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January 15,, 2007

Robert L. Pooler  
National Organic Program, AMS / USDA  
STOP 0268 – Room 4008S  
1400 Independence Avenue SW  
Washington, DC 20250-0268

ORIGINAL

Re: Petitions for the Addition of  
Non-Organic Agricultural Substances to the National List  
Pursuant to Section 205.606 of the NOP

Dear Mr. Pooler:

Thank you for your letter, dated December 20, 2006, wherein you returned our original "combined" petition for fifteen natural colorants (dated October 16, 2006) and instructed us to file fifteen "separate" petitions, one for each colorant.

Pursuant to your instructions, please find enclosed with this letter fifteen (15) separate petitions, one for each natural colorant. We enclose an original and one copy of each petition for you to review. We ask the National Organic Standards Board (NOSB) to add onto the National List the following natural colorants:

**Anthocyanins**: (1) chokeberry juice, (2) black currant juice, (3) red cabbage extract, (4) purple carrot extract, (5) elderberry juice, (6) grape juice, (7) grape skin extract, (8) red radish extract; and

**Carotenoids**: (9) annatto seed extract, (10) beta-carotene from carrots, (11) lycopene, (12) paprika, (13) saffron; and

**Betalains**: (14) beet juice; and

**Other**: (15) turmeric.

You may recall that our original petition was organized by the four categories shown above. It may be prudent -- in the interest of time -- for the NOSB to consider the enclosed petitions in these same categories / groups.

5. The source of the substance and a detailed description of its manufacturing or processing procedures: Peppers grow on low shrubs throughout South America, Africa and India. The peppers are collected, cut, and crushed into small pieces, which are physically ground against one another in vegetable oil. The oil is filtered and concentrated, producing a dark, viscous, red to orange liquid concentrate composed of the same carotenoid molecules produced inside the peppers.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance: No such government reviews of paprika are known; but carotenoids in general (particularly from carrots) have been used since antiquity to color human food. Carotenoids are therefore Generally Regarded As Safe (GRAS).

7. Information regarding EPA, FDA, and State Regulations: FDA permits the use of paprika as a color additive exempt from certification. 21 CFR 73.340 Paprika. Paprika is also permitted as a natural color additive in foods in the European Union (E160(c)) and throughout Asia.

8. The Chemical Abstract Service (CAS) number: There exists a specific CAS Number for beta-carotene. It is 1393-63-1. Further, carotenoids in general have been assigned CAS No. 7235-40-7.

9. The substance's physical properties and chemical mode of action: The carotenoids extracted from peppers / pepper oils are distinct and unique molecules. They are different from anthocyanins and betalains (other molecules used as natural color-ants). 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, carotenoids do not interact with substances used in organic food production and have no impact on the environment.

Peppers have been consumed for centuries and their growth and ultimate consumption has the exact same impact upon the environment as organically grown, biodegradable fruits and vegetables.

10. Safety information about the substance: Please see the attached Material Safety Data Sheet (MSDS). Peppers, and the carotenoids extracted from peppers, are GRAS.

11. Research information about the substance: See the attached Bibliography. There are several leading researchers on carotenoids in the US including Carol Locey (Kalsec, Inc.), Minhthy L. Nguyen (formerly of Ohio State University, Columbus), and Steven J. Schwartz (Ohio State University, Columbus).

12(G) Justification Statements:

Enhanced Visual Appeal Using Natural Colorants. Food safety dictates that processed foods must be fully cooked to assure low bacterial counts for extended shelf-life and broad geographical distribution. Many food and beverage processors also employ a low pH environment and/or low water activity and/or or low temperature distribution of the finished product (refrigeration or freezing) to further assure minimal bacterial counts. These processing parameters are challenging to colorants residing inside the "core food" (for example, chlorophyll inside florets of broccoli, paprika inside cut peppers, or anthocyanins inside strawberry preserves).

The addition of natural colorants compensates for the "original" colorants destroyed by high temperature / low pH processing. In so doing, the finished organic food or beverage product presents to the consumer the same visual appeal it would have if it were fresh. The addition of natural colorants can also enhance an existing color, making the organic food or beverage even more appealing; or it may extend the shelf-life of an organic food or beverage, making it available to more consumers both over time and geographical distance.

Without the addition of natural colorants, organic food and beverage products might lack the visual appeal and attraction of their direct non-organic competition. Thus, natural colorants help organic processors compete.

In so doing, natural colorants advance the organic philosophy by (literally) displaying to consumers visually appealing organic food and beverage products brightly colored without artificial colors such as FD&C Yellow 5.

Low Usage Levels of Natural Colorants. Because natural colorants are concentrated and very strong, they are used in organic food and beverage products at very low levels, typically less than 1%. The inherent strength of natural colorants sets in motion or "triggers" two distinct events: (1) natural colorants always fall under the 95 / 5 rule where five percent of the ingredients in an organic product may be non-certified; and (2) the volume of natural colorants purchased is very small.

By way of example, a hypothetical organic dairy develops organic certified yogurt. First, new product developers add paprika (and the appropriate emulsifiers) at 0.5% of the formula. They do not actively seek out organic certified paprika because they know the ingredient easily falls under the 95 / 5 rule. Second, the dairy's new product is successful and within the first year it produces 500 tons of organic certified yogurts. Despite such success, the dairy would purchase only 833 lb of paprika per month. This low volume of natural colorant sales, combined with inclusion of natural colorants in the "five percent non-certified" portion of the formula, provides little or no economic incentive to certify natural colorants as organic.

In the future, we anticipate the total amount of organic food and beverage products to increase. We may reach a point in time where a strong economic incentive places natural colorant crops under organic systems of production. It should be noted that no ingredient may remain on the National List for more than five (5) years without review by the National Organic Standards Board (NOSB).

The NOSB must therefore review the status of natural colorants five years hence (roughly 2012) and, at that time, may discover that an adequate supply of natural colorants is available for use in organic foods and beverages.

*International Production of Natural Colorants.* Most natural colorants are derived from International fruit and vegetable crops grown in developing countries; there is little International acreage certified organic. Most international organic acreage is utilized for corn, sugar and grains. Further, organic certification of International acreage remains problematic, plagued by cultural, financial, and language difficulties. Moreover, most fruit and vegetable crops are typically consumed where they are grown. As a result, there is a limited supply of the requisite fruit and vegetable crops needed for the creation of natural colorants.

Thus, natural colorants are not available in the appropriate quantity from International sources to meet the needs of organic processors.

*Domestic Production of Natural Colorants / The Current State of the US Organic Industry.* Certified organic cropland and pasture accounted for about 0.5% of total US farmland in 2005. Only a small percentage of top US field crops – corn (0.2%), soybeans (0.2%), and wheat (0.5%) – were grown under certified organic farming systems. Organic peppers (6% of the US carrot acreage), organic lettuce (4% of US lettuce acreage), and organic apples (3% of US apple acreage) were more commonly grown organic.

Markets for organically grown fruits and vegetables have been developing for decades in the US, and fresh produce is still the top-selling organic category in retail sales. Organic livestock was beginning to catch up with produce in 2005, with 1% of US dairy cows and 0.6% of the layer hens managed under certified organic systems. After decades of strong growth, the US organic marketplace is a bountiful “Farmers’ Market” for consumers, but it does not supply the appropriate quantity of natural colorants for organic food processors.

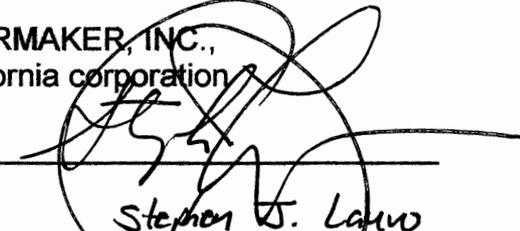
Because there is no current supply of organic certified natural colorants from International sources, and because there is no current supply of organic certified natural colorants from US sources, and because natural colorants at levels below 5% greatly improve the visual appearance of organic foods and beverages, this Petition seeks the addition of natural colorants to the National List.

13. This Petition respectfully seeks the addition of paprika, a.k.a. "oleoresin paprika," to the National List as a non-organic agricultural product under Section 205.606 of the NOP.

Respectfully Submitted,

COLORMAKER, INC.,  
a California corporation

By:



Stephen J. Lawo  
(Name & Title)

DD WILLIAMSON, INC.  
a Kentucky corporation

By:



Margaret A. Lawson  
(Name & Title)  
VP Science & Innovation

<p><b>ColorMaker, Inc.</b>  3309 East Miraloma Ave., Suite 105  Anaheim, California 92806  (714) 572-0444  (714) 572-0999 fax</p> <p><i>inquire@colormaker.com</i></p>	<p style="text-align: center;"><b>Hazard rating at a glance</b>  0-least, 1-slight, 2-moderate, 3-high, 4-extreme</p> <p>HEALTH <span style="float: right;">0</span></p> <p>FLAMMABILITY <span style="float: right;">0</span></p> <p>REACTIVITY <span style="float: right;">0</span></p>
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## MATERIAL SAFETY DATA SHEET

### 1. *Product Identification:*

- 1.1 Product Name: Standard Oleoresin of Paprika
- 1.2 Product Number: 2743
- 1.3 Ingredient Statement: Paprika
- 1.4 Description of Product: An orange liquid designed to color and function in fat & oil-based food products. Specific formulation is withheld as a trade secret pursuant to 21 CFR 20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21 CFR 73. None of the ingredients appear on the list of hazardous items established under California's Proposition 65.

### 2. *Hazardous Ingredients and Exposure Limits:*

- 2.1 It is our opinion that the above named product does not meet the definition of a "Hazardous Chemical" as defined in 21 CFR 1910.1200. This MSDS is provided as general information for health and safety reasons.

### 3. *Health Hazard Data*

- |     |                   |                              |
|-----|-------------------|------------------------------|
| 3.1 | Carcinogenic      | None known.                  |
| 3.2 | Acute Toxicity    | None known.                  |
| 3.3 | Oral LD50         | Not determined.              |
| 3.4 | Dermal LD50       | Not determined.              |
| 3.5 | Ingestion         | None known.                  |
| 3.6 | Skin Contact      | None known.                  |
| 3.7 | Irritation (skin) | None known.                  |
| 3.8 | Irritation (eye)  | May cause slight irritation. |

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#### 4. *First Aid Measures*

- 4.1 Eye Contact Remove contact lenses and flush eyes with copious amount of water for at least fifteen minutes. Contact physician if irritation persists.
- 4.2 Skin Contact No significant health hazard. Wash exposed skin with soap and water for at least fifteen minutes. If irritation persists, consult a doctor.
- 4.3 Ingestion Administer 1 - 2 glasses of water or milk to dilute. DO NOT INDUCE VOMITING. Seek medical attention if it seems advisable.

#### 5. *Fire Fighting Measures*

- 5.1 Flash Point (method used) Not determined.
- 5.2 Flammable Limits Not determined.
- 5.3 Unusual Fire & Explosion Hazard None known.
- 5.4 Extinguishing Media Carbon dioxide, dry chemical, foam, and water spray.

#### 6. *Spill, Leak, and Waste Disposal*

- 6.1 Absorb spills on vermiculite or other absorbent materials. Remove to approved disposal containers. Use rag and mop to clean small spots or dilute with large amounts of water. Colorant is biodegradable.

#### 7. *Handling and Storage*

- 7.1 Store in a cool dry area. The wearing of rubber gloves and safety glasses to prevent skin and eye contact is recommended. Store in tightly closed containers.

## 8. *Exposure Protection*

8.1	Respiratory	No special equipment under normal conditions of use.
8.2	Skin	Skin protection appropriate to use conditions.
8.3	Eye	Safety glasses must be worn at all times
8.4	Hand	Suitable gloves.
8.5	Other	None

## 9. *Physical / Chemical Characteristics*

9.1	Appearance	Orange liquid
9.2	Boiling Point	Not established
9.3	Vapor Pressure	Not established
9.4	pH value	N/A
9.5	Solubility in Water	NONE; soluble in oil
9.6	Specific Gravity	To be established

## 10. *Stability and Reactivity*

10.1	Stability	Stable.
10.2	Incompatibility	Avoid strong oxidizing agents.
10.3	Hazardous Decomposition	Not known.
10.4	Hazardous Polymerization	Not known.

## 11. *Toxicological Health Hazards*

11.1 None known. Colorant is naturally derived and biodegradable.

## 12. *Ecological Effects*

12.1 None known. Colorant is naturally derived and biodegradable

## 13. *Disposal Considerations*

13.1 Incineration. Observe local, State, and Federal regulations concerning health and the environment. Do not incinerate in sealed containers.

*The information contained herein is based upon data considered accurate and reliable. Nevertheless, an independent investigation and verification of this information should be made by the user. No warranty is made, expressed or implied, regarding the accuracy or correctness of these data. The use of this information and this product are beyond the control of ColorMaker, Inc. Therefore, it is the sole responsibility of the user to determine the conditions necessary for the safe use of this product.*

## Bibliography

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**EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST**

**Category 1. Adverse impacts on humans or the environment?**

Substance – PAPRIKA

Question	Yes	No	N/A	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		Petition; FDA regulations
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Petition; FDA regulations
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Petition; FDA Regulations
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		Petition; FDA Regulations
6. Are there adverse biological and chemical interactions in agroecosystem? [§6518 m.5]		X		Petition; FDA Regulations
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Petition; FDA Regulations
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			X	
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Petition; FDA Regulations
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Petition; FDA Regulations
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Petition; FDA Regulations

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12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			Petition; FDA Regulations
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Petition; FDA Regulations

1 If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 2. Is the Substance Essential for Organic Production?**      Substance – PAPRIKA

Question	Yes	No	N/A	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]			X	
2. Is there an organic substitute? [§205.600 b.1]		X		Petition
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	
5. Is the substance used in handling not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			Petition; FDA Regulations
6. Is there any alternative substances? [§6518 m.6]		X		Petition; FDA Regulations
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]			X	

1 If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**Category 3. Is the substance compatible with organic production? Substance – PAPRIKA**

Question	Yes	No	N/A	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			Petition; FDA Regulations
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Petition; FDA Regulations
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

1 If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

**CBI Deleted Version**  
**Petition to the National Organic Standards Board and the National Organic Program for the  
Addition of Paprika to the National List Section §205.606**

**Item A**

This is a petition to amend the National List Section §205.606 to include Paprika as a non-organically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic”.

**Item B**

**1. Substance Common Name.**

Paprika is the common name for the ground pod from scientific varieties of *Capsicum annuum L.*

**2. Manufacturers’ Names, Addresses, and Telephone Numbers.**

This petition is submitted by the International Association of Color Manufacturers’ on behalf of our members.

International Association of Color Manufacturers’  
1620 I Street NW, Suite 925  
Washington, DC 20006  
Phone: (202) 293-5800  
Fax: (202) 463-8998

Contact: Sean Taylor, IACM Scientific Director  
E-mail: [staylor@therobertsgroup.net](mailto:staylor@therobertsgroup.net)

Relevant member companies include (but are not limited to):

Kalsec, Inc.  
P.O. Box 50511  
Kalamazoo, MI 49005-0511

D.D. Williamson & Co., Inc.  
1901 Payne Street  
Louisville, KY 40206  
USA

Wild Flavors, Inc.  
1261 Pacific Avenue  
Erlanger, KY 41018  
USA

Chr. Hansen, Inc.  
9015 West Maple Street  
Milwaukee, WI 53214  
USA

**3. Intended or current use of the substance.**

Paprika is a commonly used spice that has applications in food as a coloring substance. It is used to color a variety of foods, including meat products, canned goods, and processed foods. Paprika adds a yellow-orange to red-orange color to foods, depending upon the exact concentration used. Paprika is generally used at a very low level in foods, with typical concentrations of 0.05-0.1% in the final food product. As is described in 21 CFR 73.340, Paprika is approved by the US Food and Drug Administration (FDA) for use at all concentrations that are considered Good Manufacturing Practices and that do not exceed those levels necessary to provide the intended coloring effect.

Paprika is currently used as a color additive in a variety of organic and non-organic food products. In organic foods, Paprika has been in use as an allowed non-synthetic ingredient under “Colors, non-synthetic sources only,” which is listed on the National List §205.605(a). However, the National Organic Standards Board has recommended that “Colors, non-synthetic sources only” be allowed to sunset off of the National List in October 2007. Therefore, Paprika must be added as an individual coloring substance onto the National List. Due to the minimal processing involved in its production, Paprika meets the current definition of an agricultural substance. This petition is to place Paprika as an allowed non-organic agricultural ingredient under §205.606 until such an organic form of Paprika is commercially available to organic foods producers in the necessary form, quality and quantity that is needed to fulfill the demands of the organic industry.

**4. List of crop, livestock, or handling activities for which the substance will be used. If used for handling (including processing), the substance’s mode of action must be described.**

Paprika is used in handling only for food application as described above. Paprika is commonly added during formulation of the food product. Paprika acts to supplement the inherent natural color found in the food product formulation. This natural color is often partially or completely lost during heating steps involved in the processing. As is described above, Paprika is used at very low levels in food products, and it therefore is not known to impart any other technical effect in the food product.

**5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.**

The color additive Paprika is the ground dried pod of mild capsicum (*Capsicum annuum L.*). These mild peppers are grown in a number of countries, including India, the United States, and Peru.

**CBI Deleted-Processing Information is described.**

CBI

**CBI Deleted-Processing Information is described.**

CBI

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

To the best of our knowledge, no previous reviews have been conducted to approve the use of Paprika used as a food coloring material as a nonorganically-produced agricultural ingredient in or on foods labeled as 'organic' or 'made with organic'. Currently, all food coloring substances that are non-synthetic are on the National List, Section 205.605(a), under "Colors, Non-Synthetic Sources Only" (the NOSB was provided with a technical advisory panel review of "Colors, Non-Synthetic Sources Only" that was completed in October 2005. It is included as Attachment #1 to this petition). However, the National Organic Standards Board has recommended that 'Colors, Non-Synthetic Sources Only' not be renewed to the National List, and it is therefore scheduled to sunset from the National List effective October 22, 2007. Given this regulatory history, no state or private certification programs are known to have conducted reviews of Paprika.

Information about Paprika sold as organic will be found in this petition. Please see Item B Nos. 11 & 12, Petition Justification Statement.

The Joint Expert Committee on Food Additives (JECFA) has conducted a review of the closely related substance Paprika Oleoresin. The review may be found at: <http://www.inchem.org/documents/jecfa/jecmono/v48aje10.htm> and is included here as Attachment #2.

The Canadian Organic Standards, that were published September 2, 2006, include colors for use in food products under the following listing: §5.4.2.1 Colouring, natural, from non-synthetic sources only and shall not be produced using synthetic solvents and carrier systems or any artificial preservative.

**7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.**

Paprika conforms in every aspect to the requirements mandated by the Federal Food, Drug, and Cosmetic Act. Paprika used as a coloring material is fully consistent with 21 CFR 73.340:

Sec. 73.340 Paprika.

## Paprika Petition

(a) Identity. (1) The color additive paprika is the ground dried pod of mild capsicum (*Capsicum annuum* L.). The definition of paprika in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for paprika under section 401 of the act.

(2) Color additive mixtures made with paprika may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions. Paprika may be safely used for the coloring of 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 the use of added color is authorized by such standards.

(c) Labeling. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of Sec. 70.25 of this chapter.

(d) 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.

While Paprika Oleoresin was found in the Environmental Protection Agency's (EPA) Substance Registry System (SRS), no listing was found for Paprika.

**8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, this fact should be reported.**

Chemical Abstracts Service (CAS) No.:

68917-78-2 (closest found, for Paprika Oleoresin)

European Community (EC) No.:

E160c

Color Index No.: None

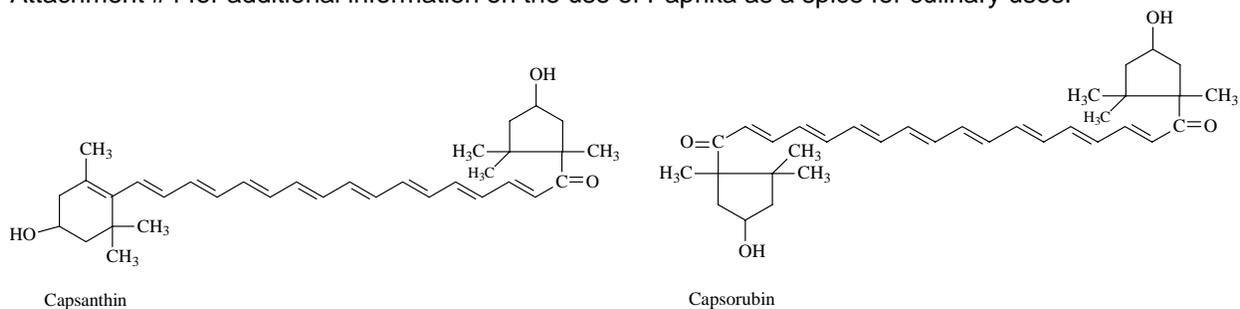
Please see Attachment #3 for label(s) of products that contain the petitioned substance.

**9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.**

Paprika is a brightly colored orange red powder. Although a variety of colored compounds are known to be present, the major coloring principles of Paprika are capsanthin and capsorubin (JECFA, 1987).

## Paprika Petition

Paprika is insoluble in water and glycerin and partially soluble in ethanol (FAO, 1988). Please see Attachment #4 for additional information on the use of Paprika as a spice for culinary uses.



### (a) Chemical interactions with other substances, especially substances used in organic production.

There are no reports of chemical interactions with other substances used in organic production of the food products in which Paprika is used as a coloring material.

### (b) Toxicity and environmental persistence.

#### Genotoxicity

Paprika is not genotoxic by weight of evidence analysis (Ueno *et al.*, 1983; Ishidate *et al.*, 1984; Goodpasture and Arrighi, 1976).

#### Acute Toxicity

The low acute oral toxicity of paprika is demonstrated by a  $LD_{50}$  that exceeds 11 g/kg bodyweight in mice (Noda *et al.*, 1984).

#### Additional Toxicological Information

Relevant studies regarding the life-time toxicity/carcinogenicity, metabolism, and reproductive toxicity of paprika were not found.

#### Environmental persistence

There is no evidence of environmental persistence from the production of paprika used as a coloring material.

### (c) Environmental impacts from its use or manufacture;

There are no environmental impacts from the production of Paprika or its use in foods. Natural agricultural recyclable material (fertilizer)

### (d) Effects on human health

As described above, paprika has not been shown to be genotoxic in animal models, suggesting that it also has no genotoxic effects in humans. Additionally, the very high  $LD_{50}$  value in acute toxicity studies suggests that it can be considered non-toxic to humans.

It should be noted that preparations of Paprika that contain small amounts of the naturally occurring substance capsaicin (chemical name 8-methyl-*N*-vanillyl-6-nonenamide). This substance is generally considered to be the “active” component of chili peppers from the genus *Capsicum*. Capsaicin has long been recognized as an irritant for mammals, in which it produces a non-harmful burning sensation. Despite its classification as an irritant, capsaicin is used as a topical treatment for the temporary relief of arthritis symptoms, muscle aches, and other acute and chronic pains, such as those pains associated with the peripheral neuropathy shingles. Chronic exposure to significant concentrations of paprika results in a reduction in the sensitivity to pain. The levels of capsaicin that are required to achieve these effects

are several orders of magnitude greater than those that are found in a typical amount of Paprika or Paprika Oleoresin when used as a spice or coloring material.

**(e) Effects on soil organisms, crops, or livestock.**

There is no evidence of any effect from Paprika on soil organisms, crops, or livestock from the production of Paprika.

**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**

A Material Safety Data Sheet for Paprika is available and included as Attachment #3. No substance report for Paprika from the National Institute of Environmental Health Studies was found.

**11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include non-organic agricultural substances onto the National List, this information item should be responded to with research concerning the availability of organic alternatives.**

Safety Reviews:

JECFA (1971). Evaluation of food additives: specification for the identity and purity of food additives and their toxicological evaluation: some extraction solvents and certain other substances; and a review of the technological efficacy of some antimicrobial agents (14th Report of the Expert Committee). FAO Nutr. Mtg. Rept. Ser. No. 48; WHO Tech. Rept. Ser., No. 462, 1971.

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- Ishidate M., Jr., Sofuni T., Yoshikawa K., Hayashi M., Nohmi T., Sawada M. and Matsuoka A. (1984) Primary mutagenicity screening of food additives currently used in Japan. *Food Chemicals Toxicology* 8, 623-636.
- Noda T., Shimiza M., Yamada A., Morita S., Ohgaki S. and Ishibashi T. (1984) Acute oral toxicities of natural food additives in rats. I. Gardenia blue color, paprika color, cochineal extract, sheanut color, and gardenia yellow. *Seikatsu Eisei* 28, 80-84.
- Ueno S., Oyamada N., Kubota, K.; Kurosawa, K. and Ishizaki, M. (1983) The spore rec-assay of natural food additive. *Nippon Shokuhin Kogyo Gakkaishi* 30, 172-174.

Other General Information:

McCormick Foods (2007) Spice Encyclopedia – Paprika (Included as Attachment #5)

Commercial Availability Research:

As justification for this petition to place Paprika for use as a food coloring substance on National List section §205.606, we have done considerable research into the commercial availability of organic forms of Paprika.

**CBI Deleted-Commercial Availability Information is described.**

CBI

**CBI Deleted-Commercial Availability Information is described.**



CBI

**12. Petition Justification Statement which provides justification for any of the following actions requested in the petition:**

Natural colors have historically been an essential component of many food products. Practically all consumers judge the palatability of foods not only on flavor, texture, and aroma, but also on appearance. A large number of these consumers would find foods that did not meet their expectations for vibrant yet reliable colors to be unappealing and perhaps would suspect that they are not sufficiently nutritious or even, in some cases, safe to eat. Consumer acceptance of these foods is therefore based in large part upon the ability of processed food manufacturers to utilize food colors to maintain expected and desirable appearances for their products.

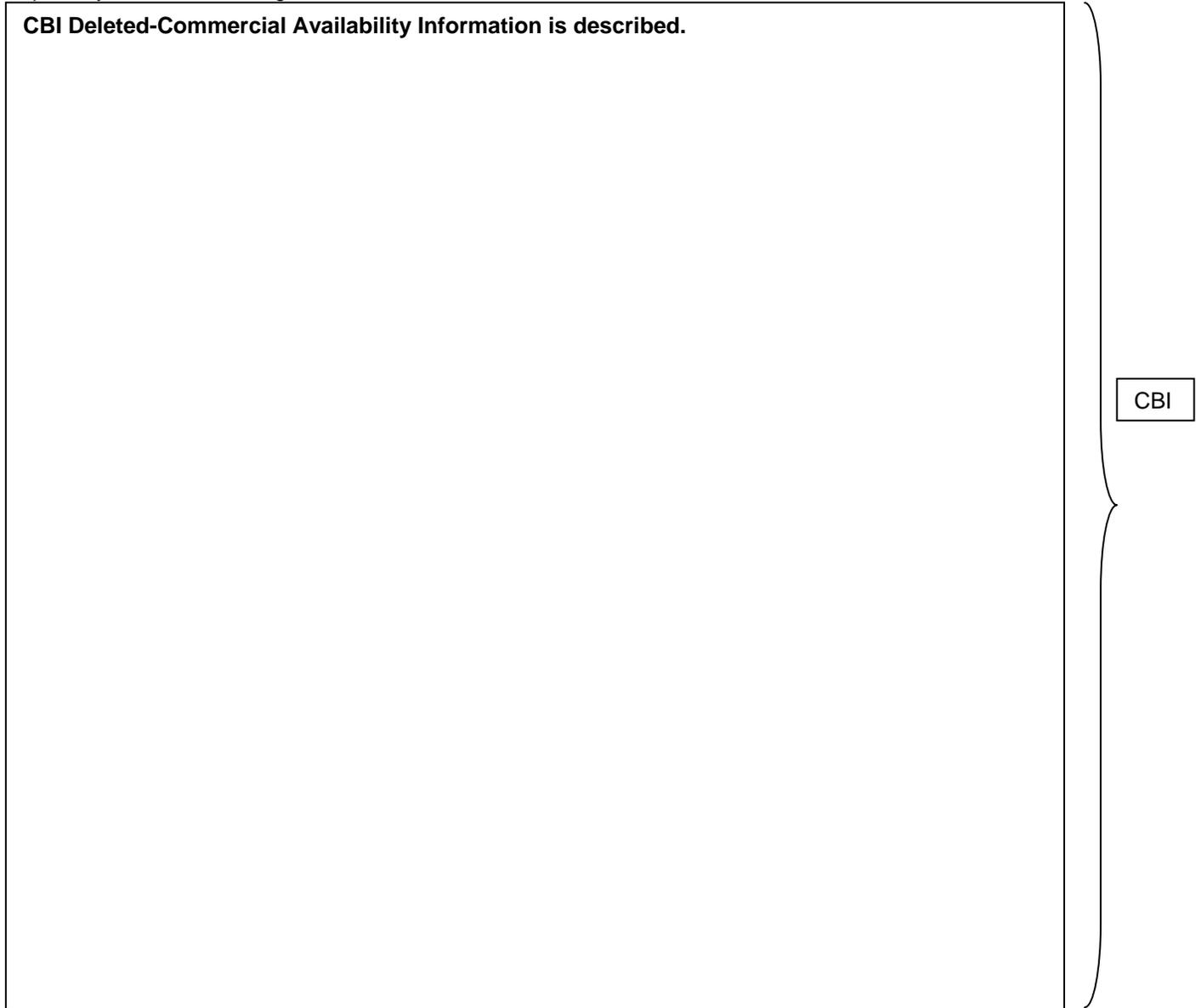
Organic consumers expect no less from their foods. Organic foods are chosen by consumers because they know that they are healthy and reliable, but also because they look good to consumers. For many foods, a large part of this positive appearance is due to the use of natural colors. Packaged organic black cherry yogurt looks like delicious yogurt with fresh black cherries swirled in because of the addition of Elderberry Juice. Organic portabello mushroom veggie hot dogs resemble a “traditional” hot dog due to the addition of Paprika. Organic strawberry cheesecake looks like, well, strawberry cheesecake through the addition of Beet Juice. In all cases, the consumer is guaranteed that in addition to the great flavor and health benefits of eating organic foods, they also have the expected appearance and a highly desirable palatability.

The use of natural colors in organic and traditional foods is critical due to the processes involved in food production. In many processes there is at least one and occasionally several heating steps

involved in the conversion of raw ingredients to final food products. In other cases the blending of ingredients changes the pH or increases the rate of oxidation. These have a deleterious effect on the colors in the raw materials, turning a bright red strawberry into something else entirely—something that consumers of traditional and organic foods might find unpalatable. Supplementing or replacing the naturally-contained color in the raw materials of food products with small amounts of natural colors ensures that the finished food products maintain the appeal of natural, unprocessed foods.

While the members of IACM and other color manufacturers endeavor to develop processes to make certified organic colors for use in organic foods, this requires time and is very challenging, especially for some coloring materials.

**CBI Deleted-Commercial Availability Information is described.**

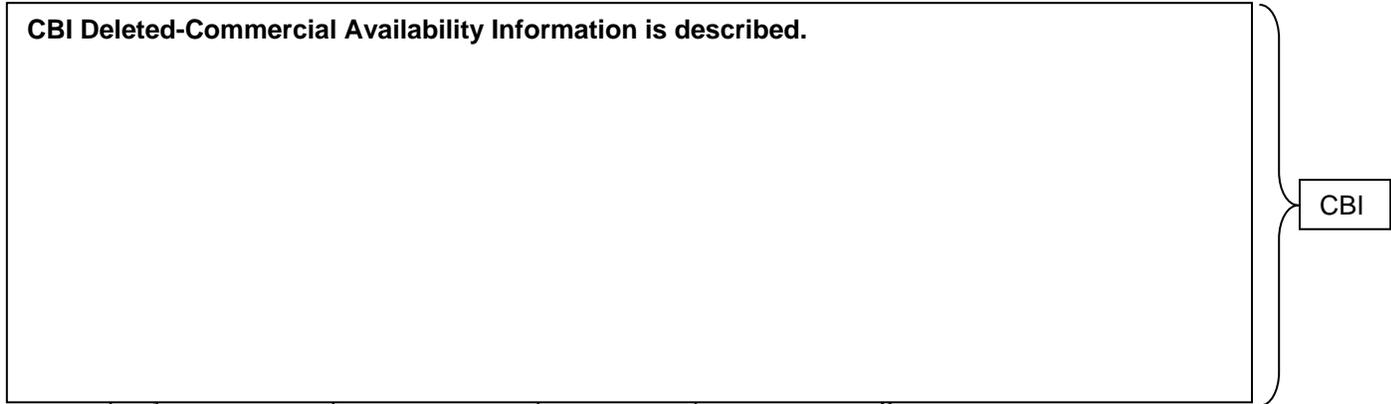


While IACM supported the renewal of “Colors, non-synthetic sources only” to the National List section 205.605(a), we do recognize that there were procedural difficulties with its initial placement on the National List that warranted its removal for legal reasons. The members of IACM have substantial interest in the potential growth of the organic industry, and we see the value in developing certified organic processes for our coloring materials. Should this petition be approved, Paprika Oleoresin, Certified Organic Oil-Extracted used as a coloring material will be supplied to our organic customers by our member companies only until such a time as processes for certified organic Paprika Oleoresin, Certified Organic Oil-Extracted that can be used as a coloring material are commercially available. Until that time,

our customer organic handlers will be able to incorporate a spectrum of vibrant natural colors into their products, and the consumers will continue to purchase organic food products that meet their desires for a healthy, colorful diet.

**13. Commercial Confidential Information Statement:**

**CBI Deleted-Commercial Availability Information is described.**



**List of Attachments**

- Attachment #1: Technical Advisory Panel Review of “Colors, Non-Synthetic Sources Only”
- Attachment #2: JECFA Evaluation of Paprika Oleoresin
- Attachment #3: Label(s) of Products containing Paprika
- Attachment #4: Culinary Uses of Paprika
- Attachment #5: Spice Encyclopedia entry on Paprika
- Attachment #6: Commercial Availability Research Information (CBI)

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**OVERVIEW OF FOOD COLOR ADDITIVES**  
**Prepared for the USDA National Organic Program and**  
**the National Organic Standards Board**  
**October 14, 2005**

6 This paper provides a general overview of color additives and how they are regulated in  
7 the United States. Use of colors in organic food production and potential adverse effects  
8 from the consumption of some specific colorants also are discussed.  
9

10 **I. EXECUTIVE SUMMARY**

11  
12 Colors are defined as any dye, pigment, or other substance that can impart color to a  
13 food, drug, or cosmetic or to the human body. Colors are regulated in the United States  
14 by the U.S. Food and Drug Administration (FDA) and are categorized either as  
15 "certifiable" (those derived primarily from petroleum and known as coal-tar dyes) or  
16 "exempt from certification" (those obtained largely from mineral, plant, or animal  
17 sources). Currently, there are no GRAS ("generally recognized as safe") exemptions for  
18 color additives. Consequently, all color additives are subject to premarket approval  
19 requirements. To obtain approval from FDA for a new color additive, the manufacturer  
20 must submit a petition demonstrating the safety and suitability of the new color additive  
21 or new use. FDA is then responsible for evaluating the petition and determining whether  
22 the color additive is safe for human consumption. Additionally, the decision regarding  
23 batch certification is made during FDA's review of the petition. If required, a sample  
24 from each manufactured batch must be submitted to FDA for analysis and certification.  
25 With this regulatory process, color additives generally have a good safety record;  
26 however, some adverse reactions have been noted. Specifically, allergic effects to  
27 Yellow No. 5 and carmine and cochineal extract have been observed. Additionally,  
28 possible carcinogenic effects have led FDA to ban uses of FD&C Red No. 3 and FD&C  
29 Red No. 2.  
30

31 **II. CHARACTERIZATION**

32  
33 Color additives are defined as any dye, pigment, or other substance that can impart color  
34 to a food, drug, or cosmetic or to the human body. Color additives include those that are  
35 white, black, and gray (Barrows et al., 2003). They also may include any chemical that  
36 reacts with another substance and causes formation of a color. In the United States, FDA  
37 is responsible for regulating color additives. For regulation purposes, FDA categorizes  
38 colors as "certifiable" (those derived primarily from petroleum and known as coal-tar  
39 dyes) and "exempt from certification" (those obtained largely from mineral, plant, or  
40 animal sources).  
41

42 Certifiable colors can be further categorized into straight colors, mixtures, and dyes and  
43 lakes. Straight colors are those color additives that have not been mixed or chemically  
44 reacted with any other substance. Mixtures are the resulting color additives that are  
45 formed by mixing one color additive with one or more color additives or non-colored  
46 diluents, without a chemical reaction. Dyes are defined as those that "...dissolve in water

1 and are manufactured as powders, granules, liquids or other special purpose forms. They  
2 can be used in beverages, dry mixes, baked goods, confections, dairy products, pet foods  
3 and a variety of other products” (FDA, 1993). Lakes are the water insoluble form of the  
4 dye. Lakes tend to be more stable than dyes and ideal for coloring products containing  
5 fats and oils or items lacking sufficient moisture to dissolve dyes. Some examples where  
6 lakes are used include coated tablets, cake and donut mixes, hard candies, and chewing  
7 gums. Additionally, certifiable colors that are added to food are chemically classified as  
8 azo, xanthene, triphenylmethane, and indigoid dyes.

### 9 10 **III. REGULATION**

#### 11 12 **A. History**

13  
14 Color additives were initially regulated in the United States under the U.S. Department of  
15 Agriculture’s (USDA) Bureau of Chemistry. In 1906, the Food and Drugs Act was  
16 passed by Congress, which prohibited the use of poisonous or deleterious colors in  
17 confectionery and the coloring or staining of food to conceal damage or inferiority. In  
18 1927, responsibility of the Food and Drugs Act was transferred to FDA. Increasing  
19 government oversight, the Federal Food, Drug, and Cosmetic Act (FFDCA) was passed  
20 in 1938 and established the three following categories for colors:

- 21 • **FD&C:** colors used in foods, drugs and cosmetics;
- 22
- 23 • **D&C:** colors used in drugs and cosmetics when in contact with mucous
- 24 membranes or ingested; and
- 25
- 26 • **Ext. D&C:** colors used in products applied externally.
- 27

28  
29 The FFDCA mandated a listing of those coal-tar colors that were determined to be  
30 “harmless and suitable” for use in foods, drugs, and cosmetics. FDA interpreted  
31 “harmless” to mean harmless at any level (Francis, 2000). Additionally, the FFDCA  
32 required the listing of new colors, mandated the previously voluntary certification  
33 program for batches of listed color with associated fees, and contained adulteration and  
34 misbranding provision for the use of coal-tar colors in food, drugs, and cosmetics  
35 (Barrows et al., 2003).

36  
37 The Color Additive Amendments to the FFDCA were established in 1960 because FDA’s  
38 interpretation of “harmless” was not workable. Under the Color Additive Amendments,  
39 “color additives” were defined and a requirement was established that only color  
40 additives (except coal-tar hair dyes) listed as “suitable and safe” for a given use could be  
41 used in foods, drugs, cosmetics, and medical devices. A current listing of FDA approved  
42 colorants, including those that do and do not require certification, is provided in Table 1  
43 (Barrows et al., 2003). As illustrated in Table 1, all of these colorants are straight colors.

1  
2

**Table 1. FDA Approved Food Color Additives**

<b>21 CFR Section</b>	<b>Straight Color</b>	<b>Use and Restrictions</b>
<b>Color Additives Subject To Certification</b>		
74.101	FD&C Blue No. 1	Foods generally
74.102	FD&C Blue No. 2	Foods generally
74.203	FD&C Green No. 3	Foods generally
74.250	Orange B	Casings or surfaces of frankfurters and sausages, NTE 150 ppm
74.302	Citrus Red No. 2	Skins of oranges not intended or used for processing, NTE 2.0 ppm (by weight)
74.303	FD&C Red No. 3	Foods generally
74.340	FD&C Red No. 40	Foods generally
74.705	FD&C Yellow No. 5	Foods generally
74.706	FD&C Yellow No. 6	Foods generally
<b>Color Additives Exempt From Certification</b>		
73.30	Annatto extract	Foods generally
73.35	Astaxanthin	Salmonid fish feed
73.40	Dehydrated beets (beet powder)	Foods generally
73.50	Ultramarine blue	Salt for animal feed
73.75	Canthaxanthin	Foods generally, NTE 30 mg/lb of solid or semisolid food or per pint of liquid food; broiler chicken feed; salmonid fish feed
73.85	Caramel	Foods generally
73.90	$\beta$ -Apo-8'-carotenal	Foods generally, NTE 15 mg/lb solid, 15 mg/pt liquid
73.95	$\beta$ -Carotene	Foods generally
73.100	Conchineal extract; carmine	Foods generally
73.125	Sodium copper chlorophyllin	Citrus-based dry beverage mixes, NET 0.2% dry mix
73.140	Toasted partially defatted cook cottonseed flour	Foods generally
73.160	Ferrous gluconate	Ripe olives
73.165	Ferrous lactate	Ripe olives
73.169	Grape color extract	Nonbeverage food
73.170	Grape skin extract (enocianina)	Still and carbonated drinks and ades; beverage bases; alcoholic beverages
73.185	Haematococcus algae meal	Salmonid fish feed
73.200	Synthetic iron oxide	Sausage casings, NTE 0.1%

21 CFR Section	Straight Color	Use and Restrictions
		(by weight); dog and cat food, NTE 0.25% (by weight)
73.250	Fruit juice	Foods generally
73.260	Vegetable juice	Foods generally
73.275	Dried algae meal	Chicken feed
73.295	Tagetes (Aztec marigold meal and extract)	Chicken feed
73.300	Carrot oil	Foods generally
73.315	Corn endosperm oil	Chicken feed
73.340	Paprika	Foods generally
73.345	Paprika oleoresin	Foods generally
73.355	Phaffia yeast	Salmonid fish feed
73.450	Riboflavin	Foods generally
73.500	Saffron	Foods generally
73.575	Titanium dioxide	Foods generally, NTE 1% (by weight)
73.600	Turmeric	Foods generally
73.615	Turmeric oleoresin	Foods generally

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The Color Additive Amendments also established the “Delaney Clause” that prohibited the listing of a color additive shown to be carcinogenic.

**B. Petition Process**

Under the current regulatory system, FDA is responsible for ensuring the safety of new food additives, including colors. However, food additive petitions are not required for food additives that are identified as “generally recognized as safe” (GRAS) substances. Currently, there are no GRAS (“generally recognized as safe”) exemptions for color additives. Consequently, all color additives are subject to premarket approval requirements. These requirements are listed in Title 21 of the Code of Federal Regulations (CFR), Part 71. In filing a color additive petition, the manufacturer is responsible for providing FDA with information including, but not limited to the following:

- Identification of the food additive;
- Physical, chemical, and biological properties;
- Chemical specifications;
- Manufacturing process description;
- Stability data;
- Intended uses and restrictions;
- Labeling<sup>1</sup>;

<sup>1</sup> Any labeling that will be required by applicable provisions of the FFDCFA on the finished food by reason of the use of the food additive.

- 1 • Tolerances and limitations<sup>2</sup>;
- 2 • Analytical methods for enforcing chemical specifications;
- 3 • Safety studies; and
- 4 • Estimate of probable exposure.

### 5 6 **C. Safety Assessment**

7  
8 A color additive petition must demonstrate the safety and suitability of the new color  
9 additive or new use. FDA is responsible for evaluating petitions and determining  
10 whether the additive is safe for human consumption. Generally, this determination is  
11 made by examining the following parameters:

- 12
- 13 • History of use or natural occurrence;
- 14 • Consumption ratio, if applicable;
- 15 • Exposure levels;
- 16 • Inherent toxicity of the substance;
- 17 • Toxicological data on the substance or on structurally-related compounds; and
- 18 • Metabolism of the substance (either known or forecasted on the basis of data for
- 19 structurally-related compounds).

20  
21 FDA's safety assessment includes a review toxicity data such as the results of controlled  
22 animal studies. Ideally, a complete range of data, including short- and long-term toxicity  
23 studies, as well as studies that examine possible reproductive, carcinogenic, mutagenic,  
24 and sensitization characteristics of the color additive would be available for review.  
25 Sometimes a complete set of toxicology data is not available. One method of gaining  
26 additional insight on a color lacking a complete set of data is to evaluate the toxicity of  
27 structurally related substances. By evaluating structurally related substances, scientists  
28 can try to determine how the compound is absorbed, distributed, and metabolized within  
29 the body, and how it may act on target organs in the body. Based on these data and  
30 various safety factors, FDA determines a safe exposure level for the color additive.

31  
32 FDA then compares the safe exposure level to the amount likely to be consumed in food  
33 taking into consideration the composition and properties of the substance and the  
34 proposed conditions of use. Because the absolute safety of any substance can never be  
35 proven, FDA must determine if the additive is safe under the proposed conditions of use,  
36 based on the best scientific knowledge available. For more information, see  
37 <http://vm.cfsan.fda.gov/~dms/opa-cg8e.html>.

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<sup>2</sup> According to 21 CFR Part 571, "If the food additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance."

1 **D. Batch Certification**

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3 As described in Section II, FDA requires certification of every manufactured batch of  
4 some color additives. Color additives requiring and exempt from batch certification are  
5 listed in Table 1.  
6

7 Batch certification is required when the composition of the color needs to be controlled in  
8 order to protect public health. Procedures for color additive batch certification are  
9 available in 21 CFR Part 80. Under these procedures, a sample from each manufactured  
10 batch of certifiable color additive, as well as a "Request for Certification," must be  
11 submitted to FDA's Color Certification Branch. The "Request for Certification" should  
12 provide information regarding the batch weight, storage conditions, and the use for which  
13 it is being certified. FDA is then responsible for evaluating the batch's physical  
14 appearance and performing chemical analyses including, but not limited to the following:  
15

- 16 • Purity (total color content);
- 17 • Moisture;
- 18 • Residual salts;
- 19 • Unreacted intermediates;
- 20 • Colored impurities other than the main color;
- 21 • Any other specified impurities; and
- 22 • Heavy metals (lead, arsenic, and mercury).

23  
24 If the sample meets FDA's requirements, FDA will issue a certificate for the batch that  
25 identifies the color additive, batch weight, uses for which the color additive is certified,  
26 the name and address of the owner, as well as other information. The batch also is  
27 assigned a unique lot number.  
28

29 Colors that are exempt from certification are usually derived from plant or mineral  
30 sources and must comply with the identity and purity specification and use limitation  
31 described in their listing regulations. According to 21 CFR 71.1(c)G, "If exemption from  
32 batch certification is requested, the reasons why it is believed such certification is not  
33 necessary (including supporting data to establish the safety of the intended use)."  
34 Consequently, a petition for exemption from certification must show why such  
35 certification is not necessary for the protection of public health (21 CFR 71.18). Color  
36 additives that are exempt from batch certification for one use may be subject to batch  
37 certification for other uses. Because natural colorants are exempt from a lengthy  
38 certification process, there has been a strong trend over the past 50 years toward the use  
39 of these color additives as compared to synthetic coal-tar dyes (Francis, 2000).  
40

41 **IV. ADVERSE EFFECTS**

42  
43 Although food colors generally have a good safety record, some adverse reactions have  
44 been noted. For example, Yellow No. 5 (listed as tartrazine on medicine labels; a color  
45 found widely in beverages, desserts, processed vegetables, drugs, makeup, and many  
46 other products) causes itching or hives in a small population sub-group (FDA, 2001).

1 Another color that causes allergic reactions is carmine and cochineal extract. Carmine  
2 and cochineal extract are scarlet red pigments that come from the female coccid insect  
3 *Dactylopius coccus* var. *Costa* (family Dactylopiidae, superfamily Coccoidea), which is  
4 parasitic on several species of cacti, particularly the cochineal figs produced by prickly  
5 pear (*Opuntia* cactus *Nopalea cochenillifera*). There have been several case reports of  
6 anaphylaxis and urticaria resulting from ingestion of food or drink containing carmine  
7 (Beaudouin et al., 1995; Baldwin et al., 1997; DiCello et al., 199a,b; Chung et al., 2001).

8  
9 In 1960, FDA banned uses of FD&C Red No. 3 including cosmetics and externally  
10 applied drugs because large amounts of the color caused thyroid tumors in male rats  
11 (FDA, 2001). In 1976, FDA issued a ban on FD&C Red No. 2 because there appeared to  
12 be a statistically significant increase in malignant tumors when fed high doses of the  
13 color (FDA, 2001).

#### 14 15 **V. USE OF COLORS IN ORGANIC FOODS**

16  
17 Colors are currently on the National List of Allowed and Prohibited Substances for use in  
18 organic foods. Colors were not added to the National List as the result of a petition.  
19 Instead, they were included among substances initially placed on the National List when  
20 USDA promulgated regulations pursuant to the Organic Food Production Act of 1990.  
21 According to 21 CFR Part 205.605, nonagricultural (nonorganic) colors are allowed as  
22 ingredients in or on processed food products labeled as “organic” or “made with  
23 organic.” Only nonsynthetic colors (as a group) are allowed.

#### 24 25 **References:**

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28 carmine dye allergy. *Annals of Allergy, Asthma & Immunology* 79:415-419.

29  
30 Barrows J.N., Lipman A.L., Bailey C.J. 2003. Color Additives: FDA's Regulatory  
31 Process and Historical Perspectives. Available at: [http://www.cfsan.fda.gov/~dms/col-](http://www.cfsan.fda.gov/~dms/col-regu.html)  
32 [regu.html](http://www.cfsan.fda.gov/~dms/col-regu.html).

33  
34 Beaudouin E., Kanny G., Lambert H., Fremont S., Moneret-Vautrin D.-A. 1995. Food  
35 anaphylaxis following ingestion of carmine. *Annals of Allergy, Asthma, & Immunology*  
36 74: 427-430.

37  
38 Chung K., Baker J.R., Baldwin J.L., and Chou A. 2001. Identification of carmine  
39 allergens among three carmine allergy patients. *Allergy* 56(1):73-77.

40  
41 DiCello M.C., Baldwin J.L., Myc A., and Baker J.R. 1999a. Anaphylaxis after ingestion  
42 of yogurt colored with carmine. *Annals of Allergy, Asthma, & Immunology* 82:73  
43 (Abstract).

44

- 1 DiCello M.C., Myc A., Baker J.R., and Baldwin J.L. 1999b. Anaphylaxis after ingestion  
2 of carmine colored foods: two case reports and a review of the literature. *Allergy and*  
3 *Asthma Proceedings* 20:377-382.  
4  
5 FDA. 2001. Food Additives Fact Sheet. Available at:  
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FAO Nutrition Meetings  
Report Series No. 48A  
WHO/FOOD ADD/70.39

**TOXICOLOGICAL EVALUATION OF SOME  
EXTRACTION SOLVENTS AND CERTAIN  
OTHER SUBSTANCES**

The content of this document is the result of the deliberations of the Joint FAO/WHO Expert Committee on Food Additives which met in Geneva, 24 June -2 July 1970<sup>1</sup>

Food and Agriculture Organization of the United Nations  
World Health Organization

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<sup>1</sup> Fourteenth report of the Joint FAO/WHO Expert Committee on Food Additives, FAO Nutrition Meetings Report Series in press; Wld Hlth Org. techn. Rep. Ser., in press.

OLEORESINS OF PAPRIKA

Biological data

Biochemical aspects

Non-pharmacologic Aspects

Injection of paprika extract or its active ingredient capsaicin into cats produced either a drop in blood pressure with low doses or a biphasic response with higher doses (Varady & Katuruya, 1931). I.v. administration of capsaicin in dogs and cats produced apnoea, bradycardia and hypotension. Vagotomy abolished the response in dogs and produced a pressor effect and hyperpnoea in cats (Toh et al., 1955). This was probably due to stimulation of baroreceptors at the pulmonary bifurcation as well as other central and peripheral factors (Pórszász et al., 1957). Intragastric administration to cats reduced body temperature (Högyes, 1878). Crystalline capsaicin raised the acid secretion of the stomach by local irritation (Toh et al., 1959). Capsaicin administered parenterally or locally to guinea-pigs, rats and mice depressed a sensory excitability (Jancso, 1955).

Acute toxicity

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Animal	Route	LD <sub>100</sub> mg/kg body-weight	Reference
Cat	i.v. capsaicin	1.6-4.3	Janesó, 1955

Large oral doses failed to kill dogs but guinea-pigs are very sensitive. Rabbits, mice and rats die from hypothermia after large oral or parenteral doses while guinea-pigs die from anaphylactic shock (Molnar, 1965). Capsaicin is a local skin irritant (Csedó, 1962).

#### Short-term studies

Rat. 10% chill was added to an artificial rat diet containing 10% ardein (a groundnut protein) which produces in controls fatty liver and cirrhosis. Out of 26 rats sacrificed after 7 months, 15 had neoplastic changes in the liver. Hepatomata multiple cystic cholangiomata, solid adenomata or adenocarcinomata of the bile duct occurred (Hoch-Ligéti, 1950).

#### Long-term studies

None available.

#### Comments

The active principle capsaicin has systemic and local irritant action. The effect observed in the short-term study in rats on a grossly subnormal diet is not relevant to an evaluation for human use.

#### Evaluation

Use as a spice will be self limiting and governed by good manufacturing practice.

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See Also:

Toxicological Abbreviations

**INGREDIENTS:** Organic wheat flour, organic evaporated cane juice invert, organic cane juice, organic apple, organic apple, organic whole wheat flour, organic powdered sugar, organic corn starch, organic vital wheat gluten, organic dextrose, organic strawberries, organic strawberry flavor, organic rice starch, sea salt, leavenings (baking soda, cream of tartar), organic honey, organic molasses, citric acid, rice bran extract, colored with beta-insulin, paprika extract (from plants), organic vanilla flavor, aiglin, sodium citrate, monocalcium phosphate, whey protein isolate.

**Allergens:** Made in plant that processes milk, soy, wheat.

**Nutrition Facts**

Serving size: 1 Pastry (52 g)  
Servings per container: 6

Amount Per Serving	Calories from Fat 35
<b>Calories 210</b>	<b>% Daily Value*</b>
<b>Total Fat 4 g</b>	6%
<b>Saturated Fat 2 g</b>	10%
<b>Trans Fat 0 g</b>	0%
<b>Cholesterol 0 mg</b>	0%
<b>Sodium 140 mg</b>	6%
<b>Total Carbohydrate 40 g</b>	13%
<b>Dietary Fiber 1 g</b>	4%
<b>Sugars 19 g</b>	
<b>Protein 3 g</b>	
<b>Vitamin A 0%</b>	<b>Vitamin C 0%</b>
<b>Calcium 2%</b>	<b>Iron 8%</b>

\* Percent Daily Values are based on a diet of other people's secrets.

	Calories	2,000	2,500
<b>Total Fat</b>	Less than 2g	5%	5%
<b>Saturated Fat</b>	Less than 300mg	60%	60%
<b>Cholesterol</b>	Less than 2,400mg	100%	100%
<b>Sodium</b>	Less than 3,500mg	100%	100%
<b>Potassium</b>	300g	60%	60%
<b>Total Carbohydrate</b>	30g	60%	60%
<b>Dietary Fiber</b>	25g	50%	50%

NURTURING PEOPLE, NATURE & SPIRIT

**MINI**



**ORGANIC**

**STRAWBERRY**

*Naturally Flavored*

**Easter Pastries**

*Frosted*

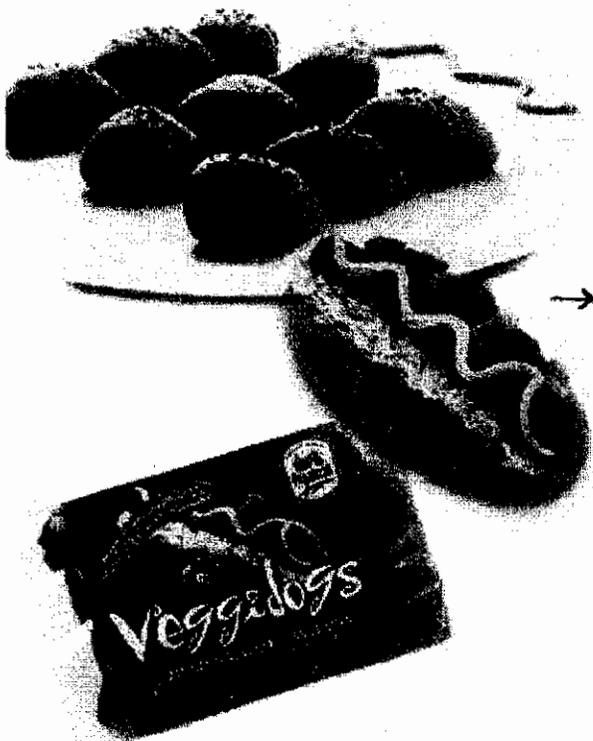
**6 Pastries**

**No Trans Fats!**

Net Wt. 11oz (312g)



USDA ORGANIC



## PORTABELLA VEGGIDOGS

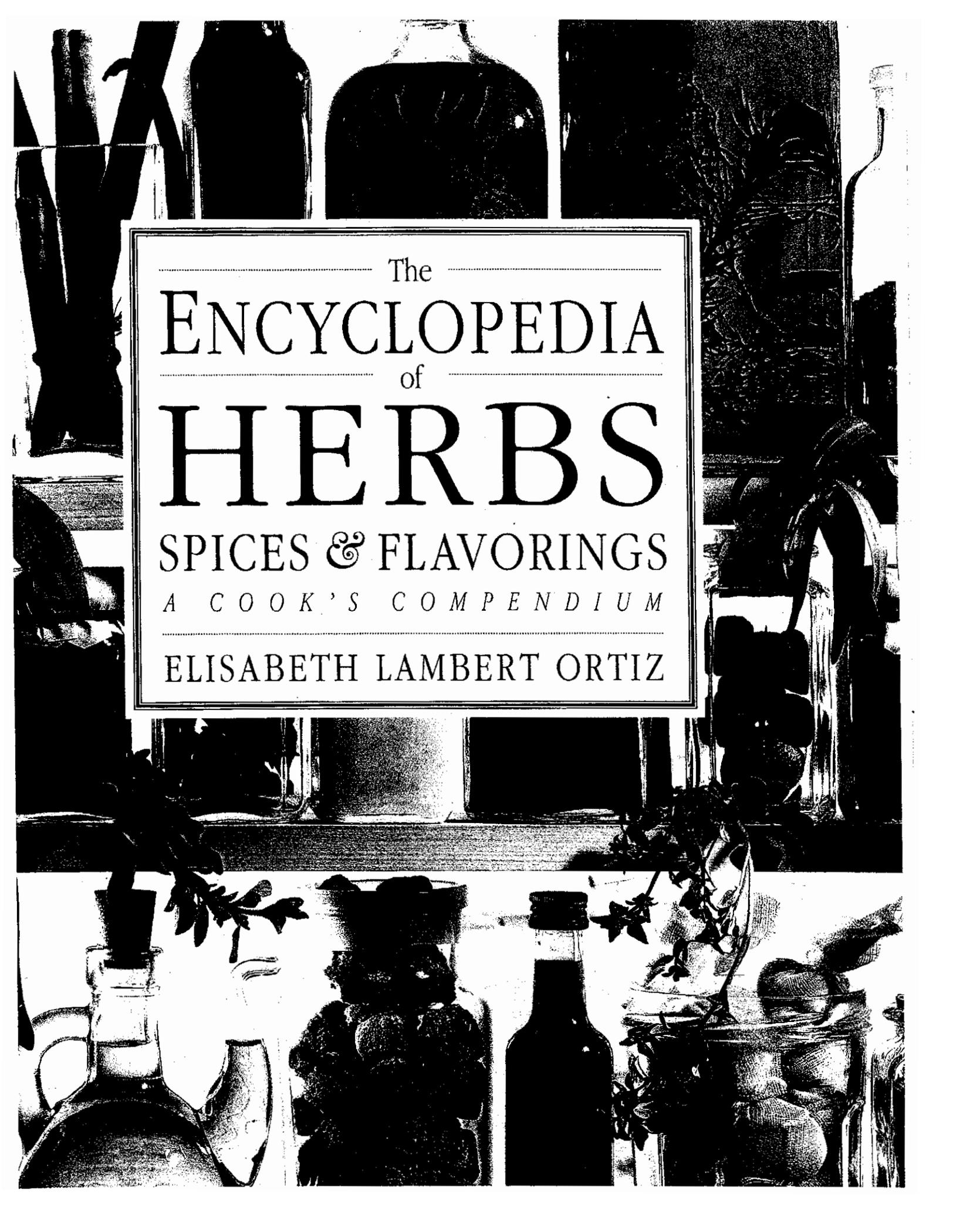
Taste does matter!

### Ingredients

Water, canola oil, soy protein isolate, egg white powder, wheat gluten, natural floavor (contains torula yeast), salt, onion powder, portabella mushrooms, rice starch, carrageenan, maltodextrin, garlic powder, carmine (for color), paprika (for color), caramel color, enzyme.

### Nutritional Facts

*(Click on to view nutritional data  
click off to close.)*



The  
ENCYCLOPEDIA  
of  
HERBS

SPICES & FLAVORINGS

A COOK'S COMPENDIUM

ELISABETH LAMBERT ORTIZ



A DORLING KINDERSLEY BOOK

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**OTHER NAMES**

Tomato pepper, tomato-squash pepper, *pimentó*, tomato pimiento, *pimentón*, Hungarian paprika, noble paprika, sweet paprika

**FORMS**

*Fresh:* Whole *Dried:* Ground



**HOW TO STORE**

*Dried:* Keep in airtight containers in a cool, dark place. Paprika loses its flavor and aroma quickly, becoming brown and stale tasting if kept too long.



**COOKING TIPS**

Buy the best quality of sweet paprika available, it is worthwhile for the superior flavor. Be careful to check the label; some are labeled hot and can be very hot indeed. For example, cans that are labeled "Spanish paprika" are not mild like paprika, they are actually spicy, like cayenne.

# PAPRIKA

The sweet peppers that are dried and ground for paprika have a complex history. The plant originated in the southernmost tip of Mexico, was taken to Spain and Morocco by the Spanish, and then found its way to Hungary, where it became naturalized and an essential ingredient in local cuisine. The thick-fleshed peppers are as broad as they are long and similar to other members of their large family, and are excellent sources of vitamin C. Whole fresh peppers can be difficult to find, but with their slightly piquant flavor, they make excellent peppers for stuffing. Ground paprika lends an appealing flavor to foods as well as a beautiful deep-red color. Spain has a similar pepper, called *pimentó*. It is a pointed, heart-shaped fruit that is used to make *pimentón*, a spice similar to paprika. In its fresh form, it is most familiar as the red stuffing inside green Spanish cocktail olives.

*Color can vary from bright red to light pink; flavor can range from sweet to fiercely hot.*



Fresh pepper



Spanish *pimentón*



Hungarian paprika



**TASTES GOOD WITH/IN**

Egg dishes, meat and poultry stews, game, rabbit, fish and shellfish, soups, boiled or steamed vegetables, rice, and cream-based sauces.



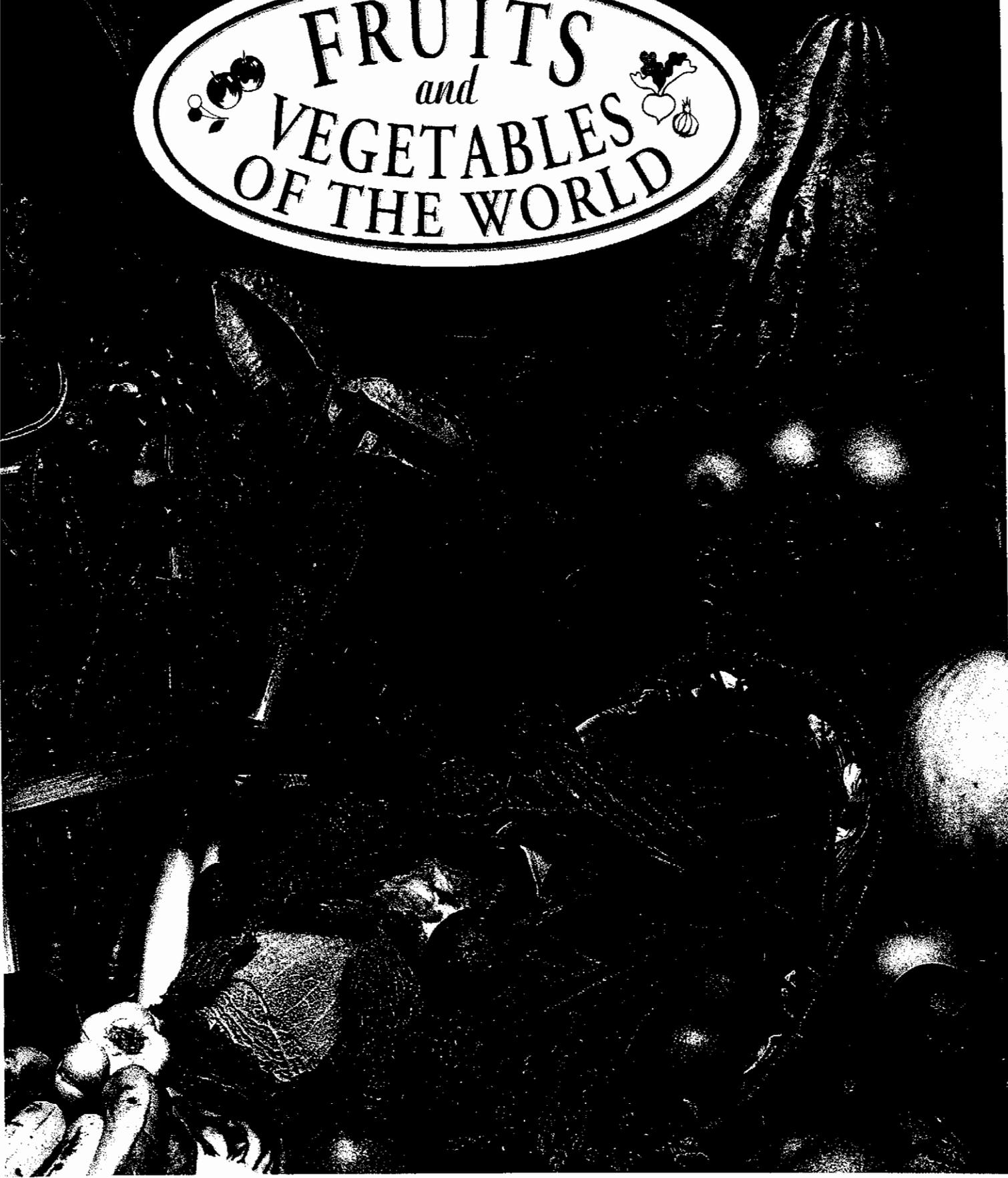
**COOK'S CHOICE  
PAPRIKA CHICKEN**

Serves 4

- 2 *tbsp* vegetable oil
- 2 *medium* onions, finely chopped
- 3 *lb* (1.5 *kg*) chicken, cut into serving pieces
- 8 *oz* (250 *g*) tomatoes, peeled, seeded, and chopped
- 1 1/2 *tbsp* paprika
- Salt
- Freshly ground black pepper
- 2 *tbsp* sour cream
- 1 *tbsp* all-purpose flour, sifted
- 1 *medium* green pepper, seeded, deribbed, and sliced
- 2 *tbsp* heavy cream

Heat the oil in a large, flame-proof casserole. Add the onions and cook over low heat until soft but not browned. Add the chicken and tomatoes and cook, covered, over low heat for 10 minutes. Stir in the paprika and season to taste. Pour in 3/4 cup (175 ml) water, cover, and continue to cook over low heat for 30 minutes. Remove the lid if there is too much liquid and continue to cook, uncovered, until the liquid has evaporated, 15 minutes longer. Mix the sour cream and flour together to make a smooth paste. Lift out the chicken pieces and keep them warm. Stir the sour cream mixture into the juices remaining in the casserole and cook, stirring constantly, until the sauce is thick and smooth, 5-10 minutes more. Add the green pepper and heavy cream and stir. Return the chicken to the casserole and cook for 5-7 minutes longer. Serve with boiled rice.

FRUITS  
*and*  
VEGETABLES  
OF THE WORLD



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## Chilis, peppers, and paprika

Every September, thousands of acres of the Hungarian countryside are covered by a bright red carpet, for this is the time of year when paprika is harvested.

Paprika is a type of chili indigenous to the tropical regions of America and was first exported to Europe in the sixteenth century during journeys back and forth to the New World.

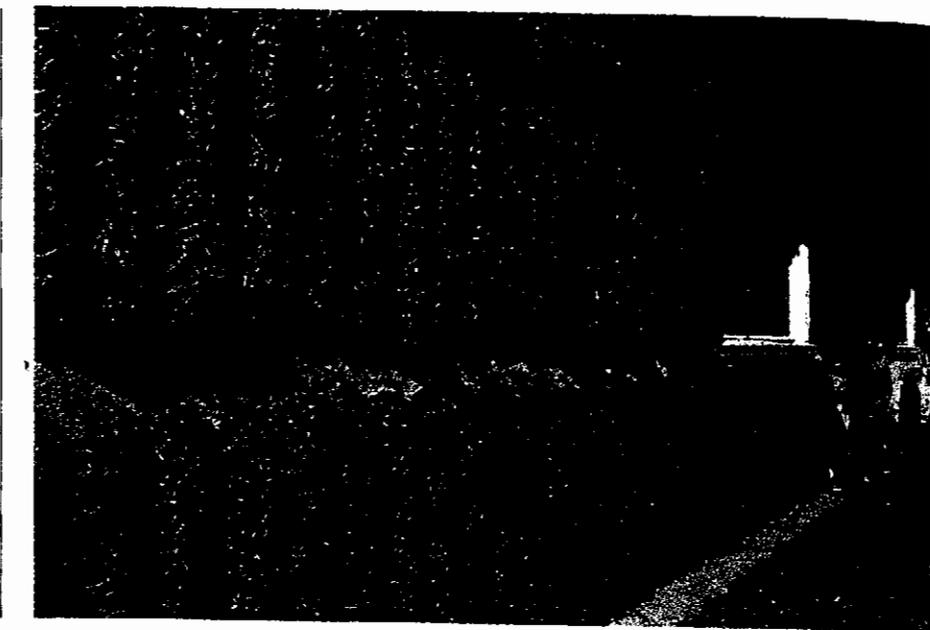
Its scientific name is *Capsicum sp.* All chili types are grouped under this appellation, whether mild, hot, Cayenne, or peppers. In all, there are more than one hundred species and over one thousand varieties of chilis.

**Chili.** Belonging to the *Solanaceae* family, chili, like the tomato, is a plant that can be grown in nearly all parts of the world, even in the most arid lands. At the end of the sixteenth century, it was already available in England and known to the Spanish court. The French, British, Portuguese, and Spanish exported it to their colonies. Africa and Asia, India in particular, adopted chili and made it one of the key ingredients of their cuisine. It was used to spice up many of their dishes, which were otherwise plain, frequently without meat, and generally fairly bland. People living in hot and dry climates favored the strong varieties that Western palates often found inedible.

In a way, the intensity of the sun acts as a barometer of the chili's strength: the stronger the sun, the higher the concentration of the spicy elements such as capsaicin: a powerful 2 per cent for fiery little chili but less than 0.01 per cent in the milder sweet peppers. In hot countries, chili is used as a spice, for example, harissa in Algeria, tabasco in Mexico, and pili-pili in Africa.

The United States and Malaysia are the biggest importers of chilis.

**Sweet peppers.** In Europe, milder varieties were developed and are referred



Above: Drying "sausages" of paprika in Hungary.



Left: The traditional way of lacing the fruits together for drying.

Left below: Paprika market in Budapest.



its mild, warm flavor from the temperate climate and sandy soil of the Hungaria plains. It has proved impossible to reproduce this subtle mix anywhere else. Over time, the flavor has become more refined, yielding a variety of different grades of paprika.

Hungary has at least five different types of paprika. The two best-known ones are from the Kalocsa and Szeged regions. There are a multitude of varieties. Depending on the soil, the light, and where they are grown, paprikas are round, long, or square, with colors that range from bright red to dark green, covering a whole gamut of yellows and oranges. Although Yugoslavia, Mexico, the Ivory Coast, and India claim to produce paprika, it has nothing more in common with the true Hungarian paprika than its name.

The lives of Hungarians from the Kalocsa region revolve around the life cycle of the paprika plant. Thousands of acres belonging to the state are sown with increasingly high-yielding varieties. The

to by the generic name of "pepper." Also known as capsicums, they are available in three main varieties: green, red, and yellow. They can be pickled in vinegar or prepared in mustard (piccalilli), but are most commonly used as vegetables, either raw or cooked (e.g. in pasta sauces, ratatouille, or on pizzas.)

**Paprika.** This plant can be classified between the chili and the pepper. It gets

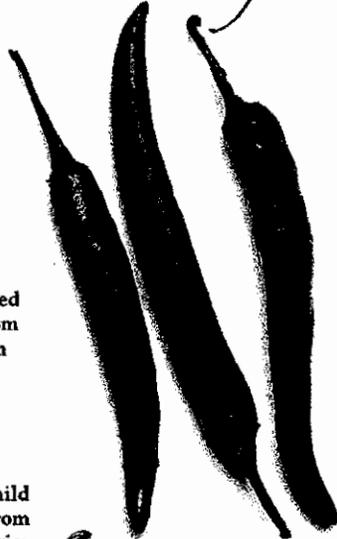
String of paprika



Cayenne chili



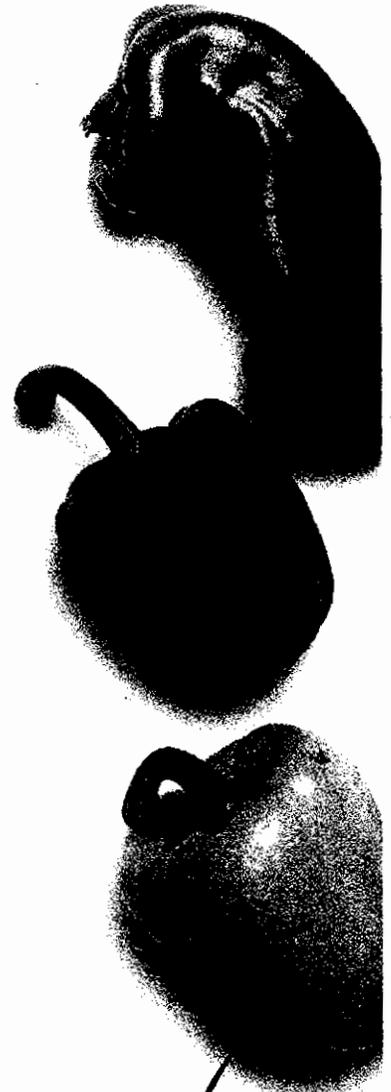
Elongated chili from Vietnam



Semi-mild chili from Africa



Green, red, and yellow sweet peppers



Fiery chili



white flowers are succeeded by long yellow or red fruits. Harvesting takes place in the fall and must be done quickly to avoid damaging frosts. During the harvesting season, school is no longer compulsory and the fields are filled with people of all ages hand-picking the fruit. This is a difficult task, despite the varieties that yield fruits which grow right above the foliage.

The fruits are stored in large bags which are then loaded onto horse-drawn carts. At the end of the day, the harvested fruits are delivered to cooperatives or taken home for drying. In days gone by, women and the elderly would tie the fruit together one at a time and hang them in long strings. Today, they are placed in large sausage-shaped nets. This system is much quicker although less effective for drying the fruit thoroughly. Many inhabitants still use the traditional method for drying their own paprika and sell the fruit dried in nets. As the harvest season advances, the village becomes draped with red nets that hang from roofs and gradually cover the walls of houses and barns.

Hungary recently started allowing state lands to be leased out to individuals, who are authorized to sell their harvests directly. This new legislation has favored the development of an intensive private

### GOULASH

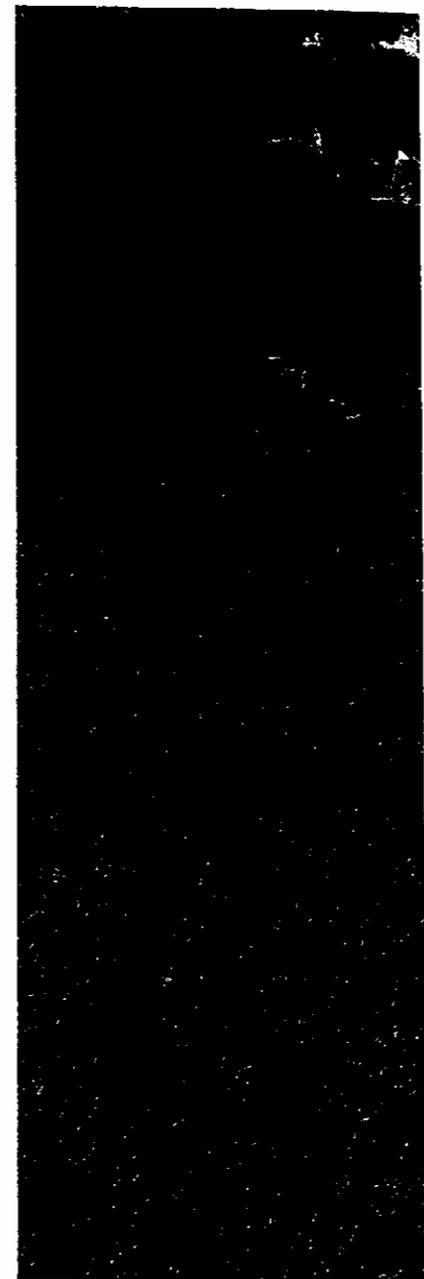
Peel 8 onions, cut them into thin round slices. Heat some oil in a pan and gently fry the onions. As soon as they begin to brown, transfer them to a casserole dish greased with lard. Add one small can of tomato concentrate with a little water, salt, pepper, 2 teaspoons of paprika, 3 red peppers sliced into thin strips, 2 1/4 pounds of beef cut into cubes and dusted with flour. Stir well and cover tightly. Cook slowly over a low heat, keeping a regular check on it. Add more water if the mix becomes too thick. The goulash is ready when the meat is tender. Serve with boiled potatoes. This dish tastes even better when reheated.



Above: Spanish dried chili.  
Top: Harvesting chili in Totana, Spain.

business. Once dry, paprika is ground to become the famed red powder that flavors all Hungarian dishes. In restaurants, there are always three small shakers on the table: salt, pepper, and paprika. For health reasons, the government officially forbids individuals from grinding their own paprika. Nonetheless, it would be hard to find a home that does not have its own small grinder which starts to turn at dusk. The real reason behind this rule is economic. The state once invested large sums to install immense dryers and mills able to process several tons of paprika. Today, as most of these factories are lacking in raw materials, Hungarians prefer to sell their paprika directly rather than to state cooperatives at lower prices. In Kalocsa,

the factory operates at only a reduced rate and must dry and grind other plants like marjoram and oregano to survive Privatization, which brought about a return to the traditional method, has enabled Hungary to produce a high quality paprika. Paprika dried according to natural methods, even in nets, bears a comparison with the output from industrial driers that expose hundreds of tons to artificial heat. Most of the vitamins are lost with the heat, even though paprika is very rich in vitamin C.



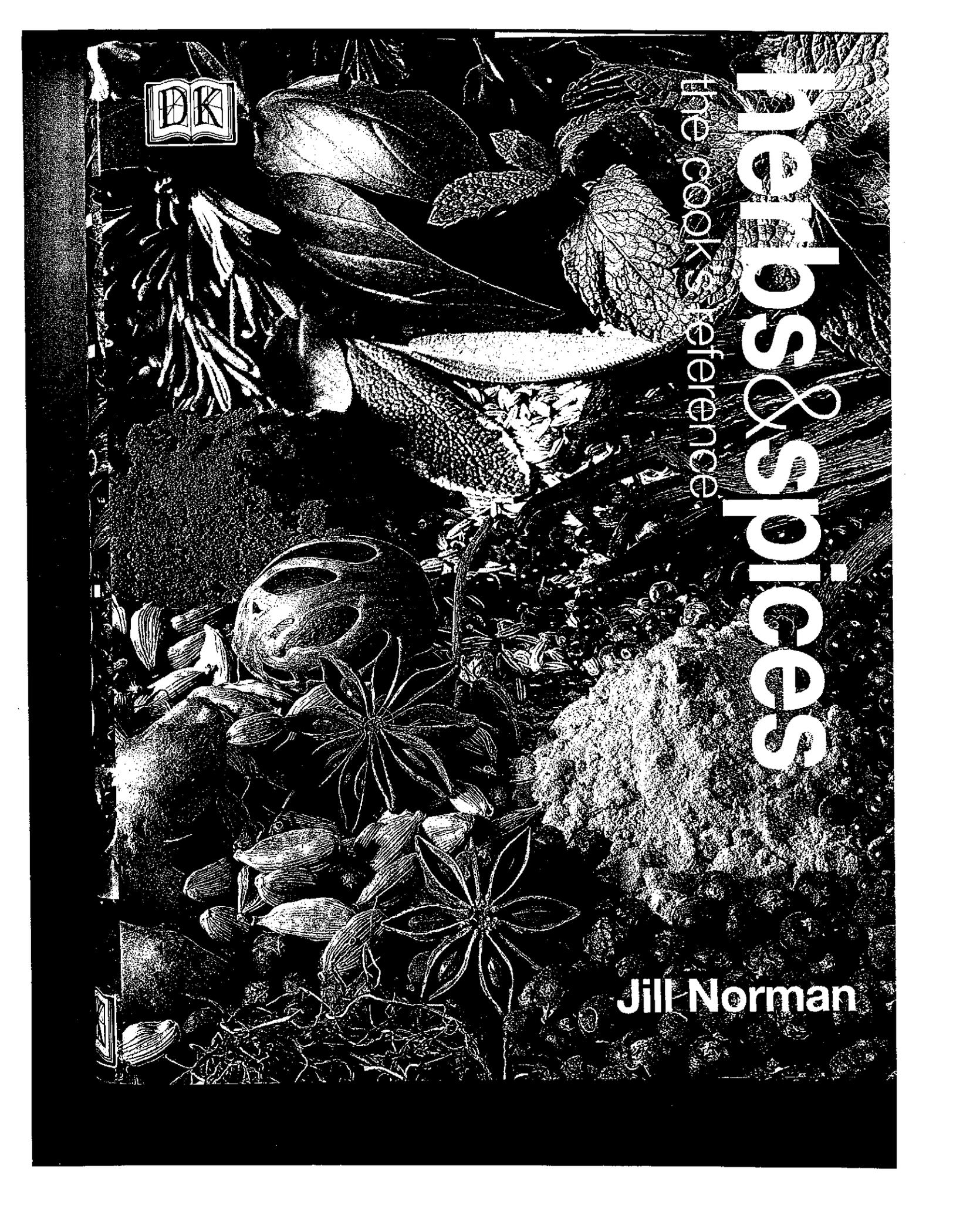
should be recalled that the Hungarian Szent Gyorgity was the first to discover one of our most essential vitamins - vitamin C, which he detected in paprika.

The best paprika comes from varieties that produce very long fruits. Those that are round and yellow like small tomatoes are not as good and are more difficult to preserve. The powder should be very fine and its color uniform and shiny. The more yellow a paprika powder, the stronger it will be; in contrast, the redder it is, the milder.

Paprika is used not only in powder form but also fresh. Depending on the varieties, its fruits can be incorporated into soup or cut into thin strips in salads. The best varieties dry very easily in less than a month. The fruit has a very low water content. As a result of this, once dry, paprika retains 80 per cent of its weight and can be stored intact for several years with no problem. To grind, simply run the paprika through a coffee mill to obtain a fragrant powder that has exceptional coloring qualities.

In Totana, Spain, chili is left to dry on a plastic sheet placed on the ground. Totana is one of the only cities in Spain where chili is dried in the traditional way. It is a product of excellent quality with a flavor not unlike that of the hottest paprika. Unfortunately, a factory for drying on an industrial scale has begun operating in the region. With this type of progress, the vitamin-filled Totana chili stands to lose some of its quality.





# Herbs & Spices

The Cook's Reference.

Jill Norman





LONDON, NEW YORK, MUNICH,  
MELBOURNE, and DELHI

For Paul, who made it possible

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What defines an herb or spice, and why are they used in cooking? Regional cuisines derive much of their character from how specific herbs and spices are combined and used. With increasing availability of fresh herbs and spices from around the world, every cook can recreate authentic regional dishes at home, and try out new combinations to his or her personal taste.

## Herbs

### Introducing herbs

14

While robust herbs such as sage do not lose their flavors if dried, most herbs are meant to be eaten fresh. Herbs added at the beginning of cooking impart their flavor to foods; adding the herbs at the end ensures that their aroma is retained. In this directory, more than 60 herbs and their varieties are grouped by aroma and taste, with details of the parts used, buying and storing, growing your own, and culinary uses worldwide.



### Fresh and mild herbs

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**TASTING NOTES**

The aroma of paprika tends to be restrained and delicate; caramel notes, fruitiness, or smokiness characterize some paprikas, while others have a nose-prickling, light heat. Flavors vary from sweetly smoky to rounded and full-bodied, or gently pungent with bitter notes.

**PARTS USED**

Dried fruits. There is no single paprika pepper: it is made from a number of different red capsicums.

**BUYING AND STORING**

Hungarian paprika is somewhat hotter than Spanish. Portuguese and Moroccan paprika tend to resemble Spanish; that from the Balkan states is closer to Hungarian. Paprika from the US is mild. All paprika should be kept in an airtight container and away from light; otherwise it will lose its vibrancy. Paprika paste and paprika sauce are also produced in Hungary.

**HARVESTING**

Once dried, stems are removed; seeds and veins are separated, then the wall of the fruit and the seeds are ground separately and blended according to the type of paprika being made. For Spanish pimentón, the peppers are dried over oak fires for a smoky flavor.

# PAPRIKA

*Capsicum annuum species*

Capsicums are native to the Americas and were first planted in Spain after the voyage of Columbus in 1492. It was the Spanish who first dried and ground the peppers to make pimentón, or paprika. Later, seeds reached Turkey and were planted there and throughout the Ottoman Empire. Ornamental Turkish pepper was recorded in Hungary in 1604. A century later paprika was mentioned there as a spice used by peasants; it was not until the 19th century that it was considered suitable for "sophisticated stomachs."

**Ground paprika**

Paprika can be sweet, bittersweet, or hot, depending on whether it is produced from mild or lightly pungent peppers, and also on the amount of ground seeds and veins included in the powder.

**HUNGARIAN PAPRIKA**

Hungarian cooks usually have different grades of paprika in the kitchen and select the one best suited to the dish being prepared.



### Culinary uses

Paprika is the predominant spice and coloring in Hungarian cooking. Fried gently with onion in lard (the main cooking fat), it forms the basis of goulash, veal or chicken paprikás, and duck or goose pörkölt; it gives color and flavor to potato, rice, and noodle dishes and many vegetables. Serbian cooks use paprika in similar ways. In Hungary, the Balkan countries, and Turkey, it is more usual to find paprika or chili flakes on the table than black pepper.

In Spain, paprika is used in sofrito, the mixture of onions and other ingredients fried in olive oil that forms the basis of many slow-cooked dishes. It appears in rice and potato dishes, is appreciated with fish and in omelettes, and is essential

to romesco sauce. In Morocco, it is widely used in spice blends, in chermoula (a marinade and sauce for fish), and in tagines; in Turkey, it flavors soups, vegetables, and meat dishes, especially variety meats. In India, its principal use is to add a red color to dishes. Everywhere it is used as an essential flavoring for sausages and other meat products.

Paprika should never be overheated since it becomes bitter. **Essential to romesco sauce.**

**Good with beef and veal, white cheeses, chicken, duck, most legumes and vegetables, pork, rice.**

**Combines well with allspice, caraway, cardamom, garlic, ginger, oregano, parsley, pepper, rosemary, saffron, thyme, turmeric, sour cream and yogurt.**

### Paprika classifications

Paprika is usually sold in sealed cans or bags bearing labels of authenticity.

Hungarian paprika comes from two regions, Szeged and Kalocsa, whose names appear on the packaging.

**Különleges** (special, delicate) is bright red, finely milled to a silky powder, with only a tiny percentage of seeds, it is sweet with a barely perceptible heat. It has a long shelf life.

**Édesnemes** (noble sweet) is darker red, sweet, rounded, with restrained heat and no bitterness. Quite finely ground.

**Delicatess** (delicatessen) is fruity, slightly hot, and bright, light red.

**Főldes** (semi-sweet) contains more veins, and is therefore less sweet and more pungent.

**Rozsa** (rose) is pinkish red and has more heat; it is made from the whole fruit.

**Eros** (strong) is made from lesser-grade whole fruits and has more pungency and a bitter aftertaste. Brownish-red and coarse, it is more like a ground hot chili.

Most Spanish paprika comes from La Vera and carries a denomination of origin; a small amount of sweet paprika from the flora pepper is produced in Murcia:

**Dulce** (sweet, mild) is a brick-red powder with a smoky aroma and a tangy flavor.

**Agridulce** (bittersweet) is deep red and piquant with an acid, bitter note.

**Picante** (hot) is red and has a sharp, pleasant heat. Spanish paprika is made from different quality of peppers that are: extra, and ordinary.

#### SPANISH PAPRIKA

The denomination of origin of pimentón de la Vera guarantees the consumer a hand-made, high-quality paprika with its characteristic smoky aroma and taste.



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## The EnSpicelopedia



# Paprika



Ground  
Paprika

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### Description

Paprika is the dried, ground pods of *Capsicum annum*, a sweet red pepper. It is mildly flavored and prized for its brilliant red color.

### Uses

Paprika is used in seasoning blends for barbeque, snack foods, goulash, chili, and the cuisines of India, Morocco, Europe, and the Middle East.

### Origins

Paprika is primarily produced in Spain, Central Europe, and the United States. Although both Spanish and Domestic Paprika are mild and sweet in flavor, several important differences exist. Domestic Paprika is characteristically fresh, green and vegetable-like, while the Spanish Paprika exhibits a more fermented and piquant flavor. Historically, the Central European varieties were more pungent, but they now exhibit a sweetness similar to Spanish Paprika.

### Folklore

Early Spanish explorers took red pepper seeds back to Europe, where the plant gradually lost its pungent taste and became "sweet" paprika. A Hungarian scientist won the Nobel Prize for research on the vitamin content of paprika. Pound for pound, it has a higher content of Vitamin C than citrus fruit.

[See recipes with Paprika.](#)

### Color

Bright Red

### Flavor & Aroma

Fragrantly Sweet

### Sensory Profile

Most paprika is mild and slightly sweet in flavor with a pleasantly fragrant aroma.

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