

Solicitation No.: FSIS-02152022
Issuance Date: 15 April 2022
Closing Date/Time: **16 May 2022 at 2pm (EST)**

SUBJECT: Questions and Answers on Solicitation for Applications for funding: Salmonella Risk Assessment – FSIS Department of Agriculture’s Food Safety and Inspection Service

Ladies/Gentlemen:

Attached are the questions and answers for Solicitation Number FSIS-02152022 for Applications for funding: Salmonella Risk Assessment – FSIS Department of Agriculture’s Food Safety and Inspection Service. If there are any additional questions or comments concerning this solicitation, please submit questions or comments via email to George Baptist III at george.baptist@usda.gov.

All formal proposals for funding must be submitted via Grants.gov by **2pm (EST) on 16 May 2022**.

Thank you in advance for your participation, the Government looks forward to receiving your application.

Sincerely,

GEORGE
BAPTIST

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BAPTIST
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George D. Baptist III
Senior Contracting Officer, USDA FSIS

Questions on the Cooperative Agreement Announcement for FSIS’ *Salmonella* Risk Assessments

1. Who may collaborate with the Food Safety and Inspection Service (FSIS) on the *Salmonella* risk assessments under this cooperative agreement?

FSIS is seeking proposals from a multi-disciplinary team (the Cooperator) to partner in the development of two risk assessments – one for *Salmonella* in chicken and one for *Salmonella* in turkey.

The team, or Cooperator, should include those who can make aggregated industry data available to FSIS in a confidential and secure manner, including data on *Salmonella* levels (e.g., counts in CFU/mL) and subtypes in chicken and turkey, both pre- and post-harvest. The team should also have expertise in dose-response modeling that takes into consideration differences in *Salmonella* virulence among subtypes.

We encourage applications from a Cooperator comprised of multiple institutions to ensure we have broad expertise. The Cooperator must designate a single Principal Investigator from a U.S. organization. Proposals may come from academic institutions, relevant non-government organizations, independent consultants specialized in microbial risk assessments for food safety, and/or multi-institutional institutions that bridge the areas of expertise and responsibilities sought as a collaborator on this work.

Applications from a Cooperator (multi-disciplinary team) representing minority serving institutions are encouraged.

2. Is the Cooperative Agreement the only way that data can be shared with FSIS for the two (chicken and turkey) *Salmonella* risk assessments?

The Cooperative Agreement is not the only way that data can be shared with FSIS for the two (chicken and turkey) *Salmonella* risk assessments. Data can be shared directly with FSIS in a secure and confidential manner similar to how industry data is currently shared through FSIS' *Salmonella* Improvement Program (SIP). Sharing of data through this Cooperative Agreement does not prevent data from being shared with FSIS in other ways.

3. What is the process the Cooperator could use to share data with FSIS as a part of this Cooperative Agreement?

FSIS anticipates that industry could share establishment data with the Cooperator (e.g., the university or other non-governmental organization leading the proposal). This data may be anonymized. The Cooperator would then analyze the data to provide summary statistics and relevant contextual information (e.g., region, season, HACCP size, number of establishments represented in the data) to FSIS for use in the *Salmonella* risk assessments.

4. How will FSIS ensure industry data is not released to the public?

FSIS will follow all applicable laws regarding data security and confidentiality.

FSIS will only receive summary statistical information on industry practices and *Salmonella* contamination in poultry products from the Cooperator for use in the risk assessments.

If industry shares de-identified data with Cooperator under this cooperative agreement, the data is prohibited from release by the Cooperator through the non-disclosure language in the general provisions and articles of the cooperative agreement. If the public submits a Freedom of Information Act (FOIA) request, the Cooperator is required to follow all the requirements of FOIA, including any applicable state and local laws related to release of information.

5. Will the industry data shared with FSIS through this cooperative agreement for use in the two *Salmonella* risk assessments be made public?

The summary statistics from industry data shared by the Cooperator will be included in risk assessment reports that will be made public on FSIS' website. These reports will include risk assessment findings, documentation of risk models, and the underlying data used in these studies.

The risk assessment reports, including documentation of the underlying models and data, will be made public after they are independently peer reviewed in accordance with Office of Management and Budget (OMB) requirements for ensuring the quality and credibility of influential science (e.g., risk assessments) used to inform regulatory decisions.

6. Can FSIS share industry data it receives through the Cooperative Agreement?

FSIS will only share publicly the data it receives directly from the Cooperator that is incorporated into the risk assessment reports that have been independently peer reviewed per OMB guidelines. FSIS will not have direct access to the data industry shares with the Cooperator. Only summary statistics will be made available to FSIS for use in the risk assessments. Consequently, FSIS will not share raw industry data with the public.

7. How will FSIS work with the collaborator to conduct the two *Salmonella* risk assessments?

The Cooperator will have substantial involvement with FSIS in the conduct of two quantitative risk assessments – one for *Salmonella* in chicken and one for *Salmonella* in turkey.

The Cooperator will be responsible for:

- gathering and analyzing industry data (industry practices and microbiological data for flocks and poultry) and providing relevant summary statistics and supporting contextual information (e.g., general (region, season, HACCP size, etc.)) on the population of establishments represented in the data, working closely with FSIS as an integral part of the project team to incorporate this information into the exposure models.
- leading the development of a *Salmonella* dose-response model that takes into consideration differences in *Salmonella* virulence among subtypes, working closely with FSIS as an integral part of the project team to discuss, evaluate and consider the supporting evidence (strengths

and limitations), characterize the uncertainty in the dose-response relationship, and develop options to ensure the dose-response relationship is “fit-for-purpose.”

FSIS also encourages the Cooperator to be an integral part of the FSIS-led project team developing the risk assessments. This includes:

- participating in the consideration of the current science,
- identifying and evaluating modeling approaches and mathematics, and/or
- supporting risk model simulations (scenario analyses, uncertainty analyses, sensitivity analyses).

8. How does FSIS plan to ensure equitable access to the information from these risk assessments?

The risk assessment reports, including documentation of the underlying models and data, will be made public after they are independently peer reviewed in accordance with Office of Management and Budget (OMB) requirements for ensuring the quality and credibility of influential science (e.g., risk assessments) used to inform regulatory decisions.

9. Can the Cooperator utilize the risk assessments (e.g., source code/models) once they are public?

The Cooperator is welcome to utilize the risk assessments (e.g., source code/risk models) once FSIS makes them public and the Cooperator can develop subsequent publications on this science in the literature. Any work that was done under the cooperative agreement in partnership with FSIS should be acknowledged and FSIS should be given authorship. If used in subsequent works, any models developed under the cooperative agreement should be cited and acknowledged as done under the cooperative agreement with appropriate attribution to all authors, including those that work for FSIS.

Before risk assessment information, including risk model results, model source code, or supporting summary data are released to the public or disseminated to individuals beyond authorized users under the cooperative agreement, the Cooperator must submit to FSIS draft copies of all papers, publications and/or products to be reviewed strictly for confidentiality purposes. In addition, FSIS will review the draft papers, publications and/or products to ensure consistency with the scope of the purposes described above.

10. Can FSIS explain in more detail what it is expecting of the collaborator in developing a dose-response relationship for *Salmonella* that take into account differences in strain virulence?

The formal risk analysis process can be divided into four discrete components:

- Hazard assessment, in which the amount of a substance discharged from various sources is estimated.
- Exposure assessment, in which the distribution of a hazardous substance among individuals in the population of concern is estimated. This may involve use of transport or attenuation models.
- Dose-response assessment, in which the relationship between the level (concentration, duration) of exposure and the likelihood of effects of various degrees of severity is assessed.
- Risk characterization, in which the information from the previous three elements is integrated.

In the past, FSIS has used the dose-response relationship developed by the World Health Organization (WHO)¹ to predict human illnesses. This dose-response relationship, however, is based on combined information for about a dozen *Salmonella* subtypes, using human feeding trials and outbreak data with no information on any subtype-specific dose-response.

In order to evaluate risk management options that consider the public health impact of controlling one or more specific *Salmonella* subtypes in chicken or turkey products, FSIS seeks assistance developing a dose-response methodology that considers differences in virulence among *Salmonella* subtypes. Data from human feeding trials may be too old to adequately represent the response in the current human population. Similarly, there may be limited outbreak data on the amount of a specific *Salmonella* subtypes case patients were exposed to for many of the *Salmonella* subtypes commonly found in chicken or turkey products. For example, of the twenty-one outbreaks used in the WHO study, thirteen represented a single *Salmonella* subtype (i.e., *Salmonella* Enteritidis). However, with the advent of newer approaches to data analytics, FSIS is aware that there may be newer and novel cutting-edge approaches to develop a dose-response model that takes into consideration differences in virulence among *Salmonella* subtypes.

Applicants should describe their experience in developing dose-response relationships and describe one or more approaches that account for differences in subtype. The collaborator will be expected to develop one or more methodologies for relating risk of illness to subtype-specific doses of *Salmonella*.

¹ Ad Hoc Expert Consultations on Risk Assessment of Microbiological Hazards in Foods, Report of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, FAO Headquarters, Rome, Italy, 17 - 21 July 2000 [Report of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods](#)