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Colorants in Food Packaging: FDA Safety Requirements

Deciphering the regulations surrounding food color additives

The U.S. Food and Drug Administration (FDA) scheme for regulating colorants used in packaging and other food contact applications is the result of a long-time-in-the-making, confusing mix of regulatory rulemakings and exceptions. Thus, although conceptually complicated because of the manner in which FDA handled the rulemakings, in fact, the practicalities of determining the status of a colorant are not terribly difficult to understand relative to any other food additive.

Pigments, dyes and the like are the subject of two statutory provisions mandated by Congress: The Food Additives Amendment of 1958 and the Color Additives Amendment of 1960. While both laws amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938, determining which of the two provisions applies, along with the applicable regulatory scheme of each, depends on the function and intended use of the substance in question. Specifically, the Color Additives Amendment applies only to substances that are used to color food, drugs, cosmetics, the human body and some medical devices; on the other hand, substances used to color a packaging material, but do not impart color to food, are regulated as food additives. The former are referred to as color additives, the latter as colorants.

Colorants for Food Packaging

The FD&C Act defines both food additives and food contact substances. A "food additive" is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food," unless it is generally recognized as safe (GRAS), subject to a prior sanction or a color additive. The act also defines a "food contact substance" as any substance intended for use as a component of a material used in the manufacturing, packing, packaging, transportation or holding of food that is not intended to have a technical effect in food. Food contact substances that migrate to food are considered to be food additives.

The FD&C Act defines a color additive, on the other hand, as a dye, pigment or other substance that when added or applied to a food, drug, cosmetic or the human body is capable of imparting color thereto, except if FDA determines that a material is used solely for a purpose other than coloring. Note that there is no GRAS or other exception to the color additive definition. Thus, if a colorant used in a food packaging material imparts color to food, it is a color additive. If it imparts color only to the packaging material and not the food, it is a food additive.

The FD&C Act requires substances that are "food additives" to be cleared or authorized by the agency prior to their use with or in food. As a consequence of the definition of a food additive and the exclusions that are provided, as with any food contact substance, a colorant may legally be used in food packaging if it is: not reasonably expected to become a component of food; considered GRAS among experts qualified by scientific training and experience to evaluate its safety; used in accordance with a prior sanction or approval issued prior to 1958; or is the subject of a "Threshold of Regulation" exemption letter, a color or food additive regulation or an effective food contact notification (FCN). We begin first with this last category.

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Regulated Colorants

Colorants and optical brighteners are explicitly cleared by FDA for use in polymers under Title 21 of the *Code of Federal Regulations* (C.F.R.) Section 178.3297 ("Colorants for polymers"). A number of colorants are also permitted for use in polymers under some Threshold of Regulation listings or applicable FCNs.

A shorter list of colorants are cleared for use with paper and paperboard under 21 C.F.R. Section 176.170 ("Components of paper and paperboard in contact with aqueous and fatty foods"). These materials are also permitted for use with paper and paperboard in contact with dry foods, under 21 C.F.R. Section 176.180, by way of the cross-referencing language of 21 C.F.R. Section 176.180(b)(1). However, colorants cleared for use in polymers under 21 C.F.R. Section 178.3297 are *not* permitted, per se, for use in paper and paperboard applications.

In addition to the colorants cleared for use with paper and paperboard under the regulations, FDA has tacitly accepted an industry listing of colorants that were used in paper and paperboard prior to the enactment of the Food Additives Amendment ("the pre-1958 list").

This list was originally compiled on the basis of a survey conducted by the American Paper Institute (API) in the late 1970s, in which API members were asked to list the colorants that had been in use in paper and paperboard prior to 1958. These colorants are the subject of an FDA letter that essentially concedes their GRAS status and assures that FDA will not take any regulatory action against their continued use unless a public safety problem arises.

When a Colorant Is Not a Food Additive

A colorant used in or on food packaging that does not migrate to food is not, by definition, a food additive and may be used without FDA preclearance or other authorization. This was established in 1979, when the U.S. Court of Appeals for the District of Columbia Circuit in *Monsanto v. Kennedy* ruled that migration occurs within the meaning of the FD&C Act only if a substance's presence in food "can be predicted on the basis of a meaningful projection from reliable data." There are a couple of ways to establish that a colorant under its intended conditions of use does not migrate into food and thus is not a food additive, namely: migration testing, a 100 percent migration calculation and diffusion modeling.

The purpose of a migration study is to determine whether a substance will migrate to food using an analytical method with a suitably low limit of detection when subjected to food simulants under conditions of time and temperature that replicate actual conditions of use. FDA's guidance, *Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations*,[1] provides direction on how to conduct migration testing, such as what food simulants should be used, the time and temperatures for testing and recommended analytical methods.

Usually, though, mathematical modeling is employed as a first step in lieu of laboratory testing. There are two main options: 1) assume 100 percent of the additive migrates to the food or 2) apply modeling based on the principles of diffusion. The purpose of the calculations or modeling is to show whether the results of a migration study are a foregone conclusion, that is, the substance will not be detected under the conditions of the study.

Another way to establish that a colorant is not reasonably expected to become a component of food is to show the presence of a functional barrier. Whether a material acts as a functional barrier depends on the composition and thickness of the material that separates the substance from the food, the formulation of the substance, the time and temperature of exposure and the type of food.

FDA has determined that the following are functional barriers for all possible migrants: aluminum foil without regard to food type or temperature, and polyethylene terephthalate film at least 25 µm thick for room-temperature applications. Colorants used in printing inks on the outside of a food package are often considered acceptable for use based on the assumption that they are separated from the food by a functional barrier.

Colorants used in food packaging that are considered GRAS are also excluded from the definition of a food additive and do not require premarket clearance by FDA. Some substances have been recognized or affirmed as GRAS by FDA and are listed as such in 21 C.F.R. Sections 182, 184 and 186. However, there are many more substances that are considered to be GRAS that are not included in the C.F.R. This is because substances may be recognized as GRAS without approval of FDA based upon factual determinations on a substance's safety as made by qualified experts and supported by the published scientific literature.

On the other hand, if recognition of a GRAS determination is sought from FDA, vehicles have always been available. For example, between 1958 and 1970, FDA would issue informal opinion letters on self-determined GRAS positions when asked. FDA also provided a petitioning process that permitted industry to seek official affirmation from the agency that a substance could be considered GRAS for an intended use.

The current method provides for the submission of a notification to FDA that a particular use of a substance has been determined to be GRAS. FDA will then evaluate the data and, once any questions of the agency are resolved, inform the notifier that either it has no questions as to the basis for the determination (which implicitly means the agency has accepted the GRAS position) or that the notice does not provide a sufficient basis for a GRAS determination. This method became available for use in 1997, with FDA publication of a proposed GRAS Notification rule. It has been the sole method used by the agency since then to review GRAS determinations.

FDA and the notion of a GRAS

exception to the definition of a food additive have come under fire over the last few years. FDA was criticized not only for never finalizing its GRAS Notification proposal but also for failing to provide guidance on what data should be included in a GRAS notification and not having a system in place to review existing GRAS substances when new scientific information becomes available.

In 2014, the nonprofit activist organization Center for Food Safety (CFS) filed suit to force FDA to abandon its GRAS Notification proposal. Under a Consent Decree issued by the U.S. District Court for the District of Columbia, FDA agreed to issue a final rule on the GRAS review program by August 31, 2016. On August 17, 2016, FDA promulgated the final rule, under which the voluntary GRAS affirmation petition process will be formally replaced with a voluntary notification procedure.

Inks

The only express FDA regulation of inks is contained in 21 C.F.R. Section 73.1, a direct "color additive" clearance that covers color additive diluents. This regulation permits the use of various inks for marking food supplements in tablet form, gum and confectionary, as well as fruits and vegetables. Although FDA does not anywhere explicitly list permitted "inks" for use in polymeric or paper packaging for food, the agency, in general, permits the use of inks in food contact materials that are composed of:

- Substances listed in 21 C.F.R. Section 73.1
- Color additives cleared for direct use in food
- GRAS substances
- Substances regulated for use in food contact material if a substance's use in the ink also complies with the applicable food contact regulation; this includes materials cleared under Section 178.3297 provided the colorant is used in a polymeric-based ink, or Section 176.170 if used in paper applications
- Substances that are the subject of a prior sanction or approval issued by FDA or the U.S. Department of Agriculture
- Substances that are separated from food by a "functional barrier," such as a lacquer over the ink, or otherwise are not reasonably expected to become components of food

Safety Requirements for All Packaging Materials

Within 21 C.F.R. Section 174.5 of the food additive regulations is a requirement that all food contact substances, including colorants, among other things, be of a purity suitable for their intended use and not render food unfit for consumption. This suitable-purity requirement means that any unavoidable residues or impurities that may migrate to food must be present at sufficiently low levels so as not to render the food adulterated (i.e., harmful or deleterious to human health or imparting an off taste or odor to the food). As a result of this requirement, a colorant can be found to comply with a relevant food additive regulation or be on the pre-1958 list of colorants and nonetheless be considered unsuitable for food contact use because of more recent information developed on its safety.

Color Additive Classifications

FDA regulations classify color additives according to whether batch certification by FDA is required. Color additives exempt from certification contain pigments derived from natural sources such as vegetables or minerals. Although exempt from certification, they must still meet certain specifications and purity requirements. FDA lists these in 21 C.F.R. Section 73 of the color additive regulations.

Certifiable color additives, on the other hand, are man-made colors derived from petroleum (sometimes called coal tar dyes); each batch of a certifiable color additive must be tested by FDA to ensure that the color meets established specifications before it can be used in food, drugs, cosmetics or medical devices as permitted by the applicable regulation. Color additives that are subject to certification are found in Part 74 of the color additive regulations. FDA does not recognize color additive clearances or certifications from any foreign country. These regulations recognize three categories of certifiable color additives:

1. Food, Drug & Cosmetic – color additives certified for use in food, drugs or cosmetics
2. Drug & Cosmetic – color additives certified for use in drugs and cosmetics only
3. External Drug and Cosmetic – color additives certified for use in drugs and cosmetics that are applied externally

Each certifiable color additive is identified according to its category and an FDA-assigned number, which identifies particular colors based on their formulation and hue. Together, the system permits accurate identification and labeling of color additives. Of the three categories of color additives, FDA holds FD&C Act colorants to the highest level of scrutiny because they are approved for the widest variety of uses, including addition to food.

Conclusion

The rules of thumb for determining the regulatory status of a pigment or dye are as follows: A substance that colors the food, even if it is in a packaging material, is a color additive and may be used only as permitted by an applicable FDA color additive regulation. Substances that color only a packaging material, and do not impart color to the food, are regulated as food additives if components of the substance are found to migrate into food. No premarket clearance by FDA is required, however, if the substance is not reasonably expected to become a component of food, is GRAS or is included on the list of "pre-1958 colorants." ■

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Reference

1. www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm081818.htm.