



# Global regulatory challenges for 2024

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## *A new global approach to regulatory consultancy*

Founded in 2019, Bloom Regulatory is a London-based regulatory consultancy **offering support in the beauty and wellness space**. We are passionate about the industry in which we operate and have a deep knowledge of the landscape for cosmetics, food supplements, candles and home fragrance.

We look beyond regulatory affairs and deliver solutions that make a difference through our **unique and innovative approaches to regulatory strategy, compliance and claims**.

Sensitive to the needs of niche, mass and luxury brands, we **support all types and sizes of businesses** to enter the global marketplace.

# Speakers



**Olivia Santoni**  
Founder and CEO



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Regulatory Affairs Director

# Common challenges

	2023	Key future challenges
Ingredient management	Ad hoc/systematic ingredient evaluations	Increased systematic ingredient evaluation Microplastics PFAS Nanomaterials
Labelling	Disposal instructions	Disposal instructions Fragrance allergens
Claims	Green claims	Green claims Efficacy claims
Packaging	Extended Producer Responsibility Recycled content Recyclability	Extended Producer Responsibility Recycled content Recyclability

## The challenges

### 1. Ever-changing ingredient restrictions / 'one formula fits all'

- EU annexes
- EU-based annexes with amended timelines
- EU-based annexes with additions
- Regions with standalone restrictions

### 2. A new EU approach under discussion: General Risk Approach (GRA)

- An **automatic trigger** of pre-determined risk management measures (e.g. packaging requirements, restrictions, bans, etc.) based on the **hazardous properties** of the chemical and generic considerations of their exposure.

### 3. Why does it matter to cosmetics?

- Groups of hazardous substances will end up being automatically regulated based on their hazard.
- Existing example: CMRs

# General Risk Approach to Substances: Endocrine disruptors

Anticipated extension of GRA for cosmetics: **endocrine disruptors**

- 'CMR style' prohibition and derogations

**What can you do?**

**Know your portfolio:**

- Look beyond CMRs
- Know the CLP substance classifications of your ingredients
  - especially endocrine disruption (new), STOT, respiratory sensitisers, PBT/vPvB
- Watch out for new classifications and risks from self-classifications

# Microplastics – definition is key

## The challenge: New EU regulation - phasing out of 'microplastic' ingredients

- 2027: microplastics in rinse-off cosmetic products
- 2029: microplastics in leave-on cosmetic products
- 2029: microplastics in the encapsulation of fragrance
- 2035: microplastics in lip products, nail products and make-up

material consisting of solid polymer-containing particles

where  $\geq 1\%$  w/w of particles have  
(i) all dimensions  $0.1\mu\text{m} \leq x \leq 5\text{mm}$ , or  
(ii), for fibres, a length of  $0.3\mu\text{m} \leq x \leq 15\text{mm}$  and  
length to diameter ratio of  $>3$

Solid may not be 'solid': may include 'solid polymers'

## How can you prepare?

- There is no list
- Know your ingredient portfolio
- Understand the behaviour of your ingredients e.g. film formers
- Plan reformulation / labelling changes

What about future restrictions overseas?

# Nanomaterials – definition is key

A number of regions currently share a definition (cosmetics). E.g. EU, New Zealand

## **The challenge: New EU horizontal definition may be applied to cosmetics:**

- *Removes ‘insoluble or biopersistent and intentionally manufactured material’ from cosmetic definition*

Impact = enlarged scope, e.g. Annex IV colours

## **Implications:**

- New substance authorisations
- Additional notifications
- Extra CPSR considerations
- Labelling amendments - what about overseas where the definition is different?
- What if you currently avoid nanomaterials? Will you now have nanomaterials in your products?

## ***How can you prepare?***

- Get involved / monitor the industry strategy to defend the continued use of individual nanomaterials in the EU
- Keep up-to-date on the EU Cosmetics Regulation revision and its implications



# PFAS: A global issue

End goal is likely to align but timeline will vary

## The challenge

### 2025: California (prohibited)

- Ban is effective 1 January 2025
- **Intentionally added** perfluoroalkyl and polyfluoroalkyl substances (PFAS)

Proposition 65: PFAS **presence** (not only intentionally added)

2024+ : EU REACH restriction proposal

2024+ : Canada prohibition proposal

## *How can you prepare?*

**Cosmetics Europe Recommendation:** Phase out intentional use by 31 December 2025

# Environmental labelling

## The challenge

Diverse array of requirements, logos, information

A global issue is evolving

RECYCLABILITY is also NOT harmonised

Most aim to encourage SEPARATION of components

## What can you do?

- Understand the markets your product will be sold through
- Understand which markets have requirements
- Arrange who will add the label (printed by brand or local distributor sticker)
- Look for opportunities to align information (challenging!)
- Consider end-of-life when choosing packaging



- Streamline your portfolio of components: limited combinations + predetermined logos as an internal library
- Use mono materials where possible: smaller labelling + potential environmental benefits
- Look for digital options

## The challenge

### 1. Phasing in of **prohibited** claims in specific markets:

- Biodegradable
- Environmentally friendly

### 2. Strengthened frameworks for enforcement action

- Example, EU Annex I ‘black list’ on unfair commercial practices

### 3. Increased focus on substantiation and life-cycle

- Focus on broad claims

**Note:** Green claims are within scope of existing rules relating to misleading claims!

## *What can you do?*

- Brands should evaluate their claims carefully
- Fundamentals:
  - consider scope of claim
  - consider a 360/life cycle viewpoint on truth and honesty

# Green Claims

## The mince beef debate

### *The positive message:*

55 / 70 % less plastic per pack

### *Analysis:*

Is it true?

What about end-of-life fate? Honest?

- Flexible plastic
- New pack unlikely to be recycled



# Efficacy Claims

## The challenge

Authorities' interest in protecting the consumer from misleading claims

**Example:** China focus on efficacy claims

- Specific tests required
- May not be able to use existing efficacy data

## The challenge

- The EU has published new requirements for additional ‘fragrance allergens’ to be labelled by
- The US will require ‘fragrance allergens’ to be labelled by
- Canada is discussing requirements to label ‘fragrance allergens’

## The real challenge: what are ‘fragrance allergens’

- The EU has a list of original list + extended list
- The US has not yet defined the substances in scope
- Canada began discussions prior to the EU extended list: will the discussions remain around the initial 26 or include the extended list?

## *How can you prepare?*

- Must comply with EU
- Monitor US and Canada developments
- Most markets accept additional allergens within the ingredient list if added when not required

## The challenges

- Hazardous substances
- Minimisation / oversized packaging
- Producer responsibilities
- Recycling targets
- PCR targets
- Additional fees / taxes e.g. plastic

Responsibility usually rests with local distributor : information may be needed from the brand

## Examples:

French distributors need to know:

- Hazardous substance information
- Recycled content information

UK producers and importers need to know:

- Plastic volumes per component
- Recycled plastic information per component

# Packaging - EU case study

Essential Requirements	Producer Responsibilities
Heavy metals and Hazardous substance limits Minimisation Packaging Design	Recovery Schemes Sorting Information Recycling target



**Harmonised within the EU**



**Divergence : Each Member State has its own rules !**



# Packaging – the future

## Obligations will increase!!!!

Countries and regions will not be aligned but companies can mostly use their data to adapt to individual systems

### *How can you prepare?*

- Know your components
- Know your recycled content
- Know your recyclability
- Know where you distribute and how much
- Expect to pay producer fees and taxes, in particular for ‘waste’
- Know about hazardous substances
- Design away from excessive packaging

# Summary

There is no predictor of future challenges, but some key overarching challenges are guaranteed:

- Ingredient management
- Labelling
- Packaging / Environment
- Claims

The EU often leads the way and can be a good preparation for challenges encountered globally.



# Q&A

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