ASEAN-Australia-New Zealand Free Trade Area (AANZFTA)
Economic Cooperation Support Programme (AECSP)

DESK RESEARCH ON GOOD REGULATORY PRACTICE IN THE COSMETICS INDUSTRY

Standards, Technical Regulations and Conformity Assessment Procedures

ASEAN - Australia - New Zealand Free Trade Area (AANZFTA)
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December 2021

The ASEAN-Australia-New Zealand Free Trade Area (AANZFTA) Economic Cooperation Support Programme (AECSP) was established in 2010 to assist AANZFTA Parties to realise the full benefits of AANZFTA through supporting the Parties and the ASEAN Secretariat to (i) operationalise and implement the AANZFTA; (ii) progress the built-in agenda of the Agreement; (iii) strengthen economic integration amongst Parties; and (iv) promote business utilisation of AANZFTA opportunities.

Under the AECSP, the *Desk Research Report on Good Regulatory Practice in the Cosmetics Sector* was prepared by Jacobs, Cordova & Associates Europe Ltd and approved for public dissemination by the AANZFTA Sub-Committee on Standards, Technical Regulations and Conformity Assessment Procedures (STRACAP) in December 2021.

Recommended citation: ASEAN-Australia-New Zealand Free Trade Area Economic Cooperation Support Programme. 2021. *Desk Research on Good Regulatory Practice in the Cosmetics Industry*. Jakarta, December.

General information on AANZFTA and the AECSP appears on the AANZFTA website at https://aanzfta.asean.org/.

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Glossary

AANZFTA: ASEAN-Australia-New Zealand Free Trade Area
ACC: ASEAN Cosmetic Committee
ACCC: Australian Competition and Consumer Commission
ACCSQ: ASEAN Consultative Committee on Standards and Quality
ACD: ASEAN Cosmetic Directive
ACL: Australian Consumer Law
ACSB: ASEAN Cosmetic Scientific Body
AECSP: AANZFTA Economic Cooperation Support Programme
AHCRS: ASEAN Harmonized Cosmetic Regulatory Scheme
AICIS: Australian Industrial Chemicals Introduction Scheme
ANDEAN: Andean Community is a free trade area with the objective of creating a customs union comprising the South American countries of Bolivia, Colombia, Ecuador, and Peru
APEC: Asian Pacific Economic Cooperation
ASEAN: Association of Southeast Asian Nations
CMR substances: Carcinogens, Mutagens or substances toxic to Reproduction
Cosmetics Committee: Standing Committee on Cosmetics Products
CPSR: Cosmetics Product Safety Report
CPTPP: *Comprehensive and Progressive Agreement for Trans-Pacific Partnership*
DG Cosmetics Unit: Technologies of Health and Cosmetics Unit, part of the Directorate General Grow of the European Commission
DG: Director General
EU: European Union
FDA: Food and Drug Administration
GMP: Good Manufacturing Practices
GRP: Good Regulatory Practice
HAS: Health Sciences Authority (HAS
HSNO Hazardous Substances and New Organisms Act 1996
HS: Harmonized System
IA: Impact Assessment
ICCR: International Cooperation on Cosmetics Regulation
ICT: Information and Communications Technology
IFRA: International Fragrance Association
INCI: International Nomenclature of Cosmetic Ingredients
ISO: International Organisation for Standardisation
ITC: International Trade Centre
OECD: Organisation of Economic Co-operation and Development
PEMSAC: Platform of European Market Surveillance Authorities for Cosmetics
PIF: Product Information File
Poisons Standard: Uniform Scheduling of Medicines and Poisons
QA: Quality Assurance
QC: Quality Control
RAPEX: Rapid Alert System (Safety Gate/RAPEX)
RIA: Regulatory Impact Assessment
SCCS: Scientific Committee on Consumer Safety
SCSC: Sub-Committee on Standards and Conformance
SDS: Safety Data Sheets
SMEs: Small and Medium Enterprises.
STRACAP: Standards, Technical Regulations and Conformity Assessment Procedures
SUEs: Serious Undesirable Effects
TBTs: Technical Barriers to Trade ---
TCIA: Taipei Cosmetic Industry Association
TPPA: Trans-Pacific Partnership Agreement
TTIP: Transatlantic Trade and Investment Partnership
UK: United Kingdom
USA: United States of America
UV: Ultraviolet
WTO: World Trade Organization

Executive Summary

The ten Member States of ASEAN have agreed with the governments of Australia and New Zealand to a Free Trade Agreement – the ASEAN Australia New Zealand Free Trade Agreement (AANZFTA). As part of this endeavour, AANZFTA Parties have established an Economic Cooperation Work Programme under which economic and regulatory cooperation between the Parties will be strengthened.

One of the components of the Work Programme is Standards, Technical Regulations and Conformity Assessment Procedures (STRACAP). The aim is to facilitate trade in goods by promoting mutual understanding of each Party's STRACAP measures and strengthening information exchange and cooperation among the Parties. It also aims to reduce unnecessary obstacles to trade and set up a framework to implement supporting mechanisms.

In May 2017 the Secretariat of STRACAP (SC-STRACAP) achieved a first milestone: the organization of a workshop in Auckland that focused on Good Regulatory Practices (GRPs) for the food and beverage sectors.

Following the success of this workshop, SC-STRACAP amplified its efforts launching a new initiative aiming at ensuring that standards, technical regulations and conformity assessment procedures do not create unnecessary obstacles to trade, specifically for the cosmetics sector within the AANZFTA region. Through the implementation of this project, the SC-STRACAP can play a key role in reducing barriers to trade and help to develop greater regional integration through a better understanding and cooperation of STRACAP measures.

The aim of this Report is to support the discussion in a similar Regional Workshop to be organized virtually (given the current health issues) during the first part of 2021. As with the 2017 precedent event, this webinar will be an opportunity for sharing of information and approaches in implementing Good Regulatory Practices (GRP) for the cosmetics sector and signal areas for improved cooperation among AANZFTA members in the coming years.

After a brief introduction setting up the context, the desk report is organized into five substantive Sections.

The first section summarizes the main regulatory models used to regulate cosmetics across the world. It underlines that except for Australia, AANZFTA members have adhered to the European Union approach which focuses on the safety and control of banned or restricted ingredients, through positive lists, product notification, and the requirement to have a safety assessment and to keep a technical file. Operationally, this regulatory model is based on industry self-regulation and strong market surveillance where authorities perform audits of the market through labelling checks, sample testing, as well as audits of the files. On the other hand, Australia has continued to improve its regulatory model based on controlling individual chemicals and ensuring effective marketing and labelling of cosmetic products.

The second section discusses the aims and ways of promoting and implementing GRP to improve the quality of the regulatory process for the producers and consumers of cosmetics. It summarizes the internationally growing GRP agenda to improve rulemaking practices through better analysis design and implementing policies, procedures, institutions and tools to produce higher quality regulations. The rationale for this approach is that the quality of a regulation is intimately related to its making.

The third section then examines the application of such rulemaking GRP to the cosmetics sector among AANZFTA members. Four GRP are highlighted. A first area of GRP development concerns the

establishing of a detailed and formalized administrative procedure to be followed when developing new technical regulations for the cosmetic sector. The comitology process applied in the European Union is used as a case study emphasising aspects such as clear transparency and accountability mechanisms for instance enhancing ways and means for industry and consumers inputs during the rulemaking or the use of ex-ante impact assessment.

A second area of new GRP developments focuses on "fostering better regulators that can produce better regulations". Here new institutions – and their governance – to drive and promote the cradle-to-grave monitoring and oversight of cosmetics regulations are discussed. Having good regulations "in the book" is necessary but not sufficient. Thus, the third area of interesting new GRP focus on improved market surveillance capabilities for the cosmetic industry. A last area for GRP in rulemaking reviewed concern the setup of increasingly sophisticated internet portal to improve the access to cosmetics regulations like a Singapore example shows.

The last substantive section of the discussion report reviews and assesses the implementation of GRP for the cosmetic sectors in ASEAN, Australia and New Zealand, and their comparison from a specifically trade-related perspective. The analyses in this section concentrate on key GRPs to improve trade and investment in cosmetics that have already been detected by STRACAP such as notification, labelling, market surveillance, claims, animal testing and fragrance allergens.

All Parties make clear their commitment to the health and safety of consumers from the use of cosmetic products and this is a strong foundation for ensuring that Parties' standards, technical regulations, and conformity assessment procedures do not create unnecessary obstacles to trade. Furthermore, this commitment facilitates and promotes mutual understanding of each Parties STRACAP. One aspect of conformity assessment that stands out as an area for discussion is the requirement for Good Manufacturing Practice which is a requirement in ASEAN Member States but not in Australia nor New Zealand, although New Zealand recognises that external markets have a GMP requirement. In the areas of Technical Regulation, all Parties could enter into discussions on the topics of animal testing and labelling of fragrance allergens. Strengthening information exchange and co-operation in market surveillance and adverse reporting would also develop and support collaboration on updates to technical regulations that potentially impact a trading bloc of nearly 700 million people.

Based on the preceding analysis and discussions and views from STRACAP members, the concluding section sets up a preliminary set of discussion topics to be proposed for the Regional Webinar on STRACAP:

- Optional Recommendation 1

  Strengthen the institutional capacity of the AANZFTA governing system through the set-up of a GRP working group under the supervision of SC-STRACAP to assess and propose recommendations to accelerate the adoption of GRPs among members, including the setting up of a new market surveillance mechanism for AANZFTA members. An ad hoc working group could start working on more harmonized rulemaking processes to draft proposed cosmetics regulations, which progressively can be deployed to other priority economic sectors as those listed in the STRACAP Work Plan Implementation Program (SWIP).

- Optional Recommendation 2

  Launch an Impact Study for drafting a binding Annex to the AANZFTA to be presented to Parties for discussion and which will look to implement a series of GRP on rulemaking among members of the AANZFTA. This work may refer to the Cosmetics Annexes for the earlier EU-US TTIP and TPPA negotiations as a framework for discussing harmonization within AANZFTA.

- Optional Recommendation 3

  Conduct a "mapping" exercise to further detect the main divergences in perspective existing among business stakeholders from the cosmetic industry within the AANZFTA region in priority areas presented in Section V of this report. A follow up action plan in a prioritized area would be presented.

- Optional Recommendation 4

  Develop and implement strategies to assist SMEs of the cosmetic industry in accessing regulations through consolidated Information Technology and Communication systems for all AANZFTA members.

- Optional Recommendation 5

  Develop mutual understanding of standards, technical regulations, and conformity assessment procedures. This will revolve around GMP for all Parties, starting with mutual recognition of ASEAN and New Zealand GMP certification, technical regulations for all Parties on fragrance allergen labelling and animal testing, and strengthening information exchange and co-operation in the areas of in market surveillance and adverse event reporting.

Next steps: The Regional Webinar on GRP for the cosmetic sector

Creating an effective Free Trade Agreement goes beyond dismantling formal tariffs. Just as important in practice are non-tariff barriers or Technical Barriers to Trade (TBTs) and it is these that are the subject of the workshop. All countries will have some barriers in practice simply because of doing the same things in different ways. Many barriers are not intended as barriers and there is no national interest in maintaining them. But a first step is avoiding the erection of TBTs from inception through the development and use of rulemaking and trade related GRP.

By bringing together trade officials, regulators, businesses representatives and other stakeholders from the 12 countries involved in AANZFTA, the Regional Webinar will aim to raise awareness of such GRP that can expand AANZFTA trade in cosmetics.

It is expected that the Regional Webinar participants will bring examples already identified in practice that can be discussed to see how far they affect intra AANZFTA trade and can be adapted and adopted among Parties. As well, the Regional Webinar should be an opportunity to further promote GRP through specific recommendations for the net benefit of cosmetic producers and consumers in the region. Those recommendations listed in the concluding section might be used as a starting point. To ensure political commitment to continue reducing TBTs in the cosmetics sector, participants might recommend issuing a letter to AANZFTA parties outlining agreed recommendations, including the adoption of GRPs in the development and implementation of regulations and standards.

I. INTRODUCTION AND CONTEXT

Cosmetic products are subject to directly or indirectly regulatory controls in all markets. The objective of all cosmetics regulations is to ensure product safety and avoid adverse effects on the health of the users.

However, the regulatory frameworks are quite different between the various parts of the World and are far from being harmonized. Many different rules in terms of definition, allowed ingredients, labelling, and industrial processes used to make them vary.

This diverse and changing regulatory environment has important impacts on the competitiveness and viability of the industry; it also gives confusing signals to the consumers. Often, consumers are sceptical as to why an ingredient banned in one country for safety reasons is allowed in their country. The inability to sell similar products across markets or the need to change formulations, packaging, claims or advertising introduces increased costs for the sector. New products and/or new ingredients can be delayed which leads to higher costs and is an impairment to innovation and market growth. Although regulations on cosmetics aim to mitigate risks on public health and consumer safety, some regulatory measure can become non-tariff barriers or Technical Barriers to Trade (TBTs) reducing the benefits for consumers and producers.

To facilitate the implementation of Chapter 6 of AANZFTA on Standards, Technical Regulations and Conformity Assessment Procedures (STRACAP) under AANZFTA[1], SC-STRACAP developed STRACAP Work Plan Implementation Program (SWIP) to support the implementation of the Work Program through three key streams, which are (1) Good Regulatory Practice, (2) Cooperation in International Standards Engagement and (3) Technical Capacity Building Implementation Work Programme.

This desk report and the associated workshop to be organized in 2021, is one of STRACAP's contributions to such issues. In particular, the project aims to strengthen information exchange and cooperation among the Parties on Good Regulatory Practice (GRP)s in the cosmetics industry.

The document is organized into four substantive sections, in addition of an introduction and concluding section and two appendices. After this Introduction, a short conceptual chapter summarizes the main regulatory models used to regulate cosmetics across the world. The third section discusses the aim of promoting and implementing GRP to improve the quality of the regulatory process for the producers and consumers of cosmetics. The fourth section then discusses GRPs applied to the cosmetics sector. The fifth section reviews and assesses the implementation of cosmetic regulations in ASEAN, Australia, and New Zealand, and their comparison and identification of similarities and differences. The concluding section offers policy option recommendations to further improve the regulatory environment inside AANZFTA.[2]

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[1] STRACAP is part of the AANZFTA Agreement, aiming to facilitate trade in goods among the AANZFTA Parties by, among others, ensuring that standards, technical regulations and conformity assessment procedures do not create unnecessary obstacles to trade; and promoting mutual understanding of each Party's standards, technical regulations, and conformity assessment procedures.

[2] The final section will be reviewed after the workshop.

II. MODELS TO REGULATE COSMETICS

1. Across the World, four Models Have Been Developed.

Schematically, four regulatory frameworks oversee the production, consumption, and trade of cosmetics.[3]

European Union (EU) model. Introduced in the '70s and slightly modified in the '90s this regulatory model focuses on the safety and control of banned or restricted ingredients, through positive lists, product notification, and the requirements to have a safety assessment and to keep a technical file. The regulatory model is based on industry self-regulation, products made according to good manufacturing practice, and strong market surveillance where authorities perform audits of the market through labelling checks, sample testing as well as audits of the files.

A large number of countries/regions have aligned their system to the EU model to develop their cosmetic regulations. Besides, ASEAN, New Zealand (see below), China, Mercosur (Argentina, Brazil, Paraguay, and Uruguay), ANDEAN Pact region (Bolivia, Colombia, Ecuador, and Peru), Algeria, India, and Israel, have developed their regulatory framework system based on the EU Model.

The USA model is based on a narrow definition dating to the 1930s. There is little restriction on the ingredients and no mandatory safety assessment. Products that do not meet the definition of cosmetics, mostly because of claims rather than composition are classified as drugs. As long as the monograph requirements are met, no registration or sales restriction is required. Overall, the system is quite formalized, relying on and being tested by the courts and ensuring a maximum of checks and balances. It relies on regulating chemicals (including ingredients used in cosmetics).

The New Zealand model is a hybrid of EU and US models: no mandatory safety assessment, no notification (except for products containing nanomaterials), banned and restricted ingredients based on the EU lists, fragrance use based on industry IFRA recommendation, cosmetic claims limited to the definition, and product safety responsibility placed on manufacturer/supplier.

The Australia model is closer to the USA one. Since 1st July 2020, the Australian Industrial Chemicals Introduction Scheme (AICIS) is the entity responsible for controlling cosmetics. Cosmetic products must be used, advertised and presented in a specific way to be considered cosmetics rather than therapeutic goods. Broadly, AICIS regulates the introduction and use of individual chemicals which include ingredients in cosmetic products, while the ACCC regulates the marketing and labelling of cosmetic products. The Poisons Standard is a national classification system that controls how medicines and chemicals are made available to the public. The Poisons Standard also establishes the required packaging (containers) and necessary label information for the safe use of domestic chemical products.

The Japan Model is a rather intermediate or mixed model. While the definition is narrow, there is

[3] For a detailed discussion, see Alain Khaiat (2011) Comparative Study of The Cosmetic Regulations in Major World Markets. Report prepared for Taipei Cosmetic Industry Association (TCIA). SEERS CONSULTING October 2011.

a requirement for notification for cosmetics but there is also a third category of products i.e., Quasi-Drugs comprising products that "have a mild physiological effect". These include Whitening, Anti-Dandruff, etc., and for this category a positive list of ingredients exists. If the formulation meets the requirements, the product needs to be registered but there is no additional requirement for safety evaluation.

2. The ASEAN Approach: The ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS)

As noted, ASEAN Member States have adopted and adapted the EU model given its dynamic aspect in terms of growth for trade and investments in cosmetics. In the past decade, further regulatory reforms and adjustments have continued to strengthen its core principle: evidence-based and science, transparency, and accountability.

The model is known as the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS), which was signed on September 2, 2003, by all ten ASEAN Member States. The Scheme aims to enhance cooperation among the Member States to ensure the safety, quality and claimed benefits of all cosmetic products marketed in ASEAN as well as eliminate restrictions to the trade of cosmetic products among the Member States through harmonization of technical requirements. AHCRS was originally based on two main pillars: the A*SEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetic* and the *ASEAN Cosmetic Directive*.

The first pillar - Schedule A – consisted of the Mutual Recognition Arrangement of Product Registration Approval. It provided that all product registration approvals in an ASEAN country were recognized in other Member Countries, where a mutual recognition arrangement had been agreed upon. Schedule A was a preparatory stage for Member States to proceed to Schedule B, but a Member Country could opt to proceed directly to Schedule B. Since 2008, Schedule A is no longer applicable.

The second pillar - Schedule B - is the ASEAN Cosmetic Directive (ACD).[4] The ACD is based on the EU Cosmetic Directive 76/768/EEC, 6th amendment, with some adaptations. Under the Product Notification at the heart of the ACD, any manufacturer or person responsible for placing cosmetic products on the ASEAN market shall notify the cosmetic regulatory authority of each Member State where the product will be marketed of the place of manufacture or the initial importation of the cosmetic product before it is placed in the ASEAN market. In most ASEAN countries, the entering into force of the ACD has resulted in a transition from a pre-market approval (registration) system to post-market surveillance.

A series of Technical Documents for Cosmetics complete the regulatory framework:

- ASEAN Definition of Cosmetics and Illustrative List by Category of Cosmetic Products
- ASEAN Cosmetic Ingredient Listings and ASEAN Handbook of Cosmetic Ingredients
- ASEAN Cosmetic Labelling Requirements
- ASEAN Cosmetic Claims Guidelines
- ASEAN Guidelines for Cosmetic Good Manufacturing Practice.

[4] The ADC became mandatory for all products in the markets by January 1st, 2011. Progressively the ASEAN Member Countries have transposed the ACD into local regulations and laws. As of 1st January 2011, all member countries apply the ACD.

Like the EU Model, AHCRS is based on product notification and the management of upstream substances and downstream market controls. It combines security and flexibility, to avoid excessive bureaucracy while ensuring the protection of consumer health.

According to the EU chief of the Unit in charge of regulating cosmetics: “for the industry and the consumers, the regulatory framework similar to the EU has led to innovations and market dynamics, when compared to regulatory frameworks in Japan, Korea, Taiwan or USA”.[5] In ASEAN, for example, the introduction of the ACD has increased the rate of new product introduction and local trade has benefited from the change and opportunities that are available for Small and Medium Enterprises (SMEs).

[5] "Salvatore D'Acunto or cosmetic exemplarity at the European Commission"; *Cosmetics Obs*, Wednesday, May 15, 2019

III. GRP IN RULEMAKING

In parallel to the development of the AHCRS, ASEAN, together with Australia and New Zealand, has been promoting GRP. There is no standard definition of what a GRP is, as the term covers many of a single set of activities or disciplines. Broadly, GRP covers, on one hand, the process of making, reviewing and evaluating regulations and, on the other hand, the substance of the regulation. This project will deal with both sides in the next section, concentrating though on the use of GRP to minimize harmful impacts in terms of the trade of cosmetics.

The GRP agenda is about three decades old. Since the mid-1980s, substantive efforts to analyse, design and implement policies, procedures, institutions and practices to produce higher quality regulations have accelerated. Starting with the Organisation of Economic Co-operation and Development (OECD), today most developed countries have adhered to promoting GRPs to increase the quality of all regulatory interventions - for instance, in the EU "Better Regulation" (since 2013)[6] in the UK "Better Regulation", in New Zealand it is "Regulatory Management System" and in Australia "Best Practice Regulation".[7]

Following these efforts, international organisations have also been investing time and effort in promoting GRPs. For instance, since 2002, the Asian Pacific Economic Cooperation (APEC). EU have been driving better regulation and the adoption of GRPs among its members (see below).[8]

This has also been the case of ASEAN. In the past few years, the organization has anchored the GRP approach in its deliberations and undertakings through a series of agreements and new collective initiatives. In 2019, the "ASEAN GRP Core Principles" were adopted by the 17th ASEAN Economic Community Council (See Box 1).

[6] https://ec.europa.eu/home-affairs/e-library/glossary/better-regulation_en

[7] For a general description of the development and use of GRPs see STRACAP (2017*) Report on Good Regulatory Practices on Food and Beverages Industry* - Standards, Technical Regulations and Conformity Assessment Procedures Report.

[8] APEC (2017) "Good Regulatory Practices in APEC Member Economies - Baseline Study". CTI Sub-Fora & Industry Dialogues Groups, Sub-Committee on Standards and Conformance (SCSC) APEC#217-CT-01.11. The report reviewed the application of selected GRPs across the 21 APEC members. This report focuses on those GRPs that promote regulatory quality standards that are particularly important to trade and investment, such as regulatory accountability, reform capacity, consultation, efficiency, and transparency.

Box 1: ASEAN GRP Core Principles

The objective of the Core Principles is to assist AMS in improving their regulatory practice and to foster ASEAN-wide regulatory cooperation. The Core Principles are non-binding, and to be implemented on a best-endeavour basis by each relevant AEC sectoral body or AMS' national regulatory systems. The principles provide broad parameters for assessing the application of GRP in ASEAN. The ASEAN GRP Core Principles do not advocate a particular model of GRP standards but focus on common elements that are applicable to the ASEAN context.

Principle 1: Clarity in policy rationale, objectives, and institutional frameworks
Principle 2: Produce benefits that justify costs and be least distortive to the markets
Principle 3: Be consistent, transparent, and practical
Principle 4: Support regional regulatory cooperation
Principle 5: Promote stakeholder engagement and participation
Principle 6: Be subject to regular review for continued relevance, efficiency, and effectiveness

See https://asean.org/wp-content/uploads/2017/11/ASEAN-GRP-Core-Principles-FINAL-ENDORSED.pdf

In practical terms, the Core Principles are transposed into a series of GRP such as:

- The preparation of new regulation should be based on evidence, rather than prejudice or political expediency, and that evidence should itself be capable of being challenged.
- The development of new regulation and its implementation, revision and revocation should be made through dialogue and engagement with stakeholders.
- The final decisions should be made after proper assessment of the intended impact of the policy and that assessment should look at impacts on a range of stakeholders and issues. The assessment of impact should be both ex-ante and ex-post. There should be an economic assessment of the costs and benefits of the proposed policy.
- As well, the management of the rule-making activities needs to be coordinated, particularly in terms of sectoral reforms, and other crucial economic policies like trade and competition.

Under these principles, governments across the world, international organizations as well as ASEAN, Australia and New Zealand, have developed and promoted new institutions, procedures, tools and methodologies and highly specific guidance to implement GRPs. For example, the ASEAN Consultative Committee on Standards and Quality (ACCSQ), published in October 2019 the ASEAN Guidelines on Good Regulatory Practices (GRP) to assist ASEAN Member States (AMS) to collectively reform and improve their technical regulations, emphasising, in particular, the use of: [9]

[9] https://asean.org/wp-content/uploads/2017/09/ASEAN-Guidelines-on-Good-Regulatory-Practices2.pdf https://www.pmc.gov.au/regulation; https://www.treasury.govt.nz/information-and-services/regulation/regulatory-stewardship/good-regulatory-practice

- Regulatory impact assessment (RIA) to ensure that better policy options are chosen by setting up a systematic and consistent framework for assessing the potential impacts of government action, including impacts on trade.
- Public consultation mechanisms to improve transparency, such as “publication for comment” and other practices that allow wide access, and the quality of consultation mechanisms.
- Portals and registers to enhance access to regulations and a reduction of discretion when applying the obligations and requirements. Improved consultation and better access to the rules, standards, regulation to be complied also aim at better achieving the implementation, enforcement and compliance of regulatory arrangements, standards and requirements.

IV. FOUR RULE-MAKING GRP RELEVANT TO THE COSMETICS SECTOR

As with all quality-driven efforts, the identification and development of GRPs is a never-ending process. Collectively as well as individually, AANZFTA members have been implementing GRPs based on the documentation, discussion, comparison, adaptation, customization or adoption of the new policies, regulations, institutions and tools. The development and design of the AHCRS is living proof of such an endeavour.

Collectively, two types of mechanisms have promoted GRPs for the cosmetics sector. On one hand, GRPs have been fostered through internal dialogue between governments, regulators and stakeholders agreeing on principles and promoting new tools. The ASEAN efforts mentioned above are a prime example. These complement other initiatives such as one of APEC members agreeing on nine principles to manage chemical regulations (see Box 2) and proposed a checklist to assist regulators to implement them – in particular when different regulatory models discussed in Section B co-exist.[10]

Box 2: APEC 2008 Principles for Best Practice Chemical Regulation

1. Do the minimum required to achieve their stated objectives?
2. Adopt a risk management approach to developing and administering regulation
3. Minimize the impact on competition
4. Utilize relevant international standards wherever possible
5. Not restrict international trade flows
6. Be developed in consultation with stakeholders, subject to public review and comment and periodic review
7. Be flexible, not prescriptive, and be compatible with the business operating environment
8. Be science-based
9. Have a clear delineation of regulatory responsibilities and effective and transparent

The second type of collective mechanism to promote the use and expansion of GRPs has been through Free Trade Agreements. For instance, the recently signed Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), in Chapter 8 – Technical Barriers to Trade, engages all trade partners "to facilitate trade, including by eliminating unnecessary technical barriers to trade, enhancing transparency, and promoting greater regulatory cooperation and good regulatory practice".[11] Some of these free trade agreements, including CPTPP, address rights and obligations on aspects governing the production and trade of cosmetics in specific annexes.

[10] http://mddb.apec.org/Documents/2014/CD/CD/14_cd_002.pdf and http://mddb.apec.org/Documents/2016/SOM/SOM1/16_som1_024anxf.pdf

[11] https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/text-texte/08.aspx?lang=eng

In terms of national initiatives, the realm of GRPs initiatives is broader and more varied. As indicated, cosmetic regulators have for many years been designing and implementing new GRPs processes and procedures to improve the quality of the regulatory framework and environment focusing, although not exclusively, on the reduction of trade and investment barriers and frictions in a globalized industry.

These efforts have drastically reformed the way the industry is regulated (like setting up a new regulatory model based on self-supervision like in the EU) to more limited rules and regulations such as those for cosmetic labelling, packaging or characteristics, conformity assessment procedures, i.e., procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; notification, accreditation and approval as well as their combinations.

This section will discuss and describe four GRP systems that can be considered relevant for regulators area who responsible for the cosmetic industry in the AANZFTA. Note that four of the GRP systems described below are mostly pertinent to the ASEAN Member States and New Zealand as they share a similar regulatory model for cosmetics regulations. They can also be relevant to Australia as some are also compatible with the type of model in place.

1. A Transparent and Formalized Rulemaking Process: The EU Comitology Process

Since setting up a new regulatory model and transforming its regulatory framework based on an EU Directive into the Cosmetic Regulation, the European Union has continued to ensure the high quality of its cosmetic regulations through a clear, transparency and evidence-based procedure.

A critical innovation has been in adjusting, expanding and adapting for the cosmetics industry, the basic rulemaking procedures – The Comitology procedure - to ensure the smooth operation of the European Internal Market.[12]

The Comitology Procedure is a well-established rule-making procedure. It is built on evidence and consultation for most regulations that do not need to follow the more precise and demanding law-making process. For the latter which includes the preparation of new Directives and Regulations, the rule makers need to follow strict administrative steps including an Impact Assessment report which, after public consultation, is challenged by an independent Regulatory Scrutiny Board.[13]

In practice, the Comitology Process is used for the preparation of annexes and amendments – and other “technical adaptations” to the EU Cosmetic Regulations.[14] The driver of the procedure is the official Standing "comitology committees", chaired by the European Commission official. On average, the Standing Committee on Cosmetics Products (hereafter the “Cosmetics Committee”) deals every year with one to three legal measures through part or all of the Comitology procedure (See Figure 1).

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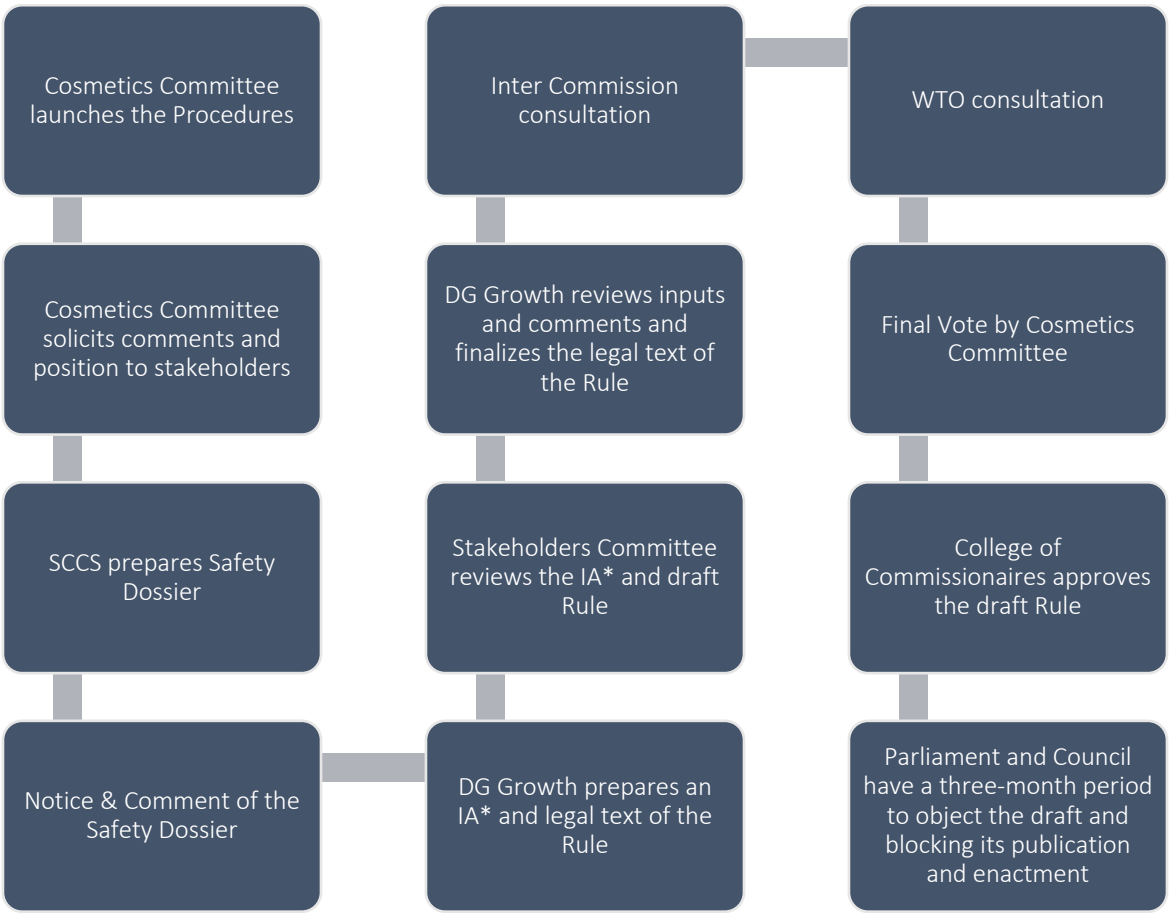
[12] The official term for the Comitology Process is “committee procedure”.

[13] https://ec.europa.eu/info/law/law-making-process_en

[14] Comitology in the European Union refers to a process by which EU law is modified or adjusted and takes place within "comitology committees" chaired by the European Commission. The official term for the process is committee procedure. Comitology committees are part of the EU's broader system of committees that assist in the making, adoption, and implementation of EU laws.

Figure 1: Standard Comitology Procedure



** Formal Impact Assessment only used for major regulations*

Furthermore, the procedure contains a democratic accountability valve. It gives Parliament and Council a period (normally of three months) to examine proposals that have been validated by the Cosmetics Committee. If Parliament objects to a proposal, the Commission cannot enact it. Instead, the Commission can either make a new proposal, taking account of the reasons for the objection (in which case the clock is re-set and Parliament can again block), or it can propose new legislation to Parliament and Council under the legislative co-decision procedure.[15]

Importantly, a series of supporting GRPs is nevertheless worth noting.

a) Transparency and Accountability Principle

At the heart, the Comitology procedures specifies and mandates at each step important GRPs to enhance transparency, consultation and accountability. As with all modern public initiatives,

[15] A new "co-decision" procedure by Council and Parliament to be establish soon will confer powers on the Commission to adopt implementing measures of general scope that can be described as "quasi-legislative" in nature (delegated legislation).

rulemaking on cosmetics relies on a series of informal contacts to monitor the progress of the dossier, possibly to complete or clarify it until the Cosmetics Committee has delivered its opinion. It also emphasises two type and complementary aspect for a successful dialogue with stakeholders organised around the use of "active" and "passive" consultation tools (See Box 3).[16]

Box 3: Active and Passive Consultation with Stakeholders

Many regulators have opened their regulatory processes. Regulatory consultation processes are a cornerstone of GRP and a major prerequisite for regulations that will meet with a high degree of acceptance and thus be enforceable. This section will review how leading regulators have been making systematic efforts to ensure that interested and affected parties can take part in meaningful consultations at all stages of the regulatory process, that is, development, implementation, evaluation, and review.

Two important categories of consultation GRPs will be reviewed in the context of the cosmetics industry: "passive consultation" where the regulator shares the regulation and expect feedback often under a notice-and-comment system; and "active consultation" complementing it. In the case of the latter, the regulator actively seeks inputs and views from implicated and concerned stakeholders through techniques like focus groups, bilateral meetings, hearings, surveys, etc.

For more information, see ***Section 6.5 of the ASEAN Guidelines on Good Regulatory Practices***.

To provide accountability to the different transparency mechanisms embedded in the Comitology Procedures, the EU Council has requested the Commission to set up a register to follow up and make accessible all key documents behind the regulatory decision.[17] Some of the most important GRPs are:

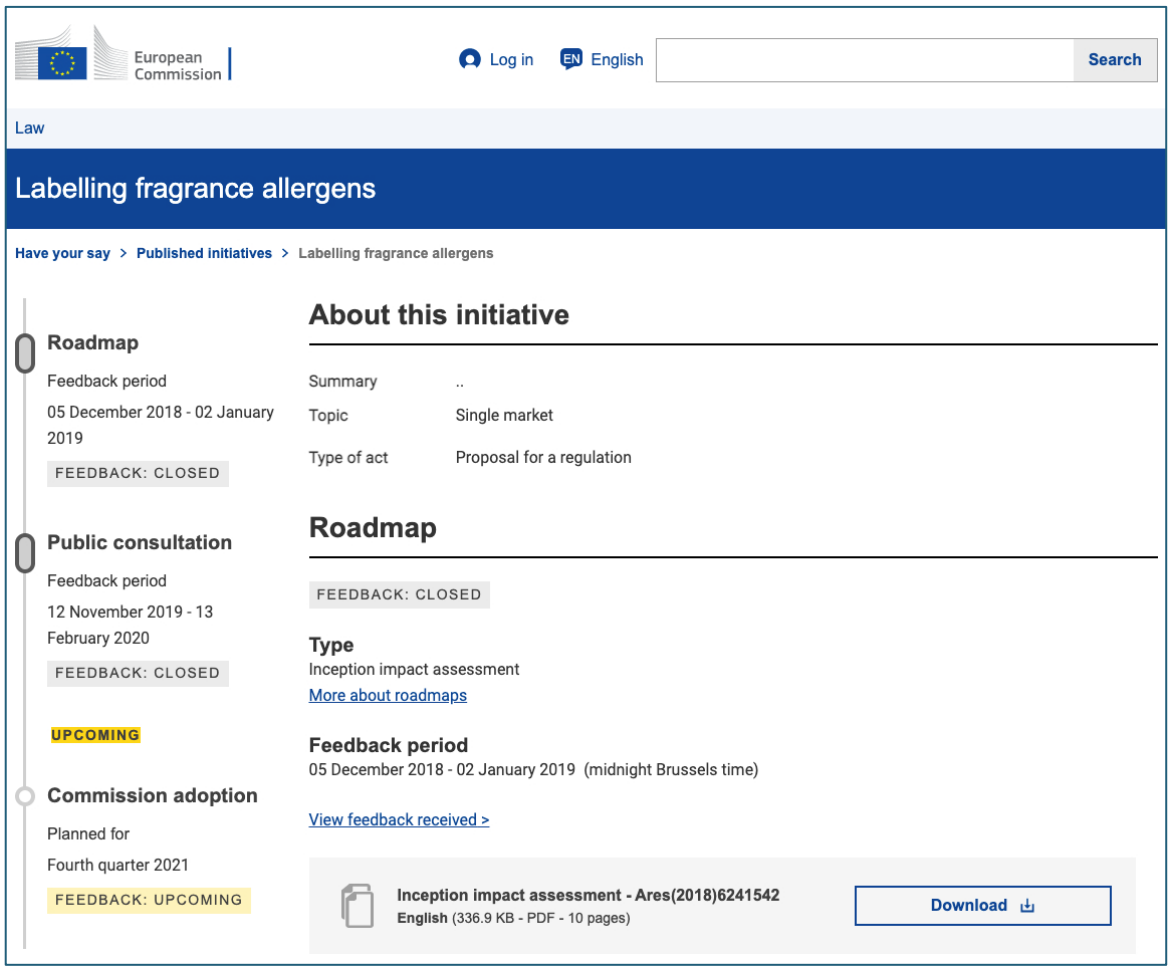
- agendas of committee meetings,
- draft implementing measures,
- summary records of committee meetings,
- voting results of opinions delivered by a committee.

Hence, the Technologies of Health and Cosmetics Unit, part of the Directorate General Growth of the European Commission (hereafter "DG Cosmetics Unit", is in charge of drafting the new rule needs to balance the different interests and priorities of a varied number of stakeholders. As the previous head of the DG Cosmetics indicated "Industry is obviously a qualified part of this dialogue, but it is only a part". As he also underscored, the Commission services (i.e., DG Cosmetics Unit in charge of cosmetics) cannot discuss with associations that are not registered in the European register of interest holders, so that the dialogue is completely open and transparent.

[16] https://ec.europa.eu/info/sites/info/files/better-regulation-guidelines-stakeholder-consultation.pdf
[17] https://ec.europa.eu/transparency/comitology-register/screen/home

Finally, the Commission and in particular the DG Cosmetics Unit has used the EU ITC state-of-the-art consultation and communication platform. For example, stakeholders can closely follow the consultation of the forthcoming Fragrance-Allergen Rule (see Figure 2).

Figure 2: Consultation System Used to Prepare the Labelling Fragrance Allergens Rule[18]



b) *Strengthening Evidence-based Rulemaking Principle*

A second, central feature of the EU Comitology rulemaking procedure is the critical role played by facts, figures and scientific evidence. Two major GRPs have been integrated into the decision-making machinery.

First, most regulatory decisions by the Cosmetics Committee need to be solidly backed by scientific analysis and a robust health risk assessment. For this, the Committee requires early in the process the official opinion of the Scientific Committee on Consumer Safety (SCCS).

The SCCS is an independent body of 12 to 18 experts in charge of evaluating the safety of cosmetic

[18] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2009-Labelling-fragrance-allergens/public-consultation

ingredients for the European Commission.[19] The SCCS is not administered by DG Growth the cosmetics regulators but by the Directorate-General for Health and Consumer Protection of the European Commission.

The SCCS role is to provide independent scientific expertise through opinions on the health and safety risks (chemical, biological, mechanical and other physical risks) of non-food consumer products (cosmetic products and their ingredients, toys, textiles, clothing, personal care, household products, etc.) and services (tattooing, artificial sun tanning, etc.).

Of course, the task is delicate. Consequently, the Cosmetics Committee considers and plans the time required to receive data and submit an opinion. Usually, the SCCS needs at least six months to arrive at a draft opinion, which should then be published to allow interested parties to make comments. Then, once the SCCS has issued its final opinion, draft Regulations are prepared to amend the annexes and submitted to interested parties in the working group.

A second key GRP to anchor the rulemaking on the evidence is the use of regulatory impact assessment (RIA) (See Box 4).[20] RIA has been at the core of the EU regulatory decision making since the early 2000s. The use of RIA at the European level complements the additional RIAs from many of the 27 European member states. Before the European Commission proposes a new initiative, it assesses the need for EU action and the potential economic, social and environmental impact of alternative policy options in an impact assessment.

Box 4: What is RIA?

An increasing number of countries have merged many of the rule-making practices into formal RIAs that precede and accompany a draft legal measure. RIA is a tool to systematically identify and assess the expected effects of regulatory proposals. The assessment is based on deciding the underlying regulatory objectives and identifying different policy interventions that are capable of achieving the objectives.

For more information, see ***Section 6.2 of the ASEAN Guidelines on Good Regulatory Practices***.

Impact assessments are prepared by the DG Cosmetics Unit and reviewed by the Cosmetics Committee, evaluated by the Regulatory Scrutiny Board and finally approved by the Commissions and other EU political bodies.[21] They are required for a certain number of initiatives that are expected to have a significant economic, social or environmental impact. These can be legislative proposals, non-legislative initiatives that define future policies (e.g., white papers, action plans, financial programmes, and negotiating guidelines for international agreements), as well as implementing and delegated acts.

[19] In EU and ASEAN safety guidelines have been established, respectively by the SCCS and the ACSB (ASEAN Cosmetic Scientific Body); while in Japan and US the guidelines have been issued by the industry.
[20] The RIA process is known in the EU as "impact assessment" as it is also used for preparing policies and other non-regulatory interventions).
[21] https://ec.europa.eu/info/law/law-making-process/regulatory-scrutiny-board_en

As part of the process, the Chief Economist Team closely follows and assists in preparing impact assessment reports for the initiatives of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs. The planning of impact assessments is communicated to the public via “inception impact assessment". Stakeholders are consulted early on and continuously on all key aspects of an impact assessment during its preparation.[22]

Furthermore, many EU Member States have expanded RIA to bring together multiple policy concerns, in part to reflect the economic, environmental and social dimensions of sustainable development and in particular during the implementation of the rule. In the latter case, replacing any cost-benefit principle with a cost efficiency one to ensure the application achieves the maximum of positive effects at the minimum cost of compliance and enforcement costs and barriers.

In practice, RIA has so far been used sparsely by the Cosmetics Committee in the European Commission compared for instance to the USA where most regulatory decisions by FDA need a RIA. However, the DG Cosmetics Unit has prepared RIA reports for major EU decisions in the area of cosmetics, including in 2011 when transforming the Cosmetics Directive into a Cosmetics Regulation. Since then, the Cosmetics Committee has overseen the preparation of two RIAs: The Impact assessment and the Fragrance Allergens currently been discussed.[23]

The adoption of RIA and its different methods has accelerated among an increasing number of ASEAN members such as Malaysia, Philippines, and Singapore. Australia and New Zealand have a longer experience including for the cosmetics sector. Sor instance, the Australian Government prepared a Regulation Impact Statement to design the reforms to industrial chemicals regulation.[24] Australia has also been one of the worldwide leaders using RIA to Ensure regulators adopt a risk based and best practice approach to implementation and enforcement of regulation, and there are effective mechanisms for business to provide feedback on regulators’ performance.[25]

c) Interagency Coordination and World Trade Organization (WTO) Consultation

The EU Comitology Procedures also emphasise internal and international coordination embedded in a series of GRPs using new communication technologies. For that, the DG Cosmetics Unit organises internal consultation within other European Commission’s Director Generals. Key inputs are requested to the DG Environment, DG Health, the Legal Service, the Secretariat General, or DG Trade.

When this phase is completed, the draft provision is notified at the international level to the World Trade Organisation to comply with the TBT agreement. This process takes two months but provides an important opportunity and venue for third countries to react.

Only after the statutory time to get comments from other WTO members can the Cosmetics

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[22] https://ec.europa.eu/growth/about-us/impact-assessment_en

[23] https://op.europa.eu/en/publication-detail/-/publication/71005243-433b-11eb-b27b-01aa75ed71a1/language-en

[24] Industrial Chemical Assessment Reform. https://ris.pmc.gov.au/2015/06/05/industrial-chemicals-assessment-reforms-%E2%80%93-regulation-impact-statement

[25] https://guideItoIusingIstandardsIandIriskIassessmentsIinIpolicyIandIregulation.pdf

Committee vote on the new rule. The voted text is in English; it must then be translated into all European languages, which is another step forward. After the vote, the rule is sent to the other EU decision making bodies and a period of control is allotted to the Parliament and the Council of the Member States. Both institutions have three months to raise an objection. According to an ex-head of DG Cosmetics Unit "Between the vote and adoption by the Commission, it is difficult to count less than six months, because there are always deadlines to send the document and receive it, then give it to the College of Commissioners for adoption… I know it may seem very long and technocratic, but it's provided for in the treaty."[26]

Overall, the rulemaking process takes months as it is recognised that the success of a rule demands time to ensure the needed checks and balances. The time may be further lengthened by the need to gather additional scientific data or by political deadlock, particularly on the most "sensitive" ingredients when Member State representatives are unable to reach an agreement. An example here is the case of CMR substances (Carcinogens, Mutagens or substances toxic to Reproduction). However, it is also a guarantee that, at the end of the process, a thoughtful, scientifically justified decision will be made with the best possible consensus.

2. The Governance of Regulatory Bodies

Important instructional embedded specialised bodies have also assisted the implementation and oversight of EU rulemaking GRPs. As noted, the governance of the regulatory framework is organised by a concert of bodies working in conjunction and participating actively. At the centre, and as key regulator, is the Standing Committee on Cosmetics Products formed by representatives of all EU Member States, which meets periodically in Brussels. Then, a well-staffed DG Cosmetics Unit, which is part of the General Directorate Growth in charge of the EU Internal Market, plays the key role of managing the Comitology process and serves as the secretariat of the Cosmetics Committee. A third important body, the Scientific Committee on Consumer Safety (SCCS), hosted by the Directorate-General for Health and Consumer Protection of the European Commission, provides independent experts in charge of evaluating the safety of cosmetic ingredients.[27]

However, in the end, the technocratic work needs political backing. This is a crucial and final step to effectively, efficiently and transparently implement the regulatory process. Therefore, after the EU Commission finalises the proposed regulations, it is sent to the European Council for approval, and for major regulations to the EU Parliament, where a formal vote of the Member States by a double qualified majority is required before being applied across the Single Market.

Finally, it is noteworthy to mention an important although non-governmental institution called the International Cooperation on Cosmetic Regulation (ICCR). ICCR is a network of regulatory authorities, created in 2007 at the initiative of the European Commission, including the US Food and Drug Administration, Health Canada, and the Ministry of Health, Labour and Welfare of Japan to provide a forum to discuss regulatory affairs relevant to the cosmetics industry. Since then, the ICCR has been promoting the understanding and adoption of GRPs. In recent years, regulatory

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[26] "Salvatore D'Acunto or cosmetic exemplarity at the European Commission"; *CosmeticsObs*, Wednesday, May 15, 2019

[27] The SCCS provides opinions on the health and safety risks (chemical, biological, mechanical and other physical risks) of non-food consumer products (cosmetic products and their ingredients, toys, textiles, clothing, personal care, household products, etc.) and services (tattooing, artificial sun tanning, etc.).

authorities from Brazil, Canada, Chinese Taipei and the Republic of Korea. This network has a rotating chair and meets every year to discuss regulatory convergence. meet on an annual basis to discuss cosmetics safety and regulation, as well as enter into a constructive dialogue with relevant cosmetics industry trade associations.[28]

3. Market Surveillance

Because the EU approach for cosmetics regulation is based on product notification not pre-market authorisation, and control over ingredients, prohibition of dangerous substances and cosmetics labelling, the role of market surveillance to ensure compliance is fundamental (See Box 5).

Box 5: GRPs to Improve Compliance

Compliance with regulation is not automatic. Regulators need to monitor and ensure compliance. However, traditional inspection systems based on the "command-and-control" system are flawed, expensive and in the end unattainable. New GRPs have emerged to deal with the crucial aspect of a high-quality regulatory framework. Conformity assessment regimes and systems for the purpose of enforcement of regulations should primarily be based on an assessment of the risks which could arise from nonconformity, looked at from the point of view of both the likelihood and the consequences of the product, service, etc., failing to conform to the specified requirements.

For more information, see ***Section 6.6 of the ASEAN Guidelines on Good Regulatory Practices***.

In this area, the EU approach has also been innovating setting a number of GRPs worth noting. Three of them constitute the backbone of Market Surveillance.

First, because EU countries are responsible for the surveillance of their markets for cosmetics and, in particular, to ensure a coherent approach to consumer products issues, the market surveillance authorities of all EU countries established a specific Platform of European market surveillance authorities for cosmetics (PEMSAC).[29]

PEMSAC aims to facilitate cooperation by:

- coordinating activities
- exchanging information
- developing and implementing joint projects
- exchanging expertise and best practices in cosmetics market surveillance

The members of PEMSAC are the representatives of market surveillance authorities in all EU countries. They meet twice a year in plenary and in two technical groups dealing with market

[28] https://www.iccr-cosmetics.org/
[29] https://ec.europa.eu/growth/sectors/cosmetics/market-surveillance_en

surveillance and analytical methods. PEMSAC has published a Guidance document[30] to assist the public authorities of Member States in market surveillance and administrative cooperation in the area of market surveillance. Crucially, thanks to PEMSAC members have been able to share the cost of inspections and cosmetic products through the elaboration of inspection plan targeting particular products, for instance, eye products. The results of the inspection are extensively distributed among the network members.

A second pillar of the market surveillance mechanisms is the RAPEX system.[31] Under the responsibility of the Directorate-General for Justice and Consumers, the EU Commission manages the Rapid Alert System (Safety Gate/RAPEX) for non-food products which pose a risk to consumers or professional users. It permits Member States to rapidly circulate information and share the measures taken to prevent or restrict the marketing or use of non-food, non-pharmaceutical or non-medical products or devices. Summaries of the alerts are published immediately after having been validated by the Commission on the Safety Gate website. Furthermore, the Commission posts a weekly report on its website every Friday.

The third GRP initiative to strengthen the market surveillance is the industry-based Cosmetic Vigilance Mechanism.[32] Similar to PEMSAC the system is based on a uniform approach to the management of serious undesirable effects (SUEs) attributable to the use of cosmetics. It provides for notification of SUEs without delay to the Competent Authorities of the Member State, including information on where the effect in question occurred, as well as the notification of any corrective measures taken by the Responsible Person or Distributor. Data on SUE become part of the Cosmetics Product Safety Report (CPSR) and have to be made available to the public. In practice, the system has worked well. For example, hundreds of cases of allergic reactions have been posted which have resulted in the cosmetics producers recalling the products in question relabelling them and taking other mitigation measures as necessary.

To implement this GRP, the Cosmetic Committee, in conjunction with the Member States and industry, established guidelines to post alerts. They aim to ensure harmonized notification of SUE by the Responsible Person or Distributor and follow-up on SUE notifications by Competent Authorities, Responsible Persons or Distributors.

4. Access to Regulation and the Regulatory Framework impacting the Cosmetics Sector

As per Principle 6 of the ASEAN Good Regulatory Practice (GRP), Core Principles the availability and access to relevant and salient regulatory information is a cornerstone of free and fair trade. Access to accurate, easy-to-understand, and accessible information on the regulations should be made available for relevant stakeholders. Different information needs may be addressed using various

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[30] file:///Users/cesarcordova/Documents/Master%2030%20JUNE%202020/AA%20JC&A%20projects/21-001%20ASEAN%20BRP%20Cosmetics/Data%20gathering/market_surv_guideline20071126_en.pdf file:///Users/cesarcordova/Documents/Master%2030%20JUNE%202020/AA%20JC&A%20projects/21-001%20ASEAN%20BRP%20Cosmetics/Data%20gathering/market_surv_guideline20071126_en.pdf

[31] https://ec.europa.eu/safety-gate-alerts/screen/webReport

[32] file:///Users/cesarcordova/Documents/Master%2030%20JUNE%202020/AA%20JC&A%20projects/21-001%20ASEAN%20BRP%20Cosmetics/Data%20gathering/sue_reporting_guidelines_en.pdf file:///Users/cesarcordova/Documents/Master%2030%20JUNE%202020/AA%20JC&A%20projects/21-001%20ASEAN%20BRP%20Cosmetics/Data%20gathering/sue_reporting_guidelines_en.pdf

tools and Information and communications technology (ICT) tools have expanded the quality and quantity of GRPs (See Box 6).

Box 6: GRPs to Increase Access

Regulatory frameworks are increasingly complex. Thousands of rules, requirements and obligations that frame any business activities need to be understood and complied with. This is even more acute for the Cosmetics industry. For improving compliance and reducing abuses, regulators have set up practices and systems to publish and post on accessible internet portals regulatory documents and supporting materials such as regulatory impact assessments.

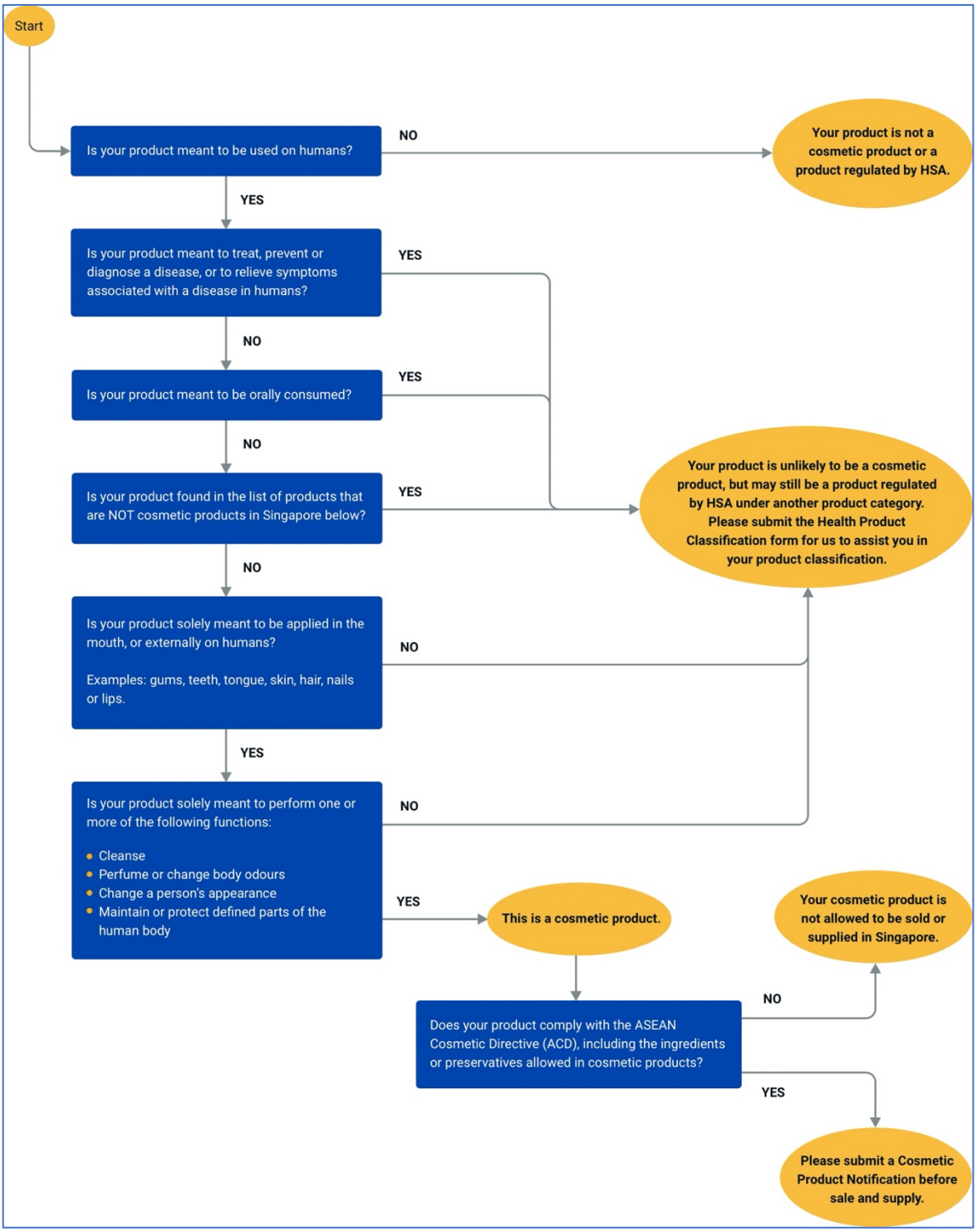
For more information, see ***Section 6.4 of the ASEAN Guidelines on Good Regulatory Practices***.

In the past decade, Asian countries have invested in and made very significant progress in improving access to the regulatory framework.[33] This has involved working on and developing machinery and systems to ensure better access to the regulatory framework on cosmetics for national and international producers of cosmetics.

Among the many GRPs in these areas, but not alone among the AANZFTA Parties, Singapore's access to rules and regulation initiative has been recognised as one of the most user-friendly ones. Built around an internet platform, the system not only provides a basic framework and information on the administrative procedures to follow but also a classification guide to help producers and importers determine whether or not a product falls under the Health Sciences Authority (HAS) cosmetic product category (See Figure 3).[34]

[33] See APEC (2017) idem
[34] https://www.hsa.gov.sg/cosmetic-products/

Figure 3: Singapore HSA Access to Regulation Website



V. REVIEW OF TECHNICAL REGULATIONS IN ASEAN, AUSTRALIA AND NEW ZEALAND[35]

1. *Introduction*

The following section of the desk research report focuses on the review and assessment of the standards, technical regulations and conformity assessment procedures for cosmetic products in ASEAN, Australia and New Zealand and draws conclusions on their similarities and differences, with a view to contributing to the background information for the workshop.

Special focus is given to cosmetic labelling, conformity assessment procedures i.e., procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; notification, accreditation and approval as well as their combinations. In addition, mechanisms for marketing surveillance across AANZFTA and "hot topics" such as fragrance allergens, product claims and animal testing are also examined. The research methodology used to obtain the information for this report primarily focused on studying the official information published by the three parties on the internet.

2. *ASEAN Cosmetics Directive*

The ASEAN Cosmetics Directive is a harmonised technical regulation for ASEAN members. It is closely based on the EU cosmetics regulation. The underlying principle to placing products on the market is the notification of products, based on an agreed definition of a cosmetic, and the preparation of a Product Information File, where the composition of the product, technical data on the ingredients, manufacturing methods, substantiated claims and a safety assessment is presented. Annexes provide data on prohibited and restricted substances as well as the positive lists of permitted ingredients for use of, for example, preservatives and ultraviolet (UV) filters.

Individual Member States establish their cosmetic regulations based on the ASEAN Cosmetic Directive. Legislation in individual member states was not reviewed as part of this desk study.

On 2nd September 2003 the Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme came into force. Consisting originally of two schedules, Schedule A dealt with the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics and Schedule B concerned the ASEAN Cosmetic Directive. However, since 2008 Schedule A is no longer applicable.

Based on the EU Cosmetics Directive, which was reformed into the European Cosmetics Regulation in 2009, the ASEAN Cosmetics Directive is essentially a Product Notification scheme based on:

a) ASEAN Definition of Cosmetics and Illustrative List by Category of Cosmetic Products
b) ASEAN Cosmetic Ingredient Listings

[35] All reasonable effort has been made to ensure that the information provided in this report is accurate, up to date, and otherwise adequate in all respects. This assessment is our own work, any errors or omission are those of the consultant not ASEAN Secretariat, and only the legal texts are authoritative.

c) ASEAN Cosmetic Labelling Requirements
d) ASEAN Cosmetic Claims Guidelines
e) ASEAN Guidelines for Cosmetic Good Manufacturing Practice

Articles of the **ASEAN Harmonized Cosmetic Regulatory Scheme**

- Article 1: Objectives
- Article 2: ASEAN Harmonized Cosmetic Regulatory Scheme
- Article 3: Technical Documents for Cosmetics
- Article 4: Other Areas of Operation
- Article 5: Dispute Settlement
- Article 6: Institutional Arrangements
- Article 7: Final Provisions

Articles of Schedule A[36]

Articles of Schedule B

- Article 1: General Provisions
- Article 2: Definition and Scope of Cosmetic Product – cross ref Appendix I and Annex V
- Article 3: Safety Requirements
- Article 4: Ingredients Listings cross ref Annex II, Annex IV part 1, Annex VI part 1, Annex VII part1, Annex III part 2, Annex 4 part 2, Annex VII part2,
- Article 5: ASEAN Handbook of cosmetic ingredients[37]
- Article 6: Labelling, cross ref Appendix II, annexes III, IV, VI, VII and VIII
- Article 7: Product Claims cross ref Appendix III
- Article 8: Product Information cross ref Appendix VI Good Manufacturing Practices (GMP), Safety assessment guide, PIF,
- Article 9: Product Analysis/ methods of analysis
- Article 10: Institutional Arrangements: ACCSQ, ACC (ASEAN Cosmetic Committee), ACSB (ASEAN Cosmetic Scientific Body), ACTLC (ASEAN Cosmetic Testing Laboratory Committee)
- Article 11: Special Cases Member State may provisionally prohibit the marketing of a cosmetic product in its territory or subject it to special conditions, if the Member State finds out that on the basis of a substantiated justification, the cosmetic product, although complying with the requirements of the Directive, represents a hazard to health or for reasons specific to religious or cultural sensitivity. Certain product claims may be permitted or prohibited in accordance with national requirements. Furthermore, the Member State for reasons related to its local organization and laws, may designate a specific competent authority and subject to a different control, a specific cosmetic product which comply with the requirements of this Directive and Annexes thereto. It shall immediately inform the other Member States with a copy to the ASEAN Secretariat stating the grounds for its decision.
- Article 12: Implementation

[36] All ASEAN Member States have entered into Schedule B since January 2008, so Schedule A is no longer applicable.
[37] No longer applicable

See below section (k) for a list of downloadable updated Ingredient Annexes in addition to documents in the footnotes:

a) Substances for use in cosmetic products (Article 4 and Article 5)

Similar to the EU Cosmetics Regulation, the ASEAN Directive contains annexes for prohibited and restricted ingredients as well as for the colorants, preservatives and UV filters permitted for those uses in cosmetics under the prescribed conditions. Member States shall adopt the Cosmetic Ingredient Listings of the EU Cosmetic Directive 76/768/EEC including the latest amendments (now EU Cosmetics Regulation 1223/2009) Notwithstanding Article 4, a Member State may authorize the use within its territory of other substances, not contained in the lists of substances allowed, for certain cosmetic products specified in its national authorization since the ASEAN Handbook of cosmetic ingredients is no longer applicable.

b) Safety

Product safety is dealt with under Article 3 of Schedule B:
A cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, instructions for its use and disposal, warning statements as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the market.

A Safety Assessment Guideline is used to help the Cosmetic Industry to assess the safety of the product as well as the Regulators in auditing the data contained in the Product Information File (PIF).

c) Labelling[38]

The following is taken from Appendix II. Full details are given in: https://asean.org/wp-content/uploads/2012/05/Appendix-II-ASEAN-Cosmetic-Labeling-Requirements.pdf

The following particulars shall appear on the outer packaging of cosmetic products or, where there is no outer packaging, on the immediate packaging of cosmetic products:

a) The name of the cosmetic product and its function, unless it is clear from the presentation of the product;

b) Instructions on the use of the cosmetic product, unless it is clear from the product name or presentation;

c) Full ingredient listing. The ingredients must be declared in descending order of weight at the time they are added. Perfume and aromatic compositions and their raw materials may be referred to by the word "perfume", "fragrance", "aroma" or "flavour". Ingredients in concentrations of less than 1% may be listed in any order after those of concentration of more than 1%. Colouring agents may be listed in any order after the other ingredients, in

[38] Appendix II ASEAN Cosmetic Labelling Requirements (September 2007

accordance with the colour index number or denomination adopted in Annex IV.

d) Claims

Appendix III of the ASEAN Cosmetics Directive[39] provides Guidelines for Cosmetics Claims. If the claim is promising cosmetic benefits and not medicinal or therapeutic benefits, it is acceptable as long as it can be substantiated. Any cosmetic claimed benefits made shall be aligned with what is accepted internationally and shall be justified either by technical data and/or cosmetic formulation or preparation itself. Refer to the ASEAN Cosmetic Claims for Guidelines for further information[40].

e) Adverse event reporting – Market Surveillance

Under Article 3 of Schedule B of the ASEAN Cosmetics Directive, a cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, instructions for its use and disposal, warning statements as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the market.

Accordingly, under the ASEAN Cosmetics Directive, there is a procedure for reporting adverse events (see Manual for adverse event reporting of the cosmetic industry[41]). Pursuant to the ASEAN Cosmetic Directive, Article 3 (1) and the Discussion Paper on Post Marketing Surveillance/Product Safety, adopted by the ASEAN Cosmetic Committee in its second meeting held in Bangkok June 7-8, 2004, it is important to harmonize the mechanism to gather and, if necessary, take action on important safety information arising from post marketing surveillance of cosmetic products.

Thus, agreed definitions and terminology, as well as procedures, will not only ensure uniform standards in the adverse event reporting process but will also facilitate product safety information sharing among ASEAN Regulatory Bodies.

f) Updates to Annexes

There is a process to update the annexes.

g) Fragrance Allergens

No information was found in the desk study about fragrance allergens. Fragrance allergens were not found in the list of restricted ingredients (Annex III).

h) Animal Testing

There is no information in the ACD about animal testing on final product or ingredients.

i) Environmental protection

No information was yet found about the impact of the cosmetic industry on the environment in the

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[39] https://asean.org/wp-content/uploads/2012/05/Appendix-III-ASEAN-Cosmetic-Claim-Guideline.pdf
[40] ASEAN General Information booklet on cosmetics
[41] https://asean.org/wp-content/uploads/2012/05/Guide-Manual-for-Adverse-Event-Reporting.pdf

ASEAN Cosmetics Directive.

j) GMP

ASEAN has a GMP standard and requirement for companies to follow GMP. Article 8 of Schedule of the ASEAN Cosmetic Directive states that the method of manufacture shall comply with the good manufacturing practice as laid down in the ASEAN Guidelines for Cosmetic Good Manufacturing Practice appearing as Appendix VI.

Appendix VI[42] of ASEAN Cosmetics Directive presents ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE. Detailed information is provided at the following website: https://asean.org/asean-cosmetic-good-manufacturing-practice-gmp-training-modules-no-1-to-no-13/

k) Additional Links for the ASEAN Cosmetics Directive

https://asean.org//wp-content/uploads/2012/05/Appendix-III-ASEAN-Cosmetic-Claim-Guideline.pdf
https://asean.org/wp-content/uploads/2012/05/Appendix-II-ASEAN-Cosmetic-Labeling-Requirements.pdf

3. Australian cosmetic regulations

The regulation of industrial chemicals in Australia, including those used as cosmetic ingredients in consumer products, is a shared responsibility between Commonwealth, state and territory governments. Product safety regulation in Australia is a shared responsibility between the Australian Competition and Consumer Commission (ACCC) and the states and territories. The Commonwealth regulates the introduction (by import or manufacture) of industrial chemicals, whereas state and territory governments regulate their use and disposal.

At the Commonwealth level, the introduction of industrial chemicals used as cosmetic ingredients is regulated by the Australian Industrial Chemicals Introduction Scheme under the Industrial Chemicals Act 2019 (the IC Act).

Under the IC Act, a person introducing chemicals in cosmetic products must be registered with AICIS, which also conducts assessments and evaluations of both unlisted and listed ingredients to aid in the protection of the Australian people and the environment by identifying risks to worker health and safety, public health and the environment.

Where risks are identified from the use of these chemicals, AICIS makes recommendations to other government agencies on appropriate regulation to mitigate these risks and publishes information to promote awareness in industry and the community of these risks.

Fundamentally the regulations revolve around the Australian Industrial Chemicals Introduction Scheme (AICIS), the national regulator of the importation and manufacture of industrial chemicals in Australia. Regulation can also involve other regulatory bodies such as the Therapeutic Goods

[42] https://asean.org/wp-content/uploads/2012/05/Appendix-VI-ASEAN-Guidelines-for-Cosmetic-GMP.pdf

Administration (TGA) and the Australian Competition and Consumer Commission (ACCC), depending on the type of product or requirement.

As a basic first step an exporter of cosmetics to Australia needs to know that Australia operates an Introduction scheme for chemicals, which will include cosmetic products (that are not categorised as Therapeutic Goods (TG)). Cosmetics products which make therapeutic claims are assessed by the TGA.

The Industrial Chemicals Act 2019 is the Australian law that regulates the importation and manufacture of industrial chemicals in Australia and the Australian Industrial Chemicals Introduction Scheme (AICIS) is the regulatory scheme that administers these laws[43].

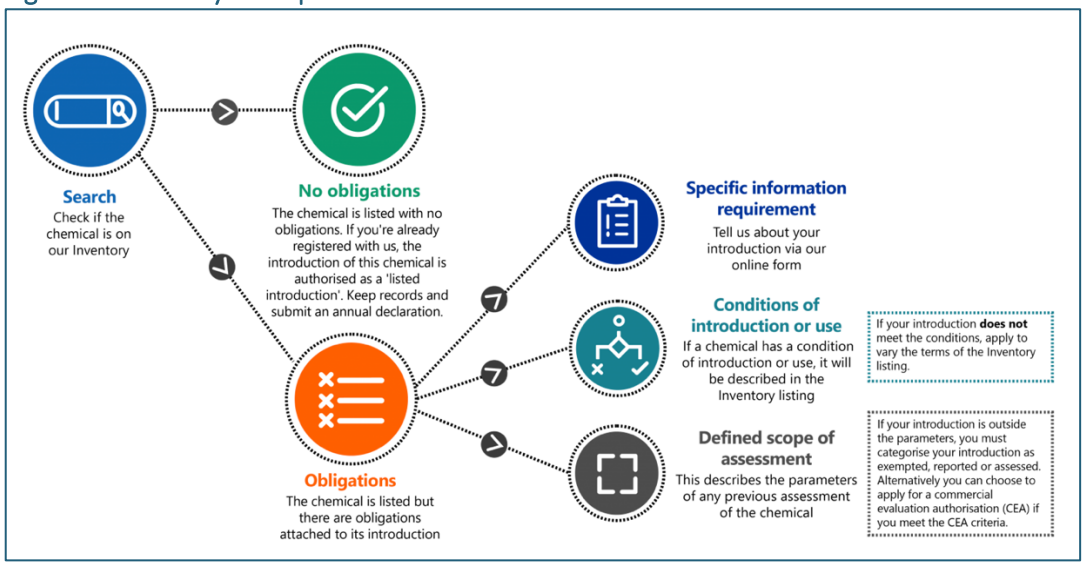
If a company exports directly to Australia (that is, without using an importing agent), that company is the introducer. The introducer must register their business with AICIS (and pay any relevant fees and charges) before any chemical is exported. To register with AICIS as a foreign company, the company needs to provide an Australian Registered Business Number (ARBN).

If the exporter has a business arrangement with an Australian agent/distributor, they are the introducer (as importer of the chemical) and the exporter is the chemical data provider. Chemical data providers do not need to register with AICIS as introducers but do need to have an account with AICIS Business Services.

There are five types of chemical introduction:

Listed introductions. A chemical introduction that is categorised as 'listed' means it is on the AICIS Inventory (with more than 40,000 chemicals listed for industrial use) and already available for industrial use in Australia. The business must be registered with AICIS and must meet any terms of the listing for that chemical. There's no fee for listed introductions (See Figure 4).

Figure 4. Summary of steps for a listed introduction



[43] From review of industrialschemicals.gov.au

Exempted introductions. A chemical introduction that is categorised as 'exempted' is considered to very low risk to human health and the environment. The chemical can be introduced without telling AICIS beforehand, as long the company is registered with AICIS. Some exempted introductions require a once-off post-introduction declaration the first time that the chemical is introduced. There's no fee for exempted introductions. Naturally occurring chemicals are exempted.

Reported introductions. A chemical introduction that is categorised as 'reported' means it is considered to be low risk to human health and the environment. The registered company must submit a once-off pre-introduction report before introducing it. There's no fee for reported introductions and no fee to submit a pre-introduction report.

Assessed introductions. A chemical introduction that is categorised as 'assessed' means it is considered it to be medium to high risk to human health and the environment. It cannot be exempted or reported. AICIS assess the introduction and issue an assessment certificate before the chemical can be imported or manufactured. There is a fee to apply for an assessment certificate.

Commercial evaluation. If you meet the commercial evaluation criteria, you can apply for a commercial evaluation authorisation as an alternative option to the exempted, reported or assessed category. There is a fee to apply for a commercial evaluation authorisation.
In Australia, there is no single list of banned or restricted chemicals. Bans and restrictions on chemicals and consumer product ingredients – including cosmetics –are regulated by each state and territory authority[44].

a) Examples of Cosmetics (as defined in Part 1 Section 9 of Industrial Chemicals Act 2019)

Face and nail

- Lipstick and lip balms with SPF sunscreen that comply with the Therapeutic Goods (Excluded Goods) Determination, 2018
- Nail care products including nail hardeners and products to deter nail biting
- Make-up such as mascara, eyeshadow, primer and bronzer
- Nail polish and varnish
- Tinted bases and foundation without SPF sunscreen, including liquids, pastes and powders
- Make-up removers
- Lipstick and lip balms without SPF sunscreen
- Face masks and scrubs

Hair care and hairdressing products

- Anti-dandruff hair care products that comply with the Therapeutic Goods (Excluded Goods) Determination, 2018
- Hair tints, hair dyes and bleaches
- Products for waving, straightening and fixing hair
- Hair-setting products such as gels, sprays and lotions
- Shampoo and hair-cleansing products, including lotions and powders
- Hair conditioner
- Hairdressing products such as lotions, lacquers and brilliantines

[44] https://www.industrialchemicals.gov.au/chemical-information/banned-or-restricted-chemicals

Oral and dental hygiene

- Toothpaste and gel
- Denture cleansers and adhesives
- Some dental bleaches and whiteners
- Desensitising toothpaste and gels are not cosmetics. They are therapeutics and are regulated by the TGA.

Perfumes

- Perfumes and colognes
- Eau de toilette
- Eau de colognes
- Eau de parfum

Personal hygiene

- Feminine hygiene products such as intimate cleaners, deodorants, wash, powder, moisturisers and gels. We do not regulate pads, tampons and panty liners because they are classified as articles.
- Deodorants
- Cleansers, including soap, deodorant, astringent and skin washes
- Shaving products, such as creams, foams and lotions
- Bath and shower preparations, such as salts, foams, oils and gels
- Depilatories
- After-bath powders
- Hygienic powders

Skin care

- Secondary sunscreen products that comply with the Therapeutic Goods (Excluded Goods) Determination, 2018
- Anti-acne skin care products that comply with the Therapeutic Goods (Excluded Goods) Determination, 2018
- Skin moisturisers without SPF sunscreen such as creams, lotions, gels and foams
- Sunbathing products without SPF sunscreen or with SPF sunscreen
- Emollients such as creams, emulsions, lotions, gels and oils for the skin
- Products for tanning without sun (without SPF sunscreen)
- Some skin-whitening products (without SPF sunscreen)
- Anti-wrinkle products (without SPF sunscreen)
- Anti-ageing products (without SPF sunscreen)

b) Therapeutic Goods

Therapeutic Goods require a Market Authorisation. The following products are examples of therapeutic goods.

- Primary sunscreens (products that are primarily used for protection from UV radiation)
- Moisturisers that contain a sun-screening agent as a secondary component and have a stated therapeutic purpose ('helps protect skin from the damaging effects of UV radiation')
- Skin-whitening lotions that inhibit the physiological process of melanin production. For example, products that contain the chemical hydroquinone

c) *Labelling*[45]

Product safety regulation in Australia is a shared responsibility between the Australian Competition and Consumer Commission (ACCC) and the states and territories. The mandatory standard for ingredients labelling on cosmetics came into effect in 1991. It was last updated on 24 November 2020 to include additional labelling requirements for hand sanitiser (ref: Consumer Goods (Cosmetics) Information Standard 2020[46]).

d) *Cosmetovigilance*[47]

There are clear procedures laid out on what suppliers must do in the event of a Product Recall. If a product is found to present a safety risk, it may need to be recalled. Recalling products identified as safety hazards can help to prevent injuries to consumers. Many suppliers voluntarily initiate their own recalls after becoming aware that one or more of their products presents a safety risk. If suppliers are identified as having sold consumer products that are unsafe, product recalls may also be negotiated by the ACCC or other regulators.

In some cases, the ACCC can recommend that the responsible Commonwealth Minister initiate a compulsory recall in order to protect the public from an unsafe product. The ACCC will direct the manner in which the compulsory recall is to occur and will enforce compliance.

e) *Market Surveillance*[48]

The ACCC has an annual surveillance program. They conduct surveillance and testing of products from physical and online stores, including those supplied via online platforms. Their surveillance program is focused on ensuring businesses are not selling consumer products that are banned or fail to meet mandatory safety standards. They also examine potentially unsafe goods that are not subject to any specific mandatory standard. The ACCC employs a risk-based approach to surveillance, ensuring resources are dedicated to high priority issues. The ACCC website has published the most recent results of market surveillance of cosmetic products.

f) *Animal Testing*[49]

Australia has now implemented a ban on the use of new animal test data for cosmetics. The legislative component of this ban is set out in the Industrial Chemicals Act 2019, which commenced on 1 July 2020. There are also restrictions on using new animal test data for chemicals with multiple end uses (including in cosmetics). There are however some limited exceptions which allow use of animal test data.

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[45] from productsafety.gov.au
[46] https://www.legislation.gov.au/Details/F2020L01469
[47] from productsafety.gov.au
[48] ibid
[49] from industrialschemicals.gov.au website

g) Responsible sourcing of products[50]

Under the Australian Consumer Law (ACL), suppliers are responsible for selling consumer products that are safe and fit for purpose.

- Sourcing products
- Testing products
- Pre-shipment inspections
- Other compliance measures
- Related resources
- More information

h) GMP[51]

GMP certification of cosmetics is not a requirement. However, other measures are recommended such as developing documented quality assurance (QA) and quality control (QC) processes, commissioning factory audits and/or requesting evidence of compliance with ISO 9000 (or equivalent) and engaging the services of professional QA and QC consultants.

i) Sourcing products[52]

As stated on the Product Safety Australia website, companies that supply consumer products in Australia at any stage in the supply chain are legally responsible for product safety. As well as products that are subject to a mandatory safety standard (such as cosmetics) or ban, they are also responsible for products that may not be subject to mandatory safety requirements.

j) Testing products[53]

When products are designed and developed for supply to consumers, it is generally not enough to have a pre-production sample of the products safety tested and no further quality assurance or control measures applied.

Suppliers should:

- request test reports from a manufacturer, wholesaler or agent to an applicable safety standard whenever you purchase products domestically or from overseas
- commission tests (where possible) to be performed by a suitably accredited laboratory – most products can be tested to an Australian standard, some of which are cited in Australian safety regulations.

[50] from productsafety.gov.au
[51] ibid
[52] ibid
[53] ibid

l) Other compliance measures[54]

There are a number of other measures companies can take to ensure products purchased for supply are safe, compliant and of acceptable quality.

These include:

- developing documented quality assurance (QA) and quality control (QC) processes
- training staff in QA and QC processes, mandatory safety standards and the ACL
- performing random stock audits in distribution centres or stores
- commissioning factory audits and/or requesting evidence of compliance with ISO 9000 (or equivalent)
- engaging the services of professional QA and QC consultants
- purchasing recall insurance.

k) Animal testing

Limited information was found from the desk study. Australia has implemented a ban on use of new animal test data in cosmetics. (See Industrial Chemicals Act 2019)

l) Fragrance Allergens

The desk study found no information about fragrance allergens in cosmetic products

m) Links to Australia Cosmetic Regulations

https://www.industrialchemicals.gov.au/chemical-information
https://www.industrialchemicals.gov.au/business
https://www.industrialchemicals.gov.au/cosmetics-and-soap
https://www.industrialchemicals.gov.au/cosmetics-and-soap/my-product-cosmetic
https://www.industrialchemicals.gov.au/cosmetics-and-soap/cosmetics-and-therapeutics
https://www.industrialchemicals.gov.au/foreign%20companies
https://www.industrialchemicals.gov.au/business/use-animal-test-data
https://www.industrialchemicals.gov.au/getting_started/what-registration-and-who-must-register
https://www.industrialchemicals.gov.au/chemical-information/banned-or-restricted-chemicals
https://www.industrialchemicals.gov.au/help-and-guides/extra-resources-help-you-categorise-your-introduction/categorisation-chemicals-cosmetics
https://www.tga.gov.au/publication/poisons-standard-susmp
https://www.tga.gov.au/therapeutic-goods-excluded-goods-determination-2018-explanatory-notes
https://www.productsafety.gov.au/product-safety-laws/compliance-surveillance/responsible-sourcing-of-products
https://www.productsafety.gov.au/product-safety-laws/legislation/mandatory-reporting
https://www.productsafety.gov.au/standards/cosmetics-ingredients-labelling
https://www.productsafety.gov.au/recalls/guidance-for-suppliers/conducting-a-recall

[54] from productsafety.gov.au

https://www.legislation.gov.au/Details/F2020L01469

4. New Zealand cosmetic regulations

The New Zealand cosmetic regulation is governed by the Cosmetic Products Group Standard 2020 that falls under the HSNO Act, and it draws on subsidiary legislation such as the Labelling Notice, Safety Data Notice and Packaging Notice etc. With the exception of cosmetic products containing nanomaterials there is no requirement for pre-market authorisation or notification. There is however the requirement to keep the record of self-assignment of a product to the group standard (in condition 10, Part 3) and have it available for inspection, by the enforcement agency.

a) Product safety

In the New Zealand regulation, the legal onus is squarely on suppliers to supply safe goods, but the law is not prescriptive as to how that should be done. The best way, therefore, of showing that a product is safe is by showing that it complies with a relevant product safety standard: https://productsafety.tradingstandards.govt.nz/for-business/requirements-for-all-businesses/.

b) Cosmetics products not to cause harm

Part 3, Condition 7 of the Cosmetic Product Safety Group Standard states:

A substance must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account in particular of the substance's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or their authorised agent.

If certain specified threshold concentration limits are exceeded for ingredients classified as hazardous, they must be included on the label.

c) Compliance with Schedules 4 to 8 of the Cosmetic Product Group Standard[55]

If a substance contains a component listed in Schedules 4 to 8, the relevant conditions and restrictions as set out in those Schedules must be complied with.

- Schedule 4: Components Cosmetic Products Must Not Contain
- Schedule 5: Components Cosmetic Products Must Not Contain Except Subject to The Restrictions and Conditions Laid Down
- Schedule 6: Colouring Agents Cosmetic Products May Contain with Restrictions
- Schedule 7: Preservatives Cosmetic Products May Contain with Restrictions
- Schedule 8: UV Filters Cosmetic Products May Contain with Restrictions

Schedules 4-8 of this Group Standard are based on (mirror) the provisions of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, which replaces Council Directive 76/768/EEC of 27 July 1976 on the approximation of the

[55] https://www.epa.govt.nz/assets/RecordsAPI/Cosmetic-Products-Group-Standard-2020-HSR002552.pdf

laws of the Member States relating to cosmetic products. These schedules were last updated in 2012. There is a project to update them.

d) 'Safe' products

There are few mandatory standards in New Zealand, but there is a general legal requirement under the Consumer Guarantees Act that all products sold in New Zealand should be 'safe'.

This isn't defined but would cover issues such as:

- testing to voluntary standards
- the likely use and foreseeable misuse of the product
- how the product is marketed — particularly whether it would be appealing to children.

The New Zealand Trading Standards, Product Standards website states "In essence, the legal onus is squarely on suppliers to supply safe goods, but the law is not prescriptive as to how that should be done. The best way, therefore, of showing that a product is safe is by showing that it complies with a relevant product safety standard (in this case Cosmetic Product Group Standard 2020). A certificate of compliance from a laboratory that's accredited to carry out testing to that standard is a good way of demonstrating this."

https://productsafety.tradingstandards.govt.nz/for-business/requirements-for-all-businesses/

New Zealand suppliers are encouraged to use NZS ISO 10377:2017 Consumer product safety — Guidelines for suppliers, to help ensure their products are safe.

e) Labelling

The Cosmetic Products Group Standard contains requirements for labelling and advertising.

(1) Substances covered by this Group Standard must comply with the relevant provisions of the Hazardous Substances (Labelling) Notice 2017 (updated now for 2020)

(2) The label on a substance covered by this Group Standard must also contain a list of ingredients in accordance with the following priority—
  (a) a list of the ingredients in the product (except colour additives) in concentrations of 1% or more in descending order by volume or mass; and
  (b) a list of the ingredients in the product (except colour additives) in concentrations of less than 1% in any order; and
  (c) colour additives in any order; and
  (d) flavour or flavours, which must be described in the list of ingredients by:
    (i) the words, "flavour" or "flavours" or "aroma" or "aromas"; or
    (ii) the ingredients in the flavour or flavours; and
  (e) fragrance or fragrances, which must be described in the list of ingredients by:
    (i) the words, "fragrance" or "fragrances" or "parfum" or "parfums"; or
    (ii) the ingredients in the fragrance or fragrances.

(3) A label must provide the manufacturer's original source or batch code information.

(4) A substance that contains a component listed in Schedules 5 to 8 must comply with the relevant labelling requirements set out in those Schedules.

(5) Despite subclause (4) a primary sunscreen may be labelled in accordance with the

requirements of the "Therapeutic Goods Order No. 69: General Requirements for Labels for Medicines 2017" of the Commonwealth of Australia.

(6) Despite subclause (4) a cosmetic product containing a component at reference numbers 67-92 of Schedule 5 may not be labelled with the name of that component, provided the label lists the flavours or fragrances which must be described by the words, "fragrance" or "fragrances" or "parfum" or "parfums", or the ingredients in the fragrance or fragrances.

Sub clauses 2 and 4 do not need to be met for products that are already compliant with current labelling requirements for cosmetic products of Australia, the United States of America (USA), Canada or the European Union, as if the substance were for sale or supply in those countries (Meaning, it is an alternative means of compliance with subclauses 2 and 4 if the requirements of those specified overseas jurisdictions are met).

If certain specified threshold concentration limits are exceeded for ingredients classified as hazardous, they must be included on the label[56].

f) Claims

No specific guidance on claims was found from the desk research. However, broadly speaking, the claims that can be made for a cosmetic product would fall within the scope of the definition of cosmetic products. In other words, claims relate to the scope of what defines a cosmetic.

The following paragraph is from Schedule 3 of the Cosmetic Product Group Standard:

Cosmetic product means any product or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.

Paragraph 4 of the Explanatory Notes lists typical examples of cosmetic products (referred to as substances).

g) Fragrance Allergens

From the Cosmetic Product Group Standard: Any fragrance material imported or manufactured under this Group Standard shall comply with the IFRA standards and restrictions as set out in the IFRA Code of Practice. NZ will look to align with EU cosmetics regulation in Schedule 5 of Cosmetic Product Group Standard.

h) Market Surveillance

Trading Standards of New Zealand carries out market surveillance, according to the Trading Standards website. Trading Standards also publishes detailed information about product recalls. A product recall should be launched when a product is found to be unsafe and poses an unacceptable

[56] https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/GHS2/Consolidated_Hazardous_Substances_Labelling_Notice_2017.pdf

level of risk to users and/or the public.

There are also the enforcement powers/offences, etc, under the HSNO Act, specifically the enforcement functions of the EPA under section 97(3)[57].

i) Animal Testing

Animal Testing for cosmetics is banned under the Animal Welfare Act

https://www.beehive.govt.nz/release/law-change-ban-cosmetic-testing-animals

j) Environmental protection

Under the Hazardous Substances and New Organisms Act[58] (which includes the Cosmetic Products Group Standard) there are environmental controls available to the Environment Protection Authority which can be product specific. In clause 4(4) of the Scope, it lists the UN GHS Hazard classifications of products that are hazardous to the aquatic environment. The Labelling Notice requires GHS environmental labelling for cosmetic products for aquatic hazards – effectively this applies similar to the EU CLP regulation for environmental labelling. This law also links to the Resource Management Act which sets out how businesses operate in the environment and promotes the sustainable management of natural and physical resources.

The Waste Minimisation Act encourages a reduction in the amount of waste New Zealand generates and disposes of and provides for substances to be banned. New Zealand has a ban in place for plastic microbeads in cosmetics under this act[59].

Environmental Protection is also covered specifically in the Cosmetic Product Group Standard, under the relevant legislation derived from the UN GHS. Furthermore, if certain specified threshold concentration limits are exceeded for ingredients classified as hazardous, they must be included on the label.

k) GMP (from CosmeticsNewZealand.org)

Cosmetic manufacturers in New Zealand can be certified to comply with ISO 22716 by Cosmetics New Zealand[60] (registered as Cosmetic Toiletry and Fragrance Association of New Zealand Inc.). This means that products are manufactured under the processes and requirements set out in both Cosmetics New Zealand's own GMP and under the International Standard ISO 22716 which ensures they are made to the highest safety standard available to cosmetics manufacturers globally.

In order to be certified the manufacturer must be a member of Cosmetics New Zealand and must undergo a rigorous audit of their premises, systems and processes. This includes checks on ingredient quality, hygiene and clean downs, suitability of the premises, clear documentation,

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[57] https://www.epa.govt.nz/assets/Uploads/Documents/EPA-Publications/Hazardous-substances-enforcement-under-the-HSNO-Act-1996.pdf
[58] https://www.legislation.govt.nz/act/public/1996/0030/latest/DLM381222.html
[59] https://environment.govt.nz/acts-and-regulations/regulations/microbeads-regulations/
[60] https://www.cosmeticsnewzealand.org.nz/membership/good-manufacturing-practice/

training and full compliance with legal obligations. Once certified the manufacturer must be re-audited every 5 years if no significant changes are made to premises or earlier if significant changes such as expanded or changed premises occur. Failure to meet the standard during a re-audit will see the GMP revoked until compliance can be achieved through remedial work by the manufacturer.

Certificates issued to the manufacturers are able to be used to provide evidence to regulators in international markets that products made in their factory are safe for those markets. Some markets have this as a mandatory requirement while others require those placing products on sale to hold the evidence of this on file should the regulator need to see it.

l) Declaration of Conformity for imported goods

From the New Zealand Trading Standards website: Goods may require certification to prove that they comply with mandatory standards. Unless the consignment has certification to prove that it complies with the relevant standard, it's likely to be stopped at Customs. The importer is liable for producing the necessary documents to prove that the goods may be brought into the country. Test Certificates must be from a laboratory that's accredited under ISO 17025 for the specific standard and tests required[61].

m) Links to New Zealand Cosmetic Regulations

https://www.epa.govt.nz/assets/RecordsAPI/Cosmetic-Products-Group-Standard-2020-HSR002552.pdf
https://productsafety.tradingstandards.govt.nz/for-business/the-product-safety-landscape/
https://www.medsafe.govt.nz/regulatory/regguidance.asp
https://www.medsafe.govt.nz/regulatory/regguidance.asp#Cosmetics
https://www.epa.govt.nz/industry-areas/hazardous-substances/guidance-for-importers-and-manufacturers/cosmetics/
https://www.medsafe.govt.nz/regulatory/categorisation-of-products.asp
https://productsafety.tradingstandards.govt.nz/for-business/requirements-for-all-businesses/
https://www.epa.govt.nz/industry-areas/hazardous-substances/group-standards/2020-group-standards/?tag=583
https://www.epa.govt.nz/assets/RecordsAPI/Cosmetic-Products-Group-Standard-Schedules-4-8-HSR002552.pdf
https://www.epa.govt.nz/industry-areas/hazardous-substances/guidance-for-importers-and-manufacturers/cosmetics/
https://www.standards.govt.nz

[61] https://productsafety.tradingstandards.govt.nz/for-business/requirements-for-all-businesses/

5. Similarities and differences across parties[62]

a) Comparing key technical regulations and conformity assessment procedures

Theme	ASEAN	AUSTRALIA	NEW ZEALAND
Definition	A "cosmetic product" shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.	***Cosmetic*** means: (a) a substance or preparation intended for placement in contact with any external part of the human body, including: (i) the mucous membranes of the oral cavity; and (ii) the teeth; with a view to: (iii) altering the odours of the body; or (iv) changing its appearance; or (v) cleansing it; or (vi) maintaining it in good condition; or (vii) perfuming it; or (viii) protecting it; or (b) a substance or preparation prescribed by the rules for the purposes of this paragraph; but does not include: (c) a therapeutic good within the meaning of the *Therapeutic Goods Act 1989*; or (d) a substance or preparation prescribed by the rules for the purposes of this paragraph. Note: An ingredient or component of a cosmetic could be an industrial chemical. Primary Sunscreens, Skin whiteners and moisturisers with sunscreen as therapeutic purpose are	Cosmetic product means any product or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.

[62] The consultant has not studied the cosmetic regulations in individual ASEAN Member States only referred to the ASAN Cosmetic Directive

Theme	ASEAN	AUSTRALIA	NEW ZEALAND
		therapeutic goods[63]	
GMP Standards	The method of manufacture complies with the good manufacturing practice as laid down in the ASEAN Guidelines for Cosmetic Good Manufacturing Practice appearing as Appen- dix VI. In the PIF a statement by the manufacturer or company that the product was manufactured according to the ASEAN GMP Guidelines or ACC approved equivalent GMP Guidelines	Documented QA/QC. No GMP requirement	No GMP requirement. Testing to voluntary standards is expected. Cosmetics New Zealand arranges GMP certification. Declaration of conformity for imported goods
Market Surveillance	Market surveillance at national level. ASEAN Member states and health authority share information via ASEAN Post Market Alert System (PMAS) during the bi-annual ASEAN Cosmetic Committee (ACC) meetings	Market surveillance procedures in place	Market surveillance procedures in place
Ingredient safety	Annexes of prohibited, restricted and positive lists for preservatives, colouring agents and UV filters (reference to EU 1223/2009)	Refer to Introduction scheme and Poison standard. There is no single list of banned or restricted chemicals in Australia. Bans and restrictions on chemicals and consumer product ingredients – including cosmetics – are	Annexes of prohibited, restricted and positive lists for preservatives, colouring agents and UV filters (reference to EU 1223/2009)

[63] Therapeutic Goods Act was not examined for this study

Theme	ASEAN	AUSTRALIA	NEW ZEALAND
		regulated by each state and territory authority in Australia	
Product safety	A cosmetic product placed on the market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, instructions for its use and disposal, warning statements as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the market. Guideline published for safety assessment of product and the Product Information File (PIF) (Signed assessment report of the safety for human health of the finished product)	Under Australian Consumer Law suppliers are responsible for selling consumer products that are safe and fit for purpose. Product safety regulation in Australia which is a shared responsibility between the Australian Competition and Consumer Commission (ACCC) and the states and territories of Australia	Imported or manufactured cosmetics products must meet the conditions of the cosmetic product group standard. Suppliers are responsible for ensuring their products are safe to use and do not cause harm.
Notification of product	before placing product in the market by submitting notification template and PIF	not required	not required, except for products containing nanomaterials other than zinc oxide or titanium dioxide
Product Labelling	INCI is an option for ingredient labelling. Requirements described in Appendix II: ASEAN Cosmetic Labelling	INCI and Mandatory Standard	INCI and Cosmetic Products Group Standard. In addition, if certain specified threshold concentration

Theme	ASEAN	AUSTRALIA	NEW ZEALAND
	Requirement		limits are exceeded for ingredients classified as hazardous, they must be included on the label
Claims	Appendix III ASEAN Cosmetic Claim Guideline	Relates to the definition of cosmetics	Relates to definition of cosmetics
Fragrance Allergens	No specific information found	No specific information found	Reference to IFRA code of practice in the Cosmetic Products Group Standard
Animal Testing	No information	New animal test data not accepted for cosmetics	Animal Testing for cosmetics is banned under the Animal Welfare Act

Notes: Colour codes: same colour = similar standard or technical regulation

6. Examples of Cosmetic Annexes for Transatlantic Trade and Investment Partnership (TTIP) and Trans-Pacific Partnership Agreement (TPPA)

For the negotiations for these Free Trade Agreements, Draft Annexes for the Cosmetics Sector were drawn up (see Appendix 2 and 3). These Annexes provide useful references for analysing and discussing the opportunities to harmonise cosmetics regulations in AANZFTA.

7. Summary of the comparison in technical regulations

Chapter six of the AANZFTA concerns Standards, Technical Regulations and Conformity Assessment Procedures. Article 1 in Chapter 6 establishes the objectives:

a. ensuring that standards, technical regulations, and conformity assessment procedures do not create unnecessary obstacles to trade
b. promoting mutual understanding of each Party's standards, technical regulations, and conformity assessment procedures
c. strengthening information exchange and co-operation among the Parties in relation to the preparation, adoption and application of standards, technical regulations and conformity assessment procedures
d. strengthening co-operation among the Parties in the work of international bodies related to standardisation and conformity assessments; and
e. providing a framework to implement supporting mechanisms to realise these objectives.

The desk study has in a short time gone a certain distance in examining the standards, technical regulations and conformity assessment procedures of the three Parties with reference to cosmetic products, with a view to contributing to the procedures in place to achieve the above objectives of Article 1 of Chapter 6 (STRACAP) of the AANZFTA.

In each of the three Parties the definition of a cosmetic product is similar, with one important difference. Whereas in ASEAN member states and New Zealand a cosmetic product cannot have therapeutic properties, in Australia cosmetics with therapeutic properties (and these are defined) are regulated by the Therapeutic Goods Act.

Each of the three Parties of the Free Trade Agreement has different requirements for placing cosmetic products in their respective markets but there are also some similarities. In ASEAN member states, there is a Notification procedure to be followed when a manufacturer places a cosmetic product on the market. This is similar to the procedure used in the European Union. In Australia there is no requirement to notify the placing of cosmetic products on the market. In New Zealand there is a requirement to notify cosmetic products that contain nanomaterials except zinc oxide and titanium dioxide.

In terms of product safety, the ASEAN model follows that of the EU whereby the safety of the product has to be assessed as part of the notification process in the Product Information File (PIF). In terms of product safety, a key element is the assessment report of the safety for human health of the finished product based on its ingredients, their chemical structure and level of exposure, signed by a qualified safety assessor. In Australia and New Zealand, under the general consumer protection legislation, companies are required to sell products that are safe and fit for purpose.

In ASEAN member states and in New Zealand the regulations concerning ingredients used in cosmetics are based on the provisions of the EU cosmetic regulation. There are annexes for prohibited ingredients, restricted ingredients and annexes with permitted colouring agents, preservatives and UV filters. By contrast, Australia has implemented an introduction scheme for chemicals. There are five types of chemical introduction. Either the importer or the exporter who is selling direct to the market has to register their business and carry out the categorisation of the chemicals in the products.

Regarding standards of manufacture for cosmetics, in ASEAN member states the company has to comply with good manufacturing practice as described in the ASEAN GMP Guidelines or another ACC approved equivalent GMP. In New Zealand there is no specific requirement for GMP. However, GMP certification is offered by the New Zealand cosmetics association in recognition of the need to demonstrate GMP especially in export markets. In Australia, suppliers must ensure that there are documented QA and QC systems in the supply chain, but there is no requirement that the manufacturer is GMP certified.

Regarding labelling of cosmetics all Parties have similar standards. In New Zealand the labelling requirements for cosmetic products of Australia, the United States of America (USA), Canada or the European Union, are accepted as an alternative means of compliance.

Regarding fragrance allergens there was no specific information about these substances in ASEAN cosmetic directive. Similarly in the Australian regulations there appears to be no specific information about fragrance allergens in cosmetics except for a general requirement in the mandatory Consumer Goods Information Standard to reduce the risk of consumers unintentionally

exposing themselves to ingredients causing allergic reactions. In New Zealand, under the Cosmetics Group Standard there is a requirement that any fragrance material imported or manufactured under this Group Standard shall comply with the IFRA standards and restrictions as set out in the IFRA Code of Practice and there is a project to look to align closer to the EU on this with the update of the Cosmetic Product Group Standard.

Insufficient information was found on the animal testing standards and requirements in ASEAN. In New Zealand animal testing for cosmetics is banned. In Australia, new animal test data is not accepted for cosmetics. However, this also requires further investigation.

As a final observation, access to information on the regulations and conformity assessment procedures published by all the Parties was more challenging when compared to the access to the European legislation.

VI. OPTION RECOMMENDATIONS FOR DISCUSSION AT THE REGIONAL WEBINAR

The aim of this draft report is to provide material for discussion at a regional webinar to be organised by ASEAN STRACAP in spring 2021. After a brief description of the main regulatory models affecting the cosmetics sector, the report reviews two type of "families" of Good Regulatory Practices impacting the rule-makers and stakeholders: those general GRPs related to the rule-making processes of designing, consulting, implementing regulations, and those specific GRPs aiming at facilitating trade and investments in AANZFTA.

In the first case, the study identified four groups of GRP to improving the institutions, processes and tools to draft, implement and enforce cosmetics regulation in order to maximise benefits for traders, investors, consumers and workers and minimise costs and risks for health, safety, the environment. In this section we focused on four of them:

1. A transparent and formalized rulemaking process the EU comitology process
2. The integration of regulatory bodies and institutions
3. Market surveillance, and
4. Access to regulation and the regulatory framework.

The second type of GRPs analysed in this report concern the adoption, adaptation, use and differences of key GRPs to improve trade and investment in cosmetics that have already been detected by STRACAP such as notification, labelling, cosmetovigilence, market surveillance, claims, animal testing, fragrance allergens.

All Parties make clear their commitment to the health and safety of consumers from the use of cosmetic products and this is a solid foundation for ensuring that individual Parties' standards, technical regulations, and conformity assessment procedures do not create unnecessary obstacles to trade. Furthermore, this commitment facilitates and promotes mutual understanding of each Parties STRACAP. One aspect that stands out as an area for discussion is the requirement for Good Manufacturing Practice. In ASEAN this is a requirement for the placing of cosmetics on the ASEAN market. Furthermore, ASEAN has a procedure to recognise other GMP guidelines. However, it is not a specific requirement in Australia or in New Zealand although New Zealand recognises that export markets have this requirement and have established a procedure for companies to obtain GMP certification via the New Zealand cosmetics association. Regarding fragrance allergens, from the desk study, it was only possible to find information about New Zealand requirements, which follow IFRA and they are looking to align more closely with the EU. In relation to allergies this is an important area of consumer safety and by way of example for comparison purposes, in the European Union it a requirement to include on the product label fragrance allergens whose concentration in the product exceeds a certain maximum threshold. All Parties have in market surveillance systems. Within ASEAN, each Member State has set up their market surveillance system and adverse event reporting. Little information was so far found on the communication of those adverse events among all the ASEAN Member States. In relation to animal testing, New Zealand has banned the testing of cosmetic products on animals and there were some references in the Australian legislation. Strengthening information exchange and co-operation in market surveillance and adverse reporting would also start to develop future collaboration on updates to

technical regulations that potentially impact a trading bloc of nearly 700 million people. Overall, the legislation on cosmetics for all Parties is fragmented and would benefit from improved presentation, organisation and consolidation.

1. Possible topics and recommendations

Based the views of STRACAP members and based on the two GRPs reviews, the following preliminary set of discussion topics could be possible topics of discussion at the Regional Webinar on STRACAP in terms of priorities that address key challenges:

- Optional Recommendation 1

Strengthen the institutional capacity of the AANZFTA governing system through the set-up of a GRP working group under the supervision of SC-STRACAP to assess and propose recommendations to accelerate the adoption of GRPs among members, including the setting up of a new market surveillance mechanism for AANZFTA members. An ad hoc working group could start working on more harmonized rulemaking processes to draft proposed cosmetics regulations, which progressively can be deployed to other priority economic sectors as those listed in the STRACAP Work Plan Implementation Program (SWIP).

- Optional Recommendation 2

Launch an Impact Study for drafting a binding Annex to the AANZFTA to be presented to Parties for discussion and which will look for implement a series of GRP on rulemaking among members of the AANZFTA. This work may refer to the Cosmetics Annexes for the earlier EU-US TTIP and TPPA negotiations as a framework for discussing harmonization within AANZFTA.

- Optional Recommendation 3

Conduct a “mapping” exercise to further detect the main divergences in perspective existing among business stakeholders from the cosmetic industry within the AANZFTA region in priority areas presented in Section V of this report. A follow up action plan in a prioritized area would be presented.

- Optional Recommendation 4

Develop and implement strategies to assist SMEs of the cosmetic industry in accessing regulations through consolidated Information Technology and Communication systems for all AANZFTA members.

- Optional Recommendation 5

Develop mutual understanding of standards, technical regulations, and conformity assessment procedures. This will revolve around GMP for all Parties, starting with mutual recognition of ASEAN and New Zealand GMP certification, technical regulations for all Parties on fragrance allergen labelling and animal testing, and strengthening information exchange and co-operation in the areas of in market surveillance and adverse event reporting.

2. Steps following the Webinar

Creating an effective Free Trade Agreement goes beyond dismantling formal tariffs. Just as important in practice are non-tariff barriers or Technical Barriers to Trade (TBTs) and it is these that are the subject of the Regional Webinar. All countries will have some barriers in practice simply because of doing the same things in different ways. Many barriers are not intended as barriers and there is no national interest in maintaining them. But a first step is avoiding TBTs from inception through the development and use of rulemaking and trade related GRP.

By bringing together trade officials, regulators, businesses representatives and other stakeholders from the 12 countries involved in AANZFTA, the Regional Webinar will aim to raise awareness of such GRP that can expand AANZFTA trade in cosmetics.

It is expected that the Regional Webinar participants will bring examples already identified in practice that can be discussed to see how far they affect intra AANZFTA trade and can be adapted and adopted among Parties. As well, the Regional Webinar should be an opportunity to further promote GRP through specific recommendations for the net benefit of cosmetic producers and consumers in the region. The recommendations listed here might be used as a starting point. To ensure political commitment to continue reducing TBTs in the cosmetics sector, participants might recommend issuing a letter to AANZFTA Parties outlining agreed recommendations, including the adoption of GRPs in the development and implementation of regulations and standards.

Appendix 1: EU-TTIP Proposal for an Annex on Cosmetics

https://trade.ec.europa.eu/doclib/docs/2016/july/tradoc_154796.pdf

This document is the European Union's proposal for an annex on cosmetics. It was tabled for discussion with the US in the negotiating round of 11-15 July 2016 and made public on 14 July 2016. The actual text in the final agreement will be a result of talks between the EU and the US.[64]

NOTE: The relationship between sectorial annexes and the architecture of TTIP, including the applicability or not of general exceptions and dispute settlement, will be considered at a later stage.

EU PROPOSAL FOR AN ANNEX ON COSMETICS

Article 1 General principles and objectives

1. Co-operation activities between the Parties shall aim at improving, and not reducing, undermining or otherwise compromising, the level of protection in public policy areas such as the protection of workers' and consumers' health, public health, and the protection of the environment, as considered appropriate by either Party. The Parties share the intention of achieving a high level of protection in these areas.
2. Nothing in this Annex shall affect the ability of each Party to apply its fundamental principles governing regulatory measures in its jurisdiction, for example in the areas of risk assessment and risk management[65].
3. Nothing in this Annex shall affect the ability of each Party to take appropriate and immediate measures when it determines that a product falling under the scope of this Annex is not safe for the consumer or does not comply with its regulatory framework. Such measures may include withdrawing the product from the market or prohibiting its placement in the market.
4. The objectives of this Annex are, in particular, to promote:
   a) convergence of technical requirements and relevant standards applicable to products falling under the scope of this Annex;
   b) alignment of ingredients labelling;
   c) use of validated alternative methods to animal testing;
   d) existing multilateral and bilateral regulatory cooperation relating to the regulation of products falling under the scope of this Annex;
5. cooperation on the review and assessment of ingredients subject to market authorization;
6. cooperation on new and emerging issues and any other matter of common interest to the Parties;
7. cooperation related to safety assessment methodologies;

while ensuring legitimate policy objectives such as a high level of protection of public health and consumers' safety and contributing to the promotion of innovation, competitiveness and trade in products falling under the scope of this Annex.

[64] The EU reserves the right to make subsequent modifications to this text and to complement it at a later stage, by modifying, supplementing or withdrawing all, or any part, at any time

[65] For the EU, such principles include those established in the Treaty on the Functioning of the European Union as well as in Regulations and Directives adopted pursuant to Article 289 of the Treaty on the Functioning of the European Union.

For the purpose of this Annex:

Article 2 Definitions

'Cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

'Medicinal product not subject to prescription' means, in the context of this Annex, products under Chapters 33 and 34 of the Harmonized System (HS) of tariff nomenclature which a Party classifies as a 'medicinal product' and which can be sold to a consumer without a prescription from a healthcare professional.

'Ingredients subject to market authorisation' means a chemical element and its compounds in the natural state or obtained by manufacturing process, for which a market approval is required prior to their use in a cosmetic product or a product considered by one of the Parties as 'medicinal product not subject to prescription'.

'Responsible authorities' means the European Commission and the competent authorities of the EU Member States and the US Food and Drug Administration.

'International Cooperation on Cosmetics Regulation (ICCR)' is a voluntary international group of cosmetics regulatory authorities from different countries that meet on an annual basis to discuss common issues on cosmetics safety and regulation.

'INCI' is the International Nomenclature of Cosmetic Ingredients.

Article 3 Scope

This Annex applies to products falling under Chapters 33 and 34 of the Harmonized System (HS) of tariff nomenclature, regardless of whether they are classified in a Party as 'cosmetic product' or as a 'medicinal product not subject to prescription'.

Article 4 Relevant international organisations and bodies

The Parties recognise that international organisations and bodies, in particular the International Cooperation on Cosmetics Regulation (ICCR), the Organisation for Economic Cooperation and Development (OECD), the International Organisation for Standardisation (ISO), the International Nomenclature of Cosmetic Ingredients (INCI) Committee are relevant for developing scientific and technical guidelines or standards with respect to products falling under the scope of this Annex.

Article 5 Participation in relevant international organisations and bodies and regulatory convergence

1. Each Party shall actively participate, in the development of scientific or technical guidelines with respect to the assessment and the regulation of products falling under the scope of this Annex in the International Cooperation on Cosmetics Regulation.

2. The Parties shall cooperate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines

relating to products falling under the scope of this Annex including, where feasible, through the presentation of joint initiatives, proposals and approaches in the International Cooperation on Cosmetics Regulation.

3. Each Party shall implement guidelines of the International Cooperation on Cosmetics Regulation unless such guidelines would be ineffective or inappropriate for the achievement of the Party's legitimate objectives.

4. Each Party shall encourage active participation of the standardisation bodies located within their respective territories in the work of the International Organisation for Standardisation in order to contribute to the harmonization, at the international level, of standards applicable to products falling under the scope of this Annex.

5. Each Party shall take into account the relevant International Organisation for Standardisation standards when developing its technical regulations and safety assessment procedures and referencing standards applicable to products falling under the scope of this Annex unless those standards are not yet available or would be ineffective or inappropriate for the achievement of the Party's legitimate objectives. In particular, each Party shall seek to use or formally recognise, for regulatory purposes, the international standard on good manufacturing practices for products falling under the scope of this Annex and the international standard on the efficacy of sunscreen products testing.

6. The Parties shall cooperate on areas of relevance for the regulation of products falling under the scope of this Annex, such as allergens labelling, traces or microbial contaminants.

Article 6 Safety assessment of ingredients subject to market authorisation

1. Each Party's responsible authorities shall inform the other Party's responsible authorities when updating the list of ingredients subject to market authorisation, for which the Party intends to carry out a safety assessment and possibly take regulatory action.

2. Upon request of a Party, the responsible authorities of the Parties shall enter into discussions when an ingredient subject to current or future market authorisation, is being assessed by one of the Parties' scientific experts or bodies. Those discussions may entail sharing the latest available scientific data concerning the safety assessment of that ingredient and of preliminary scientific findings and assessments relating to that ingredient.

3. The Parties shall not be obliged to achieve any particular joint outcome regarding the safety assessment and subsequent regulatory action regarding a given ingredient subject to market authorisation.

4. No Party shall be required to advance, suspend or delay its activities related to the safety assessment of an ingredient and subsequent regulatory action as a result of a request for discussions in accordance with paragraph 2.

Article 7 Safety assessment methodologies

1. Each Party's responsible authorities shall inform the other Party responsible authorities when reviewing the safety assessment methodologies or technical guidance documents of relevance to the regulation of ingredients subject to market authorisation.

2. Upon request of a Party, the Parties shall enter into discussions when assessment methodologies are reviewed or technical guidance documents are developed or reviewed by either Party, with a view to avoid divergences, where feasible while aiming at a high level of protection.

3. When updating or reviewing safety assessment methodologies or technical guidance documents, each Party shall take into account the work done in the international organisations and bodies referred to in Article 4, where relevant.

4. No Party shall be required to advance, suspend or delay its activities related to the safety assessment methodologies of ingredients as a result of a request for discussions in accordance with paragraph 2.

Article 8 Labelling

1. Each Party shall support international efforts to establish and maintain a globally harmonised nomenclature for labelling products falling under the scope of this Annex, in particular by active participation in the work of the International Nomenclature of Cosmetic Ingredients Committee.

2. Each Party shall take all necessary steps to align, to the greatest extent possible, its labelling requirements for products falling under the scope of this Annex with the International Nomenclature of Cosmetic Ingredients Committee nomenclature.

Article 9 Cooperation on standards relevant to products falling under the scope of this Annex

1. The Parties shall encourage cooperation between the standardisation bodies located within their respective territories and with standardisation bodies from other International Cooperation on Cosmetics Regulation members, with a view to jointly developing new international standards and adopting them, to the greatest extent possible. This cooperation may include sharing information, at an early stage, regarding standards to be developed or referenced in each Party's legislation.

2. The Parties shall encourage cooperation between the standardisation bodies located within their respective territories with a view to further aligning their existing standards with the standards adopted by the International Organisation for Standardisation.

Article 10 Alternative methods to animal testing

1. Each Party shall continue to actively support the research, development, validation and regulatory acceptance of alternative methods to animal testing.

2. Each Party shall accept, for the purpose of the safety assessment of products falling under the scope of this Annex, test results generated from validated alternatives to animal testing.
3. No Party shall require that a product falling under the definition of a cosmetic product in this Annex be tested on animals to determine the safety of that product.

4. In exceptional circumstances, where serious concerns arise as regards the safety of an existing cosmetic ingredient, a derogation from the requirements in paragraph 3 may be granted only where:

- the ingredient is in wide use and cannot be replaced by another ingredient capable of performing a similar function, or
- the specific human health problem is substantiated and the need to conduct the animal test is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.

Article 11 Cooperation on emerging issues

1. The Parties shall enter into discussions, if so, requested by either Party, on scientific information and data in the context of new and emerging issues related to the regulation of products falling under the scope of this Annex, with a view to creating a common pool of knowledge and promoting, if feasible and to the extent possible, a common understanding of the science and safety concerns related to such issues.

2. Each Party shall inform the other Party when it considers adopting regulatory measures with regard to such new and emerging issues. If both Parties consider adopting such regulatory measures, discussions shall be organised in order to avoid, if feasible and being mindful of the general principles in Article 1, divergent regulatory approaches which could create unnecessary barriers to trade.

Article 12 Exchange of regulatory information between the Parties

1. The Parties shall ensure that their responsible authorities are allowed to exchange regulatory information, including confidential information of commercial, technical or scientific nature, including trade secrets, which is not in the public domain related to products falling under the scope of this Annex.

2. A Party shall not publicly disclose confidential information of commercial, technical or scientific nature, including trade secrets, which is not in the public domain, and which it has received from the other Party, if and in so far as that information is protected under its applicable legislation on access to information or access to documents.

[NB: In the EU context, Article 4 of Regulation (EC) n° 1049/2001 as interpreted by the Court of Justice of the European Union]

Article 13 Regulatory cooperation

[NB: this Article may need to be adjusted as discussions on the Institutional, General and the actual text in the final agreement will be a result of talks between the EU and the US.

Final Provisions Chapter and on the Regulatory Cooperation Chapter proceed. This article is to be read in conjunction with the functions and roles of the Joint Committee, the Transatlantic Regulators' Forum and the Working Group on sectors as defined in the Chapter on Institutional, General and Final Provisions]

1. The regulatory cooperation between the responsible authorities of the Parties shall be guided by a joint regulatory cooperation work plan which sets out short and medium-term priorities for regulatory cooperation under this Annex.
2. The joint regulatory cooperation work plan shall be endorsed by the responsible authorities of the Parties at the political level.
3. The responsible authorities of the Parties shall transmit the joint regulatory cooperation work

plan to the Transatlantic Regulators' Forum [established under the Institutional, General and Final Provisions Chapter] and publish it on their respective websites.

4. The responsible authorities of the Parties shall regularly review the joint regulatory cooperation work plan. In this review, the responsible authorities of the Parties shall take into account, inter alia, progress achieved [during the preceding years] and consider new areas that would benefit from regulatory cooperation. For the review of the joint regulatory cooperation work plan, the responsible authorities of each Party shall consult stakeholders including small and medium-size enterprises, employers and workers representatives and public interest groups.

Appendix 2: Trans-Pacific Partnership Agreement Cosmetics Annex

https://www.dfat.gov.au/sites/default/files/8-technical-barriers-to-trade.pdf

1. This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation[66] and notification procedures of central government bodies that may affect trade in cosmetic products between the Parties. This Annex shall not apply to a technical specification prepared by a governmental entity for its production or consumption requirements or a sanitary or phytosanitary measure.

2. A Party's obligations under this Annex shall apply to any product that the Party defines as a cosmetic product pursuant to paragraph 3. For the purposes of this Annex, preparation of technical regulation, standard, conformity assessment procedure or marketing authorisation includes, as appropriate, the evaluation of the risks involved, the need to adopt a measure to address those risks, the review of relevant scientific or technical information, and the consideration of the characteristics or design of alternative approaches.

3. Each Party shall define the scope of the products subject to its laws and regulations for cosmetic products in its territory and make that information publicly available.

4. Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 3, for the purposes of this Annex, a cosmetic product may include a product that is intended to be rubbed, poured, sprinkled, sprayed on or otherwise applied to the human body including the mucous membrane of the oral cavity and teeth, to cleanse, beautify, protect, promote attractiveness or alter the appearance.

5. Each Party shall identify the agency or agencies that are authorised to regulate cosmetic products in its territory and make that information publicly available.

6. If more than one agency is authorised to regulate cosmetic products within the territory of a Party, that Party shall examine whether there is overlap or duplication in the scope of those authorities and eliminate unnecessary duplication of any regulatory requirements resulting from cosmetic products.

7. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives that support those international initiatives, as appropriate, to improve the alignment of their respective regulations and regulatory activities for cosmetic products.

8. When developing or implementing regulations for cosmetic products, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.

9. Each Party shall observe the obligations set out in Articles 2.1 and 5.1.1 of the TBT Agreement with

[66] The application of this Annex to marketing authorisations is without prejudice to whether a marketing authorisation meets the definition of a technical regulation, standard or conformity assessment procedure

respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for cosmetic products and that do not fall within the definition of a technical regulation or conformity assessment procedure.

10. Each Party shall ensure that it applies a risk-based approach to the regulation of cosmetic products.

11. In applying a risk-based approach in regulating cosmetic products, each Party shall take into account that cosmetic products are generally expected to pose a less potential risk to human health or safety than medical devices or pharmaceutical products.

12. No Party shall conduct separate marketing authorisation processes or sub-processes for cosmetic products that differ only with respect to shade extensions or fragrance variants unless a Party identifies a significant human health or safety concern.

13. Each Party shall administer any marketing authorisation process that it maintains for cosmetics products in a timely, reasonable, objective, transparent and impartial manner, and identify and manage any conflicts of interest in order to mitigate any associated risks.

    a) If a Party requires marketing authorisation for a cosmetic product, that Party shall provide an applicant with its determination within a reasonable period of time.

    b) If a Party requires marketing authorisation for a cosmetic product and it determines that a marketing authorisation application for a cosmetic product under review in its jurisdiction has deficiencies that have led or will lead to a decision not to authorise its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient.

    c) If a Party requires a marketing authorisation for a cosmetic product, the Party shall ensure that any marketing authorisation determination is subject to an appeal or review process that may be invoked at the request of the applicant. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body.

    d) If a Party has granted marketing authorisation for a cosmetic product in its territory, the Party shall not subject the product to periodic re-assessment procedures as a condition of retaining its marketing authorisation.

14. If a Party maintains a marketing authorisation process for cosmetic products, that Party shall consider replacing this process with other mechanisms such as voluntary or mandatory notification and post-market surveillance.

15. When developing regulatory requirements for cosmetic products, a Party shall consider its available resources and technical capacity in order to minimise the implementation of requirements that could:

    a) inhibit the effectiveness of procedures for ensuring the safety or manufacturing quality of cosmetic products; or

    b) lead to substantial delays in marketing authorisation regarding cosmetic products for sale on

that Party's market.

16. No Party shall require the submission of marketing information, including with respect to prices or cost, as a condition for the product receiving marketing authorisation.

17. No Party shall require a cosmetic product to be labelled with a marketing authorisation or notification number[67]

18. No Party shall require that a cosmetic product receive marketing authorisation from a regulatory authority in the country of manufacture, as a condition for the product receiving marketing authorisation from the Party. For greater certainty, this provision does not prohibit a Party from accepting a prior marketing authorisation issued by another regulatory authority as evidence that a product may meet its requirements.

19. No Party shall require that a cosmetic product be accompanied by a certificate of free sale as a condition of marketing, distribution or sale in the Party's territory.

20. If a Party requires a manufacturer or supplier of a cosmetic product to indicate information on the product's label, the Party shall permit the manufacturer or supplier to indicate the required information by relabelling the product or by using supplementary labelling of the product in accordance with the Party's domestic requirements after importation but prior to offering the product for sale or supply in the Party's territory.

21. No Party shall require that a cosmetic product be tested on animals to determine the safety of that cosmetic product unless there is no validated alternative method available to assess safety. A Party may, however, consider the results of animal testing to determine the safety of a cosmetic product.

22. If a Party prepares or adopts good manufacturing practice guidelines for cosmetic products, it shall use relevant international standards for cosmetic products, or the relevant parts of them, as a basis for its guidelines unless those international standards or relevant parts would be ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

23. Each Party shall endeavour to share, subject to its laws and regulations, information from post-market surveillance of cosmetic products.

24. Each Party shall endeavour to share information on its findings or the findings of its relevant institutions regarding cosmetic ingredients.

25. Each Part shall endeavour to avoid re-testing or re-evaluating cosmetic products that differ only with respect to shade extensions or fragrance variants unless conducted for human health or safety purposes.

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[67] This paragraph does not apply to Chile and Peru. Within a period of no more than five years from the date of the entry into force of this Agreement, Chile and Peru shall each review their respective labelling requirements in order to examine whether other regulatory mechanisms can be implemented, in a manner consistent with their obligations under this Chapter and the TBT Agreement. Chile and Peru shall separately report to the Committee about their review upon request of another Party.

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