

Responses for the NOSB Handling Committee regarding Petition to Remove Annatto from the National List 205.606

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When reviewing the petition to remove “Annatto extract color – water and oil soluble” from the general category “colors derived from agricultural products”, we ask that the NOSB please consider the below responses to the questions they developed:

1. What has changed in the five years since annatto was reviewed and approved for listing that has made annatto extract reliably available in sufficient form, quantity and quality?

Annatto extract color is no longer needed on the National List because certified organic annatto extract is now available in adequate commercial quantities and in the forms needed to meet the organic industry’s needs.

When annatto extract was added to the National List, there were no suppliers of organic annatto extract and inadequate supplies of organic annatto seeds from which to make organic annatto extracts. Since then, thanks to a determined partnership with suppliers, the situation has changed significantly. Organic annatto seeds are now commercially available and from these organic extracts can now be made. The production of organic annatto seeds worldwide has continued to grow to support increased demand. Since March 2009, organic annatto extracts have been available and demand has never exceeded supply. To avoid supply interruptions due to weather, suppliers have been developed in various regions of the globe to secure a reliable supply of organic annatto seeds.

In addition to water soluble, oil soluble, and oil soluble suspensions of organic annatto extract, an organic annatto extract powder has recently been introduced to the market. Therefore, organic annatto extracts are available in adequate commercial quantities and in the forms needed to meet the organic industry’s needs.

2. Specific to form, the NOSB has received public comment stating that two forms, dry and liquid, of annatto extract are used by handlers. What are the differences in manufacture of

these forms? What are the typical uses of each form? Please address both forms in responding to question #1.

Like the conventional product, the organic water processed annatto extract is prepared by removal of the outer coating of the seeds of the annatto tree (*Bixa orellana* L) by abrading the seeds in the presence of cold, mildly-alkaline water. Unlike the conventional product, the water soluble organic extract employs certified organic annatto seeds. This color is used in applications such as natural cheese, baked goods, snacks and confections

Like the conventional product, the organic oil processed annatto extract is prepared by removal of the outer coating of the seeds of the annatto tree (*Bixa orellana* L) by abrading the seeds in the presence of oil. Unlike the conventional product, the oil soluble organic extract employs certified organic annatto seeds and no Mono & Di – glycerides. This color is used in foods including snack foods, butter and baked goods.

The production of organic annatto powder is different than production of conventional annatto powder. Organic annatto extract powder is spray dried onto organic maltodextrin and the conventional annatto extract powder is oven dried onto a non-organic carrier. This color is used in dry mixes, baking mix, snack foods and spice blends.

3. Are you aware of any handling applications where an organic alternative of either form of annatto extract cannot be used? If so, briefly describe and explain the technical hurdles preventing use of the organic alternative.

Organic annatto extracts are now available in adequate commercial quantities and in the forms needed to meet the organic industry's needs.

Respectfully Submitted,



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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER A--GENERAL

[PART 73 -- LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION](#)

Subpart A--Foods

Sec. 73.30 Annatto extract.

(a) *Identity.* (1) The color additive annatto extract is an extract prepared from annatto seed, *Bixa orellana* L., using any one or an appropriate combination of the food-grade extractants listed in paragraph (a)(1) (i) and (ii) of this section:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under paragraph (a)(1)(ii) of this section. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures for food use made with annatto extract may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Annatto extract, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead as Pb, not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of this section are used, annatto extract shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Annatto extract may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the

name shall not be construed as requiring the declaration of residues of solvents listed in paragraph (a)(1)(ii) of this section.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

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