

MATERIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (MCRADA)

This Materials Cooperative Research and Development Agreement ("MCRADA" or "Agreement") is entered into by and between Tyson Foods Inc., an Arkansas Corporation which has its principal place of business at 2200 Don Tyson Parkway, Springdale, AR 72762 ("the Cooperator"), and the National Exposure Research Laboratory (NERL) 26 West Martin Luther King Drive, Cincinnati, OH 45268 ("the Laboratory"), of the U.S. Environmental Protection Agency ("EPA") under the authority of Title 15, United States Code §§ 3710a-3710d (commonly known as the Federal Technology Transfer Act of 1986).

This Materials Cooperative Research and Development Agreement ("Materials CRADA") has been adopted for use by the Environmental Protection Agency ("EPA") for collaborations that will not exceed two years in term; will involve transfers of essential material ("Research Material"), but no other resources; and are unlikely to result in new intellectual property. Typical applications include short-term studies to: 1) test new reagents or research tools when such assessments require collaboration between provider and recipient institutions or 2) determine the feasibility, optimal study design, and/or resource requirements for a long-term study between the collaborating institutions. Collaborative research and development studies not meeting these criteria must be submitted for approval using the standard CRADA agreement.

1. Determination of Provider and Recipient

IF COLLABORATOR IS THE PROVIDER

The Tyson Foods, Inc. ("Collaborator"), PROVIDER, agrees to transfer to the U.S. Environmental Protection Agency ("EPA"), RECIPIENT, the following Research Material: samples for analysis at EPA facilities. Tyson will also contribute data, technical assistance, and supporting research (including use of facilities, personnel and supplies) and technical writing support, as needed.

This Materials CRADA involves no other exchange of personnel or resources. This Agreement is made under authority of the Federal Technology Transfer Act, 15 U.S.C. § 3710a.

2. If the data or material that are being transferred constitute human subjects research, please visit the following intranet site to determine if your project needs review and approval by the HSRRO: <http://intranet.ord.epa.gov/p2/hsr/human-subjects-review>

Does the research involve specimens or data derived or collected from human subjects?

No

Yes – I am seeking review and approval from the HSSRO.

3. The Dual Use Research of Concern (DURC) Internal Review Entity (IRE) has determined that:

this research does not meet the DURC definition and no additional review and oversight are required. The PI must report to the IRE any results or changes in the research such that one or more of the 7 categories of experimental effects may apply, or if the PI feels that the research may be DURC.

this research meets the DURC definition and requires additional oversight under the *USG Policy for Institutional Oversight of DURC*. Corresponding USG funding agency will be notified and a draft of the mitigation plan will be submitted within 90 days of this determination.

Mitigation Plan submitted to the funding agency on

Approved mitigation Plan on file

4. To the extent permitted by law, each Party agrees to treat as confidential any of the disclosing Party's written information about this Research Material that is stamped "CONFIDENTIAL" for a period of three (3) years from the date of the disclosure. The foregoing shall not apply to information that is or becomes publicly available or which is disclosed to a Party without a confidentiality obligation. Any oral disclosures by either party that the disclosing Party wishes to be treated as confidential shall be identified as being confidential at the time of disclosure and by written notice delivered to the receiving Party within (10) days of the oral disclosure. The Laboratory may publish or otherwise publicly disclose the results of the Research Plan, but if Collaborator has given CONFIDENTIAL information to the Laboratory, such public disclosure may be made only after Collaborator has had thirty (30) days to review the proposed disclosure to determine if it contains any CONFIDENTIAL information, to the extent such review period is permitted by law.

5. The RECIPIENT agrees to retain control over this Research Material, and further agrees not to transfer the Research Material to other people not under his or her direct supervision without advance written approval of the PROVIDER. The PROVIDER reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Plan is completed or one (1) year has elapsed, whichever occurs first, or the Materials CRADA is terminated, the RECIPIENT will dispose of the Research Material as directed by the PROVIDER.

6. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO THE RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A

PARTICULAR PURPOSE. The PROVIDER makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties. The PROVIDER shall not be liable for any claims or damages arising from the RECIPIENT'S use of the Research Material; however, no indemnification is provided or intended.

7. The Laboratory and the Collaborator believe that no Subject Inventions or Computer Software will be created during the work specified in this Agreement. Should it appear that any activity of this Agreement might involve the creation of Subject Inventions or Computer Software, the Laboratory and the Collaborator will negotiate a standard CRADA in good faith. The standard CRADA will assign responsibilities for obtaining patents or other intellectual property rights pertaining to the Subject Inventions or Computer Software and will provide for appropriate allocation of any patent or intellectual property rights resulting from those Subject Inventions or Computer Software. Subject Invention means any invention, conceived or first actually reduced to practice in the performance of this Agreement. Computer Software means computer software, computer programs, computer data bases, and documentation thereof developed, in whole or in part, under this Agreement.

8. Any dispute arising under this Agreement which cannot be readily resolved shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute. If the signatories are unable to jointly resolve a dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted by EPA to the Administrator of EPA or the Administrator's designee for resolution.

9. The illegality or invalidity of any provisions of this Materials CRADA shall not impair, affect or invalidate the other provisions of this Materials CRADA.

10. Neither this Materials CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.

11. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative and shall be delivered by hand (including private courier mail service) or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

IF TO THE COOPERATOR:

Kim Dirks
Senior Director, Environmental Services
Tyson Foods
800 Stevens Port Drive, Mailcode DD709
Dakota Dunes, SD 57049

Ph: 605-235-2036
e-mail: kim.dirks@tyson.com

With a copy to:
Kevin Igli
Senior Vice President Sustainability and Chief Environmental Officer
Tyson Foods
2200 West Don Tyson Parkway
Springdale, AR 72762
Ph: 479-290-4055
e-mail: Kevin.Igli@tyson.com

IF TO THE LABORATORY:

Michael Jahne, Ph.D.
Systems Exposure Division
26 West Martin Luther King Drive, MC 593
Cincinnati, OH 45268
Office (513) 487-2354
Email: garland.jav@epa.gov

With a copy to:
Kevin Sudderth
Laboratory FTTA Coordinator,
Office (919) 541-3670
Email: sudderth.kevin@epa.gov

AND

Kathleen Graham
EPA FTTA Program Coordinator
Office: (303) 312-6137
Email: graham.kathleen@epa.gov
www.lita@epa.gov

Any party may change such address by notice given to the other party in the manner set forth above.

12. By entering into this Materials CRADA, The Laboratory does not directly or indirectly endorse any product or service provided, or to be provided, whether directly or indirectly related to either this Materials CRADA or to any patent or other intellectual property license or agreement which is related to this Materials CRADA. The Collaborator shall not in any way state or imply that this Materials CRADA is an endorsement by the U.S. Government or any of its organizational units or employees of any such product or service.

13. Either the Laboratory or the Collaborator may unilaterally terminate this entire Agreement at any time by giving written notice to the other party at least thirty (30) days prior to the desired termination date.

14. This Materials CRADA constitutes the entire agreement between the Parties and supersedes any prior understanding or written or oral agreement.

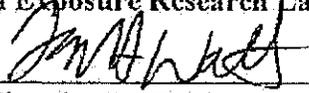
15. This Materials CRADA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

16. The undersigned expressly certify and affirm that the contents of any respective statements made or reflected in this Materials CRADA are truthful and accurate and that the signatories hereto have the authority to bind their respective organizations to this agreement.

17. This Materials CRADA shall be effective upon execution by the Parties when the last signatory has signed the document. The term of this Materials CRADA is twenty-four "24" months from execution.

18. The provisions of Articles 3, 5, 6, 9, and 15 shall survive the termination of this Materials CRADA.

National Exposure Research Laboratory "The Laboratory"

By: 
Timothy H. Watkins
Director National Exposure Research Laboratory

Date: 5/10/19

Tyson Foods, Inc. "The Cooperator"

By: 
Kevin Igli,
Senior Vice President and Chief Environmental Officer

Date: 5/20/19

APPENDIX A
RESEARCH PLAN

For

MATERIAL COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

Between

The United States Environmental Protection Agency

Office of Research and Development

And

Tyson Foods Inc.

Title of Project: Potable Water Reuse in Protein Production and Processing

Goal

The goal of this collaborative research effort is to establish a process for onsite protein processing wastewater reuse that maintains protection of food quality and consumer health. Specific objectives are to characterize the quality of protein processing wastewater (Task 1); determine the treatment requirements necessary to achieve public health benchmarks along with determination of an appropriate direct potable reuse microbial risk assessment methodology (Task 2); and identify potential treatment train configurations to meet treatment targets (Task 3).

Approach

Task 1: Source Characterization

Data describing the quality of protein processing wastewater will be collected and summarized to characterize human health hazards associated with the source material. This will be focused on microbial contamination, with an emphasis on the occurrence and density of zoonotic pathogens. Recognizing that results may be limited due to infrequent pathogen detections, data on fecal indicators will also be considered. Chemical concerns such as cleaning agents and contaminants of emerging concern (CECs) will be also identified and evaluated. Tyson utilizes a variety of wastewater treatment processes ranging from basic pretreatment to full treatment and direct

discharge across protein processing operations (poultry, beef, and swine). In order to characterize the source materials and determine associated treatment requirements, the primary focus of data collection will be untreated wastewaters (following gross solids removal); however, additional data on treated waters may also be collected to assess the potential role of existing treatment processes in potable reuse (e.g., as precursors to advanced treatment).

While initial hazard identification will be based on Cooperator input and review of scientific literature and any existing wastewater quality data, it is anticipated that additional sample collection will be required to generate sufficient characterization data to support treatment target determination (Task 2). Samples of untreated protein processing wastewater will be collected by the Cooperator from its facilities and shipped to EPA laboratories for analysis. Zoonotic pathogens will be analyzed using cultivation-based and/or molecular methods (i.e. qPCR) and could include:

- Bacteria (e.g. *Campylobacter* spp., *Salmonella* spp.)
- Viruses
- Protozoa

A specific list of microbial analytes will be developed through discussions between the Cooperator and EPA. Fecal indicator bacteria (e.g., *Escherichia coli* and *Enterococcus* spp.) will also be analyzed using cultivation-based and/or molecular methods. If deemed necessary, chemical targets may also be measured using appropriate analytical methods.

Laboratory Responsibilities: Review of scientific literature and any existing wastewater quality data; sample analysis; summarization of results

Cooperator Responsibilities: Guidance on potential risks of water reuse in protein production; provision of existing wastewater quality data (as available); collection and shipment of wastewater samples; review of results

Task 2: Treatment Target Development

Treatment targets will be determined by using quantitative microbial risk assessment (QMRA) to model the hypothetical human health risk (i.e., probability of pathogen infection) associated with reuse of untreated wastewater and comparing results to an acceptable benchmark level (e.g., 10^{-4} infections/person/year). Hazard identification will comprise the results of source characterization (Task 1). Since potable-quality treated water is required, exposure will be modeled assuming daily ingestion at reported drinking water consumption rates. Published dose-response relationships will be used to estimate infection probabilities based on modeled pathogen ingestion doses. To the extent possible, model input parameters will be represented using probability distributions, with Monte Carlo simulation used to incorporate underlying uncertainty and variability in risk estimates. Pathogen log reduction targets (LRTs) will be reported as the \log_{10} reduction in untreated wastewater pathogen concentrations necessary for 95th percentile risk estimates to meet the health benchmark level.

Laboratory Responsibilities: Selection of data inputs, including literature review and distribution fitting as necessary; model development and application; summarization of results

Cooperator Responsibilities: Assistance with selection of modeling inputs, including details of production process and any relevant available data; review of models and outputs

Task 3: Treatment Train Configurations

Potential treatment trains to achieve pathogen LRTs (Task 2) will be identified based on reported log reduction values (LRVs) for unit processes/operations commonly employed in water reuse (e.g. membrane filtration and disinfection). Existing potable reuse projects and guidance documents will be used to identify likely treatment configurations and LRV credits that will produce a water quality that meets all requirements for reuse in protein processing (i.e. drinking water quality). A multiple barrier approach will be adopted to provide continued safety during potential failure conditions.

While the selection of treatment trains will be driven by necessary pathogen reductions (Task 2), selected configurations will also be reviewed to ensure that they achieve sufficient removal of relevant chemical contaminants (Task 1), with additional unit processes recommended as necessary. Treatment components, operational conditions, and validation/monitoring approaches will be suggested, but engineering design will be the responsibility of the Cooperator. EPA will remain available to provide guidance and feedback during design, construction, and startup/testing phases.

Laboratory Responsibilities: Initial identification of treatment train options; summarization of results; consultation during design, construction, and startup/testing phases

Cooperator Responsibilities: Review and guidance on treatment train options; engineering design, construction, and system testing

Resources

National Exposure Research Laboratory (NERL)

The Laboratory "National Exposure Research Laboratory" (NERL) will contribute technical assistance, logistical support, and analysis of samples. This will include use of EPA facilities, supplies, equipment, and personnel.

Tyson Foods, Inc.

The Cooperator "Tyson Foods" will provide samples for analysis at EPA facilities. The Cooperator will also contribute data, technical assistance, and supporting research (including use of facilities, personnel and supplies), as needed.

Work Products

Product 1

Description

Sole element of Task 1: Source Characterization. EPA technical experts, in consultation with the Cooperator, will identify potential hazards associated with water reuse in protein production. Scientific literature and any available wastewater quality data will be reviewed to characterize identified hazards (occurrence rates and concentrations), focusing on microbial pathogens but also considering chemical risks. As necessary, wastewater samples will be collected by the Cooperator and shipped to EPA facilities for analysis of bacterial pathogens and indicator bacteria. EPA will summarize results of literature/data review and microbial testing as an internal report.

Timeline

Internal report delivery is dependent on logistics of sample collection and analysis, estimated 6-8 months from initiation of study.

Use

Results will inform determination of treatment requirements (Task 2) and selection of treatment trains (Task 3), as well as generate new data on the microbial quality of protein processing wastewater and summarize relevant health risks (microbial and chemical) associated with its reuse.

Product 2

Description

Sole element of Task 2: Treatment Target Development. EPA technical experts, in consultation with the Cooperator, will develop a QMRA model of pathogen risks associated with protein processing wastewater reuse based on risks characterized in Task 1 along with an appropriate direct potable reuse microbial risk assessment methodology. This will be used to identify treatment requirements (pathogen LRTs) necessary to meet human health benchmarks. EPA will summarize results of the QMRA model as an internal report.

Timeline

Internal report delivery is dependent on completion of Task 1 (but may be started concurrently), estimated 8–10 months from initiation of study.

Use

Results will inform selection of potential treatment trains (Task 3), as well as generate a new QMRA model of consumer exposure to pathogens in protein processing wastewater and recommend pathogen reduction targets for its reuse.

Product 3

Description

Sole element of Task 3: Treatment Train Configurations. EPA technical experts, in consultation with the Cooperator, will select treatment train configurations that achieve pathogen LRTs determined in Task 2. Configurations will be reviewed to ensure that they maintain a multiple

barrier approach and can achieve removal of chemical hazards identified in Task 1. EPA will summarize potential treatment trains as an internal report.

Timeline

Internal report delivery is dependent on completion of Tasks 1–2 (but may be started concurrently), estimated 10–12 months from initiation of study.

Use

Results will allow the Cooperator to design and implement a treatment system for onsite protein processing wastewater reuse, as well as generate new treatment train recommendations for general industry use.

Product 4

Description

Synthesis of Products 1–3. A peer-reviewed journal article summarizing results of Tasks 1–3.

Timeline

Article delivery is dependent on completion of Tasks 1–3 (but may be started concurrently), estimated 18–24 months from initiation of study.

Use

Journal article will disseminate results of this study, including source characterizations, pathogen reduction targets, and recommended treatment trains for direct potable reuse, for general use by the protein industry and other interested parties.