

Resolution #1 – FDA’s Use of Private Laboratories

AFDO requests FDA to explore appropriate authority to establish basic criteria for domestic third party laboratories and other third party inspectional entities so that appropriate standards are established as they are with state food safety programs and state food laboratories. AFDO recommends that FDA first utilize state FERN laboratories or other state laboratories that have achieved ISO/IEC 17025 accreditation for any domestic regulatory food testing when needed.

Response

Laboratories play a vital role in ensuring the safety and quality of the food supply. FDA is committed to working with our state, local, territorial, and tribal partners to maintain a nationally integrated laboratory science system that:

- Facilitates the sharing of results between strategic partners;
- Assures comparability of analytical methods and acceptability of laboratory results between partners;
- Develops and implements processes to leverage laboratory resources and increase knowledge about the food supply chain;
- Advances initiatives among strategic partners for the use of best practices to prepare human and animal food testing laboratories for accreditation.

FDA currently provides multi-year cooperative agreements to states to initiate, maintain and improve capacity for state laboratory based activities. These cooperative agreements include the food emergency response network (FERN), Integrated Laboratory System to Advance the Safety of Human and Animal Food, Rapid Response Teams (RRT’s), and the FDA Scientific Conference Cooperative Agreement Program (ScC CAP).

FDA agrees with AFDO regarding the importance of obtaining analyses from laboratories using a reliable quality management system. Moreover, FDA recognizes the importance of laboratory accreditation to achieving these results and has funded a Cooperative Agreement with AFDO/APHL/AAFCO for the past 4 years to provide training materials and assistance to state and local partner laboratories related to achieving and maintaining ISO 17025 accreditation. FDA also worked with the Partnership for Food Protection to develop a manual of best practices in this area. In addition to several state funding opportunities for laboratories, funding awarded to APHL, AFDO, and AAFCO for the integrated laboratory cap averages \$1.2 million per year.

The state food safety programs are critical partners in improving food safety and public health. As the FDA Food and Veterinary Medicine Program finalizes the development and implementation of its large-scale (future-state) sampling program, the Agency will increasingly rely on its state laboratory partners (particularly FERN laboratories) to conduct such targeted, non-research surveillance of high risk commodities. For example, the FERN microbiology

cooperative agreement program (micro-CAP) laboratories played a key role in one of the initial large-scale surveillance pilots (avocado testing for *Listeria monocytogenes*) in 2014. This testing relationship will continue to expand as this new surveillance paradigm is implemented pending funding availability.

FDA does not use data supplied by private laboratories as the basis for regulatory action, but occasionally fills data gaps or obtains data that can be more timely and cost effectively obtained through contracts with private laboratories. Examples include the assessment of newly developed methods for validation suitability, acquisition of data used to support risk assessments, or to obtain baseline data on a particular commodity for the purpose of modeling or to support policy development. In some cases, the surveys encounter samples that represent a public health concern. When that occurs, samples that would represent a concern for Public Health are referred to ORA for follow-up. Regulatory action would be based on data gathered by ORA and investigations conducted by ORA.

In general, these contracts are administered through the Center for Food Safety and Applied Nutrition (CFSAN) and require the laboratories meet a number of contract terms associated with quality management, including accreditation. Any of these sampling contracts clearly stipulate the private laboratory must be ISO 17025 accredited, use validated methods approved by FDA and demonstrate proficiency with these methods. Further, contracts require submission of isolates and complete analyst worksheets to CFSAN. Isolates are confirmed and subtyped by CFSAN and analyst worksheets are reviewed by an appropriate SME. Additionally, CFSAN conducts regular, rigorous quality assurance inspections of these laboratories. CFSAN and ORA have developed written procedures for all cases involving samples collected and analyzed under these contracts that may represent a public health hazard.

FDA agrees with AFDO regarding the importance of obtaining analyses from laboratories using a reliable quality management system. The FDA's current use of these accredited contract laboratories for the above-specified research should be viewed as a prelude to the establishment and implementation of additional data acceptance criteria for domestic third-party laboratory submissions for regulatory review beyond accreditation. FSMA mandates that private food and feed laboratories be accredited-particularly those laboratories testing products for import into the United States. Accreditation establishes a minimum threshold of standards and proficiencies for lab activities under a defined quality management system whose aim is to provide consistently valid results. In the future, data acceptance by the FDA will not be based solely on the accreditation status of the laboratory. Additional criteria beyond those standard elements for which accreditation is granted will bear equal weight to the acceptability of the data. To this end FDA is currently working with state and public stakeholders to define such additional criteria.

With these perspectives in mind, FDA recognizes the valuable perspective AFDO provides and appreciates the ability to provide clarification on the use of private laboratories, as well as FDA's agreement with AFDO regarding the importance of timely, reliable analytical data.

Resolution #2 – Cost for Analytical Samples

AFDO requests FDA to consider possible funding mechanisms to state and local government food laboratories that perform environment and/or finished product testing relating to the surveillance of food. AFDO request FDA to work with them in developing work plans to assure state and local food laboratories are properly utilized to assure adequate coverage of food commodities.

Response:

FDA agrees with AFDO regarding the importance of reliable analytical data and strong partnerships with states. The Office of Regulatory Affairs (ORA), Office of Partnerships (OP) works closely with the states to develop and administer cooperative agreement programs (CAPs) related to food safety and human health issues. Through ORA/OP, the FDA has provided significant funding to promote laboratory development and advance partnerships with state laboratories, amounting to \$135 million from 2005 to 2015.

FERN laboratories have participated in special projects such as the Special Event Food Defense Assignments dating back to 2007 and in the Microbiological Surveillance Sampling initiative that began in 2014. In the Microbiological Surveillance Sampling initiative, FDA piloted the use of select state laboratories to support the Agency's sample large-scale analytical needs. In addition, FDA continues to pursue mutual reliance pilots to build a foundation for using state laboratory results and data to support the FDA regulatory mission.

FSMA implementation requires transformative change in how FDA does its work. As FDA implements the prevention-oriented standards, inspections will focus on assessing whether systems are working effectively to prevent problems and taking immediate action to protect public health. In implementing the new framework, FDA will rely on a variety of tools, which will continue to include food testing and likely rely increasingly on environmental sampling.

FDA anticipates using the lessons learned from the FERN Microbiological Surveillance Sampling initiative, the future mutual reliance pilots, the continuing efforts of the Partnership for Food Protection for enhancing integrated food safety, and FDA's own evolving inspection structure to help inform future funding and work planning opportunities between the federal, state, local laboratories.

Resolution #3 - Decrease in FDA Contract Inspections for States

AFDO requests FDA to clarify, as specifically as possible, its policy/position on state contract inspections as it relates to joint work planning and leveraging of state resources, and AFDO advises FDA of the need for better coordination, consistency, guidance, and monitoring of work planning between FDA Districts and states to ensure efficient use of limited resources, and maintain adequate inspection coverage and public health protection.

Response:

FDA's policy position on state contract inspections as it relates to joint work planning and leveraging of state resources is that FDA and the states work collectively together in a "One Work Force model." Not only is this more efficient, but it maximizes work coverage and is mutually beneficial. FDA acknowledges that it would not be able to meet the high risk and non-high risk inspection frequency mandate without state partners, and values the continued collaboration and coordination of operational activities in support of our national Integrated Food Safety System.

FDA recognizes that there continue to be challenges with work planning, with a need for better coordination, consistency, guidance, and inspection audits between partners for both contract and non-contract inspections. Challenges include scheduling of high risk and non-high risk firms to not only meet the FSMA inspection frequency mandate but to go beyond the mandated frequencies especially for high risk firms; assigning work with the complexity and in such numbers to allow federal and state investigators and inspectors to maintain expertise in specific areas such as Low-Acid Canned Food or Seafood HACCP; poor data quality in firms registering pursuant to the Bioterrorism Act of 2002; the need for improvements in inventory clean-up within the states and FDA; and an increase in foreign inspections.

To meet these challenges, we will clearly communicate expectations from senior FDA leaders to the districts through updated and modernized procedures, enhancing the joint work planning and leveraging state resources. We will utilize the Partnership for Food Protection best practices document as a framework for districts to use. We will ensure accountability, equity and fairness in the work planning process. The FSMA inspection frequency mandate is considered the minimum number of inspections that must occur and we welcome AFDO thoughts on how to facilitate work planning between Districts and state partners. We collectively strive for creative, flexible options that are advantageous to both FDA and state agencies. FDA's Field Management Directive #50 (FMD-50, *State Correspondence*) outlines how and when FDA District Offices and State Cooperative Program Directors should be communicating and meeting in support of work planning and coordination of operational activities throughout the year. FMD-50 will be updated to address communicating in advance when changes are made to state contracts, as well as to address the new multi-year systems approach to work planning.

Resolution #4 – Marijuana Infused Edibles

AFDO requests FDA to clarify, as specifically as possible, its policy position on marijuana infused edibles. AFDO advises FDA of the need for federal leadership on the matter of marijuana infused edibles and for providing 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.

Response:

FDA is aware that a number of states have developed, or are in the process of developing, regulatory systems associated with the cultivation, distribution, sale, and possession of marijuana, including marijuana infused edibles. We have been working with our state partners to provide information on scientific and FDA regulatory matters related to marijuana and its constituents.

The fact that a product takes a form that is associated with a conventional food does not necessarily mean that the product is properly classified as a conventional food. Any product, including an edible marijuana product that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease is classified by FDA as a drug. Furthermore, products that are intended to affect the structure or any function of the body are classified as drugs unless they meet the statutory definition of a conventional food or a dietary supplement.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), marijuana cannot be lawfully added to products that are properly classified as foods. Furthermore, FDA has concluded that section 301(l) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food (including any animal food or feed) to which cannabidiol (CBD) or tetrahydrocannabinol (THC) has been added. This is because CBD and THC are both drugs for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. Section 301(l) contains exceptions, including when the drug was marketed in food before any substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these exceptions apply for CBD or THC.

Resolution #5 – Review for Potential Harmonization of VNRFRPS and MFRPS

AFDO recommends the creation of an Ad Hoc joint committee from both organizations co-chaired by the Conference for Food Protection Chair and the AFDO President to review the VNRFRPS and MFRPS with no more than a total of three members from each organization and one member on the Board of both organizations. Further, AFDO recommends that this Ad Hoc committee will review both sets of program standards looking for areas of potential harmonization between standards and make recommendations to both organizations for potential revisions in both sets of program standards.

Response:

Resolution #2015-4 requested that FDA create a retail food regulatory program alliance modeled after the Manufactured Food Regulatory Program Alliance and that FDA move the management of the Voluntary National Retail Food Regulatory Program Standards (Retail Standards) from Office of Foods' Center for Food Safety and Applied Nutrition to the Office of Regulatory Affairs, Office of Partnerships. FDA invested considerable resources on an internal review and deliberation over this and did not come to a full agreement. FDA strongly supports AFDO's 2016 resolution to bring together interested organizations for a discussion around developing recommendations for harmonizing these standards. FDA stands willing to participate in discussions in this endeavor.

Resolution #6 – Best Practices in Environmental Assessments

AFDO requests FDA to finalize and release the current best practices for conducting environmental assessments of manufactured foods facilities and farms or that a working group including FDA, state and local officials be established to review and finalize the unreleased best practices so they may be utilized by federal, state, and local food inspectors/investigators to standardize the approach for conducting environmental assessments.

Response:

The Environmental Assessment Process Overview (EA) document represents a comprehensive resource designed to efficiently and effectively support the development of detailed environmental assessment procedures for specific situations. FDA has issued the EA Process Overview document to district Directors of Investigative Branch. The Environmental Assessment Overview document is a companion document to a Compliance Policy Guide (CPG) currently in development by ORA.

In 2016, the EA Process Overview document was utilized by an interdisciplinary team to develop a Delmarva Region specific Environmental Assessment procedure. Representatives from ORA-ORS, CFSAN-ORS and Produce Safety, CORE, the Baltimore District Office and resident posts as well as representatives from the Maryland and Virginia Rapid Response Teams and Delaware Department of Agriculture contributed to the development of the Delmarva Region Environmental Assessment procedure document. In July 2016, a table top exercise was attended by more than 25 individuals at the Baltimore District office and shared through WebEx. This table top exercise validated the content of the environmental assessment and the on the ground procedures to conduct the assessment should one be assigned as a result of an outbreak.

In addition to the development of the EA Process Overview document, over the last several years FDA has worked to incorporate the principles of environmental assessment and root cause analysis into training utilized for FDA investigators/consumer safety officers in the field as well as state and local partner training. FDA looks forward to working with state and local partners as the EA Process Overview CPG is finalized to take advantage of opportunities to enable federal, state, and local partners to utilize this information.

Resolution #7 – Laboratory Long Term Sustainability

AFDO request FDA to work with State Food Laboratories to identify an appropriate level of federal support for state laboratory CAPs, which may be necessary to help State Food Laboratories sustain and enhance ISO/IEC 17025 accreditation and ensure a robust system of accredited laboratories supporting an IFSS.

Response:

FDA agrees with AFDO regarding the importance of a robust quality management system that enables regulatory laboratories to produce reliable analytical results. Laboratory accreditation remains an important aspect of continuing efforts to advance an integrated food safety and the mutual reliance pilots currently in development. FDA is aware that many states rely heavily on the ISO/IEC 17025:2005 Cooperative Agreement Program to achieve accreditation. In addition to this Resolution, a number of states have raised concerns regarding the long-term sustainability of laboratory accreditation in the absence of a funding mechanism for accreditation. As a result, FDA is in the process of evaluating the resource needs and implications for long-term sustainability of state laboratory accreditation and will continue to maintain dialogue with AFDO and other relevant organizations as information on future options becomes available.

Resolution #8: Liquid Nitrogen and Dry Ice used as Food and Beverage Ingredients

AFDO requests FDA to clarify, as specifically as possible, its policy position on liquid nitrogen and dry ice used as food and beverage ingredients. AFDO advises FDA of the need for federal leadership on the matter of liquid nitrogen and dry ice used as food and beverage ingredients and for providing 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.

Response:

Resolution #2016-8 requested FDA clarify our policy position on liquid nitrogen and dry ice used as food ingredients. The CFSAN Office of Food Additive Safety and Office of Food Safety worked together to evaluate authorities in the applicable to liquid nitrogen and dry ice as ingredients. The two offices reviewed the Food Code and the applicable food additive requirements.

FDA is aware of widespread use of liquid nitrogen and dry ice in classroom settings, gastronomy, and for recreational purposes with few reports of injuries associated with their use. Safety concerns associated with the use of liquid nitrogen and dry ice in beverages at retail are based on the physical state of the substances and accidents surrounding their use rather than toxicity associated with either substance. Similar to extremely hot water and hot cooking oils, liquid nitrogen and dry ice, due to their extremely low temperatures, may cause severe damage to skin and internal organs if they come in direct contact with the skin or are ingested. While such injuries can be severe, their incidence is very low. Of the few cases of accidental ingestion of liquid nitrogen and dry ice from beverages we identified, none were associated with food establishments in the United States.

The Retail Food Protection Staff (RFPS) in the CFSAN Office of Food Safety would like to continue open dialogue with AFDO and other stakeholders regarding 1) the concerns, incidence, and relative risk of accidental ingestion of liquid nitrogen and dry ice at food establishments in the United States, and 2) approaches that minimize these concerns, incidence, and risks.

At this time, CFSAN does not believe regulatory action is appropriate and RFPS is in support of collaborative efforts with AFDO to further monitor the social trends surrounding the use of liquid nitrogen and dry ice in beverages at food establishments. As part of our continuing dialogue with state and local partners, FDA will rely on information from state and local partners if any incidents occur that raises the risk to public health and action is appropriate.

Resolution #9: Good Manufacturing Practice Regulations for Cosmetics

AFDO endorse the adoption of ISO 22716: 2007 Cosmetics - Good Manufacturing Practices (GMP) -- Guidelines on Good Manufacturing Practices by the Food and Drug Administration as regulations to be followed by domestic and imported cosmetic manufacturers and importers.

Response:

In 2007, the International Cooperation on Cosmetic Regulations (ICCR), a voluntary international group of cosmetic regulatory authorities from Canada, the European Union, Japan and the United States, met for the first time and agreed that it would be useful for the cosmetic industry to have a standardized scheme for GMPs that could apply to each of their jurisdictions. As a result, the regulators from these four jurisdictions agreed to take ISO standards for cosmetic GMPs into consideration when developing or updating guidances/guidelines or other measures addressing GMPs. In developing the draft guidance of 2013, FDA incorporated elements of ISO 22716, as appropriate, and consistent with FDA regulations.

In addition, you may be aware that over the last several years there have been multiple proposed bills for revisions to FDA's cosmetic authority under the Federal Food Drug and Cosmetic Act which have been introduced and which have provisions for and describe the importance of cosmetic GMPs. These bills have separate industry and trade group, Nongovernmental Organization (NGO), and consumer advocacy support.

FDA thanks AFDO for the collaborative dialogue regarding the complexities associated with cosmetics GMPs on November 1, 2016 regarding cosmetics and looks forward to continued dialogue.