

March 24, 2000

Glenda Lewis, Consumer Safety Officer
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington, DC 20204

Dear Ms. Lewis:

Thank you for sending us a copy of the draft *Implementation Guidance for the Consumer Advisory Provision* of the FDA Food Code, dated February 29, 2000. We appreciate the opportunity to review the document and hope you will consider our comments. We still have not received a response to our previous letter of November 3, 1999 regarding our questions and suggestions to improve this document. Apparently, none of our previous observations or suggestions have been incorporated into the current draft.

Since the restaurant and retail industries will bare the costs of understanding and implementing this proposed consumer warning and brochure scheme, we believe that a regulatory-industry cooperative consensus is very important. On numerous occasions over the past two years we have attempted to give substantive input to the FDA regarding the development of a reasonable interpretation guide and brochure for the FDA Food Code section 3-603.11. Unfortunately, each subsequent revision has increased the size and complexity of the interpretation guide. Many completely new, unrealistic and overly restrictive requirements have been added at each step. It is our belief that the current document bares little resemblance to the compromise reached at the 1998 Conference for Food Protection (CFP) or the intent of Section 3-603.11 of the 1999 FDA Food Code.

The current nine-page draft interpretation is so complex that we believe it will be difficult for many regulators, restaurant employees and operators to understand. The document has incorporated completely new terms, overly restrictive definitions and additional mandates, which in our opinion, does not facilitate reasonable interpretation of the FDA Food Code Section 3-603.11.

It is our opinion that the current interpretive proposal represents an unrealistic view. Ultimately, it will be difficult for the restaurant industry to implement and for the regulatory authority to enforce. As both the FDA and the restaurant industry are aware, simple point of sale warnings impart little useful information to most educated consumers and are generally unwanted by the majority of consumers. The basic intent as stated in the opening of this document is "*to assure that all consumers are informed about the increased risk to especially vulnerable populations.*" Clearly, it is an unrealistic goal for the restaurant industry alone to be the educator of all consumers.

We understand that simple consumer warnings remain popular with some activist groups and regulators and recognize that we can provide meaningful information to consumers that request it. We submit, however, that the esteem some uninformed groups place on the value of consumer advisories should not be the sole basis for a realistic, science-based interpretive guide. At the last CFP, a general consensus was reached on the "Consumer Advisory" section. We continue to support that consensus and strongly feel that consumer education must move beyond simple point-of-sale warnings and scare tactics as advocated by some. A short, targeted informational brochure for all settings, including restaurants, supermarkets, doctors offices and community events should be our goal when attempting to provide consumers with meaningful food safety information.

We urge the FDA to maintain consistency with the specific language in the FDA Food Code regarding consumer advisories and definitions. Additionally, we urge the agency to work on developing a simple guide and consensus brochure that will effectively inform *vulnerable consumers* of the increased risks associated with consumption of raw or partially-cooked animal foods. This will allow the development of consistent, responsible messages to effectively reach the right people in the appropriate manner at the appropriate time. Lessons can be taken from the FightBAC® campaign that such goals can be achieved in full partnership without unrealistic and overly restrictive mandates.

Our major concerns with the current draft *Interpretation Guide* and brochure are as follows:

- The opening of the document states that the intent is "*to assure that all consumers are informed about the increased risk to especially vulnerable populations.*" Clearly, this totally unrealistic goal is beyond the intent of the FDA Food Code and the abilities of the restaurant industry alone to assure that all consumers are informed. Furthermore, to assure that **all** consumers are informed is not an appropriate function for the restaurant industry and must be accomplished by competent public health professionals.

The intent section is overly broad and unrealistic, and should be deleted. The intent is to provide a simple guide to the implementation of the FDA Food Code "Consumer Advisory" mandate.

- The “Definitions of Terms” section introduces completely new terms which are not incorporated in the FDA Food Code and go beyond commonly accepted meanings today. This section should be deleted in its entirety. Only terms defined in the FDA Food Code should be used with common or reasonable meanings.

The terms we are most concerned with are:

1. **ESSENTIAL CRITERIA:** Under the interpretive guidelines only the FDA-contemplated consumer advisory brochures would be used. The FightBAC® campaign, existing retail or USDA brochures would not meet these overly restrictive essential criteria as defined.
 2. **MENU:** This definition basically eliminates verbal menus or verbally-communicated menu items. Daily specials or changes to the menu that are communicated verbally to consumers are omitted from this overly restrictive definition.
 3. **PUBLICLY AVAILABLE:** According to the interpretive guidelines, this definition means “...*readily accessible to consumers (without their having to request it) prior to placing their food orders or making their selections.*” Apparently, this definition would eliminate the use of public signs to comply with the consumer advisory mandate. How can a restaurant operator ever assure this in the real world? Would we have to require that each customer read a brochure or give them a quiz before accepting their order? Again, this definition goes far beyond any reasonable interpretation of the Food Code or the ability of the operator to assure compliance.
 4. **REMINDER:** This definition mandates written reminders to the exclusion of all other forms of communication. This is clearly an overly restrictive definition and may be in violation of the Americans with Disabilities Act.
- The “Consumer Advisory” section of the FDA Food Code is identified by the FDA as a critical item. Any minor or technical violation of this highly complex, nine-page interpretation may place the restaurant operator’s restaurant at risk. Clearly, there is no direct relationship between violations contained in this section of the FDA Food Code to food safety. According to the Centers for Disease Control and Prevention, failure to provide a consumer advisory has never been identified as the primary cause of a foodborne illness outbreak in the United States.

We strongly recommend that the Consumer Advisory Section 3-603.11 be designated as a non-critical item.

- In the “Product-Specific Advisories” section, a new, totally inappropriate requirement has been added. In establishments where only raw shellfish are offered for sale, “*the ISSC brochure must be made PUBLICLY AVAILABLE.*” We are perplexed as to the genesis of this highly inappropriate requirement. No one to our knowledge has seen the brochure, nor has it ever been provided or discussed at any FDA-industry consumer advisory meetings over the past seven years. We strongly feel that it is highly inappropriate for the FDA to mandate that the restaurant industry purchase and distribute a non-governmental organization’s brochure that we have never been given access to.
- The “Satisfactory Compliance” section essentially requires the operator to distribute the FDA brochure to each customer and then verify that the customer reads it prior to ordering. This is so overly restrictive that almost every restaurant that tries to comply with this section could be found in violation. It appears that the FDA has never contemplated that consumers may not want to read the brochure or that there are other forms of communication besides written. Again, the average consumer is not requesting this information and has shown negative reactions when confronted with the mandated warnings. Availability of information should be the only criteria to achieve compliance.
- The “Disclosure and Reminder” sections have been expanded beyond any relevance to the original consensus reached at CFP in 1998. Quite frankly, the current disclosure and reminder sections are so confusing and convoluted that we feel it would be impossible for us to determine acceptable compliance in any real-world setting. This section goes on to require footnotes and written warnings on each and every page of a menu. When the operator uses verbal menus or specials, written warnings must be provided. As we read these overly restrictive requirements, a posted sign of any kind could not be used as a means of full compliance for both disclosure and reminder. It appears that FDA has unilaterally eliminated one of the most effective and easiest means of full compliance identified specifically in the 1999 FDA Food Code and by the ISSC as acceptable compliance.

Unfortunately, instead of clarification of the Consumer Advisory provision in the FDA Food Code, this disclosure and reminder interpretation appears to have been developed to create unnecessary complexity and severely restrict operator options for compliance. Again, this interpretation bears no relation to the consensus reached at the 1998 CFP and the FDA Food Code itself. The current proposal should be deleted and reasonable, sensible guidance for restaurant operators and regulators should be jointly developed.

- The FDA Model Brochure text is too long, is inappropriate for settings other than restaurants and incorporates inaccurate information. The introduction is unnecessary and provides no useful information to the consumer. Item No. 1 is overly complex and implies that Caesar salads and desserts are always made with raw or undercooked ingredients. Again, this brochure is only focused on the restaurant industry and is obviously written to create consumer concern.

- The FDA Model Brochure Chart is confusing, inappropriate and, at times, is inaccurate in its generalities. It should be deleted.
- The definition of “Essential Criteria” is overly complex and the method of compliance with these criteria is obscure. After review, we question whether the FDA Model brochure even meets the essential criteria as established.

In the interim, we are reevaluating our position on this issue and the provisions in the 1999 FDA Food Code. Our assessment is that the proposed FDA draft *Implementation Guidelines for the Consumer Advisory* and the brochure do not meet the spirit or intent of the consensus reached at the 1998 CFP. Therefore, we have no choice but to begin efforts to develop an industry-state interpretive guide and brochure for state adoption.

Please feel free to call on me to discuss this issue, and we remain available to launch a new cooperative effort at any time.

Sincerely,

Steven F. Grover, R.E.H.S.
Vice President, Health and Safety Regulatory Affairs

cc: Steven C. Anderson, President and Chief Executive Officer
Lee Culpepper, Senior Vice President, Government Affairs and Public Policy
Janice Oliver, FDA
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