An overview of existing cosmetics frameworks: common principles and compatibility

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the personal care association

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Europe is the global flagship producer of cosmetic products (> 78 B€ in 2019) around the world, offering a mature and detailed cosmetic regulation, globally recognized, since more that 40 years.

Cosmetics Europe (CE) is the European trade association for the cosmetics and personal care industry since 1962

Our members include cosmetics and personal care **manufacturers** as well as **associations** representing our industry at national level.

⇨ *Thousands of big and small companies, right across Europe*

CE is the main industry contact for the EU Institutions on regulatory issues regarding cosmetics.

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International cosmetic framework

Key principles

Every cosmetic framework around the world is aiming for the same objective:
the deliverance of **safe**, **high quality** and **effective** personal care products to consumers



⇨ However, these key principles are implemented across the world:

- with different approaches/regulatory frameworks
  regulations, directives, acts, monographs, standards, certifications, principles or self-regulations…

- and under different responsibilities
  manufacturer, a third party or the responsible authority

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How does it impact international trade compatibility?

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Key principles:

Safety

Quality

Efficacy

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Safety

⇨ The provision of safe product for the general population under normal use conditions

Ingredient safety

The assurance of the safety of a product starts from the safe use of ingredients:

- ⇨ Risk-based assessment of the ingredient
- ⇨ formulation of cosmetic product in compliance with specific ingredient restrictions

Finished product safety

Ensure that the product is safe

- ⇨ pre-market (predictive) assessment by a suitably qualified professional
- ⇨ built on the safety profiles of the ingredients:
- ⇨ considering the product type, its use pattern and exposure
- ⇨ complemented, if needed, by confirmatory testing on finished product

Cosmetovigilance

Post/in-market-safety feedback
products are required “to be safe” **BUT “zero risk” does not exist**
small proportion of consumers will inevitably experience undesirable effects

⇨ Management of (serious) undesirable effect reports

Quality

⇨ The provision of the expected product / conformance to specification:

aspect/color/odor, physico-chemical properties, stability, control of contaminants (pathogenic micro-organisms or impurities)…

Quality is achieved through the implementation of "**Good Manufacturing Practices:**

- defined and documented production and testing processes
- suitable premises and materials
- trained personnel
- production of appropriate documentation
- reproducibility and traceability

Applied to

Raw materials management, production, control, packaging, labelling, storage, shipment… of cosmetic products

GMP does not in itself ensure safe products, but it contributes by ensuring that **products are consistently produced, controlled and documented** according to quality standards.

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Efficacy

⇨ The provision of product that will meet consumer expectations

The cosmetics industry is a fast moving and highly innovative industry. **Claims are an important part of cosmetic innovation**, allowing to continuously reflect scientific advancement and enabling consumers to find the product that suits them the best.

Claims are an important driver for product innovation and industry development.

However, claims on cosmetic products:

- should not go beyond the definition scope of cosmetics
- should not be deceptive or unclear
- should not be unfair towards competitors
- should **be substantiated** - especially important when claims could have safety implication (e.g. sun protection)

⇨ Framing the use of claims is important to ensure fair competition and avoid misleading of consumers, **BUT it should not hinder innovation**

All the pieces come together to deliver safe, high quality and effective personal care products…
… but under whose responsibility?

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All the pieces come together to deliver safe, high quality and effective personal care products…
… but under whose responsibility?

Manufacture compliance

Inspection & control

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Can be with an **in-market control** approach,
or a **pre-market registration**

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So, which regulatory model should be used?

Responsibility and control of compliance

The compliance of the product can be controlled through different approaches

Pre-market registration

The **responsible authority or a third party** has the responsibility to control and approve the SQE **of every cosmetic product** prior to the introduction of the product in the market

- ⇨ The product is approved once, based on submitted samples
- ⇨ Usually no further control is performed in the market
- ⇨ Delays access to the market, and expiration of the product registration after a determined period

In-market control

Full **responsibility of the manufacturer** to comply with the SQE requirements of the given market.

- ⇨ The responsible authority is informed of the putting in the market through notification system, enabling product traceability.
- ⇨ No delay to access the market once the product is compliant
- ⇨ The responsible authorities is in charge to check compliance via in-market control
- ⇨ Products can be inspected at any time during their 'lifespan' on the market, inspected products are reflective of what is actually on the market

Format of the framework

- A **regulation-based framework**: made and maintained by the responsible authority:

  Regulation, Order, Act, Monograph, Directive, … prescribing legally all the requirements applying to safety, quality, efficacy of cosmetic products

- **A standard-based framework**: national or regionally/internationally recognized:

  *A standard is a technical document designed to be used as **a rule, guideline or definition**.*
  It is a consensus-built, repeatable way of doing something (material, product, process or service).

  (CEN website)

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Typical elements of cosmetics frameworks

Can be covered by regulations or standards

Objectives, basic requirements

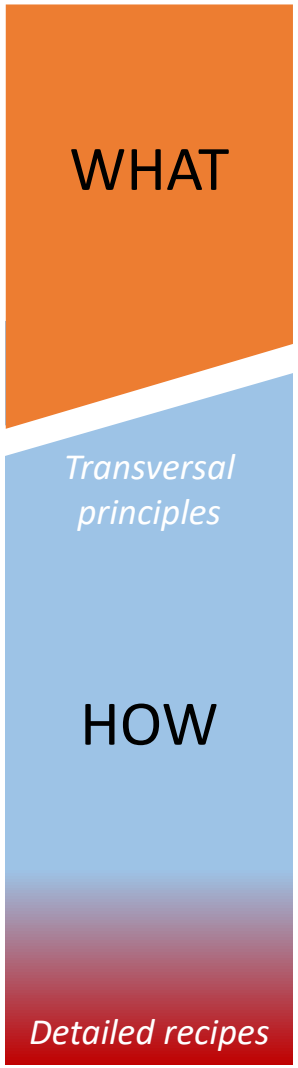
- Definition of cosmetic
- Requirement for products to be safe
- Allocation of responsibility for safety and compliance
- GMP
- Labelling & claims
- Product Notification (or Registration*)
- Market surveillance (and/or Registration dossier inspection*)

Detailed requirements & Guidance for implementation

- Specific substance restrictions
- Pictures / symbols required for labelling
- Technical and process related information
- Mandatory Technical / Safety Documentation
- Claim substantiation
- Microbiology
- Cosmetovigilance
- …

Vertical standard

- Formulation recipes
- Product requirement



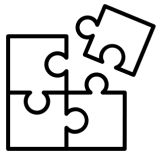
Basic requirements applicable to all the products and operators

Methods and processes to ensure SQE requirements, applicable to all products

Detailed composition requirements for specific product categories

**depending on fundamental approach taken*

Compatibility



regulation-based

standard-based

in-market control

pre-market registration

All these principles come together to create different models.

Not always ‘pure’ – more often ‘hybrid models’

All models can in principle implement and achieve the SQE principles
However, important from a trade perspective:
How compatible are different models with each other ?

Criteria for international trade compatibility

- ⇨ Aligned SQE principles under manufacturer responsibility
- ⇨ Not contradictive legislation/requirements
- ⇨ Alignment with international standards and practices
- ⇨ Easiness of access of the goods (rationality & proportionality)
- ⇨ Room for progress / innovation margin

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Overview of existing cosmetics frameworks

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Overview of existing cosmetics frameworks

		IN-MARKET CONTROL	PRE-MARKET REGISTRATION
REGULATION-BASED		**Regulation-based in-market control** 	
STANDARD-BASED	"horizontal"		
	"vertical"		

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Case study:

European Union – Cosmetic Regulation EC n°1223/2009

SQE Principles: WHAT ?

SAFETY

- "a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use"
- **Safety and compliance must be established prior to market** and documented by the entity placing the product on the EU market
- **Specific EU ingredient restrictions** must be respected during formulation development
- Labelling requirement for: use instructions, safety warnings, durability, INCI ingredient list
- Documentation **(PIF) must be kept accessible** to authorities' inspection
- **In-market safety performance** is managed through **collection and analysis of adverse event reports**; serious cases must be reported to the authorities

QUALITY

- Products must be manufactured **according to GMP**

EFFICACY

- Claims must **respect the cosmetics definition** and respect **certain criteria** regarding truthfulness & fairness
- Efficacy claims must be **substantiated** by evidence

Case study:

European Union – Cosmetic Regulation EC n°1223/2009

SQE Principles: HOW ?

SAFETY

- Safety assessment template in the Regulation
- **Guidelines on Safety Assessment**
  - Part A: Safety Information (ingredient profiles, use pattern, exposure assessment)
  - Part B: Reasoned Safety Assessment & Credentials of the Safety Assessor
- **Ingredient Annexes to the Regulation**
  - **Positive lists of colorants, preservatives and UV filters**
  - **Negative lists of banned and restricted substances**
- Glossary of INCI names
- Guidelines on management of adverse events and reporting of serious cases

QUALITY

- **ISO GMP 22716 as the recommended preferred standard**

EFFICACY

- Secondary legislation laying down criteria which all claims need to respect
- **Guidelines on claims and claims substantiation**

Case study: European Union – Cosmetic Regulation EC n°1223/2009

Responsibility for compliance and enforcement

- Unique and indivisible responsibility for safety and compliance carried by the entity placing the product on the EU market
- So-called "**Responsible Person**" (by default: EU manufacturer or importer)

- **Products need to be notified to a central EU Web-portal CPNP** to make sure that authorities are aware which products are on the market
- The objective of the CPNP notification is to **identify products on the market**, not to check their compliance!
  - ⇨ compliance is checked and enforced through in-market control

- **National authorities are legally obliged to carry out in-market inspections** 'at adequate scale' (but not systematically for all products!)
- **Random checks**, risk-based priorities OR triggered by concerns/complaints/suspicions
- Main elements for in market control:
  - **Products picked from the market** (visual inspection/labelling and chemical analysis)
  - **Product Information File**, including Safety Assessment
  - **Cosmetovigilance** reports
  - **GMP documentation** and inspection of premises – but no obligation to be ISO-certified

Overview of existing cosmetics frameworks

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Regulation-based, in-market control

Pros and Cons

- Manufacturer responsibility for safety and legal compliance
- **High level of consumer safety** without managing cosmetics like drug
- **No lead time** to place on the market, adapted to fast moving consumer goods
- **Assessment of the safety done prior to the market** but **surveillance done on what is actually placed on the market**
- Flexibility to **prioritise authorities' resources on risky products** (rather than systematically assessing every product)
- **Boundaries of permitted behaviour rather than detailed and restrictive "cooking recipes" ⇨ encourages innovation**
- Legislative process follows strict rules including transparency and **public consultation**
- Hierarchical level of legislation, primary and implementing laws, ensuring consistency of the framework
- Can be codified in a single text creating an easy accessible reference (primary legislation and implementing technical annexes, ingredient lists,…)

- **Perceived lack of authorities' control of what goes on the market**
- Need a certain level of technical and regulatory maturity to be able to comply with the law and/or to enforce it
- ***Inability to systematically check 100% of the products:***
  ⇨ ***is this really needed?***

Potential for international compatibility:

- SQE principles can be written, implemented and enforced **based on international best practices**
- **Regulatory cooperation** can be included in bilateral and multilateral trade agreements, leading to increased compatibility
- Regulation is by its nature more flexible and inclusive, thus **industry supportive information for SQE can be portable** between differently worded legislations
- **In-market control is more globally harmonized** than administrative pre-market registration processes
- **Simple and immediate** market access for global formulation

Overview of existing cosmetics frameworks

		IN-MARKET CONTROL	PRE-MARKET REGISTRATION
REGULATION-BASED		**Regulation-based in-market control:** - European Union - Most of Latin American countries - ASEAN countries - "Australia – Canada – US – New Zealand – China – Japan – South Korea – Taiwan – Russia" **for ordinary cosmetics**	**Regulation-based pre-market registration:** 
STANDARD-BASED	"horizontal"		
	"vertical"		

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Regulation-based, pre-market registration

Case study: Morocco - Circular N°79 DMP/00

Safety-based regulation prescribing all the requirements (WHAT and HOW) applying for the cosmetic products:

- Respect of **specific ingredient restriction** (referring directly to EU annexes)
- Manufacture in compliance with **GMP principles** (recommended ISO 22716, self-compliance certificate)
- Labelling requirements…

This regulation prescribes as well the registration procedure applying to every cosmetics before accessing market:

- Deposition of a **safety sheet to the poison control and pharmacovigilance center**
- **Registration file submission** and **fees payment** against the Drug and Pharmacy Authority (DMP)
- Sworn statement that:
  - the product was developed in accordance to international safety, quality and efficacy norms
  - the **Product Information File** is available at the address of the declarant

After acceptation (lengthy) of the registration file

⇨ obtention of a registration certificate (needed for customs clearance)
5 years validity, renewable (renewal fees)

⇨ the Ministry of Health is in measure to request the **registration certificate** or the **PIF** at anytime

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Regulation-based, pre-market registration

Pros and Cons

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- Legislative process follows strict rules including transparency and public consultation
- Hierarchical level of legislation, primary and implementing laws, ensuring consistency of the framework
- Can be codified in a single text creating an easy accessible reference (primary legislation and implementing technical annexes, ingredient lists,…)
- **Provides more detailed guidance and instructions for registrants**
- **Transparency of what is registered for the market…**

- **Weakening of manufacturer responsibility** on safety and compliance
- **Increased time to market** & paper works, not adapted to fast moving consumer goods
- **Drug-like management** approach, without bringing more safety
- **Risk of unfocused use of authorities’ resources** on every product intended to be put on the market
- **Registration fees**
- **Expiry date**/renewal of the registration
- May **slow down innovation**

- …but **lack of visibility on what IS actually on the market**

Potential for international compatibility:

- SQE principles can be written, implemented and enforced based on international best practices
- Regulatory cooperation can be included in bilateral and multilateral trade agreements, leading to increased compatibility
- Regulation is by its nature more flexible and inclusive, thus industry supportive information for SQE can be portable between differently worded legislations
- Registration processes are detailed oriented processes offering **much less portability and harmonization**
- **Increased and/or unpredictable time to market** may hinder global launches

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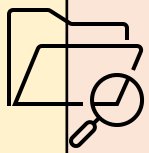

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Horizontal-based standard framework

GSO 1943/2016: Safety Requirements Of Cosmetics And Personal Care Products

Harmonized Technical Regulation between the **Gulf Cooperation Council countries**:

- *Kingdom Saudi Arabia*
- *UAE*
- *Bahrain*
- *Kuwait*
- *Oman*
- *Qatar**

- Prescribes all the **requirements applying for cosmetic products (WHAT)** to ensure **their safety, quality and efficacy** under manufacturer responsibility

  ⇨ Mirrors the EU cosmetic regulation (with minor adaptation):
  - formulation of cosmetic product in compliance with **specific ingredient restrictions** (direct reference to EU annexes + few additional restrictions)
  - Manufacture in compliance with GMP (such as GSO/ISO 22716) without certification or imposed standard
  - Truthful claim approach

- Listing of recommended "HOW" guidances for cosmetic products (horizontal standards for testing)

- However, the GSO 1943/2016 **does not prescribe completely how to implement the requirements** in the different markets

  ⇨ Each Authority follows its own scheme/framework of implementation

**Qatar follows the GSO 1943/2009 - Cosmetic Products - Cosmetic Products Safety Requirements*

Horizontal-based standard, **in-market control**

Case study: Saudi Arabia: SFDA.GSO 1943/2016

Formerly a pre-market registration system, **Saudi Arabia became an in-market control system** with the implementation of a free notification portal*: **eCOSMA portal** (similar to CPNP)

⇨ Every product put on the Saudi market has to be notified on the eCOSMA portal

⇨ **The SFDA (responsible authority) is performing in-market inspections** (picking product on the shelf):
- for product control (labelling, …)
- lab analysis (composition & impurities)
- or to request additional documentation to the manufacturer (GMP compliance, …)

Particularity: imported product have to be accompanied by a **pre-shipment Certificate** of Conformity (CoC)
- delivered by a **Certification Body**
- simple procedure **to ensure that the product is well notified** (eCOSMA notification numbers required)
- no testing required, but **certification fees**
- 1 CoC per shipment listing all the product
- needed for customs clearance in Saudi Arabia

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*the eCOSMA notification became mandatory in 2016

Horizontal-based standard, **in-market control**

Pros and Cons

- **Manufacturer responsibility** for safety and legal compliance
- High level of consumer safety without managing cosmetics like drug
- **No lead time** to place on the market, adapted to fast moving consumer goods
- **Assessment of the safety done prior to the market** but surveillance done on what is actually placed on the market
- Flexibility to **prioritise authorities' resources on risky products** (rather than systematically assessing every product)
- Boundaries of **permitted behaviour** rather than detailed and therefore restrictive "cooking recipes" -> **encourages innovation**

- **Perceived lack of authorities' control** of what goes on the market
- *Inability to systematically check 100% product of all product:*
  ⇨ is this really needed?
- Issuance of the **certificate of conformity** for every shipment
- Possible **certification fees**
- **Flat hierarchy between standards** developed by different expert groups => bigger risk of inconsistencies between the texts

Potential for international compatibility:

- SQE principles can be written, implemented and enforced based on international best practices **and international standards** (ISO…)
- **Standards are by nature more detailed and prescriptive**, thus industry supportive information for SQE may be less portable between different national standards
- In-market control is more globally **harmonized** than administrative pre-market registration processes
- **Simple and immediate** market access for global formulation
- No regulatory cooperation but **leveraging of international standardisation activities** (ISO, OECD)

Horizontal-based standard, **pre-market registration**

Case study: United Arabic Emirates: UAE.S GSO 1943/2016

UAE Technical Regulation - Resolution No.18 of the year 2014

Implementation of the **ECAS* product registration system**

Every domestic or imported cosmetic product has to be registered before being put within the UAE Market

- submission of a **registration file** to a Notified Body / third party
- payment of service **fees**
- review of product compliance with UAE Technical Regulation (UAE.S GSO 1943/2016)
- **Issuance of the ESMA Conformity Certificate**

⇨ **1 year validity**, to be renewed **on annual basis** (renewal fees)

Imported product cannot clear customs without the ESMA Conformity Certificate

**Emirates Conformity Assessment Scheme*

Horizontal-based standard, **pre-market registration**

Pros and Cons

- Boundaries of **permitted behaviour** rather than detailed and therefore restrictive “cooking recipes” -> encourages innovation
- Provides more **detailed guidance** and instructions for registrants
- Transparency of **what is registered** for the market….

- **Weakening of manufacturer responsibility** on safety and compliance
- **Increased time to market** & paper works, not adapted to fast moving consumer goods
- **Drug-like management** approach, without bringing more safety
- **Unfocused use of authorities’ resources** on every product intended to be put on the market
- Registration/certification **fees**
- **Expiry date**/renewal of the registration
- May **slow down innovation**
- … but lack of visibility on **what IS actually on the market**
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Potential for international compatibility:

- SQE principles can be written, implemented and enforced based on international best practices and international standards (ISO…)
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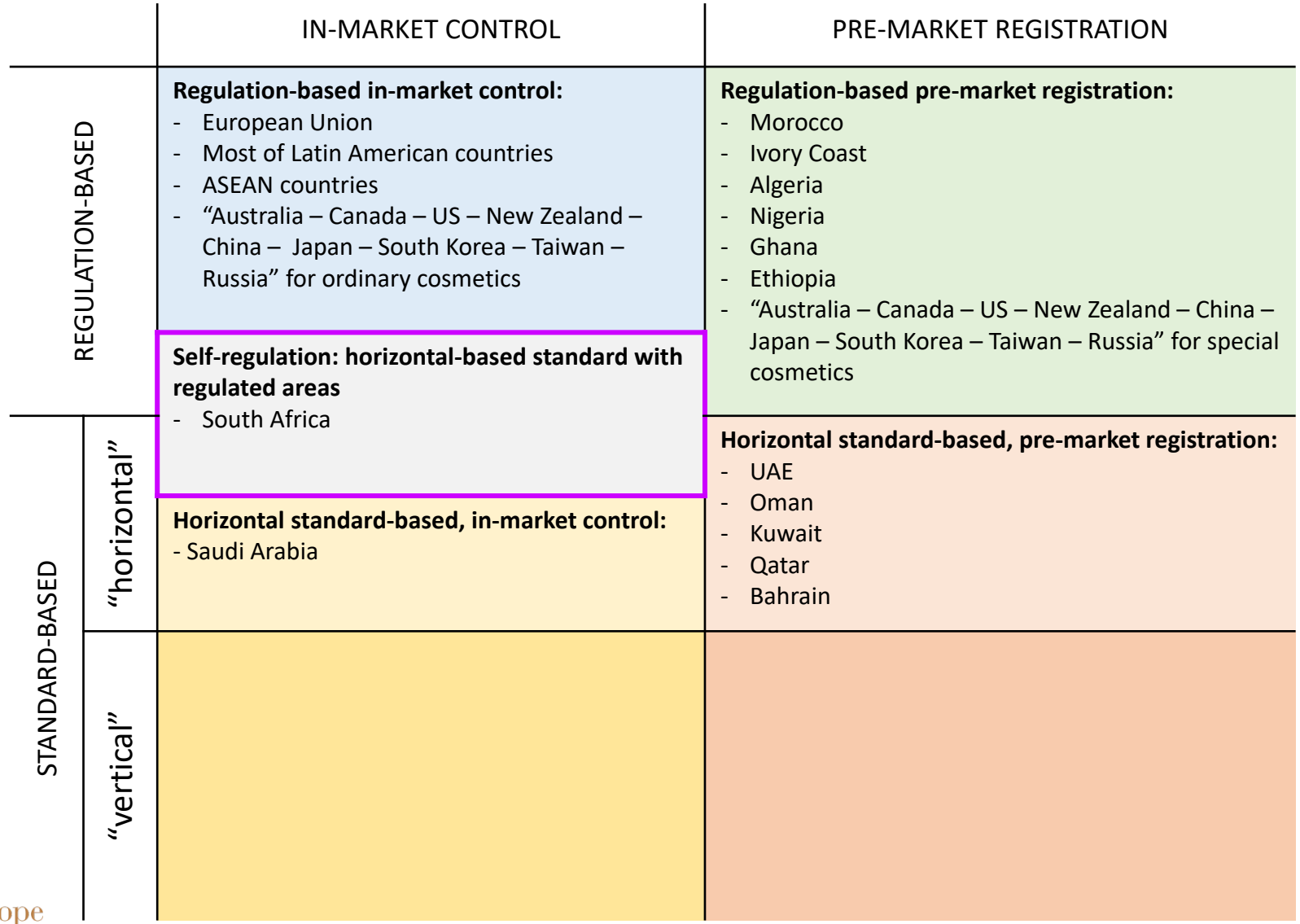

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	"vertical"		**Vertical standard-based, pre-market registration**

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Vertical-based standard, pre-market registration

Case study: India – Cosmetics Rules, 2020

Cosmetic framework in India is composed of an association of Rules and vertical standards:

⇨ **Rules** prescribing **general requirements** applying for domestic or imported products (HOW):

- labelling requirements
- detailed **GMP requirements**
- Registration **processes, fees and expiration**

⇨ Reference to all the mandatory standards applying to **cosmetics products** (HOW):

Few horizontal standards:

- IS 4707 (part 1) list of allowed colorant for cosmetic products
- IS 4707 (part 2) list of forbidden ingredients in cosmetic products
- IS 4011:2018 **methods of test for safety evaluation** of cosmetics

Listing of all the vertical standard applying for each type of cosmetic products

all the Quality, Performance and Labelling requirements are additionally prescribed in the product standards

"No cosmetic shall be imported or manufactured unless it complies with BIS standards of composition, quality and safety"

Submission of the registration file for each cosmetic product, payment of fees
⇨ Issuance of the **registration certificate** (~3 months), **5 years validity** (renewal fees)

Vertical-based standard, pre-market registration

Pros and Cons

- Provides **exact detailed guidance and instructions for formulation and registration**
- Transparency of what is registered for the market
- **Easy compliance check**

- Based on prescriptive **cooking recipes**
- Leaves **little room for innovation and trends**
- **Difficult to update** and synchronise, gradually falling behind scientific advancements
- **Restricts consumer choice**
- It **limits the potential for industry development**
- Weakening of manufacturer responsibility on safety and compliance
- Increased time to market & paper works, not adapted to fast moving consumer goods
- Drug-like management approach, without bringing more safety
- Unfocused use of authorities' resources on every product intended to be put on the market
- Registration/certification fees
- Expiry date/renewal of the registration
- Lack of visibility on what IS actually on the market
- Flat hierarchy between standards developed by different expert groups => risk of inconsistencies between the texts

Potential for international compatibility:

- Strong **product-by-product components** rather than a SQE framework
- **Low potential for principles-based international compatibility**
- **Very low portability** with international trade partners
- Registration processes are detailed oriented processes offering much less portability and harmonization
- Increased and/or unpredictable time to market may hinder global launches
- No regulatory **cooperation, no leverage of international** standards (ISO, OECD)

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Conclusion

All cosmetic frameworks around the world **aim to achieve the same SQE objectives…**

Safety, Quality, Efficacy

- Most frameworks are structured around WHAT (basic requirements) and HOW (practical implementation), without entering into detailed formulation recipes

- Existing frameworks differ significantly in their form and in the **allocation of responsibility for compliance and control**
    - Legislation-based vs. standard-based
    - pre-market registration vs. in-market control

… but **some types are more appropriate** for **fast-moving consumer products**, more compatible from an **international trade perspective** and thus **more encouraging for innovation and industry development**.

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Conclusion

- Compared to pre-market registration, in-market control based frameworks:
  - allocate **responsibility for safety and compliance to the industry**
  - allow **faster market access** of compliant products
  - ensure that compliance checks and enforcement are carried **on the real-life marketed products**
  - **avoid duplication of data generation** for cross-border trade because administrative processes and data requirements are less detailed and country-specific

Conclusion

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  - allocate **responsibility for safety and compliance to the industry**
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  - ensure that compliance checks and enforcement are carried **on the real-life marketed products**
  - **avoid duplication of data generation** for cross-border trade because administrative processes and data requirements are less detailed and country-specific

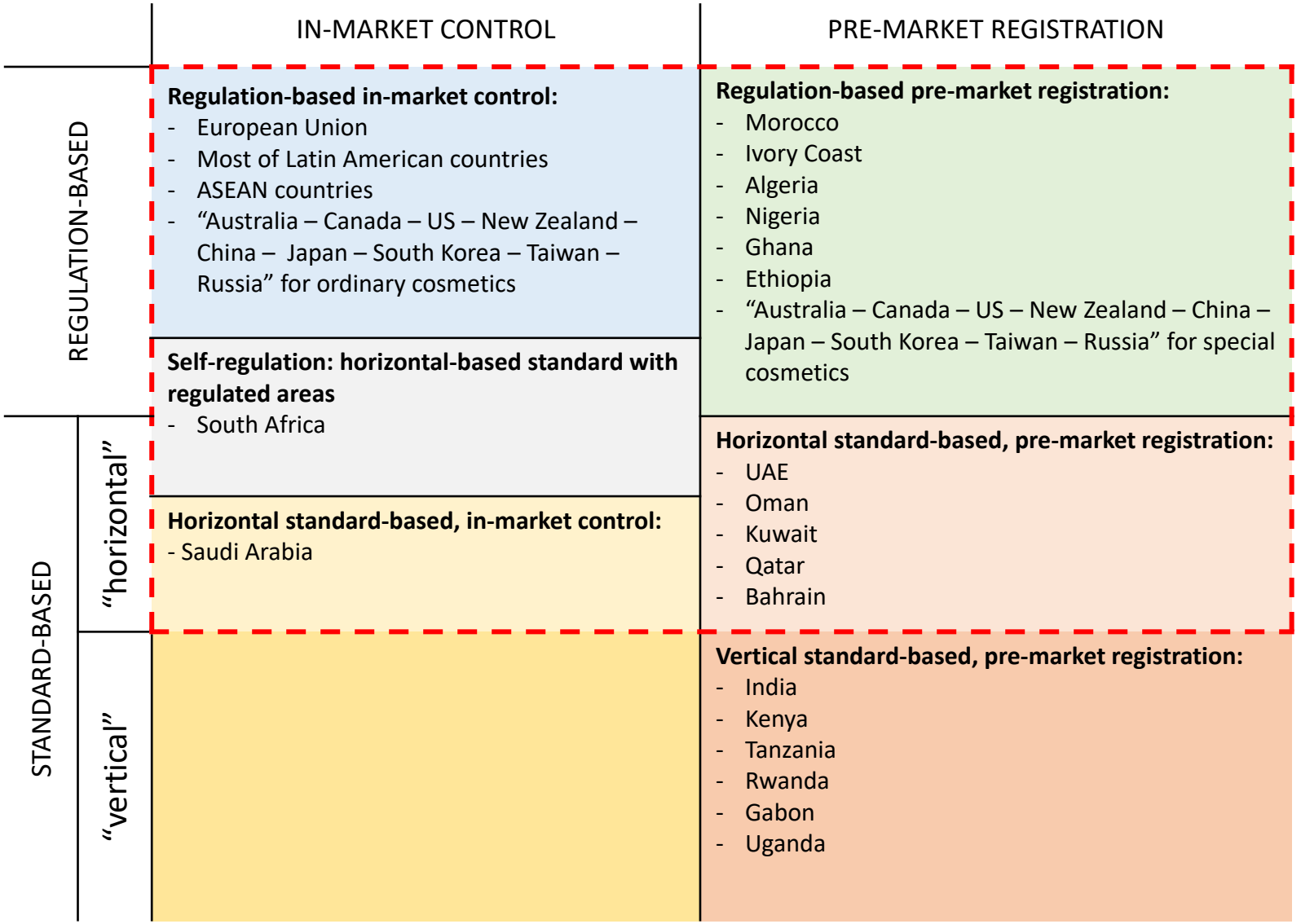
- Compared to standards-based frameworks, **legislation-based frameworks are typically more flexible** on HOW to achieve the SQE objectives, and **benefit from international regulatory co-operation** for regulatory convergence and facilitated trade

- Standards tend to be detailed, prescriptive, less flexible and – **at the level of national standards often not compatible between countries**.

- Trade compatibility of standard-based frameworks can be **improved through the adoption of international standards** (e.g. ISO, OECD) rather than national standards.

- Vertical standards on characteristics of specific product categories (composition, pH, …) **are not necessary to achieve SQE objectives**. They are **not compatible with fast-moving consumer goods** and can significantly hinder innovation and industry development.

Overview of existing cosmetics frameworks



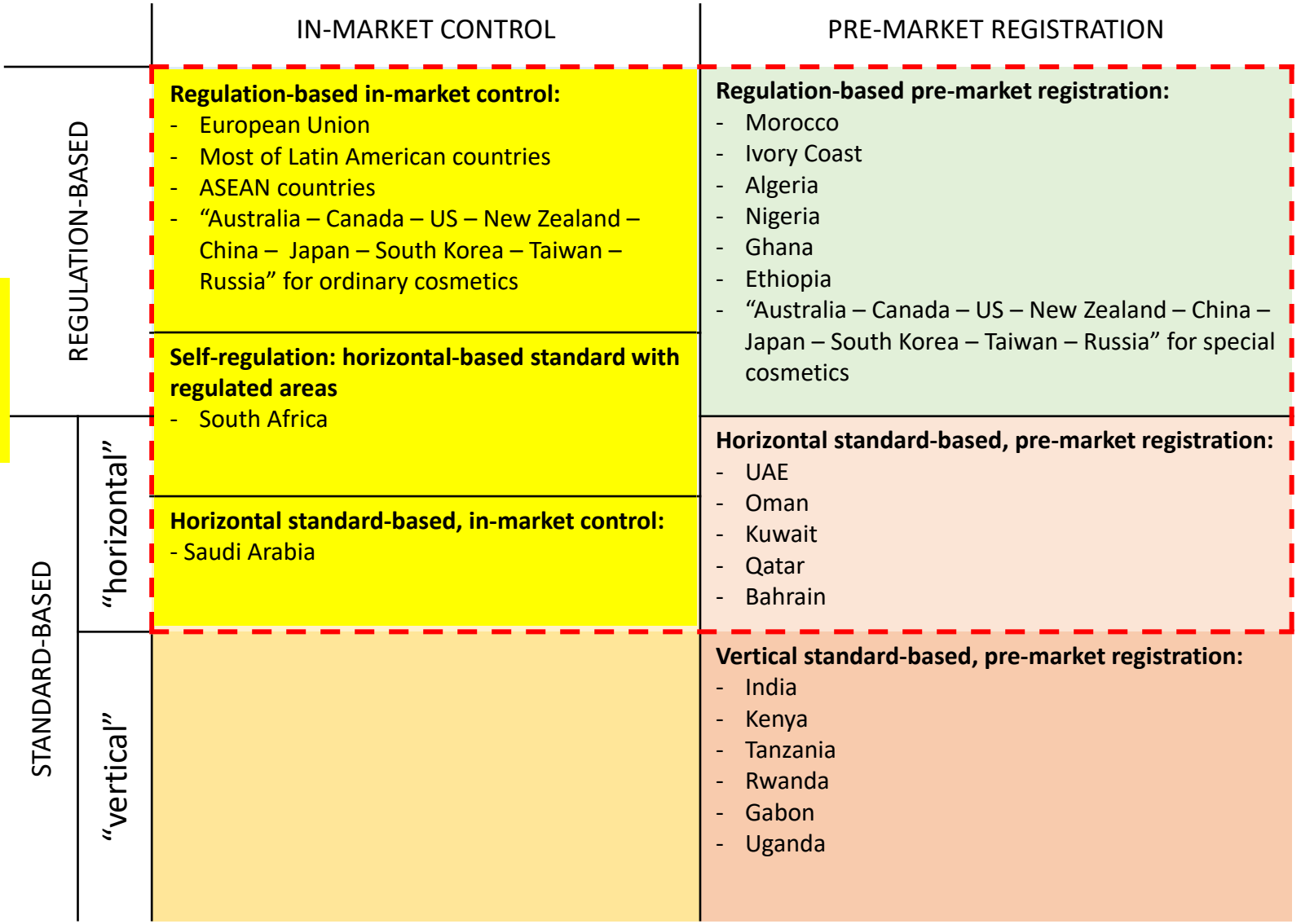
Models with the higher opportunities for international trade compatibility

Cosmetics Europe
the personal care association

We personally care

Overview of existing cosmetics frameworks

Ideal for market access, fast moving goods and enabling trends and innovations



Models with the higher opportunities for international trade compatibility

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An overview of existing cosmetics frameworks: common principles and compatibility

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Thank you !

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