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# REGULATORY REQUIREMENT FOR MARINE-DERIVED COMPOUNDS IN COSMETICS, FOOD SUPPLEMENTS, AND MEDICINES

An Academic presentation by
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- Marine-derived compounds, such as those from algae, fish, and coastal plants, have diverse applications in food supplements, medicines, and cosmetics.
- Both food supplements and medicines are heavily regulated, and products must meet stringent safety, efficacy, and quality standards based on their intended application.
- Manufacturers must carefully categorize their products and ensure compliance with relevant regulations.

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- The cosmetic industry, which is dynamic and fast-paced, also requires strict regulation. Regulatory frameworks worldwide are quite similar, though differences exist between regions.

- Below is an overview of key regulatory bodies and laws governing cosmetic products across different countries.

| Country/Region | Regulatory Bodies | Key Laws/Regulations |
|---|---|---|
| United States | Food and Drugs Administration (FDA) | Federal Food, Drug, and Cosmetic Act (FD&C Act), Fair Packaging and Labeling Act (FPLA) (1) |
| Canada | Health Canada | Cosmetic Regulation Act (1977), Food and Drugs Act (1985) (2) |
| Brazil | Ministry of Health, ANVISA, GHCOS | Various regulations overseeing cosmetic safety and quality (3) |
| Japan | Ministry of Health, Labor, and Welfare | Pharmaceutical and Medical Devices Law (PMDL) (4) |
| China | SAMR, NMPA, GAC | Cosmetic Supervision and Administration Regulation (CSAR), replacing CHSR in 2021 (5) |
| European Union | European Commission | Regulation (EC) N° 1223/2009 (6) |

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## EUROPEAN COSMETIC REGULATIONS (EC) N° 1223/2009

- In the European Union, Regulation (EC) N° 1223/2009 (6) is the primary regulatory framework governing cosmetic products.
- It mandates that all cosmetics placed on the market must be safe for human health when used under normal or foreseeable conditions.
- This regulation focuses on ensuring product safety and setting guidelines for manufacturers, including the preparation of a Cosmetic Product Safety Report (CPSR).

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## SAFETY REQUIREMENTS

**Cosmetic Product Safety Report (CPSR):**The CPSR includes two key parts:

- **Part A:** Cosmetic product safety information (e.g., toxicological profile, chemical structure, exposure).
- **Part B:**Cosmetic product safety assessment.
- The CPSR, along with the Product Information File (PIF), must be kept updated by manufacturers and available for authorities if required.

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## Animal Testing and Alternative Methods

- Animal testing for cosmetics has been banned in many countries, including the EU. Therefore, raw material safety is evaluated using alternative validated methods such as:

**In vitro tests:**

- **Skin/Eye Irritation:** EpiDerm (OECD 439) and EpiOcular (OECD 492).
- **Mutagenicity/Genotoxicity:** Ames Test (OECD 471) and Chromosome Aberration Test (OECD 473).
- **Photo-toxicity:** 3T3 NRU.

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**In vivo tests:**

- Human Repeated Insult Patch Test (HRIPT).

## REACH REGULATION FOR CHEMICALS

- Any chemical, whether macro-, micro-, or nano scale, introduced into the EU market must comply with the REACH regulation (Regulation (EC) No 1907/2006). This ensures a thorough assessment of hazards and exposure risks.

## GOOD MANUFACTURING PRACTICES (GMP)

- Regulation N° 1223/2009 requires that all cosmetics must be produced in accordance with Good Manufacturing Practices (GMP). GMP ensures a clean production environment and guarantees that products are free from contamination during manufacturing.

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## INGREDIENT DECLARATION AND LABELING

- **INCI Compliance:** Ingredients must be listed using the International Nomenclature of Cosmetic Ingredients (INCI) on the product packaging or in an enclosed leaflet if space is limited.
- **Cosmetic Products Notification Portal (CPNP):** Before products can be sold in the European market, they must be listed in the CPNP database.
- This allows authorities (e.g., poison centers) to access cosmetic product information for market surveillance and safety planning.

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## COSMETIC CLAIMS AND LABELING

- The EU Cosmetics Regulation has specific requirements regarding the labeling of products.
- This includes the name of the product, list of ingredients, expiration dates, and any special precautions for use.
- Labels must also adhere to rules governing claims made about the product's effectiveness and characteristics.

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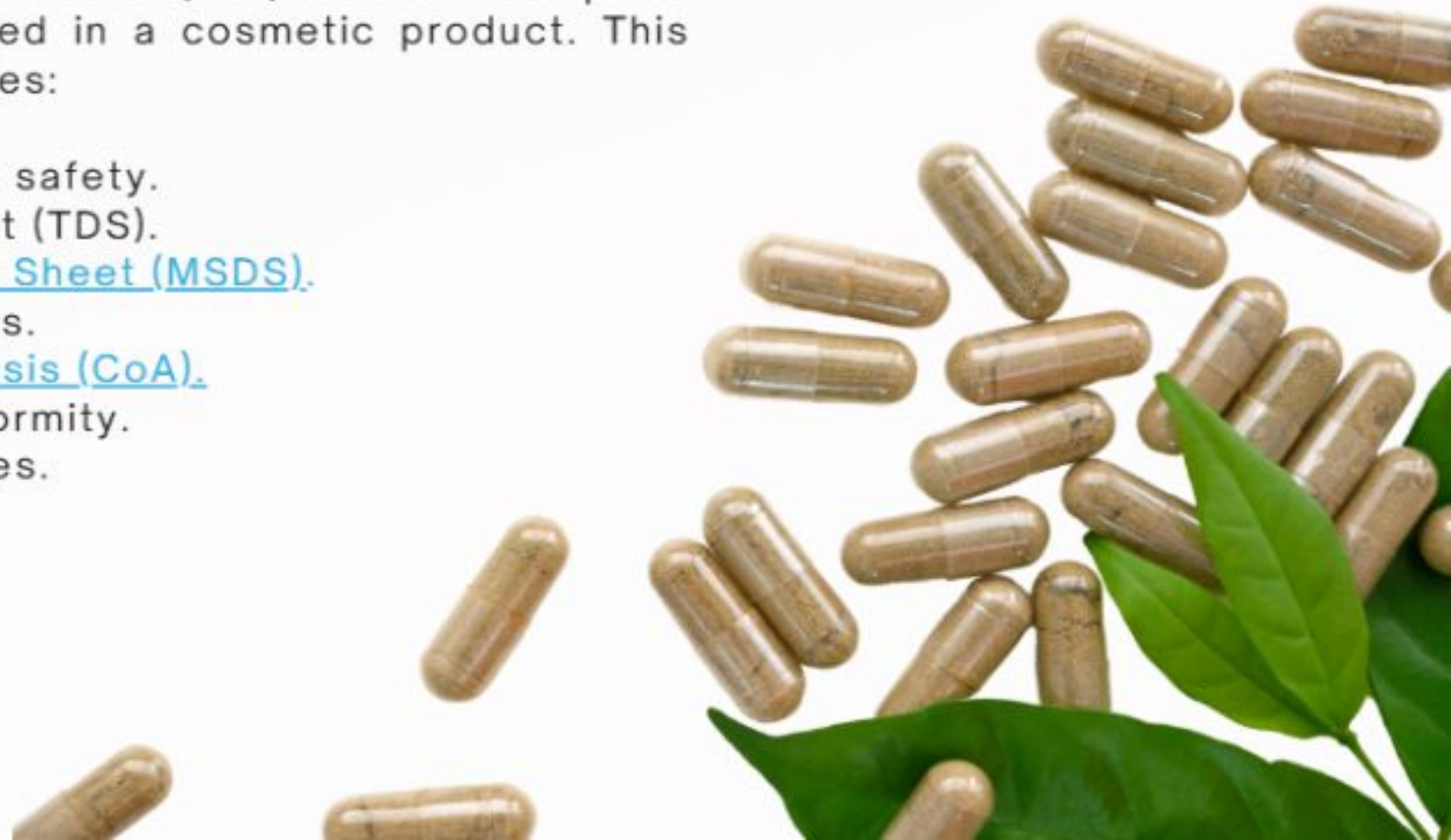
## COSMETIC INGREDIENT DOSSIER (CID)

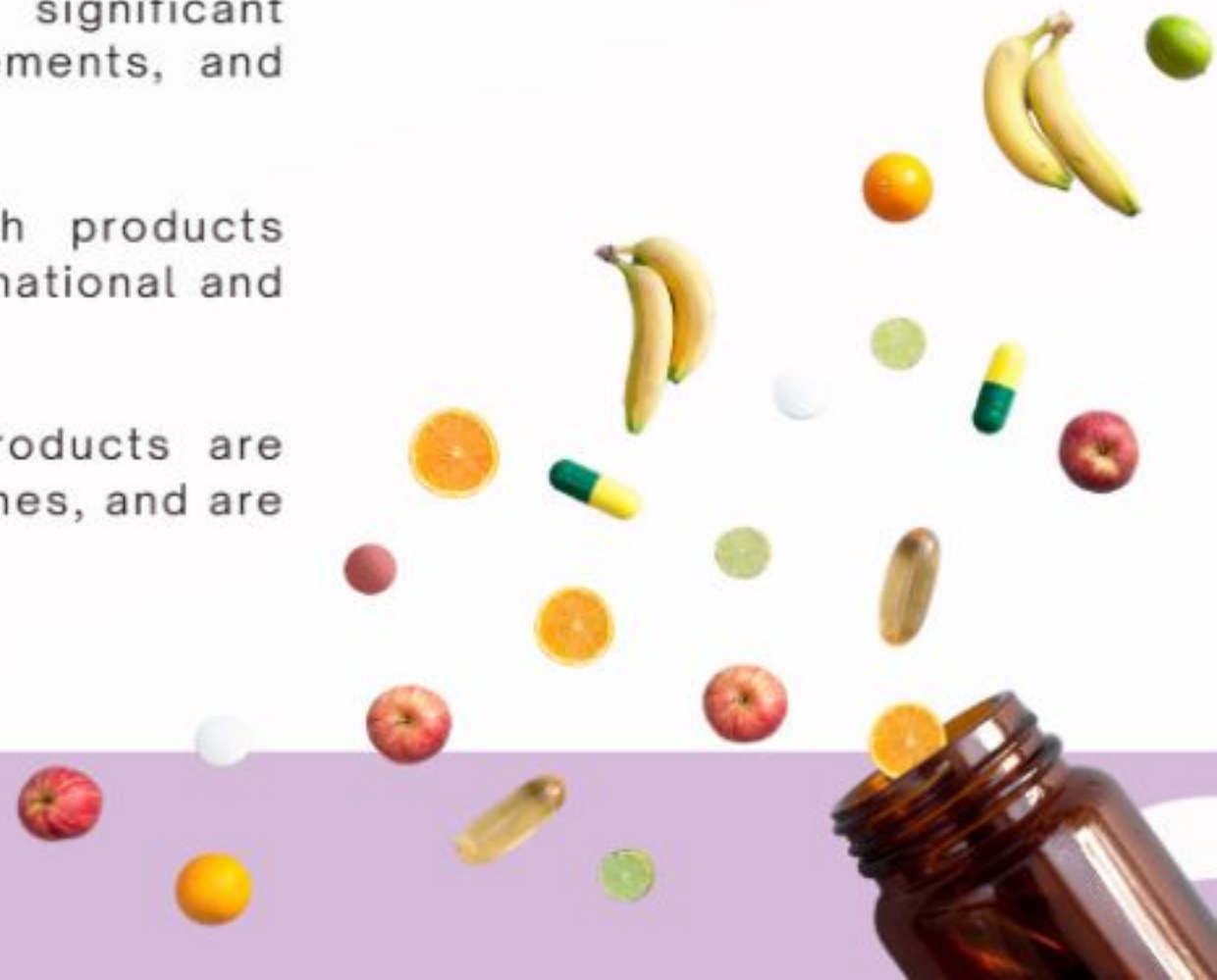
A Cosmetic Ingredient Dossier (CID) must be compiled for each ingredient used in a cosmetic product. This dossier typically includes:

- Raw data: Evaluating safety.
- Technical Data Sheet (TDS).
- Material Safety Data Sheet (MSDS).
- Allergen Declarations.
- Certificates of Analysis (CoA).
- Certificates of Conformity.
- Free-from Certificates.
- Efficacy Studies.



## CONCLUSION

- Marine-derived compounds hold significant potential in cosmetics, food supplements, and medicines.
- However, the development of such products requires strict adherence to various national and international regulatory frameworks.
- Manufacturers must ensure their products are safe, comply with established guidelines, and are properly labelled and marketed.



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- The full potential of marine-derived compounds with FRL has expertise formulation services for cosmeceuticals.

- Our team ensures products meet standard regulatory requirements across global markets, including quires and compliance with EU regulations.

- We help you with the process of complexities of ingredient verification, Cosmetic Product Safety Reports (CPSR), and Good Manufacturing Practices (GMP), ensuring efficiency, safety with market upgrades.

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