



February 25, 2002

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 2061
Rockville, MD 20852

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Dear Ladies and Gentlemen:

Founded in 1919, the National Restaurant Association is the leading trade association for the restaurant industry. Representing more than 52,000 members and 254,000 restaurant outlets in 50 states, the District of Columbia, Puerto Rico and the U.S. Virgin Islands, the National Restaurant Association has long supported uniform, science-based regulations governing foodservice establishments. As such, we have a vested interest in the 2001 revision of the FDA Model Food Code released in December 2001 and wish to submit formal comments for the record concerning Docket No. 01D-0532, Federal Register, Volume 66, No. 237, Monday, December 10, 2001, pages 63713-63714. We appreciate the opportunity to comment on the newly revised FDA Model Food Code and are encouraged that the Agency has finally requested input from the restaurant industry and other stakeholders regarding their model code recommendations for restaurant and retail industries.

We believe that a nationally recognized uniform model food safety code that local health authorities can use as a template for state and local adoption can make a substantial and positive impact on food safety in the United States. For decades, the NRA has participated in the Conference for Food Protection which was established to provide an industry / regulatory dialogue on food safety and code related issues regarding food safety and sanitation. We are encouraged that recommendations of the Conference for Food Protection and affected industries will now be recognized by the FDA to provide technical guidance to the Agency on future FDA Model Food Code development. According to the FDA in the Federal Register Notice of December 10, 2001, "each revision of the Food Code is part of an 'ongoing dialogue' based on comments received on a previous code and issues presented to the CFP for further development and discussion."

It was stated in the Federal Register Notice of December 10, 2001 that CFP will provide guidance to the FDA for Food Code modification. Upon review of the new 2001 FDA Food Code we find some inconsistencies with that agency Federal Register statement. The Agency has apparently failed to incorporate or fully address several of the CFP recommendations made following the 2000 CFP and sent directly to the FDA after the Conference. Nearly half of the recommendations forwarded to the FDA after the 2000 CFP were not incorporated or addressed in the 2001 Food Code. The 2000 Conference for Food Protection made 25 recommendations to the FDA regarding Food Code revisions or clarifications. In our count, we can only ascertain that 13 were addressed by changes in the 2001 FDA Food Code. Furthermore, repeated attempts to resolve several controversial issues within the FDA Food Code by the National Restaurant

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Association and others in the food industry, directly and indirectly, have also not been addressed in the new 2001 FDA Food Code. Unfortunately, the newly released 2001 FDA Food Code provides no real resolution to at least 6 longstanding contentious issues which have time and again delayed the goal of national Food Code uniformity. The 2001 FDA Food Code also incorporates at least 12 completely new requirements that were not discussed at the 2000 Conference for Food Protection or with any restaurant or food industry group. The new, and in some cases, controversial provisions introduced into the 2001 FDA Food Code apparently have never been discussed outside of the FDA Center for Food Safety and Applied Nutrition (CFSAN) staff. As a result, there has never been an opportunity for input or comment from any stake holder or non-federal regulatory group on the new provisions. Clearly, these actions fall far short of the goal of an inclusive and open process of new Food Code regulatory development and will do little to foster improved industry and state regulatory support for the 2001 FDA Food Code.

It also appears that the FDA CFSAN staff is not fully working with other Federal Government Agencies to ensure regulatory agreement during the Food Code revision process. Since the Food Code was released in 1993, the agency staff has stated that the provisions contained in the document do not conflict with existing regulations such as those established by the Equal Employment Opportunity Commission (EEOC) or ADA regulations. A recent meeting held by the National Restaurant Association with the EEOC staff on January 24, 2002, would indicate otherwise. EEOC representatives indicated that the 2001 FDA Food Code was not technically reviewed by the EEOC prior to its release to ensure continuity between the FDA Food Code and other government regulations. This development is especially disturbing to us and may require changes in certain provisions of the newly released Food Code.

Input and comments from all stakeholders, along with a real attempt to resolve the remaining controversial issues in the FDA Food Code will be critical to the voluntary acceptance of the Code in the states and the furthering of national Food Code uniformity. Contrary to the FDA Federal Register Notice and Food Code statements, the current approach of addressing only a limited number of agency acceptable Conference for Food Protection recommendations and ignoring most restaurant or food industry recommendations as evidenced in the new 2001 FDA Food Code has left many questioning the Agency's desire for national Food Code uniformity. This leaves us and others with the perception that the FDA staff is unwilling to accept constructive input from those in regulated industries or local health authorities regarding Food Code modifications. We hope that our input and comments will be taken with consideration and in the spirit that they are given in an effort to bring about a new look at the FDA Food Code revision process and make it more inclusive and consensus based.

After a complete review of the 2001 Food Code, the National Restaurant Association suggests that the Agency take another fresh look at the following sections and make a new attempt to work with us and others in the impacted industries to resolve the long standing impediments to full regulatory and industry acceptance of the FDA Food Code. We are confident that together we can create a Model Food Code that is more workable under real world conditions while continuing to afford the highest level of real public health protection possible. The following are our specific recommended modifications to the 2001 FDA Food Code, which will facilitate the

adoption of the FDA Food Code at the state and local levels, facilitate full compliance and make national food code uniformity a real possibility.

- **Section 8-402.11** This section allows a representative of the regulatory authority to conduct inspections, and look at establishment records. We believe that it is important for Health Department representatives to demonstrate certain minimum professional food safety training competency, before they conduct food safety inspections in restaurants. We feel that this demonstration of food safety knowledge must be at least equivalent to the demonstration of knowledge required of food service managers in Section 2-102.11 of the 2001 FDA Model Food Code. Requiring inspectors to demonstrate knowledge in food safety protects the public health, improves communication and raises the professional standing of these regulators among the retail industry. We recommend that a new provision be added that mandates inspector certification.
- **Section 3-603.11** This section requires a mandatory written consumer warning if the establishment serves undercooked (or cooked to order) meats, poultry, fish, eggs, etc. In a striking contradiction, other non-animal potentially hazardous foods which are consumed without cooking pose a significant risk to “especially vulnerable” consumers and do not require warnings. Current research shows that there is little danger when intact meats, fish or eggs are cooked rare or medium rare. Furthermore, FDA research on consumer advisories has shown that consumer advisories in general impart little useful information to consumers and are generally unwanted by consumers at retail. We strongly feel that to be effective, consumer education must move beyond simple menu warning statements and scare tactics involving specific food groups at the restaurant and retail level. Public health education, as related to foodborne illness, is a shared responsibility of the government, food industry, medical, health care professionals and academia. It should not be placed solely on simple point of sale warnings in restaurants or supermarkets for selected foods.

This section also considers it a “Critical Violation” if a written warning is not delivered to a customer requesting anything other than well done. We strongly feel that the lack of a Consumer Advisory should not be a “Critical Violation” and that this requirement must be changed. There has never been a single documented case of foodborne illness associated with the lack of a menu advisory. We believe that the FDA should consider that this overemphasized and confusing section be entirely deleted from the Food Code. However, FDA has stated repeatedly that consumer advisories are key to their foodborne illness intervention strategies.

If the Agency is unwilling to remove the section completely, to provide clearer direction and guidance to industry and regulators, a modification of section 3.603.11 can be made and read as follows: “...if an animal food such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish that is raw, undercooked, or not otherwise processed to eliminate pathogens is offered in a ready-to-eat form as a deli, menu, vended, or other item; or as a raw ingredient in another ready-to-eat food, the permit holder shall inform consumers by any means such as brochures, deli-case placards, signage or verbal warnings of the increased health risks that may read:

Consuming raw or undercooked foods may increase your risk of foodborne illness, especially if you have certain medical conditions”.

- **Section 3-301.11** This section states that “...food employees may not contact exposed, ready-to-eat food with their bare hands....” While Food Code Annex 3 goes on to give some guidance on possible exceptions to the absolute prohibition, Annex 3 is not part of the mandatory code. Therefore, the annex has proven difficult to comply with and has generally been lost during state adoption. This section, in some states that have adopted the provision, has been enforced as a mandatory glove law with no reasonable alternatives. The FDA has publicly stated that this is not the Agency’s intent, but the Food Code in Section 3-301.11 and in Annex 3 states that “bare-hand contact with ready-to-eat food...is prohibited....”

This issue was undertaken by the National Advisory Committee on Microbiologic Criteria for Foods (NACMCF), an FDA advisory committee in September 1999. NACMCF found that scientific data do not support a “blanket prohibition” and that “minimizing bare-hand contact with ready-to-eat foods provides an additional means of interrupting” foodborne disease. However, the Food Code in Annex 3 states that NACMCF cited three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral route including “no-bare hand contact with ready-to-eat foods.” While the FDA believes that the Code is in harmony with NACMCF findings of minimizing bare-hand contact, clearly it is not as NACMCF findings have been inaccurately characterized.

The Code language should be written to clearly recognize NACMCF recommendations. Therefore, we recommend that the current language be modified to accommodate a more practical approach to limiting bare-hand contact. Language for consideration may include: *“Except when washing fruits and vegetables, food employees should attempt to limit contact with exposed, ready-to-eat food with their bare hands” and include the guidance language in Annex 3 relating to section 3.301.11 in the Code language.*

- **Section 3-501.16(B) and (C)** This section allows jurisdictions to give a five year “phase-in” period from the time of local code adoption, for replacement of refrigeration equipment that fails to meet the new refrigeration standard of 41°F. Since April 1998, most newly NSF listed refrigeration equipment has been manufactured to meet this new 41°F standard. Unfortunately, the five-year exemption does not allow for a reasonable 12-year economic payback period for pre-1998 equipment. Furthermore, there is little public health justification for the standards application to short-term refrigerated storage, such as open top, grill line and prep reach-in units.

We recommend that the five-year “phase-in” period be extended to ten years from the date of local adoption of the statute. Furthermore, we recommend an exemption for the life of the refrigeration equipment (grandfathering) be given for all small open top, grill line and prep reach-in units intended for short-term storage of three days or less. This is a

reasonable request that will greatly reduce the equipment cost to operators and have absolutely no negative impact on food safety or public health.

- **Section 3-501.17(A)** This section states that "...refrigerated, ready-to-eat, potentially hazardous food prepared and held in a food establishment for **more than 24 hours** shall be clearly marked..." We believe that the 24 hour requirement is overly stringent, and clearly believe there is no public health significance in requiring labeling of a food product within 24 hours, if maintained at the required safe cold holding temperature. Since the majority of RTE PHF's are sold or served well before the Code's maximum of 4 to 7 days, imposing the datemarking requirement adds a substantial labor cost to the industry without improving food safety in any measurable way. Furthermore, the requirement adds time to the already pressed inspector's schedule to adequately monitor the requirement without demonstrated public health benefit. Therefore, we would recommend modifying the code language of section 3-501.17(a) to accommodate a more practical approach. The following language should be considered:

*"...refrigerated, ready-to-eat, potentially hazardous food prepared and held **more than 48 hours** in a food establishment shall be clearly marked..."*

- **Section 3-501-17(B)** This section, as written, requires a container of refrigerated, ready-to-eat potentially hazardous food prepared and packaged by a food processing plant to be clearly marked upon opening of the container and discarded after 7 calendar days if held at 41°F or less, or 4 calendar days if food is maintained at 45°F or less. Potentially hazardous, ready-to-eat foods prepared in a food processing plant have already been clearly marked by the manufacturer either with the "Sell by" date and/or "Best if used By" date. The safety of the food product has already been clearly specified by the manufacturer, if stored at the required safe holding temperatures. We recommend that this section be modified to recognize "sell by" and "use by" dates. The following language resolves this issue and should be considered for replacement in this section:

"...a container of refrigerated, ready-to-eat potentially hazardous food prepared and packaged by a food processing plant shall be clearly marked to indicate the "Sell By" date, "Best used By" date, or a date by which the food shall be consumed."

- **Section 3-501.16** This section requires that potentially hazardous food be held at or over 140°F. Scientifically, if the potentially hazardous food is properly cooked or reheated and then held hot, it can safely be held at 130°F indefinitely. We believe that the holding temperature of 140°F should be lowered to 130°F. The academic community, food scientists, and many in the regulatory community have agreed for years that 130°F is a microbiologically safe hot holding temperature. The state of South Carolina has used the 130°F standard for a number of years with no reported problems.

If the Code should not be modified, we believe that violation of this section should be considered a non critical-item. Restaurant operators are being forced to discard foods that are safe per science and in some instances may be closed because of violation of this

section. The Code should, at minimum, be modified to incorporate a non-critical violation be deemed if potentially hazardous foods are being held hot above 130°F.

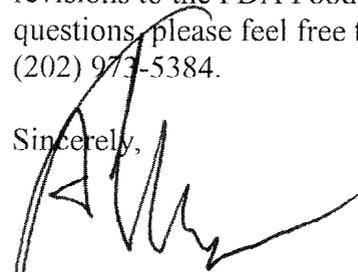
- **Section 1-201.10(B)(70)(b)(iv)** This section defines “ready-to-eat food” as one that includes “All potentially hazardous food that is cooked to the temperature and time required...and cooled....” Previous versions of the Code did not include this criterion. Section 3-301.11 prohibits food employees from contacting ready-to-eat foods with their bare hands. As written, the inclusion of these foods would, in essence, prohibit all food employees from contacting cooled foods with their bare hands even if they are to be reheated. This is overly restrictive and scientifically unjustified. Therefore, we recommend that deletion of this section of the 2001 Food Code be deleted.
- **Section 3-501.14(A)(2)** This section requires that cooked potentially hazardous foods be cooled within 2 hours from 140°F to 70°F and “within 6 hours from 140°F to 41°F or less, or 45°F or less....” While the requirement continues to enable operators to cool foods within 6 hours, the revised wording in the 2001 Code is awkward and does not clearly convey the intent of the section. Therefore, we strongly recommend that the Code be modified to read as the 1999 FDA Model Food Code: “Cooked potentially hazardous food shall be cooled: (1) Within 2 hours from 140°F to 70°F; and (2) Within 4 hours, from 70°F to 41°F or less, or to 45°F as specified....”
- **Section 3-501.16(A)(2)** This section requires that all potentially hazardous foods be held cold at “41°F or less for a maximum of 7 days; or at 45°F or between 41°F and 45°F for a maximum of 4 days....” The Code does not consider, by definition, food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution to be potentially hazardous. However, the definition of potentially hazard food, as written, would include packaged, processed foods such as milk, salads, etc. Therefore, this section would force operators to discard all of these types of foods regardless of “sell-by” or “usc-by” dates established by the manufacturer whether the foods packaging was opened or not. Clearly, this requirement is overly restrictive and scientifically justifiable. Therefore, we strongly recommend that this section be modified to read as the 1999 FDA Model Food Code: “...potentially hazardous food shall be maintained at “41°F or less...at 45°F or between 45°F and 41°F”
- **Section 4-204.117** This section requires that all dish machines installed after adoption of the Code automatically dispense detergents and sanitizers; and that they have a visual or audible means to verify that detergents and sanitizers are delivered. These requirements impose an unnecessary burden on both manufacturers of the equipment as well as restaurant operators. This implies that detergent and sanitizer feeders must be on the dishwasher when it is shipped from the factory. Typically, installations of “free” feeders are installed by chemical companies at the restaurant site. Under this requirement, dishwasher manufacturers will have to charge restaurant owners for feeders that will most often be discarded on site. Furthermore, small facility owners will be required to purchase dispensers where they may have been manually adding chemicals in

the past. Additionally, dish machines are not currently manufactured with audible alarms to indicate sanitizer is needed. We strongly recommend that this section be deleted.

- **Section 5-203.15** This section requires that a double check valve be installed upstream from a carbonating device and downstream from any copper in the water line. The requirement of a vent on soft drink carbonators is targeting an issue that at most is an extremely rare occurrence. There is no standard for testing these devices and the device will have to be designed to vent carbon dioxide into enclosed spaces—possibly a restaurant—potentially creating more of a hazard than the one that the requirement is designed to eliminate. We recommend that this section be deleted entirely.

While we have noted specific proposed suggestions for modification to the problematic sections in the 2001 FDA Food Code, our suggestions are by no means the only acceptable resolution to the noted problems. The National Restaurant Association is striving to have issues responsibly addressed and welcomes any increased cooperative efforts to resolve these long standing issues in an open, responsible dialogue with the FDA, CFSAN or agency staff regarding the FDA Food Code and the revision process. We appreciate the opportunity to formally comment on the 2001 revisions to the FDA Food Code and look forward an agency response. Should you have any questions, please feel free to contact our Health and Safety Regulatory Affairs Department at (202) 973-5384.

Sincerely,



Steven C. Anderson, CAE
President and Chief Executive Officer



Steven F. Grover, R.E.H.S.
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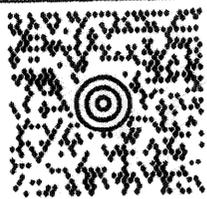
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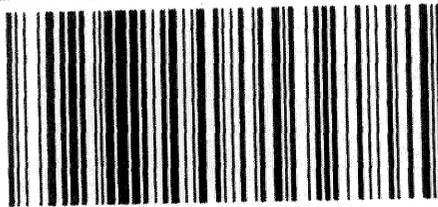


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