

Implementation Guidance for the Consumer Advisory Provision of the FDA Food Code

(Section 3-603.11 in the 1999 FDA Model Food Code)

Section 3-603 of the 1999 Food Code
FDA Model Brochure Text
Implementation Guidance for the Consumer Advisory Provision

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Intent

The intent of the Consumer Advisory provision of the Food Code is to assure that all consumers are informed about the increased risk to especially vulnerable populations of eating raw or undercooked animal foods. The FDA believes that informed consumers play a significant role in protecting themselves from foodborne illness and that that role is one that no one else can assume for them. Informed consumers are best able to assess their individual risk and assume responsibility for their ordering decisions, based on their knowledge and understanding of the situation.

This guidance document is to assist regulators and industry in the implementation of the Consumer Advisory provision. It should be used in conjunction with the FDA Food Code.

Applicability

The consumer advisory is intended to apply to all food establishments where raw or undercooked animal foods or ingredients are sold or served for human consumption in a raw or undercooked form. This includes all types of food establishments whenever there is a reasonable likelihood that the food will be consumed without subsequent, thorough cooking - such as restaurants, raw bars, quick-service operations, carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood departments.

Definition of Terms

The following definitions apply in the interpretation and application of the Consumer Advisory provision. The defined terms and all forms of those defined terms, are in italics throughout this document.

Disclosure means a written indication as to which items are, or can be ordered, raw or undercooked in their entirety, or items that contain an ingredient that is raw or undercooked.

Essential Criteria means the specifications that must be met when developing a custom-designed consumer advisory brochure regarding consuming raw or undercooked animal foods.

Menu means whatever consumers read (table tent, placard, chalk board, or other written means) to make their order selections.

Publicly Available means readily accessible to consumers (without their having to request it) prior to their placing their food orders or making their selections.

Reminder means a written statement concerning the health risk of consuming raw or undercooked animal foods.

Molluscan Shellfish means any edible species of raw or undercooked oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle. Also referred to as *Shellfish* in the *reminder* statements.

Shellstock means raw, in-shell *molluscan shellfish*.

The Consumer Advisory as a Critical Item

Under § 8-405.11 of the Food Code, critical items must be corrected within 10 days of the occurrence of the violation. If an establishment is found in violation of the Consumer Advisory provision, methods of compliance such as those mentioned in this document and other alternatives that fulfill the objectives of satisfactory compliance should be explored cooperatively by the establishment and the Regulatory Authority. Provided a climate of good-faith effort prevails, certain situations including this initial phase of instituting the consumer advisory in retail food establishments warrant affording additional time for compliance before any enforcement action is initiated.

Product-Specific Advisories

Consumer advisories may be tailored to be product-specific if a food establishment either has a limited *menu* or offers only certain animal-derived foods in a raw or undercooked, ready-to-eat form. For example, a raw bar serving *molluscan shellfish* on the half shell, but no other raw or undercooked animal food, could elect to confine its consumer advisory to *molluscan shellfish*. The raw bar might also choose *reminder statement 2* of this document to highlight the increased risk incurred when persons with certain medical conditions ingest *molluscan shellfish* that have not been adequately heat-treated.

In food establishments where the only raw, ready-to-eat food items sold or served are *shellstock* or shucked *molluscan shellfish*, the Interstate Shellfish Sanitation Conference (ISSC) written brochure for raw oysters and clams constitutes satisfactory compliance. In such cases, the ISSC brochure must be made *publicly available*.

Satisfactory Compliance

Overall Objective:

Satisfactory compliance with the Food Code's Consumer Advisory provision is fulfilled when both a *disclosure* and *reminder* are provided in a manner that is consistent with this guidance. The information contained in both the *disclosure* and *reminder* is to be *publicly available* and readable so that consumers have benefit of the total message (*disclosure* and *reminder*) before making their order selections.

A guidance document cannot anticipate all possible situations. Therefore, there will always be need for discussion between the food establishment and the Regulatory Authority as to the most effective way to meet the objectives of satisfactory compliance.

Format specifications for *disclosure* and *reminder*:

Language: The language for the menu items is to match the language used for the *disclosure* and the *reminder*. For example, a menu written in English would have the *disclosure* and the *reminder* in English. The *disclosure* and *reminder* may also be in other languages.

Text size: Text size for statements on hand-held *menus* or table tents is to be visually equivalent to a minimum of 11 point.

For statements on a placard, the statements are to be equally readable as menu items that are on the placard. Whether the placard is also a *menu* or it is used solely for the *reminder*, the text size must be readable from the point at which consumers would normally stand to read it.

For statements on labels affixed at the retail level, a good guideline is the CFR pursuant to the Fair Packaging and Labeling Act, 21CFR 101.2 which addresses text size relative to the size of the display panel. Other factors can also affect readability, such as type of font and background versus type color.

Disclosure

Objective:

Disclosure must:

- be on the *menu* or, in the absence of a *menu*, be presented in writing to consumers, and
- identify the food items that require *disclosure*, and
- specify that those food items are, or contain, raw or undercooked animal-derived foods.

Methods of compliance:

1. *Disclosure* by description: Items are described, such as:
 - Oysters on the half-shell (raw oysters),
 - Raw-egg Caesar salad, and
 - Hamburgers (can be cooked to order); or
2. *Disclosure* by asterisking the food items to a footnote that states, depending on the situation, that the items:

"Are served raw or undercooked," or

"Contain (or may contain) raw or undercooked ingredients"; and

3. When a *menu* is used:
 - Modify the *menu* through the use of permanent adhesive stickers; or
 - Reprint the *menu*; or
 - Present a separate written *disclosure* notice to the consumer in conjunction with the *menu*; or
4. In the absence of a *menu*:
 - Present a written *disclosure* notice to the consumer.

Reminder

Objective:

If either of the two *reminder* statements containing the actual advisory information is used, the statement must be in conjunction with the *disclosure* and placed according to one of the following:

- at least once on any page of the *menu* (preferably the first or last page) and located within the *menu* so that the consumer may easily find it, or
- on a placard, table tent, or by other written means.

Methods of compliance:

1. Use one of the two *reminder* statements containing the actual advisory:

- *Reminder* Statement 1:

"Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness"; or

- *Reminder* Statement 2:

"Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

2. Use a consumer advisory brochure.

Option 1:

The 1999 Food Code provides an option to have the disclosed items footnoted to a *reminder* statement that refers the reader to a consumer advisory brochure:

"Regarding the safety of these items, written information is available upon request."

When the brochure is used to remind consumers of their risk and the brochure is not *publicly available*, the above *reminder* statement has to be mentioned on the *menu*.

When the brochure is used to remind consumers of their risk and the brochure is *publicly available*, the above *reminder* statement does not have to be mentioned on the *menu*.

Option 2:

- Use the text of the FDA model brochure below, or
- Use a custom-designed brochure that meets the Essential Criteria in this document.

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FDA Model Brochure Text

Introduction

You're probably already taking precautions against foodborne illness at home, but you need to be careful when you are away from home too. Here are four easy steps you can take to protect yourself and your loved ones when you are selecting foods that are ready to eat at a restaurant, delicatessen, take-out counter, or grocery store.

No. 1. Be Aware of Raw or Undercooked Foods

Foods from animals such as meat, poultry, fish, shellfish, and eggs when eaten raw or undercooked sometimes contain harmful viruses and bacteria that can pose a risk of foodborne illness. Young children, pregnant women, older adults, and those with compromised immune systems are particularly vulnerable. You are at increased risk if you suffer from liver disease or alcoholism, if you have decreased stomach acidity (due to gastric surgery or the use of antacids), or if you have a compromised immune system due to: steroid use; conditions such as AIDS, cancer, or diabetes; or treatments such as chemotherapy.

To reduce your chances of foodborne illness you should stay away from:

- Raw fish or shellfish --oysters, clams, sushi, sashimi, ceviche
- Meat or seafood ordered undercooked such as "rare" hamburger, beef, lamb, pork, or fish.
- Eggs ordered undercooked and food with uncooked egg ingredients--such as "runny" fried or poached eggs; dressings or sauces such as hollandaise, homemade mayonnaise, and Caesar salad dressing; desserts like chocolate mousse, meringue pie, and tiramisu.

No. 2 Ask about preparation

Recipes vary. If you're not sure whether a ready-to-eat item contains undercooked ingredients, ask how the food is prepared.

No. 3 Request that food be thoroughly cooked

If the item you are interested in selecting contains raw or undercooked meat, fish, shellfish, or eggs, ask if that ingredient can be eliminated. If the food is prepared to order, ask for it thoroughly cooked.

No. 4 Make a different choice

With certain foods, such as oysters on the half shell or an egg-based mousse, it may be impossible to accommodate your request for thorough cooking. In that case, simply choose something else. It is a minor inconvenience compared to the major problems caused by foodborne illness.

To learn more about foodborne illness and ways to prevent it, talk to your health care professional or your local health department, or visit the www.foodsafety.gov web site.

FDA Model Brochure Chart of Who's at Risk, Risky Foods, and Cause of Illness

While the following model chart is included in the FDA model brochure, inclusion in a custom-designed brochure, in whole or in part, is optional. Portions of the chart may be selected for use rather than using the entire chart, **if** only certain portions apply based on the foods offered. For example, a food establishment serving only shucked *molluscan shellfish* such as oysters on the half shell, may opt to include the portion of the chart dealing with shucked *molluscan shellfish* and omit the other portions.

The model chart is not intended to be used independently of the brochure. Use of the chart alone constitutes noncompliance with the *reminder* requirement.

Foodborne illness is preventable - if you take the right precautions		
RISKY FOODS (This is a partial listing)	WHO IS AT RISK	CAUSE OF ILLNESS
Raw or undercooked eggs: Caesar salad dressing; soft-cooked eggs; Monte Cristo sandwich; meringue pie; some puddings and custards; mousse; sauces made with raw eggs (e.g., Hollandaise)	Everyone, especially Older Adults Young Children Immune-Compromised	Salmonella Enteritidis
Raw dairy products: Raw or unpasteurized milk; some soft cheeses like... Camembert, Brie	Everyone, especially Pregnant Women Older Adults Immune-compromised Young Children	Listeria monocytogenes E. coli O157:H7 Campylobacter Salmonella
Raw or rare meat: Hamburger, carpaccio	Everyone, especially Older Adults Young Children	E. coli O157:H7 Salmonella
Raw or undercooked: <i>Molluscan shellfish</i> ; Raw clams or oysters on the half shell	Everyone, especially Persons with liver disease or alcoholism Immune-compromised	Vibrio vulnificus Other vibrios Hepatitis A
Raw fish: Sushi, ceviche, tuna carpaccio	Everyone, especially Immune-compromised Older Adults	Parasites Vibrio parahaemolyticus

Essential Criteria for a Custom-Designed Consumer Advisory Brochure Regarding Consuming Raw or Undercooked Animal Foods

Essential Criteria	How to Meet the Criteria / What Specifically to Address
1. Provide science-based information to meet criteria below	1. Brochure information must be consistent with scientific information related to the consumer advisory from the CFSAN web page (www.cfsan.fda.gov/~mow/foodborn.html) & with the Model Brochure.
2. Describe the hazard	2. Describe as: Broad categories, e.g., bacteria, viruses, parasites, or "Germs", or Specific pathogens
3. Explain why raw or undercooked animal food presents a hazard	3. Indicate that a hazard is created because the animal food is not thoroughly cooked or not otherwise heat-treated to control harmful bacteria
4. State which consumers are at greatest risk of illness	<p>4. Four (4) categories must be mentioned:</p> <ul style="list-style-type: none"> • Older adults • Young children • Pregnant women • Immune-compromised people <p>Recommend mentioning people with:</p> <ul style="list-style-type: none"> • Liver disease (mention alcoholism) • Decreased stomach acidity due to the use of antacids or gastric surgery • Weakened immune system due to conditions such as AIDS, cancer, chemotherapy treatments, diabetes, taking steroids
<p>5. Give guidance to ALL consumers emphasizing especially vulnerable persons</p> <p>Include a statement listing the foods involved: Animal food offered in a ready-to-eat form that is raw, undercooked, or not otherwise processed to eliminate pathogens.</p> <p>For example, raw or undercooked foods such as beef, eggs, fish, lamb, milk, pork, or <i>molluscan shellfish</i> that are offered in a ready-to-eat form</p>	<p>Be aware of the problem. Everyone is at risk, but certain persons are at higher risk of foodborne illness and thorough cooking reduces that risk.</p> <p align="center">Consumer Choices:</p> <hr/> <p>(Brochure can be tailored to the <i>menu</i> / food choices)</p> <ul style="list-style-type: none"> • Be aware of raw or undercooked animal foods • Ask how the food item is prepared • Request that the food item be thoroughly cooked; or If the item contains a raw or undercooked ingredient, request it without that ingredient • Make a different choice in the case where food items such as oysters on the half shell cannot be changed upon request

<p>6. Maintain visibility in layout, format, graphics</p>	<p>Language for <i>disclosure</i> and <i>reminder</i> statements: The language for the <i>menu</i> items is to match the language used for the <i>disclosure</i> and the <i>reminder</i>. For example, a <i>menu</i> written in English would have the <i>disclosure</i> and the <i>reminder</i> in English. The <i>disclosure</i> and <i>reminder</i> may also be in other languages.</p> <p>Text size for <i>disclosure</i> and <i>reminder</i> statements: Text size for statements on hand-held <i>menus</i> or table tents is to be visually equivalent to a minimum of 11 point. Statements on placards are to be equally readable as the <i>menu</i> items on the placard and readable from the point at which consumers would normally stand to read it. For statements on labels affixed at the retail level, a good guideline is the CFR pursuant to the Fair Packaging and Labeling Act, 21CFR 101.2 which addresses text size relative to the size of the display panel. Other factors can also affect readability, such as type of font and background versus type color. Graphics: Text color is to provide a clear contrast to background colors used.</p>
<p>7. State ways to get more specific information (the reader's health care professional must be mentioned along with other authoritative sources)</p>	<p>Recommended Statement: <i>"To learn more about foodborne illness and ways to prevent it, talk to your health care professional or your local health department, or visit the www.foodsafety.gov web site"</i></p>
<p>8. A model chart illustrating who is at risk, the risky foods, and the cause of illness is included in the FDA model brochure. <i>Inclusion of the FDA model chart, in whole or in part, is optional.</i> The model chart is not intended to be used independently of the brochure. Use of the chart alone constitutes noncompliance with the <i>reminder</i> requirement.</p>	

Satisfactory Compliance Flow Chart

