The Regulation of Cosmetic Product Safety

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Regulatory Definitions

In the US, cosmetics are defined by their intended use as:

> "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" (FD&C Act, sec. 201(i)).

In the UK/EU, cosmetics are defined as:

A ‘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; (EC No 1223/2009 Article 2 1(a)).

Regulatory Definitions

Products like Sunscreens, Skin Protectants, Acne, Antiperspirants, Diaper Rash Creams, Fever Blister/Cold Sore and Corn/Callus Remover are called over-the-counter drug products or OTC drug products.

OTC Drugs are regulated by the FDA monograph system. These monographs specify conditions whereby OTC Drug ingredients are generally recognized as safe and effective, and not misbranded. The monographs list exactly which active ingredients can be used, the safe and effective use levels and the claims that can be made about a product.

OTC Drugs are defined by their intended use as:

> "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

Regulatory Definitions

Claims play an important role in defining the intended use of a product which is often the difference between whether a product is a cosmetic or an OTC drug

Ingredients are another driver, however, OTC drug actives may also have a cosmetic function

- Claims and ingredients define the intended use
  - Example: Products with Titanium Dioxide may or may not be defined as an OTC Drug in the US. Face Creams containing Titanium Dioxide with sunscreen claims are OTC Drugs
- Levels of ingredients are the difference between a cosmetic and an OTC Drug
  - Example: Face wash with 0.25% Salicylic Acid
- Certain combinations of OTC Drugs are not permitted
  - Acne + Sunscreen

Regulatory Definitions

OTC Drugs or Borderline Products are regulated via a guidance document on the demarcation between the Cosmetic Products Directive 76/768 (now EU No. 1223/2009) and the Medicinal Products Directive 2001/83 as agreed between the Commission Services and the competent authorities of Member States.

The UK's Medicines & Healthcare Products Regulatory Agency (MHRA) regulates Borderline Products also known as General Sales Medicines

Claims are typically what distinguishes Cosmetics from Drugs in the EU, but it depends on the cosmetic product type. Acne is a drug; blemish is a cosmetic.

- Example: A claim to "protect skin" must be qualified to "protects skin from dryness" to be a cosmetic claim.
- Example: A claim to "soothe irritation", can be used with a cosmetic product, while claims referring to "inflammation" and "infection" are used in medicinal products.

All About the Ingredients

When determining if a formula is compliant, we first look at the raw materials.

There are 4 primary schemes that regulate raw materials.

1. Cosmetic Positive Lists – All ingredients used in a cosmetic product must be on an approved list of ingredients. Example: China, Australia
2. Cosmetic Negative Lists – All ingredients used in a cosmetic product must not be on a prohibited list. Example: US
3. Combination Restricted + Negative – Ingredients used in a cosmetic product must not be on a prohibited list and if on a restricted list, are used as set out in the regulations. Example: EU, UK, MERCOSUR, Canada, India, ASEAN
4. Drug Positive Lists (Monographs) – All ingredients used in a specific type of drug product must be listed and used at specified levels. Example: USA, Canada, Japan

All About the Ingredients

In the US, there are 20+ ingredients in the regulations that are not permitted to be used in cosmetic products. This is the negative list.

The safety of thousands of ingredients have been evaluated by the FDA for inclusion in the monographs. Only those that were found to be both safe and efficacious are permitted for use in OTC products. The safety of all of these ingredients has been documented.

Colorants are highly regulated:

- Each batch of straight colorants and their lakes must be certified by the FDA before being sold to manufacturers. Many have extensive purity requirements.

All About the Ingredients

In those markets that have combined restricted and negative lists, they are generally set out as in the UK/EU:

Annex II – Prohibited Ingredients

Annex III – Restricted Ingredients

Annex IV – Permitted Colorants

Annex V – Permitted Preservatives

Annex VI – Permitted UV Filters

All About the Ingredients

How are ingredients regulated?

Ingredients are continuously reviewed by the Scientific Committee for Consumer Safety (SCCS). This guidance becomes the basis for the restriction or prohibition of ingredients in the Annexes.

The European Chemicals Agency (ECHA) reviews the safety of ingredients as part of the REACH program.

Many markets follow the UK/EU's lead in restricting and banning ingredients.

The US cosmetic industry has the Cosmetic Ingredient Review (CIR) which, like the SCCS, consistently reviews the safety of cosmetic ingredients and publishes the results.

Notification and Registration

Notification and Registration

Notification – Must tell the government of your intent to sell the product
Registration – Must receive government approval prior to selling the product

US
Cosmetics – Voluntary Cosmetic Registration Program (VCRP)
Drugs – Must be notified with the FDA

Canada
Cosmetics – Notification of ingredients
Drugs – Must be registered with Health Canada to receive Non-Prescription (DIN) or Natural Health Product (NHP) Number

UK/EU Notification Requirements

- Must have an UK/EU Safety Assessor and Responsible Party/Legal Representative
- A Cosmetic Product Safety Review (CPSR) or safety assessment must be conducted
- Upon completion of a positive safety assessment, the Responsible Party will notify products in the EU Cosmetic Product Notification Portal (CPNP) and provide the CPNP number
- Post-Brexit, products are also notified in the UK Cosmetic Product Notification Portal (UKCP) and provide the UKCP number

Most Common Myths on the Safety of Cosmetics

Myth #1 – The US FDA does not explicitly prohibit the use of dangerous chemicals in cosmetics.

The US FDA ***DOES*** regulate cosmetics. The FDA has two overarching regulatory requirements that mean that there is no need for banned substance lists – Adulterated and Misbranded

A product is adulterated if one or more of the following are true:

- It contains a poisonous or unsafe ingredient that may cause harm to users when the product is used as described on the product label.
- It contains a *"filthy, putrid, or decomposed substance."*
- It is packaged, prepared or manufactured in unsanitary conditions where it may be contaminated with microbial organisms or any substance that renders the product harmful to the consumer.
- It is packaged in a container that is composed of poisonous or harmful substances that renders the product harmful to the user.
- It's not a hair dye but contains an unsafe color additive as determined by the FD&C Act. (Section 721(a) of the FD&C Act [21 U.S.C. 379(a)]

Most Common Myths on the Safety of Cosmetics

To assure that products are not adulterated, brands conduct testing to ***prove*** the safety of their products.

In the absence of safety testing, the FDA requires the product label to display the following statement:

> "Warning – The safety of this product has not been determined." (21 CFR 740.10)

Standard safety tests:

- Human Repeat Insult Patch Testing (HRIPT)
- Microbial testing (water activity, preservative efficacy, microbial limits)
- In some cases, eye safety (HET-CAM, epi-ocular)

Standard quality tests that may impact safety:

- Stability and compatibility

Most Common Myths on the Safety of Cosmetics

In contrast to the US, the UK/EU does not explicitly define the testing of cosmetics for safety except microbiological testing, stability and compatibility.

- Safety is determined via calculations or “paper toxicology” to determine whether or not a product is safe for use based on daily exposure limits.

Still yet, in many other countries, there is no need to prove that your product is safe to place it on the market.

Safety is not substantiated by:

- Retailer Clean Lists
- Free of Claims
- Environmental Working Group and other NGOs rating systems

Most Common Myths on the Safety of Cosmetics

Myth #2 – The cosmetic industry does not effectively police itself.

Safety

- Consumer confusion around the terms clean, safe, non-toxic and natural.

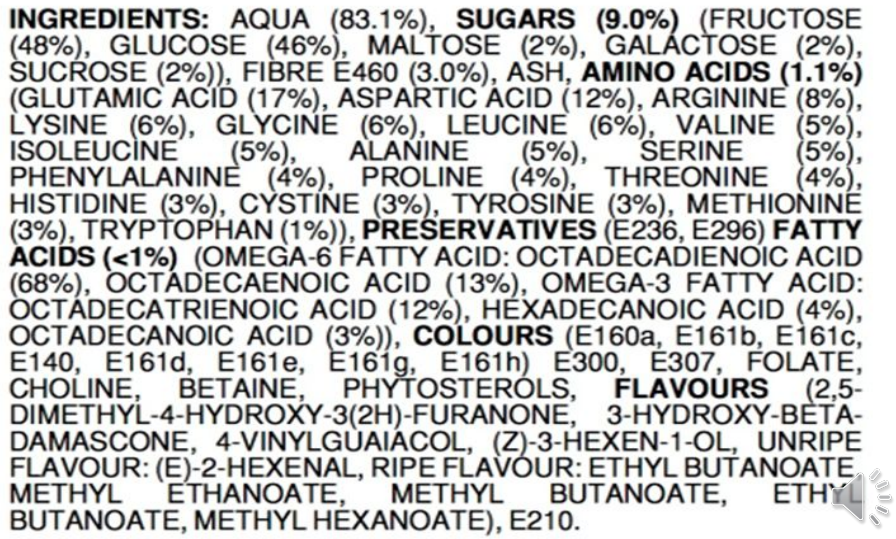
Claims

- Claims are regulated. Everything printed on a label is regulated by one or more agencies. In the US, if a product has false and/or misleading data, it is considered to be misbranded.
- EU has 6 common criteria that must be followed when making claims (EC No. 655/2013) including legal compliance, truthfulness, evidential support, honesty, fairness and informed decision making.

Most Common Myths on the Safety of Cosmetics

Myth #3 – If a government doesn't pre-approve products, then cosmetic companies get away with adding in unsafe ingredients and leave hazardous ingredients off of the label.

This myth is often driven by the use of fragrance. Fragrances can be made from one essential oil or a blend of 250+ items. Industry simply uses the word fragrance/parfum.


INGREDIENTS: AQUA (83.1%), **SUGARS (9.0%)** (FRUCTOSE (48%), GLUCOSE (46%), MALTOSE (2%), GALACTOSE (2%), SUCROSE (2%)), FIBRE E460 (3.0%), ASH, **AMINO ACIDS (1.1%)** (GLUTAMIC ACID (17%), ASPARTIC ACID (12%), ARGININE (8%), LYSINE (6%), GLYCINE (6%), LEUCINE (6%), VALINE (5%), ISOLEUCINE (5%), ALANINE (5%), SERINE (5%), PHENYLALANINE (4%), PROLINE (4%), THREONINE (4%), HISTIDINE (3%), CYSTINE (3%), TYROSINE (3%), METHIONINE (3%), TRYPTOPHAN (1%)), **PRESERVATIVES** (E236, E296) **FATTY ACIDS (<1%)** (OMEGA-6 FATTY ACID: OCTADECADIENOIC ACID (68%), OCTADECAENOIC ACID (13%), OMEGA-3 FATTY ACID: OCTADECATRIENOIC ACID (12%), HEXADECANOIC ACID (4%), OCTADECANOIC ACID (3%)), **COLOURS** (E160a, E161b, E161c, E140, E161d, E161e, E161g, E161h) E300, E307, FOLATE, CHOLINE, BETAINE, PHYTOSTEROLS, **FLAVOURS** (2,5-DIMETHYL-4-HYDROXY-3(2H)-FURANONE, 3-HYDROXY-BETA-DAMASCONE, 4-VINYLGUAIACOL, (Z)-3-HEXEN-1-OL, UNRIPE FLAVOUR: (E)-2-HEXENAL, RIPE FLAVOUR: ETHYL BUTANOATE, METHYL ETHANOATE, METHYL BUTANOATE, ETHYL BUTANOATE, METHYL HEXANOATE), E210.

Most Common Myths on the Safety of Cosmetics

Myth #4 – Natural and organic ingredients are safer than synthetic ingredients.

- Natural/organic ingredients are often more potent than synthetic ingredients. The full safety of a natural ingredients is not understood until it has been used extensively.
- Natural ingredients, like minerals, contain heavy metals.
- There are harmful toxins that are natural. Mercury, lead, asbestos, snake venom, arsenic, and ricin from castor beans can cause serious injury, even death.
- Many synthetic ingredients are inert and have very high safety profiles.
- Example: Lavender Oil. Natural lavender oil is high in fragrance allergens like linalool that can irritate the skin, whereas synthetic lavender oil can be created to remove the allergens.

Myth Merchants

Who is responsible for these misconceptions and why? Creates consumer confusion.

- Independent, third-party non-governmental organization (EWG) - $$$
- Retailer “clean” lists - $$$
- Uneducated brand founders, marketers - $$$
- Uneducated bloggers, social media “stars”, TikTok and Instagram influencers - $$$
- Investigative journalists – HBO Max’s *Not So Pretty* - $$$
- Scientists looking to make a name for themselves (parabens, PFAFs, Benzene in Sunscreen) - $$$

Consumer Confusion - NGOs

EWG

- Must score in the green section (1-2) of Skin Deep
- Cannot contain any ingredients on EWG's "Unacceptable" list
- Must comply with the regulations of most markets to include:
  - Ingredients EWG's Restricted List = Regulations
  - Labeling
    - INCI nomenclature
    - Fragrance Allergens and complete fragrance breakdown
    - PAO/Expiration
  - Testing
  - Good Manufacturing Practices
- Must submit adverse events to EWG and FDA

Consumer Confusion - Retailers

Examples of inconsistencies

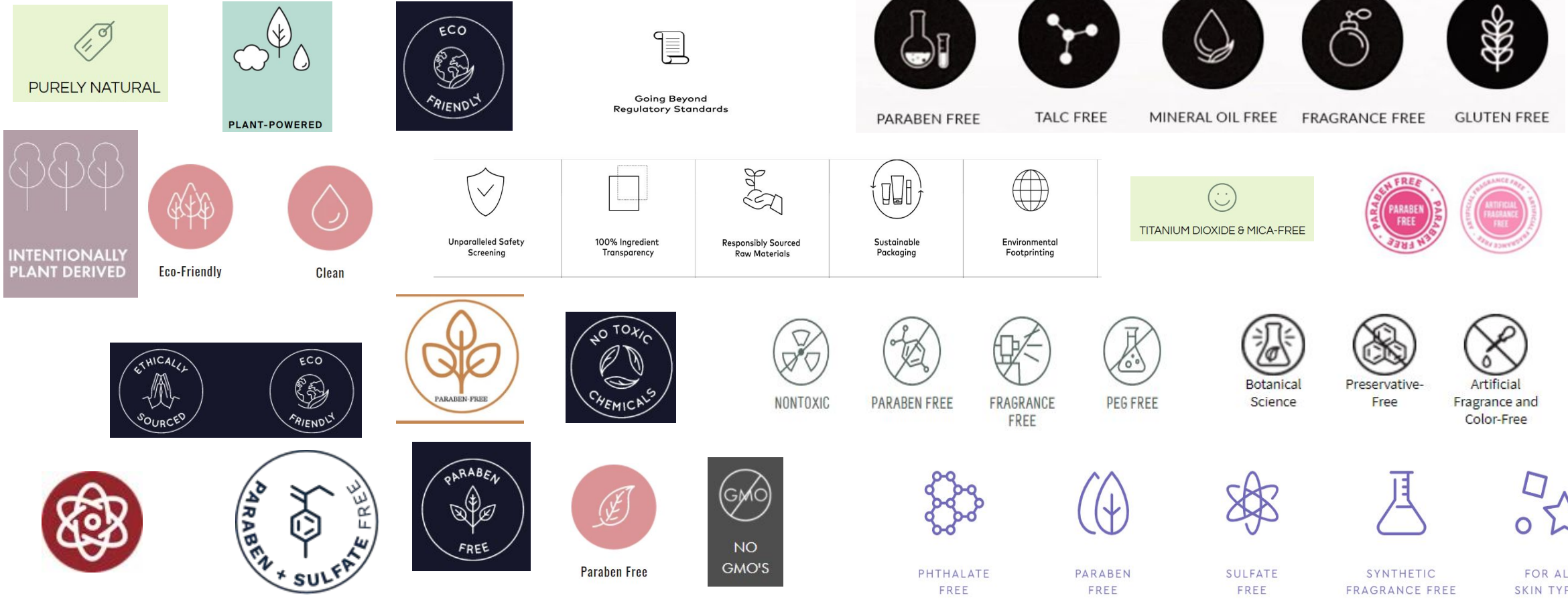
	Sephora	Ulta	Credo	Regulations
Prohibited				
Aluminum Powder	Permitted except in antiperspirants	Prohibited except in loose powder & lip products	Prohibited	Permitted
Aluminum Salts	Prohibited	Permitted except in antiperspirants	Permitted	Permitted
BHT	Permitted below 0.1%	Permitted below 0.05%, Prohibited in 2022	Prohibited	Permitted
ETA / MEA / DEA / TEA	Prohibited	2022	Prohibited	DEA is Prohibited in the EU
Mineral Oil	Prohibited	Non-USP Grades	Prohibited	Permitted
Petrolatum	USP Grade	USP Grade	Prohibited	Permitted
Paraffin	USP Grade	USP Grade	Prohibited	Permitted
Cyclical Silicones	Prohibited in 2022, <0.1% contaminent	2022 - D4	Prohibited	Maximum permissible use level in rinse-off products 0.01% in EU
Sulfates	SLS, SLES	2022	Permitted	Permitted
Methylchloroisothiazolinone/Methylisothiazolinone	Prohibited	2022	Prohibited	0.0015% (of a mixture in the ratio 3:1)
1,4 Dioxane	< 10 ppm for rinse off products, <3ppm for leave-on products	< 10 ppm for rinse off products, <3ppm for leave-on products	No Ethoxylated Ingredients	Prohibited
EDTA and Derivatives	As of 2022, max use 0.2% as chelating agent	Permitted	Prohibited	Permitted
Retinyl Palmitate	Prohibited	2021	Permitted	Permitted with limits

Consumer Confusion - Brands

In place of true independent certifications, brands are creating:

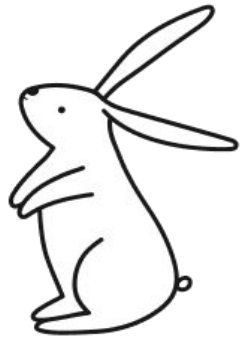
- Their own definitions for natural, clean, safe and non-toxic
- Symbols to imply certification rather than being certified
- “Free of” symbols
- Consumer confusion between official and brand symbols
- Consumer confusion around ingredient safety

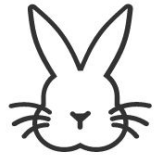
Symbol Confusion – “Free of”, Clean, Safe



Symbol Confusion - Vegan

Symbol Confusion – Cruelty Free





Summary

As an industry, we work very hard to make products safe

US FDA could help by providing more specific regulatory guidance rather than overarching terms like adulterated and misbranded so that brands are not left to interpret intent. Enforcement could be better to stop those few bad industry players.

European Commission could help by streamlining all of the Annexes to make finding all of the restrictions on a single ingredient easier to understand for its safe use in cosmetics.

Thank you for your attention