



**Food Colors
Global Alignment**

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Sensient Colors LLC, on behalf of IACM
July 19, 2018**



Disclosure

This speaker is employed by Sensient Colors LLC, a member company of the International Association of Color Manufacturers (IACM), and is a Board of Director of IACM.

In her role today, she is representing IACM.

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Agenda

About IACM

Uses and Benefits of Colors

The Importance of Global Harmonization

Colors at Codex

Global Alignment of Standards

Exposure Considerations



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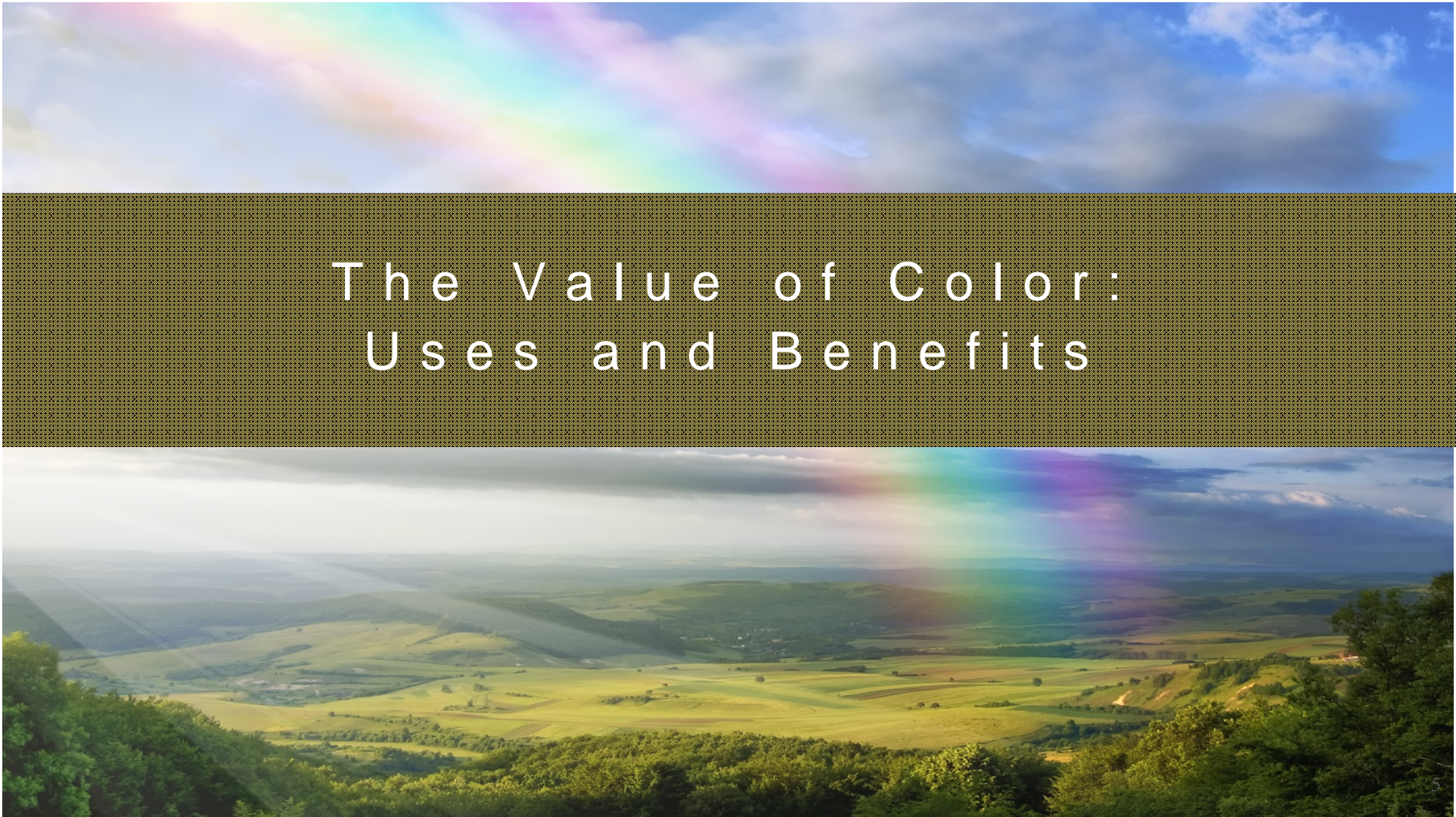
IACM Objectives

- To protect and expand the worldwide use of colors.
- To serve as a trusted resource to interact with regulatory bodies and global organizations.
- To enhance confidence in the safe use of color.
- To provide members with a central source of scientific and regulatory expertise.
- To advocate global harmonization of standards and regulations.



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The Value of Color: Uses and Benefits

Why do we even use color in Food and Beverages?

- Science tells us that “taste” is a multi-sensory perception constructed from taste buds, visual appearance, aroma, and mouthfeel.
- “Flavour is not just as simple as the way it tastes as all the other senses come into play, and some can dominate the brain’s interpretation of food. For example, we have found there is a clear difference in the intensity of flavour people experience when we play with the colour of a drink with a tasteless and odorless dye. It is the same drink but people think it tastes better.”

Dr. Francis McGlone, Head of Somatosensory & Affective Neurosciences and Psychology Liverpool JM University,
Former Neuroscientist at Unilever

- Taste perception is influenced by color.

If taste is king, then color is its queen, and they very much work hand-in-hand to win consumers over.



Source: 2008 UK Telegraph: 'Sounds and colour influence the taste of food'

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Recent Academic Studies Show Color Impacts Preference

A 2007 study by Hoegg & Alba evaluated consumer preference for orange juice by varying color intensity and/or sweetness level



- They concluded that taste perception was influenced only by color change and not by changes in actual sweetness level

Source: Hoegg and Alba, Journal of Consumer Research March 2007

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Recent Academic Studies Show Color Impacts Preference

A 2016 study by Perloni, Pergola, and Rumiati examined the role of human trichromatic vision in food evaluation



- Study participants were more attracted to red over green shades
- Reddish color in fruits and leaves generally indicate higher protein and nutrient content – important for early humans
- Conclusion is that attraction to color in food is not cultural but innate to all human beings

Why use colors

- It's important not to underestimate how much color can influence consumer taste expectations.
- Brighter color = better taste
- Consumers believe products with more vibrant color will taste better, have superior sweetness, and are more flavorful.
- More than any other attribute, taste expectation motivated consumer liking, so this is an important correlation.



The image is a landscape photograph of a valley with rolling green hills and a rainbow in the sky. A horizontal band with a dark, textured background is overlaid across the middle of the image, containing the title text. The top and bottom portions of the image show the sky and the valley respectively, with the rainbow arching over the horizon.

The Importance of Global Harmonization

Colors are safe to use

To protect the customer, food laws have been developed around the world and have evolved primarily as positive lists that define substances that may be added to color food with the maximum amounts allowed, per strict purity specifications.

Several expert committees such as EFSA and JECFA are mandated to assess the safety of food additives and to make recommendations to policy makers who are responsible for controlling the use of additives via regulations and standards, or through harmonizing of international guidelines.

Global Harmonization

- The harmonization of food additive regulations has become a priority for many nations interested in the global commerce of foods, beverages and food additives.
- A dominant trend in the global regulation of food constituents is the development of open, positive lists of substances that may be safely added to foods.
- This trend is consistent with premarketing approval controls that have been the foundation of food additive regulation in the U.S. since the passage of the 1958 Food Additives Amendments to the Federal Food, Drug, and Cosmetic Act.



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US Food and Drug Administration

Color Additives Require Pre-Market Approval

- All color additives, except for some hair dyes, are subject to FDA pre-market approval before they may be used in:

Food, Drugs, Cosmetics, and Medical devices that come in contact with the bodies of people or animals for a significant period of time



US Food and Drug Administration

Color Additive Petition Review

What exactly is the substance and what is the projected exposure?

- Identity and composition
- Method of manufacture
- Specifications and purity
- Use level and exposure
- Technological justification

Is it safe for its intended use?

- Toxicology studies
- FDA Redbook requirements

Is other case-specific information needed?



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US Food and Drug Administration

Color Additive Petition Identity and Specifications

Chemical Identity

- Analytical chemistry and spectra
- For plant sources, description of plant source
- Physical, chemical and biological properties

Specifications and Methods (for enforcing specs)

- Multi-batch analyses
- Identification of secondary coloring matters
- Identification of non-coloring matters, impurities

Manufacturing Process

- Conditions; methods
- Solvents; reagents
- Variation/purity

Stability



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US Food and Drug Administration


Color Additive Petitions Exposure



- Petitions must include exposure estimate
 - Proposed concentrations that will be used in food
 - Consumer intake of foods that will contain the potential color additive
- For main color additive, FDA generally considers chronic intake
- Worst case scenario of exposure is considered
- FDA experts will produce an Estimated Daily Intake (EDI) for the color additive, and determine safety based on results of toxicity testing and no-observed effect levels

Importance of Global Harmonization

- IACM advocates for global harmonization of standards and regulations.
- IACM supports collaboration and cooperation in building regulatory coherence and international harmonization to facilitate trade and to increase consumer confidence in global food supply
- IACM participates as a NGO at Codex Alimentarius and is an active participant in CCFA
- IACM encourages adoption of Codex standards when countries are developing new food regulations.
- However, some colors approved for use in US not currently in GSFA due to the slow, deliberate Codex process, not due to safety concerns.



Colors
at
Codex



JECFA & Codex Alimentarius

JECFA is Joint FAO/WHO Expert Committee on Food Additives of the FAO and is responsible for:

- Establishing specifications for the **identity** and **purity** of individual food additives
- Determining **safe levels** of use
- Setting standards of consumption and acceptable daily intake for food additives specified in the **Codex Alimentarius**.
- Codex Alimentarius publishes the General Standards for Food Additives (**GSFA**)



Colors at Codex

IACM participates as non-governmental observer (NGO) at Codex Alimentarius

- Active participant in Committee on Food Additives (CCFA)

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

- However, some colors approved for use in US and/or EU not currently in GSFA due to slow, deliberate Codex process, not due to safety concerns

GSFA Not a Positive List

It was not the intent of the creators of the GSFA for it to be adopted as a positive list at this stage of development. Footnote 1 of the GSFA states,

Notwithstanding the provisions of this Section of the General Standard, the lack of reference to a particular additive or to a particular use of an additive in a food in the General Standard as currently drafted, does not imply that the additive is unsafe or unsuitable for use in food. The Commission shall review the necessity for maintaining this footnote on a regular basis, with a view to its deletion once the General Standard is substantially complete.



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Current GSFA Status

Materials for each CCFA meeting contain working document with adopted AND draft GSFA provisions

These are as indicated. They are available at

www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFA&session=50



Item No.	Item Description	Date	Document Type	Language	Version
5.1	General Standard for Food Additives (GSFA): Provisions for food additives in Codex	22/02/2018	Adopted	English	18/50/7 Add.1
5.2	General Standard for Food Additives (GSFA): Proposals for new and/or revision of food additive provisions (replies to CL 2017/47-FA)	02/03/2018	Draft	English	CX/FA 18/50/8
5.3	Discussion paper on the use of nitrates (INS 251, 252) and nitrites (INS 249, 250)	13/02/2018	Draft	English	CX/FA 18/50/9
5.4	Discussion paper on the use of the terms "unprocessed" and "plain" in the GSFA	18/01/2018	Draft	English	CX/FA 18/50/10
6	Proposed draft revision to the International Numbering System (INS) for Food Additives (CAC/GL 36-1989)	09/02/2018	Draft	English	CX/FA 18/50/11
6.1	Comments at Step 3 of Brazil, Columbia, Paraguay, Republic of Korea, United States of America, CCC, EFEMA, EU Specialty Food Ingredients, IACM, ICGMA, IFAC and ISC	20/03/2018	Draft	English	CX/FA 18/50/11 Add.1
7	Proposals for additions and changes to the priority list of substances proposed for evaluation by JECFA	05/02/2018	Draft	English	CX/FA 18/50/12
8	Discussion paper on "Future Strategies for CCFA"	23/11/2017	Draft	English	CX/FA 18/50/13 Rev.1
8.1	Replies to CL 2017/92-FA of Costa Rica, Ecuador, Russian Federations, AMFEP, BEUC, CCC, CEFS, EU Specialty Food Ingredients, FoodDrinkEurope, IACFO, IACM, ICA, ICBA, ICGA, ICGMA, IDF, IFAC, IFU, IOFI, ISA, ISDI and NATCOL	26/02/2018	Draft	English	CX/FA 18/50/13 Add.1
8.2	Additional replies to CL 2017/92-FA of Brazil, European Union(EU), New Zealand, Nicaragua, Sudan, Enzyme Technical Association(ETA) and Food Industry Asia (FIA)	20/03/2018	Draft	English	CX/FA 18/50/13 Add.2
12	Information document to the discussion on the GSFA	03/11/2017	Information	English	FA/50 INF/01
13	Information document on food additive provisions in commodity standards	19/12/2017	Information	English	FA/50 INF/02
101	Division of competence between the European Union and its Member States	14/03/2018	Draft	English	CRD01
102	Report of the 50th CCFA's Physical Working Group on the Codex General Standard for Food Additives (GSFA)	26/03/2018	Draft	English	CRD2
103	Report of the in-session working group on endorsement and/or revision of maximum levels for Food additives and processing aids in Codex Standards	27/03/2018	Draft	English	CRD03
104	Report of the in-session Working Group on the International Numbering System (INS)	27/03/2018	Draft	English	CRD04
105	Report of the in-session working group on Priorities for evaluation by JECFA	27/03/2018	Draft	English	CRD05
106	Comments on Agenda item 5(c) from JECFA secretariat	09/03/2018	Draft	English	CRD06
107	Comments on Agenda item 5(a) from China, Morocco, Nicaragua, Philippines, Republic of Korea, GOED, IDF and IFU	20/03/2018	Draft	English	CRD07
108	Comments on Agenda item 2 from Morocco and Republic of Korea	22/03/2018	Draft	English	CRD08
109	Comments on Agenda item 3(b) from Philippines	22/03/2018	Draft	English	CRD09



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CCFA Information Document on the GSFA

fa50_info_01e.pdf - Adobe Acrobat Pro DC

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 **CODEX ALIMENTARIUS COMMISSION**  **World Health Organization**

Food and Agriculture Organization of the United Nations

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Agenda Item 5 **FA/50 INF/01**
November 2017

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD ADDITIVES
Fiftieth Session

INFORMATION DOCUMENT TO THE DISCUSSION ON THE GSFA

The 38th Session of the Committee (CCFAC38) requested the Codex Secretariat to prepare every year an updated version of the "Working document for information and support to the discussion on the GSFA" similar to CX/FAC 06/38/8 (ALINORM 06/29/12, para. 72).

Note from the Codex Secretariat

The following should be noted with respect to the revised Tables 1 and 2 of the GSFA (Appendix I and Appendix II, respectively):

- The "Step" column indicates the status of specific provisions in the Codex elaboration procedure. Food additive provisions for the priority additives to be discussed by CCFAS0 are listed at Step 3 or Step 6. Food additive provisions that require future work by the Committee are listed at Step 4 or Step 7. Food additive provisions that have been adopted at Step 8 by the Commission contain the notation "adopted" and the year of adoption.
- The functional class(es) listed for each additive in the GSFA are derived from the functional class titles for food additives in the International Numbering System (INS)¹.

The following should be noted with respect to the revised Table 3 of the GSFA (Appendix III):

- The status of each additive in the Codex procedure is indicated in columns entitled "Step". If the inclusion of a specific additive has been adopted at Step 8 by the Commission, the year of this decision is noted in the column entitled "Year".

Due to their volume, the appendices to this document are only being distributed electronically.

The Appendices of this document may be downloaded by clicking the hyperlinks below:

- Appendix I ([Table 1](#))
- Appendix II ([Table 2](#))
- Appendix III ([Table 3](#))

Codex GSFA Step Process

- 46 colors with draft and/or adopted provisions in GSFA
- As of 49th CCFA, 1,898 draft and adopted provisions for colors in the GSFA
- Colors that have not completed the Step process for adoption are largely at Steps 4 and 7.
- Step 4: the draft text has been prepared, circulated to member countries and all interested parties for comment and are awaiting review at the Committee level before being sent to the Commission for review
- Step 7 additives have already been endorsed by the Commission, agreed to be put forth for finalization and are simply awaiting finalization by the Committee



Codex GSFA Step Process

- The Committee agreed at its 50th meeting in 2018 to begin consideration of draft color provisions
- Initially focused on with food categories 5.2 (Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4), 5.3 (Chewing gum) and 5.4 (Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces).
- It is anticipated that CCFA will work as quickly as possible through the additional draft color provisions in future meetings



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IACM Supports Global Harmonization

- Since current omission from GSFA not due to safety concerns, IACM encourages countries to consider colors approved for use in US, EU OR Codex as basis for regulations
- Adopting the GSFA as a positive list means that currently approved colors and/or uses for certain colors will be banned
- Each country takes its own approach to color additive approval and reauthorization and should consider need for colors not in GSFA
- Populations have different needs and requirements for colors due to cultural variations
- There is no reason for a country to disallow the use of a color or a use already approved due its position at Step 7 rather than Step 8



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Global Alignment of Standards

JECFA Conclusions on Color Additives

- The JECFA program is a sound, scientifically valid program that provides the best available safety assessments of color additives.
- JECFA has evaluated a number of color additives and provided ADIs.
- The color additives assigned ADIs by JECFA provide a sound basis for international harmonization efforts.
- JECFA has begun a program to re-evaluate color additives, based on priority, due to colors being among those additives first evaluated by JECFA and the desire for ADIs to be based on the most up to date safety information.



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Global Alignment of Standards

- Any revision of standards for colors needs to be aligned with JECFA
- Specification/purity limits should consider both scientific justification and global trade implications
 - Synthetic colors, including Allura Red, Brilliant Blue, Erythrosine, Fast Green FCF, Indigotine and Tartrazine, and Fast Green FCF recently re-evaluated by JECFA with updated specifications
 - ADI was maintained in all cases except for Brilliant Blue (lowered in harmonization with EFSA) and Tartrazine (increased ADI)



Global Alignment of Standards Tartrazine/FD&C Yellow No. 5/E 102

	US	EC	JECFA
Pure Dye	87.0% min	85.0% Min	85.0% min.
Moisture & Salts	13% max.	--	15% max.
Water Insoluble Matter	0.2% max.	0.2% max.	0.2% max.
Intermediates (combined total)	--	0.5% max.	0.5% max.
Sulfanilic Acid	0.2% max.	--	--
Ethyl Ester of Pyrazolone T	0.1% max.	--	--
Pyrazolone T	0.2% max.	--	--
Triazene (DAADBSA)	0.05% max.	--	--
Subsidiary Dye (combined total)	--	1.0% max.	1.0% max.
Lower Sulfonated	0.5% max.	--	--
Ester of Color	1.0% max.	--	--
(*)Peak 5	1.0% max.	--	--
(*)Peak 7	1.0% max.	--	--
Total Primary Amines (as Aniline)	--	0.01% max.	0.01% max.
Aniline	100 ppb max.	--	--
Benzidine	1 ppb max.	--	--
4- Aminobiphenyl	5 ppb max.	--	--
4-Aminoazobenzene	75 ppb max.	--	--
Ether Extract	--	0.2% max.	0.2% max.
Mercury	1 ppm	1 ppm max.	--
Arsenic(as As)	3 ppm	3 ppm max.	--
Lead (Pb)	10 ppm	2 ppm max.	2 ppm max.
Cadmium	--	1 ppm max.	--



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Global Alignment of Standards

Sunset Yellow FCF/FD&C Yellow No. 6/E 110

	US	EC	JECFA
Pure Dye	87.0% min.	85.0% min.	85.0% min.
Moisture & Salts	13.0% max.	--	15.0% max.
Water Insoluble Matter	0.2% max.	0.2% max.	0.2% max.
Intermediates	--	0.5% max.	0.5% max.
Sulfanilic Acid	0.2% max.	--	--
Schaeffer Salt	0.3% max.	--	--
Triazene (DAADBSA)	0.1% max.	--	--
Disodium Salt of 6,6'-oxybis (2- naphthalene-sulfonic acid)	1.0% max.	--	--
Subsidiary Dye	--	5.0% max.	5.0% max.
Higher Sulfonated	5.0% max.	--	--
Lower Sulfonated	1.0% max.	--	2.0% max.
Total Primary Amines (as Aniline)	--	0.01% max.	0.01% max.
Aniline	250 ppb max.	--	--
Benzidine	1 ppb max.	--	--
4- Aminobiphenyl	15 ppb max.	--	--
4- Aminoazobenzene	50 ppb max.	--	--
1-(Phenylazo)-2-naphthalenol (Sudan 1)	10 ppm max.	0.5 ppm max	1 ppm max.
Azobenzene	200ppb max.		
1,3-Diphenyltriazene	40 ppb max.		
Ether Extracts	--	0.2% max.	0.2% max.
Mercury	1 ppm max.	1 ppm max.	--
Arsenic(as As)	3 ppm max.	3 ppm max.	--
Lead (Pb)	10 ppm max.	2 ppm max.	2 ppm max.
Cadmium	--	1 ppm max.	--



Global Alignment of Standards

Allura Red AC/FD&C Red No. 40/E 129

	US	EC	JECFA
Pure Dye	85.0% min.	85.0% min.	85.0% min.
Moisture & Salts	14% max.	--	15.0% max.
Water Insoluble Matter	0.2% max.	0.2% max.	0.2% max.
Cresidine Sulfonic Acid (CSA)	0.2% max.	0.2% max.	0.2% max.
Schaeffer Salt	0.3% max.	0.3% max.	0.3% max.
Disodium Salt of 6,6'-oxybis (2- naphthalene-sulfonic acid) (DONS)	1.0% max.	1.0% max.	1.0% max.
Subsidiary Dye	--	3.0% max.	3.0% max.
Higher Sulfonated	1.0% max.	--	--
Lower Sulfonated	1.0% max.	--	--
SC-NTR	1.0% max.	--	--
Total Primary Amines (as Aniline)	--	0.01% max.	0.01% max.
Ether Extract	--	0.2% max.	0.2% max.
Mercury	--	1 ppm max.	--
Arsenic(as As)	3 ppm max.	3 ppm max.	--
Lead (Pb)	10 ppm max.	2 ppm max.	2 ppm max.
Cadmium	--	1 ppm max.	--




Global Alignment of Standards Brilliant Blue FCF/FD&C Blue No. 1/E 133

	US	EC	JECFA
Pure Dye	85.0% min.	85.0% min.	85.0% min.
Moisture & Salt	15.0% max.	--	15.0% max.
Water Insoluble Matter	0.2% max.	0.2% max.	0.2% max.
Leuco Base	5.0% max.	5.0% max.	5.0% max.
Sulfo benzaldehyde (o,m,p)	1.5% max.	1.5% max.	1.5% max.
ESBSA	0.3% max.	0.3% max.	0.3% max.
Subsidiary Dye	6.0% max.	6.0% max.	6.0% max.
Total Primary Amines (as Aniline)	--	0.01% max.	0.01% max.
Ether Extracts		0.2% max.	0.2% max.
Mercury	--	1 ppm max.	--
Arsenic(as As)	3 ppm max.	3 ppm max.	--
Lead (Pb)	10 ppm max.	2 ppm max.	--
Cadmium	--	1 ppm max.	2 ppm max.
Chromium	50 ppm max.	--	50 ppm max.
Manganese	100 ppm max.	--	--



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Exposure Considerations

Exposure Considerations

- Contribution of food color to heavy metal exposure is significantly overestimated in typical exposure assessments
- The fractions of foods containing these colors are lower than 100% in each category, which is not considered in most exposure assessments



Are consumers exposed to too much synthetic color?

	Typical Use Levels*		Maximum Use Levels*		µg/kg bw/day	
	Mean	95%	Mean	95%	ADI	% ADI
Sunset Yellow	11.6	37.9	27.1	89	4,000	2.23
Allura red	15.5	53.3	28.5	91.8	7,000	1.31
Tartrazine	5	16.3	13.4	42.1	10,000	0.42
Indigo carmine	0.8	2.6	3.5	13.8	5,000	0.28
Brilliant Blue	1.9	6.3	5.1	18	6,000	0.14
Erythrosine	0.3	1.1	1.6	3.8	100	3.80
Fast green	<0.05	0.1	<0.05	0.2	25,000	0.001

*includes straight color and lake where appropriate



Maria Bastaki, Thomas Farrell, Sachin Bhusari, Xiaoyu Bi & Carolyn Scrafford (2017) Estimated daily intake and safety of FD&C food-colour additives in the US population, Food Additives & Contaminants: Part A, 34:6, 891-904, DOI: [10.1080/19440049.2017.1308018](https://doi.org/10.1080/19440049.2017.1308018)

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Do children consume high levels of synthetic color additives?

		Typical Use Levels*		Maximum Use Levels*		μg/kg bw/day	
		μg/kg bw/day		μg/kg bw/day		ADI	% ADI
		Mean	95%	Mean	95%		
Sunset Yellow	2-5y	33.7	86.6	78.5	204.7	4,000	5.12
	6-12y	22.3	59.3	52.2	142.8		3.57
Allura red	2-5y	45.5	115.2	81.8	216.8	7,000	3.10
	6-12y	31	90.2	54.4	152.4		2.18
Tartrazine	2-5y	15.6	41.1	40.7	101	10,000	1.01
	6-12y	9.8	25.7	26.2	70.7		0.71
Indigo carmine	2-5y	2.8	10.4	11.8	36.9	5,000	0.74
	6-12y	1.5	4.9	6.8	23.6		0.47
Brilliant Blue	2-5y	1.3	3.5	3.6	10.8	12,500	0.09
	6-12y	1.9	6.3	5.1	18		0.14
Erythrosine	2-5y	1	2.6	4.2	11.4	100	11.40
	6-12y	0.6	1.9	2	6.5		6.50
Fast green	2-5y	0.1	0.1	0.1	0.2	25,000	0.001
	6-12y	<0.05	0.1	0.1	0.2		0.001

*includes straight color and lake where appropriate



Key Takeaways

- Colors are useful additives that provide important and beneficial technical effects.
- Codex GSFA should not be adopted as positive list; need to consider draft provisions as well as those already adopted.
- IACM supports science-based regulations on color use and global harmonization to the extent possible.





THANK YOU