Organic Materials Review Institute

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RE: Sunset Recommendations - Colors
Sent Via E-Mail to: Katherine.Benham@usda.gov.

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Dear Ms. Benham:

OMRI appreciates the opportunity to comment on the proposed renewal of sunset items on the USDA National List of Allowed and Prohibited Substances (National List), 7 CFR 205.601 – 205.606. As stated in previous comments, OMRI sees the Sunset process as an important and necessary step in maintaining the National List and keeping it up to date.

As a general rule, however, OMRI does not take position regarding the renewal or renewal or removal of any substances on the list. Only in cases where our work has identified confusion or a lack of clarity with resulting inconsistencies do we comment.

Executive Summary

'Colors–Nonsynthetic sources only' should not be renewed on the National List of allowed non-organic nonagricultural ingredients used in or on organic processed foods. As currently listed, the item does not have a clear standard of identity. The annotation is not enforceable and subject to varying interpretation. There is no petition for non-synthetic colors as a category, no TAP review, and no NOSB recommendation prior to its appearance on the National List. The review conducted for sunset fails to address the criteria in the Organic Foods Production Act. Individual colors may be synthetic or non-synthetic depending on the origins and processes used to manufacture them. Most natural colors are agricultural products. OMRI recommends that colors be removed from 7 CFR 205.605(a), that colors in organic food from agricultural sources be treated as any other agricultural ingredient, and that non-agricultural colors be considered on an individual basis through the petition process.

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Colors

OMRI is responding to the NOSB Processing Committee's recommendation on both colors and flavors. While most of our comments focus on colors, we acknowledge that many of the comments apply also to flavors. There are, however, significant technical differences. The NOSB should consider the colors and flavors separately.

The inclusion of colors on the National List is problematic for five reasons that we have identified:

1) Standard of Identity
2) Procedural Irregularities
3) Process Verification
4) Agricultural Origins
5) Health concerns

Standard of Identity

Even if so-called 'colors, nonsynthetic sources only' remain on the National List, there is ambiguity over what colors comply with the annotation. It is difficult to comment on 'colors, nonsynthetic' because it is not clear what falls within the category. Some colors are commonly referred to as 'natural colors,' but even that term has no accepted industry standard of identity. The Color Additives Amendment of 1960 removed any prior differentiation between synthetic and non-synthetic colors (Zuckerman, 1964). The Technical Advisory Panel (TAP) Overview provides a description of the batch certification process and exemption from batch certification, so there is no need to repeat it here (TAP, 2005). Natural occurrence is a factor in exempting a color from batch certification. However, the exemption from batch certification does not ensure that a given color is non-synthetic, and not all non-synthetic colors are exempt from batch certification.

One source considers all color additives to be 'fabricated' products (Marmion, 1991). The FDA Policy Guidance on food labeling indicates an objection to the reference to colors as either 'food' or 'natural.'

> The use of the words "food color added," "natural color," or similar words containing the term "food" or "natural" may be erroneously interpreted to mean the color is a naturally occurring constituent in the food. Since all added colors result in an artificially colored food, we would object to the declaration of any added color as "food" or "natural." (US FDA, 1976).

Most items that appear on the National List are single substances rather than categories of substances. There are a few broad categories of substances, such as enzymes and flavors, but both of these categories have a petition from the industry and a record of what the NOSB considered to fall within those categories prior to making their recommendation. A major reason for the lack of clarity regarding non-synthetic colors arises from the lack of a petition and TAP review.

Procedural Irregularities

As noted in the Overview conducted by the TAP, colors were not added to the National List as the result of a petition (TAP, 2005). Unlike every other substance on the National List, there is no record of a TAP review, position paper, or NOSB recommendation prior to natural colors appearing on the National List. In 2001, OMRI requested that colors be removed from the National List as a technical correction to an apparent drafting error (Brown Rosen and Baker, 2001).

Because natural colors were never petitioned and because colors are not a single, well defined substance, it is unclear what substances are covered by the listing. In response to the 1997 proposed rule, the USDA received considerable public comment against placing any item on the National List that had not gone through all the steps in the petition process.

Colors are distinctly different from other items scheduled for sunset. Various references acknowledge that the use of color additives have long been controversial and often considered a deceptive practice (Saltmarsh, 2000). A survey of organic food processors found that colors were considered one of the additives least compatible with organic processing (Raj, 1990). The lack of a petition indicates that there was no solid support for colors so there was no point to debate or challenge them. The procedural issues are a concern for public health, because the food safety literature has identified that specific colors such as annatto and carmine are capable of eliciting allergic sensitization (Taylor and Hefle, 2001).

While the overview provided to the NOSB for sunset addresses some of the criteria in the OFPA, they are not all addressed. In fact, the Overview identifies a number of concerns for specific colors that should be studied in greater depth, suggesting that a case-by-case review is more appropriate. Like all other items on the National List, individual coloring substances should be petitioned, that petition should be reviewed by the Technical Advisory Panel, and the NOSB should make a recommendation based on that TAP review and petition. Without a petition, it is not possible to understand what the industry requested. Without a TAP review it is not possible to assess the claims made regarding the health, safety, and environmental impacts of permitting using the criteria in the Organic Foods Production Act.

The NOP standards allowance of non-organic colors poses several issues for international trade. Non-organic colors are not categorically permitted in the European Union Regulations on organic food products [EC 2092/91], the Japanese Agricultural Standards for organic processed food products [JAS 60], the Codex Alimentarius guidelines on organically produced foods [CAC GL32-1999 rev. 1-2001], or the IFOAM Basic Standards (IFOAM, 2005). Conversely, the FDA identifies color additives that are not permitted in the US, but appear in imported food to be a problem area (FDA, 2001b). Therefore, the assumption that FDA regulations are sufficient to address safety concerns related to colors may not be valid when dealing with imported organic food products.

Process Verification

With the NOP's evaluation of the NOSB's recommendation on the definition of synthetic (Frances, 2006a), and recommended framework to further clarify the definition of synthetic (Frances, 2006b), the need for a case-by-case review of colors becomes even more apparent. Certifiers often do not check the origin, sources, and manufacturing processes of non-agricultural substances that appear on the National List.

With single, well-identified items that are on the National List, verification that a given ingredient meets the established standard of identity is relatively simple. The presumption is that because a substance was petitioned, received a TAP review, and was recommended by the NOSB, no further verification is needed. With flavors, the NOSB came up with clear, verifiable guidelines consistent with organic production and handling, even though it did not require a full TAP review or case-by-case evaluation of flavors.

The premise that certifiers do not need to look at the manufacturing process of a non-organic ingredient because it was evaluated during the National List process is obviously false in this case. The NOSB did not recommend that colors extracted using volatile synthetic solvents or in synthetic carriers appear on the National List. Such solvents are synthetic incidental ingredients that would need to be reviewed. It is unclear what meets standard of identity for non-synthetic colors, particularly when petroleum derived solvents are used in the extraction process. For example, turmeric oleoresin may be extracted by one or a combination of the following solvents: acetone, ethyl alcohol, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, and trichloroethylene (Marmion, 1991). While this was considered and discussed with flavors, there are significant technical differences with colors that need to be considered.

More important to the case of colors are the aniline, azo, and other coal tar derivatives used to make dyes, and the metals that are used to make lakes. These are obviously synthetic substances, but their coloring agents often come from plant or animal sources. It is OMRI's opinion that such colors are synthetic. The industry needs greater clarity what given colors are 'non-synthetic.' Every component needs to be non-synthetic, including substances used to extract, stabilize and disperse the coloring agent.

Colors that are exempt from batch certification are not necessarily natural. Some familiar 'natural' colors may be wholly synthesized. While some may assume that all ß-carotene (INS 160; CAS 7235-40-7) is naturally derived from carrots or other orange vegetables, in more recent years commercial sources have been factory produced by synthesis from acetone (Marmion, 1991). These are acknowledged to be synthetic, and are marketed as 'nature identical' as opposed to 'natural' (Downham and Collins, 2000). Also, a growing number of coloring agents are potentially produced from genetically modified organisms or by 'excluded methods' prohibited under 7 CFR 205.105(e) (Downham and Collins, 2000).

Because of international trade, it is not safe to assume that all organic handlers and processors are operating under the FDA's jurisdiction or subject to FDA regulations. A

number of colors that have been banned in the United States could be considered to be non-synthetic, thus rendering the safety of a blanket category of 'colors–non-synthetic' suspect.

Various synthetic dyes are given natural sounding names. For example, amaranth is a plant that is cultivated and could potentially be a source for a non-synthetic color. However, amaranth is also known as FD&C Red Dye #2. While the amaranth plant was once used in the process to make FD&C Red Dye #2, it is more accurately described as a monoazo or azoaniline coal tar derivative. FD&C Red Dye #2 was banned by the FDA (2001a).

Some ingredients used for coloring may be of agricultural origin, but also are produced synthetically and commonly contain synthetic ingredients used as preservatives or carriers. FD&C Blue No. 2 can be made from indigo, and is one of the oldest known and most extensively utilized natural pigments (von Elbe and Schwartz, 1996). FD&C Blue No. 2 can also be synthesized (Merck, 2001). However, indigo is not exempt from the requirement of batch certification, even when it is extracted from an indigo plant [21 CFR 74.102].

Agricultural Origins

Agricultural products are often used to make colors. Corn, cottonseed, beets, carrots, grapes, marigolds, turmeric, and paprika all are clearly agricultural and therefore do not qualify to be included in a category that appears on a list of 'nonagricultural' substances.' Agricultural ingredients used as ingredients in organic food products are supposed to be organically produced [7 CFR 205.270; 7 CFR 205.301]. Colors of agricultural origin should be subject to the same rules as any other agricultural commodity. The growing market for organic food is seen as an obstacle as well as an opportunity for the makers of food colorings in those markets—such as the European Union—that do not permit non-organic colors (Downham and Collins, 2000).

Health Concerns

Annatto, caramel, and carmine can be used as models to illustrate the various origins of colors, and discuss possible health concerns related to specific colors.

Annatto

Annatto (INS 160b; CAS 1393-63-1) is a carotenoid pigment produced from the bean-like fruit of achiote, *Bixa orellana,* a tropical bush that originated in South America and is cultivated in various tropical regions. Annatto is extracted from the thin layer of intense pigmentation on the pericarp on the seed. The principle components of annatto that provide color are bixin, an oil-soluble orange-red and its water-soluble analogue norbixin. One method of extraction uses alkaline hydrolysis that involves a 5% solution of potassium hydroxide at a pH of 12-14. Annatto can also be obtained through oil processing or solvent extraction. The FDA also allows acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, and trichloroethylene all

to be used as solvents to extract annatto. Solvent extracted forms are arguably synthetic, or at least inconsistent with the parallel standard applied to natural flavors.

Products sold as annatto may contain diluents, pigment enhancers, and other substances that may be synthetic. The Food Chemicals Codex has established residual tolerances of solvents of not more than 0.003% for acetone; not more than 0.0025% for hexanes; not more than 0.005% for isopropyl alcohol; not more than 0.005% for methyl alcohol; and not more than 0.003% for trichloroethylene and dichloromethane;

There are also food safety concerns about the use of bixin and norbixin. The UN's Joint Evaluation Committee for Food Additives (JECFA) recommends that countries place restrictions on the Average Daily Intake of Annatto and Bixin, and the extraction process used drives these limits. Annatto was historically prepared in an alcohol solution (MacPhail, 1864). More recently, propylene glycol (Kocher, 1958) and other synthetic carriers are used. These carriers would make the color synthetic.

Various organic products certified under the National Organic Program use organic annatto as an ingredient. When extracted with a 5% solution of potassium hydroxide, seeds from organically produced achiote would meet NOP standards to be labeled 'organic annatto,' which could in turn be used in a processed product labeled as 'organic.'

Caramel

Caramel (INS 150; CAS 8028-89-5) is made most simply from the heating of sugar (Merck, 2001). Sugar is an agricultural commodity and organic sugar is commercially available from a number of sources. Such a caramel color would be known as Class I (INS 150a), For example, caramel color can be produced by the browning of sugars without the use of synthetic acids or alkalis. Some sources consider caramel to be an 'artifact' as distinct from a natural or artificial color (MacKinney and Little, 1962).

It is unclear if caramel would be considered synthetic or non-synthetic. The answer would depend on the manufacturing process. Four distinct classes of caramel can be distinguished by the reactants used in their manufacture (Food Chemicals Codex, 2003).

Class I caramel (INS 150a) is known as 'plain caramel' and is prepared by the heating of carbohydrates, often simple refined sugar or sucrose. Class I caramel's standard of identity permits the use of synthetic acids and bases in their processing. 'Caustic caramel' is a form of Class I caramel that has been alkali treated. Some of the acids and bases used to make Class I caramel are on the National List—such as citric acid, sodium hydroxide, and potassium hydroxide.

Caramel made in the presence of sulfite compounds such as sulfur dioxide but without the use of ammonium compounds is considered Class II caramel (INS 150b). Class II caramel may or may not involve the use of acids or alkalis. Food Chemicals Codex permits a maximum of 0.2% sulfur dioxide and caramel color (Food Chemicals Codex, 2003).

Class III caramel is prepared by heating carbohydrates in the presence of ammonium compounds. Class III caramel also may or may not be treated with acids or alkalis. The NOSB determined that ammonia is synthetic, and it follows that the reaction products of ammonia would be as well (NOSB, 2001).

Class IV caramel is prepared using both ammonium and sulfite compounds, either with or without acids or alkalis.

It is therefore possible to make caramel entirely from sugar alone or sugar and substances on the National List. If sugar is an agricultural product that is commercially available in organic form, it is therefore possible to make an organic caramel. All caramel acceptable for use in organic production would be Class I, but not all Class I caramel would meet organic standards even if the main ingredient was organic sugar. Caramel made from organic sugar and that is reacted with an acid or base on the National List that does not exceed 5% by weight net of the water would qualify as 'organic' caramel.

It is OMRI's opinion that if colors remain on the National List with their current annotation, natural caramel would be limited only to plain caramel. Caustic caramel would not meet the annotation, even if it is Class I. Class II, Class III, and Class IV are all synthetic as defined by the NOP rule, and the presence of sulfites in Class II and Class IV caramel raises serious concerns regarding the general prohibition of added sulfites in organic food and associated adverse health effects on a segment of organic food buyers.

Carmine

Carmine and carminic acid (INS 120; CAS 1390-65-4) are obtained from cochineal *Coccus cacti (Dactylopius coccus costa)*–a scale insect that lives on cactus plants endemic to Mexico. The process by which the coloring agent is extracted from the insect would need to be reviewed by the NOSB in order to determine if the coloring agent is acceptable for use under the current annotation. Carmine used in food coloring is usually not the naturally extracted acid but rather an aluminum lake or aluminum-calcium lake of carminic acid produced by reaction of aluminum hydroxide (Merck, 2001). Aluminum hydroxide is a synthetic substance not on the National List and is therefore prohibited in organic handling [7 CFR 205.105(c)] Sodium benzoate is also commonly added as a preservative (Marmion, 1991).

Carmine is cited as an example of a 'natural' color exempted from safety requirements and has never been fully reviewed for its safety to the same degree as other, more recently developed colors (Barrows, Lipman, and Bailey, 2003). While the FDA has withdrawn approval for some uses, it is reported as 'permanently listed' and is considered by some to be non-synthetic (Winter, 1989). The TAP overview notes that carmine is associated with adverse health effects, in particular allergic reactions (TAP, 2005). Carmine has also been associated with salmonella poisoning (Komarmy, Oxley, and Brecher, 1967; Lang et al., 1971).

As with beeswax and shellac, carmine is the product of domesticated insects that can be managed consistently with organic livestock standards. While there is no known source of organic carmine at the present time, the development of apiculture standards can be extended to the production of cochineal bugs.

Recommendations

Once again, OMRI urges the NOSB and NOP work together to correct the technical errors in the National List.

1) The NOSB should address colors separately from flavors when considering their renewal.
2) The NOSB should *not* renew natural colors on the National List of nonagricultural ingredients used to process or handle organic agricultural products because:
   (a) there is no clear standard of identity,
   (b) the NOSB has not been presented with a petition or TAP review that addresses the OFPA criteria and did not make a recommendation prior to the appearance of colors on the National List.
   (c) Verification that sources are nonsynthetic is inadequate.
   (d) Most non-synthetic colors can be obtained from agricultural sources.
   (e) There are health concerns that need to be addressed by a more comprehensive review.
3) Sources and manufacturing processes need to be disclosed to determine whether a specific color is synthetic or non-synthetic.
4) Colors currently used in organic processing are agricultural in origin and should be treated as all other agricultural ingredients in organic food products.
5) Colors from non-agricultural sources should be petitioned on a case-by-case basis subject to the criteria in 7 CFR 205.600.

Thank you for your consideration,

David DeCou
Executive Director

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