

Technical Challenges and Regulatory Considerations for Color Reformulation

Color reformulation is not an easy task and requires heavy lifting across the supply chain from sourcing to packaging. Selecting, sourcing and preparing facilities to use natural (exempt) colors¹ takes longer and includes different logistical considerations than sourcing FD&C (certified) colors².

The 2027 deadlines set by California and FDA to revoke the allowance for certain FD&C colors is aggressive and will not be sufficient for companies who had not already begun reformulation. Given the additional factors companies must consider when selecting and sourcing natural colors vs. FD&C colors, brands must consider natural color options much earlier in the development process, lengthening the timeline for achieving substitution.

Realistically, it will take at minimum 5 years, and up to a generation, for the entire food and beverage market to comply with restrictions on FD&C colors and reformulate their products with natural colors. Companies must address multiple technical challenges and regulatory considerations to successfully achieve color reformulation.

- Challenge: Shade Matching
 - Higher use levels are needed for natural colors to “match” color of FD&C color in products.
 - An inexact match could turn off consumers. Consumer research has consistently demonstrated that there is a strong connection between color and flavor, that color is what consumers notice first when making food and beverage purchases, and that when the color is modified, consumers will perceive that the flavor is different.
- Challenge: Supply Chain
 - Crop growth and production variability from year to year affect color quality and supply.
 - More crop acreage will be necessary to support a wholesale shift to natural colors which will reduce the acreage for staple foods and give rise to potential sustainability issues.
 - Natural colors are perishable and have a finite shelf life, which not only limits supply but requires companies to invest in additional refrigeration storage.
 - Natural color supply is at the mercy of factors outside of the manufacturer’s control, such as weather, farmers, and other factors that influence crops and yield.
 - It takes time to cultivate, grow and harvest the ingredients necessary to create natural colors at the scale necessary once an appropriate shade is identified.
 - Companies must confirm color needs at least a year in advance for crop planning.
- Challenge: Quality Control & Stability

¹ [21 CFR Part 73](#)

² [21 CFR Part 74](#)

- As agriculturally based products, natural colors also present quality control challenges as there will be deviations among crops of key ingredients.
- Synthetic colors are the most regulated food ingredient in the world. In the U.S., every single time a synthetic color manufacturer produces a product, that batch goes to the FDA for approval and certification, ensuring a consistent, reliable and safe product. There is no comparable standard for any natural colors. Of note, while other jurisdictions require synthetic colors to meet certain specifications, only the U.S. FDA requires synthetic colors to be certified and labeled as FD&C.
- Colors from natural sources may contain heavy metal and pesticide contaminants which need to be controlled and that are not present in FD&C colors.
- Colors from natural sources have a shorter shelf-life both prior to use in production and for the finished products using these colors.
- The shade of natural colors changes over time, which requires products made with these colors to have different packaging needs to maintain a stable color. While this may be less of an issue for certain food, colors used in products such as dietary supplements must have the stability to maintain a sufficiently long shelf life to be viable.³
- Challenge: Regulatory Inconsistencies
 - Different countries have different regulations for natural colors, with inconsistent approval from country to country.⁴
 - Food companies must consider regulations of all the ingredients and food contact substances used in their product. Just because a natural color may be approved for use, are other regulatory considerations that may not allow for that color to be used as desired.
 - Not every natural color source material has been approved for use as a color by the FDA. All colors, including natural colors, must go through the FDA Color Additive Petition process, which can be quite lengthy. Once a color achieves approval by the FDA, there is no guarantee that other countries will also approve the color.
- Challenge: Higher Cost
 - Natural colors account for a larger portion of a product's overall economics than a synthetic color, which represents just a tiny fraction of a product's overall costs.
 - Companies experience higher "cost-in-use" for colors from natural sources, needing to use 3 – 10 times more of a natural color in a food product, which will increase the overall cost, regardless of the cost/pound.

³ Chapman, S. (2001). Guidelines on approaches to the replacement of tartrazine, allura red, ponceau 4R, quinoline yellow, sunset yellow and carmiosine in food and beverages.

⁴ Song, H. & Chen, K. (2010). Trade effects and compliance costs of food safety regulations: The case of china. *Agriculture and Agricultural Science Procedia*, 1, pp. 429-438.

- Natural colors require higher capital expenditure due to the need for facility refrigeration, refrigerated transportation and different storage needs.

FD&C colors do not present supply issues, off-notes impacting the taste, formulation challenges or global regulatory inconsistencies. Given their strong history of safety and lack of impact on a product's actual nutritive value, prohibiting FD&C colors should not be a priority for action to improving the health or safety of the U.S. food supply.