**27 CFR**

**Sec. 4.32a Voluntary disclosure of major food allergens.**

 (a) Definitions. For purposes of this section the following terms

have the meanings indicated.

 (1) Major food allergen. Major food allergen means any of the

following:

 (i) Milk, egg, fish (for example, bass, flounder, or cod),

Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts

(for example, almonds, pecans, or walnuts), wheat, peanuts, and

soybeans; or

 (ii) A food ingredient that contains protein derived from a food

specified in paragraph (a)(1)(i) of this section, except:

 (A) Any highly refined oil derived from a food specified in

paragraph (a)(1)(i) of this section and any ingredient derived from such highly refined oil; or

 (B) A food ingredient that is exempt from major food allergen

labeling requirements pursuant to a petition for exemption approved by

the Food and Drug Administration (FDA) under 21 U.S.C. 343(w)(6) or

pursuant to a notice submitted to FDA under 21 U.S.C. 343(w)(7),

provided that the food ingredient meets the terms or conditions, if any,

specified for that exemption.

 (2) Name of the food source from which each major food allergen is

derived. Name of the food source from which each major food allergen is

derived means the name of the food as listed in paragraph (a)(1)(i) of

this section, except that:

 (i) In the case of a tree nut, it means the name of the specific

type of nut (for example, almonds, pecans, or walnuts);

 (ii) In the case of Crustacean shellfish, it means the name of the

species of Crustacean shellfish (for example, crab, lobster, or shrimp);

and

 (iii) The names ``egg'' and ``peanuts'', as well as the names of the

different types of tree nuts, may be expressed in either the singular or

plural form, and the term ``soy'', soybean'', or ``soya'' may be used

instead of ``soybeans''.

 (b) Voluntary labeling standards. Major food allergens (defined in

paragraph (a)(1) of this section) used in the production of a wine may,

on a voluntary basis, be declared on any label affixed to the container.

However, if any one major food allergen is voluntarily declared, all

major food allergens used in production of the wine, including major

food allergens used as fining or processing agents, must be declared,

except when covered by a petition for exemption approved by the

appropriate TTB officer under Sec. 4.32b. The major food allergens

declaration must consist of the word ``Contains'' followed by a colon

and the name of the food source from which each major food allergen is

derived (for example, ``Contains: egg'').

 (c) Cross reference. For mandatory labeling requirements applicable

to wines containing FD&C Yellow No. 5 and sulfites, see Sec. Sec.

4.32(c) and (e).

[T.D. TTB-53, 71 FR 42267, July 26, 2006]

**Sec. 4.32b Petitions for exemption from major food allergen labeling.**

 (a) Submission of petition. Any person may petition the appropriate

TTB officer to exempt a particular product or class of products from the

labeling requirements of Sec. 4.32a. The burden is on the petitioner to

provide scientific evidence (including the analytical method used to

produce the evidence) that demonstrates that the finished product or

class of products, as derived by the method specified in the petition,

either:

 (1) Does not cause an allergic response that poses a risk to human

health; or

 (2) Does not contain allergenic protein derived from one of the

foods identified in Sec. 4.32a(a)(1)(i), even though a major food

allergen was used in production.

 (b) Decision on petition. TTB will approve or deny a petition for

exemption submitted under paragraph (a) of this section in writing

within 180 days of receipt of the petition. If TTB does not provide a

written response to the petitioner within that 180-day period, the

petition will be deemed denied, unless an extension of time for decision

is mutually agreed upon by the appropriate TTB officer and the

petitioner. TTB may confer with the Food and Drug Administration (FDA)

on petitions for exemption, as appropriate and as FDA resources permit.

TTB may require the submission of product samples and other additional

information in support of a petition; however, unless required by TTB,

the submission of samples or additional information by the petitioner

after submission of the petition will be treated as the withdrawal of

the initial petition and the submission of a new petition. An approval

or denial under this section will constitute a final agency action.

 (c) Resubmission of a petition. After a petition for exemption is

denied under this section, the petitioner may resubmit the petition

along with supporting materials for reconsideration at any time. TTB

will treat this submission as a new petition for purposes of the time

frames for decision set forth in paragraph (b) of this section.

 (d) Availability of information--(1) General. TTB will promptly post

to its public Web site, http://www.ttb.gov, all petitions received under

this section as well as TTB's responses to those petitions. Any

information submitted in support of the petition that is not posted to

the TTB Web site will be available to the public pursuant to 5 U.S.C.

552, except where a request for confidential treatment is granted under

paragraph (d)(2) of this section.

 (2) Requests for confidential treatment of business information. A

person who provides trade secrets or other commercial or financial

information in connection with a petition for exemption under this

section may request that TTB give confidential treatment to that

information. A failure to request confidential treatment at the time the

information in question is submitted to TTB will constitute a waiver of

confidential treatment. A request for confidential treatment of

information under this section must conform to the following standards:

 (i) The request must be in writing;

 (ii) The request must clearly identify the information to be kept

confidential;

 (iii) The request must relate to information that constitutes trade

secrets or other confidential commercial or financial information

regarding the business transactions of an interested person, the

disclosure of which would cause substantial harm to the competitive

position of that person;

 (iv) The request must set forth the reasons why the information

should not be disclosed, including the reasons the disclosure of the

information would prejudice the competitive position of the interested

person; and

 (v) The request must be supported by a signed statement by the

interested person, or by an authorized officer or employee of that

person, certifying that the information in question is a trade secret or

other confidential commercial or financial information and that the

information is not already in the public domain.

[T.D. TTB-53, 71 FR 42267, July 26, 2006]

**Sec. 5.32a Voluntary disclosure of major food allergens.**

 (a) Definitions. For purposes of this section the following terms

have the meanings indicated.

 (1) Major food allergen. Major food allergen means any of the

following:

 (i) Milk, egg, fish (for example, bass, flounder, or cod),

Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts

(for example, almonds, pecans, or walnuts), wheat, peanuts, and

soybeans; or

 (ii) A food ingredient that contains protein derived from a food

specified in paragraph (a)(1)(i) of this section, except:

 (A) Any highly refined oil derived from a food specified in

paragraph (a)(1)(i) of this section and any ingredient derived from such

highly refined oil; or

 (B) A food ingredient that is exempt from major food allergen

labeling requirements pursuant to a petition for exemption approved by

the Food and Drug Administration (FDA) under 21 U.S.C. 343(w)(6) or

pursuant to a notice submitted to FDA under 21 U.S.C. 343(w)(7),

provided that the food ingredient meets the terms or conditions, if any,

specified for that exemption.

 (2) Name of the food source from which each major food allergen is

derived. Name of the food source from which each major food allergen is

derived means the name of the food as listed in paragraph (a)(1)(i) of

this section, except that:

 (i) In the case of a tree nut, it means the name of the specific

type of nut (for example, almonds, pecans, or walnuts);

 (ii) In the case of Crustacean shellfish, it means the name of the

species of Crustacean shellfish (for example, crab, lobster, or shrimp);

and

 (iii) The names ``egg'' and ``peanuts'', as well as the names of the

different types of tree nuts, may be expressed in either the singular or

plural form, and the term ``soy'', soybean'', or ``soya'' may be used

instead of ``soybeans''.

 (b) Voluntary labeling standards. Major food allergens (defined in

paragraph (a)(1) of this section) used in the production of a distilled

spirit product may, on a voluntary basis, be declared on any label

affixed to the container. However, if any one major food allergen is

voluntarily declared, all major food allergens used in production of the

distilled spirit product, including major food allergens used as fining

or processing agents, must be declared, except when covered by a

petition for exemption approved by the appropriate TTB officer under

Sec. 5.32b. The major food allergens declaration must consist of the

word ``Contains'' followed by a colon and the name of the food source

from which each major food allergen is derived (for example, ``Contains:

egg'').

 (c) Cross reference. For mandatory labeling requirements applicable

to distilled spirits products containing FD&C Yellow No. 5 and sulfites,

see Sec. Sec. 5.32(b)(5) and (7).

[T.D. TTB-53, 71 FR 42268, July 26, 2006]

**Sec. 5.32b Petitions for exemption from major food allergen labeling.**

 (a) Submission of petition. Any person may petition the appropriate

TTB officer to exempt a particular product or class of products from the

labeling requirements of Sec. 5.32a. The burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method specified in the petition, either:

 (1) Does not cause an allergic response that poses a risk to human

health; or

 (2) Does not contain allergenic protein derived from one of the

foods identified in Sec. 5.32a(a)(1)(i), even though a major food

allergen was used in production.

 (b) Decision on petition. TTB will approve or deny a petition for

exemption submitted under paragraph (a) of this section in writing

within 180 days of receipt of the petition. If TTB does not provide a

written response to the petitioner within that 180-day period, the

petition will be deemed denied, unless an extension of time for decision

is mutually agreed upon by the appropriate TTB officer and the

petitioner. TTB may confer with the Food and Drug Administration (FDA)

on petitions for exemption, as appropriate and as FDA resources permit.

TTB may require the submission of product samples and other additional

information in support of a petition; however, unless required by TTB,

the submission of samples or additional information by the petitioner

after submission of the petition will be treated as the withdrawal of

the initial petition and the submission of a new petition. An approval

or denial under this section will constitute a final agency action.

 (c) Resubmission of a petition. After a petition for exemption is

denied under this section, the petitioner may resubmit the petition

along with supporting materials for reconsideration at any time. TTB

will treat this submission as a new petition for purposes of the time

frames for decision set forth in paragraph (b) of this section.

 (d) Availability of information--(1) General. TTB will promptly post

to its public Web site, http://www.ttb.gov, all petitions received under

this section as well as TTB's responses to those petitions. Any

information submitted in support of the petition that is not posted to

the TTB Web site will be available to the public pursuant to 5 U.S.C.

552, except where a request for confidential treatment is granted under

paragraph (d)(2) of this section.

 (2) Requests for confidential treatment of business information. A

person who provides trade secrets or other commercial or financial

information in connection with a petition for exemption under this

section may request that TTB give confidential treatment to that

information. A failure to request confidential treatment at the time the

information in question is submitted to TTB will constitute a waiver of

confidential treatment. A request for confidential treatment of

information under this section must conform to the following standards:

 (i) The request must be in writing;

 (ii) The request must clearly identify the information to be kept

confidential;

 (iii) The request must relate to information that constitutes trade

secrets or other confidential commercial or financial information

regarding the business transactions of an interested person, the

disclosure of which would cause substantial harm to the competitive

position of that person;

 (iv) The request must set forth the reasons why the information

should not be disclosed, including the reasons the disclosure of the

information would prejudice the competitive position of the interested

person; and

 (v) The request must be supported by a signed statement by the

interested person, or by an authorized officer or employee of that

person, certifying that the information in question is a trade secret or

other confidential commercial or financial information and that the

information is not already in the public domain.

[T.D. TTB-53, 71 FR 42268, July 26, 2006]

**Sec. 7.22a Voluntary disclosure of major food allergens.**

 (a) Definitions. For purposes of this section the following terms

have the meanings indicated.

 (1) Major food allergen. Major food allergen means any of the

following:

 (i) Milk, egg, fish (for example, bass, flounder, or cod),

Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts

(for example, almonds, pecans, or walnuts), wheat, peanuts, and

soybeans; or

 (ii) A food ingredient that contains protein derived from a food

specified in paragraph (a)(1)(i) of this section, except:

 (A) Any highly refined oil derived from a food specified in

paragraph (a)(1)(i) of this section and any ingredient derived from such

highly refined oil; or

 (B) A food ingredient that is exempt from major food allergen

labeling requirements pursuant to a petition for exemption approved by

the Food and Drug Administration (FDA) under 21 U.S.C. 343(w)(6) or

pursuant to a notice submitted to FDA under 21 U.S.C. 343(w)(7),

provided that the food ingredient meets the terms or conditions, if any,

specified for that exemption.

 (2) Name of the food source from which each major food allergen is

derived. Name of the food source from which each major food allergen is

derived means the name of the food as listed in paragraph (a)(1)(i) of

this section, except that:

 (i) In the case of a tree nut, it means the name of the specific

type of nut (for example, almonds, pecans, or walnuts); and

 (ii) In the case of Crustacean shellfish, it means the name of the

species of Crustacean shellfish (for example, crab, lobster, or shrimp);

and

 (iii) The names ``egg'' and ``peanuts'', as well as the names of the

different types of tree nuts, may be expressed in either the singular or

plural form, and the name ``soy'', ``soybean'', or ``soya'' may be used

instead of ``soybeans''.

 (b) Voluntary labeling standards. Major food allergens (defined in

paragraph (a)(1) of this section) used in the production of a malt

beverage product may, on a voluntary basis, be declared on any label

affixed to the container. However, if any one major food allergen is

voluntarily declared, all major food allergens used in production of the

malt beverage product, including major food allergens used as fining or

processing agents, must be declared, except when covered by a petition

for exemption approved by the appropriate TTB officer under Sec. 7.22b.

The major food allergens declaration must consist of the word

``Contains'' followed by a colon and the name of the food source from

which each major food allergen is derived (for example, ``Contains:

egg'').

 (c) Cross reference. For mandatory labeling requirements applicable

to malt beverage products containing FD&C Yellow No. 5, sulfites, and

aspartame, see Sec. Sec. 7.22(b)(4), (b)(6), and (b)(7).

[T.D. TTB-53, 71 FR 42269, July 26, 2006]

**Sec. 7.22b Petitions for exemption from major food allergen labeling.**

 (a) Submission of petition. Any person may petition the appropriate

TTB officer to exempt a particular product or class of products from the

labeling requirements of Sec. 7.22a. The burden is on the petitioner to

provide scientific evidence (including the analytical method used to

produce the evidence) that demonstrates that the finished product or

class of products, as derived by the method specified in the petition,

either:

 (1) Does not cause an allergic response that poses a risk to human

health; or

 (2) Does not contain allergenic protein derived from one of the

foods identified in Sec. 7.22(a)(1)(i), even though a major food

allergen was used in production.

 (b) Decision on petition. TTB will approve or deny a petition for

exemption submitted under paragraph (a) of this section in writing within 180 days of receipt of the petition. If TTB does not provide a written response

to the petitioner within that 180-day period, the petition will be

deemed denied, unless an extension of time for decision is mutually

agreed upon by the appropriate TTB officer and the petitioner. TTB may

confer with the Food and Drug Administration (FDA) on petitions for

exemption, as appropriate and as FDA resources permit. TTB may require

the submission of product samples and other additional information in

support of a petition; however, unless required by TTB, the submission

of samples or additional information by the petitioner after submission

of the petition will be treated as the withdrawal of the initial

petition and the submission of a new petition. An approval or denial

under this section will constitute a final agency action.

 (c) Resubmission of a petition. After a petition for exemption is

denied under this section, the petitioner may resubmit the petition

along with supporting materials for reconsideration at any time. TTB

will treat this submission as a new petition.

 (d) Availability of information--(1) General. TTB will promptly post

to its public Web site, http://www.ttb.gov, all petitions received under

this section as well as TTB's responses to those petitions. Any

information submitted in support of the petition that is not posted to

the TTB Web site will be available to the public pursuant to 5 U.S.C.

552, except where a request for confidential treatment is granted under

paragraph (d)(2) of this section.

 (2) Requests for confidential treatment of business information. A

person who provides trade secrets or other commercial or financial

information in connection with a petition for exemption under this

section may request that TTB give confidential treatment to that

information. A failure to request confidential treatment at the time the

information in question is submitted to TTB will constitute a waiver of

confidential treatment. A request for confidential treatment of

information under this section must conform to the following standards:

 (i) The request must be in writing;

 (ii) The request must clearly identify the information to be kept

confidential;

 (iii) The request must relate to information that constitutes trade

secrets or other confidential commercial or financial information

regarding the business transactions of an interested person, the

disclosure of which would cause substantial harm to the competitive

position of that person;

 (iv) The request must set forth the reasons why the information

should not be disclosed, including the reasons the disclosure of the

information would prejudice the competitive position of the interested

person; and

 (v) The request must be supported by a signed statement by the

interested person, or by an authorized officer or employee of that

person, certifying that the information in question is a trade secret or

other confidential commercial or financial information and that the

information is not already in the public domain.

[T.D. TTB-53, 71 FR 42269, July 26, 2006]