

Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated 27 July 2020

Joanna Richards

Standards Management Officer

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 135 on 31 July 2020. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the Food Standards (Proposal P1050 – Pregnancy warning labels on alcoholic beverages) Variation.

2 Variation to standards in the Australia New Zealand Food Standards Code

The Schedule varies Standards in the Australia New Zealand Food Standards Code.

3 Commencement

The variation commences on the date of gazettal.

4 Effect of the variations made by this instrument

- (1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variations made by this instrument.
- During the transition period, a food product may be sold if the product complies with one of the following:
 - (a) the Code as in force without the variations made by this instrument; or
 - (b) the Code as amended by the variations made by this instrument.
- (3) A food product that was packaged and labelled before the end of the transition period may be sold after the transition period if the product complies with one of the following:
 - (a) the Code as in force without the variations made by this instrument; or
 - (b) the Code as amended by the variations made by this instrument.
- (4) For the purposes of this clause, the **transition period** means the period commencing on the variation's date of commencement and ending 36 months after the date of commencement.

Schedule

Standard 1.1.2

[1] Standard 1.1.2 is varied by inserting in subsection 1.1.2—2(3) in alphabetical order

individual unit means a container that:

- (a) is an innermost package; and
- (b) contains a beverage with more than 1.15% alcohol by volume.

pregnancy warning label means either the pregnancy warning pictogram or the pregnancy warning mark.

pregnancy warning mark means the following image comprising

- (a) the pregnancy warning pictogram,
- (b) the signal words "Pregnancy Warning" and
- (c) the statement "Alcohol can cause lifelong harm to your baby",

all within a border.



pregnancy warning pictogram means the following pictogram with the silhouette of a pregnant woman holding a wine glass within a circle with a strikethrough:



prescribed alcoholic beverage means a beverage that

- (a) has more than 1.15% alcohol by volume; and
- (b) either:
 - (i) is for retail sale; or
 - (ii) is sold as suitable for retail sale without any further processing, packaging or labelling; and
- (c) does not include a beverage that:
 - (i) is sold for retail sale; and
 - (ii) is packaged in the presence of the purchaser.

Standard 1.2.1

- [2] Standard 1.2.1 is varied by
- [2.1] omitting the Note to subsection 1.2.1—6(1), substituting

Note 1 See section 1.2.1—9 for information requirements for food for sale that does not need to bear a label.

Note 2 See Division 4 of Standard 2.7.1 for the requirements relating to a *pregnancy warning label.

[2.2] omitting the Note to subsection 1.2.1—6(2), substituting

Note 1 See also section 1.2.1—24

Note 2 See Division 4 of Standard 2.7.1 for the requirements relating to a *pregnancy warning label.

Standard 2.7.1

- [3] Standard 2.7.1 is varied by
- [3.1] inserting after Note 2 to Standard 2.7.1

Division 1 Preliminary

[3.2] omitting the Note to section 2.7.1—2, substituting

Note In this Code (see section 1.1.2—2):

individual unit means a container that:

- (a) is an innermost package; and
- (b) contains a beverage with more than 1.15% alcohol by volume.

pregnancy warning label means either the pregnancy warning pictogram or the pregnancy warning mark.

pregnancy warning mark means the following image comprising

- (a) the pregnancy warning pictogram,
- (b) the signal words "Pregnancy Warning" and
- (c) the statement "Alcohol can cause lifelong harm to your baby",

all within a border.



pregnancy warning pictogram means the following pictogram with the silhouette of a pregnant woman holding a wine glass within a circle with a strikethrough:



prescribed alcoholic beverage means a beverage that:

- (a) has more than 1.15% alcohol by volume; and
- (b) either:
 - (i) is for retail sale; or
 - (ii) is sold as suitable for retail sale without any further processing, packaging or labelling;and
- (c) does not include a beverage that:
 - (i) is sold for retail sale; and
 - (ii) is packaged in the presence of the purchaser

standard drink, for a beverage containing alcohol, means the amount that contains 10 grams of ethanol when measured at 20°C.

size of type means the measurement from the base to the top of a letter or numeral.

[3.3] inserting after section 2.7.1—2

Division 2 Requisite statements

[3.4] inserting after section 2.7.1—4

Division 3 Restricted representations

[3.5] inserting after section 2.7.1—7

Division 4 Pregnancy warning labels

2.7.1—8 Requirement to display a pregnancy warning label

- (1) A *prescribed alcoholic beverage that has one layer of packaging must display a *pregnancy warning label on its package.
- (2) A *prescribed alcoholic beverage that has more than one layer of packaging must display a *pregnancy warning label on:
 - (a) the outer package; and
 - (b) either:
 - (i) the *individual unit; or
 - (ii) each *individual unit—if the packaging includes more than one individual unit.
- (3) Subsection (2) does not require a *pregnancy warning label to be on the outer package if a pregnancy warning label on an *individual unit is clearly discernible and not obscured by the outer package.
- (4) Subsection (2) does not require a *pregnancy warning label to be on the bladder within a box of a *prescribed alcoholic beverage.

2.7.1—9 Pregnancy warning label for one layer of packaging

- (1) A *prescribed alcoholic beverage that:
 - (a) is required by subsection 2.7.1—8(1) to display a *pregnancy warning label on its package; and
 - (b) is listed in Column 1 of the table to subsection (3):

must display the pregnancy warning label listed in Column 2 of that table on its package.

- (2) The pregnancy warning label required by subsection (1) must comply with any corresponding size requirements listed in Columns 3, 4 and 5 of the table to subsection (3).
- (3) The table to this subsection is:

Pregnancy warning label required

Column 1	Column 2	Column 3	Column 4	Column 5
Prescribed alcoholic beverage	Pregnancy warning label to be displayed	Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark	*Size of type of the signal words	*Size of type of the statement of a pregnancy warning mark
A *prescribed alcoholic beverage with a volume not more than 200 ml.	The *pregnancy warning pictogram.	At least 8 mm diameter	Not applicable	Not applicable
A *prescribed alcoholic beverage with a volume more than 200 ml but not more than 800 ml.	The *pregnancy warning mark.	At least 6 mm diameter	At least 2.1 mm	At least 1.6 mm
A *prescribed alcoholic beverage with a volume more than 800 ml.	The *pregnancy warning mark.	At least 9 mm diameter	At least 2.8 mm	At least 2.1 mm

2.7.1—10 Pregnancy warning label for an outer package

- (1) A *prescribed alcoholic beverage that:
 - (a) is required by paragraph 2.7.1—8(2)(a) to display a *pregnancy warning label on its outer package; and
 - (b) is listed in Column 1 of the table to subsection (3);

must display the pregnancy warning label listed in Column 2 of that table on its outer package.

- (2) The pregnancy warning label required by subsection (1) must comply with any corresponding size requirements listed in Columns 3, 4 and 5 of the table to subsection (3).
- (3) The table to this subsection is:

Pregnancy warning label required

Column 1	Column 2	Column 3	Column 4	Column 5
Prescribed alcoholic beverage	Pregnancy warning label to be displayed	Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark	*Size of type of the signal words	*Size of type of the statement of a pregnancy warning mark
A *prescribed alcoholic beverage with: a volume not more than 200 ml; and packaging that includes only one *individual unit.	The *pregnancy warning pictogram.	At least 8 mm diameter	Not applicable	Not applicable
All other *prescribed alcoholic beverages.	The *pregnancy warning mark.	At least 11 mm diameter	At least 3.5 mm	At least 2.7 mm

2.7.1—11 Pregnancy warning label for an individual unit

- (1) A *prescribed alcoholic beverage that:
 - (a) is required by paragraph 2.7.1—8(2)(b) to display a *pregnancy warning label on one or more individual units; and

- (b) is an individual unit that is listed in Column 1 of the table to subsection (3); must display the pregnancy warning label listed in Column 2 of that table on each such individual unit.
- (2) The pregnancy warning label required by subsection (1) must comply with any corresponding size requirements listed in Columns 3, 4 and 5 of the table to subsection (3).
- (3) The table to this subsection is:

Pregnancy warning label required

Column 1	Column 2	Column 3	Column 4	Column 5
Individual unit	Pregnancy warning label to be displayed	Size of the *pregnancy warning pictogram or the pictogram of a *pregnancy warning mark	*Size of type of the signal words	*Size of type of the statement of a pregnancy warning mark
An *individual unit with a volume not more than 200 ml.	The *pregnancy warning pictogram.	At least 8 mm diameter	Not applicable	Not applicable
An *individual unit with a volume more than 200 ml but not more than 800 ml.	The *pregnancy warning mark.	At least 6 mm diameter	At least 2.1 mm	At least 1.6 mm
An *individual unit with a volume more than 800 ml.	The *pregnancy warning mark.	At least 9 mm diameter	At least 2.8 mm	At least 2.1 mm

2.7.1—12 Required form for pregnancy warning labels

- (1) A *pregnancy warning label required by this Division to be displayed must comply with this section.
- (2) The background of the *pregnancy warning label must be in the colour white.
- (3) The circle and strikethrough of the *pregnancy warning pictogram must be in the colour red.
- (4) The silhouette of a pregnant woman on the *pregnancy warning pictogram must be in the colour black.
- (5) The signal words of the *pregnancy warning mark must be:
 - (a) in the colour red; and
 - (b) in bold font; and
 - (c) in a sans-serif typeface; and
 - (d) in capital letters; and
 - (e) in English.
- (6) The statement of the *pregnancy warning mark must be:
 - (a) in the colour black; and
 - (b) in a sans-serif typeface; and
 - (c) in sentence case; and
 - (d) in English.
- (7) The border of the *pregnancy warning mark must be in the colour black.
- (8) The *pregnancy warning mark must be displayed on the package with a clear space that:

- (a) surrounds the outside of the border of the pregnancy warning mark; and
- (b) is at least 3mm in width.
- (9) The *pregnancy warning label must be displayed as a whole and without modification.

Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared P1050 to consider mandatory pregnancy warning labelling on packaged alcoholic beverages. The Authority considered the proposal in accordance with Division 2 of Part 3 and has approved a draft variation to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation to:

- amend Standards 1.1.2, 1.2.1 and 2.7.1 of the Code to require pregnancy warning labels in the form of a pictogram or a pictogram with associated wording, on packaged alcoholic beverages for retail sale or sold as suitable for retail sale with more than 1.15% alcohol by volume: and
- amend Standard 2.7.1 to prescribe the form, legibility and design of pregnancy warning labels for different packages of alcoholic beverages.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of P1050 included one round of public consultation following an assessment and the preparation of a draft variation and associated reports. Submissions were called for on 4 October 2019 for a three week submission period.

The Office of Best Practice Regulation (OBPR) exempted the Authority from a requirement to undertake a Regulation Impact Statement as the potential regulatory change had already been considered through the Decision Regulation Impact Statement prepared by the Food Regulation Standing Committee.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] varies Standard 1.1.2.

Item [1] varies subsection 1.1.2—2(3) by inserting in alphabetical order new definitions for *individual unit, pregnancy warning label, pregnancy warning mark, pregnancy warning pictogram* and *prescribed alcoholic beverage*:

- An individual unit means a container that: is an innermost package; and contains a beverage with more than 1.15% alcohol by volume.
- A pregnancy warning label is defined as being either the specified pregnancy warning pictogram, or the specified pregnancy warning mark.
- Prescribed alcoholic beverage means a beverage that has more than 1.15% alcohol by volume, and is either for retail sale or sold as suitable for retail sale (without any further processing, packaging or labelling); but does not include a beverage sold for retail sale that is packaged in the presence of the purchaser (this means, for example, wine or beer served in a glass in a restaurant or bar is not required to display a pregnancy warning label). Retail sale includes, for instance, prescribed alcoholic beverages that are: made and packaged on the premises from which they offered for retail sale; delivered packaged and ready for consumption at the express order of the retail purchaser; sold at a fund raising event; displayed in an assisted service display cabinet; sold from a vending machine; or sold at retail in a hamper.

These new definitions apply to the new pregnancy warning label requirements in Division 4 of Standard 2.7.1 (see item [3.5] below).

Item [2] varies Standard 1.2.1.

As explained below, Item [2] inserts Notes into Standard 1.2.1. No variations are made to Division 4 of Standard 1.2.1 as the other sales to which that Division applies are not required to display a pregnancy warning label. Division 5 of Standard 1.2.1 applies to pregnancy warning labels because a pregnancy warning label is a 'label' on a package of food (see the definition of 'label' in subsection 1.1.2—2(3) of the Code). The general legibility requirements in Division 6 of Standard 1.2.1 also apply to pregnancy warning labels, however, additional specific legibility requirements relating to pregnancy warning labels are set out in Division 4 of Standard 2.7.1 (see item [3.5] below).

Item [2.1] omits the Note to subsection 1.2.1—6(1) and substitutes it with two Notes: 'Note 1' (consisting of the existing Note) and a new 'Note 2' referring to the new pregnancy warning label requirements in Division 4 of Standard 2.7.1. Note 2 advises that requirements relating to pregnancy warning labels are set out separately in that Division (see item [3.5] below).

Item [2.2] omits the Note to subsection 1.2.1—6(2) and substitutes it with two Notes: 'Note 1' (consisting of the existing Note) and a new 'Note 2' referring to the new pregnancy warning label requirements in Division 4 of Standard 2.7.1. Note 2 advises that requirements relating to pregnancy warning labels, where there is more than one layer of packaging of a prescribed alcoholic beverage, are set out separately in that Division (see item [3.5] below).

Item [3] varies Standard 2.7.1.

Item [3.1] inserts a new heading 'Division 1 - Preliminary' after Note 2 of Standard 2.7.1. Division 1 contains section 2.7.1—2 – Definitions.

Item [3.2] omits the Note to subsection 2.7.1—2 and substitutes it with a new Note. The new Note restates the reference to the *standard drink* definition and adds references to the definitions of the following terms in subsection 1.1.2—2(3):

- individual unit;
- pregnancy warning label;
- pregnancy warning mark;
- pregnancy warning pictogram;
- prescribed alcoholic beverage; and
- size of type.

Item [3.3] inserts a new heading 'Division 2 – Requisite statements' after section 2.7.1—2. Division 2 contains existing sections 2.7.1—3 and 2.7.1—4, which set out the labelling provisions for the statement of alcohol content and the statement of the number of standard drinks respectively.

Item [3.4] inserts a new heading 'Division 3 – Restricted representations' after section 2.7.1—4. Division 3 contains existing sections 2.7.1—5, 2.7.1—6 and 2.7.1—7, which restrict representations relating to 'low alcohol', 'non-intoxicating' and 'non-alcoholic' respectively.

Item [3.5] inserts a new Division after subsection 2.7.1—7.

The new Division is 'Division 4 – Pregnancy warning labels' and contains new sections 2.7.1—8 to 2.7.1—12. The new Division and sections set out the new requirements for pregnancy warning labels. The effect of the new sections is as follows:

Section 2.7.1—8 imposes a requirement for a package of a prescribed alcoholic beverage to display a pregnancy warning label in specified circumstances.

The requirement imposed by section 2.7.1—8 is limited to the package of a prescribed alcoholic beverage. The requirement therefore does not apply to the package of a product sold other than by retail sale or sold other than as suitable for retail sale. This means, for example, that a transportation outer is not required by section 2.7.1—8 to display a pregnancy warning label.

Subsection 2.7.1—8(1) requires a prescribed alcoholic beverage that has one layer of packaging to display a pregnancy warning label on its package. For example, for a bottle containing wine or spirits (the wine or spirits being the beverage, and the bottle being the single layer of packaging), the bottle is required to display a pregnancy warning label.

Subsection 2.7.1—8(2) requires a prescribed alcoholic beverage that has more than one layer of packaging to display a pregnancy warning label on the outer package (paragraph 2.7.1—8(2)(a)); and either on the individual unit, or each individual unit if the packaging includes more than one individual unit (paragraph 2.7.1—8(2)(b)). The outer package is the most outer layer of packaging for retail sale. For example, a pregnancy warning label must be displayed:

- for a box containing a bottle of wine, on the box and the bottle of wine.
- for a carton containing multiple bottles of wine, on the carton and on each bottle of wine.
- for a pack containing six bottles of beer, on the pack and on each bottle of beer.

Any package between the outer package and the individual unit(s) is not required to display a pregnancy warning label. For example, tissue paper between the outer box and individual unit(s) is not required to display a pregnancy warning label.

Subsection 2.7.1—8(3) exempts the outer package from the requirement to display a pregnancy warning label if this label can be clearly seen on an individual unit and is not obscured by the outer package (for example, where there is clear wrapping around a bottle of wine, or where the pregnancy warning label on a bottle of beer in a 6-pack can be seen).

Subsection 2.7.1—8(4) exempts the bladder within a box of a prescribed alcoholic beverage from the requirement to display a pregnancy warning label (for example, the bladder within a cask of wine will not be required to display a pregnancy warning label).

Section 2.7.1—9 sets out how the requirement imposed by subsection 2.7.1—8(1) will apply to the package of a prescribed alcoholic beverage with one layer of packaging.

Subsection 2.7.1—9(1) provides that a prescribed alcoholic beverage required by subsection 2.7.1—8(1) to display a pregnancy warning label on its package, and which is listed in Column 1 of the table to subsection 2.7.1—9(3), must display the pregnancy warning label listed in Column 2 of that table. This requires:

- a pregnancy warning pictogram to be displayed on the package of a prescribed alcoholic beverage with a volume not more than 200 ml.
- a pregnancy warning mark to be displayed on the package of a prescribed alcoholic beverage with a volume more than 200 ml.

Subsection 2.7.1—9(2) provides that the pregnancy warning label required by subsection 2.7.1—9(1) must comply with any corresponding size requirements listed in columns 3, 4 and 5 of the table to subsection 2.7.1—9(3). The size requirements that apply (as set out in the table to the subsection) depend on the volume of the prescribed alcoholic beverage.

The table to subsection 2.7.1—9(3) prescribes the minimum of: the diameter size (in millimetres) of the pictogram to be used (for both a pregnancy warning pictogram and for the pictogram in a pregnancy warning mark); and where applicable—the size of type of the signal words and statement of a pregnancy warning mark (in millimetres).

Section 2.7.1—10 sets out how the requirement imposed by paragraph 2.7.1—8(2)(a) will apply to the outer package of a prescribed alcoholic beverage.

Subsection 2.7.1—10(1) provides that, a prescribed alcoholic beverage required by paragraph 2.7.1—8(2)(a) to display a pregnancy warning label on its outer package, and which is listed in Column 1 of the table to subsection 2.7.1—10(3), must display the pregnancy warning label listed in Column 2 of that table. This requires:

- A pregnancy warning pictogram to be displayed on the outer package of a prescribed alcoholic beverage with a volume not more than 200 ml and packaging that only contains one individual unit. This means, for example, an outer box which contains a singular bottle of spirits which has a volume not more than 200 ml.
- A pregnancy warning mark to be displayed on the outer package for all other prescribed alcoholic beverages. This means the pregnancy warning mark is required on the outer package of all other prescribed alcoholic beverages with volumes greater than 200 ml (regardless of the number of individual units in the outer package); and for prescribed alcoholic beverages with: volumes not more than 200 ml; and packaging that contains more than one individual unit.

Subsection 2.7.1—10(2) provides that, the pregnancy warning label required by subsection 2.7.1—10(1) must comply with any corresponding size requirements listed in columns 3, 4 and 5 of the table to subsection 2.7.1—10(3). Different size requirements apply for the pregnancy warning pictogram and pregnancy warning mark.

The table to subsection 2.7.1—10(3) prescribes the minimum of: the diameter size (in millimetres) of the pictogram to be used (for both a pregnancy warning pictogram and for the pictogram in a pregnancy warning mark); and where applicable—the size of type of the signal words and statement of a pregnancy warning mark (in millimetres).

Subsection 2.7.1—11 sets out how the requirement imposed by paragraph 2.7.1—8(2)(b) will apply to an individual unit.

Subsection 2.7.1—11(1) provides that a prescribed alcoholic beverage required by paragraph 2.7.1—8(2)(b) to display a pregnancy warning label on an individual unit, and has an individual unit that is listed in Column 1 of the table to subsection 2.7.1—11(3), must display the pregnancy warning label listed in Column 2 of that table on each of those individual units. The liquid volume of the individual unit will determine which pregnancy warning label must be displayed on that unit. That is:

- A pregnancy warning pictogram must be displayed on an individual unit if the individual unit has a liquid volume not more than 200 ml.
- A pregnancy warning mark must be displayed on an individual unit if the individual unit has a liquid volume more than 200 ml.

For example:

- for two 100 ml bottles of liqueur contained in a box, a pregnancy warning pictogram must be displayed on each 100 ml bottle of liqueur
- for a 1L bottle of spirits and a 100 ml bottle of liqueur contained in a box, a pregnancy warning mark must be displayed on the 1L bottle and a pregnancy warning pictogram must be displayed on the 100 ml bottle;
- a pregnancy warning mark must be displayed:
 - for six 750ml bottles of wine contained in a carton, on each bottle of wine.
 - for six 375ml cans of beer contained in a pack, on each can of beer.

Subsection 2.7.1—11(2) provides that, the pregnancy warning label required by subsection 2.7.1—11(1) must comply with any corresponding size requirements listed in columns 3, 4 and 5 of the table to subsection 2.7.1—11(3). The size requirements that apply depend on the liquid volume of the individual unit.

Section 2.7.1—12 sets out the required form for pregnancy warning labels.

For a pregnancy warning label (pregnancy warning pictogram or pregnancy warning mark), the section prescribes the background colour of the label.

For the pregnancy warning pictogram, the section prescribes the colour of the circle and strikethrough and the silhouette of a pregnant women. This applies to the pictogram when used alone, or when used in the pregnancy warning mark.

For the pregnancy warning mark, the section prescribes the format of the signal words and the statement (for example, colour, typography, English language), as well as the colour of the border of the mark. The section also prescribes the size of clear space (in millimetres) surrounding the outside border of the pregnancy warning mark.

The section also prescribes that a pregnancy warning label must be displayed as a whole and without any modification.

Transitional arrangements

The above variations will commence or take effect on the date of gazettal. See clause 3 of the instrument of variation.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of the above variations. See clause 4 of the instrument of variation.

Clause 4 provides two transitional arrangements. First, there is a general transitional arrangement where during a three year transition period commencing on the date of gazettal, a prescribed alcoholic beverage may be sold if the beverage complies with either the Code as in force without the amendments made by the draft variation; or the Code as amended by the draft variation. Second, there is a specific transitional arrangement where prescribed alcoholic beverages packaged and labelled *before* the end of the transition period may be sold after the transition period without having to display a pregnancy warning label. The intent of these transitional arrangements is to assist in minimising the costs of complying with the draft variation for industry while not unduly delaying exposure of the pregnancy warning label to consumers.