

engineered products, must be maintained prior to patient administration. The culture-based compendial methods currently used to assess product purity (specifically to ensure absence of microbial contamination) typically take weeks, which is inadequate for patients in urgent need of life-saving therapies. These methods are also incompatible with products that have a limited shelf-life and cannot meet good manufacturing practices required in process control and release testing. Alternative rapid microbial testing methods are needed to ensure fit for purpose safety assessments for this broad class of advanced therapeutics.

NIST is establishing the RMTM Consortium to address this need. The Consortium's purpose is to develop solutions and standards to support the use of rapid microbial testing methods for regenerative medicine products. The Consortium efforts will focus on the following areas:

### (1) Repository of Relevant Microorganisms

NIST intends to establish a repository of microorganisms relevant to regenerative medicine product contamination, including contaminants found in products, in manufacturing environments, and other relevant microorganisms. Sets of microorganisms from the repository will be selected for interlaboratory studies and for incorporation into a candidate reference material, based on input from the Consortium. The reference material will be designed to increase confidence in the use of RMTMs and is expected to consist of multiple microorganisms. There will be opportunities for Consortium members to contribute relevant microorganisms to the repository.

### (2) Rapid Microbial Testing Methods

The NIST RMTM Consortium intends to develop an inventory of potential measurement methods and protocols for rapid microbial testing of regenerative medicine products. This inventory will include molecular methods and protocols that have been adopted successfully for rapid microbial detection as well as considerations for implementing test methods and approaches to validate protocols.

### (3) Interlaboratory Studies

The NIST RMTM Consortium intends to organize at least one interlaboratory study based on candidate reference materials with the goal of utilizing a common material to collect reproducible data on rapid microbial

testing methods in support of measurement assurance and standards development.

There is no cost for participating in the consortium.

**Process:** Interested parties with relevant rapid microbial testing associated capabilities (see below), products, and/or technical expertise to support this Consortium should contact NIST using the information provided in the **ADDRESSES** section of this notice. NIST will then provide each interested party with a letter of interest template, which the party must complete and submit to NIST. NIST will contact interested parties if there are questions regarding the responsiveness of the letters. NIST will select participants who have submitted complete letters of interest based on the capabilities listed below. Eligibility will be determined solely by NIST based on information provided by interested parties and upon the availability of necessary resources to NIST.

To participate in the NIST RMTM Consortium, the eligible applicant will be required to sign a CRADA with NIST.

**Requirements:** Each letter of interest should provide the following information:

(1) A description of the experience in development or use of rapid microbial testing methods or production of regenerative medicine products or related expertise.

(2) Topic areas of interest for participation.

(3) List of interested party's anticipated participants.

Letters of interest may not include business proprietary information. NIST will not treat any information provided in response to this Notice as proprietary information. NIST will notify each organization of its eligibility. NIST does not guarantee participation in the Consortium to any organization submitting a letter of interest.

**Authority:** 15 U.S.C. 272; 21 U.S.C. 356g.

**Kevin A. Kimball,**

*Chief of Staff.*

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

[RTID 0648-XA202]

### Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice; public meeting.

**SUMMARY:** The Mid-Atlantic Fishery Management Council's (MAFMC) Bluefish Advisory Panel will hold a public meeting, jointly with the Atlantic States Marine Fisheries Commission (ASMFC) Bluefish Advisory Panel.

**DATES:** The meeting will be held on Tuesday, June 23, 2020, from 9 a.m. to 12 p.m. For agenda details, see

**SUPPLEMENTARY INFORMATION.**

**ADDRESSES:** The meeting will be held via webinar with a telephone-only connection option. Details on the proposed agenda, webinar listen-in access, and briefing materials will be posted at the MAFMC's website: [www.mafmc.org](http://www.mafmc.org).

**Council address:** Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331 or on their website at [www.mafmc.org](http://www.mafmc.org).

**FOR FURTHER INFORMATION CONTACT:** Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

**SUPPLEMENTARY INFORMATION:** The purpose of this meeting is for the Advisory Panel to develop a fishery performance report (FPR) and comment on draft alternatives for the Bluefish Allocation and Rebuilding Amendment. The intent of the FPR is to facilitate a venue for structured input from the Advisory Panel for the bluefish specifications process. The FPR will be used by the MAFMC's Scientific and Statistical Committee (SSC) and the Bluefish Monitoring Committee (MC) when reviewing 2021 management measures designed to achieve the recommended bluefish catch and landings limits.

### Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: June 2, 2020.

**Tracey L. Thompson,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

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