



November, 2019

Steve Mandernach, Executive Director  
Ernie Julian, Ph.D., President  
Association of Food and Drug Officials  
2550 Kingston Road, Suite 311  
York, Pennsylvania 17402

Re: Food and Drug Administration (FDA) Responses to the 2019 Association of Food and Drug Officials (AFDO) Resolutions

Dear Messrs. Mandernach and Julian:

The FDA greatly appreciates working with AFDO to advance shared public health goals through federal, state, and local collaborations and partnerships. This letter is in response to your 2019 resolutions completed at the 123<sup>rd</sup> Annual Educational Conference in Atlanta, Georgia. Attached are the FDA responses to each of the four resolutions.

As always, we are happy to provide you with these written responses and hope this will facilitate further communication on these topics.

The FDA would like to thank AFDO for your continued partnership and collaboration as we work together to advance a National Integrated Food Safety System, as well as ensure food and medical product safety. We recognize the value in supporting our fellow food and drug officials and appreciate your input.

Sincerely,

A handwritten signature in black ink, appearing to read "Melinda K. Plaisier".

Melinda K. Plaisier, MSW  
Associate Commissioner for Regulatory Affairs  
Office of Regulatory Affairs (ORA)

A handwritten signature in purple ink, appearing to read "Susan T. Mayne".

Susan T. Mayne, Ph.D.  
Director  
Center for Food Safety and Applied Nutrition  
(CFSAN)

**Attachment: 2019 AFDO Resolutions and FDA Responses**

## **Resolution #2019-1: Charcoal aka Activated Carbon Used as a Food or Beverage Ingredient**

**Summary:** AFDO advises the FDA of its concern with the safety of charcoal (aka activated carbon) as a food and beverage ingredient. AFDO requests the FDA to examine current industry use of activated charcoal in retail to determine if it is compatible with the requirements of the FDA Food Code. If its use is not prohibited, AFDO requests the FDA to identify appropriate controls to ensure consumer safety and provide guidance and technical assistance to the states on appropriate regulatory intervention in order to avoid the creation of a patchwork of state regulations covering this issue.

**FDA Response:** Currently, there are no food additive or color additive regulations in Title 21 of the U.S. Code of Federal Regulations that permit the use of charcoal as an ingredient in food or beverages. Furthermore, the FDA has not received any submissions from industry to our GRAS (Generally Recognized As Safe) notification program informing us of their conclusion that charcoal added directly to food or beverages is GRAS for its intended use. While independent GRAS conclusions may have been made for certain uses of charcoal in food or beverages, charcoal used to impart color to a food or beverage is an unapproved color additive use and would render the food or beverage adulterated under section 402(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). We additionally note that the FDA recommends in its [guidance](#) that companies maintain proper documentation to support an independent conclusion of GRAS status.

In September 2015, we issued [guidance to industry](#) that describes the regulatory requirements of using color additives such as charcoal and red clay to color sea salt. This guidance is applicable to food in general, and it is shared with stakeholders when they contact us with questions about the regulatory status of charcoal. Furthermore, the FDA is available at [premarkt@fda.hhs.gov](mailto:premarkt@fda.hhs.gov) to provide technical assistance to states/locals, manufacturers, and consumers regarding the regulation of substances added to food.

The FDA supports efforts to further examine current retail food industry use of activated charcoal. We welcome and recommend future dialogue with all stakeholders to further examine current retail food industry use of activated charcoal. While the FDA does not collect retail food industry use data, we are open to engagement with retail industry partners through the existing Restaurant Food Safety Partnership and the Retail Food Store Partnership. With these forums in place, the FDA is open to initiating discussions regarding the current state of use, consumer exposure, and potential mitigations of any concerns, incidence, and risk associated with the culinary uses of activated charcoal as a food ingredient within retail food establishments.

## **Resolution #2019-2: Incorporating General Education Online Courses into Program Standards**

**Summary:** AFDO requests the FDA to consider developing a plan to assist state, local, tribal, and territorial (SLTT) regulatory programs to incorporate the newly completed general education online courses into the regulatory program standards.

**FDA Response:** The FDA worked with the International Food Protection Training Institute (IFPTI), other federal agencies, and volunteers from SLTT human and animal food regulatory agencies to develop a variety of general education (GenEd) courses. These eLearning courses provide on-line training for the entry level inspectors/investigators and serve as the basic level of the [Integrated Food Safety System Food Protection Profession Curriculum Framework](#). The courses are available for free to individuals employed by a government agency through ORA [Office of Training, Education, and Development's \(OTED\) Pathlore system](#), or at a low cost for industry partners through [IFPTI](#).

The FDA will develop a communication plan to promote the awareness and availability of the GenEd courses. This awareness plan will be widely distributed to SLTT regulatory agencies, human and animal food regulatory/public health associations, other federal agencies, national conferences (e.g., Conference for Food Protection), and the Partnership for Food Protection (PFP). The FDA recognizes that each of the national regulatory program standards (i.e., Voluntary National Retail Food Regulatory Program Standards, Manufactured Food Regulatory Program Standards, and Animal Feed Regulatory Program Standards) utilize their own collaborative processes for soliciting proposed changes, as well as vetting and accepting changes to the regulatory program standards. By sharing the awareness and availability of the GenEd courses, the FDA recognizes that each of these established pathways can best determine how the GenEd courses should be incorporated into future versions of the program standards (recognizing that the FDA currently participates in the process updates).

Through partnership with the FDA, AFDO has greatly assisted in the solicitation of volunteers for training course development and promotion of training curricula to support the national regulatory program standards. The FDA looks forward to continued collaboration with AFDO to resolve mutually agreed upon areas and to improve the awareness and delivery of eLearning courses.

### **Resolution #2019-3: Availability of Level 1 and General Education Online Training to Academic Institutions**

**Summary:** AFDO requests the FDA to consider providing online trainings, including “Level 1” and the general education courses, to educational institutions.

**FDA Response:** The FDA looks forward to continuing our work with AFDO on improving the Level 1 and General Education courses. We recognize the need for our state/local regulatory partners to be proactive in establishing a “pipeline” of interested, eligible candidates for key regulatory positions. To that end, FDA ORA Office of Partnerships and Operational Policy (OPOP) and AFDO have been working together to develop a long-term solution to having future students educated and trained in the human and animal food regulatory programs. This initiative was announced by Erik Mettler at the 2019 Manufactured Food Regulatory Program Alliance (MFRPA) meeting in March 2019. The initiative is being explored first with California Polytechnic Institute; however, discussions will follow with several other universities. The initiative will target food safety, food technology, medical, engineering, and similar majors to increase awareness of regulatory and public health occupations of importance to the FDA and our state/local regulatory partners.

The FDA will continue to explore the expansion of course offerings to all of our Integrated Food Safety

System (IFSS) partners. We are committed to finding new and novel ways to assure additional training courses are available and that potential hires are identified and prepared with work experience/training to apply for regulatory positions.

#### **Resolution #2019-4: Evaluating and Establishing Prerequisites for FDA Classroom-Based Courses**

**Summary:** AFDO requests the FDA to consider incorporating a process for SLTT and/or regulatory association representation and participation in determinations of prerequisites for OTED courses, to ensure that impacts on state and local food safety programs are considered during those discussions and determinations.

#### **FDA Response:**

FDA/ORR/OTED understands the potential impact to our SLTT partners when determinations and/or changes are made to the prerequisite requirements for training courses. In keeping with our practices for planning and course development:

- FDA/ORR/OTED routinely seeks SLTT representation on our course development teams to ensure we have their voice in the process.
- FDA/ORR/OTED has undertaken a complete review of our prerequisites to ensure we have a clear line on prerequisite requirements, pre-course work, and resources provided as part of our training courses to reduce confusion.

Per our discussions with AFDO, we are cognizant that recent changes in prerequisites for the Preventive Controls for Regulators course were not communicated in a timely fashion to allow for appropriate planning by our SLTT partners. While we made allowances in fiscal year 2019 in those cases where there was significant impact on a partner agency, it is not a long-term solution or appropriate process for future operations.

FDA/ORR/OTED is working to develop a better timeline for communicating changes to any prerequisites and for allowing feedback to be gathered for assessing the impact on our SLTT regulatory partners. We will be revising our communication procedures to include specific messages to be shared via FDA ORR communication mechanisms, including working closely with ORR's Office of Partnerships (OP). In addition to providing clear communication about any prerequisite changes, we are evaluating the implementation timeline of these changes in order to not create a tremendous burden to our SLTT partners. FDA/ORR/OTED will share these changes with regulatory associations, such as AFDO, and we look forward to discussions regarding impact and implementation to our SLTT partners.

In addition, as previously discussed with AFDO Board members, we look forward to quarterly calls between AFDO members and OTED to continue to open the lines of communication, address concerns at the earliest possible, and communicate any changes or updates to our prerequisites. These quarterly calls, known as "Chat with Pats," will be hosted by AFDO starting in October 2020.