MOU# 225-19-015

MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. DEPARTMENT OF COMMERCE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY HOLLINGS MANUFACTURING EXTENSION PARTERSHIP PROGRAM AND THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS

I. PURPOSE

This Memorandum of Understanding (MOU) constitutes an agreement between the U.S. Department of Commerce (DOC) National Institute of Standards and Technology (NIST) Hollings Manufacturing Extension Partnership Program (MEP) and the U.S. Food and Drug Administration (FDA) Office of Regulatory Affairs- hereinafter referred to individually as "Party" and collectively as the "Parties."

The purpose of this MOU is to define an agreement through which both Parties intend to establish collaborative efforts to support the United States (U.S.) food manufacturing sector and advance and improve safe food manufacturing practices in the U.S. Both Parties intend to promote the joint efforts established under this MOU, subject to the availability of funding and other necessary resources, which will be based on communication as the foundation of the two Parties working together to advance safe food manufacturing practices in the U.S.

II. AUTHORITIES

The authorities to enter this framework MOU are:

NIST MEP: 15 U.S.C. §§272 (b)(l), and 278k

FDA: 21 U.S.C. § 393(b) [Section 1003(b) of the Federal Food, Drug, and Cosmetic Act]

III. BACKGROUND

Both Parties recognize that the dissemination of information on required and recognized food safety manufacturing practices is critical to the success of the Food Safety Modernization Act (FSMA), as well as other regulations and industry standards. To help facilitate the dissemination of such information and associated training, the FDA, together with U.S. Department of Agriculture (USDA), has funded a network of public and private partners in state, federal, tribal and international governments, industry, and academia for the development and delivery of training.

Likewise, DOC NIST MEP has funded and operates a nationwide network of results-based, locally operated and staffed non-profit, university-based, and state-based organizations that are specifically focused on providing hands-on technical assistance to U.S. manufacturers. The National Network of

state and regional MEP Centers in every U.S. state and the Commonwealth of Puerto Rico leverages federal, state and local, and private resources to facilitate and accelerate the transfer to U.S. manufacturers of technology, best practices, expertise, and other necessary approaches and information that manufacturers need to enhance their technological productivity, compete effectively in global markets, and grow profitably.

The MEP National Network has a special focus on serving the needs of small-and-medium manufacturers (SMMs) in the U.S., including SMMs operating in the food sector. Both the FDA training network and the MEP National Network serve as spaces for dialogue, information-sharing, alignment and collaboration for all those providing training and assistance to manufacturers in the food sector. Both Parties recognize that food safety training is the responsibility of, among others the food industry, FDA, and its partners. FDA is committed to helping the food industry to comply with requirements like the FSMA rules by making food safety and FSMA training accessible and comprehensive.

Via this MOU, the MEP National Network is also being recognized by the FDA as an additional, value-adding resource to extend assistance to small U.S. food processors relating to food safety best practices, understanding what needs to occur to operate in compliance with food safety regulations, and FSMA training. NIST MEP seeks to leverage the FDA network of public and private partners in state and federal governments, industry, and academia for access to training needed by small U.S. food processors, including the delivery of existing and established training, as well as the development and delivery of new training as needed. In doing so, NIST MEP intends to document and share complementary assistance best practices across the National Network of MEP Centers, including, for example, sharing facilities for group events, employing webinars for virtual events, establishing joint newsletters, and sharing websites to facilitate dissemination of new manufacturing funding initiatives and implementation services available to food processors.

Annually, the NIST MEP network typically works with over 25,000 manufacturers across the U.S., serving as trusted advisors, focused on solving manufacturers' process and product challenges and identifying opportunities for growth. The food industry is ubiquitous across the Nation, with food processors operating in every U.S. state. While the concentration of food processors varies from state-to-state, all MEP centers have food industry clients. This MEP operational basis provides an opportunity for FDA to serve as a resource for the MEP- as it engages food processor clients to promote and provide food safety training opportunities.

In this regard, areas of collaboration between the Parties established via this MOU may include, but are not limited to, the following efforts:

- Provide training and technical support to U.S. food processors to plan for and adopt safe food manufacturing practices.
- Acquire, preserve and share knowledge regarding food safety practices consistent with FDA policies, such as those represented in the FSMA, with NIST MEP.
- Promote and co-sponsor joint training events beneficial to U.S. food processors.
- Establish direct and consistent relationships at multiple organizational levels within both Parties to document and share complementary assistance best practices.
- Develop clear objectives, benchmarks and goals to measure success, added value, and synergy of collaborations between NIST MEP and FDA.
- Establish an interagency rotational assignment program to strengthen awareness and understanding of each other's missions and identify opportunities for further collaboration.

IV. SUBSTANCE OF AGREEMENT

Roles and Responsibilities for the Parties:

1. FDA will serve as a partner resource to the N1ST MEP to assist with providing food safety training and awareness to small U.S. food processors across the Nation that otherwise are challenged to receive information on food safety requirements and FDA guidances via existing FDA networks and alliances.
2. The Parties will jointly promote and co-sponsor training events beneficial to U.S. food processors.
3. FDA will participate in NIST MEP dialogues, training and educational events that are intended to help the MEP National Network to accurately and effectively create and support awareness and understanding of laws enforced by FDA and FDA guidances.
4. The Parties will jointly develop a plan that outlines goals, objectives, and current gaps in training, technical support, and information/data dissemination to various sized U.S. food processors, to ensure added value by both Parties.
5. NIST MEP will establish direct and ongoing relationships with the FDA at the program Office level and District Office levels to maintain active and timely communications for the bi-directional dissemination of current information about food safety requirements and food processor needs.
6. NIST MEP will conduct regular FDA and MEP informational sessions to extend the reach of the Parties' collaboration to other relevant stakeholders and partners to most effectively leverage resources, including other government agencies, trade associations, food science-oriented institutions, and training institutions.
7. The Parties will jointly develop clear objectives, benchmarks and goals to measure success of the collaboration outlined in this MOU.

V. MOU Management

The Parties agree that this MOU is non-exclusive and nothing contained herein prevents either Party from entering into similar agreements with any third party. If any terms of this MOU are inconsistent with existing authorities or directives of either of the Parties entering into this MOU, those portions of this MOU that are determined to be inconsistent shall be invalid; the remaining terms and conditions shall remain in full force and effect.

Nothing herein shall be construed to create any joint venture or similar relationship or to subject the Parties to any implied duties or obligations respecting the conduct of their affairs that are not expressly stated herein. Neither of the Parties shall have any right or authority to assume or create any obligation or responsibility, either expressed or implied, on behalf of or in the name of the other Party, or to bind the other Party in any matter whatsoever. Neither Party shall be deemed to be an agent or principal of the other.

A Liaison Officer for each Party will be responsible for facilitating exchanges of information and expeditiously informing other interested parties within each respective organization on matters requiring prompt attention. Each Party agrees to provide notification of any changes in Liaison Officer appointments. Such notification shall constitute an amendment to and not require a revision of the Agreement. Contact Information for both Parties is provided below:

A. Liaison Officer FDA:

Alan M. Tart
Deputy Director, Office of Partnerships
Office of Regulatory Affairs
U.S. Food and Drug Administration
12420 Parklawn Drive
Rockville, Maryland 20857
Tel: 301-975-4588
Alan.Tart@fda.hhs.gov

B. Liaison Officer NIST MEP:

Dileep Thatte
Senior Technical Advisor, Extension Services Division
NIST MEP
100 Bureau Drive Stop 4800
Gaithersburg, MD 20899
Tel: 301-975-4588
dileep.thatte@nist.gov

C. Metrics and Targets

The Parties intend to share information related to the Parties' goals, and to work collaboratively to seek continuous improvement and enhanced performance over time.

D. Limitations

Nothing in this MOU is to be construed as indicating a financial commitment or obligation of funds by a Party for the expenditure of funds.

This MOU does not - and is not intended to - impose any legally binding requirements on the Parties. If necessary or desirable, the Parties may jointly agree upon formal written interpretations of this MOU and background materials upon which it is based.

This MOU does not constitute final agency action on any issue. Any activities contemplated by this MOU are to be carried out by the Parties in accordance with all applicable laws and policies.

E. Commencement/Duration/Modification/Termination

This MOU is to take effect upon the last signature date of the Parties and shall remain in effect for a period of 5 years. This MOU may be extended or modified at any time while it is in effect by written agreement. Additionally, a Party may terminate its participation in this MOU at any time by providing written notice to the other Party's Liaison Officer at least 60 days in advance of the desired termination date.

VI. DATA SHARING

The Parties acknowledge that the sharing of nonpublic information, whether written or oral, must be done in a manner consistent with the requirements of 21 CFR 20.85. Should it become mutually desirable to exchange or receive such information, pursuant to 21 CFR 20.85, the Parties will enter into a separate written agreement that will establish safeguards to ensure that such nonpublic information is protected from unauthorized disclosure or use. Such safeguards help ensure compliance with other applicable laws and regulations.

VII. RESOURCE OBLIGATIONS

This MOU represents the broad outline of the Parties' intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and Parties to the agreement. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Partners. This MOU does not create binding, enforceable obligations against any Party. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and Parties operate.

Signed,

Carroll Thomas
Director, Hollings Manufacturing Extension Partnership Program
National Institute of Standards and Technology
U.S. Department of Commerce

Date: 7/30/2019

Melinda K. Plaisier
Associate Commissioner for Regulatory Affairs
Office of Regulatory Affairs
U.S. Food and Drug Administration

Date: 8/2/2019