The European Preservation Challenge: How Will We Preserve Products Safely, Effectively and Legally in the Future?

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Agenda

- EFfCI: who we are
- The cosmetic preservation challenge:
  - A European perspective to a global issue
- The issue for preservatives today and future
- Industry activities towards a solution
- Who we are

• Established in 2000, European trade association bringing together manufacturers of synthetic and natural ingredients for the cosmetics and personal care industry

• Advocates the collective interests of more than 100 cosmetic ingredients companies in Europe

• National associations representing the cosmetic ingredients manufacturing industry, suppliers and service providers in UK, Spain, Switzerland, France, Germany, Italy

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Ingredients Defence Working Group

- Set up in 2012

- Reactively:
  - Identify emerging regulatory issues for classes of ingredients
  - Contribute to EFfCI’s voice of the European ingredients suppliers

- Proactively:
  - Collaboration and alignment with Trade Association partners
  - Ingredients advocacy and issues management efforts
    - E.g. for preservatives, often in the media spotlight and are constantly up for scientific reviews
    - Seek to address the issue of the ‘shrinking toolbox’

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Preservation when Making Cosmetics

• A topic of paramount importance for today’s formulator

• Factors in the selection of a preservative
  – Type of formulation
  – Efficacy required
  – Consumer need
  – National or global regulation
  – Company technical or marketing requirements
  – Safety
  – What’s available…
The Need for Preservatives

• A number of important factors why preservatives are used
  – Legal Compliance
  – Consumer Safety
  – Product Performance
The Need for Preservatives

• Legal Compliance:

• A fundamental requirement of the Cosmetic Products Regulation, EC No:1223/2009:
  – Formulators must ensure the microbiological safety of cosmetics products
  – AND the Regulation also specifies requirements to:
    • Perform challenge testing
    • Report in the mandatory Cosmetic Product Safety Report
The Need for Preservatives

• Legal Compliance:

• SCCS* notes for guidance:
  Describes the issue:
  – Microbial contaminants usually come from two different origins: during production and filling, and during the use of the cosmetic by the consumer.

  And the need:
  – ensure the microbial safety of cosmetics for the consumer,
  – maintain the quality and specifications intended of the product,
  – confirm hygienic and high-quality handling.

* Scientific Committee for Consumer Safety, European Commission

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Role of Preservatives

- Protect products against contamination by microorganisms (during storage and continued use)
  - Without preservatives, possible development of bacteria, yeast, mould → Product deterioration, spoilage, loss of expected performance.
  - Contamination of products, especially those used around the eyes and on skin, can potentially cause significant health problems. (RAPEX* notifications, publications)

- Conclusively, preservatives:
  - protect the consumer,
  - contribute to sustainable use of resources and
  - maintain product quality to meet consumer expectations

*RAPEX: Rapid alert system for dangerous consumer goods

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EC 1223/2009 Annex V: what’s the problem?

- Today there is an extensive EU positive list of 59 entries of preservatives approved for use in cosmetics.
- Regulatory process in place to ensure that new ones can be added.

59 actives
On Annex V

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Annex V: what’s the problem?

- Today: 59 approved preservatives on the EU list
  - But a limited number are in common use
    - Grandfathered list
    - Performance/compatibility, marketing claims/restrictions
- And, new ones being added?
  - But only 2 in last 10 years
- Limited sub-set in use

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Annex V: what’s the problem?

- Today: 59 approved preservatives on the EU list
  - But a limited number are in common use
    - Grandfathered list
    - Performance/compatibility, marketing claims/restrictions
    - Many in use are facing regulatory review and uncertainty
- And, new ones being added?
  - But only 2 in last 10 years
  - Very high barrier to entry
- Limited sub-set in use
  - And still reducing

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The issues with Annex V today

• High barriers to entry for adding new preservatives on to the list restricts innovation
  – Animal testing ban limits ability to perform product safety studies to demonstrate or confirm safe use
    • Validated alternatives not yet available for most endpoints
  – Business uncertainty:
    • High up-front development and safety screening costs
    • Return on investment may not even start for c.10 years due to extended regulatory approval timeframe
    • Risk of non-approval after significant investment of time and money
• The practical reality is we are unlikely to see many or any new preservatives added to Annex V.

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European Animal Testing Ban for Cosmetics

- Applies to ingredients as well as formulations
- EFFfCI legal challenge to establish:
  - Tests which are genuinely performed as a requirement under REACH do not trigger the marketing/testing ban. This applies whether substances are for solely cosmetics use or for use in other (non-cosmetic) applications. (UK Court judgement)
  - Tests in third countries either for cosmetics or non-cosmetics use: pending decision by European Court of Justice

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The view of the EU Consumer:

- Good, rational statements exist in the public domain:
  
  …not there because evil cosmetic companies don't care…

  …there to protect you…

  If you use preservative-free products you risk coming across some real "nasties", micro-organisms…

- But many consumer blogs and consumer organisations that question the need, value and safety of preservatives
The issues with Annex V today

• The total burden is carried today by the relatively few:
  ▪ Increased potential for resistance to a specific mode of action
  ▪ Exposure of greater section of consumer population to a particular type of preservative/hazard.

• The current approach of one-by-one conservative assessment of Annex V listed preservatives diminishes the options for selection, without recognising the need for a choice of preservation options.
Conclusion

- There is a serious, critical and immediate need for a new approach to regulation that:
  - Promotes innovation
  - Is truly based on science and risk assessment
  - Recognises societal need and value, the contribution of preservatives to sustainable use of cosmetics

- Industry, regulators and consumers need a diverse palette of actives presenting different modes of action, different performance spectra and a balanced set of risks
Alternative preservation

• Today there is a lot of focus on “non-traditional” preservation solutions to complement the range of Annex V preservatives

• Traditional:
  – Preservatives that have developed safe use data when used at recommended levels and a long history of use,
  – Global approvals/positive listing: Annex V, allowed in USA, listed in Japan

• Non-traditional preservatives will likely have an increasing role to play in product formulation

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Alternative preservation

- Non-traditional’ chemistries covers a range of ingredients which are variously:
  - Included in Annex V (eg organic acids)
  - Sometimes lower efficacy, higher use levels, or may have performance gaps or pH dependency
  - Used for other functions (eg emollient) but bring some reduction in the overall need for preservation
  - Depending on use level, may be more difficult to formulate
  - Generally gaining wider acceptance by consumers and consumer associations

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Alternative preservation

- The question on how to address ‘multifunctionals’ within the scope of the Cosmetics legislation has entered the EU regulatory debate
  - Maintain as a secondary claim to other properties (but with risk that main preservatives will further reduce)
  - Interaction with REACH
  - ‘retirement’ of positive listing under Annex V ????

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Defence of Preservatives: 
Collaboration within Industry

• To date, the focus has been specific preservative ingredient defence during regulatory review

• In keeping with need for better, holistic regulatory approach, Industry needs to develop a broader proactive approach to ingredient, and specifically, preservative defence

• Whilst European legislation tends to act as the benchmark for cosmetics ingredients, this should be seen as a global issue

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Three pillars of European Industry Activity:

- Communication
- Risk Management
- Risk Assessment
Gain recognition of the benefit, need and value of preservatives and their contribution to the sustainable use of cosmetics

- Seeking a collaborative approach between EFfCI and Cosmetics Europe
- Address all stakeholders: consumers, scientific community, media, wider industry
Stakeholder Analysis

EU COMMISSION

- SCCS
- Industry
- International
- National Authorities
- Scientists

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Stakeholder Analysis

- Companies
- Authorities
- Consumer magazines
- Scientific Community
- Media
- National Associations
- NGOs
- Consumer groups

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Preservatives Defence: Communication

- Engagement with EU Commission
  - Achieved recognition of the issue
  - Workshop 20th October 2015

- Involvement in International Cooperation on Cosmetics Regulation (ICCR)
  - Dialogue with European and international regulators and Industry partners
  - Presentation of jointly authored FAQ at ICCR 9, Brussels November 2015

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Preservatives  Defence: Risk Management

• How to ensure currently approved preservatives are reviewed holistically, recognising the interactive effect of restrictions and ensuring adequate coverage
  – Dialogue on the one-by-one conservative review of preservatives
  – Future of Annex V?
  – Incorporation of multifunctionals

• Better and collaborative use of post-marketing data, from clinics, Cosmetovigilance, RAPEX
• Risk Assessment has to be risk (not hazard) based.
• Additional tools need to be fully available:
  – Eg: Quantitative Risk Assessment for local effects (eg allergy)
    • Already in discussion for some years IFRA/RIFM*
    • Currently being assessed by JRC*
    • Not yet accepted as a regulatory tool
  – Continued and accelerated activities to develop validated in-vitro testing
• Appropriate read-across strategies

*IFRA/RIFM: International Fragrance Association, Research Centre
*JRC: Joint Research Centre of the EU Commission
Concluding remarks

• No simple solution to a complex issue
• Risk Assessment needs to be robust, timely and science-based, supporting innovation
  – Tools for appropriate risk assessment need to be developed and approved
• Risk Management must consider the bigger picture and coordinate data from several sources
Thank you!

Questions?

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