

# Synthetic and Natural Food Colorants

Robert R. Maronpot<sup>a)</sup> Shim-mo Hayashi<sup>b)</sup>  
Maria Bastaki<sup>c)</sup>

<sup>a)</sup> Maronpot Consulting LLC

1612 Medfield Road, Raleigh, North Carolina 27607, USA

<sup>b)</sup> Division of Food Additives, National Institute of Health Sciences, Kawasaki, Japan

<sup>c)</sup> International Association of Color Manufacturers (IACM), Washington DC, USA

## Summary

There is increasing contemporary appeal and interest in natural versus synthetic food and beverage colorants based on increasing health awareness and global demand for chemical-free food products. There are many commonalities in defining and regulating food colorants among countries and specifics are provided for the United States, the European Union, and Japan.

Overall global guidance for food colorant safety and marketing is provided by international bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Codex Alimentarius Commission (CAC) and contemporary safety assessment standards and regulations are in place in many countries to maximize protection of consumers.

## 1. Food Color and Consumer Expectations

The timeless practice of adding coloring to foods dates as far back as 3500 BC in early Indus Valley civilizations and was common starting around 1500 BC when candy makers added natural extracts and wine to improve the appearance of their products<sup>1)</sup>.

Food color additives are critical to the food and beverage industries as important constituents of product formulations that aim to satisfy consumer expectations. Even before taste, the consumer's initial experience of food is visual<sup>2-4)</sup>. Color is added to enhance the sensory experience of food for the consumer and to match the product flavor<sup>5,6)</sup>. Humans are conditioned by evolution and tradition to associate color and flavor across cultures. It's been shown that the brain automatically associates color with flavor within the first 90 seconds of observation with 75% of this assessment being based on color<sup>7)</sup>. Thus, it is not surprising that the food and beverage industry depends upon consistent availability of food colorants of high quality and relies on the food colorant market for variety of options.

An increasing number of contemporary consumers are interested in "clean-label" products and place increased emphasis on ingredients of natural sources, including food colorants. This trend is mainly driven by increasing health awareness among the consumers, changing perceptions about healthy foods and lifestyles, and rising demand for "chemical-free" food products across the globe<sup>8-10)</sup>. To meet trending consumer preferences, natural food colorants should exist in nature and all manufacturing and extraction processes must be free of non-water based solvents<sup>11)</sup>. These criteria essentially compose the lay definition of the term "natural food color", although the same materials may have other definitions in different regulatory jurisdictions, as explained below. Consumer expectations and perceptions of "naturalness" for food includes absence of additives such as synthetic colors, flavors, sweeteners and preservatives. While consumers seek appealing foodstuffs and their selection and acceptance of foods is influenced by the organoleptic effects of color, at the same time they expect food additives such as natural colorants to be safe<sup>12)</sup>.

The contemporary financial impact of food color on marketing is a multibillion-dollar endeavor. The natural and synthetic food color market was projected to reach \$2.3

billion by the end of 2019<sup>13</sup>). With a compound annual growth rate of greater than 7%, the global food color market is expected to reach \$4.6 billion by 2024<sup>14</sup>). Based on product type, natural colors were estimated to account for the largest share of the global food colors market in 2019.

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## 2. Synthetic Food Colorants

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The first synthetic color, mauveine, was developed by Sir William Henry Perkins in 1856<sup>10</sup>). In the early 1900s, chemically synthesized colorants were derived from aniline, were easy to produce and, compared to traditionally used natural colorants, were less expensive, had superior coloring properties, were more uniform and better characterized, encompass a wider array of hues than natural colorants, and blended easily without imparting unwanted flavors to food. Synthetic dyes used as food colorants were attractive because of their versatility in different food matrices and the ability to generate intense and uniform colors by controlling the number of azo-groups and different other substitution groups on the main structure frame. Added color has a long history of use to improve the organoleptic characteristics of foods and certified colorings remain a popular type of food colorant.

The long history of adding color to foods was punctuated by several episodes of fraudulent and harmful uses of substances as food colors<sup>2,10</sup>). Examples include adding lime, chalk, alum and even crushed bones to whiten bread, use of copper to color pickles, and adding mercury, red and white lead, copper salts and arsenic to color sweets. The harmful effects of such practices became known in the early 1800's but regulatory attempts in Europe were not sufficiently enforced and early regulations were ignored in the US. Ultimately, enforceable regulatory control took hold with the Food Adulteration Act of 1899 in Europe and the Wiley Act of 1906 outlawing the use of metal salts for food coloring in the US<sup>2,10</sup>).

With the industrial age beginning in the late 19<sup>th</sup> century, food preparation gradually shifted from the home kitchen to commercial production of processed food. Food processing resulted in loss of the natural pigments present

in fresh food. The need to preserve an appealing color typically associated with freshness fostered the use of synthetic colorants. While there were several options for safe use of food colors, unfortunately, there were also flagrant incidents of food adulteration including use of some materials that were overtly toxic. The ensuing increased scrutiny eventually resulted in the development of more refined regulations and amendments and in the approval of a short list of synthetic food colors that have been tested for safety and are still used today<sup>15</sup>). Two recent exposure assessments, one conducted based on industry provided use levels<sup>16</sup>) and one based on concentrations determined analytically in products in the market<sup>17</sup>), reported that the estimated daily intake (EDI) of each color is low in the US population, across different age groups and significantly below the established acceptable daily intake (ADI) for each color.

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## 3. Natural Food Colorants

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For food color additives to be considered natural they should exist in nature and should contain natural raw materials<sup>11</sup>). They may be derived from plant, animal, mineral or microbial sources<sup>18</sup>) and the chromophore should not be modified chemically during extraction or manufacturing<sup>19</sup>). In some jurisdictions, a special category termed "nature identical" is recognized for chemically synthesized substances that are of identical chemical structure to natural pigments.

Lists of natural colorants in use are long and variable among countries. Most natural colorants can be grouped into the following categories: carotenoids, anthocyanins, betanins, caramel coloring, a wide variety of fruit juices, annatto, carmine, lycopene, paprika, turmeric, and saffron. Blue colors are especially rare in nature, but a blue pigment obtained from the *Gardenia jasminoides* plant is currently approved for use in Japan and a blue pigment extracted from the algae *Spirulina platensis* is also approved for use in many countries.

Many publications on natural food colorants mention that evolving (or modern) consumer preferences and eating desires favor natural over synthetic colorants. This interest

in increased use of natural food colorants has been influenced by some purported associations between the intake of synthetic colorants and exacerbation of some conditions, such as attention deficit and hyperactivity in children, and allergies, in sensitive subpopulations<sup>10,20-22</sup>. However, despite scientific expert evaluations concluding on their safety and continued regulatory approval, the public concerns about synthetic food colorants remain and are an influential force in shaping current market trends toward colors from natural sources. Consumer interest in natural colorants is also influenced by health benefit claims that are published in the scientific and lay literature. Therefore, industry is actively pursuing the development of new natural colors and new applications for existing natural colors despite cost and stability considerations<sup>10,12,13,19,23-25</sup>.

Contemporary efforts to address cost and stability concerns include investigating various technological options, such as microencapsulation and nanoformulations<sup>26</sup>, use of carrier materials, sequestrants and antioxidants to reduce color loss, and improved processing and packaging. Biotechnological development of natural colorants using cell cultures<sup>27</sup> and using filamentous and marine fungi as colorant sources are being investigated to address production costs. Microbial pigments can be produced in large quantity at relatively low cost<sup>26</sup> compared to extraction from plants.

## 4. Defining and Regulating Food Colorants in the US

In the United States, regulations for the safe use of color additives were developed in the 1950s and 1960s and were further refined with later amendments that facilitated effective enforcement to ensure a safe food supply<sup>2,22</sup>. The US Food and Drug Administration (FDA) defines a color additive as “any dye, pigment, or substance that imparts color when added or applied to a food, drug, or cosmetic or to the human body”<sup>15,28,29</sup>. Color additives are classified as “certified color additives” when they are chemically synthesized, or “exempt from certification” when they are derived from natural sources (plant, animal, mineral origin). In the US, all food colors are considered food additives

regardless of their synthetic or natural origin and as such they are subject to the same safety requirements and approval process. In contrast to the European distinction between color additives and coloring foods (see later section), the United States definition of food colors makes no such distinction. However, the US regulations include colors derived from fruit juices and vegetable juices in the list of exempted from certification color additives.

There are 9 FDA certified (FD&C) color additives approved for food use in the United States (See Table 1), five of which are also formulated as aluminum lakes. They have been rigorously tested for safety, are permitted at levels consistent with good manufacturing practices (GMP) and are subjected to batch certification for purity, subsidiary colors, and heavy metals by US FDA labs. With two exceptions, certified FD&C color additives can be used in all foods. Exceptions are Citrus Red No. 2 that is approved for use only on skins of mature oranges and Orange B that is approved for use only on surfaces and casings of frankfurters and sausages. Synthetic colorants are available in a large number of shades, have excellent stability, and can be produced at low cost<sup>10</sup>.

For additional details related to U.S. regulations on colorants, see Cox, J. Interesting Aspects of Color Additive Regulation in the U.S., pp.137-143 in this issue.

The FDA lists over 30 colorants that are exempt from certification and permanently listed for food use<sup>30</sup>. Some widely used exempt for certification color additives include annatto extract, beta carotene, canthaxanthin, caramel, carrot oil, cochineal extract carmine, dehydrated beets, fruit juice, paprika, riboflavin, saffron, titanium dioxide, tomato lycopene extract, turmeric, and vegetable juice. These include colors obtained from plant, animal or mineral sources as well as (nature identical) synthetic variations of natural colorants and the use of certain exempt colors may be limited to specific food categories<sup>31</sup>. Colors exempt from certification by FDA would typically be considered as natural colors in other countries. The FDA does not consider food ingredients that add their own color to foods, such as cherries in cherry yogurt, to be color additives.

All color additives require premarket approval by the FDA and, once approved, their identity must be clearly

declared on food and beverage product labels<sup>31</sup>). Unlike other substances added to food, there is no Generally Recognized As Safe (GRAS) exemption for color additives. Demonstration of adequate safety assessment and suitability for intended use are required for all color additive approval by FDA according to procedures established in the related FDA Guidance<sup>32</sup>). Further, the Delaney Clause (which prohibits the use of substances that are shown to be carcinogens in animals or humans) applies to all substances added to food including color additives regardless of origin.

The process to market new food colorants in the USA is the same for certified and exempt from certification colorants and requires submission of a color additive petition (CAP) to the US FDA Office of Food Additives Safety. A series of communications between the petitioner and FDA may take place to assist the petitioner through the CAP process. Information required for a successful CAP includes chemical identity

and composition of the colorant, method of manufacture, specification and purity data for the colorant, stability, intended use level and expected human exposure, and a technological justification for marketing the colorant. Demonstration of safety is required and typically involves a series of toxicity studies following FDA Redbook requirements<sup>33</sup>). The FDA determines an ADI for the color additive based on the toxicity testing and a no-adverse-effect-level. This process for gaining approval to market for a colorant is similar to the WHO/FAO JECFA process for determining acceptable daily intakes (ADIs). The presence of color additives in food products in the US must be declared on the product label, regardless of whether the colorant is certified or exempt from certification. Certified colors are declared on the product label by name and the FD&C designation while more general language is used to declare exempt from certification colors (e.g. color added). Labeling requirements are defined in the Code of Federal

Table 1. Permitted synthetic food colors in Europe, United States and Japan<sup>a</sup>

Synthetic Color	Synonyms	E number	EU	US	Japan
Acid Red	Acid Red		-	-	+
Allura Red AC	FD&C Red No. 40	E129	+	+	+
Amaranth	FD&C Red No. 2	E123	+	-	+
Azo Rubine	Carmoisine	E122	+	-	-
Brilliant Black	Black PN	E151	+	-	-
Brilliant Blue FCF	FD&C Blue No. 1	E133	+	+	+
Brown HT	Chocolate Brown HT	E155	+	-	-
Citrus Red No. 2	Citrus Red No. 2		-	+ <sup>b</sup>	-
Erythrosine	FD&C Red No. 3	E127	+	+	+
Fast Green FCF	FD&C Green No. 3		-	+	+
Green S	Green S	E142	+	-	-
Indigotine	FD&C Blue No. 2	E132	+	+	+
Orange Bl	Orange B		-	+ <sup>c</sup>	-
Patent Blue V	Patent Blue	E131	+	-	-
Phloxine	Phloxine		-	-	+
Panceau 4R	Cochineal Red A	E124	+	-	+
Quinoline Yellow	Quinoline Yellow	E104	+	-	-
Rose Bengal	Rose Bengal		-	-	+
Sunset Yellow FCF	FD&C Yellow No. 6	E110	+	+	+
Tartrazine	FD&C Yellow No. 5	E102	+	+	+

a - Not including lakes

b - Citrus Red No 2 for use on skins of mature oranges

c - Orange B for use on surfaces and casings of frankfurters and sausages

Regulations (CFR) and do not allow the term “natural” to describe exempt from certification colors on the product label.

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## 5. Defining and Regulating Food Colorants in the European Union

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In Europe, food colorants fall under the food additive regulation<sup>34)</sup> as Annex I and are defined as follows:

*“Colours” are substances which add or restore colour in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of this Regulation.”*

The EU color additive regulation does not define “natural” and makes no distinction between “natural” and “synthetic” colors. Unlike the US labeling requirements, labeling requirements in the EU do not include the name of the color but an instead require an assigned E-number which, provides no information regarding the origin of the color<sup>35)</sup>. Furthermore, the EU identifies three classifications of food color additives: as a food color, as a flavor with coloring properties, and as a coloring food<sup>6,36)</sup>. “Coloring food” represents edible raw material obtained from its source without selective extraction, defined as extraction that would result in pigment enrichment of >6-fold<sup>37,38)</sup>. For example – use of spinach in its natural form without extraction to color pasta is a “coloring food” but pigments selectively (>6-fold enrichment) extracted from spinach and applied to e.g., pasta would represent a “food color” additive. EU permitted colorants of natural origin are reviewed by chemical class with discussion of extraction procedures<sup>19)</sup>.

The EU also maintains stringent safety evaluation requirements irrespective of the origin of a food color additive. With over two dozen member states, it has taken the EU many years to develop regulations with the first

directive related to food colorants agreed to in 1962, leading to the establishment of the E number classification system. However, member states retain some independent flexibility regarding adoption and implementation in choosing which foods contain additives and at what level. Specific risk assessment for safety of color additives is provided to the EU by the related risk assessment body, the European Food Safety Authority (EFSA) and its scientific panels who evaluate the safe use of food additives. EU regulations related to food additive purity are aligned with JECFA recommendations. Starting from 2008, the EU older directives were replaced with updated framework directives for food additives and the publication of a guidance document with the establishment of a decision tree process for determination of a coloring food versus food color additive<sup>6,37,38)</sup>. As of 2017 there were 39 colors authorized as color additives for use in food in the EU<sup>39)</sup>.

Similar to labeling requirements in the USA, EU has specific labeling directives that include an official name and/or the E number of the additive. Additional labeling requirements exist for some additives, including a warning label for six specific synthetic colors stating “may have an adverse effect on activity and attention in children.”<sup>35)</sup>

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## 6. Defining and Regulating Food Colorants in Japan

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The first comprehensive law dealing with food safety and listing of safe food additives in Japan was the 1947 Food Sanitation Act (FSA) established by the Ministry of Health and Welfare (the present Ministry of Health, Labour and Welfare (MHLW)). This was the first comprehensive act for food safety/hygiene and it created a positive list system ( “designation system” ) for food additives and set the standards and specifications for food and food inspections<sup>40)</sup>. Under this system, only additives designated as safe by the Minister of Health, Labour and Welfare may be used in foods. However, this designation system had been applied only to chemically synthesized additives until 1995 when the FSA was amended. Currently, all types of additives are equally subject to the safety designation system, regardless of synthetic or natural origin, with some exceptions. The

FSA defines “food additive” as (i) substances used in or on food in the process of manufacturing food, or (ii) substances used for the purpose of processing or preserving food. Consequently, “food additive” includes both substances remaining in the final products, such as food colors and preservatives, and substances not remaining in the final products, such as sterilizing agents and filtration aids. Regardless of whether or not food additives are from natural origin, all substances used for the above purposes are categorized as food additives in Japan.

Food additives in the FSA are divided in “designated” and “existing”, as defined below. These two lists of additives were created in 1995 when the FSA was revised. Since then, all new additives (including chemically synthesized substances and substances of natural origin) are evaluated through the designation system. Designated food additives and existing food additives that are permitted for use in food in Japan are limited to those listed at the following URLs including colors, preservatives, sterilizing agents, and manufacturing agents but excluding natural flavoring agents and ordinary foods used as food additives.

●Designated Additives

Designated additives are those designated by the Minister of Health, Labour and Welfare as substances that were evaluated for safety and were determined to be unlikely to harm human health based on Article 10 of the FSA. <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-desin.add-x>

●Existing Food Additives.

Certain substances are permitted for use and distribution in Japan, as exception, without going through a safety evaluation to be included in the designation system as provided by the FSA for the reason that they are widely used in Japan and have a long history of consumption by humans. They are referred to as existing food additives and are placed on the List of Existing Food Additives. <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-exst.add>

●Standards for Use of Food Additives

Food additives with use standards (i.e., target foods and maximum use limits/residue limits) shall meet these standards when these substances are used. <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/stanrd.use>

There are two substance categories that are exempted

from the designation system: “natural flavoring agents” and “ordinary foods used as food additives.”

Examples of additives coming under these categories are placed on following lists.

●Natural Flavoring Agents

These substances are natural products that are obtained from animals and plants and used for flavoring substance. (e.g., vanilla flavoring and crab flavoring). The amount used is generally very low. <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-nat.flavors>

●Ordinary Foods Used as Food Additives

They are substances that are generally provided for eating or drinking as food and also used as food additives (e.g., strawberry juice and agar). <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-general.provd.add>

The FSA requires MHLW to prepare an official compilation of food additive specifications and standards. The compilation contains compositional specifications for individual additives as well as standards for manufacturing and use of these additives. The compilation is updated periodically to introduce new and improved test methods commensurate with the progress in science and technology, and to achieve international harmonization of standards. Japan’s Specifications and Standards for Food Additives is the English translation of the official compilation of food additives. [http://www.nihs.go.jp/dfa/dfa-j/shokuten\\_kikaku\\_j.html](http://www.nihs.go.jp/dfa/dfa-j/shokuten_kikaku_j.html)

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## 7. International Guidelines for Food Colorants

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There are two international organizations established to address food additive safety, standards, and guidelines. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) was established in 1955 as an independent scientific expert committee to foster harmonization of food laws among countries as well as internationally agreed-upon standards. JECFA scientific committees examine the technical purpose of specific food additives, perform risk assessments, define conditions for their safe use, and provides expert advice to FAO, WHO and the member countries of these organizations, as well as to the Codex

Alimentarius Commission (CAC) through subsidiary general subject committees (<http://www.fao.org/fao-who-codexalimentarius/committees/en/>). The advice to CAC on food additives, contaminants and naturally occurring toxicants is provided through the Codex Committee on Food Additives (CCFA). For color additives, JECFA considers all relevant information from literature, governmental sources and industry to determine a safe level of human exposure, the acceptable daily intake (ADI). The ADI is based on the best scientific data on hazard characterization from all available toxicity studies and data related to metabolism and pharmacokinetics of the colorant. JECFA makes a safety determination based on the ADI and taking into account estimated daily (human) intake (EDI) from data provided on the amount of the food colorant in food with a goal of contributing to international harmonization of safe food standards. Food colors concluded by JECFA to be safe for use in foods are generally acceptable in countries that either adopt Codex in its national regulations or look to Codex in the absence of their own food regulations.

CAC was created in 1963 to carry out the implementation of the joint work of the FAO and WHO on matters related to food standards, including additives and food additive regulations. One of the CAC goals is to develop food standards, guidelines and global food-related practices that impact health and technology. An important activity of the Codex Alimentarius is preparation of documents as reference standards for safe food production in all countries and to foster harmonization of food laws among countries<sup>41</sup>. The CODEX General Standard for Food Additives (GSFA) containing provisions for use of food additives, including colors is updated annually<sup>42</sup>.

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## 8. Safety Assessment of Food Colorants

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Safety assessment of directly added food colorants is part of food additive risk assessment and is conducted according to published safety assessment guidelines of international organizations (e.g. JECFA), as well as under guidelines of individual countries (e.g. Australia, Canada,

Japan, US) or regional jurisdictions (e.g. EFSA). Even though most countries have food additive safety regulations in place and their processes for safety assessment may vary, there are many commonalities in data requirements, required batteries of toxicity tests, listings of approved substances, and requirements for premarket approval of direct food additives. Some general safety principles related to food additives, including food colorants, are universally applicable in all countries and jurisdictions. Directly added food colorants undergo safety assessment testing including at minimum a battery of *in vitro* tests to identify cellular and genetic damage and animal studies to test for *in vivo* toxicity, and may additionally include testing for reproductive toxicity, and carcinogenicity.

The safety assessment of food color additives follows the general principles of hazard assessment, exposure assessment and risk assessment:

- There is no test system that can prove a negative, i.e. absolute absence of effect in the entire population. Safety testing systems *in vitro* and *in vivo* are only proxy models of toxicity from which effects in humans can be extrapolated based on common biological mechanisms.
- The safe human intake level of a food additive, termed the acceptable daily intake, ADI, is based on a no-observed-adverse-effect-level (NOAEL) derived from well-designed animal studies.
- Consideration should be given to potential interactions with other food components that may form potentially harmful substances.
- Use levels should be based on scientific judgment of the conditions of use that result in no harm to humans. Use levels needed for technological effect are used to estimate human exposure relative to the ADI and if needed maximum levels (ML) are established to ensure the ADI is not exceeded.
- Consideration should be given to uniquely susceptible subpopulations of humans.

The US FDA has rigorous testing guidance in place for all substances added to food, including food color additives with testing parameters defined in the FDA Redbook<sup>33</sup>. However, there are different levels of concern regarding the toxicity potential of a substance that are based on anticipated human intake, structural alerts for toxicity

and/or preliminary toxicity data. The level of concern determines the extent of required toxicity testing. Expert scientific judgment is needed for the interpretation of results of initial tests and key issues and findings that may or may not trigger the need for additional tests. The higher the level of concern in predicting a hazard that might result in human harm, the more extensive animal testing that will be required.

For Europe, all food additives must be authorized and listed with conditions of use based on a safety assessment, the technological need, and assurance that use of the additive will not mislead consumers. The EU directive<sup>34</sup> specifies specific conditions for use of color additives and labeling requirements for foods containing certain food colorants. Risk assessments and safety for food additive colorants are evaluated by EFSA expert panels based on review of all published and relevant scientific toxicity studies as well as data on human exposure, and consideration of potential allergenicity, as described in several published EFSA guidance documents<sup>43-46</sup>. As of 2016, the EFSA Scientific Panel on Food Additives and Nutrient Sources Added to Food (ANS) completed the re-evaluation of the safety of 41 previously authorized food colors in use before 2009 taking into account any available new studies. EFSA is charged with evaluating the safety of new food colors or new uses of existing food colors before they are authorized in the EU.

The Japanese Food Safety Basic Law, established in May 2003, provides the basis for food additive regulations with creation of the Cabinet level Food Safety Commission that recommends and implements policies on effects of food, including food additives, on human health<sup>47</sup>. The Commission identifies hazardous substances in food products and combined with scientific knowledge determines risk to health based on food intake. Determination of maximum use levels falls to MHLW and the Ministry of Agriculture, Forestry and Fisheries (MAFF). Guidelines to define the necessary data required to assess the safety of food additives are prescribed by the Food Safety Commission of Japan (FSC)<sup>48</sup>.

The safety assessment of food color additives conducted within the different national and regional jurisdictions as described above are consistent with international risk

assessment guidance documents<sup>49,50</sup>. All the above guidance documents describe similar procedures for risk assessment of chemical substances added to food including food colors. Furthermore, these risk assessment criteria and procedures used by JECFA, the US FDA, EFSA, or Japan's FSC apply to food colors regardless of their synthetic or natural origin. For color additives from natural edible sources, due considerations are given to their intake from the original sources and the long history of safety of human consumption of the foods of origin. These considerations are included in their safety evaluation. The complex composition of extracts from natural sources compared to chemically synthesized substances often require additional information on their manufacturing process and composition with attention to possible impurities or enrichment of any co-extracted natural constituents as described in the JECFA safety evaluation guidance<sup>50</sup>. In Europe, color additives defined as coloring foods are assessed with different safety criteria by virtue of their definition as foods rather than additives, as described in an informal guidance document that was developed by Standing Committee on the Food Chain and Animal Health, EU member states and relevant stakeholders and published in 2013<sup>37</sup>. A technical report was published in 2015 by the Joint Research Center to support the implementation of this guidance of the European Commission<sup>38</sup>. The 2013 guidance document is currently undergoing legal review by the European Commission and an updated version is expected to be republished upon completion.

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[日本語訳(要旨)]

## 合成および天然着色料

Robert R. Maronpot<sup>a)</sup> Shim-mo Hayashi<sup>b)</sup> Maria Bastaki<sup>c)</sup>

<sup>a)</sup>Maronpot Consulting LLC

<sup>b)</sup>Division of Food Additives, National Institute of Health Sciences

<sup>c)</sup>International Association of Color Manufacturers (IACM)

健康意識の向上とケミカルフリー食品の世界的な志向を背景に、近年、食品および飲料に使用する着色料は合成着色料から天然着色料へ関心と需要が移りつつある。各国の着色料の定義と規制には多くの共通点があり、米国、EUおよび日本からはその詳細が提供されている。FAO/WHO合同食品添加物専門家会議 (JECFA) およびコーデックス委員会 (CAC) といった国際的な組織からは、着色料の安全性からその製造販売に至るまでの全般的なグローバルガイダンスが提供されており、消費者の安全を最大限に確保すべく、最新の安全性評価基準と規制が多くの国々で整備されている。

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 PROFILE
 

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**Robert R. Maronpot**

 Maronpot Consulting LLC  
 DVM, MS, MPH, DACVP, DABT, FIATP

Dr. Maronpot received his Doctorate of Veterinary Medicine in 1965 from Michigan State University, an M.S. in nutritional pathology from Michigan State University in 1966, and an M.P.H. from Harvard University in 1972. He is a Diplomate of the American College of Veterinary Pathologists as well as the American Board of Toxicology and has worked over 50 years in experimental pathology with emphasis on animal models of carcinogenesis and liver histopathology. Dr. Maronpot previously served as President of the Society of Toxicologic Pathology, President of the International Academy of Toxicologic Pathologists, served on several journal editorial boards, and was Editor-in-Chief of Toxicologic Pathology from 2001 to 2004, received the Society of Toxicologic Pathology Lifetime Achievement Award in 2008. In addition to over 300 peer-reviewed publications, he has edited a comprehensive text entitled "Pathology of the Mouse" (1999) and co-edited a book entitled "Pathology of Genetically Engineered Mice" (2000).


**Shim-mo Hayashi**

 Division of Food Additives, National Institute of Health Sciences  
 Visiting Professor, Tokyo University of Agriculture and Technology  
 Visiting Scientist, Osaka Prefecture University  
 DVM, MS, PhD, DJSTP, DJCLAM, FIATP

Dr. Hayashi received his Doctorate of Veterinary Medicine in 1985 from Osaka Prefecture University College of Veterinary Medicine, an MS in veterinary pathology from Osaka Prefecture University, completed an anatomic and molecular pathology residency at Osaka City University Medical School, and a PhD degree in veterinary and toxicologic pathology from Osaka Prefecture University. He went to National Institute of Environmental Health Sciences, North Carolina in the United States as a guest pathologist from 1999 to 2000. He is a diplomate of the Japanese Society of Toxicologic Pathologists (JSTP) as well as the Japanese College of Laboratory Animal Medicine, and is a Fellow of the International Academy of Toxicologic Pathology (IATP). Dr. Hayashi is globally recognized for his scientific expertise and serves in multiple scientific advisory roles including the IATP Accreditation Committee representative for Asia/Pacific Region, the JSTP board of Directors and Chairperson of the JSTP International Committee. He is an *ad hoc* member of Global Toxicologic Pathology President's Groups. He is also an active member of the Executive Council of Global Editorial Steering Committee (GESC) of the International Harmonization of Nomenclature and Diagnostic Criteria for Lesions (INHAND). GESC oversees the overall objectives of the INHAND projects to perform a collaborative process to review, update, and harmonize existing nomenclature documents and databases. Based on his scientific and technical credentials and scientific knowledge, Dr. Hayashi serves a current official member of the Japanese delegation for CODEX Committee of Food Additives. He serves as a council of several professional societies other than JSTP including the Japanese Society of Veterinary Science, the Japanese Society of Toxicology, and the Japanese Society of Food Chemistry. In addition to several journal editorial boards, he served the Director of Foods and Food Ingredients Journal of Japan from 2017 to 2019. He received an Outstanding Contribution in Reviewing Award from "Food and Chemical Toxicology" in 2017. He has published numerous peer-reviewed journal articles and book chapters, and most recently he co-edited the JSTP Textbook entitled "Toxicologic Histopathology" in 2017 (Nishimura Company Limited, Tokyo, Japan). He has been fostering and promoting the need for global harmonization and assessment of multiple regulatory safety requirements for food additives especially food flavorings and food colorants.


**Maria Bastaki**

 Scientific Director  
 International Association of Color Manufacturers (IACM)  
 PhD

Dr. Bastaki received her Doctorate of Pharmacology in 1994 and her Bachelor of Science in Pharmacy in 1988 from the University of Patras, Greece. She has engaged in academic research on angiogenesis inhibitors, tumor growth, and endothelial cell biology at the Gray Laboratory, London, UK and the University of Brescia, Italy; mechanisms of hepatocyte polarity at Johns Hopkins School of Medicine; and molecular epidemiology and genetic susceptibility at the University of California, Berkeley. Dr. Bastaki is the Scientific Director of the International Association of Color Manufacturers and senior staff toxicologist for two food flavor industry associations, the Flavor and Extract Manufacturers Association and the International Organization of the Flavor Industry. She conducts safety assessments as leads scientific efforts and activities in support of flavor ingredients and food colors safety, including conduct of new toxicity studies, exposure assessment, new color additive petitions, and communication of scientific information to the US FDA, EFSA, JECFA and other regulatory or expert bodies. Dr. Bastaki has authored numerous publications on food color and flavor ingredient safety.