PARTNERSHIP AGREEMENT BETWEEN THE U.S. FOOD AND DRUG ADMINISTRATION AND THE IOWA DEPARTMENT OF INSPECTIONS & APPEALS (DIA), FOOD AND CONSUMER SAFETY

MOU Tracking No. MOU 225-22-022

I. PURPOSE

This Partnership is entered into by the Iowa Department of Inspections & Appeals ("DIA") and the United States Department of Health and Human Services (HHS), Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA), Office of Human and Animal Food Operations West – Division 2 (HAFW2) (hereinafter referred to as "the Partners"). The purpose of this document is to establish a formal Partnership which is intended to assist the Partners in strengthening the public health by fostering interaction and cooperation to establish a streamlined and efficient process to coordinate and enhance communication, increase program familiarity, maximize efficiency, minimize duplication, and set a foundation for the ongoing development of an Integrated Food Safety System (IFSS) in Iowa. The Partners share mutual interest in collaborating on information sharing, compliance, and enforcement activities that directly impact food safety and public health and understand the importance of leveraging resources to increase effectiveness.

This PA does not affect or supersede any existing or future agreements, arrangements, contracts, or cooperative agreements between the Partners and does not affect the ability of the Partners to enter into other agreements or arrangements related to this PA.

II. DURATION OF AGREEMENT

This Partnership Agreement (PA) covers a period of three (3) years from the date of signature. This time frame will give the Partners sufficient time to measure the PA outcomes, modify the PA if warranted, and renew the PA with consent of the Partners. This PA is effective upon signing and shall remain in effect until termination by any Partner upon thirty (30) day advance written notice to the other Partner.

III. DEFINITIONS AND ACRONYMS

C.F.R. – Code of Federal Regulations
DIA – Iowa Department of Inspections & Appeals
DIDP – Division of Information and Disclosure Policy
FDA – U.S. Food and Drug Administration
HAFW2 – Office of Human and Animal Food Operations West – Division 2
IFSS – Integrated Food Safety System
OEI – Official Establishment Inventory
ORA/OP/DI – Office of Regulatory Affairs, Office of Partnerships, Division of Integration
PA – Partnership Agreement
The Partners – HAFW2 and DIA
POC – Points of Contact
RRT – Rapid Response Team
SME – Subject Matter Experts

IV. GOALS, OBJECTIVES, AND INTENDED OUTCOME

The Partners are committed to pursuing the vision of an IFSS. A key step in pursuit of that vision is achieving domestic mutual reliance.

Domestic mutual reliance is a seamless partnership that enables 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.

Once achieved, domestic mutual reliance will allow for more efficient and effective use of resources and collaboration on risk-informed decision-making about activities that may be carried out by either Partner. The Partners seek to enhance regulatory cooperation, improve coordination, and ensure greater reliance on each other for follow-up when a regulatory concern arises. The Partners will benefit from leveraging each other's resources to improve industry compliance with regulatory requirements, with a goal of improving public health and consumer protection.

This PA will document and formalize an agreement about ongoing coordination and collaborative efforts between the Partners to establish domestic mutual reliance for the regulatory oversight of human and animal food for which both participants have statutory responsibilities. Continuous conformity with applicable regulatory program standards is a foundational concept and must be maintained as the Partners work towards achieving domestic mutual reliance and set a foundation for the ongoing development of an integrated food safety system.

The work towards domestic mutual reliance through this PA will focus on the following key areas:

1. Data/Information Sharing
2. Official Establishment Inventory (OEI) maintenance; comparison and reconciliation of inventories to minimize inspection duplication
3. Work Planning and Risk Prioritization/Categorization, including inspection frequency mandates
4. Exploring ways to support collaborative inspection, compliance, enforcement, and corrective actions (i.e., non-contract, non-high-risk inspection sharing)
5. Training of field staff
6. Emergency and incident response, investigation of outbreaks and complaints, recalls
7. Industry and consumer education
8. Identifying, establishing, and monitoring key mutual reliance metrics

V. RESPONSIBILITIES

FDA:

A. **Data and Information Sharing:** FDA will, in accordance with federal laws and regulations, work with DIA on a regular basis to compare, reconcile, and maintain FDA OEI food firm inventories.
B. **Inspection Sharing and Reduction of Duplication:** As part of HAFW2's inspection mandate, FDA will explore ways to enhance collaborative counting of non-contract, non-high-risk inspections conducted by DIA.
C. **Training:** FDA will provide DIA with technical expertise, training, and support to state regulatory personnel, as requested.

DIA:

A. **Data and Information Sharing:** DIA will maintain the appropriate long-term 20.88 Information Sharing Agreement so that DIA will be able to receive and protect inspectional, investigative, compliance, laboratory, and regulatory information from the FDA.
B. **Inspection Sharing and Reduction of Duplication:** As part of DIA's scheduled inspections, DIA will explore ways to enhance collaborative counting of non-contract, non-high-risk, no action indicated inspections conducted by HAFW2.
C. **Training:** DIA will provide FDA with technical expertise and training, as requested.

JOINT:

A. **Data and Information Sharing:**
   1. The Partners will meet no less than two times a year for work planning and inspectional coordination.
   2. The Partners will continue to explore ways to enhance collaborative oversight activities (including responding to consumer or industry complaints) for jointly regulated firms.
   3. The Partners will leverage technology to support information exchange.
   4. The Partners will explore ways to support collaborative inspection activities, compliance, enforcement, and corrective actions (e.g., non-contract, non-high-risk, no action indicated).

B. **Inspection Sharing and Reduction of Duplication:**
   1. Joint inspections may be requested by either partner.
   2. Independent inspections by either Partner may occur at a specific firm in the same year. Both Partners will coordinate these independent inspections to maximize, to the greatest extent possible, the time between inspections.
   3. The Partners will continue to coordinate response and information sharing in

emergency and outbreak situations utilizing the state's RRT procedures.

C. Emergency Response

1. The Partners will review current after-action review processes to determine opportunities for improvement.

D. Industry Outreach

1. The Partners will work together and with their food protection task force to identify how best to regulate mixed-type facilities.

E. **PA Monitoring and Evaluation:**

1. The Partners will identify, establish, and monitor key mutual reliance metrics.
2. The Partners will complete a joint annual evaluation report that includes ongoing PA outputs and outcomes to document program accomplishments and areas for enhancement.

VI. RESOURCES

FDA: HAFW2 will provide DIA with technical assistance and support, upon request and availability.

DIA: DIA will provide FDA technical assistance and support, upon request.

JOINT: Both Partners will collaborate with ORA/OP/DI to identify, establish, and monitor key mutual reliance metrics for performing an annual evaluation of the PA.

VII. LEGAL STATUS

No consideration has been given or received by either Partner to this PA. This PA is not legally binding and does not constitute a promise on the part of either Partner for performance. It does not create a legally enforceable contract and the Partners agree that no remedies at law or equity will be sought by either Partner for non-performance of this PA. It does not impose additional legal duties, rights, benefits, or responsibilities, or remedies of either the Partners or of a third party. This PA imposes no duty on either Partner to act or to refrain from acting.

VIII. INFORMATION DISCLOSURE

Access to non-public information, where appropriate, shall be governed by separate Information Sharing Agreements in accordance with 21 C.F.R. Part 20. Under 21 C.F.R. § 20.88 (20.88 agreement), state agencies must agree and certify in writing that they shall not further release, publish, or disclose FDA non-public information, and that they shall protect such information from public disclosure. No proprietary data, trade secrets, or personal privacy information shall

be disclosed among the Partners unless permitted by applicable law.

To confirm the applicability of an existing 20.88 agreement, to enter into a 20.88 agreement, and prior to sharing any FDA-provided information, Partners shall contact ORA's Office of Strategic Planning and Operational Policy, Division of Information Disclosure Policy (DIDP) by sending a request via email to ORAInfoshare@fda.hhs.gov.

IX. ASSESSMENT AND EVALUATION

This PA may be amended or modified by mutual consent of the Partners. The Partners will review the PA and goals annually. The Partners will make all reasonable attempts to meet, at a minimum annually, to discuss the current PA, monitor key mutual reliance metrics, evaluate its usefulness, and make modifications, as needed. During the annual review and evaluation meeting, the Partners will jointly prepare options for follow-up. If new areas for developing PA activities are identified and agreed upon, this PA may be revised to reflect them. This PA may be submitted for consideration and approval by the signatories of this PA prior to annual renewal.

X. STATEMENT OF NO FINANCIAL OBLIGATIONS

Signature of this PA does not constitute a financial obligation on the part of the FDA or DIA. Each Partner will use and manage its own funds in carrying out the purpose of this PA. Permanent transfers of funds or items of value are not authorized under this PA.

XI. ACTIVITY LIAISON OFFICIALS:

Office of Partnerships POC: Priscilla Neves, Consumer Safety Officer, PA Coordinator

FDA Partner POC: Julie Vosilus, State Liaison, HAFW2

State Partner POC: Mark Speltz, Bureau Chief, DIA Food and Consumer Safety

XII. CONCLUSIONS AND RECOMMENDATION

The Partners agree to the provisions in this document.

ENDORSEMENTS

(SIGNATORIES OF RESPONSIBLE PARTIES MUST INCLUDE PRINTED NAME, SIGNED NAME AND DATE OF SIGNATURE)

Accepted for the U.S. Food and Drug Administration:

Erik P. Mettler -S

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Date: 2022.07.18 08:43:18 -04'00'

Erik P. Mettler
Assistant Commissioner
FDA Office of Regulatory Affairs
Office of Partnerships and Operational Policy

Date Signed

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PARTNERSHIPS AND OPERATIONAL POLICY

Michael Rogers

7/16/2022

Michael Rogers
Assistant Commissioner
FDA Office of Regulatory Affairs
Office of Human and Animal Food Operations

Date Signed

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF HUMAN AND ANIMAL FOOD OPERATIONS

LaTonya M. Mitchell

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Date: 2022.07.18 07:54:32 -05'00'

LaTonya Mitchell, PhD
Program Division Director
FDA Office of Regulatory Affairs
Office of Human and Animal Food Operations West 2

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OHAFO WEST DIVISION 2

Date Signed

Accepted for (partnering agencies):

Mark Speltz
Bureau Chief
Iowa Department of Inspections & Appeals
Food and Consumer Safety

Iowa Department of INSPECTIONS & APPEALS

7/15/2022
Date Signed

Larry Johnson, Jr.
Director
Iowa Department of Inspections & Appeals

Iowa Department of INSPECTIONS & APPEALS

Revision History	Date	Description
v0.1	4/11/22 DRAFT	Creation (ORA OP DI/ORA HAFW2/DIA)
	4/18/22 DRAFT	DOP/HKubicki
	4/25/22 DRAFT	DIDP/LBellows
		OC/OCC