (Andean Community [CAN], 2021, Art.1). The change extended the adaptation time for operators, with effects on purchase scheduling and labeling. In the ARCSA, criteria were adjusted to authorize exhaustion according to the new date. In SENAE, the extension maintained the entry of items with transition labeling, which required reviewing authorizations and documentary coherence between supports and DAI in documentary and physical capacity (National Customs Service of Ecuador [SENAE], 2024).

2.2.5. Andean Technical Regulations on Labeling and Operational Effects in 2024

The Andean Technical Regulation on the Labeling of Cosmetic Products was approved by Resolution 2310 of the CAN, of December 16, 2022. Before its adoption, labeling was governed by prior provisions and national guidelines, with differences between countries. This Community regulation on the labelling of cosmetic products set minimum contents, language, legibility and rules for the complementary label. Its final provision establishes 24 months for entry into force from publication (General Secretariat of the Andean Community, 2022). With that deadline, the RTA projects enforceability in December 2024, forcing information changes to be planned. Numeral 4.4 regulates the complementary label when mandatory information is lacking. For ARCSA and SENAE, the scheme redefines the revision of labeling in the primary zone and may generate observations due to inconsistencies with the DAI (National Customs Service of Ecuador [SENAE], 2024).

The RTA's entry into 2024 relates to previous transitions. Between 2020 and 2021, Decision 857 reduced requirements associated with printing the NSO number, and Decisions 868 and 872 enabled stock-outs with pre-labeling. In 2024 those mechanisms had expired and the standard of Resolution 2310 remained. Prior to the due date, the operator could adjust labels and supports to avoid observations. After the entry of the RTA, Article 7 regulates the complementary label when mandatory information is lacking, with readability rules (General Secretariat of the Andean Community, 2022). For SENAE, the probability of observations in physical capacity increases when the labeling does not coincide with the DAI or with the health authorization (National Customs Service of Ecuador [SENAE], 2024).

Table 3

2020–2024 Comparative Matrix on Requirements, Procedures and Operational Effects on the Import of Cosmetics (ARCSA–SENAE)

Process phase	2020: requirements	2020: Procedures	2020: Operational effects	2024: Requirements	2024: Procedures	2024: Operational effects
Prior health authorization (ARCSA)	Transition context with coexistence of previous rules and adjustments towards the community regime based on the NSO code; definition of the applicable procedure (NSO issuance, recognition or authorization).	Management oriented to documentary support, with institutional adaptation due to regulatory changes; prior health control as a condition for first marketing.	Increase in correction requirements due to validity and inconsistencies of the health support with commercial data; delays in the preparation of the file for the DAI when the support is not issued or does not coincide with the declared owner/manufacturer/labeling.	Sanitary standard with NSO as an operational identifier; Digitized and traceable compliance.	Processing in electronic systems linked to the VUE; Registration of statuses, changes and renewals with digital media.	Less burden of face-to-face procedures, with an increase in observations when the sanitary support is not in force or when there is inconsistency between NSO, owner, manufacturer, product version and labeling; possible blockage of the release if the prior control document is observed.
NSO code recognition (when applicable)	Temporary flexibilities in documentary support for recognition, with acceptance of simple copies within defined deadlines.	Procedure with emphasis on simple digital or physical support during the authorized window, maintaining the obligation to keep verifiable evidence.	Reduction of certification costs; greater dependence on the digital file under review; Observations focused on the integrity of the file and correspondence of the acknowledgment with the declared product.	Return to the ordinary standard after the deadlines; requirements and instructions that order evidence and custody of the file.	Standardized process by modules and integration of the support to the digital file for prior control.	Observations focused on the validity and correspondence of the recognition with the DAI; when the recognition does not correspond or is not in force, prior control observation is recorded and the dispatch remains pending until corrected.
Dispatch Preparation (Operator)	Commercial and prior control requirements for the DAI: invoice, transport document and health support applicable as the case may be.	Assembly of the file with transition to digital annexes; dependence on documentary support to avoid observations in capacity.	Longer internal review time due to transients; frequent errors in commercial description, product version and coincidence with NSO, with an increase in the probability of documentary observation in capacity.	Digital file as the basis for compliance; current sanitary supports and consistent with the DAI at the time of release.	VUE–ECUAPASS interoperability-oriented preparation; uploading of documents and electronic traceability of annexes.	Friction is concentrated in consistency and validity; Inconsistencies generate observations before the release and force corrections of the file or replacement of the support.

Customs Import Declaration (SENAE/DAI)	DAI with commercial annexes and prior control documents; Review guided by risk management and selectivity.	Transmission, validation, channel assignment and capacity; In the event of observations, correction is required within the flow of the system.	Higher probability of observations due to health transitions and heterogeneity of supports; delays for correction and justifications within the office.	DAI supported by operating manuals and interoperable prior control statements.	Formalized flow: validation, settlement, payment, selectivity and capacity; observations and corrections recorded in the system.	Blocking of the release when the pre-control support is not in force or there is an inconsistency between NSO, labeling, description, origin and annexes; The dispatch continues after the correction accepted.
Control in the primary area (documentary/physical capacity)	Adjustments that reduce visual supports on the label with respect to the printing of the NSO number, with the control shifting to document comparison.	In documentary, DAI-annexes are verified; In physical form, the brand, batch, labeling and identity of the product is inspected in front of the sanitary support.	Intensification of documentary comparison due to the absence of printed data; Temporary authorizations and transition labeling increase observations in physical capacity and document the need for additional backups.	Greater weight of labelling by the Community technical framework; minimum content requirements, language, readability and complementary label where applicable.	Documentary and physical capacity with lists and manuals; systematic contrast between merchandise, ICD and sanitary supports, with verification of labeling.	Observation in physical capacity when the labeling does not coincide with the ICD or with the sanitary support; need for rectification/correction or presentation of applicable support (e.g., current version or supplementary label in accordance with applicable rules).
Surveillance and subsequent control (market)	Obligation to safeguard technical files and backups; possibility of requirements in control and surveillance actions.	Surveillance triggered by security verification and labeling; minimum traceability requirement despite temporary flexibilities.	Corrective actions and labeling or file adjustments when the evidence does not match the NSO; indirect impact on future imports due to a history of non-compliance.	Traceability reinforced by digitization of validities, changes and renewals; subsequent control linked to file-label coherence.	Surveillance supported by electronic history; Tracking of versions and changes reported in the system.	Preventive corrections and possible suspension of imports of the product when the sanitary support does not reflect the imported version or the labeling does not comply; Increased pressure to align file, label, and declared data.

Note. Prepared by the author based on the 2020–2024 regulatory and operational analysis on the import of cosmetics (ARCSA–SENAE) developed in Chapter 2

2.3. ARCSA Procedures in the Importation of Cosmetics

The ARCSA intervenes in the import of cosmetics as the health authority that issues the NSO and processes authorizations related to marketing. During the period 2020–2024, the most visible change was the transition to electronic procedures aligned with Decision 833 and the Ecuadorian Single Window. The agency publishes the obtaining of NSO through an automated system and requires data on the owner, manufacturer, technical manager, formula and label project. The Ecuadorian Single Window functions as a channel of interaction for foreign trade procedures with various entities. Digitization reduces and prioritizes document traceability. The standardization is supported by instructions from ARCSA's Transitional System 833, which specify steps for code issuance, recognition, changes, and complementary records (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022).

2.3.1. Obtaining, Validating and Renewing the Mandatory Health Notification

Obtaining NSO is a prerequisite for marketing and conditions the importation of cosmetics. Prior to the entry into force of Decision 833, the applicant followed national schemes with records and certified copies. With Decision 833, the request is based on an affidavit with minimal information; while the technical file remains in the custody of the owner, for eventual controls (Andean Community [CAN], 2018). In Ecuador, ARCSA publishes requirements for company data, manufacturer, technical manager, composition and label project. Procedure managed online. The assigned code acts as a reference in subsequent procedures and can be declared when the DAI requires proof of health control. The coherence between the NSO, label and DAI is reviewed in the capacity (National Customs Service of Ecuador [SENAE], 2024).

2.3.2. Recognition of the NSO Code and Adaptation to the Transitional System 833

The adaptation of the ARCSA to Decision 833 is formalized in the External Instruction of the Transitory System 833. Before the EU came into force, the operator faced varying requirements. The instruction standardizes access to the system, creation of requests and payments, and incorporates modules for code issuance, recognition, parallel importer and notification of changes (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022). The document adopts the logic of affidavit provided for in Article 9 of Decision 833 of the CAN, aligning the responsibility of the user and the registration of data (Andean Community [CAN], 2018). In 2020–2024, evidence of compliance is expressed in

procedure numbers, electronic receipts, and PDF attachments. This evidence is part of the filer of the declarant and supports the DAI in the ECUAPASS when prior control documents are reviewed.

The recognition of the NSO code enables the marketing in Ecuador of a cosmetic notified in another member country. Prior to August 2020, the process required certified copies of documentation associated with the NSO. Between August 2020 and December 2021, Resolution 216 and Decision 873 of the CAN authorized simple copies, physical or digital, with limited validity (General Secretariat of the Andean Community, 2021; General Secretariat of the Andean Community, 2020). After December 31, 2021, the ordinary standard returned and the ARCSA published formally supported requirements, including certified copies and representative documents, as the case may be (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022). In the office, the recognition operates as a health support and is compared with the DAI under the assigned capacity channel.

2.3.3. Information on Changes and Modifications of Cosmetic Products

Modifications to a cosmetic with the NSO in force are managed through the process of information of changes and/or modifications. Prior to Decision 833, variations in manufacturer, formula, or labeling could require extensive paperwork or re-registration. With Decision 833, Article 13 distinguishes changes subject to notification and alterations that require modification of the code, under harmonized criteria (Andean Community [CAN], 2018). The ARCSA publishes a procedure to report changes in cosmetics and requires the owner to keep the file updated and report authorized variations (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022). In imports, the batch must correspond to the current version declared. In SENAE, the DAI can receive observations if the label or manufacturer differs from the sanitary support; The evidence of modification supports differences between operations.

The validity and renewal of the NSO condition the continuity of importation. The ARCSA informs a seven-year validity for the NSO of cosmetics and the possibility of renewal for equal periods. With Community harmonization, the NSO code functions as a reference and the holder assumes the burden of keeping the authorization in force in each market. During the period 2020–2024, this rule was linked to digitization, because the system registers expirations, renewals and changes, generating traceability of statuses (National Agency for Sanitary Regulation, Control and Supervision [ARCSA], 2022). In

foreign trade, an expired code may give rise to observations by a prior control document that is not in force, under documentary and physical gauging channels (National Customs Service of Ecuador [SENAE], 2024). Preventive control incorporates the monitoring of validity and permanent updating.

2.3.4. ARCSA Special Procedures: Parallel Importer, Stock Out and Samples with No Commercial Value

The parallel importer has an impact on the identification of the authorized operator before the health authority. Prior to the standardization of Decision 833, importation was rigidly linked to the holder or his representative. With the CAN's Transitional System 833, the ARCSA enables a module to register parallel importers associated with an existing NSO, without transferring ownership of the product (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2022). The technical file remains in the custody of the owner, while the parallel importer assumes commercial and customs responsibilities. In imports, the registration avoids observations due to discrepancies between the declarant and the authorized operator in the sanitary support. At SENAE, traceability improves risk management by linking DAI, importer, holder and product. In gauging, brand, lot and labeling are verified (National Customs Service of Ecuador [SENAE], 2024).

The ARCSA operationalizes the depletion of stocks through a specific procedure. Prior to CAN Decision 868 of September 30, 2020 and CAN Decision 872 of January 15, 2021, the sale of products labeled under the previous regime could generate uncertainty. With the decisions, ARCSA published a procedure for requesting authorization to deplete stocks of cosmetics, with requirements and steps (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2023). The applicant identifies the product and its NSO, supports inventory, batches and dates, and submits a marketing plan within the authorized timeframe. The authorization affects imports when previous batches enter with transitional labeling, because it can be required as support in customs. In SENAE, having a sanitary authorization reduces observations when the gauge detects differences in etiquette compared to the current standard and verifies the temporary protection.

Imports of samples with no commercial value require differentiated treatment because they are not intended for sale. The ARCSA publishes a procedure to authorize the import of cosmetic samples, with requirements on identification of the applicant, description of the product, purpose, quantities and commercial documents (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2024). Prior to standardization in the one-

stop shop, this type of entry could be managed with less uniform criteria. In the period 2020–2024, the formalization of the procedure reduces uncertainty about the applicable regime and delimits the relationship between quantity and use. In SENAE, the authorization is incorporated as a support and is reviewed during the capacity when the merchandise enters by courier or under simplified modalities, where the risk is evaluated based on the description, declared value and documents (National Customs Service of Ecuador [SENAE], 2024).

2.3.5. Subsequent Health Control and Surveillance

Health management does not end with the issuance of the NSO. ARCSA maintains control and surveillance powers, including security verification and labeling. With Decision 833 of the CAN, the technical file is in the custody of the owner and can be required by the authority, reinforcing the obligation to keep backups of formulas, tests and labels (Andean Community [CAN], 2018). In the period 2020–2024, digitalization facilitated histories of changes and renewals. When non-compliances are detected, the operator can adjust products or stop imports while regularizing the situation. In SENAE, interaction appears when the system requires current support such as prior control documents, or when the risk incorporates health alerts to assign physical capacities and review goods, labeling and attached documentation.

The labeling connects the sanitary assessment with the customs inspection. In 2020, CAN Decision 857 reduced the requirement to print the NSO number on the label, shifting control to the file and code (Andean Community [CAN], 2020). In 2022, the labeling RTA was approved by Resolution 2310 of the CAN, with entry projected in December 2024, and the regulation made to the complementary label in the within numeral 4.4 of said resolution (General Secretariat of the Andean Community, 2022). Prior to enforceability, ARCSA and operators adjust labels; Now, the control focuses on ensuring that the mandatory information is present, legible and consistent with the file. At SENAE, the labeling is reviewed in physical capacities and is also contrasted with the DAI.

2.4. SENAE Procedures in the Import Clearance of Cosmetics

2.4.1. Customs Import Declaration and Supporting Documents

SENAE exercises customs authority over the entry of goods and administers import clearance through ECUAPASS. The operation begins with the transmission of the DAI, accompanied by commercial documents, invoices and transport documents, and by

additional documents when the goods are subject to a specific control. In the period 2020–2024, interoperability with the Single Window strengthened data exchange and reduced duplication of deliveries. For cosmetics, DAI may require ARCSA supports, such as NSO, recognition, and authorizations, as the case may be. In the dispatch, health compliance is translated into a prior control document that must be in force at the time of release, under the capacity channel assigned by the risk profile (National Customs Service of Ecuador [SENAE], 2024).

2.4.2. Clearance Stages, Customs Selectivity and Risk Management

Import clearance is structured in the transmission of the DAI, settlement, payment, selectivity and capacity. The 2024 procedure indicates that the DAI is validated in the ECUAPASS, settled, paid and submitted to selectivity for channel assignment under the risk profiles. In the documentary capacity, the technician reviews the declaration and can request corrections or justifications, suspending the flow until its acceptance. In prior control documents, if the competent authority registers observations, the declarant corrects within the system's deadlines (National Customs Service of Ecuador [SENAE], 2024). For cosmetics, the observations are usually related to the validity of the NSO, data consistency or lack of authorizations. In the period 2020–2024, online exchange predominates, with an emphasis on data quality and document traceability.

Customs selectivity is based on risk management and determines the control applied to each DAI. SENAE describes automatic, documentary, physical and non-intrusive physical channels, assigned by risk profiles (National Customs Service of Ecuador [SENAE], 2024). In the period 2020–2024, digitalization strengthened data analysis and the use of annexes, reducing dependence on physical delivery. The approach coincides with standards from the World Customs Organization, which recommend focusing inspections on higher-risk operations and strengthening documentary controls (World Customs Organization, 2021). The assigned channel defines the depth of the labeling control and the need for physical inspection in the primary area.

2.4.3. Documentary, Physical Intrusive and Non-Intrusive Physical Gauging

Documentary capacity is frequent in cosmetics due to its dependence on health supports and data coherence. In the Specific Manual for the Modality of Clearance with Document Gauging Channel for Import (SENAE-MEE-2-2-011-V4), it is established that the technician reviews the DAI and the digitized documents, validates consistency of data

and requirements, and registers observations in the event of inconsistencies (National Customs Service of Ecuador [SENAE], 2026). In the period 2020–2024, the review is based on the electronic file of the declarant, a requirement that increases the burden of documentary quality and correspondence with numbers of health procedures issued by the ARCSA. A typical inconsistency is declaring an NSO expired or unrecognized, which generates requirements before release. The modality favors the targeting of resources and reserves physical inspection for higher-risk operations, in line with customs risk management (World Customs Organization, 2021).

Intrusive physical gauging combines documentary review and material verification of the goods. The Specific Manual for the Modality of Dispatch with Import Intrusive Physical Gauging Channel (SENAE-MEE-2-2-004-V7), indicates that the technician inspects packages, compares merchandise with the DAI and reviews digitized documents, recording findings and results (National Customs Service of Ecuador [SENAE], 2024). In cosmetics, the modality verifies labeling, language, brand, batch and correspondence with the health support. In the period 2020–2024, the technician operates with electronic annexes and cross-referencing of information, maintaining the inspection of the packaging and the product. The projected enforceability of the RTA increases the sensitivity of the physical control, because the labeling becomes a verifiable element against community standards, when complementary label is used or when there are reported changes in presentation (General Secretariat of the CAN, 2022).

The non-intrusive physical gauging incorporates inspection technologies that reduce the opening of packages. The Specific Manual for the Modality of Dispatch with Non-Intrusive Physical Import Gauging Channel (SENAE-MEE-2-2-004-V1), establishes a procedure that combines documentary review with non-intrusive tools to detect inconsistencies between what is declared and what is transported (National Customs Service of Ecuador (SENAE), 2023a). In cosmetics, the modality helps to verify the number of packages, densities and signs of undeclared merchandise, reserving intrusive inspection for cases where the risk justifies it. In the period 2020–2024, the decision to open a shipment is supported by data, operator history and health supports, which reduces physical intervention when documentary evidence is consistent (National Customs Service of Ecuador (SENAE), 2023a).

2.4.4. Management of Prior Control Documents

The prior control documents are managed in coordination between the competent authorities depending on the nature of the product and SENAE. In the Single Window, the competent authority registers the approval or observations and the ECUAPASS reflects that status within the DAI flow. In the 2020–2024 period, interoperability reduced in-person procedures and expanded the traceability of reviews. For cosmetics, documents issued by the ARCSA, such as the NSO, recognition or authorization of samples, act as conditions for release under sanitary control (ARCSA, n.d.). If the ARCSA registers an observation, the respondent corrects it in the system; if it does not, the dispatch is stopped according to the respective procedure. In the period 2020–2024, simple copies in recognition facilitated digital support and reduced revision times (Andean Community [CAN], 2021). Coordinating requires continuous control.

2.5. Comparison of Regulatory Effects between ARCSA and SENAE

2.5.1. Impact of Documentary and Labeling Flexibilizations

Between 2020 and 2024, two flexibilizations altered files reviewed in Customs: simple copies in recognition and no requirement to print the NSO number on the label. Prior to these measures, the importer presented endorsements more formally and the inspection could rely on the printed number. CAN Resolution 2161 of August 10, 2020 and CAN Decision 873 of February 25, 2021 authorized simple copies in recognition for limited periods, and CAN Decision 857 of May 26, 2020 reduced a labeling requirement (Secretariat of the Andean Community, 2021; Secretariat of the Andean Community, 2020; General Secretariat of the Andean Community, 2020). In SENAE, the annexes were digitized with a lower certification burden and verification was oriented towards other identifiers. At ARCSA, the measures maintained procedures during restrictions, without eliminating the duty to preserve verifiable evidence for subsequent controls.

2.5.2. Projection of Andean Labeling in Sanitary and Customs Control

In 2024, the change with the greatest projection in SENAE is linked to labeling by the entry of the RTA. Before its enforceability, the labeling control was based on previous references and health supports, with intense review in physical capacity. CAN Resolution 2310, of December 12, 2022, sets community parameters and regulates the complementary label in numeral 4.4 (General Secretariat of the Andean Community, 2022). For SENAE, the framework favors incorporating labeling variables in risk profiles and in checklists of

intrusive capacity, where merchandise is compared with the DAI and the annexes (National Customs Service of Ecuador [SENAE], 2025). For ARCSA, surveillance is aimed at consistency between file and label, with traceability of versions and support for authorized changes in the system.

2.5.3. Functional Division and Documentary Articulation between ARCSA and SENAE

The institutional comparison shows a functional division with documentary contact. ARCSA controls prior sanitary clearance and manages the NSO code lifecycle, with associated acknowledgment, changes, and importers (ARCSA, 2022). SENAE controls the entry of goods at the border and administers the DAI, applying selectivity and capacity according to the risk profile (SENAE, 2024a). Prior to 2020, contact was concentrated on certified copies and formal verifications. In the period 2020–2024, contact shifts to electronic evidence: processing numbers, digitized attachments, and prior control document statuses at the Ecuadorian Single Window. The health support becomes data that can be crossed with the declaration. The coherence between NSO, etiquette, and DAI dominates the review in documentary and physical capacity (SENAE, 2024c).

Between 2020 and 2024, community standards adjusted labeling and documentary evidence, with impacts on ARCSA and SENAE in Ecuador. In labeling, before the change, the NSO number could be required to be printed; then, CAN Decision 857 provided that printing will not be required for products under CAN Decision 833 (Andean Community [CAN], 2020). The ARCSA reoriented control to file and code, and SENAE reinforced documentary comparisons. In documentary evidence, before the change, the recognition required certified copies; then, CAN Resolution 2161, of August 10, 2020, and CAN Decision 873, of February 25, 2021, admitted simple copies until December 2021 (Andean Community Commission, 2021; General Secretariat of the Andean Community, 2020). ARCSA reduced legalization burdens and SENAE received digitized files, maintaining verification.

The exhaustion of stocks shows the relationship between Community legislation and national procedure. Prior to September 2020, pre-labeled inventories could be out of compliance during the transition. CAN Decision 868 authorized the sale of products under previous conditions until June 30, 2021, and CAN Decision 872 of February 25, 2021, extended until December 31, 2021 (Andean Community Commission, 2020; Andean Community Commission, 2021). The ARCSA implemented an exhaustion authorization

procedure with requirements on the NSO, inventory, lots and marketing plan (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2021). In SENAE, the authorization supports the DAI when previous batches enter with transition labeling; their absence generates observations. After the measure expires, in 2024 the planning is oriented to the labeling RTA (General Secretariat of the Andean Community, 2022).

Two ARCSA procedures illustrate the adaptation of sanitary control to different purposes: sample authorization and parallel importer registration. Before their formalization, these cases could be managed with less standardized routes, generating uncertainty in Customs. In the period 2020–2024, the ARCSA publishes a procedure to authorize samples with no commercial value and a module to register parallel importers linked to an NSO (ARCSA, 2022; ARCSA, 2024). In SENAE, both cases are reflected in the DAI file: the authorization justifies quantity and purpose, and the registration of the parallel importer supports the identity of the operator. In the documentary review, the technician compares annexes; in manual review, it verifies presentation and labeling (SENAE, 2024c). Digital evidence and data consistency underpin border control.

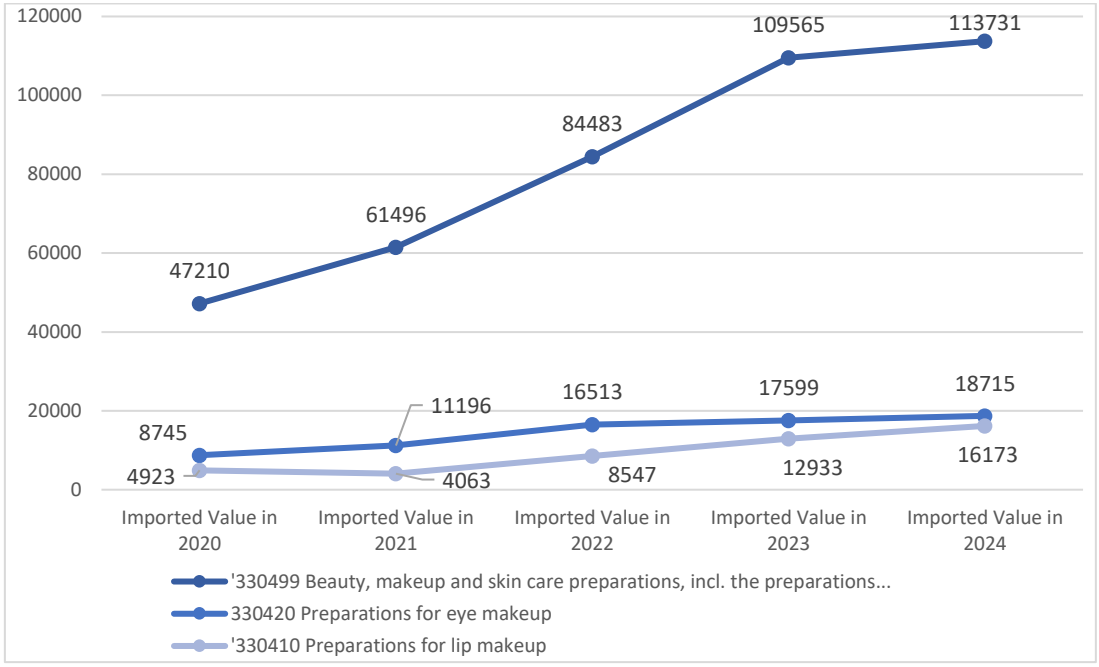
2.6. Impact on Cosmetic Import Values and Volumes

The different regulatory changes that have taken place in SENAE and ARCSA during the period 2020-2024, after the COVID-19 pandemic, have caused the figures on cosmetics imports to be affected, for which reliable databases that reflect this information have been analyzed, where the study focuses on the three main tariff subheadings of cosmetics. Figure 1 shows the values of these imports of the subheadings, for which their values were taken into account to classify the following:

1. 330499 Beauty, make-up and skincare preparations, incl. sunscreen preparations and tanning (excl. medicinal products, lip or eye make-up preparations, manicure or pedicure preparations and powders, incl. compacts)
2. 330420 Preparations for eye make-up
3. 330410 Lip make-up preparations

Figure 1

Imports of the Main Tariff Items of the Cosmetics Sector in Ecuador in the Period 2020-2024

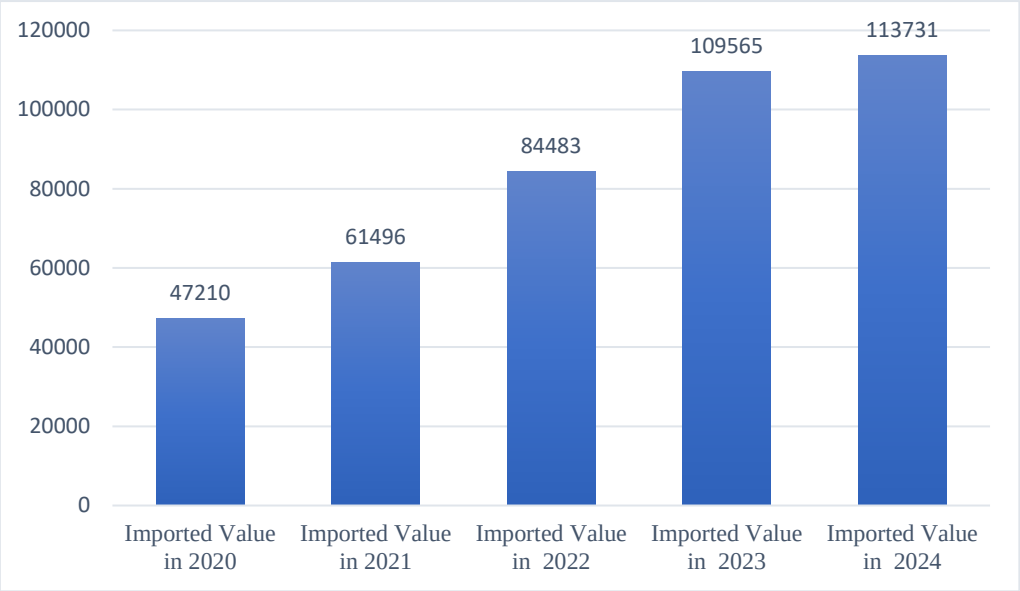


Note. Values expressed in thousands of dollars. Adapted from *Trade Map*, by the International Trade Centre (2026).

Looking at Figure 2, on the main tariff subheading 330499, which belongs to "Beauty, make-up and skin care preparations, incl. anti-sun preparations and tanning (excl. medicines, preparations for lip or eye make-up, preparations for manicures or pedicures and powders, incl. compacts)", which includes all those products considered basic in the area of cosmetics. It can be seen that within the period 2020-2024 the subheading has been positively affected by the regulatory evolution of both SENAE and ARCSA, since its values have been increasing over the years. In 2020, its imports had a value of $47,210 thousand dollars, while in 2024 the increase was radical with a value of $113,731 thousand dollars. This reflects that between 2020 and 2024 imports rose by 58.5%, being a fairly considerable value and thus evidencing that the different decisions that were taken in that period to facilitate foreign trade were the right ones.

Figure 2

Imports of subheading 330499 Beauty, make-up and skincare preparations, incl. anti-sun preparations and tanning agents (excl. Medicines, Preparations for Lip or Eye Make-up, Preparations for Manicures or Pedicures and Powders, incl. Compacts) in the Period 2020-2024

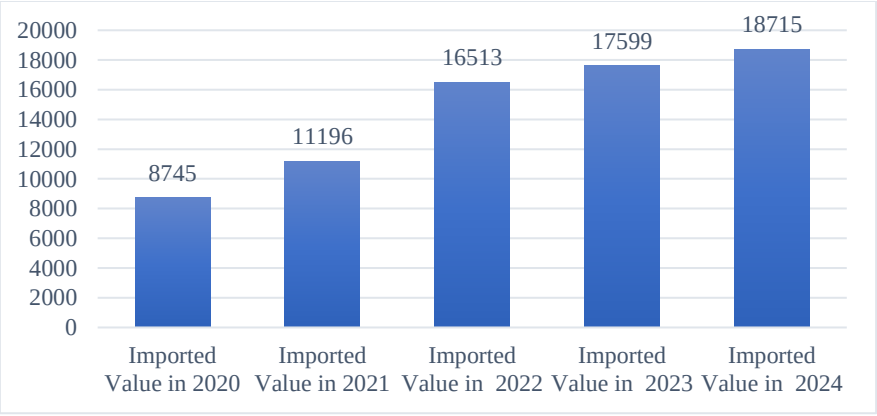


Note. Values expressed in thousands of dollars. Adapted from *Trade Map*, by the International Trade Centre (2026).

As for Figure 3, on the second tariff subheading of cosmetics: 330420 of preparations for eye makeup, the reaction is similar, since its figures also increased during this period, without any exception within these years. In 2020 it had a value of $8,745 thousand dollars, while in 2024 it has a value of $18,715 thousand dollars, thus evidencing the increase in its imports by 53.3%. However, the most noticeable change in this subheading occurs between 2021 and 2022 where the increase was 32.2%, which can be linked to the total reactivation after the COVID-19 pandemic.

Figure 3

Imports of Preparations for Eye Make-up Subheading 330420

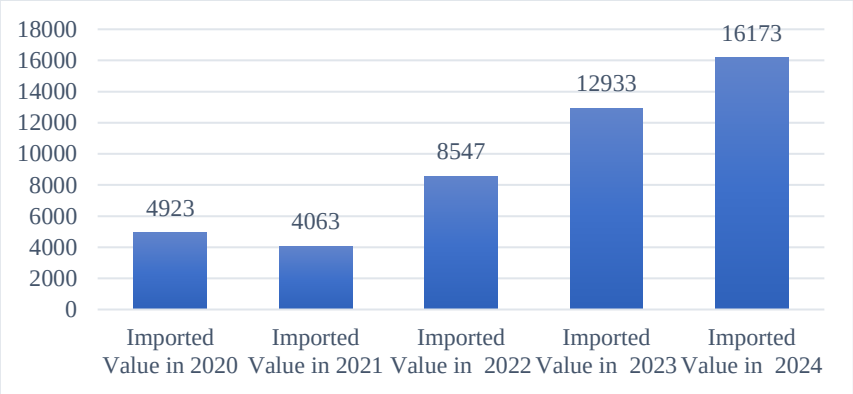


Note. Values expressed in thousands of dollars. Adapted from *Trade Map*, by the International Trade Centre (2026).

And as third on this list is subheading 330410 which belongs to preparations for lip makeup. In Figure 4, it can be seen that in this one the picture is different, since in relation to 2020 with 2021 the figures fell by -21.2%, which could be related to the use of masks at that time due to the pandemic, so these products became unnecessary for most consumers since they had other priorities. However, in 2022 this value increases by 52.5%, which responds to the relaxation of health measures.

Figure 4

Imports of subheading 330410 Preparations for lip make-up



Note. Values expressed in thousands of dollars. Adapted from *Trade Map*, by the International Trade Centre (2026).

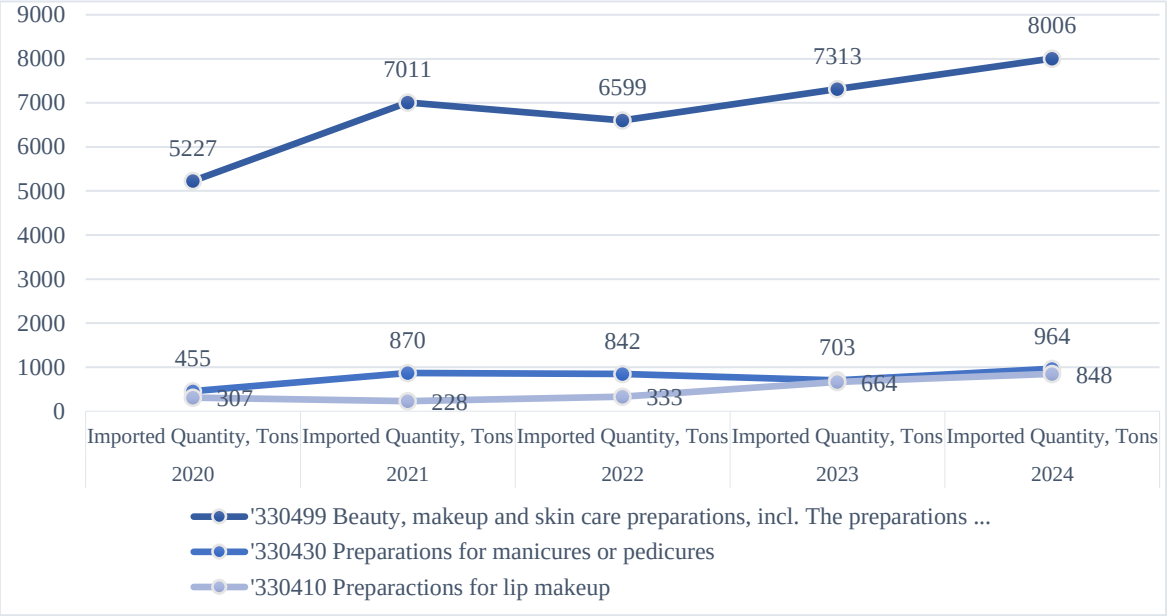
After analyzing the behavior of cosmetics imports based on monetary values, it is essential to compare whether they identify the same three main subheadings in terms of their physical volume, in order to know if the economic recovery is due to a greater demand for the products or to significant changes in the unit cost. To begin with, there is Figure 5, which identifies the three main tariff subheadings based on the quantity in tons of them. Where the following were recognized as the three main tariff subheadings:

1. 330499 "Beauty, make-up and skincare preparations, incl. sunscreen preparations and suntan lotions" (excl. medicines, preparations for lip or eye make-up, preparations for manicures or pedicures and powders, incl. compacts)"
2. 330430 "Preparations for manicures or pedicures"
3. 330410 "Preparations for lip makeup"

This analysis reveals that two of the main tariff subheadings, based on their values in thousands of dollars, are also the most representative in terms of their quantity in tons imported.

Figure 5

Imports of the Main Tariff Items of the Cosmetics Sector in Ecuador in the Period 2020-2024

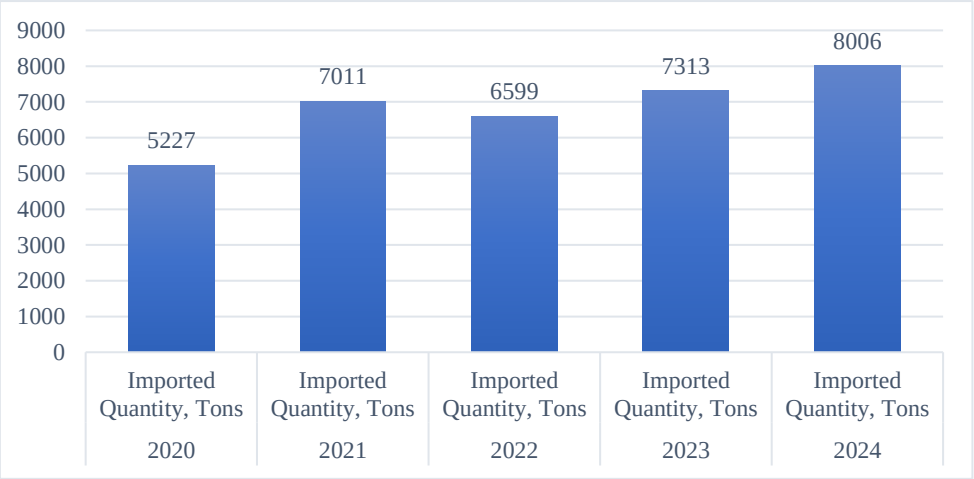


Note. Values expressed in tonnes. Adapted from *Trade Map*, by the International Trade Centre (2026).

Figure 6, corresponding to the main tariff subheading in terms of quantity in tonnes, which is 330499, belonging to beauty, make-up and skin care preparations, incl. anti-sun preparations and tanning (excl. medicines, preparations for lip or eye make-up, preparations for manicures or pedicures and powders, including compacts). Which it also led based on its value in thousands of dollars. It was perceived that this subheading has an irregular behavior, since, between the years it has suffered increases and decreases. Between 2020 and 2021, it increased by 25%. However, for the following year this did not change and decreased by -6%. For the following years, only increases were observed where it was determined that despite the negative value between the period 2020-2024, its volume increased by 35%.

Figure 6

Imports of subheading 330499 Beauty, make-up and skincare preparations, incl. anti-sun preparations and suntan lotions (excl. Medicines, Lip or Eye Make-up Preparations, Manicure or Pedicure Preparations and Powders, incl. Compacts) in the Period 2020-2024

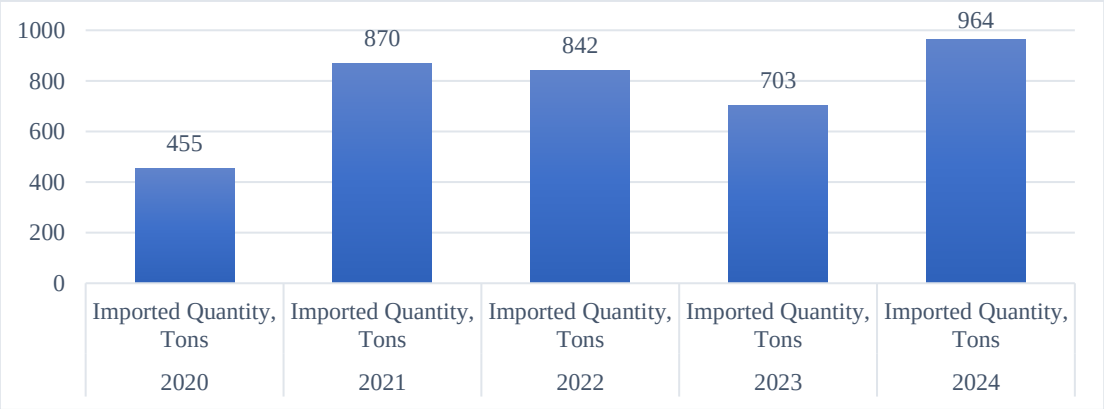


Note. Values expressed in tonnes. Adapted from Trade Map, by the International Trade Centre (2026).

When evaluating Figure 7 of subheading 330430, which corresponds to preparations for manicures or pedicures, it was found that only its behavior based on the volume of imports makes this subheading within the three main ones. Which means that these products are those of mass consumption, but with relatively lower prices, which makes them so attractive to consumers. Therefore, the NSO is of utmost importance when entering a product into the country, since in this way it is ensured that the product that is being imported is safe despite being of a high or low price.

Figure 7

Imports of Subheading 330430 of Preparations for Manicures or Pedicures in the Period 2020-2024

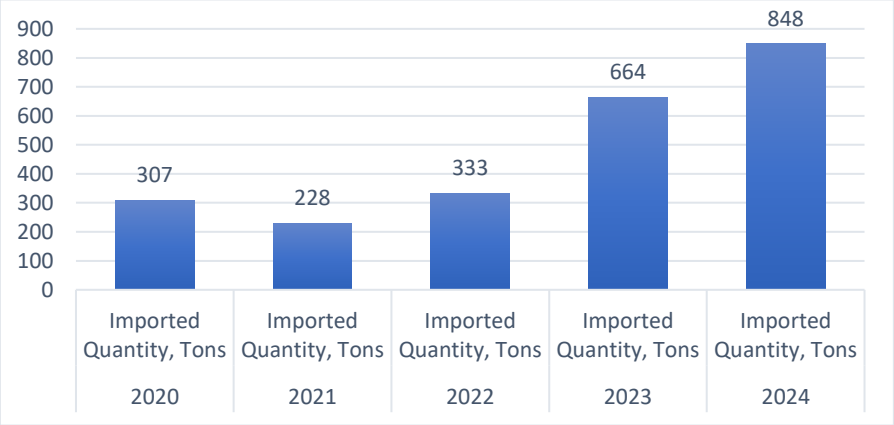


Note. Values expressed in tonnes. Adapted from *Trade Map*, by the International Trade Centre (2026).

As for Figure 8, on subheading 330410 of Preparations for lip make-up. Initially, in relation to 2020 and 2021, it suffers a significant drop of -35%, which can be attributed to external factors such as the COVD-19 pandemic. However, this is not repeated since as of 2021 its figures are increasing. Therefore, between 2020 and 2024 the increase was 64%.

Figure 8

Imports of Subheading 330410 of Preparations for Lip Make-up in the Period 2020-2024



Note. Values expressed in tonnes. Adapted from Trade Map, by the International Trade Centre (2026).

CHAPTER 3
NON-TARIFF BARRIERS

The Ecuadorian legal system's main justifications for non-tariff barriers on cosmetic products are the protection of public health and consumers' right to safety. These measures do not constitute taxes, but technical requirements that must be justified before the National Agency for Sanitary Regulation, Control and Surveillance (ARCSA) and the National Customs Service of Ecuador (SENAE), so that they can release the products (Resolution No. ARCSA-DE-006-2017-CFMR: Technical Sanitary Regulations for the Manufacture, Importation, Conditioning, Storage, Distribution, Transport and Marketing of Cosmetic Products., 2017). "The interaction of these institutions and their regulations guarantees that, even if there is trade liberalization, the country's health protection requirements will not be violated." (Resolution No. ARCSA-DE-006-2017-CFMR: Technical Sanitary Regulations for the Manufacture, Importation, Conditioning, Storage, Distribution, Transport and Marketing of Cosmetic Products., 2017).

The country's legal framework that justifies these measures is found in the Organic Code of Production, Trade and Investment (COPCI), which grants the Legislative Branch the power to establish non-tariff regulations, if there is a sanitary need. The provisions of the COPCI consider border control as the primary means of enforcing the Ecuadorian Technical Standards (NTE) or their internationally recognized equivalents. These standards, in the case of cosmetics, are the requirements of the Mandatory Health Notification (NSO) (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2021).

The controls and processes for the management of barriers have been systematized through the Ecuadorian Single Window (VUE), where each of the control entities have the possibility of presenting their documents and carrying out their controls. In this sense, the ARCSA is the one that authorizes the prior control document, which is a mandatory requirement for the transmission of the Customs Import Declaration (DAI). This, in terms of windows and documents, ensures that no cosmetic product is nationalized without the existence of a technical file that guarantees safety and composition (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2017).

At the supranational level, Decision 833 of the Andean Community (CAN) establishes a regulatory framework for the harmonization of barriers at the level of non-tariff requirements within member countries (Andean Community [CAN], 2021). The aim is to

ensure that the technical requirements are, as far as possible, equivalent in the region, so that sanitary requirements do not constitute unjustified technical barriers to trade (TBT). Therefore, within the framework of the CAN, Ecuador is obliged to ensure that its physical and documentary inspection controls at Customs are compatible with the provisions of the Andean cosmetics regime.

The application of these non-tariff measures responds to the principle of proportionality, preventing these health controls from being protectionist measures. As a contracting party to the WTO and the Agreement on Technical Barriers to Trade, Ecuador must also comply with the corresponding regulation that prevents technical regulations from being more rigorous than necessary to meet a logical objective, such as the protection of national security and the defense against practices that may be misleading (General Secretariat of the Andean Community, 2021). The above-mentioned institutions collaborate and set local requirements to be able to comply with international trade facilitation commitments.

The barriers indicated have a direct impact on the time the goods remain in temporary storage warehouses. Although Ecuadorian customs regulations establish that control is strict, customs supervision must be efficient enough so that the importer does not suffer an economic detriment in relation to the cost of the supervision service. (National Assembly of the Republic of Ecuador, 2014). The implementation of digital processes through ECUAPASS allows, among other things, that ARCSA and SENAE can cross-reference information in real time, reducing the discretion of the official and standardizing the application of the regulations.

3.1 Level of Presumption of Knowledge

The presumption of knowledge in Ecuadorian foreign trade means that any economic operator who chooses to import cosmetics must be familiar with existing sanitary and customs regulations. The importer may not allege ignorance of the law in relation to the importation of unauthorized products that do not have an NSO or unlabeled products that violate the Regulations of Decision 833. This duty of knowledge of the law, in the case of imports, falls on the importer, who is responsible for having all the respective documentation updated and in order (National Assembly of the Republic of Ecuador, 2014).

In this order of ideas, the Ecuadorian Organic Health Law is essential to distribute responsibilities to commercial operators. Article 138 of this law officially establishes the burden of the proponent:

Article 138. - The sanitary notification is the communication by which the interested party informs the national health authority, under affidavit, that he will market in the country a manufactured product, and in the case of an international product, that it meets the quality and safety requirements.

This level of assumption suggests that the act of notification is a commitment to uphold the truth of a statement. The importer claims to have knowledge of the ingredients in its product and that they do not appear on the Andean Community's lists of prohibited substances. Therefore, the State, in a subsequent control, finds a restricted component, acts under the assumption that the operator did this intentionally or, failing that, negligently, since the law on ingredients is readily available and must be observed at the time of importation (Presidency of the Republic of Ecuador, 2011).

Therefore, it is not legitimate for the importer to claim ignorance of the law regarding the illegal importation of products without an NSO or unlabeled products that do not comply with the provisions of the CAN Decision 833 Regulations. This legal responsibility falls on importers, who are obliged to keep all their technical files updated and verified.

In this sense, the Organic Health Law in Ecuador is definitive in determining the liability of commercial agents. From the customs perspective, the Regulations on the Title of Customs Facilitation for Trade, Book V of the Organic Code of Production, Trade and Investment (COPCI) contemplate this (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2017). The importer, by signing the customs declaration, accepts responsibility for the truthfulness and accuracy of all items, including the tariff item. Misclassification to evade an ARCSA permit is considered a serious infraction, since the ECUAPASS system operates under the presumption that the user is aware of the border and related restrictions for each tariff code.

In addition, the ARCs, as part of Resolution ARCSA-DE-2021-016-AKRG, inform that the owner of the NSO must be aware of the scientific advances on their products. If a substance that was previously permissible becomes restricted according to a recently updated Official Aide Memoire, the importer must update the dossier or withdraw the product from the market within a term, otherwise, the substance is considered known to the trade

throughout the life of the cosmetic and not only at the time of granting the permit (National Customs Service of Ecuador (SENAE), 2023).

With such knowledge required, it is evident that there is a non-tariff administrative barrier of a particular kind. Therefore, importers have to spend resources ensuring that they have properly trained personnel, or even specialized customs agencies, to handle such administrative burdens. Where all requirements are met, this allows for a more streamlined clearance process; On the other hand, the lack of diligence in the regulatory knowledge on the part of importers is the main cause of the generation of customs sanctions (National Customs Service of Ecuador (SENAE), 2023).

This 'presumption of knowledge' means that the importer expects that uneven updates in international regulations will necessitate the restructuring or labeling of products to comply with the Ecuadorian market. What is also presented with a marked presumption is the labeling regulations, which receive continuous observations in the district of Cuenca. The Regulations of the Organic Law on Consumer Defense establish that the information must be truthful and in Spanish. An importer must understand that, under Decision 833, data such as an ingredient list (INCI nomenclature) and warnings of use are mandatory; Arguing that such data is missing under the Andean format is not an excuse for a labeling sanction in the primary zone (General Secretariat of the Andean Community, 2021).

The presumption of knowledge also falls on the importer with respect to the "Health Alerts" that are present in international surveillance networks. When ARCSA issues a ruling banning a batch of a particular foreign product, the importer must act ex officio. Ecuadorian regulations do not establish the need for a particular notification for the operator to stop marketing; the official publication in the CAN Gazette or on the ARCSA website, is understood as an act that binds the operator, who is required to comply with the duty to protect the final consumer (Presidency of the Republic of Ecuador, 2011).

3.2 Violations

The penalty system for the import of cosmetic products into Ecuador covers both sanitary administrative violations and customs violations. A violation is considered to exist when the importer fails to comply with procedures aimed at ensuring product safety and truthfulness in the customs declaration (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2020). For the period 2020-2024, the collaboration between

ARCSA and SENAE has allowed for better detection of violations such as document forgery and the marketing of products with expired notifications.

The Organic Health Law establishes severe penalties for not obtaining or maintaining NSO. The official wording of the law states:

Article 242. Failure to comply with post-control regulations will lead to the cancellation of the health notification and the prohibition of the marketing of the product, without prejudice to civil or criminal actions that may arise from damage to public health.

This penalty is applied when ARCSA, after laboratory analysis, finds that the imported product does not match the declared formula. In such cases, not only the product is removed from the shelves, but the importer's ability to request further notifications is also blocked until the administrative file is resolved. Fines are also calculated based on the unified basic salary, depending on the severity of the infraction, and the ARCSA Administrative Collection Regulations establish a scale of fines to be applied.

On the other hand, the Organic Code of Production, Trade and Investment (COPCI) classifies customs violations. The most common contravention in the cosmetics sector is the failure to submit the prior control documentation within the established deadlines. If, during a physical inspection, SENAE detects that the merchandise does not coincide with the ARCSA permit (for example, an unreported change of brand or a change of presentation), the merchandise could be immobilized or the seizure of it due to a declaration error as stated in Article 176 of the COPCI. It could even be considered a contravention in the event that it is determined that the errors give rise to differences in favor of the State, where a complementary settlement will be issued, based on the provisions of Article 144 of the COPCI.

CAN Decision 833 also unifies the reasons for the cancellation of the NSO at the regional level. Article 51 of this supranational Regulation establishes that the cancellation of the NSO will proceed when it is found that the product is harmful to health, there has been falsification of documents in the application, or the product does not comply with the technical requirements established in Decision 833 ejusdem. This means that an infringement found in Ecuador can lead to a report to the health authority in Colombia or Peru, and this affects cross-border trade to the importer.

Thus, the acceptance of fines as operating costs has become one of the main bases of compliance management for Ecuadorian importers. The implementation of electronic

signatures and digital traceability in the VUE have minimized manual failures, but have increased the level of control regarding the veracity of the information. Companies must accept that a health infraction does not simply imply administrative management, it is an attack on the system of trust on which a State is based, and can even lead to the doors being permanently closed to import activity.

Most of the infractions that occur in the import process are due to the lack of formal documentation or incorrect tariff classification. In Ecuador, incorrect classification or the request for the wrong permit can cause interruptions in the flow of goods, which increases the acquisition time of the same. SENAE Risk Management, through profiles, establishes which statements will be subject to documentary review or physical review.

Common causes of observations are non-compliance with labelling requirements or lack of batch traceability, as these are essential for causal analysis and product recalls in the event of adverse situations. The Comprehensive Organic Criminal Code (COIP) criminalizes in its scope the type of crimes that may arise from very serious administrative infractions in the field of public health. Article 217 penalizes the sale of products that are expired or do not comply with what the law requires (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2017).

Within this context, it is possible for an importer to enter cosmetic products that are counterfeit or that do not have an NSO, circumventing the controls that SENAE has. From this legal perspective, a technical-administrative infraction that is detected by the ARCSA, on a hanger, could generate an investigation by a prosecutor if what is at risk is the lives of consumers (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2017).

It is a right of importers, at the legal level, to file appeals against a sanction, if they consider that the gauge has interpreted the technical standard in an erroneous way. However, success in this type of appeal depends on the solid unity of information that exists in the file through the documents that were submitted to the ARCSA. Administrative jurisprudence in Ecuador is characterized by the tendency to confirm the sanction in cases in which it is evident that the importer did not carry out the stability or safety tests established by the Andean Technical Regulations.

3.3 Know-How

The know-how of successful importers in Ecuador focuses on document preparation and traceability management. The preparation and response of the regulator to an eventuality depend on the quality of the safety file and the consistency of the documentary traces provided by the importer. An operational aspect that we must not fail to consider is the following: the regimes that regulate the activity of foreign trade and the regulatory activity of the sanitary authorities, the phytosanitary control and response centers and customs, have a level of response that is not known outside their instances.

The analysis of cosmetics import experts such as Customs Broker and Customs Broker Assistant shows how non-tariff barriers affect different market players based on their operational scale. Guayaquil, being the main port, has large national distributors that enjoy economies of scale and have legal departments dedicated to ensuring regulatory compliance. In contrast, Cuenca is characterized by importers and medium-sized companies that face greater logistical and administrative barriers to comply with the regulatory requirements of the ARCSA.

Ecuador's legal framework is neutral with respect to the size of the importer when it comes to safety requirements. The Technical Sanitary Regulations on Good Storage, Distribution and Transport Practices are clear in outlining the storage requirements that the parties must comply with within their jurisdiction. Establishments in the country must have an active operating permit and implement technical conditions to ensure that cosmetic products do not deteriorate in their properties due to weather conditions or mishandling (National Agency for Health Regulation, Control and Surveillance [ARCSA], 2020).

All rational economic actors determine the expected costs and benefits given the available data before making a business decision. A business opportunity is only viable if the expected profitability outweighs the costs involved. In light of the prevailing economic situation in the country, it is likely that companies will carry out import and business operations and only offer products whose demand exceeds the available supply and, consequently, generate positive profits in the country. Representative actors are trying to close these gaps by professionalizing their health notification processes.

Traceability management also remains a critical point for importers in those regions. In accordance with the provisions of Decision 833:

NSO holders are obliged to keep information available to the National Competent Authority, which is useful to them to identify the production batch and trace the product in the national market in the event of a health alert.

Currently, importers have developed and implemented warehouse management systems (WMS) that connect directly to NSO, allowing them to audit and respond to ARCSA in less than 24 hours. In the case of importers who have developed this technology, those who have not been able to integrate this technology face higher costs and the risk of suffering sanctions derived from market intervention.

It can be concluded that the situation of importers indicates the progress that the cosmetics sector has achieved in the country. Compliance with border restrictions with the country has been the main element of survival in the market. Companies that have the best management of the provisions of the ARCSA and SENAE, in addition to having faster shipments, generate a level of confidence with the institutions that will allow them a sustained growth in the import of cosmetic products.

By managing the information systems that exist between ARCSA and SENAE, importers balance the technical and control aspects of documentation, thus minimizing document rejections and optimizing customs surveys. The management of the "know how" includes the management of the Qualitative Formula, which is protected information under Decision 833 of the CAN and is confidential management. An expert importer knows how to present this information to ARCSA in such a way that it complies with technical transparency, without revealing the technical confidentiality of its foreign supplier. Secrecy is crucial to obtaining international exclusivity contracts. Mismanagement of this information could lead to the loss of brand representation in Ecuador or loss of sanitary permit due to opaque active components.

Practical knowledge, finally, is articulated in the ability to perform "simulated withdrawals" of the product. Importers who are familiar with Andean regulations have incident response protocols that are periodically approved by the technical manager of the establishment. This level of preparation, in the face of an observation by SENAE or an audit by ARCSA, guarantees that the company can prove that it has total control of each imported unit, from the ports to the final consumer, anywhere in the national territory.

CHAPTER 4
METHODOLOGY

The present research was carried out through a mixed approach, unifying quantitative and qualitative processes, merging the strengths of both types of inquiry, reflecting what Hernández Sampieri and Fernández-Collado (2014) mentioned about this methodology. Since, foreign trade cannot be correctly understood if only the laws or only the numerical part are analyzed, but both parties are required for a comprehensive analysis. To this end, the qualitative study began following the idea of Flick (2015) , where he mentions the importance of analyzing the documents, in this case the laws, to understand how this process takes place, for which the regulatory evolution that has occurred for the import of cosmetics in Ecuador in the period 2020-2024 has been analyzed. After that, the quantitative analysis was carried out following the principles of Kerlinger and Lee (2002), which allows us to provide a numerical basis through the study of the values and volumes of imports of the main tariff items of cosmetics in Ecuador.

4.1 Participants

For this research work, the selection process of the participants was based on a specific group of experts in the field of foreign trade, due to their ease of access and the relevance of their profiles. For which a non-probabilistic sampling method by judgment was used, which was based on criteria of experience and relevance considering their professional profile and years of experience with various importers in the country, which guarantees the veracity and depth of the information obtained, where two participants were selected.

4.1.1 Profile of Informants

1. **Customs Agent:** Mr. Santiago Malo, customs agent, teacher and recognized business leader in the city of Cuenca, specialized in strategic and regulatory advice for foreign trade. With an outstanding career for presiding over the Chamber of Industries of Cuenca, Governor of the province of Azuay, undersecretary of the Ministry of Foreign Trade, Industrialization, Fisheries and Competitiveness in the Austro and official of the Central Bank of Ecuador at the head of the deputy management of Foreign Trade for more than 10 years. Currently, he is a reference figure for entrepreneurs and companies seeking legal certainty in their international operations, thanks to his experience of more than 15 years linked to customs activities and foreign trade in Cuenca.

2. **Customs Agent Assistant:** Mr. Patricio Auquilla, customs agent assistant who is defined by his technical specialization and operational capacity in the area of foreign trade in Cuenca. Founding manager of AUCOMER S.A.S., advisor to SMEs in the Austro and current manager of SICOMEXA, with more than 15 years linked to the customs sector of the city of Cuenca.

4.1.2 Selection Criteria

For the selection of participants, the following criteria were taken into account:

- **Experience:** Possess a minimum of 10 years of experience in the customs area, ensuring that they know the necessary information within the period 2020-2024.
- **Territorial Scope:** Reside in the city of Cuenca, but have experience in nationalization of goods for importers from different parts of the country, guaranteeing knowledge about the dynamics of foreign trade at the regional and national level.

4.1.3 Justification of the Selection

The selection of these profiles is the fundamental point for the research, since this allows us to have a technical vision from two different points such as the strategic-legal and the operational-practical. The information provided allows us to counteract how the regulatory evolution in the established period impacted the values and volumes of imports of cosmetics, in addition to the importance of non-tariff barriers and know-how in this process.

4.2 Instruments

For the development of the methodology, the instruments that were analyzed were:

- **Documentary matrix:** It was used for the systematic survey of the sources, where it was possible to organize the rules, regulations, decisions and resolutions issued by organizations such as SENAE, ARCSA and CAN. Focusing on the import regime 10 for the specific consumption of tariff heading 3304 during the period 2020-2024.
- **Regulatory analysis sheet:** It was implemented as a tool to analyze the content on non-tariff barriers within the regulations governing the import regime 10 for the consumption of cosmetics. This made it easier to extract the key information that impacts the process of nationalization of cosmetics.

- **Trade Map Data Analysis Matrix:** Tabulation instrument in which the data obtained from Trade Map was structured. This made it possible to find the main tariff subheadings of heading 3304 of imports in Ecuador, their values and their volume within the period 2020-2024.
- **Semi-structured interview guide:** Resource of own authorship made to the customs agent of the city of Cuenca Mr. Santiago Malo and an Assistant Customs Agent of the city, who provides his work to various importers in the country. It was prepared to obtain qualitative information on the process of importing cosmetics in Ecuador.

4.3 Procedure

Phase 1: Regulatory Analysis and Regulatory Evolution: A multi-source document review technique was carried out, the survey was structured through the study of documentation issued by official and academic sources, where the entities and databases specialized in the import process of tariff heading 3304 belonging to cosmetics were first used. In addition, primary and secondary sources were found.

- **Primary sources:** Decisions of the Andean Community (CAN), resolutions issued by ARCSA and SENAE regulations.
- **Secondary sources:** Scientific articles, academic articles, books and government web portals.

Criteria for selecting regulations

The following criteria were applied for the selection of the regulations:

- **Criterion of authority:** The search was limited to organizations that were directly linked to the sector, such as the CAN, SENAE and ARCSA.
- **Specialty criterion:** All those standards that are specifically linked to the process of importing cosmetics in Ecuador were selected.
- **Time criterion:** Documentation was limited within the 2020-2024 period, allowing regulations issued outside this period for the sole purpose of highlighting the modifications made.

Phase 2: Analysis of quantitative data: After this, Trade Map data was obtained on the 3 main tariff subheadings of heading 3304 under regime 10 of import for consumption in Ecuador, where the behavior of these subheadings was studied both in their values in

thousands of dollars, and in their volume in tons. All this in relation to the various regulatory changes that took place in the period 2020-2024.

Phase 3: Data collection: An interview was conducted with the customs agent of the city of Cuenca, Mr. Santiago Malo and an assistant customs agent from the city, where the central point was the importation of heading 3304 belonging to cosmetics, highlighting the know-how in this process, the requirements to carry it out, the efficiency of the current EUVs and the presumption of knowledge of the importers.

Phase 4: Joint analysis: A combined study of the results obtained through the regulatory and data analysis that took place previously was carried out. To counteract the quantitative part with the qualitative part, and find their interrelation in this process. He also highlighted the importance of the know-how that was evidenced through the interviews carried out with the different experts.

CHAPTER 5
RESULTS

The results obtained indicate that the regulatory evolution in Ecuador of the import of cosmetics, during the period 2020-2024, had visibility in sanitary and customs procedures and in the values and volumes of entry of these goods. From the research carried out, it was evident that the changes promoted by the CAN, the ARCSA and the SENAE transformed the dynamics of the sector, modifying the document traceability, dispatch times and the demanding compliance condition.

In this regard, one of the most relevant findings was the progressive process of simplification of sanitary and customs protocols. The digitalization of procedures, especially those activities linked to the EUV and the cross-referencing of institutional information, allowed a considerable reduction in the time taken to obtain the NSO and in the processing of documents prior to obtaining the clearance. This situation confirms that the administrative modernization process had positive impacts whenever there was a combination of greater interoperability between entities and greater clarity in the rules of operators.

From the qualitative perspective, the interview with the customs agent, Mr. Santiago Malo, and the customs agent's assistant, served to interpret in greater depth the scope of these changes. What these experts in the area explained was that the relaxation of the sanitary registration was understood as the turning point of the process, since before a registration was required for each presentation of the product, even if it was the same cosmetic. The possibility of being able to validate several submissions with the same registration translated into technical and economic relief for importers, something that partly explains the growth observed in the figures for the period under analysis.

This type of behavior is tied to import values. Subheading 330499, which corresponds to beauty, make-up and skincare preparations, including sunscreen preparations and tanning (excluding medicinal products, preparations for lip or eye make-up, preparations for manicures or pedicures and powders, including compacts), has been consolidated as the most important product in the investigated sector. The analysis indicates that it went from 47,210 thousand dollars in 2020 to 113,731 thousand dollars in 2024, with an increase of 58.5%. This trend suggests that the facilitation measures accessed after the pandemic coincided with a gradual recovery in demand and a higher level of response from the import system.

In terms of interpretation, these results should not only be understood as an effect of greater regulatory flexibility, but are also a reflection of a recomposition of consumption in the years after the pandemic, where cosmetics once again had a space within the Ecuadorian market. However, the research argued that the recovery would not have reached such proportions in a less fragmented regulatory framework. Therefore, the regulations did not act as an isolated system but as an element that made it possible to channel more effectively a demand that was strengthened again in the following years.

The analysis of the physical volume also serves to nuance the reading obtained from the values in money. The same subheading also has the largest volume of tonnes imported, despite achieving rather irregular results. Between 2020 and 2021 there was an increase of 25%, throughout 2022 there was a drop of 6% and, then, it registered continuous growth until closing the entire period analyzed with an increase of more than 35%. This variation in physical volume shows that the market, in the period 2020-2024, did not advance in a linear manner, but did so through adjustments and partial recoveries.

If this logic is considered, a greater increase in values above volume suggests that the dynamism shown by the sector was not only explained by a greater quantity of imported goods, but is also related to a change in the composition of the market, to changes in unit prices and to the commercial significance of some products. The discussion reflects, therefore, that the recovery of the cosmetics sector combined two different dimensions: the real increase in the circulation of goods and the valorization of strategic sub-items, in particular the explanation of them linked to personal care and products of daily use.

It delved into subheading 330499, which relates to beauty, make-up and skin-care preparations, including anti-sun preparations and tanning (excluding medicinal products, preparations for lip or eye make-up, preparations for manicures or pedicures and powders, including compacts), which highlighted that between 2020 and 2021 it was the target of a sharp drop of 35%, as a result of the pandemic, but that since 2021 it began an expansion process that resulted in a growth of 64% between 2020 and 2024. This expression is evident of a significant recovery and at the same time is part of the reasoning that establishes that the cosmetics market recovered some sub-items that the impact of the health crisis had caused to decline.

In a different way, the subheading corresponding to preparations for manicures or pedicures was only noted for volume, never for value. This difference allowed us to postulate that certain cosmetics have a mass consumption that is associated with relatively lower

prices. This observation is relevant because it confirms that the importance of NSO and sanitary control does not depend on the price of the product but on the potential risk associated with the product in use and the need to guarantee consumer safety in all market strata.

However, the research also showed that institutional modernization did not completely eliminate friction in the process. This is explained by the interviewed agent, given that the ARCSA has made progress in the implementation of digital tools, but the review of requests is no longer necessarily carried out in the city where the procedure is entered, but is by random assignments between districts. This reorganization affected communication and made it difficult to obtain the true status of the process, reducing part of the supposed advantages of digitization.

The association related to the supposed updating of knowledge was particularly transcendental, where the case study placed many importers as assuming that, given the fact that they had already repeated over time a significant number of previous requirements, they tend to glimpse changes, adjusting to rules that are supposed to be stable and of low attention to the new provisions. That assumption, almost an operational trust, ends up becoming the evidence of infractions, documentary omissions, sanctions or even reshipments. Therefore, it is verified that the main risk is not the standard, but the inactivity itself in the face of its updating.

Similarly, the testimony collected also corroborated how the change in public servants affected the costs of the process. Cuts in administrative staff and the concentration of operational load in a smaller number of people caused delays in the processing times, despite digital support systems. This contradiction suggests that the efficiency of the regulations does not depend solely on the technology of digital platforms, but on the human and institutional capacities to maintain them; When these capacities decrease, logistics costs reappear and limit part of the benefits that had been achieved by simplifying the regulatory regulations.

It should be noted that the customs agent assistant considered that cosmetics imports in parallel represented only 2% of the country's imports. Although such a quota seems small, the perspective of it is very interesting, as it shows how even sectors with a lower relative weight could reveal important regulatory transformations, becoming thermometers of inter-institutional functioning. In this sense, the cosmetics sector allowed us to see how the

technical elaboration of a regulation can correctly impact a highly specialized foreign trade operation.

Finally, both the customs agent and the customs agent assistant agree that know-how is a fundamental point for the development of these processes, since experience together with knowledge facilitates that everything is developed according to the regulations, avoiding inconveniences in the development of the process through knowledge and practice of the same.

CONCLUSIONS

It was concluded that the regulatory evolution carried out by ARCSA and SENAE between 2020-2024 strengthened the work of importing cosmetics in Ecuador since it simplified procedures, improved document traceability and reduced operational times in obtaining the NSO and in customs clearance. This regulatory update had a direct impact on the dynamics of the sector, since it put regulatory compliance and commercial continuity of goods subject to regime 10 of import for consumption in the country in more favorable conditions, during the period 2020-2024.

From the analysis, it was concluded that the process of regulatory changes maintained a certain visible relationship with the growth of the values and import volumes of the main cosmetic sub-headings analyzed. Sub-items 330499 and 330420 showed the highest performance values, going from 47210 to 113731 thousand dollars between 2020 and 2024, while other sub-items showed sustained recoveries after the pandemic. These results made it possible to establish that the facilitation of foreign trade, accompanied by regulatory modifications and digital tools built, favored the progressive and sustained reactivation in the cosmetics sector within the scope of Ecuadorian trade.

On the other hand, it was concluded that the presumption of knowledge and the lack of constant updating of importers continue to be risk factors within the process. The repetition of previous practices, the lack of knowledge of regulatory variations and the limitation of communication, produce observations, deadlines that were not met, potential sanctions and extra costs. In this framework, the know-how of customs agents was consolidated as a decision-making element to avoid documentary errors, correctly direct new operators and promote a safer, more efficient and more reliable import process.

REFERENCES

Andean Community Commission. (2021). Decision 873: Extension for simple copies in recognition of the NSO code [Dataset]. Andean Community. https://www.comunidadandina.org/DocOficialesFiles/decisiones/compilacion.pdf

Andean Community. (2018). Decision 833: Harmonization of Laws on Cosmetic Products [Dataset]. https://www.comunidadandina.org/DocOficialesFiles/Gacetas/Gaceta%203450.pdf

Barthe, M., Bavoux, C., Finot, F., Mouche, I., Cuceu-Petrenci, C., Forreryd, A., Chérouvrier Hansson, A., Johansson, H., Lemkine, G. F., Thénot, J.-P., & Osman-Ponchet, H. (2021). Safety Testing of Cosmetic Products: Overview of Established Methods and New Approach Methodologies (NAMs). Cosmetics, 8(2), 50. https://doi.org/10.3390/cosmetics8020050

Cao, C., & Zheng, X. (2024). Application of Artificial Intelligence Technology in the Supervision of Customs Clearance Machine Inspection. World Customs Journal, 18(2). https://doi.org/10.55596/001c.122754

Cao, Q., & Zheng, X. (2024a). Application of Artificial Intelligence Technology in the Supervision of Customs Clearance Machine Inspection. World Customs Journal, 18(2). https://doi.org/10.55596/001c.122754

Cao, Q., & Zheng, X. (2024b). Application of Artificial Intelligence Technology in the Supervision of Customs Clearance Machine Inspection. World Customs Journal, 18(2). https://doi.org/10.55596/001c.122754

Central Bank of Ecuador. (2021). Evolution of the Trade Balance January-December 2020 (Evolution of the Trade Balance January-December. https://contenido.bce.fin.ec/documentos/Estadisticas/SectorExterno/BalanzaPagos/balanzaComercial/ebc202202.pdf

Central Bank of Ecuador. (2021). Evolution of the Trade Balance January-December 2020 (Evolution of the Trade Balance January-December 2020, p. 37) [Technical Report]. Central Bank of Ecuador.

Decision 833, Legislation No. 833, Decision 833 Harmonization of Laws on Cosmetic Products 18 (2021).

Decision 857: Amendments to Decision 833 and related provisions. (2020). https://www.comunidadandina.org/DocOficialesFiles/decisiones/DECISION857.docx

Decision 868: Exceptional provision for the depletion of stocks of cosmetic products. (2020).

Decision 872: Amendment of Decision 868. (2021). https://www.comunidadandina.org/DocOficialesFiles/Gacetas/Gaceta%204174.pdf

Dominguez Prost, E. R., & Scattolo, G. (2024a). Inspections in Customs: A Case Study of the Role of Tariff Dispersion on Red Lane Classification in Argentina. World Customs Journal, 18(1). https://doi.org/10.55596/001c.116521

Dominguez Prost, E. R., & Scattolo, G. (2024b). Inspections in Customs: A Case Study of the Role of Tariff Dispersion on Red Lane Classification in Argentina. World Customs Journal, 18(1). https://doi.org/10.55596/001c.116521

Dominguez, E. R., & Scattolo, G. (2024). Inspections in Customs: A Case Study of the Role of Tariff Dispersion on Red Lane Classification in Argentina. World Customs Journal, 18(1). https://doi.org/0.55596/001c.116521National Agency for Health Regulation, Control and Surveillance [ARCSA]. (2022). External Instructions for obtaining the Mandatory Health Notification (NSO) of cosmetic products through the Transitory

System 833 [External Instructions]. ARCSA. https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2022/06/IE-B.3.1.1-COS-02-Cosmeticos-a-traves-de-ST-833.pdf

Fell, J., & Duver, A. (2024). Non-tariff measures: A methodology for the quantification of bilateral trade effects of policy measures at a product level. Applied Economics, 56(36), 4374-4388. https://doi.org/10.1080/00036846.2023.2211336

Ferreira, M., Matos, A., Couras, A., Marto, J., & Ribeiro, H. (2022). Overview of Cosmetic Regulatory Frameworks around the World. Cosmetics, 9(4), 72. https://doi.org/10.3390/cosmetics9040072

Flick, U. (2015). The design of Qualitative Research. https://edmorata.es/wp-content/uploads/2020/06/Flick.DiseñoInvestigacionCualitativa.PR_.pdf

Flick, Uwe. (2015). The Design of Qualitative Research (First edition in Spanish, Vol. 1) [Pdf]. Ediciones Morata. https://dpp2017blog.wordpress.com/wp-content/uploads/2017/08/disec3b1o-de-la-investigacic3b3n-cualitativa.pdf (Original work published in 2007, SAGE Publications)

General Secretariat of the Andean Community. (2020). Resolution 2161: Temporary authorization of simple copies for recognition of the NSO code. [Dataset]. Andean Community. https://www.comunidadandina.org/DocOficialesFiles/decisiones/compilacion.pdf

General Secretariat of the Andean Community. (2024). Resolution 2458: Modification of the term of entry into force of the Andean Technical Regulation for the labeling of cosmetic products). [Dataset]. Andean Community. https://www.comunidadandina.org/DocOficialesFiles/resoluciones/RESOLUCIONN%C2%B02458.docx

Ghodsi, M. (2023). Exploring the 'non-tariff measures black box': Whose regulatory NTMs on which products improve the imported quality? International Economics, 173, 45-67. https://doi.org/10.1016/j.inteco.2022.11.007

Giuffrida, M., Jiang, H., & Mangiaracina, R. (2021). Investigating the relationships between uncertainty types and risk management strategies in cross-border e-commerce logistics. The International Journal of Logistics Management, 32(4), 1406-1433. https://doi.org/https://doi.org/10.1108/IJLM-04-2020-0158

Giuffrida, M., Jiang, H., & Mangiaracina, R. (2021). Investigating the relationships between uncertainty types and risk management strategies in cross-border e-commerce logistics. The International Journal of Logistics Management, 32(4), 1406–1433. https://doi.org/10.1108/IJLM-04-2020-0158

Giuffrida, M., Mangiaracina, R., Perego, A., & Tumino, A. (2019). Cross-border B2C e-commerce to China: An evaluation of different logistics solutions under uncertainty. International Journal of Physical Distribution & Logistics Management, 50(3), 355-378. https://doi.org/10.1108/IJPDLM-08-2018-0311

Grainger, A. (2024). Customs Tariff Classification and the Use of Assistive Technologies. World Customs Journal, 18(1). https://doi.org/10.55596/001c.116525

Grainger, A. (2024a). Customs Tariff Classification and the Use of Assistive Technologies. World Customs Journal, 18(1). https://doi.org/10.55596/001c.116525

Grainger, A. (2024b). Customs Tariff Classification and the Use of Assistive Technologies. World Customs Journal, 18(1). https://doi.org/10.55596/001c.116525

Heijmann, F., Tan, Y.-H., Rukanova, B., & Veenstra, A. (2020). The Changing Role of Customs: Customs Aligning With Supply Chain and Information Management. World Customs Journal, 14(2). https://doi.org/10.55596/001c.116423

Hernández Sampieri, R., & Fernandez-Collado, C. F. (2014). Research Methodology (P. Baptista Lucio, Ed.; Sixth edition). McGraw-Hill Education.

Integral Organic Criminal Code (COIP)., 297 (2014).
Karklina-Admine, S., Cevers, A., Kovalenko, A., & Auzins, A. (2024). Challenges for Customs Risk Management Today: A Literature Review. Journal of Risk and Financial Management, 17(8), 321. https://doi.org/10.3390/jrfm17080321
Kerlinge), Fred, & Lee, Howard. (2002). Behavioral Research (4.a ed.) [Pdf]. McGraw-Hill / Interamericana Editores. https://padron.entretemas.com.ve/INICC2018-2/lecturas/u2/kerlinger-investigacion.pdf (Original work published in 2000, Wadsworth/Thomson Learning)
Kuo, Y.-H., & Chou, S.-C. (2021). Manifest Monitoring Model as Support for Customs Risk Management: Evidence From Taiwan. World Customs Journal, 15(2). https://doi.org/10.55596/001c.116449
Lee, H. B. (2002). Behavioral Research. https://padron.entretemas.com.ve/INICC2018-2/lecturas/u2/kerlinger-investigacion.pdf
Lucca, J. M., Joseph, R., Hussain Al Kubaish, Z., Mohammad Al-Maskeen, S., & Ali Alokaili, Z. (2020). An observational study on adverse reactions of cosmetics: The need of practice the Cosmetovigilance system. Saudi Pharmaceutical Journal, 28(6), 746-753. https://doi.org/10.1016/j.jsps.2020.04.017
Mavlonov, A. (2023). The Effect on Anti-Corruption of the Customs Information Systems of the Republic of Uzbekistan. World Customs Journal, 17(2). https://doi.org/10.55596/001c.88098
Morel, S., Sapino, S., Peira, E., Chirio, D., & Gallarate, M. (2023). Regulatory Requirements for Exporting Cosmetic Products to Extra-EU Countries. Cosmetics, 10(2), 62. https://doi.org/10.3390/cosmetics10020062
Morini, C., Pieri Leonardo, F., Chaudhary, V., & Hintsa, J. (2024a). A Paradigm Shift in Cross-Border E-Commerce Regulatory Compliance: Evidence From Brazil. World Customs Journal, 18(2). https://doi.org/10.55596/001c.123504
Morini, C., Pieri Leonardo, F., Chaudhary, V., & Hintsa, J. (2024b). A Paradigm Shift in Cross-Border E-Commerce Regulatory Compliance: Evidence From Brazil. World Customs Journal, 18(2). https://doi.org/10.55596/001c.123504
Morini, C., Pieri, F., Chaudhary, V., & Hintsa, J. (2024). A Paradigm Shift in Cross-Border E-Commerce Regulatory Compliance: Evidence From Brazil. World Customs Journal, 18(2). https://doi.org/10.55596/001c.123504
National Agency for Health Regulation, Control and Surveillance [ARCSA]. (2023). Authorization for the depletion of stocks of cosmetic products. Government of Ecuador. https://www.controlsanitario.gob.ec/solicitud-de-agotamiento-de-existencias-de-productos-en-general/
National Agency for Health Regulation, Control and Surveillance [ARCSA]. (2024). Authorisation for the import of samples with no commercial value for cosmetic products. Government of Ecuador. [Dataset]. Government of Ecuador. https://www.controlsanitario.gob.ec/autorizacion-importacion-de-muestras-sin-valor-comercial-con-fines-de-estudio-de-mercado/
National Agency for Health Regulation, Control and Surveillance. (2022). External Instructions for obtaining the Mandatory Health Notification (NSO) of cosmetic products through the Transitory System 833 ARCSA. https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2022/06/IE-B.3.1.1-COS-02-Cosmeticos-a-traves-de-ST-833.pdf
National Customs Service of Ecuador (SENAE). (2023a). Specific manual for the modality of clearance with a non-intrusive physical gauging channel for imports (SENAE-MEE-2-2-047-V1). [Dataset].

https://www.aduana.gob.ec/gacnorm/data/2023/02/28/12/SENAE-MEE-2-2-047-V1.pdf
National Customs Service of Ecuador (SENAE). (2023b). Resolution No. SENAE-SENAE-2023-0056-RE [Dataset]. https://www.aduana.gob.ec/gacnorm/data/2023/08/01/16/SENAE-SENAE-2023-0056-RE.pdf
National Customs Service of Ecuador [SENAE]. (2020). Resolution No. SENAE-SENAE-2020-0017-RE (Administrative Resolution SENAE-SENAE-2020-0017-RE). National Customs Service of Ecuador (SENAE). https://www.aduana.gob.ec/resolucion/senae-senae-2020-0017-re-3/
National Customs Service of Ecuador [SENAE]. (2022a). Manual for the Delivery of Goods in Primary Zones: Actions for the control and delivery of goods (SENAE-MEE-2-3-013, version 3.0). Ecuadorian Customs. https://www.aduana.gob.ec/gacnorm/data/2023/02/28/12/SENAE-MEE-2-3-013-V3.pdf
National Customs Service of Ecuador [SENAE]. (2022b). Specific Manual for Inspections in Import Cargo (SENAE-MEE-2-3-013-V3). (Specific Manual SENAE-MEE-2-3-013; p. 25). National Customs Service of Ecuador (SENAE). https://www.aduana.gob.ec/gacnorm/data/2022/10/28/13/SENAE_MEE_2_3_019_V5.pdf
National Customs Service of Ecuador [SENAE]. (2025). Specific Manual for the Modality of Dispatch with Import Intrusive Physical Gauging Channel (Specific Manual SENAE-MEE-2-2-004). National Customs Service of Ecuador (SENAE).
National Customs Service of Ecuador [SENAE]. (2025). To import. Ecuadorian Customs. https://www.aduana.gob.ec/servicio-al-ciudadano/para-importar/
National Customs Service of Ecuador [SENAE]. (2026, February). Specific Manual for the Import Clearance of Goods Under the Expedited Courier Exception Regime (SENAE-MEE-2-2-030-V7). https://www.aduana.gob.ec/gacnorm/data/2026/02/23/12/SENAE-MEE-2-2-030-V7.pdf
National Customs Service of Ecuador. (2024). RX import: User manual. Ecuadorian Customs. https://www.aduana.gob.ec/gacnorm/data/2024/10/08/12/SENAE-MEE-2-2-047-V2_Manual_RX_importacion.pdf
National Customs Service of Ecuador. (2024). Specific manual for the modality of clearance with intrusive physical gauging channel for importation. [Dataset]. Ecuadorian Customs. https://www.aduana.gob.ec/gacnorm/data/2025/05/06/16/SENAE-MEE-2-2-004-V7.pdf
National Customs Service of Ecuador. (2025). To import Ecuadorian Customs. https://www.aduana.gob.ec/servicio-al-ciudadano/para-importar/
Nayak, M., Sreedhar, D., Prabhu, S. S., & Ligade, V. S. (2021). Global Trends in Cosmetics Use-Related Adverse Effects: A Bibliometric Analysis of Literature Published during 1957–2021. Cosmetics, 8(3), 75. https://doi.org/10.3390/cosmetics8030075
Official Gazette No. 162, 162 Official Gazette § Executive Function (2010).
Ouyang, W., & Park, I. (2024). Estimating the Extensive Margin of Exports in the Chinese Market: The Impact of Digital Trade Facilitation on Export Diversification. International Area Studies Review, 27(2), 95-121. https://doi.org/10.69473/iasr.2024.27.2.95
Procedure for obtaining the Mandatory Health Notification of cosmetic products, absorbent personal hygiene products and household hygiene products through Transitory System 833 (External Instruction IE-B.3.1.1-COS-02, version 2.0)., Legislation No. Sanitary

Control (2022). https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2022/06/IE-B.3.1.1-COS-02-Cosmeticos-a-traves-de-ST-833.pdf

Regulations to the Title of Customs Facilitation for Trade, Book V of the Organic Code of Production, Trade and Investment and its current amendments, Legislation No. Supplement to the Official Register No. 452, Decree No. 758 Book V of the Organic Code of Production, Trade and Investment 125 (2011). https://www.aduana.gob.ec/gacnorm/data/REGLAMENTO-AL-TITULO-DE-LA-FACILITACION-ADUANERA-PARA-EL-COMERCIO-DEL-LIBRO-V-DEL-COPCI.pdf

Resolution 2108: Regulation of Decision 833 "Harmonization of Legislation on Cosmetic Products", 2108 Resolution No. 2108 20 (2021). https://www.gob.ec/sites/default/files/regulations/2021-11/Documento_Resoluci%C3%B3n-%202108-Reglamento-Decisi%C3%B3n-833-Armonizaci%C3%B3n-Legislaciones-en-materia-productos-cosm%C3%A9ticos.pdf

Resolution 2206: Andean Technical Regulation of Good Manufacturing Practices for cosmetic products (2021). https://www.comunidadandina.org/DocOficialesFiles/resoluciones/RESOLUCION2206.docx

Resolution 2310: Andean Technical Regulation on Labeling of Cosmetic Products, Resolution No. 2310 11 (2022). https://www.comunidadandina.org/DocOficialesFiles//resoluciones/RESOLUCIONN%C2%B02310.docx

RESOLUTION ARCSA-DE-2021-016-AKRG, 21065 ECOTC21065 38 (2021).

Resolution No. ARCSA-DE-006-2017-CFMR: Technical Sanitary Regulations for the Manufacture, Importation, Conditioning, Storage, Distribution, Transport and Marketing of Cosmetic Products. (2017).

Resolution No. SENAE-SENAE-2024-0093-RE: Amendment to Resolution No. SENAE-SENAE-2023-0078-RE (Regulations for the Exception Regimes of Postal Traffic and Expedited Courier or Courier), Legislation No. Second Supplement to the Official Register No. 658, Official Gazette No. 658 SENAE-SENAE-2024-0093-RE 5 (2024).

Resolution SENAE-SENAE-2020-0030-RE: Exclusive user service by electronic means during the health emergency. (2020). https://www.aduana.gob.ec/gacnorm/data/SENAE-SENAE-2020-0030-RE.pdf

Sanitary Technical Regulations on Good Storage, Distribution and/or Transport Practices for Pharmaceutical Establishments and Medical Device Establishments for Human Use., Legislation No. Official Register Special Edition No. 455, ARCSA-DE-002-2020-LDCL 28 (2020).

Silva, R. J., & Tamburic, S. (2022). A State-of-the-Art Review on the Alternatives to Animal Testing for the Safety Assessment of Cosmetics. Cosmetics, 9(5), 90. https://doi.org/10.3390/cosmetics9050090

Substitute Sanitary Technical Regulations for cosmetic products, household hygiene products and absorbent personal hygiene products, Legislation No. Supplement to the Official Register No.566, Resolution ARCSA-2021-016-AKRG Official Gazette 72 (2021). https://www.gob.ec/sites/default/files/regulations/2022-05/Documento_Regulaci%C3%B3n%20ARCSA-2021-016-AKRG-Normativa-T%C3%A9cnica-Sanitaria-sustitutiva-para-productos-cosm%C3%A9ticos-productos-higiene-dom%C3%A9stica-y-productos-absorbentes-comprimido.pdf

Technical sanitary regulations for cosmetic products, absorbent personal hygiene products and household hygiene products (Resolution ARCSA-DE-006-2017-CFMR,

amended) (2018). https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2018/12/Resoluci%C3%B3n-ARCSA-DE-006-2017-CFMR-Reformado-COSM%C3%89TICOS.pdf

Thu Hien, P. T., & Quang, B. T. (2022). Enhancing Trade Compliance to Benefit Small and Medium-Sized Enterprises (SMEs) in Trade Facilitation Agreement (TFA) Implementation in Vietnam. World Customs Journal, 16(1). https://doi.org/10.55596/001c.116460

Vieira, D., Duarte, J., Vieira, P., Gonçalves, M. B. S., Figueiras, A., Lohani, A., Veiga, F., & Mascarenhas-Melo, F. (2024). Regulation and Safety of Cosmetics: Pre- and Post-Market Considerations for Adverse Events and Environmental Impacts. Cosmetics, 11(6), 184. https://doi.org/10.3390/cosmetics11060184

World Customs Organization. (2021). SAFE Framework of Standards (FAC 2022-2; p. 88). World Customs Organization. https://www.wcoomd.org/-/media/wco/public/global/pdf/topics/facilitation/instruments-and-tools/tools/safe-package/safe-framework-of-standards.pdf

World Customs Organization. (2021). SAFE Framework of Standards World Customs Organization (WCO) . https://www.wcoomd.org/-/media/wco/public/global/pdf/topics/facilitation/instruments-and-tools/tools/safe-package/safe-framework-of-stan

Yeleussizova, B. K., Kazbekova, S. Z., & Zeinelgabdin, A. B. (2024). Cross-border Retail E-Commerce and De Minimis: The Case of Kazakhstan. World Customs Journal, 18(1). https://doi.org/10.55596/001c.117024

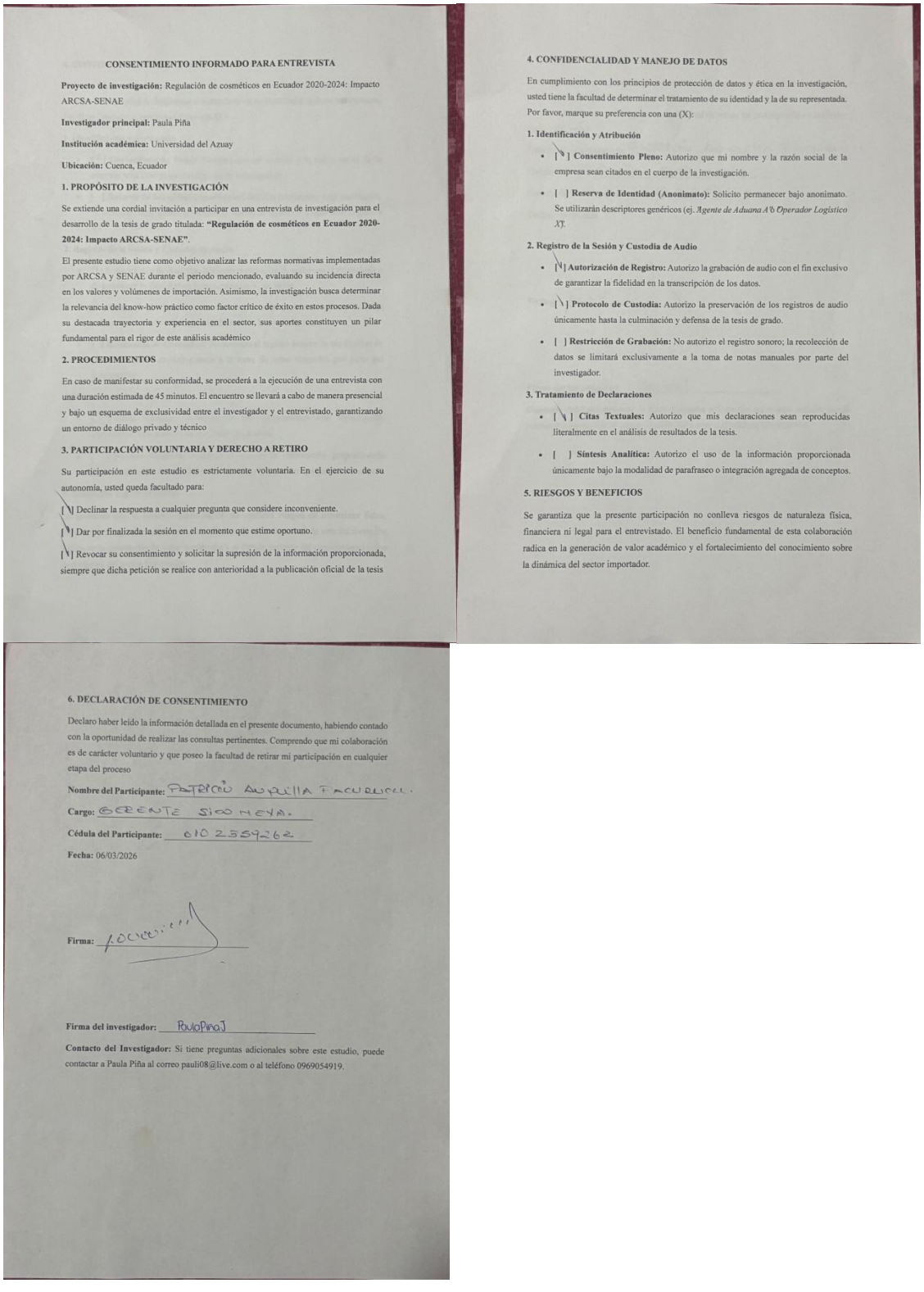
Yeleussizova, B. K., Kazbekova, S. Zh., & Zeinelgabdin, A. B. (2024a). Cross-border Retail E-Commerce and De Minimis: The Case of Kazakhstan. World Customs Journal, 18(1). https://doi.org/10.55596/001c.117024

Yeleussizova, B. K., Kazbekova, S. Zh., & Zeinelgabdin, A. B. (2024b). Cross-border Retail E-Commerce and De Minimis: The Case of Kazakhstan. World Customs Journal, 18(1). https://doi.org/10.55596/001c.117024

APPENDICES

Appendix 1

Informed Consent Mr. Patricio Auquilla



CONSENTIMIENTO INFORMADO PARA ENTREVISTA

Proyecto de investigación: Regulación de cosméticos en Ecuador 2020-2024: Impacto ARCSA-SENAE

Investigador principal: Paula Piña

Institución académica: Universidad del Azuay

Ubicación: Cuenca, Ecuador

1. PROPÓSITO DE LA INVESTIGACIÓN

Se extiende una cordial invitación a participar en una entrevista de investigación para el desarrollo de la tesis de grado titulada: **"Regulación de cosméticos en Ecuador 2020-2024: Impacto ARCSA-SENAE"**.

El presente estudio tiene como objetivo analizar las reformas normativas implementadas por ARCSA y SENAE durante el periodo mencionado, evaluando su incidencia directa en los valores y volúmenes de importación. Asimismo, la investigación busca determinar la relevancia del know-how práctico como factor crítico de éxito en estos procesos. Dada su destacada trayectoria y experiencia en el sector, sus aportes constituyen un pilar fundamental para el rigor de este análisis académico

2. PROCEDIMIENTOS

En caso de manifestar su conformidad, se procederá a la ejecución de una entrevista con una duración estimada de 45 minutos. El encuentro se llevará a cabo de manera presencial y bajo un esquema de exclusividad entre el investigador y el entrevistado, garantizando un entorno de diálogo privado y técnico

3. PARTICIPACIÓN VOLUNTARIA Y DERECHO A RETIRO

Su participación en este estudio es estrictamente voluntaria. En el ejercicio de su autonomía, usted queda facultado para:

[X] Declinar la respuesta a cualquier pregunta que considere inconveniente.

[X] Dar por finalizada la sesión en el momento que estime oportuno.

[X] Revocar su consentimiento y solicitar la supresión de la información proporcionada, siempre que dicha petición se realice con anterioridad a la publicación oficial de la tesis

4. CONFIDENCIALIDAD Y MANEJO DE DATOS

En cumplimiento con los principios de protección de datos y ética en la investigación, usted tiene la facultad de determinar el tratamiento de su identidad y la de su representada. Por favor, marque su preferencia con una (X):

1. Identificación y Atribución

- [X] **Consentimiento Pleno:** Autorizo que mi nombre y la razón social de la empresa sean citados en el cuerpo de la investigación.
- [ ] **Reserva de Identidad (Anonimato):** Solicito permanecer bajo anonimato. Se utilizarán descriptores genéricos (ej. *Agente de Aduana A* o *Operador Logístico X*).

2. Registro de la Sesión y Custodia de Audio

- [X] **Autorización de Registro:** Autorizo la grabación de audio con el fin exclusivo de garantizar la fidelidad en la transcripción de los datos.
- [X] **Protocolo de Custodia:** Autorizo la preservación de los registros de audio únicamente hasta la culminación y defensa de la tesis de grado.
- [ ] **Restricción de Grabación:** No autorizo el registro sonoro; la recolección de datos se limitará exclusivamente a la toma de notas manuales por parte del investigador.

3. Tratamiento de Declaraciones

- [X] **Citas Textuales:** Autorizo que mis declaraciones sean reproducidas literalmente en el análisis de resultados de la tesis.
- [ ] **Síntesis Analítica:** Autorizo el uso de la información proporcionada únicamente bajo la modalidad de parafraseo o integración agregada de conceptos.

5. RIESGOS Y BENEFICIOS

Se garantiza que la presente participación no conlleva riesgos de naturaleza física, financiera ni legal para el entrevistado. El beneficio fundamental de esta colaboración radica en la generación de valor académico y el fortalecimiento del conocimiento sobre la dinámica del sector importador.

6. DECLARACIÓN DE CONSENTIMIENTO

Declaro haber leído la información detallada en el presente documento, habiendo contado con la oportunidad de realizar las consultas pertinentes. Comprendo que mi colaboración es de carácter voluntario y que poseo la facultad de retirar mi participación en cualquier etapa del proceso

Nombre del Participante: PATRICIO AUQUILLA FACUNDICH.

Cargo: GERENTE SICO MEYA.

Cédula del Participante: 010 255262

Fecha: 06/03/2026

Firma:

Firma del investigador: PaulaPiñaJ

Contacto del Investigador: Si tiene preguntas adicionales sobre este estudio, puede contactar a Paula Piña al correo pauli08@live.com o al teléfono 0969054919.

Appendix 2

Interview transcribed by Mr. Patricio Auquilla

1. **Since what year have you been providing your nationalization services and how many clients in the cosmetics sector do you currently handle?**

We have provided the service since 2001 or so, we have been around for about 24 or 25 years in customs agency, and in the field of cosmetics we have had very few customers due to the difficulty that this branch entails. I estimate that one or two clients may deal with cosmetics.

2. **What percentage do cosmetics represent within your total imports?**

Two percent, no more.

3. **How critical is the cosmetics sector within your operation compared to other products subject to prior control?**

Well, it is quite complex, we manage processes such as agricultural seeds that obtain a prior control document. Tires that a prior control document is also obtained. In these fields, the regulations are already clear and concrete and help us to a certain extent quickly to get the licenses. On the subject of cosmetics, it is always more critical, it is always more complex because of the difficulty involved in obtaining the permits.

4. **What relevant regulatory changes have you identified between 2020 and 2024 in the import of cosmetics?**

The way the records are obtained, the way the ARCSA responds: sometimes fast, sometimes delayed, fundamental changes. Hence changes in the bases, no, because the regulations have been in force for some time in the requirements to obtain the certificate of free sale, the label, the fees that are paid according to each tariff heading that make up cosmetics, because we are talking about lipsticks, powders, makeup, etc. So, there's a lot of variety. Changes, yes, rather in the response issues of the entity that issues the certificates, in this case the ARCSA.

5. **How have these changes impacted clearance times and total import costs?**

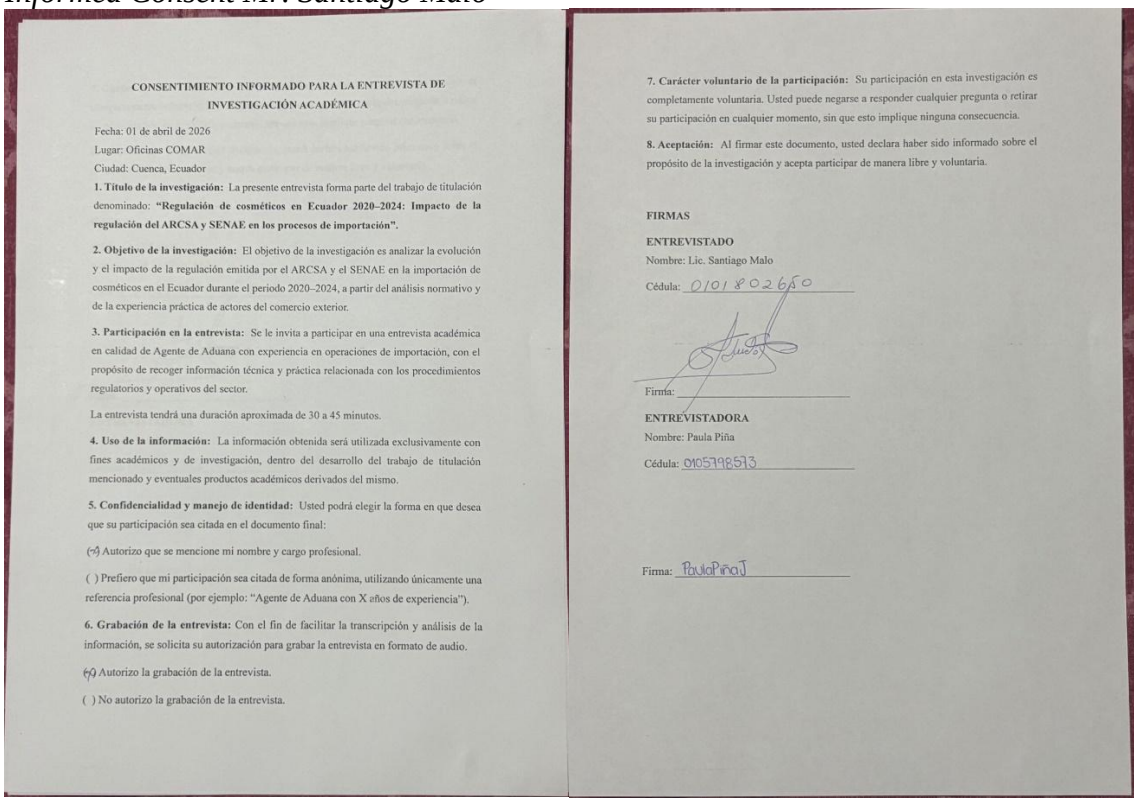
They have a greater impact on costs, because there is, for example, a fee that costs 904 dollars and the rest of the licensing process also has its cost. In the import clearance, it should not affect because obviously being a prior control document, the moment it reaches nationalization the product already has the license. Unless customs considers that the tariff heading that was obtained, the sanitary receipt is not correct, then the process of releasing the merchandise could be stopped, already at the capacity itself, but normally the sanitary registration is obtained before shipment with the specific tariff heading. I repeat, in customs the gauge will always have the power to say that the tariff heading is not the correct one.

6. **How has the efficiency and interoperability between the single window and ECUAPASS for the validation of NSOs changed over the years?**

The one-stop shop does work as a tool that helps us a lot, it is fast, obviously you have to have the documentation ready scanned for each step to upload the documents and as I mentioned in the previous question here come more response times from the ARCSA. But the upload, as the documents to the VUE are technically called, does work fast. Now lately the ECUAPASS has been having many problems, but normally it does not happen like that.

Appendix 3

Informed Consent Mr. Santiago Malo



CONSENTIMIENTO INFORMADO PARA LA ENTREVISTA DE INVESTIGACIÓN ACADÉMICA

Fecha: 01 de abril de 2026
Lugar: Oficinas COMAR
Ciudad: Cuenca, Ecuador

1. Título de la investigación: La presente entrevista forma parte del trabajo de titulación denominado: **"Regulación de cosméticos en Ecuador 2020–2024: Impacto de la regulación del ARCSA y SENAE en los procesos de importación".**

2. Objetivo de la investigación: El objetivo de la investigación es analizar la evolución y el impacto de la regulación emitida por el ARCSA y el SENAE en la importación de cosméticos en el Ecuador durante el periodo 2020–2024, a partir del análisis normativo y de la experiencia práctica de actores del comercio exterior.

3. Participación en la entrevista: Se le invita a participar en una entrevista académica en calidad de Agente de Aduana con experiencia en operaciones de importación, con el propósito de recoger información técnica y práctica relacionada con los procedimientos regulatorios y operativos del sector.

La entrevista tendrá una duración aproximada de 30 a 45 minutos.

4. Uso de la información: La información obtenida será utilizada exclusivamente con fines académicos y de investigación, dentro del desarrollo del trabajo de titulación mencionado y eventuales productos académicos derivados del mismo.

5. Confidencialidad y manejo de identidad: Usted podrá elegir la forma en que desea que su participación sea citada en el documento final:

(X) Autorizo que se mencione mi nombre y cargo profesional.

( ) Prefiero que mi participación sea citada de forma anónima, utilizando únicamente una referencia profesional (por ejemplo: "Agente de Aduana con X años de experiencia").

6. Grabación de la entrevista: Con el fin de facilitar la transcripción y análisis de la información, se solicita su autorización para grabar la entrevista en formato de audio.

(X) Autorizo la grabación de la entrevista.

( ) No autorizo la grabación de la entrevista.

7. Carácter voluntario de la participación: Su participación en esta investigación es completamente voluntaria. Usted puede negarse a responder cualquier pregunta o retirar su participación en cualquier momento, sin que esto implique ninguna consecuencia.

8. Aceptación: Al firmar este documento, usted declara haber sido informado sobre el propósito de la investigación y acepta participar de manera libre y voluntaria.

FIRMAS

ENTREVISTADO
Nombre: Lic. Santiago Malo
Cédula: 0101802650
Firma:

ENTREVISTADORA
Nombre: Paula Piña
Cédula: 0105798573
Firma: PaulaPiñaJ

Appendix 4

Interview with Mr. Santiago Malo

1. **From your professional experience, what have been the main regulatory changes that have affected the import of cosmetics in Ecuador during the period 2020–2024?**

The regulations that the government required at the time for the import of cosmetics and related to that line, is the creation of the sanitary registry where it was mandatory that all products that are marketed in the country must comply with obtaining the sanitary registration, granted by the ARCSA. Beyond the fact that the product abroad complies with all health regulations, and requirements for use on the skin or in humans, here it is required that this be approved. So, there are 2 scenarios:

- ✓ Some countries that do not have the homologation that Ecuador requires and that is a bit of a problem. Sometimes Arab countries, for example, have to ask for certain regulations to be complied with, beyond the fact that the product can comply with its origin, but we need the rigor to comply with our standard so that it can come.

It also took an important step to:

- ✓ be able to use the sanitary registration number in a single obtaining and that it can validate several presentations because before 2021, it seems to me in 2018, you had to obtain a sanitary registration for each presentation even though it is the same product. For example, you had a Cartier perfume for women, that Cartier perfume came in 100ml, it had to have a registration number, the 250ml another registration number, the 500ml another registration number, that was a cumbersome issue for the importer because you had to be passing test tests for each of the presentations.

That leap did occur, today all presentations are included within a single sanitary registry, so that if it is a facility that seen from the technical point of view is the rational thing to do because the sanitary registration is to the product itself, beyond whether they come in a small bottle or in a large bottle, it is the product itself. So that is an important step that has given speed to obtaining licenses and being able to have a higher import rate.

2. **How have the provisions of the ARCSA, particularly in relation to Mandatory Health Notification (NSO), influenced import times and procedures?**

There is an issue that has to continue to be improved, although ARCSA is the regulatory entity and the control entity, also from my perspective it lacks a higher level of speed in the attention to the orders made by importers. Important steps have been taken, if we go back a few years, the documentation had to be physically delivered to an office, at a window and wait for a series of internal processes to pass in that office. Nowadays the jobs are online, you upload the information online through the portal and obtain the licenses. What happens is that it is being raffled at the national level, what do I mean, that, if I enter online, here, in Cuenca, as a user of Cuenca my order, the analysis can go to Quito, it can go to Quevedo, it can go to Guayaquil, it can go to Loja in any office that exists of the ARCSA. Which shouldn't matter, because if it's an online job through a platform where you are physically it is the least of it. However, if it starts to matter a little because when there are delays we have to start looking for the official who is with the procedure and then if we get an official in Loja, we have to start calling him or having someone visit to find out the reason for the delay with our procedure, beyond the fact that he may have an excessive workload and that is why he does not attend to that he no longer has a level of proximity. I don't think it should go back to those in Cuenca processing only in Cuenca because we would be breaking a principle of integration, but it should be a platform that allows the user to have more contact with the one assigned to them in any part of the country, since that does delay a little the speed with which trade can be carried out.

3. **Have you observed relevant changes in the interaction between the SENAE system (ECUAPASS) with respect to the Ecuadorian Single Window module during this period?**

Yes, this time the integration system is much better. The information integration and information cross-referencing system today is much more agile than in previous years

4. **In your experience as a customs broker, what are the most frequent errors or inconsistencies that cosmetics importers present in their customs declarations?**

Sometimes it happens that the repeatability in practice of the importer who has been for example an importer of perfumes historically, due to repeatability perhaps loses attention in keeping himself informed of the modification of regulations. Many times, it has happened to us that soap of such a

composition, nowadays because it has organic components, requires a higher level of control that it did not have before. So many times, the importer says, but I have never been asked for this before, exactly before today it is needed, but we have not known, if exactly, that is why we have to enlighten ourselves more. Although the regulations are published in the official registry, they are public knowledge, it is not that the regulations are sent to each importer and they say sir, please read. That does not happen, so there is a need for a little more concern from the foreign trade area of importers so that they are a little closer to the possible regulations that can be changed within a period of time on the product they import. So, on that part, some importers have had many problems.

5. **To what extent do you think that ignorance of health or customs regulations influences the commission of infringements or delays in clearance?**

Let's see it is fundamental; the incidence is very high. Let's see, within the framework of foreign trade, we have categorized products into: products of prohibited importation, products of restricted importation and products of free importation.

The term is prohibited, to give you an example, the importation of drugs is prohibited, the importation of certain calibers of weapons is prohibited, the importation of bullets is prohibited. The restricted if we touch on the same term as weapons, you can import a certain type of caliber of weapons as long as the Ministry of Defense gives you an authorization. The same thing happens with perfumes, perfumes are in the restricted category, they are not prohibited, you can bring them, but you need to get prior licenses. And those of free import, which can be a calculator, a television.

So of course, not knowing the regulations implies that the moment the merchandise arrives at customs, customs is a control and compliance entity, so it must be remembered that customs is not the one who issues restrictions, the issuance of restrictions are in other instances as in the case of ARCSA, for example the Ministry of Health through ARCSA issues a restriction for perfumery, the only thing customs does is that it must control that the importer complies with the restriction issued by another agency. So, the time you get to customs, the only thing customs does is check that you comply and if you don't, customs has to exercise there if what the customs law says.

Depending on the level of infraction, the law of the organic code has to apply the part of the customs chapter where it is perfectly stipulated what is a regulatory offense, what is a contravention or what is a presumption of crime. Depending on which of these is classified by not having a certain document, customs begins. But that means, first of all, that it takes time if it is a document that should have been obtained and did not obtain it, and customs tells you have 30 days to go and obtain it, if it is possible to obtain it, the only thing that occurs is delay and extraction. But if you can't get it, customs tells you it knows you can't pass, asks you to re-embark, that is, to take it out of the country again and all this involves costs/time. That is why it is very important and I always call on the importing sector to identify the product that they want to import before carrying out an import, and the first thing they have to do is visit a company like ours, that we are permanently linked to the regulations, we are up to date with the regulations and that obviously we can give them prior advice so that they also have to make an analysis if they are not interested in the import. The whole process as such, plus the costs involved in an import, ends up being favorable to enter the market.

6. **How have regulatory changes affected clearance times and logistics costs for cosmetics importers?**

Well, it also has to be seen that here in the process not everything is rosy from the customs point of view. There are also delays in the PROGRESS IN CUSTOMS not due to lack of regulations or ignorance of the importer, but due to Customs problems and that is no longer the fault of the importer, but it does influence its cost, its production process and its marketing process, in that it must continue to pressure the national customs service. Lately, for example, there have been huge changes in customs, they have changed personnel and they have removed a large number of people. They are in the process of restructuring and cleaning customs professionals, so if you had 25 gauges in Guayaquil in the port before and from one day to the next only 5 appear with a workload that Guayaquil has of about 400 to 500 dispatches a day. So of course, the claims that we have made many times to the authorities because they attend to us at customs tell us that we are without personnel, yes, but you should have foreseen before asking for the departure of those who were going to put in. So that is already an internal structural issue of the institutions, not only of customs, but in general of public institutions. Many times, you go to a local or national public institution and you find that they have

high workloads, many of them because they took out personnel beyond the fact that there will be some who do not do what they have to do, but all that does imply.
Now in the general context of trade all that ends up being costs, and that is why many times compared to other countries it is not necessarily more expensive to make an import because of an issue of a tax value that it has, but because of the time it takes. Nowadays, we have a much easier time setting up a company, since you can open a SAS that takes between 4 to 5 days and costs you $500-$600, a limited company that takes you 3 months or something like that. But to give an example, in the United States you incorporate a company in about 24 hours online. So, if I say I want to start a business of bringing coffee and if my whole process to newly incorporate a company is going to take me 2 to four months, that time implies loss of value because I could have started 3 months ago. So, all this leads to the levels of competitiveness, especially in the industrial sector, becoming complicated, when the times are too long and these have a direct impact on production. We are talking about cosmetics these days, which is a commercial issue, which we do not manufacture. But let's take a company like Indurama that manufactures kitchens and has to bring supplies from abroad, the fact that they are delayed by the containers with the parts and pieces of a product and that they have to delay their production process and go to the market, that is money for them.

7. **From your professional experience, what do you consider to be the most important aspects that a new cosmetics importer should know before starting operations in Ecuador?**

For me, for any business beyond cosmetics, it would have to be the identification of the market. Let's remember that today we have to visualize our business model based on the fact that I cannot bring a product and from there I will see where I sell, but first I have to go and ask what they want to buy and know what the market is looking for. So, although I may have in my mind an idea of a new line of cosmetics with certain organic components and everything, first I have to see if the market has enough sensitivity to accept that innovative product and is going to sue me, because otherwise I am not going to keep the product here.
The first step would be to look for demand, the second step would be to see what regulations my legislation requires for me to be able to venture with a new product, and the third if it already involves a cost. To get to the end, and tell a supplier I can't come with this product with these prices because in the market they wouldn't accept me. I'll give you a quick example, if today a perfume X on the market pays me $20 and my sanitary registration with all the necessary procedures for this affects me $1 for each perfume, maritime transport, taxes, ice and everything affects my $10, and my profitability index of a reasonable 20 or 30% that I can have, all this added up and taking into account that my supplier wants to sell me for $15, I can no longer bring the product because I am going over the RRP price at which I can sell. So, I have to tell my supplier I can enter with your product as long as you sell me for $8 in France, if you don't give me for $8 in France, I can't reach the Ecuadorian market for $20 and if I arrive with more than $20 no one buys me because I have a similar product that will compete with me. With the exception of certain specific products, which, due to their nature of exclusivity or quality, are not determined in the market by value but rather by quality. I have always given the example of some motorcycles, not with the desire to talk about one brand or another, but there are motorcycles of all prices, you have very high-end motorcycles, for example, such as Harley Davidson, which is a high-end motorcycle that costs $100,000, where the market is extremely small, but where the price does not matter, but the level of appetite and quality for the final consumer, who is small, matters. but that has an enormous profitability index, that if I want to enter the case of perfumes in a mass market that it is necessary to be at the level of the competition. Without leaving aside that perfumes also have selectivity, there are certain branches in which they are very personal.

8. **What practical recommendations would you give to an entrepreneur to avoid delays or inconveniences in the process of nationalizing cosmetics?**

Prior advice is the basic point. Where I start from a previous meeting with my customs agent, with a foreign trade consulting company where I tell him this is my product I want to bring what he has to tell me before I start my first step to a shipment, what are the inconveniences or potential problems that I have.
If I take the first step, well advised, the rest flows. Customs does not have longer delay times when the profilers of the importers are good, what do I mean by profiler. Within customs there are 3 gauging channels which are: automatic gauging, documentary gauging and physical gauging. Therefore, if your customs procedures have been good, you enter an automatic gauging channel,

where the goods and documents are not reviewed, that is, nothing is checked, only the agent makes a clearance. Customs signs and says I trust that importer and that customs agent, take the merchandise and take it. So that generates a chain that flows at an enormous speed, but to get to that we must have an adequate record and the adequate record is born from a good import without problems, which the origin of this ends up being good advice.

9. Could you share any practical examples or recurring situations that show the main problems in this type of imports?

Of course, we had a problem with some creams that came from Colombia. We must remember that we have agreements with certain countries, for example, what is happening to us today with Colombia, we are members of the CAN (the Andean Community of Nations) where Colombia is also a part, that is why these tariffs that are being imposed today between Colombia and Ecuador are outside the legislation of the CAN. There will be possible sanctions for both, but well, that is an issue that we leave to the politicians to deal with. But since there are agreements we have tariff preferences, for example, in the case of creams manufactured in Colombia we do not pay taxes, but in order to determine that this is originating in that country, the Colombian government has to issue a certificate of origin to the Ecuadorian importer, because the only one that can tell me if the product is manufactured and meets the rules of origin is the government from which I come. So, there we had a small problem because when the import was made, the Colombian supplier told our customer here that the product was manufactured in Colombia, when the merchandise arrived here at the Ecuadorian customs and we asked for the certificate of origin, the Colombian government denied it. Because many of the components of these creams were imported, imported from other countries and did not give the necessary percentage to give them origin. Then the Ministry of Foreign Trade in Colombia, which I don't remember well what the agency is called, which is something similar to our Ministry of Foreign Trade, said I can't give it origin because it doesn't meet the component and the supplier said if it is original and sent everything, they denied us the certificate of origin and we couldn't release it. So, the whole scheme, the importer's cost was damaged because he said I am not going to pay here in full he had to pay. So that is a practical case, so if it is also good as a recommendation to importers who venture into this type of product that they have some specific and own commercial relationship, validate and make sure. Nowadays we are opening up to many markets, remember that we have just signed with China, for example, we also have tax reliefs, but not 100% in all of them, so it is good to first know that the product can truly obtain the certificate of origin. Here the work is being closed a little to certain Chinese trades that cannot export legally, because not everything in the world is legal, it is painful because everything should always be legal because there is no reason not to be, but it is not always. So there are certain trades in China that are also not authorized by the Chinese government to sell abroad and have been selling, so with them what happens that you tell them to get me a certificate of origin for your product and they can't get it because the Chinese government does not have them categorized within the protocols that they must comply with to export, So it is good to have that type of prior information.