### **Regulatory Around the World**

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### United States based on State Population

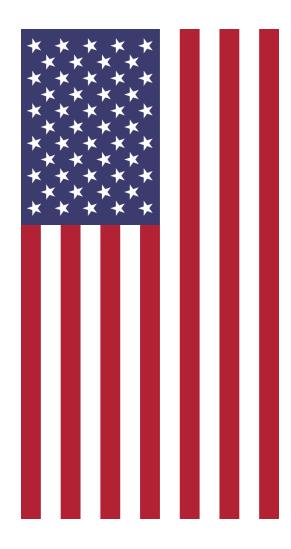


# CALIFORNIA

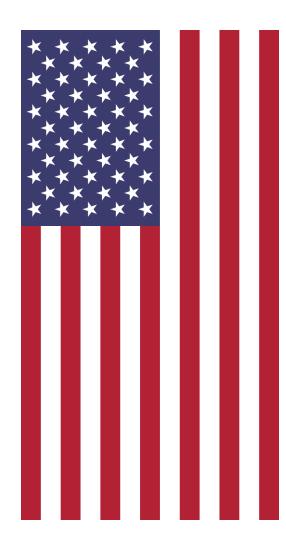


California legislature has adjourned for the year

- 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

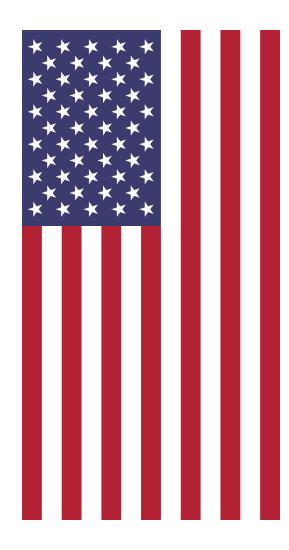


- Guidance on Cosmetic Inspections
  - Formal cooperation between CFSAN and CDER
  - Areas of focus:
    - Microbial contamination
    - Colorants
  - Safety substantiation of ingredients with specific mention of nanomaterials



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  - Draft Guidance available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





- 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



- 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

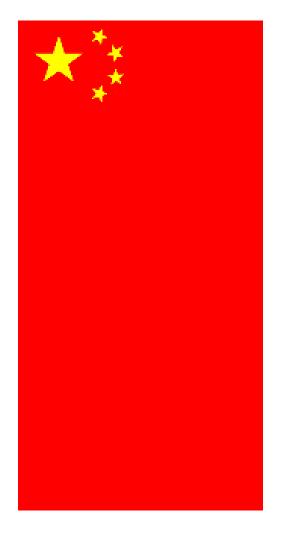
### **EUROPEAN UNION**



#### Titanium Dioxide

- Sunscreen:
  - Effective Aug 3, 2016 nano-TiO2 allowed as UV filter up to 25%
  - 25% is cumulative for nano and nonnano 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