Color Additive Safety

Who is IACM?

- Founded in 1972 by color industry leaders as the Certified Color Manufacturers Association, IACM continues to be a strong voice in support of the safe use of color additives.
- IACM is the only association representing the interests of the color additives industry, both natural and synthetics, as well as the color user community, on the state, national, and international levels.
- We are respected by regulatory bodies around the world for our unparalleled knowledge and access to leading scientific researchers and color industry experts.

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U.S. Federal Update

POLITICAL, NOT SCIENTIFIC

Science vs. Politics

- Industry battling misinformation

Make America Healthy Again movement

- Opposed to “artificial” food additives, including colors
- Fear of chemicals & misunderstanding of toxicity
- Not scientific

HHS Secretary Kennedy

- Amplifying MAHA messaging and misinformation
- Attempting to use platform to create/modify policy

Status of FDA color approvals remains unchanged

- FD&C Red No. 3 (erythrosine) delisting due to invocation of Delaney Clause
- JECFA agreed no new data available to support further assessment & its 2018 evaluation remains valid

No identified safety concerns driving activity

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U.S. State Activity

POLITICAL, NOT SCIENTIFIC

U.S. states proposing to limit color additive use in their state

- More than 90 bills have been introduced in 33 states this year
- Laws passed in 5 states

Of all the proposals, laws have passed limiting colors use in only 5 states

- Laws passed limiting colors in foods served in schools in California, Virginia, Utah, West Virginia and Arizona
- Laws passed prohibiting specific color use in California (Red 3/erythrosine) and West Virginia (FD&C colors)

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Why Colors are Used

Offset color loss due to light, air, extremes of temperature, moisture, and storage conditions

Enhance colors that occur naturally

Provide colorful identify to foods

Identification/Prevent Medication Errors

Flavor perception

What are “Synthetic” Colors?

- Synthetically produced dyes, lakes or pigments
- Derived from organic chemicals
- Impart an intense, uniform color
- Easy to blend to create a variety of hues
- ~16 synthetic colors in use globally

Name	JECFA
Brilliant blue FCF	INS 133
Indigotine (Indigo carmine)	INS 132
Fast Green FCF	INS 143
Erythrosine	INS 127
Allura red AC	INS 129
Tartrazine	INS 102
Sunset yellow FCF	INS 110
Quinoline Yellow	INS 104
Azorubine (Carmoisine)	INS 122
Amaranth	INS 123
Ponceau 4R (cochineal red A)	INS 124
Patent blue V	INS 131
Green S	INS 142
Brilliant black (Black PN)	INS 151
Brown HT	INS 155
Lithol rubine BK	INS 180

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What are “natural” colors?

Some are readily recognizable as foods or derived from natural food sources such as vegetables	Ex. paprika, turmeric, tomato lycopene, grape skin extract, annatto extract, beet juice
Some have animal sources	Ex, cochineal/carmine
Others are mineral in origin	Ex. titanium dioxide
Or synthesized/processed	Ex. caramel, canthaxanthin, beta carotene
Natural colors can be used as alternative to synthetic colors in many, but not all, situations	May not be stable in certain food May add unintended flavors to food

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Safety Profile for Synthetic Colors

JECFA, EFSA & FDA safety conclusions all based on OECD-guideline, GLP studies

Synthetic colors are not genotoxic

- Negative in definitive *in vitro* studies
- Negative in definitive *in vivo* studies

Synthetic colors do not cause cancer

- Negative in chronic carcinogenicity studies

Whether a color additive is synthetic or natural has no bearing on its overall safety.

- All color additives are subject to rigorous standards of safety prior to their approval for use in food.

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JECFA Evaluations

- JECFA is a sound, scientifically valid program that provides the best available safety assessments of color additives
- JECFA has evaluated many color additives
- Color additives assigned numerical ADI or ADI not specified by JECFA provide a sound basis for international harmonization efforts
- JECFA recently re-evaluated synthetic colors and confirmed their safety

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Codex & GSFA

Codex Alimentarius publishes the General Standards for Food Additives **(GSFA)**

IACM participates as NGO at Codex Alimentarius

- Active participant in Committee on Food Additives (CCFA)

After completing JECFA evaluation, colors can be included in GSFA

IACM encourages countries to look to Codex standards and levels when developing new or amending food regulations

Colors have been reviewed by CCFA for adoption into GSFA annually over last 4 years

- GSFA now contains significant number of color provisions for colors where use, exposure and safety recently confirmed

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U.S. FDA Premarket Approval for Color Additives

FDA requires pre-market approval via color additive petition process

- Requirements for color additive petitions create substantial safety data for approved colors

Exempt & certified colors subject to same safety requirements for regulatory approval

- Colors listed in US Code of Federal Regulations, Part 21, Sections 73 & 74

Permanently listing a color additive for a proposed use is prohibited unless scientific data establishes its safety

- Safety standard: reasonable certainty of no harm

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FDA Approved Colors

Certified (FD&C) Colors

Synthetically produced colors with a known structure

Exempt Colors

Derived or extracted from natural sources

EFSA Color Evaluations

Color additives reviewed by EFSA Panel on Food additives & Flavorings

New draft guidance document on data required for risk assessment of food/color additive applications

Safety evaluation results in numerical ADI or *quantum satis*

Provisions listed in EC Food Additives database

Color additives vs. coloring foods

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Key Takeaways

- No new safety data supporting current U.S. activity on colors; it is driven by political movement & misinformation
- Colors are useful additives that provide important and beneficial technical effects.
- All colors undergo premarket review for safety prior to entering commerce
- Codex/JECFA/EFSA all recently reviewed and reconfirmed safety
- It is crucial to support science-based regulations on color use

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Thank you!