



# Navigating The Evolving Regulatory Landscape For Colors

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## FDA Past, Present And Future?

- Bisphenol A
- 2010 GAO audit of GRAS program
- 2011 Food advisory committee meeting on color additives
- Lawsuits
- GRAS final rule
- New guidelines, new policies and new color issues
- Lawsuits
- The next four years/ the next ten months

# Where There Is Confusion There Is Opportunity And Risk?

- The broken color additive petition process
- Risk assessment/toxicity testing guidelines
- The Delaney clause
- The toxicology of windows of vulnerability
- “Natural” labeling

# Areas of Colorful Regulation in the US

- Printing inks
- Paper and paperboard colorants
- Tattoo inks
- Colors in medical devices

# Colors And Food Contact Applications

- New EU activity: reconsideration of guidelines and framework for food contact materials
  - Endocrine activity
  - Mixture toxicology/ cocktail effect
- New harmonized regulations
  - Paper and paperboard
  - Coatings
  - Printing inks
  - Adhesives

# Colors And Food Contact Applications

- Inks and packaging
  - German regulations
  - FDA regulation of inks
  - China regulation of inks
  - Mercosur, Japan, South Korea, FSANZ, India, ASEAN
- FDA colors in paper and paperboard
  - API List

# Conclusions

- OFAS has been moving to more conservative positions for at least 6 years but internal pressure may well be relaxing
- There may opportunities to engage with FDA on several areas where regulatory or regulatory science questions may be raised
- We could be living in “colorful” times
- EU activity can drive change in the U.S. and elsewhere
- Evolving U.S. regulation (or EU) can trigger movement elsewhere in the world