EU Cosmetics Regulation

Current and Future Regulatory Challenges

15 March 2019

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I love the EU Cosmetics Regulation

- Most modern Cosmetics Regulation worldwide
- Building on over 40 years of regulatory experience
- Stable regulatory environment
- Proven to ensure
  - Functioning of the internal market
  - High level of protection of human health
- An inspiration for international regulatory alignment

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But this does not mean there are no regulatory challenges

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Borderlines:
Personalised Products,
Microbiome Products

Endocrine disruptors
CMR Substances
Preservatives
Nanomaterials

Microplastics

Digital Labelling

Enforcement

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Borderlines:
Personalised Products,
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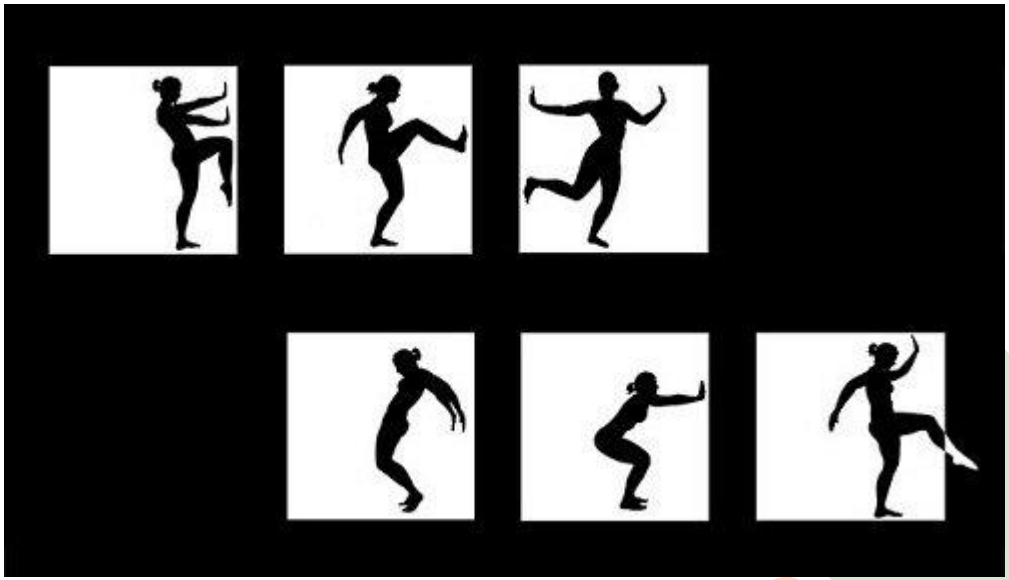
Borderlines

- Cosmetics are highly innovative sector
- Regularly new uses and product categories appear on the market
- In 1976 regulators defined a list of **26** cosmetic product types / categories
- In 2013, the CPNP database defined about **60 categories and 150 Frame formulations**
- Scientific progress allows the development of ever more active and effective products

- **Can the Cosmetics Regulation handle such products ?**

- **Do we need to break out of the box ?**



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Borderlines

- Compared to other regions, EU Definition is wide and flexible
- One single regulatory approach for all cosmetics.
- No additional category of ‘cosmetic drugs’ or ‘special cosmetics’

- EU Definition allows secondary, non-cosmetic benefits
- It does not prohibit a physiological effect (as long as the product does not cure/prevent a disease)
- It does not prescribe/ prohibit specific mode of action

Overall, the box is pretty large and allows innovation

Borderlines – What does Cosmetics Europe do ?

- Regular ‘reality checks’ in the EU Commission/Member States/Industry Working Group on Borderline Products
- Protect the EU cosmetics definition
- Participation to the EU Commission Working Group on Borderlines Definitions
- Working on detailed Guidelines for the Cosmetics/Drug Borderline

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Personalised Products

Products made for a single consumer

Formula chosen after an assessment of consumer needs	Personalization criteria
• Questionnaire • Assessment by beautician • Instrumental Measurement • Genetic measurement	• Age • Habitus • Skin condition • Hydratation, sun exposure • Lifestyle …

Manufactured at  Plant  Home  Shop

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Are personalised products covered by the EU Cosmetic Regulation ?

Article 1 +2

This Regulation establishes rules to be complied with by any cosmetic product …[supplied] for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge…

No indication that personalised products should be excluded

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The question is not whether personalised products are cosmetics, but rather, how to apply the Cosmetics Regulation on them

- Identification of Responsible Person
- Scope of PIF
- Safety Assessment

- Notification
- Labelling
- Manufacturing
- Cosmetovigilance

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Identification of Responsible Person (RP)

Art. 4: The RP is the entity to whose name the product is manufactured or the importer (or a third party, based on mandate)

Principle can be easily applied to personalized products manufactured in plants.

What about products mixed in the shop or at home ?

Two main scenarios:

1) Ingredients are **<u>obtained independently</u>** from a recipe
   → entity preparing the finished product is the RP

2) Recipe and ingredients are **<u>obtained together</u>**
   → entity selling the recipe & ingredients is the RP
   → entity preparing the finished product is a distributor

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Product Information File & Safety Assessment

- In case of a personalized product, what is the 'Product':
  - Each personalized formulation ?
  - The range of similar formulations ?

- No direct answer from the text of the Regulation

- Variants can be covered in one PIF / Safety Assessment if
  - no significant different product type, claims, main composition, safety
  - clear description allowing link of the PIF to the product

- Precedence exists (variability of natural ingredients, colour ranges, …)

Practical approach for PIF & SA

In addition to ‘classical PIF’:

- Base formula and description of variation range
- Variation rules, incl. permitted / excluded combinations
- “Maximum” ingredient list with concentration ranges
- Safeguards that prevent manufacture of excluded combinations
- Naming rules for variants allowing to identify exact composition
- Justification why the different combinations can be considered as variations of the same product

Safety assessment based on hypothetical ‘worst case’ product with all variable ingredients present at maximum concentration

Personalised Substances – What does Cosmetics Europe do ?

- Develop position, argumentation and guidance in support of safe personalised cosmetic products (GMP Guidelines for personalised products)
- Dedicated breakout session at last year's Cosmetics Europe Conference (June 2018, Brussels)
- Advocate reasonable approach in major trading regions (e.g. China)

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Microbiome Products

- Products that influence the microflora on the skin to achieve a cosmetic effect (e.g. skin protection, keeping in good condition)

- Can contain live microorganisms, dead microorganisms or ingredients promoting / shifting the microbial balance

Are microbiome products covered by the EU Cosmetic Regulation ?

- The cosmetics definition is fulfilled if the product is
  - A substance or mixture
  - Applied to the external parts of the human body …
  - With a main or exclusive cosmetic function …
- Microflora is part of normal, healthy skin
- Intended effect is a cosmetic effect
- Mechanism of action is not relevant

No indication that microbiome products should be excluded, but need clarity how to apply requirements on safety assessment and claims.

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Microbiome Products – What does Cosmetics Europe do ?

- Develop position, argumentation and guidance in support of safe cosmetic microbiome products
  - Definitions
  - Legal assessment
  - Guidance on Safety Assessment, Claim substantiation

- Dedicated breakout session at the Cosmetics Europe Conference (June 2019, Brussels)

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Endocrine disruptors
CMR Substances
Preservatives
Nanomaterials

Microplastics

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Endocrine Disruptors

- Long-standing issue and debate (1962 book ‘Silent Spring’)
- Started as environmental issue, linked to pesticides
- Debate widened to chemicals and all sources of exposure
- Cosmetics debate initially in the context of specific ingredients, but Cosmetics Regulation included ED as a generic issue:

> “When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties.”

Endocrine Disruptors – Status under the Cosmetics Regulation

- Commission review published in January 2019
- Concludes that substances fulfilling ED criteria can be addressed case-by-case through SCCS review and listing/restricting in the Regulation Annexes.
- No need for new regulatory approach.
- Commission to establish priority list of potential ED for review by SCCS, stakeholder input requested
- Industry will be requested to submit safety dossiers on these substances
- In parallel, a cross-sector Fitness Check of Regulations will be carried out in 2020

Endocrine Disruptors – What does Cosmetics Europe do ?

- Contributed to the Commission review and supports its conclusions
- Provide input to the priority list of potential ED
- Organise preparation of safety dossiers on priority substances that are of industry interest
- Contribute to the cross-sector Fitness Check and defend Cosmetics Regulation approach

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CMR substances

- Substances classified under chemical legislation as **c**arcinogenic, **m**utagenic or toxic for **r**eproduction
- Classification criteria are hazard based and do not consider actual risk under cosmetic use
- Few cases in the past, but REACH is expected to significantly increase the number

→ Safe cosmetic ingredients can become classified

Regulation of CMR substances under Article 15

- European Commission is obliged to ban the use of CMR substances in cosmetics
- Exceptionally exemptions can be granted, if SCCS concludes that cosmetic use is safe (additional criteria need to be fulfilled for CMR Cat 1)
- Debate since 2010 whether bans are effective automatically after chemical classification or need to be implemented via the Cosmetics Regulation.
- Clarification in 2019:
  - ✓ CMR Bans and exemptions require an act under the cosmetics legislation
  - ✓ Must be done within 15 months after the publication date of the chemical classification

Practical Implementation: Annual "CMR Omnibus Regulation"

- Annual update of the Cosmetics Regulation to ban/exempt all substances whose CMR classification was published the year before
- No transition time for products on the market !
- All exemption criteria must be fulfilled +/- at the time of CLP publication
- Industry exemption dossier must be submitted 12 months before CLP publication
- Industry needs to firmly decide on the defence and start dossier preparation **3 years** before CLP publication (at this time, the final classification is not yet known with certainty !)

CMR Substances – What does Cosmetics Europe do ?

- Establish a process that allows fast decision making over defence/not defence of upcoming CMR substances
- Need to assume worst case classification and prepare to satisfy all exemption criteria
- Start CE actions at the time of CMR Registry of intentions, i.e. 4-5 years prior to the ban
- If a substance is not defended by CE, members will be informed immediately
- If a substance is defended, members will be continuously informed over progress / outlook of success
- Exemptions from CMR bans will be rare – but at least companies will have the chance to react in time

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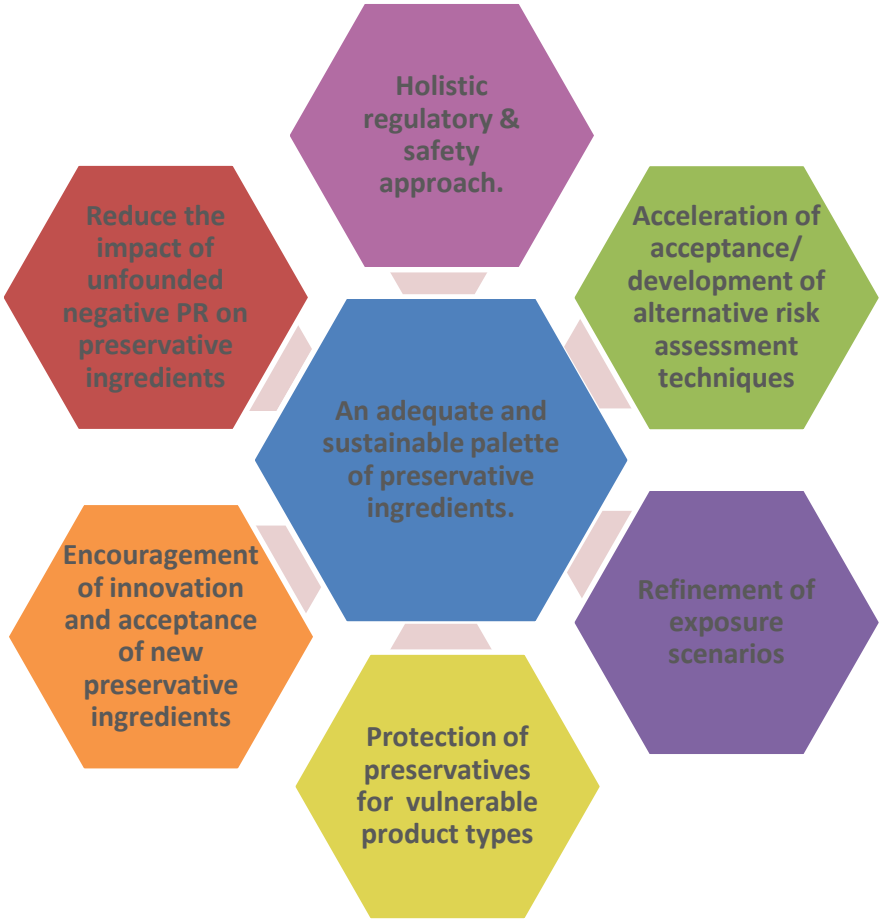
The Product Preservation Challenge

- Today: 58 preservatives in the EU positive list
- Limited sub-set actually used by Industry
  - Performance/compatibility, marketing claims/restrictions
  - Many of those are facing regulatory review and uncertainty
  - And still reducing
- Only 2 new preservatives added in last 10 years
  - Very high barriers to entry:
  - Lengthy time-frame for return on high up-front investments
  - Business uncertainty
  - No validated in-vitro alternatives to some animal tests

Preservatives – What does Cosmetics Europe do ?

CE Product Preservation Programme



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Nanomaterials: Uncertainty as a source of mistakes

- Commission obliged to publish an annual report of nanomaterials used in cosmetics
- Based on CPNP notifications (‘does the product contain a nanomaterial ?’)
- Commission checklist:
  - if notified nanomaterial is a preservative, UV filter, colorant → is it listed in the respective annex in its nanoform ?
  - Otherwise, is it listed in Annex III in its nanoform ?
  - If none of the above, has an an Article 16 nanonotification been made ?

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Nanomaterials: Uncertainty as a source of mistakes

- Commission detected a number of materials, notified as nanomaterial under Article 13, that were :
  - Preservative, UV-Filter, Colorant **BUT** not listed as the nanoform in the respective positive list
  - Other ingredients **BUT** not listed as the nanoform in Annex III **NOR** notified with a safety dossier under Article 16

→ Potential non-compliance

- In most instances, the ingredient was wrongly identified as nanomaterial
- Commission asked Responsible Persons several times to make correction
- Next Step will be strict enforcement !

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Nanomaterials – What does Cosmetics Europe do ?

- Provide information, guidance and training to its member associations
- Raise awareness that supplier definition of ‘nano’ may not be the same as cosmetics definition.
- Should nano-requirements be re-openend by the EU Commission (2018 report pending), work towards more clarity I the requirements and definitions.

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Microplastics

- Since 2010 major public and environmental-policy concern
- Microplastics from cosmetics constitute an extremely small fraction of the overall environmental load
- Nevertheless, cosmetics selected as 'poster child' by media and NGO campaigns
- Strong political pressure to take regulatory action against microplastics
- National regulatory action jeopardises EU internal market
- Impossible to regulate under the Cosmetics Regulation (out of scope)

→ REACH Restriction identified as regulatory tool

REACH process

- Launched in December 2017; ECHA produced an initial restriction proposal ('The Annex XV Dossier') in January 2019
- Scope covers all intentionally added microplastics in any sector
- Extremely wide scope:

  Any material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ x ≤ 5mm, or (ii), for fibers, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3.

- Derogation for natural polymers, biodegradable polymers
- REACH Restriction could be published by end 2020/mid 2021

For Cosmetics…

- Immediate ban on scrubbing/exfoliating microbeads
- Ban for other microplastics in rinse-off with four year transition
- Ban for microplastics in leave-on with six year transition

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Risk ?

- The ECHA dossier states:

  '….some previous studies have questioned the perception that microplastics pose an unacceptable risk to the environment……however based on all the evidence….[we] conclude that it is impossible to conclude with certainty that microplastics do not cause harm to the environment…'

- ECHA claims further that Microplastics are 'extremely persistent ' in the environment and that there is no safe threshold;

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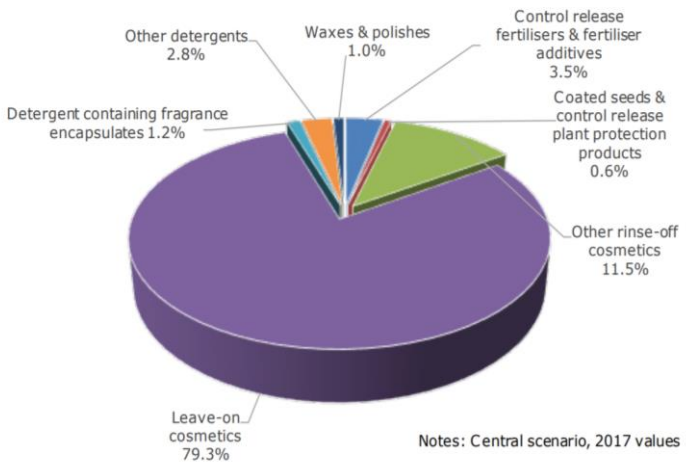
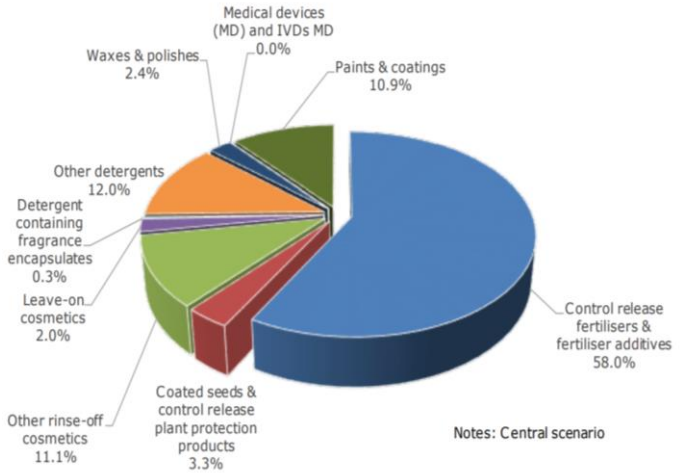
Proportionality ?

ECHA proposal states that **79.3% of the costs** will be borne by leave-on cosmetics products, that are estimated to be **2% of intentionally added microplastics**.

ANNEX XV RESTRICTION REPORT – MICROPLASTICS





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Microplastics – What does Cosmetics Europe do ?

- In 2015, Cosmetics Europe recommended that its members remove microbeads used for exfoliating and cleansing in wash off products;
- Cosmetics Europe followed up the recommendation with surveys to monitor compliance;
- Earlier this year we found that 97.6 % of microbeads used for exfoliating and cleansing had been removed.

- Contribute to public consultation on the draft REACH Restriction and argue for a proportionate approach (cost/benefit)

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Digital Labelling

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Digital Consumer Information

- **The Digital Revolution**: rapidly increasing integration of digital communication technologies and tools in consumers' daily lives

The **connectivity to the internet** is steadily growing; currently*:

- there are 90 active mobile broadband SIM cards per 100 people in the EU (40 million new subscriptions added every year over the last 5 years)
- 97% of EU homes are covered by fixed and fixed-wireless technologies

* *source: European Commission*

- Opportunity to evolve the approach on mandatory and voluntary consumer information: Printed on label → Digital Consumer information

Digital consumer information not yet recognised in the Cosmetics Regulation →

CE Voluntary Initiative on Digital Ingredient Labelling

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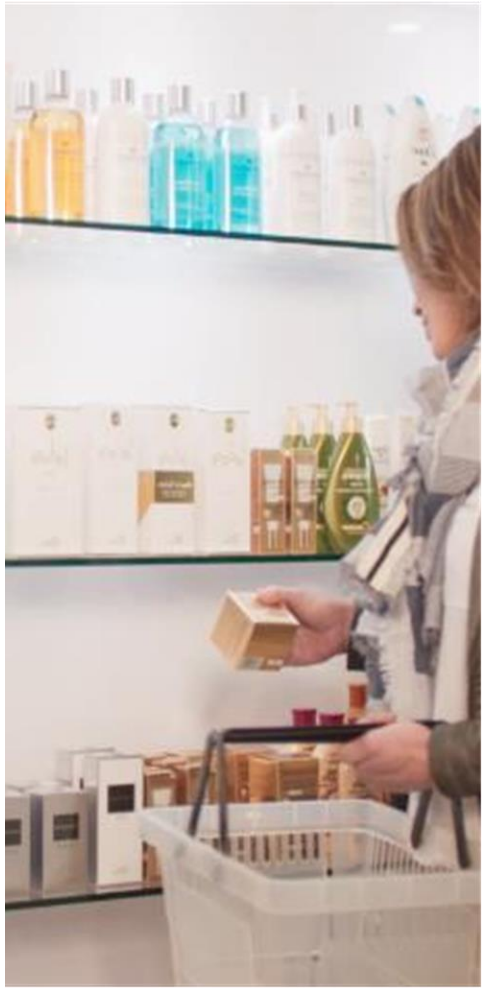
Benefits of Digital Ingredients List



- **modernise** the way in which consumers access the list of ingredients contained in cosmetic products
- **accurate and reliable information on and around ingredients** (counter smartphone applications conveying mis-leading / hazard-based information on ingredients)
- increase **engagement with consumers**
- **digital communication with retailers**
- **image boost** through modernisation and through all the digitalisation benefits for consumers and health professionals
- **business efficiency with cost and time savings** (artworks in case of formulation changes, labelling management of small products)
- **sustainable management of packaging**
- A solution to manage additional labelling of **fragrance allergens**

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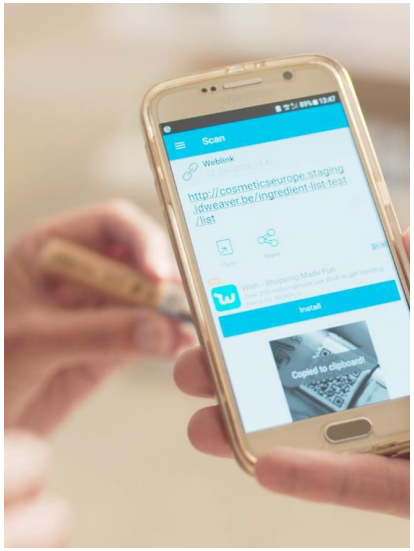
Digital Ingredient Labelling – What does Cosmetics Europe do ?

Initial Pilot Study showed that the digital mode of accessing the ingredients list is

- **a viable option**, welcomed by a significant proportion of consumers, be they habitual users of internet or not
- **technically feasible and manageable** if implemented gradually by companies



Voluntary DIL Initiative started 2019

- **demonstrate on a larger scale the technical feasibility** ahead of a future revision of the Cosmetic Regulation
- CE training webinars, feedback sessions at EU level
- National Associations translate and disseminate the Call for the Voluntary Implementation of the DIL to their members and encourage them to apply it
- replicate at national level the supporting training webinars and feedback collection

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Examples

(mock-ups courtesy of Pierre Fabre)

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Enforcement

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Enforcement – In market Control

- EU Cosmetics Regulation is based on industry responsibility and authorities' in-market control
- Good functioning of this system creates a fair and level playing field and is strongly supported by the EU Industry
- Digitalisation and online selling (within EU and cross border) creates significant challenges for control and enforcement authorities

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EU Harmonised Enforcement Regulation

- EU Institutions are currently finalising a Regulation on “Market surveillance and compliance of products”
- Covers all products that are subject to EU harmonised legislation (i.e. Cosmetics are included)
- For cosmetics placed on the market in a ‘traditional’ manner, no major changes expected (Cosmetics Regulation and enforcement practice is already very advanced)
- Strong focus and detailed requirements for on online sales products:
  - Clarifies when an online sale product is considered ‘placed on the EU market’
  - Defines Roles and Responsibilities (internet providers, online shops, fulfilment centers, …)
  - Coordination between National authorities

Enforcement – What does Cosmetics Europe do ?

- Supports an effective in-market control of cosmetics across the EU
- Follows closely the adoption progress of the draft EU Regulation
- Provides comments to ensure consistency with current best practice under the Cosmetics Regulation
- Through our national association network, we will contribute to guidelines and other implementation measures as necessary

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In Conclusion

- Despite all challenges, I continue to love the EU Cosmetics Regulation as it stands
- The principle approach and provisions of the Cosmetics Regulation are surprisingly ‘future proof’
- Most challenges arising from technological or policy development do not require fundamental changes or additions to the CPR.
- They can be addressed by interpreting and translating the current requirements into the new situation
- This regulatory stability will not last forever. One day, there will be a need to fundamentally update the Regulation – but probably not within the next 5 years.

Thank you for your attention !

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