MOOT PROBLEM

VALARIA – MEASURES AFFECTING THE IMPORTATION AND MARKETING OF COSMETIC PRODUCTS

1. BACKGROUND

1.1. The Federal Republic of Valaria (Valaria) is a developed nation located in the Catan region with a population of 24 million people. The region shows significant variations in rainfall, altitude, geological history and topography, resulting in a wide variety of habitats. Of all the wildlife that inhabits the region, nearly 45% of the birds, 59% of the mammals, 71% of the amphibians, and 83% of the reptiles are endemic to Valaria. This level of endemism is attributed largely to Valaria's tectonic stability and the consequences of a unique pattern of climate change on its soil and flora over time. Due to its high number of endemic species, Valaria is distinguished as one of the world's few *megadiverse* countries.

1.2. Valaria's Biodiversity Protection Act 1984 (BP Act) regulates the treatment of wildlife in Valaria. Valaria implements its international commitments under agreements such as the Convention on International Trade in Endangered Species, Convention on Biological Diversity, and the World Heritage Convention through the BP Act. This Act also contains several provisions on the import and export of Valarian flora and fauna, including restrictions on illegal trade. Illegal trafficking of wildlife is made punishable through high fines and imprisonment that may range from three to ten years, depending on the severity of the offence. The Valarian Ministry of Forest and Wildlife Conservation (MoFWC) has established an Animal Welfare Board to assess compliance with, and ensure enforcement of, the provisions of the BP Act concerning wildlife protection.

1.3. Valaria is home to several indigenous communities, which account for nearly 6.7% of its total population. Several important habitats in Valaria serve as places of spiritual significance for such communities. These communities are known to utilise plants and animal populations effectively as resources while managing them sustainably. To learn from their experiences, the MoFWC has launched several initiatives in partnership with indigenous peoples under the BP Act. Of these, the Collaborative Partnership on Wildlife Management focuses on building skills and knowledge

towards the sustainable use of animal resources. More recently, this initiative also seeks to control the development and proliferation of genetically modified animals in research facilities to address concerns about the potential adverse impact these animals could have on the environment and indigenous populations if they are released or escape.

1.4. Valaria is a founding Member of the World Trade Organization (WTO). It regularly advocates for initiatives that reconcile environmental sustainability, economic prosperity, and resilience at the WTO.

2. THE SUSTAINABLE CONSUMPTION AND PRODUCTION INITIATIVE

2.1. According to sociological studies conducted from 2008 to 2013, the trends in Valarian society favoured a greener economy in which environmental degradation was adequately addressed, and resource efficiency and sustainable lifestyles were promoted. Riding on this sentiment, the Green Party led by Victor Olän assumed power in Valaria in 2013. One of the pillars of the party's manifesto was their proposal to introduce a Sustainable Consumption and Production Initiative (SCPI) to ensure the fulfilment of the United Nations Sustainable Development Goals (UN SDGs).

2.2. The SCPI was launched on 1 January 2014. In a press conference held on this day, President Olän commented:

> "*I am not one to renege upon campaign promises. Valaria must show leadership in meeting the UN SDGs and other international commitments that we have towards sustainability. In this light, I have decided to address one of the most pressing concerns of the global community related to climate change – carbon emissions resulting from production.*"

2.3. On 4 March 2014, Valaria adopted a resolution introducing a series of legislative reforms aimed at reducing carbon emissions by 50% within a 10 year period. The most significant of these was the Sustainable Taxation Act enacted on 1 April 2014, which established an internal tax for carbon emissions. The Act was passed by a 78-32 majority in the Valarian Parliament. The Act also applied carbon costs equivalent to those borne by local producers to importers with a view to prevent carbon leakage.

2.4. In 2019, five years after the enactment of the Sustainable Taxation Act, a Regulatory Scrutiny Board constituted by the Valarian Parliament conducted an implementation review of the Act and issued its report. The report made several findings about the achievements and shortcomings of the Act. Notably, the Board concluded that narrowing the coverage of the Act to fewer sectors – at least during the initial stage of the implementation of the Act – would have made its implementation more manageable. In his press conference, President Olän commented on the findings of the Board and assured that he would take into account these findings in future legislations.

2.5. The Government of Valaria soon began considering the next phase of the SCPI. To better understand and consider the viewpoints of all stakeholders affected by the SCPI, a national online survey was held in February-March 2020. The survey was open to the general public and aimed to gather their opinions on the expansion of the SCPI.

2.6. The survey garnered responses from industries, consumers, and civil society organisations. The results of the survey showed that Valarian citizens considered sustainable development to be "the single most important goal for a society in the 21st century". Over eight out of ten participants agreed that the government should actively regulate practices that are detrimental to environmental health, including biodiversity. 86% of the respondents expressed their support for the Sustainable Taxation Act. With respect to other policies that would contribute to sustainable development, 77% of the respondents considered the preservation of wildlife to be an important goal within the framework of the SCPI. A majority (53%) of Valarians said that they were already taking individual action in this regard, such as eating less meat, using natural fabrics, and donating to wildlife conservation efforts.

2.7. Following the results of this survey, the Valarian government decided to focus its efforts towards securing a high level of animal welfare and protection of biodiversity in the country. In order to identify the areas in which legislative action should be prioritised, the MoFWC commissioned a follow-up survey in May-June 2020. The MoFWC further consulted various animal welfare organizations and the representatives of indigenous communities involved in the Collaborative Partnership on Wildlife Management.

2.8. When asked to identify the scope of future policies on biodiversity conservation and animal welfare concerns, respondents of this survey answered that these should include higher standards for treatment of farm animals, curbs on animal testing, and prohibition of blood sports and hunting. Nevertheless, a large number of respondents were unaware of the conditions farm animals were kept in, and around 30% of respondents indicated that they did now know whether the ingredients or products currently available in Valaria were tested on animals.

2.9. 61% of consumers that participated in the survey believed that they could make a difference through their purchasing decisions, and 51% stated that they were willing to pay a premium for a product that was more animal welfare friendly. Nearly 80% of the respondents said that the same animal welfare standards should apply to imports as are applied to goods produced within Valaria. With respect to production, 42% of the respondents considered that improving animal welfare could have positive effects on production. The results of the survey and consultations pointed at three product areas in which action to promote animal welfare was preferred and organized them in decreasing order of priority as follows: (i) housing appliances; (ii) food and clothing; (ii) drugs, cosmetics and household products.

2.10. On 3 July 2020, President Olän presented the findings of the survey and consultations before the Valarian Parliament, noting that:

> "*My government is encouraged by the findings of this survey and by the recognition of the moral status of wildlife among our citizens. The people's choice is clear – they have a strong preference for the consumption and production of goods and services that have minimal impact on the environment. They reject practices that hamper sustainable development, contribute to the depletion of our living and non-living natural resources, or otherwise threaten the future of our people and planet. My government will shortly take targeted steps to give effect to the people's mandate. We intend to make all efforts possible to replicate the success of our past legislations in those that are forthcoming.*"

2.11. On the following day, the MoFWC directed the Animal Welfare Board to set up a committee to study the environmental impacts of animal research and testing in the three product sectors identified in the survey results. In its communication to the Animal Welfare Board, the MoFWC noted its "intention to take into account the environmental implications of animal testing in addition to ethical and scientific reasons weighing in favour of alternative test methods".

2.12. A Special Committee of the Animal Welfare Board released its report on 28 September 2020. The committee noted the large-scale uses of animals in research and testing across a variety of sectors, including drugs, medical devices, chemicals, cosmetics and personal care products, and household products. Its report also clarified that its numerical estimates in this regard were conservative, as a vast majority of research facilities consulted were unable to provide data on the number of cold-blooded animals, farmed animals used in agricultural research, or rats, mice, or birds bred and used for research. Additionally, it noted that the use of animals had increased exponentially following the rise in the use of genetically modified animals and the introduction of large-scale chemical testing programs. The committee made the following key findings:

"**CONCLUSIONS**

a. Animal research and testing is resource-intensive, consuming vast amounts of wildlife and energy.
b. Animal research and testing is a significant source of air pollution (especially that resulting from incineration of carcasses or waste), groundwater and public drinking water contamination, and soil contamination.
c. Waste produced in laboratories may be biologically hazardous. Laboratory conditions in animal research facilities are known to lead to zoonotic disease transmissions, with severity ranging from mild symptoms to death. In light of Valaria's recent experiences with SARS-CoV-2 and its potentially zoonotic origins, this is a cause for grave concern.
d. Animal research and testing compound threats to Valarian biodiversity, as evinced by the rapid decline of long-tailed and rhesus macaques in Valaria. While captive breeding obscures the devastating impact of this decline, the release of animals bred and raised in captivity only serves to further threaten wild species.
e. Aggravated concerns arise from the use of genetically modified animals in animal testing due to the possibility of these animals escaping and interbreeding with or out-competing wild populations.
f. Increased regulation and record-keeping of the environmental aspects of animal research and testing are necessary to achieve Valaria's sustainability goals."

2.13. On 15 October 2020, the *Valaria Herald* reported that "the wheels of the state machinery are already turning. President Olän's government is convinced about the need to capitalize on the momentum generated in recent months. A government official, who spoke on the condition of anonymity, revealed that the government has decided to take action to minimize animal testing conducted to demonstrate the safety of cosmetic products. According to the official, while the government has considered the results of both surveys and the report of the Special Committee, it is mindful of the recommendations made by the Regulatory Scrutiny Board in 2019. Earlier this year, we reported that the consumption of cosmetic products in Valaria has reached a value of 16.5 billion Valarian Krones (VK) following increasing promotion on social media and our expectation is that this number will keep rising. We also reported that Valaria's own cosmetics industry is struggling to stay afoot with imports. One can only wonder how much of the government's plan has to do with disciplining animal testing in a dominant industry where it is prevalent and unchecked, as opposed to protecting Valaria's own thriving cosmetics industry."

2.14. On 1 April 2021, the Valarian Parliament tabled the Draft Ethical Cosmetics Act 2021. On the same day, a draft amendment to the Sustainable Taxation Act was published, which established an internal tax for the use of animal test data. Considering that animal welfare was a cross-border issue and that there might be divergence in the level of animal welfare action taken by trading partners, an equivalent import fee was also included in this draft legislation.

2.15. The CEO of *Sens*, Valaria's largest cosmetics producer specialised in luxury cosmetics, expressed support for the government's efforts to promote ethical cosmetics. In an interview to *Femme*, Mr. Lézarde commented:

> *"For years, Sens has been a leader in the domestic cosmetics industry and has consistently advocated for vegan and cruelty-free cosmetic products. In our efforts to achieve conscientious production, we have always lost market share to cheaper, more harmful imports. Given the increased demand for cosmetic products in Valaria in recent times, more and more of these inhumane imports are entering our market. Together with other leading manufacturers in Valaria, we have been campaigning for stricter laws against animal testing and are relieved to see our efforts come to fruition. This will not just help the wildlife that Valaria holds dear, but will also ensure the competitiveness of an industry relying on ethical practices."*

2.16. Shortly thereafter, the Valarian government launched comprehensive educational and public awareness programmes on the risks posed by animal testing to both animal and human health, and about the environmental benefits of curbing reliance on animal testing and research. This included advertisement campaigns in print and audio-visual media; training and sensitization programmes addressed to media professionals, educators, decision-makers, administrators and other concerned persons; and engaging indigenous leaders in developing and implementing intersectoral programmes and strategies for curbing animal testing as well as consumption of animal-tested products. President Olän, through Executive Decree No. 1510/2021, also set up the SCPI Collective Action Fund under which grants would be awarded "to encourage cutting-edge research into alternatives to animal testing". Executive Decree No. 1510/2021 provided that grant applications would be accepted as soon as the Ethical Cosmetics Act 2021 came into force.

3. DISCUSSIONS IN THE WTO TECHNICAL BARRIERS TO TRADE (TBT) COMMITTEE

3.1. On 23 April 2021, Valaria notified the Draft Ethical Cosmetics Act 2021 to WTO's TBT Committee under Articles 2.9.2 and 5.6.2 of the Agreement on Technical Barriers to Trade (TBT Agreement). The notification indicated that this legislation covered products under Chapter 33 of the Harmonized Tariff Schedule. In the two months following this notification, written comments were received from 16 WTO Members.

3.2. In the meeting of the TBT Committee held on 3-4 July 2021, several members commented on Valaria's proposed law:

> "4.4. The representative of the People's Republic of Hyperborea, referring to the detailed written comments sent on 16 May 2021, raised concerns regarding the labelling requirements in the Ethical Cosmetics Act 2021. Hyperborea noted that there are no real animal welfare or consumer protection objectives behind this requirement. Hyperborea expressed deep concerns and its disappointment that, on the contrary, the labelling of certain cosmetic products as "harmful" without any qualification misleads the consumers into believing that the use of those cosmetic products is harmful to them.
>
> …

4.12. The representative of the Isle of Nysa provided the following statement. The Isle of Nysa acknowledges the right of all WTO Members to regulate to achieve legitimate environmental objectives. However, we would like to raise concern on the draft Valarian law on cosmetic products, which sets out labelling requirements and a conformity assessment procedure as conditions for access to the Valarian market. Apparently, these laws are aimed at advancing Valaria's environmental goals and securing animal health. It is no secret that Valaria has a thriving cosmetics industry, including a large luxury cosmetics market, which struggles to compete with cheaper imports. By introducing a conformity assessment procedure that is cumbersome for imported products, Valaria seeks to promote its domestic cosmetics industry. Clearly, this is a protectionist aim. Here, we also wonder whether Valaria has considered equivalency arrangements with other Members with the view to increase the pool of certification bodies empowered under Section 8 of the Ethical Cosmetics Act 2021 and, if yes, why it has decided to exclude this possibility. Equivalency arrangements could potentially alleviate burdens on Nysan products and allow Nysan certified products to be labelled as "cruelty-free" in Valaria without having to undergo re-certification by Valarian authorities. Additionally, this would also relieve the burden on Valarian authorities and prevent unnecessary disruptions in trade.

…

4.16. The representative of the Kingdom of Saturnalia provided the following statement. The Kingdom of Saturnalia welcomes the Valarian decision to harmonize its cosmetics regulation with emerging global regulatory best practices and to model it, *inter alia*, on the Saturnalian approach. However, the Kingdom of Saturnalia requests Valaria to consider eliminating the requirement to obtain a certificate of recognition and to allow imports to be marketed promptly once the importer submits adequate information that the product is appropriately labelled. The procurement of the certificate causes significant delays and unnecessary costs in placing a product on the Valarian market. Many Saturnalian producers would be disincentivised to seek product re-certification under the Ethical Cosmetics Act 2021 due to prohibitive costs and technical difficulties related to product certifications and availability of certifiers.

Cosmetics are fast-moving goods that depend largely on seasonal sales and fashion trends. As a result, the ability to place them immediately on the market is crucial.

4.17. The representative of the Plurinational State of Arcadia welcomed the steps taken by Valaria to secure animal welfare both within its territory and globally. The Plurinational State of Arcadia hoped that Valaria would simplify and streamline the conformity assessment procedure in the Ethical Cosmetics Act 2021. It suggested that to avoid barriers to trade, Valaria should grant partial exemptions for certain substances and mixtures used in cosmetic products, especially if no alternatives to animal tests were available. The Plurinational State of Arcadia also recommended that the implementation of the requirement to furnish a "certificate of recognition" be postponed by at least one year to allow supply chains to adjust.

4.18. The representative of the Federal Republic of Valaria said that Valaria remained committed to pursuing the legitimate objective of animal welfare, environmental protection and related consumer awareness, especially in an industry known to disregard the concerns related to these objectives, in accordance with its international trade commitments. By making the information set out in the new labels available to consumers, it enabled them to make informed choices. Valaria fully respected its international commitments, as well as the principles established in the WTO Agreements, notably the non-discriminatory treatment of imported and national goods. Valaria reaffirmed its commitment not to develop, adopt or apply technical regulations that could lead to unnecessary barriers to international trade, as established in the TBT Agreement."

4. DANIZIA'S PANEL REQUEST TO THE WTO DISPUTE SETTLEMENT BODY (DSB)

4.1. Danizia is a large island nation in the Barando Ocean and a Member of the WTO. It is widely regarded as a hub for testing on marine animals for scientific and market purposes. The Danizian chemicals industry relies extensively on tests conducted on cephalopods and decapods, including octopuses, crabs and lobsters, which Danizians do not recognise as sentient beings. This testing has immensely benefitted researchers and producers in fields such as psychiatric drugs,

neuroscience, and genetic mutations, among others. Recently, Danizian researchers pioneered research on camouflage clothes and cosmetics that change colour based on the lighting in a room using octopuses. Danizia does not have laws prohibiting animal testing, as industry stakeholders have repeatedly expressed concerns that any measure affecting animal testing would hinder their ability to keep up with advancements in international research.

4.2. Following the publication of Valaria's draft laws, Danizian exporters of cosmetic products contacted the Chemicals Export Promotion Board expressing concerns that the Valarian labelling and tax measures were more burdensome than necessary to achieve the objectives allegedly pursued by them. Having considered these concerns, Danizia sent written comments in response to Valaria's notification to the TBT Committee, requesting it to reconsider its laws on animal testing. In particular, Danizia questioned the inclusion of cephalopods within the scope of the Draft Ethical Cosmetics Act 2021. Danizia cited research suggesting that there is not sufficient evidence of disease in cephalopods and their sensitivity to pain. Danizia further noted that the Draft Ethical Cosmetics Act 2021 arbitrarily equated humane and inhumane animal testing conditions without consideration for the fact that the former adequately balanced animal welfare concerns with the advancement of scientific research.

4.3. On 17 October 2021, Valaria enacted the Ethical Cosmetics Act 2021 and the Sustainable Taxation (Amendment) Act 2021. The two Acts were notified in the Federal Register on the same day and were identical to the draft versions published earlier that year. With this notification, Valaria also published a list of certification bodies accredited under Section 8(2) of the Ethical Cosmetics Act 2021. The list contained the names of 11 Valarian entities. By December 2021, Valaria had accredited multiple certification agencies in countries with similarly progressive animal testing legislations. Additionally, it has also accredited seven renowned regional agencies specialised in cosmetics research, with a view to encompass all of the world's geographical regions. Valaria is currently reviewing the application for accreditation filed by Danizia's CosLab Agency, a Danizian accredited certification body. Valaria has not accredited any other certification body in Danizia.

4.4. Danizia, seeking an amicable solution to this matter, initiated consultations with Valaria under Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) and Article XXII of the General Agreement on Tariffs and Trade 1994 (GATT 1994).

Consultations were held on 10 November 2021. These consultations failed to resolve the dispute and, on 23 November 2021, Danizia requested the establishment of a panel pursuant to Articles 4 and 6 of the DSU.

4.5. Danizia's request for the establishment of a panel contained the following claims:

a. Through the labelling requirement in Section 6 of the Ethical Cosmetics Act 2021, Valaria applies a technical regulation with the view to and with the effect of creating unnecessary obstacles to international trade, in violation of Article 2.2 of the TBT Agreement;

b. Through the certification requirement in Section 8 of the Ethical Cosmetics Act 2021, Valaria sites facilities used in conformity assessment procedures in a manner such as to cause unnecessary inconvenience to applicants or their agents, in violation of Article 5.2.6 of the TBT Agreement; and

c. Through the equivalency fee in Section 5 of the Sustainable Taxation (Amendment) Act 2021, Valaria subjects imported cosmetic products to internal taxes or other internal charges in excess of those applied to like domestic products, in violation of Article III:2 of the GATT 1994.

4.6. Danizia argued that these violations appear to nullify or impair benefits accruing to it directly or indirectly under the covered agreements within the meaning of Article XXIII:1(a) of the GATT 1994. With respect to claim (b) above, Danizia further requested the panel to recommend that the implementation of the certification requirement be postponed by a year until sufficient certification bodies are accredited.

4.7. In response to Danizia's panel request, Valaria argued that each of the measures identified in the panel request was prepared and is being applied in conformity with its obligations under the TBT Agreement and the GATT 1994. Valaria contended that, in any event, Article 2.2 of the TBT Agreement and Article XX of the GATT 1994 recognize its right to pursue legitimate policy objectives, such as animal welfare, environmental protection and consumer awareness. With respect to Danizia's request for a recommendation, Valaria stated that the exercise of the panel's discretion under Article 19.1 of the DSU would be improper since a Member is best placed to assess the manner in which it should comply with the panel's findings.

4.8. At its meeting on 17 December 2021, the DSB established a panel pursuant to the request of Danizia in document WT/DS666/2, in accordance with Article 6 of the DSU. The panel was established with standard terms of reference, as set out in Article 7.1 of DSU. Further to the agreement of the parties on the three panellists to serve in this dispute, the Panel was composed on 8 January 2022 as follows:

Chairperson: Mr. George Oscar Bluth II
Members: Ms. Margaret Lizer
Mr. Barry Zuckerkorn

4.9. Elysia, Hyperborea, Arcadia, Themiscyra, and Saturnalia notified their interest in participating in the Panel proceedings as third parties.

4.10. Before its first substantive meeting, the Panel received a request from the Isle of Nysa to file an *amicus curiae* brief. The Isle of Nysa seeks to provide factual information concerning the lack of effectiveness of popular alternatives to animal testing. It further seeks to demonstrate the necessity of retaining animal testing for a number of safety assessment procedures for which there are no alternative methods available. The Isle of Nysa would also like to put forward legal arguments regarding the interpretation of "like products" under the WTO Agreements.

4.11. In a letter dated 4 February 2022, Valaria objected to the acceptance and consideration of this request, noting that the Isle of Nysa had not exercised its right to participate as a third party. Danizia expressed its support for the request from the Isle of Nysa in a letter received on 6 February 2022. The Panel directed the parties to advance written and oral arguments on this issue.

THE ETHICAL COSMETICS ACT, 2021

We, the people of the Federal Republic of Valaria,

Recognizing the importance of preserving Valarian biodiversity and natural heritage,

Bearing in mind the obligations concerning sustainable development and wildlife conservation undertaken in international agreements,

Desiring to support production processes that are respectful of animal welfare,

Endeavouring to reduce the use of animals for experimental purposes in the manufacturing and testing of cosmetic products,

Resolved to promote the research, development, and acceptance of non-animal based alternative methods of experimentation,

Determined to facilitate informed consumer choices,

Seeking to develop a global approach to animal welfare, including through international cooperation on data sharing,

enact as follows:

1. Short title, extent and commencement

1. This Act may be called the Ethical Cosmetics Act, 2021.

2. It extends to the whole of Valaria and its overseas territories.

3. It shall come into force on the date of its notification in the Federal Register.

2. Definitions

In this Act, unless the context otherwise requires, -

(a) "animal test data" means any data or information that results from tests involving:

i. application of a substance or mixture to a live vertebrate animal (other than a human being) or cephalopods; or

ii. experimentation to test any effects of a substance or mixture using a live vertebrate animal (other than a human being) or cephalopods.

…

(g) "cosmetic products" or **"cosmetics"** means any substance or mixture intended to be placed in contact with any external part of the human body, including the mucous membranes of the oral cavity or the teeth, with a view to altering the odours of the body, changing its appearance, cleansing it, maintaining it in good condition, perfuming it, or protecting it, but does not include a substance or mixture intended to be implanted, ingested, inhaled, or injected into the human body[1]

Provided that such products shall not include "drugs" as defined under the Pharmaceuticals Act, 2002 as amended.

(h) "end use" means a purpose to which the substance or mixture can be applied by a consumer or a professional.

(i) "**environment hazard characteristic**" of a substance or mixture means that the substance or mixture is:

i. known to cause acute aquatic toxicity, as described in chapter 4.1 of the GHS (category acute 1 to 3) or chronic aquatic toxicity due to non-rapidly degradable substances, as described in chapter 4.1 of the GHS (category chronic 1 or 2);

ii. known to have ozone-depleting potential as described in chapter 4.2 of the GHS (category 1); or

[1] The assessment of whether a product is a cosmetic product has to be made on the basis of a case-by-case assessment, taking into account prescribed use, intended use, and tariff classification among other factors.

iii. known to contain arsenic, cadmium, lead, or mercury.

(j) "GHS" means the Globally Harmonized System of Classification and Labelling of Chemicals;

(k) "**human hazard characteristic**" of a substance or mixture means that the substance or mixture is:

i. known to exhibit acute toxicity effects, as described in chapter 3.1 of the GHS (category 1 to category 5);

ii. known to produce irreversible damage to the skin, as described in chapter 3.2 of the GHS (category 1);

iii. known to produce serious eye damage, as described in chapter 3.3 of the GHS (category 1);

iv. known or likely to produce hypersensitivity of the airways in humans, as described in chapter 3.4 of the GHS (category 1);

v. known, presumed or suspected to induce or may induce mutations in the germ cells of humans, as described in chapter 3.5 of the GHS (category 1 or 2);

vi. known, presumed or suspected human carcinogen, as described in chapter 3.6 of the GHS (category 1 and 2);

vii. known, presumed or suspected to produce adverse effects on sexual function and fertility, as described in chapter 3.7 of the GHS (category 1 or 2);

viii. known or presumed to produce specific target organ toxicity after either a single exposure, as described in chapter 3.8 of the GHS (category 1 or 2), or repeated exposure, as described in chapter 3.9 of the GHS (category 1 or 2); or

ix. known or presumed to cause aspiration toxicity, as described in chapter 3.10 of the GHS (category 1 or category 2).

…

(p) "mixture" means a mixture or solution composed of two or more substances.

…

(t) "substance" means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

…

5. Safety assessment

The responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product as well as its constituent substances and mixtures have undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annexure A.

6. Requirements for labelling of cosmetic products

1. Cosmetic products whose safety report does not contain any animal test data obtained from tests conducted on or after the date on which this Act comes into force may be marketed as "cruelty-free" in accordance with Annexure B.2 of this Act.

2. Cosmetic products that do not meet the requirements of subsection (1) above must be marketed as "harmful" in accordance with Annexure B.3 of this Act.

3. Subsection (2) above shall not apply in the following circumstances:

(a) the animal test data is the only information that can demonstrate whether a substance or mixture has a particular environment hazard characteristic or human health hazard characteristic, as defined in Article 2;

(b) the animal test data has been derived from tests conducted on animals involving a substance or mixture that is not solely used in cosmetics production; or

(c) the animal test data has been derived from tests conducted on animals involving a substance or mixture other than a substance or mixture listed in the cosmetic product's safety report and the other substance or mixture is not solely used in cosmetics production.

…

8. Compliance

1. Compliance with Section 6 of this Act must be demonstrated through a certification of recognition furnished before the product is marketed.

2. The certification required under subsection (2) must be obtained either from a certification body whose accreditation has been issued or recognized by the Cosmetic Accreditation Authority (CAA) or from one which has been appointed by the Ministry of Industry and Chemicals.

ANNEXURE A

Cosmetic Product Safety Report

The cosmetic product safety report shall, as a minimum, contain the following:

PART A – Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product

The qualitative and quantitative composition of the cosmetic product, including the chemical identity of the substances or mixtures (including chemical name according to the International Nomenclature of Cosmetic Ingredients where possible) and their intended function. In the case of perfume and aromatic compositions, description of the name and code number of the composition and the identity of the supplier.

2. Physical/chemical characteristics and stability of the cosmetic product

The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product.

The stability of the cosmetics product under reasonably foreseeable storage conditions.

3. Microbiological quality

The microbiological specifications of the substance or mixture and the cosmetic product. Particular attention shall be paid to cosmetics used around the eyes, on mucous membranes in general, on damaged skin, on children under three years of age, on elderly people, and on persons showing compromised immune responses.

…

5. Normal and reasonably foreseeable use

The normal and reasonably foreseeable use of the product. The reasoning shall be justified in particular in the light of warnings and other explanations in the product labelling.

6. Exposure to the cosmetic product

Data on the exposure to cosmetic product, taking into consideration the findings under clause 5, in relation to:

(a) The site(s) of application;

(b) The surface area(s) of application;

(c) The amount of product applied;

(d) The duration and frequency of use;

(e) The normal and reasonably foreseeable exposure route(s); and

(f) The targeted (or exposed) population(s). Potential exposure of a specific population shall also be taken into account.

The calculation of the exposure shall also take into consideration the toxicological effects to be considered (e.g. exposure might need to be calculated per unit area of skin or per unit of body weight). The possibility of secondary exposure by routes other than those resulting from the direct application should also be considered (e.g. non-intended inhalation of sprays, non-intended ingestion of lip products, etc.).

Particular consideration shall be given to any possible impacts on exposure due to particle sizes.

7. Exposure to the substances

Data on the exposure to the substances or mixtures contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under clause 6.

8. Toxicological profile of the substances

The toxicological profile of substance or mixture contained in the cosmetic product for all relevant toxicological endpoints.

9. Undesirable effects and serious undesirable effects

All available data on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data.

10. Information on the cosmetic product

For the purposes of clauses 6, 7, 8 and 9 above, the source of the data and the method by which it was gathered and processed shall be clearly identified.

In case of animal test data, the reasoning for the use of such data shall be specifically justified.

PART B – Cosmetic product safety assessment

1. Assessment conclusion

Statement on the safety of the cosmetic product in relation to Section 5 of the Act.

2. Labelled warnings and instructions of use

Statement on the need to label any particular warnings and instructions of use.

3. Reasoning

Explanation of the scientific reasoning leading to the assessment conclusion set out under clause 1 and the statement set out under clause 2. This explanation shall be based on the descriptions set out under Part A. Where relevant, margins of safety shall be assessed and discussed.

4. Assessor's credentials and approval of part B

Name and address of the safety assessor.

Proof of qualification of safety assessor.

Date and signature of safety assessor.

ANNEXURE B

Labelling of Cosmetic Products

1. Definitions

…

(j) "package" means the outer container of a product, such as a box or folding carton, and may also refer to the immediate container, such as the bottle, jar or aerosol can that holds the product, if the immediate container is not displayed in a box or folding carton;

(k) "principal display panel" means that part of a package that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel;

…

2. "Cruelty-free" labelling

The "cruelty-free" label as set out in Section 6(1) of the Act may consist of the expressions "CRUELTY-FREE PRODUCT" and "NOT TESTED ON ANIMALS", accompanied by the following logo and design on the principal display panel:

3. Labelling as "harmful"

The "harmful" label as set out in Section 6(2) of the Act shall consist of the expressions "HARMFUL" and "TESTED ON ANIMALS", accompanied by the following logo and design on the principal display panel:

4. Labelling features

The labels shall be included on the packaging indelibly and shall not be partially or completely obscured by any other element. The labels shall be placed on the principal display panel of the product package, preferably on the upper area of the main front face, using the dimensions set out below:

Package shape	**Dimensions of the principal display panel**[2]	**Dimensions of the label**
Rectangular	height x width of one entire side	Covering at least 6% of the surface of the principal display panel
Cylindrical or nearly cylindrical	At least 40% of height x circumference	
Any other shape of container[3]	At least 40% of total container surface	

[2] In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars.

[3] Where such container presents an obvious "principal display panel" such as the top of a triangular or circular package, the area shall consist of the entire top surface.

SUSTAINABLE TAXATION (AMENDMENT) ACT, 2021

We, the people of the Federal Republic of Valaria,

Reaffirming the importance of preserving Valarian biodiversity and natural heritage,

Endeavouring to reduce the use of animals for experimental purposes in the manufacturing and testing of cosmetic products,

Resolved to promote the research, development, and acceptance of non-animal based alternative methods of experimentation,

Desiring to support production processes that minimize negative externalities,

Determined to address the risk of cruelty leakage,

enact as follows:

…

2. Definitions

In this Act, unless the context otherwise requires, -

(a) "animal testing" means any process or production method that yields animal test data, as defined in Section 2(a) of the Ethical Cosmetics Act, 2021.

(b) "cosmetic products" means cosmetic products as defined in Section 2(g) of the Ethical Cosmetics Act, 2021.

…

(f) "safety assessment" means an assessment conducted in accordance with Section 5 of the Ethical Cosmetics Act, 2021.

(g) "safety report" means the report prepared in accordance with Annexure A of the Ethical Cosmetics Act, 2021.

3. Scope

This Act shall apply to cosmetic products that rely on animal test data for safety assessment in any part of their production, including in the safety assessment of constituent substances and mixtures.

4. Amount of tax

1. If a cosmetic product's safety report demonstrates that animal test data used in the safety assessment of a cosmetic product relates to less than 15% of the constituents of the product, no taxes are levied.

2. If animal test data used in the safety assessment of a cosmetic product relates to more than 15% of the constituents of the product, the amount of tax levied shall be as follows:

15%-40%	1.5 VK per unit
40%-70%	3 VK per unit
70%-100%	6 VK per unit

3. The tax shall be borne by the manufacturer of the finished product.
Provided that if the product is resold, the tax shall be borne by the reseller.

5. Equivalency fees and refunds

1. In the case of any cosmetic product exported from Valaria, the appointed authority may provide an equivalency refund to the manufacturer or reseller exporting such product equal to the cost associated with the tax imposed in Section 4 above.

Provided that any foreign costs of animal testing which are to be paid upon their importation shall be deducted from this refund.

2. In the case of any cosmetic product imported into Valaria that would have had an increased cost imposed by Section 4 had that product been produced in Valaria, the appointed authority may impose an equivalency fee on the importer of such product equivalent to the tax that would have been imposed under Section 4, had that product been produced in Valaria.

3. In case an imported cosmetic product was subject to any tax or charge on animal testing in the country of manufacturing, the importer may apply for a reduction in the fee under subsection (2) above, so long as the evidence is provided and the aforementioned tax or charge is not subject to any form of compensation on exportation.

THE PHARMACEUTICALS ACT, 2002

…

2. Definitions

In this Act, unless the context otherwise requires, -

(e) "drugs" means (A) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (B) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (C) articles intended for use as a component of any article specified in clause (A) or (B). An article is not a drug solely because the label or the labelling contains such a claim.