

Regulatory Around the World

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The views expressed in this presentation do not necessarily represent those of Mary Kay Inc.

United States based on State Population



CALIFORNIA

CALIFORNIA REPUBLIC



California legislature has adjourned for the year

- AB2125 Healthy Nail Salon Recognition Program
 - Signed by Governor Brown
 - Voluntary Program
- SB423 Surplus Household Consumer Product
 - The amended bill defines “surplus household consumer product” as a household consumer product that cannot or will not be sold to a consumer through that product’s primary market
- DTSC aquatic toxicity test for hazardous waste

UNITED STATES



US FDA

- Guidance on Cosmetic Inspections
 - Formal cooperation between CFSAN and CDER
 - Areas of focus:
 - Microbial contamination
 - Colorants
 - Safety substantiation of ingredients with specific mention of nano-materials

UNITED STATES



US FDA

- Quality Metrics
 - Draft Guidance available
 - Reporting Establishment
 - 1 report for each API or each Finished Dosage Form
 - Challenges for complex supply chains

Bulk

Packaging

Testing

Single Report

UNITED STATES



US FDA

- Quality Metrics

- 4 required

- Lot Acceptance Rate
- Product Quality Complaint Rate
- Invalidated Out-of-Spec Rate
- Annual Product Review On Time Rate

- 3 optional

- Senior Management Engagement in APRs
- CAPA Effectiveness (% for re-training)
- Process Capability/ Performance Questions

UNITED STATES



US FDA

- Anti-Microbials
 - 19 listed ingredients no longer available for OTC consumer hand washes
 - Rulemaking deferred for benzalkonium chloride, benzethonium chloride and chlorxylenol
 - Leave-on products containing >50% alcohol not affected by rule-making

CANADA



- CHP Framework
 - OTC, NHP, disinfectants, cosmetics
 - Goal is a consistent regulatory approach for consumer goods based on risk
- Drug Fact/ Product Facts harmonization
 - French language requirement
- Microbeads
 - Proposed ban of mfg and import by end of 2017
 - 1-year extension for OTC and NHP

EUROPEAN UNION



- Brexit
 - Two-year exit
 - Many unknowns
- Endocrine Disruption
 - 45 cosmetic ingredients screened
 - Disclaimer that screening results should not prejudice future decisions
- Microplastics
 - UK – microbead ban end of 2017
 - France – ban as part of CBD law
 - Italy – draft proposal
 - EU MEPs have called for microplastics ban

EUROPEAN UNION



Titanium Dioxide

- Sunscreen:
 - Effective Aug 3, 2016 – nano-TiO₂ allowed as UV filter up to 25%
 - 25% is cumulative for nano and non-nano TiO₂ in formula
 - Not to be used in applications with inhalation exposure
 - Several restrictions on nano-TiO₂ characteristics
- ECHA:
 - French proposal to ECHA as 1B carcinogen via inhalation
 - Would set precedent as first CMR with exposure route

CHINA



- CSAR - Cosmetic Surveillance and Administration Rule
 - Cosmetics Hygiene Standard revision
 - Cosmetics Labeling Regulation
 - Cosmetics safety assessment guidance
 - Cosmetics efficacy assessment guidance
 - Cosmetics manufacturing operation regulation
- Endocrine Disruption