An American Spice Trade Association Self-Regulation Program for the Enforcement of the Food and Drug Administration's Regulations Regarding Spices

Introduction

The American Spice Trade Association (ASTA) was founded in 1907 and represents the interests of approximately 150 members including companies that grow, dehydrate, and/or process spices in the United States for domestic consumption and for export. ASTA's members include U.S.-based agents, brokers, and importers, companies based outside of the U.S. that grow spices and ship them to the U.S., and other companies associated with the U.S. spice industry. ASTA's members manufacture and market the vast majority of spices sold in the U.S. at retail, and to food processors. ASTA is active in research and education on spices, government relations, and trade relations.

Several very important aspects of the spice industry are regulated by the U.S. Food and Drug Administration (FDA), including the safety, identity, and labeling of spices. ASTA's members have a significant interest in its members' compliance with FDA regulations to assure that consumers have ready access to safe and wholesome spices in a competitive marketplace.

Many of ASTA's members are competitors, and ASTA fully supports open and vigorous competition in the spice industry. ASTA has adopted an anti-trust and competitive practices policy to assure that ASTA's policies and actions do not in any way diminish competition among its members (Appendix 1).

This self-enforcement program is available to ASTA members and is intended to foster and encourage competition within the regulations governing the sale of safe and wholesome spices in the United States.

The Regulation of Spices by the Food and Drug Administration

FDA addresses the safety of spices through the agency's conclusions that they are generally recognized as safe (GRAS). The marketing of spices is largely regulated by FDA through its authority to regulate what may not be included in spices, and how spices may be labeled (i.e. adulteration and misbranding).

The FDA Definition of Spice

The Food and Drug Administration defines "spice" as:

". . . any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onion, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle as been removed."
21 CFR 101.22(a)(2).

The FDA definition at 21 CFR 101.22(a)(2) also contains a list of materials considered spices that is largely consistent with the ASTA spice list, and the FDA list of GRAS spices at 21 CFR 182.10. The definition also points out that paprika, turmeric, saffron, and other spices may be multi-functional and may be used for their coloring properties in addition to their contribution to a food's flavor.

Safe Spices

FDA has specific authority related to the safety of spices granted by the 1958 Food Additive Amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA). The Amendments created the "GRAS" exception to the definition of "food additive" (FFDCA Sec. 201(s)) and accordingly FDA considers spices to be generally recognized as safe (GRAS) for use in food as described at 21 CFR 182.10. It is important to note that many essential oils derived from spices are also considered GRAS as described at 21 CFR 182.20.

The Marketing of Spices

FDA regulates certain aspects of the marketing of spices pursuant to its general authority under Sections 402 (Adulterated Food) and 403 (Misbranded Food) of the FFDCA. FDA has codified most of its regulations relevant to the marketing of spices at 21 CFR Part 101.

Under the general adulteration provisions of FFDCA Section 402 a food, including a spice, is considered adulterated if it

- Contains any added "poisonous or deleterious substance"
- Contains filth
- Contains unapproved food or color additives

Or

- If any valuable constituent has been omitted or removed
- If any substance has been substituted for it
- If inferiority is concealed
- If any substance has been added to increase bulk or weight, or to make it appear more valuable

Under the general misbranding provisions of FFDCA Section 403 a food, including a spice, is considered misbranded

- If its labeling is false or misleading
- If it is offered for sale under the name of another spice
- If it is an imitation of a spice unless labeled as such
- If its container is made or filled to be misleading

- If it contains added color unless so declared

FDA Food Labeling Requirements Relevant to Spices

For food labeling purposes, the FDA permits spices to be declared by their common or usual name (e.g. basil, black pepper etc.) or generically as "spice" on food labels. 21 CFR 101.22(h)(1). Spices such as paprika, turmeric, saffron, and other spices that may be used for their coloring properties shall be declared for labeling purposes as "spice or coloring" or by their common or usual name. 21 CFR 101.22(a)(2).

It is important to note that the definition of spice excludes, for labeling purposes, substances that have been traditionally regarded as foods, such as onion, garlic and celery, and these substances must be declared on the food label by their common or usual name (e.g. onion, garlic or celery). 21 CFR 101.22(a)(2).

A spice offered for sale at either bulk or retail must bear a label with its common or usual name (e.g. paprika, black pepper etc.), or an otherwise accurate description of identity, and is considered misbranded if it does not. 21 CFR 101.3, 102.5.

The ASTA Self-Enforcement Program

An ASTA member having knowledge of a spice product subject to FDA regulation that the member believes is adulterated and/or misbranded in violation of the Federal Food, Drug, and Cosmetic Act and FDA regulations may report such violation in confidence to ASTA's Executive Director.

Spices Covered by the Program

The ASTA Self-Enforcement Program applies to spices included in the ASTA Spice List (Appendix 2).

Fees for Submitting a Report of a Violation

The fee for submitting a report of alleged adulteration or misbranding is $1,000.00. This fee will cover the costs of necessary analyses, investigation, and interaction with the alleged offender.

The fee of $1,000 applies to each allegation, including allegations of the same offense for the first, second and third instances. For example, an initial report of a violation for adulterating paprika would require payment of the $1,000 fee, as would additional reports for the second and third violations should the alleged adulteration and/or misbranding be believed to continue.

The fees are intended to provide ASTA only with cost recovery for administering the self-enforcement program, and are not intended to be a significant source of revenue for the association.

Allegations of Adulteration

When adulteration is alleged, the Executive Director will have a sample analyzed in confidence by a competent laboratory that is uninvolved in the alleged violation. If the analysis substantially confirms the allegation, the Executive Director shall proceed as described below.

Allegations of Misbranding

In instances of alleged misbranding, the Executive Director in consultation with Counsel shall conduct the appropriate legal analysis of the relevant law and regulations and establish an opinion of compliance or non-compliance, and if the allegation is confirmed then he shall proceed as described below. As with allegations of adulteration, confidential analyses will be conducted as needed.

Actions by the Executive Director in Consultation with Counsel

The Executive Director, in consultation with Counsel, shall act with appropriate discretion in pursuit of allegations of adulteration and misbranding, and shall exercise due care to assure that the pursuit of allegations is in the best interests of ASTA. If necessary and appropriate, the Executive Director shall consult with the officers of ASTA, without revealing confidential information, to assure that ASTA's best interests are addressed.

Extreme care shall be exercised by the Executive Director to assure that the information developed in investigations is accurate and reliable. If the report of allegations received by ASTA's Executive Director is confirmed through the appropriate actions described above, the manufacturer of the product will be contacted in confidence by the Executive Director for discussion about the alleged violation and requested to take corrective action if warranted. When notifying the manufacturer of a confirmed first violation, ASTA's Executive Director will inform the manufacturer that a second confirmed violation of the same provision or standard will result in a report to the U.S. Food and Drug Administration.

Upon the detection and confirmation of a second violation of the same provision or standard, the manufacturer shall be notified in confidence by the Executive Director and requested to take corrective action. The manufacturer shall also be informed that a report will be filed with the U.S. Food and Drug Administration concerning the violation. The manufacturer will then be given the opportunity to review the analytical results confirming the violation, and will have 30 days to present evidence, for review by the ASTA Executive Director and Counsel, that rebuts the alleged violations. This evidence may include but is not limited to certified laboratory analysis or other records. Additional testing of samples at ASTA's expense is at the discretion of the ASTA Executive Director and Counsel.

Following review of the evidence presented by the manufacturer, the ASTA Executive Director and the Counsel will confer on whether reporting the violation to the U.S. Food and Drug Administration is appropriate.

Immediate Notification to U.S. Food and Drug Administration

If during the consideration of an alleged violation under the ASTA Self Regulation Program the ASTA Executive Director finds credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals he/she shall inform the manufacturer or importer of the product as well as the U.S. Food and Drug Administration as soon as possible.

Confidentiality of Allegations

The utmost care shall be taken to assure the confidentiality of the information submitted to, and gathered by, the Executive Director. The Executive Director shall not identify the company reporting the alleged violation, or the alleged violator, to any member or additional staff of ASTA. The identity of the alleged violator shall only be divulged to the Food and Drug Administration, or Counsel should the need arise to do so.

Parties submitting reports of alleged violations shall not make public in any manner information related to the fact that they have filed a report of an alleged violation. Parties submitting reports of alleged violations shall keep such information confidential and shall not disclose the filing of reports outside of their companies.

Requirements for Reports of Alleged Adulteration

In addition to a check for $1,000 (made payable to the American Spice Trade Association), reports of alleged adulteration shall be reported to the Executive Director accompanied by the following information (you may use the form in Appendix 3):

1. The name and address of the party reporting the alleged violation

2. A description of the nature of the alleged adulteration.

3. The name and address of the manufacturer.

4. A sample of the product with labels affixed, or in the case of a bulk product, a sample of the product with an accompanying label.
   - If the sample is a retail product, four unopened samples shall be provided accompanied by an affidavit affirming that the samples were not altered in any way.
   - If the sample is a bulk product, four representative samples shall be provided accompanied by an affidavit affirming that the samples were not altered in any way.

5. The location from which the product was obtained.

6. The date the product was obtained.

7. How the product was obtained (e.g. purchased).

8. The results of analyses demonstrating adulteration, and information fully describing the analyses conducted (e.g. type of filth analysis, GS/MS for chemical adulteration etc.).

Requirements for Reports of Alleged Misbranding

In addition to a check for $1,000 (made payable to the American Spice Trade Association), reports of alleged misbranding shall be reported to the Executive Director accompanied by the following information (you may use the form in Appendix 4):

1. The name and address of the party reporting the alleged violation

2. A description of the nature of the alleged misbranding.

3. The name and address of the manufacturer.

4. A sample of the product with labels affixed, or in the case of a bulk product, a sample of the product with an accompanying label.

5. The location from which the product was obtained.

6. The date the product was obtained.

7. How the product was obtained (e.g. purchased).

Requirements for Reports of Alleged Adulteration AND Misbranding

It is common for instances of adulteration to also include the violation of misbranding. For example, a spice containing an illegal substance is also commonly labeled (i.e. misbranded) to mislead the consumer with respect to the presence of the illegal substance. If reporting such an instance, the report will constitute one report requiring the payment of one $1,000 fee. However, all of the necessary information required for reporting the individual alleged violations of adulteration and misbranding must be submitted- the information described above and in the appropriate forms and samples as required.

Instructions on How to Submit a Report of Alleged Adulteration and/or Misbranding

Please pay particular attention to the requirements for information to be provided for reports of alleged adulteration and misbranding on Pages 5 and 6 of this document. You may use forms in Appendices 3 and 4 to provide information.

Please send the required information marked “Confidential,” including the required samples of product and labels as appropriate, with your check for $1,000 payable to The American Spice Trade Association to:

Cheryl Deem
American Spice Trade Association
2025 M St., NW
Suite 800
Washington DC 20036

You may contact Mrs. Deem to discuss the submission of reports at 202-367-1207. Pre-submission discussions are encouraged.

When submitting samples of product, please be sure to seal the packaging so that product will not spill or leak out.

Please honor the intent of the program and keep all information related to the submission of a report confidential. It is not appropriate to discuss the submission of a report, or any information related to a report, with other members of the industry.

Appendix 1

ASTA Policy on Anti-Trust and Competitive Practices

Review Responsibility: Board of Directors and General Counsel

Policy Statement: Trade associations are associations of competitors who work together to accomplish common goals that are appropriate under U.S. law. Trade associations cannot take actions intended to diminish competition among its members.

Members of an association cannot use the association to accomplish objectives that would benefit single members, or select groups of members by diminishing competition. An association's activities must be generally consistent with it goals and objectives when its membership is examined as a whole.

An area of recent emphasis among regulators and the judiciary is the effects of innovation on competition. Associations cannot take actions to diminish innovation, and therefore competition.
A particularly significant issue often is the establishment by an association of standards, guidelines, or codes of conduct. Associations cannot establish standards, guidelines, or codes of conduct that cannot be reasonably met by current or prospective members or that have the intent of reducing competition or innovation.

Meetings, conference calls, and other activities among ASTA's members, including meetings of the Board of Directors and the association's committees and task forces, and other activities in which members participate representing ASTA (e.g. ESA and IOSTA meetings), should be occasions when members:

- Discuss regulatory, legislative, or scientific issues relevant to the spice industry, and ASTA's mission and critical objectives.
- Identify and implement actions to advance the mission and critical objectives.
- Participate in a forum to identify and implement solutions to industry problems.
- Discuss issues important to the operation and administration of the association.

Meetings, conference calls, and other activities among ASTA's members, including the Board of Directors and the association's committees and task forces, and other meetings in which members participate representing ASTA, cannot be used to:

- Discuss actions by ASTA or its members that are intended to discourage competition or innovation among members.

- Discuss prices, pricing policies or any marketing policy with an indirect effect on pricing.
- Discuss the manipulation of the supply of spices through coordinated action so that prices would be affected.
- Discuss the division or allocation of markets or customers.
- Establish “blacklists” or boycotts of suppliers, purchasers, or competitors.
- Coerce members to implement particular programs or policies.
- Resolve problems particular to a single ASTA member or a small, select group of members with the intent of diminishing competition.

Purpose: To assure that ASTA conducts its business in a manner consistent with U.S. law and regulations regarding competitive practices.

Procedure: A printed statement will be available at all Board meetings, and competitive practices principles will be reviewed at appropriate intervals with the membership by the General Counsel.

Appendix 2

AMERICAN SPICE TRADE ASSOCIATION, INC.

SPICE LIST

Spices

ASTA recommends that for the purpose of complying with FDA food labeling regulations (21 CFR Sec. 101.22), the following items may be declared in a product's ingredient statement either individually by its common or usual name or included under the term "spice" as permitted in 21 CFR Sec. 101.22(h). The spices on this list, and their derivatives (e.g. extracts and oleoresins), are considered by FDA to be generally recognized as safe (GRAS), or approved food additives (See 21 CFR Secs. 172.510, 182.10, and 182.20).

COMMON OR USUAL NAME(s)	PART OF PLANT	BOTANICAL NAME(s) OF PLANT SOURCE(s)
Allspice (Pimento)	Berry	Pimenta officinalis
Anise Seed	Seed	Pimpinella anisum
Star Anise	Fruit	Illicium verum Hook
Balm (lemon balm)	Leaf	Melissa officinalis L.
Basil Leaves (Sweet)	Leaf	Ocimum basilicum
Bay Leaves (Laurel Leaves)	Leaf	Laurus nobilis
Black Caraway (Russian Caraway Black Cumin)	Seed	Nigella sativa
Camomile, English or Roman	Flower	Anthemis nobilis L.
Camomile, German or Hungarian	Flower	Matricaria chamomilla L.
Capsicums	Fruit	Capsicum spp.
Caraway Seed	Seed	Carum carvi Maton.
Cardamom[1]	Fruit	Elettaria cardamomum
Cassia/Cinnamon	Bark	Cinnamomum spp.
Celery Seed	Seed	Apium graveolens
Chervil	Leaf	Anthriscus cerefolium
Chives	Leaf	Allium schoenoprasum
Cilantro (Coriander Leaf)	Leaf	Coriandrum sativum

Cinnamon/Cassia	Bark	Cinnamomum spp.
Cloves	Bud	Syzygium aromaticum
Coriander Seed	Seed	Coriandrum sativum
Cumin Seed (Cummin)	Seed	Cuminum cyminum
Dill Seed	Seed	Anethum graveolens/Anethum sowa
Dill Weed	Leaf	Anethum graveolens/Anethum sowa
Fennel Seed	Seed	Foeniculum vulgare
Fenugreek Seed (Foenugreek Seed)	Seed	Trigonella foenum-graecum
Ginger	Root	Zingiber officinale
Horseradish	Root	Armoracia lapathfolia Gilib.
Juniper	Berry	Juniperus communis
Lavender	Flower	Lavandula officinalis Chaix.
Mace	Aril	Myristica fragrans
Marjoram Leaves	Leaf	Majorana hortensis Moench
Mustard Seed	Seed	Brassica juncea/B. hirta/B. nigra
Nutmeg	Seed	Myristica fragrans
Oregano Leaves	Leaf	Origanum vulgare/Lippia spp.
Paprika	Fruit	Capsicum spp.
Parsley (Dehydrated Parsley, Parsley Flakes)	Leaf	Petroselinum crispum
Black Pepper	Berry	Piper nigrum
White Pepper	Berry	Piper nigrum
Green Peppercorns	Berry	Piper nigrum
Pink Peppercorns	Berry	Schinus terebinthifolius
Peppermint Leaves (Peppermint Flakes)	Leaf	Mentha piperita
Poppy Seed	Seed	Papaver somniferum
Rosemary Leaves	Leaf	Rosmarinus officinalis
Sage Leaves	Leaf	Salvia officinalis/Salvia triloba
Savory Leaves	Leaf	Satureia montana/Satureia hortensis
Sesame Seed[1]	Seed	Sesamum indicum
Spearmint Leaves (Spearmint Flakes)	Leaf	Mentha spicata
Tarragon Leaves	Leaf	Artemisia dracunculus
Thyme Leaves	Leaf	Thymus vulgaris/Thymus serpyllum/Thymus satureioides
Vanilla Bean	Fruit	Vanilla planifolia/Vanilla tahitensis Moore

Dehydrated Vegetables Used As Spices

Because, in addition to their use as spices (e.g. granulated or powdered onion and garlic), these items are traditionally regarded as foods, they shall be declared by common or usual name consistent with 21 CFR Sec. 101.22(a)(2):

COMMON OR USUAL NAME(s)	PART OF PLANT	BOTANICAL NAME(s) OF PLANT SOURCE(s)
Garlic	Bulb	Allium sativum
Onion	Bulb	Allium cepa

Spices Used As Color Additives

Consistent with 21 CFR Sec. 101.22(a)(2), the following spices, which can be used to impart color as well as flavor, shall be declared as "spice and coloring" or declared individually by common or usual name:

COMMON OR USUAL NAME(s)	PART OF PLANT	BOTANICAL NAME(s) OF PLANT SOURCE(s)
Annatto Seed	Seed	Bixa orellana
Paprika	Fruit	Capsicum spp.
Saffron	Stigma	Crocus sativus
Turmeric	Root	Curcuma longa

FOOTNOTE:
[1]Must be listed by specific form (i.e., natural or hulled).

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Appendix 3

An American Spice Trade Association Self-Regulation Program for the Enforcement of the Food and Drug Administration's Regulations Regarding Spices

Report of Alleged Adulteration

Name and Address of Reporting Party

_____

_____

_____

Name and Address of Alleged Offending Party

_____

_____

_____

Description of the Adulteration (with accompanying sample)

_____

_____

_____

Location from which the product was obtained

_____

Date product was obtained

_____

How the product was obtained (purchased of otherwise)

_____

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Results of analysis demonstrating adulteration

- Attach information as needed

_____

_____

_____

_____

_____

_____

Certification

I, _____, certify that the information contained in this report is accurate to the best of abilities. I also certify that any samples submitted with this report have not been altered in any way by me or my associates, and that the samples accurately represent my belief in the allegations contained in this report. I agree to keep the information contained in this report confidential and to not make public in any way the information in this report, including information related to the fact that this report has been submitted.

Signature Date

_____ _____

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Appendix 4

An American Spice Trade Association Self-Regulation Program for the Enforcement of the Food and Drug Administration's Regulations Regarding Spices

Report of Alleged Misbranding

Name and Address of Reporting Party

_____

_____

_____

Name and Address of Alleged Offending Party

_____

_____

_____

Description of the Adulteration (with accompanying product with labels affixed, or other relevant materials – attach as needed)

_____

_____

_____

_____

_____

Location from which the product was obtained

_____

Date product was obtained

_____

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How the product was obtained (purchased of otherwise)

_____

Certification

I, _____, certify that the information contained in this report is accurate to the best of abilities. I also certify that any samples submitted with this report have not been altered in any way by me or my associates, and that the samples accurately represent my belief in the allegations contained in this report. I agree to keep the information contained in this report confidential and to not make public in any way the information in this report, including information related to the fact that this report has been submitted.

Signature Date

_____ _____