Regulation and Safety of Food Colors in India: Challenges, Compliance, and Future Perspectives

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Abstract: **The regulation of food Colors plays a vital role in maintaining food safety and protecting public health. In India, the Food Safety and Standards Authority of India (FSSAI) governs the use of food Colorants, permitting eight synthetic dyes within permissible limits and encouraging the adoption of natural alternatives. Synthetic food Colors, while widely used for their cost-effectiveness and stability, have been associated with adverse health effects such as hyperactivity, allergic reactions, and carcinogenicity. Despite regulatory frameworks, enforcement remains a significant challenge, particularly in the informal food sector. Growing consumer awareness and demand for clean-label products have accelerated the shift towards natural food Colorants like curcumin, carotenoids, and anthocyanins. However, issues related to their stability, solubility, and production scalability persist. Recent advancements in metabolic engineering, nano-formulations, and encapsulation techniques have shown potential to enhance the viability and safety of natural pigments. This paper explores the current regulatory landscape, health implications, and industry compliance challenges in India, while highlighting future perspectives aimed at achieving sustainable and globally aligned food Coloring practices.**

Keywords: **Food Color Regulation, FSSAI Guidelines, Synthetic Dyes, Natural Pigments, Food Safety, Consumer Health**

I.INTRODUCTION

Color psychology explores the meaning of colors, their influence on our emotions, body, and mind, and how they can be used for maximum benefit. In the food industry, Color plays a key role in consumer preferences. Studies show that green, brown, and red are widely accepted, while blue, purple, and black are often associated with danger, tracing back to early human instincts. Blue, in particular, is known to suppress appetite and is rarely used in food branding. While Color perception is subjective, its impact on consumer behavior remains significant. Changes in food Color can alter taste perception and affect quality assessment. Consumers often make purchasing decisions based on Color, leading to an increased demand for food colorants, sometimes resulting in adulteration. Color also plays a crucial role in branding and marketing, influencing consumer preferences and cultural associations. Marketers strategically use visual elements like packaging and imagery to shape purchasing behavior before consumption. Today, a large portion of our diet consists of processed foods, where additives and colorants are used to enhance shelf life, safety, and appearance. In the U.S., 70% of the average diet comprises processed foods, a significantly higher figure than in India. Common examples include soft drinks, packaged snacks, baked goods, processed meats, instant soups, and ready-to-eat meals. While natural food Colors are considered safe and may provide health benefits, synthetic Colors, derived from coal and petroleum, raise concerns due to potential health risks. Despite this, synthetic Colors continue to dominate the industry because of their lower cost, higher stability, and longer shelf life, making them a more economically viable option than natural alternatives.

A. Global and Indian Regulations on Food Colorants

Food additives, including colorants, are strictly regulated worldwide, with each country having specific guidelines on approved colorants, purity, permissible food applications, and concentration limits. Regulatory bodies such as the FDA (U.S.), EFSA (EU), PMDA (Japan), SFDA (China), CDSCO (India), and KFDA (South Korea) oversee food Color safety and compliance. In India, Rule 26 of the Prevention of Food Adulteration (PFA) Act permits the use of 11 natural food Colors, including Lactoflavin, Caramel, Annatto, Saffron, and Curcumin, which are also approved by the FDA and EU. The Food Safety and Standards Authority of India (FSSAI) regulates synthetic food Colors, allowing eight synthetic dyes within a 100ppm limit

while banning harmful dyes like Metanil Yellow and Sudan Dyes. Under FDA regulations, a food colorant is not considered "natural" unless it is inherently part of the food itself (e.g., strawberry juice in strawberry ice cream). In 1958, the FDA classified additives into three categories: pre-approved substances (1938–1958), GRAS (Generally Recognized as Safe) substances, and FDA-evaluated additives requiring approval before commercialization. Additionally, natural Colors listed under section 205.606 are permitted only in organic foods. India's food Color regulations align with global standards, ensuring food safety and consumer protection, but challenges remain in compliance, enforcement, and awareness.

B. Current regulation of Color additives as provided by US-FDA

US FDA has established regulations for Color additives in Title 21 of the CFR, parts 70-82. Out of the parts 70-82, parts 73,74 and 82 have provided list of Color additives, its chemical specifications, its intended use, its restrictions i.e. dosage forms where it is restricted for its use as Color additive, its labeling requirement and whether it needs to be certified Color. The regulations in 21 CFR part 71 describe the pre-market approval process required for new Color additives and new uses for listed Color additives, if applicable. 21 CFR part 80 describes the actual stepwise procedure to be followed for the certification of Color additive. Additional regulations that provide specific requirements for Color additives in foods, drugs, cosmetics, and medical devices are found in other parts of the CFR

C. Food Color Regulations and Governing Authorities

The FSSAI is the primary regulatory body overseeing food Color standards in India. It follows guidelines established by international bodies such as the Codex Alimentarius Commission (CAC), World Health Organization (WHO), and Food and Agriculture Organization (FAO). The FSSAI has set strict guidelines on the types of food Colors permitted in food products and their allowable concentrations.

Under FSSAI regulations (2009, 2011)

- The final concentration of synthetic food colorants should not exceed 100 ppm in foods and beverages.
- There are eight synthetic food Colors permitted in India: Ponceau 4R, Carmoisine, Erythrosine, Tartrazine, Sunset Yellow FCF, Indigo Carmine, Brilliant Blue FCF, and Fast Green FCF.

Certain synthetic dyes, including Fast Red, Rhodamine B, Metanil Yellow, Green S, and Sudan dyes (I-IV), are strictly prohibited due to their carcinogenic and toxic nature.

Despite regulations, studies have revealed widespread misuse of non-permitted Colors in food items, particularly in unorganized sectors such as street food vendors and small-scale industries. Adulteration with carcinogenic dyes like Melanil Yellow in products such as turmeric and sweets has been reported, raising concerns about enforcement mechanisms.

D. Growing Demand for Natural Food Colors

The increasing visual appeal of food products, rising consumer preference for clean-label ingredients, and the expansion of the food and beverage industry are key factors driving the demand for natural food Colors. Consumers favor vibrant, naturally sourced colorants over artificial additives, prompting manufacturers to expand their offerings. Economic growth in developing regions has further fueled this trend, as rising disposable incomes drive demand for diverse food choices. Additionally, the influence of social media and food photography has heightened the focus on food aesthetics, encouraging brands to use natural colorants to create visually appealing, social media-friendly products. (Grand View Research., 2023)

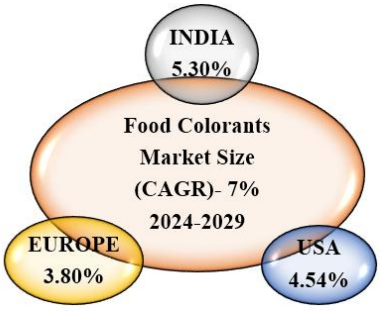

Figure A: Food colorant market size

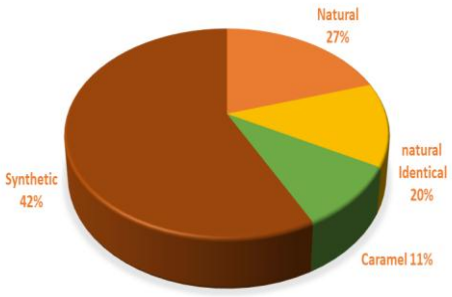

Figure B: The global food Color market

Color Name	INS Number	Color Shade	Common Uses	Health Concerns
Ponceau 4R	INS 124	Red	Bakery, confectionery, beverages	Potential allergen, hyperactivity in children
Carmoisine	INS 122	Red	Sweets, jams, sauces, beverages	May cause hypersensitivity reactions
Erythrosine	INS 127	Pink	Candies, icings, bakery, canned fruits	Linked to thyroid issues at high doses
Tartrazine	INS 102	Yellow	Soft drinks, snacks, desserts, pickles	Hyperactivity, allergic reactions
Sunset Yellow FCF	INS 110	Orange	Dairy products, beverages, jams	Can cause hypersensitivity reactions
Indigo Carmine	INS 132	Blue	Ice creams, sweets, pharmaceuticals	Possible allergic reactions
Brilliant Blue FCF	INS 133	Blue	Confectionery, soft drinks, dairy products	Potential gastrointestinal discomfort
Fast Green FCF	INS 143	Green	Beverages, ice creams, desserts	Possible allergic reactions in sensitive individuals

Table 1: Synthetic and Natural Food Color Used in India

Natural Color Name	INS Number	Source	Color Shade	Common Uses	Health Benefits
Curcumin	INS 100	Turmeric	Yellow	Pickles, dairy, sweets	Antioxidant, anti-inflammatory
Carotenoids	INS 160a-f	Carrots, paprika, tomatooes	Yellow to Orange	Beverages, dairy, baked goods	Vitamin A precursor, boosts immunity
Anthocyanins	INS 163	Berries, grapes, red cabbage	Red to Purple	Fruit juices, jams, desserts	Antioxidant, heart health benefits
Chlorophyll	INS 140, 141	Green leafy vegetables	Green	Ice creams, beverages	Detoxifying, supports liver function
Annatto	INS 160b	Annatto seeds	Orange	Dairy products, snacks	Rich in antioxidants
Beetroot Red	INS 162	Beetroot	Red	Sweets, beverages, sauces	Improves blood circulation
Spirulina Extract	-	Algae	Blue-Green	Health drinks, confectionery	Rich in proteins and vitamins

Table no: 1.2 Permitted Natural Food Colors in India

II. SAFETY CONCERNS ASSOCIATED WITH FOOD COLORS

A Health Risks of Synthetic Colors:

The use of natural colorants in India is generally considered safe when used within permitted limits and in approved food products. However, instances of unregulated usage have been reported, such as the addition of annatto to cow milk to give it a yellowish tint, mimicking buffalo milk.

- Moreover, the term "natural" does not always imply that a colorant is completely risk-free or has undergone extensive clinical testing to rule out potential adverse effects. Certain plant-based

pigments have been associated with allergic reactions, including urticaria, angioedema, hypotension, and anaphylaxis in hypersensitive individuals, highlighting the need for systematic clinical research on their safety.

- While natural pigments are often considered a safer alternative to synthetic dyes, further studies are required to establish acceptable safety limits and regulatory guidelines for their controlled use.
- Hyperactivity in children (ADHD) – Studies suggest dyes like Tartrazine and Sunset Yellow may exacerbate hyperactivity.
- Allergic Reactions – Synthetic dyes may trigger allergies and skin reactions in sensitive individuals.
- Carcinogenic Risks – Banned Color such as Metanil Yellow and Sudan Dyes have been found to be potentially carcinogenic
- While food Colors enhance visual appeal, they pose potential health risks, especially synthetic dyes containing heavy metals like lead, mercury, and arsenic. Studies link them to hyperactivity in children, allergic reactions, organ damage, and carcinogenic effects. Excessive consumption may cause respiratory issues, liver and kidney dysfunction, and hormonal imbalances.
- Misuse of banned and non-permitted Colors in unregulated markets further raises safety concerns. Strict regulations, proper labeling, and consumer awareness are essential to minimize health risks and ensure food safety compliance.

Health Concern	Details	Examples of Problematic Dyes
Behavioral Issues	Several studies have linked artificial food dyes to behavioral problems in children, including hyperactivity and attention deficits. The American Academy of Pediatrics recommends limiting children's exposure to these dyes.	Red Dye 40, Yellow Dye 5, Yellow Dye 6
Cancer Risks	Some research suggests that certain artificial food dyes may be associated with an increased risk of cancer. For instance, Red Dye 40 has been linked to potential cancer risks.	Red Dye 40
Allergic Reactions	Artificial food dyes have been known to trigger allergic reactions, particularly in children. Yellow Dye 5 and Yellow Dye 6 are known to cause hypersensitivity and allergic reactions.	Yellow Dye 5, Yellow Dye 6

Table 1.3 The Scientific Evidence for Potential Health Risks Associated With Artificial Food Dyes for Decades

B. Health Impact of Food Colors:

Even approved food Colors are not entirely risk-free, and excessive consumption can have harmful health effects. Synthetic dyes often contain heavy metals like lead (Pb), mercury (Hg), arsenic (As), copper (Cu), and nickel (Ni), which studies have linked to hyperactivity, concentration issues in children, thyroid tumors, allergies, and organ damage. Prolonged exposure can lead to respiratory issues, liver and kidney dysfunction, bone marrow disorders, and even carcinogenic effects.

Food should be pure, fresh, and free from hazardous substances to ensure safety. However, due to lack of awareness and regulatory loopholes, many industries illegally use banned synthetic dyes, including textile and cosmetic colorants, to enhance the appearance of food products.

Recent reviews of new evidence on azo dyes used as food colorants indicate that their toxicity and actual population exposure levels are continuously assessed by food safety authorities such as the EFSA and JECFA. Information on the food categories in which these Colors are used can be found in the European and US FDA databases. Regular evaluations also monitor their presence in specific food products. Current ADI limits set by regulatory agencies generally align and suggest safety. In some cases, newly discovered mechanisms of action have opened possibilities for pharmacological repurposing. Recently, discussions have emerged about replacing potentially harmful additives with functional, plant-based alternatives that are both non-toxic and beneficial to human health while also being environmentally sustainable.

III. KEY COMPLIANCE CHALLENGES FOR MANUFACTURERS

A. Evolving Regulations:

Regulations on synthetic food Colors frequently change due to new scientific research or consumer concerns. A Color permitted today may be banned tomorrow, making it essential for manufacturers to stay updated with regulatory changes to ensure compliance.

B. Ingredient Transparency:

Consumers are increasingly demanding clear labeling of food additives, including synthetic food Colors. Manufacturers must provide detailed ingredient disclosures, ensuring transparency about the colorants used in their products.

C. Testing and Certification:

Regulatory authorities conduct rigorous safety and quality tests before approving synthetic food Colors for use in food, cosmetics, and pharmaceuticals. In India, the FSSAI inspects product batches to verify compliance with safety standards. Manufacturers must also obtain certifications such as ISO, GMP, or HACCP to demonstrate adherence to food safety regulations.

D. Cultural and Market Preferences:

Different regions have varying regulations and consumer attitudes toward synthetic food Colors. For instance, European Union regulations are more stringent compared to other markets, reflecting cultural preferences and stricter safety standards. Manufacturers must adapt to these regional requirements to ensure market access.

IV. CHALLENGES IN ENFORCEMENT AND COMPLIANCE

Despite existing regulations, India faces several challenges in implementing food Color safety norms effectively:

- Unregulated use in street foods and small vendors: Many street food vendors use non-permitted dyes due to lack of awareness and economic constraints.
- Adulteration and Black Market: The sale of banned food Colors in the black market continues to pose a significant threat to food safety.
- Lack of Consumer Awareness: Surveys indicate that a large portion of the population is unaware of the potential health risks associated with synthetic food Colors.
- Inadequate Testing Infrastructure: The monitoring of food Color use requires advanced high-performance liquid chromatography (HPLC) and spectrometry techniques, which are not widely available in all food safety laboratories across India.

V. SOLUTIONS TO OVERCOME COMPLIANCE CHALLENGES

A. Adherence to Regulatory Frameworks:

- The article follows the Food Safety and Standards Authority of India (FSSAI) guidelines, as established under the Food Safety and Standards Act, 2006.
- It references the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which specify permitted and banned synthetic food Colors and their permissible limits.
- The article discusses international compliance benchmarks, including regulations by the U.S. Food and Drug Administration (FDA) and the European Food Safety Authority (EFSA).

B. Scientific Validity and Evidence-Based Approach:

- It cites approved synthetic food Colors and natural alternatives, explaining their safety concerns, health risks, and benefits. The article highlights scientific studies linking synthetic dyes to health effects, such as hyperactivity, allergic reactions, and potential carcinogenicity.
- It emphasizes the importance of testing methods, such as high-performance liquid chromatography (HPLC) and mass spectrometry, to ensure compliance with regulatory limts.

C. Compliance with Ethical and Safety Considerations:

- It promotes consumer awareness and public safety, advocating for stricter enforcement, transparent labelling, and education on food additives.
- The article addresses ethical concerns regarding the misuse of banned Colors in unregulated sectors, such as street food and small-scale industries.

D. Alignment with Global Best Practices:

- The article suggests harmonizing Indian food safety standards with global regulatory

practices, ensuring that India's regulations evolve in line with international safety protocols.

- ❖ It proposes policy recommendations, including stricter pre-market approvals, periodic re-evaluation of food Colors, and tax incentives for natural alternatives.

F. Practical and Industry Compliance:

- ❖ The article discusses challenges in enforcement, including black-market sales of banned dyes, inadequate laboratory infrastructure, and lack of monitoring.
- ❖ It calls for regular inspections and better compliance mechanisms, ensuring that the food industry adheres to safety regulations.

VI. FUTURE PERSPECTIVES

A. Evolution and Future of Food Colorants

- ❖ Historical Issues: Food colorants have faced scandals in the 80s and 90s, causing consumer distrust, especially toward synthetic dyes.
- ❖ Shift to Natural Dyes: Consumers now prefer natural colorants (from plants, insects, or synthesized mimics), such as annatto, paprika, β-carotene, lutein, carotenoids, anthocyanins, betalains, chlorophylls, curcumin, and carminic acid.
- ❖ Regulatory Trends: While EFSA and FDA don't differentiate between synthetic and natural colorants, the EU has approved more natural dyes.
- ❖ Emerging Techniques: Analytical methods like chemometrics and nanotechnology are enhancing food dye quality and safety.
- ❖ Sustainable Innovations: Use of vegetable residues and algae for natural dyes promotes sustainability and circularity in the food industry.
- ❖ Future Outlook: With growing consumer demand, new technologies and research will drive safer, higher-quality, and more sustainable food colorants.

B. Metabolic Engineering and Stability Enhancements for Natural Pigments

- ❖ Metabolic Engineering Benefits: Improves product yields, transfers pathways from slow to fast-growing organisms, and enables directed biosynthesis of pigment analogs to modify Color or properties.
- ❖ Cell Factories: Techniques like CRISPR-Cas9 and heterologous expression of biosynthetic pathways from known or novel pigment producers offer effective strategies.

C. Stability and Solubility Solutions:

- ❖ Micro-encapsulation and nano-formulations enhance the stability and solubility of natural food colorants, expanding their application in food products.
- ❖ Encapsulated pigments are easier to handle, more soluble, and better resistant to ambient conditions.
- ❖ Nano-emulsions improve solubility and create invisible particles, ideal for Coloring clear and semi-clear beverages.

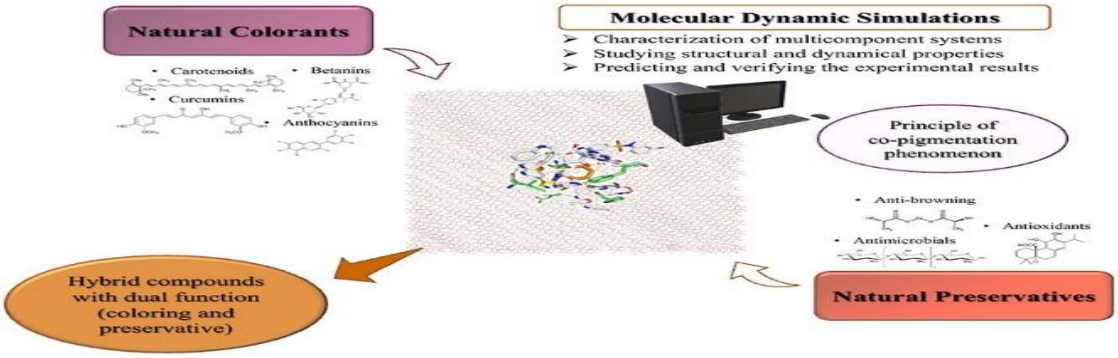

Figure:3 Advancements and Challenges in Natural Food Color Production

- ❖ Metabolic engineering plays a crucial role in enhancing natural pigment production, but it comes with regulatory challenges. This technology enables higher product yields, pathway transfers from slow-growing to fast-growing organisms, and the biosynthesis of pigment analogs to modify Color and other properties. Using CRISPR-Cas9 and heterologous expression, cell factories can be developed to optimize pigment production from known and novel sources.
- ❖ One of the key challenges of natural colorants is their poor stability and low solubility. Techniques like micro-encapsulation and nano-

formulations help improve their handling, solubility, and stability, ultimately extending shelf life.

- Nano-emulsions can further enhance solubility and allow for invisible particles, making them suitable for clear and semi-clear beverages. Despite the limited variety of natural Colors compared to synthetic alternatives, consumer demand for natural food colorants is growing. Discovering new pigment sources and developing cost-effective production technologies are critical to competing with synthetic dyes.
- Advancements in organic substrates, enhanced microbial pigment production, and stabilization methods can make natural pigments more viable and commercially competitive. Future research should focus on expanding the Color spectrum, leveraging health benefits, improving pigment shelf life, and reducing production costs to meet the increasing demand for safe and sustainable food colorants.

VII.CONCLUSION

The regulation of food Colors in India is a crucial aspect of food safety, ensuring that consumers are protected from potential health risks while maintaining the aesthetic and commercial appeal of food products. The Food Safety and Standards Authority of India (FSSAI) has implemented strict guidelines governing the use of food Colors, limiting the number of permitted synthetic additives and encouraging the use of natural alternatives. Compliance with these regulations helps prevent health concerns such as allergic reactions, hyperactivity in children, and long-term toxic effects, which have been associated with certain synthetic dyes.

Despite the benefits of food Colors in enhancing food presentation, continuous research and monitoring are essential to assess their safety. Regular food Color testing, clear labeling, and adherence to permissible limits are necessary steps to ensure consumer safety and transparency in the food industry. Additionally, food manufacturers must stay updated with evolving regulatory frameworks both in India and globally, as international bodies like the European Food Safety Authority (EFSA) and the U.S. Food and Drug Administration (FDA) frequently revise their guidelines based on new scientific findings.

Going forward, the food industry must strike a balance between aesthetic appeal and health concerns by promoting safer, natural alternatives where possible. Public awareness campaigns and stricter enforcement of food Color regulations can further enhance consumer confidence and encourage informed choices. The continued efforts of regulatory authorities, manufacturers, and researchers will be key to ensuring that food Color additives remain both safe and beneficial for the food industry and consumers alike.

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