

Petition to remove Annatto from section 205.606

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Joint Petition From:

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Petition Purpose: To remove “Annatto extract color – water and oil soluble” from the general category “colors derived from agricultural products” of the National List .

Please accept the attached petition to remove “Annatto extract color – water and oil soluble” from the general category “colors derived from agricultural products” included on the list of non-organically produced agricultural products allowed as ingredients under 7CFR 205.606. We request review at the earliest opportunity. We respectfully request that this petition be expedited as it is a “petition to remove” a material from the National List and also considering the on-going Sunset review of colors.

“Annatto extract color – water and oil soluble” was placed on the National List in March 2007. D.D. Williamson was one of the original petitioners to add Annatto color to the National List under Section 205.606. Since then, the supply of organic annatto extract has evolved to the point that there are now certified organic annatto extracts available to replace the need for non-organic water and oil soluble forms of extract.

In preparing this petition, we have sought examples of prior “petitions to remove” and found few to follow. We have made every effort to comply with the requirements in 7CFR Part 205 and the 2007 Federal Register Notice outlining National List petition requirements.

Thank you for your assistance in putting this petition before the NOSB. If you need any additional information, please contact either Jennifer Guild or Kim Dietz.

Item A

This is a petition to remove “Annatto extract color – water and oil soluble” from the general category “colors derived from agricultural products” appearing in Section 205.606 of the National List of non-organically produced agricultural products allowed as ingredients in or on processed products labeled as “organic”.

Item B

Since “Annatto extract color – water and oil soluble” has already been accepted onto the National list, responses in this section will focus on organic certified Annatto extract color – water and oil soluble.

1. The substance’s chemical or material common name.

Organic Annatto Extract

Organic annatto extract is the extract from the seed coat of *bixaceae bixa orellana* (family, genus, species). This agricultural substance is also commonly known as “organic annatto”.

2. The manufacturer’s name, address and telephone number.

D.D. Williamson Colors LLC
815 Sunset Road
Port Washington, WI. 53074
United States
262-268-7272

3. The intended or current use of the substance.

Like non-organic annatto extract, organic annatto extract is used as a naturally derived color additive in baked goods, beverages, candies, condiments, dairy products, desserts, jams & gelatins, pet foods, snack foods, soups & sauces, and compressed tablets. Its usage as a color additive exempt from certification is permitted by the US Food and Drug Administration (FDA) pursuant to 21 CFR 73.30.

Organic annatto extract, as a naturally derived color additive, supports and promotes the organic philosophy as it is used to improve the visual appeal of organic food and beverage products which need to compete with conventional products colored with synthetic colors such as FD&C Red 40. Thus, organic annatto extract may advance the organic movement by helping organic producers present to consumers a wide variety of organic food and beverage products with competitive visual appeal.

4. Handling or processing activities for which the substance will be used.

Organic annatto extract is identical in functionality to non-organic annatto extract.

Organic annatto extract develops a deep orange to light yellow color in organic food and beverage products, depending upon its concentration. It is

used as a naturally derived color additive to enhance the visual appeal of organic products. The color itself results from very high concentrations of carotenoid molecules in the annatto seeds.

5. The source of the substance and a detailed description of its manufacturing or processing procedures.

Organic annatto seeds grow on small trees in many regions including those of the Caribbean, South America, Africa and the USA. The organic annatto seeds are collected, hulled, and crushed into small pieces, which are physically ground against one another in organic vegetable oil or alkali water. The oil or water are then filtered and concentrated, producing a dark, viscous, orange liquid concentrate composed of the same carotenoid molecules produced inside the annatto seeds.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.

In terms of government approval as a naturally derived color additive, organic annatto extract is identical to non-organic annatto extract. There are many government reviews of annatto extract, and carotenoids in general have been used since antiquity to color human food.

The United States Food and Drug Administration (FDA) recognizes Annatto Extract as a color additive exempt from certification permitted for use in foods pursuant to 21CFR 73.30.

The Food Chemical Codex (FCC) has developed a monograph for Annatto Extracts.

The European Union (EU) recognizes annatto extracts as ‘annatto, bixin, norbixin’, classified as E 160b and allowed for use in foods pursuant to 94/36/EC.

Japan Ministry of Health and Welfare (MHLW) recognizes annatto extract as the substance composed mainly of norbixin and bixin obtained from the seed coats of annatto seed. Annatto Extract is classified as a food additive of ‘natural origin’, according to the ‘List of Existing Food Additives’.

The Joint FAO/WHO expert Committee on Food Additives (JECFA) has developed monographs for aqueous processed annatto extracts.

7. Information regarding EPA, FDA, and State Regulations.

The United States Food and Drug Administration (FDA) permits the use of annatto extract, organic and conventional, as a color additive exempt from certification pursuant to 21 CFR 73.30.

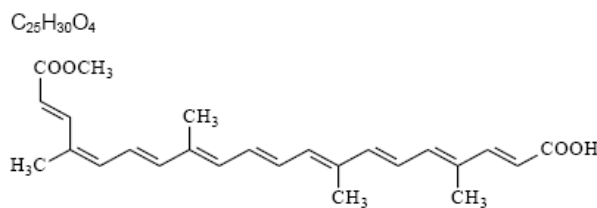
8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contain the petitioned substance.

In terms of CAS and EINECS numbers, organic annatto extract is identical to non-organic annatto extract.

The Chemical Abstract Service (CAS), a division of the American Chemical Society, assigns a unique number to each molecule in its database. Because plants rarely if ever produce a single colorant molecule, multiple CAS numbers have been assigned to multiple – but unique – molecules extracted from specific plants. For example, annatto is assigned four CAS numbers: 1393-63-1 (annatto seed); 89957-43-7 (annatto extract); 626-76-6 (cis-norbixin); and 6983-79-5 (cis-bixin). The **E**uropean **I**nventory of **E**xisting **C**ommercial chemical **S**ubstances (EINECS) assigned three EINECS numbers: 215-735-4 (annatto seed); 289-561-2 (annatto extract); and 230-248-7 (cis-bixin).

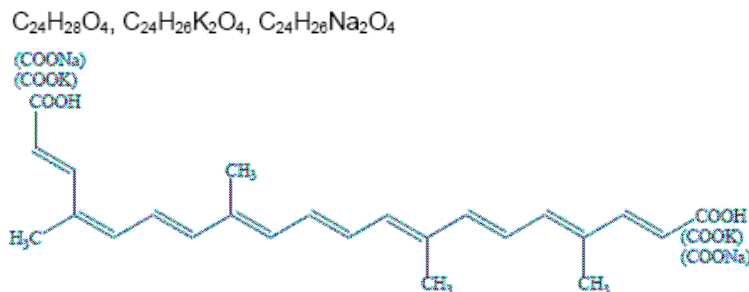
9. The substance's physical properties and chemical mode of action.

Organic annatto extract is physically identical to non-organic annatto extract.



cis-Bixin

and/or



cis-Norbixin

Organic annatto extract is a red-brown to red-purple liquid or powder used to develop a deep orange to light yellow color in organic food and beverage products, depending upon its concentration.

Like non-organic annatto, the carotenoids extracted from organic annatto seeds are distinct and unique molecules from anthocyanins and betalains (other molecules used as natural colorings). Carotenoids are sensitive to light and heat, degrading rapidly under high heat and/or direct sunlight. In addition, carotenoids display very strong antioxidant properties which now appear beneficial to human health. Beyond these unique properties, to the best of our knowledge, carotenoids do not negatively interact with substances used in organic food production and have no negative impact on the environment.

Naturally derived annatto extract has been consumed for centuries and its consumption has the exact same impact upon the environment as other organically grown, biodegradable fruits and vegetables.

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.

For safety purposes, organic annatto extract is at least as safe as non-organic annatto extract.

11. Research information about the substance.

See the attached Bibliography. Research on non-organic annatto extracts should also be applicable to organic annatto extracts. There are several leading researchers on carotenoids in the US including Minhthy L. Nguyen (formerly of Ohio State University, Columbus) and Steven J. Schwartz (Ohio State University, Columbus). In addition, there are many government reviews of annatto seed extract, and carotenoids in general have been used since antiquity to color human food.

12. (G) Justification Statements.

This is a petition to remove “Annatto extract color – water and oil soluble” from the general category “colors derived from agricultural products” appearing in Section 205.606 of the National List of non-organically produced agricultural products allowed as ingredients in or on processed products labeled as “organic”.

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.

The non-organic annatto extract still being used in organic products is developed from non-organic annatto seeds that have been grown employing conventional methods (eg. pesticides, etc.). Eliminating the use of non-organic annatto extracts would eliminate the use of non-organic annatto seeds, and the associated conventional methods, from the organic supply

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chain. Organic annatto extract would support the organic farmer, support the organic consumer and still support the organic manufacturer needing an annatto extract color. The suggested change would improve the clarity of 205.606 and make it easier for certifiers to apply and enforce. It would also remove much of the incentive for finding ways to continue using non-organic annatto extracts in organic products.

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, the situation has changed significantly. Organic annatto extracts are commercially available. Since March 2009, organic annatto extracts have been available and demand has never exceeded supply. The production of organic annatto seeds worldwide has continued to grow to support increased demand.



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13. Confidential Business Information Justification Statements.

Information contained in this petition is considered (a) financial or commercial information that the petitioner does not want disclosed for competitive reasons. Thank you for your consideration.

Respectfully Submitted,



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