The Cosmetic Industry: Comparing The Industry Oversight In The European Union And The United States

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I. INTRODUCTION

The United States Food and Drug Administration ("FDA") oversees the regulation of food, drugs, cosmetics, biologics, medical products, and tobacco in the United States ("U.S."), while in the European Union ("EU") the European Commission ("EC"), executive branch of the EU, is responsible for proposing legislation and implementing decisions related to the cosmetic industry.[1] The FDA was given authority to control cosmetics in 1938 through the passage of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and the EC was given authority to control finished cosmetic products under the Council Directive 76/768/EEC of July 1976 ("Council Directive of 1976").[2] Since 1938 the FDC Act has been amended many times, however, no such amendments have changed the FDA's regulatory power over cosmetics.[3] On the other hand, the Council Directive of 1976 is no longer valid law today and was repealed by Regulation (EC) No. 1223/2009 ("EC Regulation").[4]

Despite the FDA's failure to the bring the FDC Act up-to-date, the EC Regulation attempts to take into consideration the latest technological developments (e.g., nanomaterials) and continues to reinforce product safety.[5] The EU continues to monitor harmful toxins to protect consumers, while the U.S. continues to ignore these harmful toxins and cause harm to the U.S. consumers.[6]

1 Peter Barton Hutt, et al., Food and Drug Law Case and Materials, 4th Ed., 77 (2014); *see also* Cosmetics Info, U.*S. and EU Cosmetic Regulation*, (September 5, 2019), https://cosmeticsinfo.org/cosmetics-regulation.
2 *Id.*
3 *See* Commission Regulation 1223/2009, 2009 O.J.L (342) 59; *see generally* 21 U.S.C §§ 361-364.
4 *Id.*
5 European Commission, *Legislation*, (September 5, 2019), https://ec.europa.eu/growth/sectors/cosmetics/legislation_en.
6 Alyssa Katzenelson, et al., *On Cosmetics Safety, U.S. Trails More than 40 Nations*, (September 5, 2019), https://www.ewg.org/news-and-analysis/2019/03/cosmetics-safety-us-trails-more-40-nations.

This paper will compare the FDA's regulatory power over cosmetics, or lack thereof, with the EC's regulatory power. For example, the FDA has minimal authority over labeling, ingredients, and manufacturer facilities, while the EC has more authority over such measures.

II. Legal Authority Over The Cosmetic Industry

A. U.S. LEGAL AUTHORITY

The FDC Act was enacted in 1938 which gave the FDA power to regulate the cosmetic industry and no such amendments have been passed since 1938 that affect their power over cosmetics.[7] Prior to the enactment of the 1938 FDC, the FDA did not have the authority to regulate cosmetics.[8] The FDC Act defines a "cosmetic" as:

> (1) articles intended to be rubbed, poured, sprinkled, sprayed on, introduced into, or otherwise applied to the human body … for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except the term shall not include soap.[9]

Examples of cosmetics includes, but is not limited to, skin moisturizers, perfumes, lipsticks, fingernail polish, eye and facial makeup, cleansing shampoos, hair dye, and deodorants.[10] Products that fit within this definition are treated as cosmetics and are subject to the FDA's cosmetic regulations, specifically the FDC Act.[11] However, products can be dual-classified as both drugs and cosmetics when the product has more than one intended use and fits within the definition of both a drug and cosmetic.[12] Examples of dual-classified products include anti-dandruff shampoo, antiperspirant deodorant, hair growth products, wrinkle remover, and moisturizer.[13] In the event that a product is dual-classified as both a drug and cosmetic, the product is subject to the

7 *See generally* 21 U.S.C §§ 361-364, *supra* note 3.
8 *Id.*
9 *See generally* 21 U.S.C § 321(i).
10 *Id.*
11 *See* Hutt, *supra* note 1 at 78.
12 *Id.* at 110-113.
13 *Id.* at 117.

requirements of both categories (e.g., labeling, ingredients, and other approval process requirements).[14]

Cosmetics are the least intensively regulated class of products under the FDA's authority.[15] Unlike drugs, the FDA does not require cosmetics to go through pre-market approval before entering interstate commerce.[16] The FDA employs minimal requirements over the labeling of cosmetic products and the ingredients which can be contained within such products.[17] Despite the FDA's lack of oversight over cosmetics, the cosmetic industry is a $70 billion per year industry.[18]

B. EU LEGAL AUTHORITY

Cosmetics in the EU are discussed in the EC Regulation, which was enacted in 2009.[19] Such Regulation governs cosmetic products made available on the market, which is much broader than the FDA's definition of cosmetics.[20] "Cosmetic products" means:

> any substance or mixture intended to be placed in contact with the external parts of the human body (epi- dermis, 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.[21]

Examples of cosmetics include, but is not limited to, lotions, skin products, soaps, facemasks, bath products, toiletries, deodorant, sunscreen, and the like.[22] The EU does not classify products as

14 *Id.* at 110.
15 *Id.*
16 *Id.* at 109.
17 FDA, *Cosmetic Labeling Regulations,* (April 10, 2019), https://www.fda.gov/Cosmetics/Labeling/Regulations/default.htm.
18 Statista, *Revenue of the leading 20 beauty manufacturers worldwide in 2018 (in billion U.S. dollars)*, (April 10, 2019), https://www.statista.com/statistics/243871/revenue-of-the-leading-10-beauty-manufacturers-worldwide/.
19 *See generally* EC Regulation, *supra* note 3
20Research Gate, *Better Safe Than Sorry the Impact of the EU-US Negotiations Under TTIP on the Regulation of Cosmetic Products,* (September 5, 2019), https://www.researchgate.net/publication/292355411_Better_Safe_Than_Sorry_The_Impact_of_the_EU-US_Negotiations_under_TTIP_on_the_Regulation_of_Cosmetic_Products.
21 EC Regulation, *supra* note 3 at art. 2 (1)(a).
22 Export.gov, *The EU Cosmetics Regulation*, (September 9, 2019), https://www.export.gov/article?id=The-EU-Cosmetics-Regulation.

being dual-classified, as the U.S. does.[23] For example, sunscreen containing bug repellant is either a cosmetic or biocide in the EU.[24] By way of another example, anti-cavity toothpaste is considered a cosmetic in the EU, however, in the U.S. it is regulated as an over the counter ("OTC") drug.[25] It is the responsibility of the U.S. exporters to correctly classify the product according to the laws of the EU Member States. Exports may consider: (i) purpose and use of the product; (ii) marketing of the product; and (iii) ingredients used to manufacturing the product.[26] The difference in definitions creates obstacles for companies who market their products in both the U.S. and EU.[27]

The EC Regulation is binding on all Member States and is enforced at a national level.[28] Each Member State of the EU has a competent authority that is responsible for upholding compliance with the EC Regulation.[29] However, the EC Regulation is much more comprehensive and up-to-date with today's technological advancements compared to the FDC Act.[30] For example, more than 1300 ingredients are banned in the EU, while only eleven are banned in the U.S.[31] By way of another example, the EC Regulation requires all products marketed in the EU to be registered before being placed on the market, unlike the U.S.'s voluntary registration protocol.[32] Further, the EU has a General Product Safety Directive ("GPSD") that regulates RAPEX, an EU rapid alert system for facilitating the exchange of information between the Member States and the EC with regard to product recall.[33] Overall, the EC Regulation attempts to

[23] *See generally Id.*
[24] *See generally* Export.gov, *supra* note 22.
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] Commission Regulation 1223/2009, art. 14, 2009 O.J.L (342) 59, *supra* note 3 at p. 1.
[29] *Id.*
[30] *See generally id.*
[31] Oliver Milman, *The US allows 1,300 chemicals banned by Europe to be used in cosmetics. Why?,* (September 10, 2019), https://www.msn.com/en-us/news/us/the-us-allows-1300-chemicals-banned-by-europe-to-be-used-in-cosmetics-why/ar-AABJ9mt.
[32] European Commission, *Cosmetics*, (September 9, 2019), https://ec.europa.eu/growth/sectors/cosmetics_en.
[33] Cosmetics Europe, *Compliance with Regulation 1223/2009 on Cosmetic Products_Roles and Responsibilities Along the Supply Chain,* May 4, 2019), Compliance_with_regulation_1223-2009_new.pdf.

protect consumer safety and is consistently monitoring the state of the cosmetic industry to bring the laws up-to-date.

III. Labeling Requirements

A. U.S. LABELING REQUIREMENTS

The FDA requires cosmetics to abide by minimal labeling requirements, however, the labeling does not need to be approved before the product enters the market.[34] The FDA prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce.[35] The labeling must be truthful such that consumers are not misled.[36] A cosmetic is considered misbranded if the label is false or misleading, the label fails to provide the required information, or if the label information is not properly displayed.[37] It is the responsibility of the manufacturer and/or distributor to ensure the cosmetic products are properly labeled, rather than the cosmetic company itself.[38] Including the label "FDA APPROVED" on cosmetics is false and/or misleading and is prohibited.[39] The FDA does not approve products, so such label is misleading to the consumers.[40]

The FDA distinguishes between a principle display panel and an information panel when outlining the labeling requirements.[41] A principle display panel ("PDP) is the part of the label that is most likely displayed or examined under customary conditions of display for sale.[42] On the other hand, an information panel is a panel that can accommodate label information where the consumers are likely to see it.[43] The PDP must include an identity statement that indicates the nature and use

[34] 21 U.S.C §§ 321-392.
[35] *Id.*
[36] *Id.*
[37] *See* FDA, *supra* note 17.
[38] *Id.*
[39] *See generally* 21 CFR 710.8.
[40] *Id.*
[41] *Id.*
[42] *See generally* 21 CFR 701.10.
[43] *Id.*

of the product and an accurate statement of the net quantity of contents.[44] The identity statement must indicate the nature and use of the product in terms of the name commonly understood by the public or may include an illustration.[45] The net quantity of contents must be in terms of weight, measurement, numerical count, or a combination of such.[46] The information panel must include the following: (i) name and place of business, (ii) distributor statement, (iii) material facts, (iv) warning and caution statements, and (v) ingredients.[47] The warning and caution statements must be prominent and conspicuous.[48] If the cosmetic product may be hazardous to consumers the product must bear appropriate label warnings.[49] For example, if the product is flammable the product must bear the appropriate flammable product warning label required by law.[50] The ingredients must appear in descending order of predominance.[51] The ingredients must be listed in font that is no less than 1/16 inches in height and without obscuring design, vignettes, or crowding.[52] The use of established labeling names (also known as specific ingredients) is permissible if not misleading to consumers, for example, trichlorofluoromethane may be labeled as Chlorofluorocarbon 11.[53] All labeling information required above must be in English and the only exception to this is for products distributed solely in the United States ("U.S.") territory where the predominant language is different than English.[54]

[44] *Id.*
[45] *Id.* at § 701.11.
[46] *Id*. at § 701.13.
[47] *See generally* 21 CFR 700-740.
[48] 21 CFR 700.
[49] 21 CFR 740.1.
[50] *Id.*
[51] *Id.* at § 701.3.
[52] *Id.*
[53] *Id.*
[54] *Id.* at § 701.2(b).

Often cosmetic companies include labels such as "alcohol free" or "organic" to enhance the marketability of the product.[55] Such labels can be misleading to consumers because the industry definition and consumer understood definition differs.[56] "Alcohol free" means that the product does not contain ethyl alcohol, however, as a chemical family alcohol does not just refer to only ethyl alcohol.[57] The cosmetic product may still contain other alcohols such as cetyl, stearyl, or the like.[58] "Organic" has no legal definition and is thought to be safer by consumers.[59] Products that are labeled "organic" are subject to the laws of the United States Department of Agriculture ("USDA") and FDA.[60] The USDA regulates the organic claim, while the FDA regulates the cosmetic portion (e.g., labeling and safety requirements).[61]

The FDA does not require cosmetic companies or manufacturers to print expiration dates on the labels of cosmetic products.[62] It is the responsibility of the manufacturer to determine the shelf life for products as part of their responsibility to substantiate product safety.[63] A cosmetic's shelf life generally means the length of time you can expect a product to look and act as expected and to be safe for use.[64] Cosmetics begin to degrade over time and often consumer's behavior aids in the degradation process. For example, dipping a finger in the product introduces microorganisms like bacteria and fungi into the product, which affects the preservatives in the products.[65]

55 *See generally* FDA, *"Alcohol Free"*, (April 11, 2019), https://www.fda.gov/cosmetics/cosmetics-labeling-claims/alcohol-free.; *see also* FDA, "Organic" Cosmetics, (April 11, 2019), https://www.fda.gov/cosmetics/cosmetics-labeling-claims/organic-cosmetics.
56 *Id.*
57 FDA, *"Alcohol Free"*, (April 11, 2019), https://www.fda.gov/cosmetics/cosmetics-labeling-claims/alcohol-free.
58 *Id.*
59 FDA, "Organic" Cosmetics, (April 11, 2019), https://www.fda.gov/cosmetics/cosmetics-labeling-claims/organic-cosmetics.
60 *Id.*
61 *Id.*
62 FDA, *Shelf Life and Expiration Dating of Cosmetics*, (April 10, 2019), https://www.fda.gov/cosmetics/labeling/expirationdating/default.htm.
63 *Id.*
64 *Id.*
65 *Id.*

Temperature and exposure to sunlight and heat can cause changes in the color, texture, and smell of the product.[66] All of these external sources negatively impact the product and reduce the shelf life of the product.[67]

B. EU LABELING REQUIREMENTS

Chapter VI (titled "Consumer Information") governs the requirements for cosmetic containers and packaging.[68] The label of the product must include:

> (i) the name or registered name and address of the responsible person; (ii) the nominal content at the time of packaging, given by weight or volume; (iii) date of minimum durability; (iv) precautions observed in use and listed in Annex III through VI, as well as, precautions for professional use products; (v) batch number of manufacture; (vi) function of the product; (vii) ingredient list; (viii) impurities in the raw materials used; and (ix) subsidiary technical materials used but not present in the final product.[69]

The aforementioned information must be indelible, easily legible, and in visible lettering, similar to the U.S.[70] With respect to (iii), products with a lifespan longer than thirty months must show a period after opening time.[71] If the lifespan is shorter than thirty months then the product must show a "best before the end of" date.[72]

Article 20 prohibits product claims which are false or misleading to the consumers.[73] Like the U.S., the EU does not want consumers being deceived as to the function of the cosmetic products or characteristics therein.[74] The Article tasks the EC with adopting a list of common criteria for claims to be used in cosmetic products, in cooperation with the Scientific Committee

66 FDA, *Shelf Life and Expiration Dating of Cosmetics*, (April 10, 2019), https://www.fda.gov/cosmetics/labeling/expirationdating/default.htm.
67 *Id.*
68 *See generally* Chapter VI of EC Regulation.
69 Commission Regulation 1223/2009, art.19, 2009 O.J. L (342) 59.
70 *Id.*
71 *See* FDA, *supra* note 17.
72 *Id.*
73Commission Regulation 1223/2009, art. 20, 2009 O.J. L (342) 59.
74 *Id.*

on Consumer Safety (SCCS).[75] Claims which are not in conformity with the common criteria will require the EC to ensure compliance with the Member States.[76]

Unique to the EU, the EC Regulation requires the responsible person, a natural or legal person within the EU who shall ensure compliance with the relevant obligations set out in the EC Regulation, to keep a product information file ("PIF") for the product.[77] The PIF is required for each product that is placed on the EU market and its purpose is to gather relevant information on the product.[78] The PIF helps Member States to ensure that products entering the market are in compliance with the EC Regulation.[79] The PIF must be kept for 10 years after the last batch was placed on the market.[80] There are five information requirements for the PIF.[81] The PIF must include:

> (a) description of the cosmetic product to enable the PIF to be attributable to the product; (b) cosmetic product safety report; (c) description of the method of manufacturing and statement on compliance with GMPs; (d) where justified by the nature or the effect of the cosmetic, proof of the effect claimed on the product; and (e) data on any animal testing performed by the manufacturer.[82]

The responsible person must make the PIF readily available and be in a language understood by the Member States.[83] The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept.[84]

[75] *Id.*
[76] *Id.*
[77] *See generally,* Commission Regulation 1223/2009, art.11, 2009 O.J. L (342) 59.
[78] Ecomundo., *How to Create Your Cosmetic Product Information File?,* (September 9, 2019), https://www.ecomundo.eu/en/blog/product-information-file-cosmetics-guide.
[79] *Id.*
[80] Commission Regulation 1223/2009, art. 11, 2009 O.J. L (342) 59.
[81] Ecomundo, *supra* note 78.
[82] Commission Regulation 1223/2009, art. 11, 2009 O.J.L (342) 59.
[83] *Id.*
[84] *Id.*

IV. Ingredients

A. U.S. INGREDIENT REQUIREMENTS

Cosmetic products cannot contain ingredients that make the product harmful to the consumers when used according to the directions on the label.[85] Cosmetics may include any ingredient provided that:

> (i) the ingredient and the finished cosmetic product are safe under labeled or customary condition;
> (ii) properly labeled; and
> (iii) use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.[86]

However, the FDA does not require cosmetic products and ingredients to go through an "approval process" before hitting the shelves.[87] If a product is dual-classified it must meet the pre-market approval requirements for drugs.[88] The FDA has regulations that prohibit or restrict the use of a number of ingredients for use in cosmetics.[89] For example, the FDA prohibits the use of Bithionol, Chlorofluorocarbon propellants, Chloroform, Halogenated salicylanilides, Hexachlorophene, Mercury, Methylene chloride, cattle materials, and the like.[90] However, the FDA does not have the authority to require cosmetic manufacturers to reveal their safety data to the FDA.[91] The burden is on the FDA to prove that a particular product or ingredient is harmful when used according to the label directions.[92]

85 FDA, *Prohibited & Restricted Ingredients in Cosmetics*, (April 9, 2019), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics.
86 FDA, *Guidance Regulation of* Cosmetics, (April 9, 2019), https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm.
87 *Id.*
88 FDA, *Premarket Approval (PMA),* (April 9, 2019), https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma.
89 FDA, *Guidance Regulation of* Cosmetics, (April 9, 2019), https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm.
90 *Id.*
91 *See* FDA, *supra* note 85.
92 *Id.*

A cosmetic that includes a "Fragrance" and/or "Flavor" ingredient can simply list the ingredients as "Fragrance" and/or "Flavor" on the label.[93] The FDA does not require the cosmetic company to disclose the fragrance and/or flavor formulas because those formulas may be "trade secrets."[94] Often individuals may be allergic or sensitive to certain components of the fragrance formula, however, the FDA does not have the legal authority to require allergen labeling for cosmetics.[95] A commonly used chemical found in fragrance products is diethyl phthalate ("DEP").[96] The health effects of DEP in cosmetics is not clear, however, at high levels the chemical may have a negative impact on reproductive health.[97] Due to these health concerns, the FDA has been closely monitoring the levels of DEP in cosmetics and has developed an analytical method for determining the levels of DEP in products.[98] The FDA advises consumers that if they are worried about chemicals like DEP in products they should avoid products with the label "Fragrance" in the ingredient list.[99]

B. EU INGREDIENT REQUIREMENTS

Chapter IV of the EC Regulation (titled "Restrictions for Certain Substances") puts a number of restrictions on substances used in cosmetics.[100] For example, Article 14 prohibits the use of colorants, substances listed in Annex II, preservatives, ultraviolet ("UV") filters, and substances that are not in accordance with Annex III.[101] Annex II lists over 1300 substances that are prohibited, for example, phenol, nickel, asbestos, and crude and refined coal tars.[102] The U.S.

93 FDA, *Fragrances in Cosmetics*, (May 1, 2019), https://www.fda.gov/cosmetics/cosmetic-ingredients/fragrances-cosmetics#labeling.
94 *Id.*
95 *Id.*
96 *Id.*
97 FDA, *Phthalates*, (May 1, 2019), https://www.fda.gov/cosmetics/cosmetic-ingredients/phthalates.
98 *Id.*
99 *Id.*
100 *See generally* Commission Regulation 1223/2009, ch. IV, 2009 O.J.L (342) 59.
101 Commission Regulation 1223/2009, art. 14, 2009 O.J.L (342) 59.
102 Commission Regulation 1223/2009, annex II, 2009 O.J.L (342) 59.

has banned only a handful of ingredients, including but not limited to, bithionol, chlorofluorocarbon propellants, chloroform, hexachlorophene, mercury compounds, methylene chloride, and vinyl chloride.[103] Despite the dangers of asbestos, U.S. had not banned such ingredient in cosmetics.[104] There have been a number of lawsuits involving asbestos in cosmetics, including, the Johnson & Johnson baby power case and the Claire's case.[105]

The EC Regulation also outlines the requirements for including ingredients on cosmetic labels.[106] Ingredients must be titled "INGREDIENTS" and follow a number of other requirements.[107] For example, the ingredients must be listed in order of weight in the product. This is important for those who have allergies to ingredients. The names used in the ingredients list must be from the INCI name system, which ensures that there is consistency between all cosmetic products in the EU. Perfume mixtures must be labeled as "parfume", except for certain specified perfume ingredients, and flavors may be listed as "aroma" Colors must be labeled using the Color Index ("CI") Number, which is an international naming system. For example, a CI number may include CI 15580, which is used for red.[108]

The Scientific Committee on Consumer Safety (SCCS) provides opinions on health and safety risks of non-food consumer products, including cosmetics.[109] Often the SCCS generates reports in response to a specific request.[110] The SCCS is responsible for reviewing all ingredients

[103] FDA, *Prohibited & Restricted Ingredients in Cosmetics*, (April 9, 2019), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics.
[104] *Id.*
[105].Alyse Shorland, *Episode: 'v. Johnson & Johnson*, (April 9, 2019), https://www.nytimes.com/2019/10/04/the-weekly/johnson-johnson-baby-powder-cancer-lawsuits.html.
[106] Commission Regulation 1223/2009, 2009 O.J.L (342) 59.
[107] Commission Regulation 1223/2009, art. 19, 2009 O.J.L (342) 59.
[108]EU Open Data Portal, *Cosmetic Ingredient Database—List of Colorants Allowed in Cosmetic Products*, (May 1, 2019), https://data.europa.eu/euodp/en/data/dataset/cosing-list-of-colorants-allowed-in-cosmetic-products/resource/8245f050-761a-49f3-829a-d878f3b17b63.
[109] European Commission, *Scientific on Consumer Safety (SCS),* (May 1, 2019), https://ec.europa.eu/health/scientific_committees/consumer_safety_en.
[110] *Id.*

forward to them by the EU for consideration and determination of safety usage.[111] For example, category 2 CMR substances (e.g., UV filters) may only be used in cosmetics if approved by the SCCS.[112] The SCCS ensures that the ingredients used are safe and works to promote the safety of consumers, unlike in the U.S.

V. Recall and Inspection Power

A. U.S. RECALL AND INSPECTION POWER

The FDA does not have recall power, instead cosmetic companies may voluntarily recall their products if them deem necessary.[113] The FDA can request that a product be recalled if the company is not willing to voluntarily recall such product.[114] However, the FDA does have an active role in recalls.[115] For example, the FDA monitors the progress of a recall and conducts their own audit checks to verify the recall's effectiveness.[116] The FDA evaluates the health hazard presented by the recalled product and assigns a classification (e.g., Class I-III) to indicate the level of danger posed to consumers.[117] Class I classifications are assigned to products that will cause serious adverse health consequences, or even death.[118] Class II products are those which may cause temporary or medically reversible adverse health consequences.[119] Class III products are those in which the product is likely to cause adverse health consequences.[120] In the event that the FDA requests a recall, the FDA develops a recommended strategy for the cosmetic company which

111 Commission Regulation 1223/2009, annex VI, 2009 O.J.L (342) 59; see also Commission Regulation 1223/2009, art. 15, 2009 O.J.L (342) 59.
112 *Id.*
113 FDA, *FDA Recall Policy for Cosmetics*, (April 12, 2019), https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-recall-policy-cosmetics.
114 *Id.*
115 *Id.*
116 21 CFR 7.53.
117 *See* 21 CFR 7.3(m); *see also* 21 CFR 7.41.
118 21 CFR 7.3(m).
119 *Id.*
120 *Id.*

includes how the FDA expects the recall to be carried out and the necessity for a press release.[121] If the company develops a recall strategy on their own, the FDA reviews and comments on such strategy.[122]

The cosmetic company does have their own responsibilities when it comes to recalls.[123] The company is expected to notify the customers and the notification should include the hazard presented by the product and the recall strategy developed for the product.[124] When initiating a recall, the company should notify the appropriate FDA district so that the FDA is able to ensure that recall protocols are being followed.[125] The company should submit periodic recall status reports to the appropriate FDA district to assess the progress of the recall.[126] The company is responsible for the disposition of the recalled product, whether that means the product is destroyed or the product is brought into compliance with the FDA regulations.[127]

The FDA does have inspection power over manufacturing facilities to ensure cosmetic product safety.[128] Often the FDA uses their inspection power to determine whether products are adulterated or misbranded.[129] The manufacturing facilities do not have to follow any Good Manufacturing Procedures ("GMP") because there are no such GMP guidelines for cosmetic manufacturers.[130] The FDA has issued guidance documents to suggest GMP guidelines, but such documents are not binding on the manufacturers.[131]

121 *See* FDA, *supra* note 113.
122 21 CFR 7.42(a)(2).
123 *See generally* 21 CFR Part 7.
124 *Id.* at § 7.49.
125 *Id.* at § 7.46(d).
126 *Id.* at § 7.53.
127 *Id.* at § 7.55.
128 FDA, *Inspection of Cosmetics,* (April 9, 2019), https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/inspection-cosmetics.
129 *Id.*
130 *Id.*
131 *Id.*

Cosmetics that are imported into the U.S. are often not inspected or sampled upon entry into the U.S.[132] The FDA inspects less than 1% of the three million products that come into the U.S.[133] Of those products inspected, about 15% are found to be contaminated or contain dangerous ingredients.[134] The U.S. Customs and Border Protection ("CBP") works closely with the FDA to ensure that adulterated or misbranded products are not let into the country.[135] The CBP monitors the imported product requirements and destroys products that might be a danger to U.S. consumers.[136] A list of "Import Refusals" are listed on the FDA's website as well as "Import Alerts" to advise inspectors about the current trends in violations.[137]

B. EU RECALL AND INSPECTION POWER

The EC Regulation has an enhanced focus on product safety and has had an impact on the amount of recalls.[138] Unlike the FDC Act, Article 27 of the EC Regulation gives competent authorities the ability to withdraw, recall, or restrict availability of products that present or could present a serious risk to human health.[139] The competent authorities are required to immediately notify the EC and competent authorities of other Member States.[140] The EC will determine whether the provisional measures were justified and consult interested parties and the SCCS if needed.[141]

[132] NCBI, *Appendix E, The U.S. Food and Drug Administration and Imported Food Safety*, (May 1, 2019), https://www.ncbi.nlm.nih.gov/books/NBK220404/.
[133] *Id.*
[134] *Id.*
[135] *Id.*
[136] CBP, *Importing into the United States A Guide for Commercial Importers*, (May 1, 2019), https://www.cbp.gov/sites/default/files/documents/Importing%20into%20the%20U.S.pdf.
[137] *Id.*
[138] SGS, *Insight into Cosmetics Recalls Since EU Cosmetic Regulation Implementation*, (May 1, 2019), https://www.sgs.com/en/news/2014/12/insight-into-cosmetics-recalls-since-eu-cosmetic-regulation-implementation.
[139] Commission Regulation 1223/2009, art. 27, 2009 O.J. L (342) 59.
[140] *Id.*
[141] *Id.*

RAPEX is the EU's rapid system for identifying dangerous products that may pose serious health and/or safety risks to consumers.[142] In 2018 alone, the system had 2257 alerts across the EU and 4050 follow-up actions.[143] The system allows Member States to monitor the products and identify recall categories that pose a threat.[144] For example, the system had identified 9 recall categories that posed a threat to consumers, including, heavy metals, preservatives, microbiological content, prohibited substances, hydroquinone, methyl methacrylate, hydroxide/monomers/acid, phthalates, and hydrogen peroxide.[145]

The EC Regulations requires that all cosmetic products placed on the EU market comply with GMPs, unlike the FDC Act.[146] The GMPs are set by the ISO 22716 standard ("ISO 22716"), which defines that quality and reproducibility of cosmetics.[147] The purpose of the ISO 22716 GMPs is to ensure access to the EU market and validate the compliance of the EC Regulation.[148] An added declaration of compliance associated with the manufacturing facility to required as part of the PIF.[149]

VI. Registration

A. U.S. REGISTRATION REQUIREMENTS

Although the FDA does not require cosmetic companies to submit safety data and other information to the FDA, the companies may voluntarily register their products through the FDA's

[142] HSA, *EU Weekly RAPEX Alerts,* (May 1, 2019), https://www.hsa.ie/eng/Safety_Alerts/EU_Weekly_RAPEX_Alerts/.
[143] European Commission, *Rapid Alert System Statistics*, (May 1, 2019), http://81.247.254.96/QvAJAXZfc/opendoc.htm?document=Rapid_Alert_System_statistics.qvw&host=QVS%40vsrv1463&anonymous=true.
[144] SGS, *Insight into Cosmetics Recalls Since EU Cosmetic Regulation Implementation*, (May 1, 2019), https://www.sgs.com/en/news/2014/12/insight-into-cosmetics-recalls-since-eu-cosmetic-regulation-implementation.
[145] *Id.*
[146] Ecomundo, *Good Manufacturing Practice (GMP) for Cosmetic Products: ISO 22716,* (May 1, 2019), https://www.ecomundo.eu/en/blog/gmp-cosmetics-good-manufacturing-practice
[147] *Id.*
[148] *Id.*
[149] *Id.*

Cosmetic Registration Program ("VCRP").[150] The VCRP only applies to cosmetic products being sold to consumers in the U.S. and does not apply to those products sold "for professional use only."[151] It also does not apply to products that are not for sale, which includes samples, free gifts, and the like.[152]

The VCRP helps the FDA by carrying out its responsibility to regulate the cosmetic industry, because the FDA is not granted authority to do so under the current FDC Act.[153] The voluntary nature of the program provides the FDA with the best information available about the products and ingredients, frequency of use, and businesses engaged in their manufacturing and distribution.[154] This information allows the FDA to evaluate the products on the market and ensure that consumers are not harmed.[155] Furthermore, the information has been used by the Cosmetic Ingredient Review ("CIR") to assist the CIR Expert Panel in establishing their priority for assessing ingredient safety.[156]

B. EU REGISTRATION REQUIREMENTS

The Cosmetics Product Notification Portal ("CPNP") is the centralized system of notification in the EU.[157] The purpose of the CPNP is to provide a tool for competent authorities to monitor products on the EU market.[158] Specifically, the CPNP provides easy access to the contact details of the responsible person and the address where the PIF is accessible.[159]

150 FDA, *Cosmetics & U.S. Laws*, (May 2, 2019), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/cosmetics-us-law#Cosmetic_Registration.
151 *See generally Id.* at § 710; *see also Id.* at § 720.
152 *Id.*
153 *Id.*
154 Federal Register, vol. 73, 76360; see also Federal Register vol. 69, 9339.
155 *See* FDA, *supra* note xcvii.
156 Federal Register, vol. 73, 76360.
157 Cosmetics Europe, *Compliance with Regulation 1223/2009 on Cosmetic Products_Roles and Responsibilities Along the Supply Chain,* May 4, 2019), Compliance_with_regulation_1223-2009_new.pdf.
158 *Id.*
159 *Id.*

The EU has a mandatory registration protocol, while the U.S. has a voluntary protocol.[160] The EU requires that all products that are to be marketed in the Member States of the EU to be registered before being placed on the market.[161] This allows the EU to monitor the products being placed on the market before potentially harming consumers.[162] The retroactive system of the U.S. waits until consumers are harmed before monitoring the products.[163] The responsible person must submit the following information to the EC:

> (a) category of the product and its name(s); (b) name and address of the responsible person where the PIF is accessible; (c) country of origin in the case of import; (d) Member State in which the product is to be placed on the market; (e) contact details of a physical person to contact; (f) presence of substances in the form of nanomaterials; (g) name and Chemicals Abstract Service ("CAS") or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR); and (h) frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.[164]

These requirements make Member States of the EU responsible for market surveillance at a national level.[165]

VII. Conclusion

The FDC Act of 1938 should have been amended many years ago to cure the shortfalls of the outdated legislation and align more closely with the EC Regulation. The FDA does not have the power they need over the cosmetic industry to protect consumers from the hazardous chemicals put inside these cosmetics. Cosmetics should not be the least intensively regulated class of products under the FDC Act because of the harm that the products may have on consumer's bodies. The EC Regulation has been amended numerous times as technology advances to protect consumer health and safety, however, the EC Regulation has its shortfalls as well. There is no perfect

160 NHP Consulting, *Product Review and Registration-EU (CPSR/CPNP),* (September 9, 2019), https://www.nhpconsulting.ca/cosmetics/eu-cpsrcpnp/.
161 *Id.*
162 *Id.*
163 *Id.*
164 Commission Regulation 1223/2009, art. 13, 2009 O.J. L (342) 59.
165 *Id.*

cosmetic legislation, however, both legislations should protect consumers and aim to ensure that the products being sold in the respective markets be safe to use.