

FDA FACT SHEET

PARTNERSHIP AGREEMENTS

Program Description:

- Partnership Agreements (PAs) are a specific type of MOU detailing a collaborative relationship down to the activity level to carry out the mission of advancing public health
- PAs are formal written documents that clearly define specific goals, activities, and responsibilities of each partner with no obligation of fiscal resources (as required in contracts, grants, and cooperative agreements).
- PAs are a non-binding relationship anchored in common goals, responsibilities, and values. A partnership is a union of common purposes, where both parties benefit from the synergies of cooperation and is mutually beneficial.
- PAs confer no legal obligation on either partner and may be revised or terminated at any time.
- PAs can be used to support complementary funding opportunities such as cooperative agreements or grants.
- PAs can also be used to formalize and document the advancement toward domestic mutual reliance (DMR).
- PAs are publicly posted on the FDA's Memoranda of Understanding Website: Domestic MOUs | FDA

Intended Outcomes:

- PAs provide the tools and resources that enable the FDA to work with regulatory partners to build systems that complement national uniformity of regulated products.
- DMR PAs are designed to capture engagement that work toward a seamless partnership that enables the FDA and states with comparable regulatory public health systems, as trusted partners, to fully rely on, coordinate with, and leverage one another's work, data, and actions to achieve the public health goal of a safer national food supply.
- PAs seek to achieve maximum protection of consumer safety without duplication of regulatory activities among the FDA and implementing partners.
- Both generic and DMR PAs have the option of creating a supporting strategic plan to detail activities conducted by partners for the duration of the agreement.
- Meaningful metrics are tailored to each PA which annually evaluate program outputs and outcomes and measure success.

Program Metrics:

- Current number of active agreements: (5)
 - MOU 225-20-007 Partnership Agreement Between U.S. Food and Drug Administration and the Alaska Department of Environmental Conservation and its Addendum: MOU 225-20-007 | FDA
 - MOU 225-21-010 Partnership Agreement Between U.S. Food and Drug Administration and the Utah Department of Agriculture and Food Division of Regulatory Services: <u>MOU 225-21-010</u>
 <u>FDA</u>
 - MOU 225-21-018 Partnership Agreement Between U.S. Food and Drug Administration and the California Department of Health - Food and Drug Branch: <u>MOU-225-21-018 with FDA/ORA</u> <u>HAFW5/DWCI and CDPH-FDB | FDA</u>



- MOU-225-21-019 Partnership Agreement Between U.S. Food and Drug Administration Division of Human and Animal Food East-4 And the Florida Department of Agriculture and Consumer Services: MOU 225-21-019 | FDA
- MOU 225-21-020 Partnership Agreement Between U.S. Department Of Health And Human Services Food And Drug Administration Office Of Human And Animal Food Operations- Division 1 West And The Wisconsin Department Of Agriculture, Trade And Consumer Protection - Division Of Food And Recreational Safety: MOU-225-21-020 with FDA HAFW1 and WDATCP | FDA

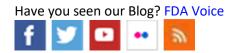
Success Stories:

- The Alaska Department of Environmental Conservation (ADEC) (renewal)
 - This project developed radionuclide capability in the state of Alaska which has been beneficial for both routine annual radionuclide monitoring but more importantly for capacity in emergency response, if needed. Additionally, the Food and Drug Administration and Alaska Department of Environmental Conservation have been annually monitoring coastal finfish samples in response to the Fukushima event at the request of the public and the Fukushima Interagency Workgroup. ADEC's Addendum modified the original PA to add detail to the defined roles and responsibilities pertinent to the data collection, management, and reporting activities related to the gamma-ray analysis of harvested fish (or other matrix) using the portable gamma ray analysis system. ADEC has develop and published a list of finfish of concern. ADEC's activities are posted at: https://dec.alaska.gov/eh/radiation/. This partnership experienced success from 2016- 2019 and was renewed and expanded for the period 2020-2023.
- On October 7th, 2021, the U.S. Food and Drug Administration (FDA) announced that California, Florida, Utah, and Wisconsin entered into domestic mutual reliance agreements with the agency.
 - These Mutual Reliance agreements facilitate a coordinated effort between the FDA and individual states with goals to reduce human foodborne illness outbreaks, reduce duplication of regulatory oversight and increase public health protection by focusing on areas of higher risk.
 - These new mutual reliance agreements help the FDA to work in cooperation with the states of California, Florida, Utah, and Wisconsin to rely on, coordinate with and leverage one another's work, data, and actions to achieve a safer national food supply.
 - As envisioned in the FDA Food Safety Modernization Act (FSMA), the Partnership for Food Protection and the New Era of Smarter Food Safety blueprint, the mutual reliance agreements will enhance the existing relationships with states and government counterparts, moving the nation toward an Integrated Food Safety System.
 - The FDA will collaborate with partner states, as trusted partners, to establish oversite of human food for which both participants have statutory responsibilities. Key areas of mutual reliance focus on data sharing, risk prioritization, inspections, outbreak investigations, development and monitoring of key metrics and laboratory capacity, among many other key focus areas.
 - The domestic mutual reliance framework provides opportunities for the FDA and partners to jointly identify needs to better protect the public and leverage work from other regulatory programs. In addition, it will provide knowledge to build quality management systems and infrastructures to support national regulatory standards, including those related to resource allocation, training, outreach, and information exchange.



• Related Information:

- Domestic Mutual Reliance | FDA
- <u>FDA Announces Signing of Domestic Mutual Reliance Agreements with California,</u> Florida, Utah and Wisconsin | FDA
- Florida is Fourth State to Sign Domestic Mutual Reliance Agreement (food-safety.com)
- Food Safety Modernization Act (FSMA)
- <u>New Era of Smarter Food Safety</u>



The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.