External Peer Review of the FDA/CVM Draft Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm

Peer Review Report

Office of Food Safety and Veterinary Medicine
Center for Veterinary Medicine
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I. Introduction

The Food and Drug Administration (FDA) has conducted a qualitative risk assessment (RA) related to manufacturing, processing, packing and holding activities for animal food when such activities are conducted on farms. This RA was conducted to satisfy requirements of the FDA Food Safety Modernization Act (FSMA). FSMA requires FDA to conduct a science-based risk analysis and to consider the results of that analysis in determining whether to exempt certain small or very small businesses from the requirements of Section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including hazard analysis and risk-based preventive controls, and the mandatory inspection frequency in Section 421 of the FD&C Act, or whether to modify such requirements for such facilities. Exemptions or modifications of the requirements may be considered for small or very small businesses engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that FDA determines to be low risk involving specific animal foods FDA determines to be low risk. The purpose of the RA is to provide a science-based assessment of on-farm activity/animal food combinations to determine which are considered low risk.

Under the statutory and regulatory framework applicable to farms and to animal food facilities co-located on farms, a specific activity (such as mixing) may have a different classification within the classes of manufacturing, processing, packing and holding (with consequences for the risk associated with the activity) depending on several factors. The determination of the classification is based on whether the food being operated upon is a raw agricultural commodity (RAC) or a processed food, and whether a RAC was grown or raised on the farm performing the activity or a farm under the same ownership. The FDA used the classifications in organizing the activities for consideration in its science-based assessment of low risk activity/animal food combinations. The RA follows a structured approach, including risk assessment sections on Hazard Identification, Hazard Characterization, Exposure Assessment, and Risk Characterization.

II. Peer Review Charge and Questions

In June 2012, FDA contracted Versar, Inc. to organize and conduct an external peer review of FDA's draft document "Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (the draft RA). The independent expert peer reviewers (see Section IV below) were selected by Versar, Inc. and also deemed by Versar to have no conflicts of interest. The goal of the peer review was to provide FDA with a comprehensive appraisal of and feedback on the nature of the approach taken, the scope and purpose of the draft RA, the definitions used in the draft RA, the questions asked in the draft RA, and the clarity and transparency of the draft RA. The peer reviewers were first asked to evaluate and comment in a general way about the scientific basis and quality of the draft RA (see "General Impressions" Section III, Part A below). Second, they were asked to respond to a list of specific charge questions that addressed various aspects of the draft RA (see "Peer Reviewer Response to Charge Questions" in Section III, Part B below). Finally, the peer reviewers were asked to provide any additional comments, feedback or scientific information they had that might improve the draft RA (see "Specific Observations" Section III, Part C).

The questions posed to the reviewers are as follows.

Charge Question 1. Are the risk analysis framework and the risk management approach appropriate for the intended purpose of the QRA?

Charge Question 2. Are the definitions of "low-risk activity" and "low-risk activity/animal food combination" reasonable?

Charge Question 3. Is the approach for determining animal food types and activity/animal food combinations that we considered outside the scope of the draft QRA and those that were included in the draft QRA reasonable given the purpose of the QRA? If not, how might this be revised?

Charge Question 4. Are the scope and purpose of the QRA clearly identified? If not, what additional information should be provided?

Charge Question 5. Are the questions to be addressed in the QRA appropriate, given the scope and purpose of the QRA? If not, what changes would you suggest?

Charge Question 6. Does the QRA adequately cover the activity/animal food combinations that are not within the farm definition and that would be conducted by farm mixed-type facilities? If not, what other activity/animal food combinations should be included?

Charge Question 7. Considering the scope and purpose of the QRA, are the approaches to hazard identification, hazard characterization, exposure assessment, and risk characterization appropriate?

Charge Question 8. Is the report written in a transparent and clear manner? Does the report adequately address the questions and stated objectives? If not, how might the report be revised?

Charge Question 9. Do you have any additional comments that might improve the document?

NOTE: In the document the Agency submitted for external peer review, the Agency had abbreviated "Qualitative Risk Assessment" as "QRA." Thus, the peer reviews also refer to the "QRA". However, the abbreviation "QRA" is frequently associated with a quantitative risk assessment. Subsequent to the peer review request the Agency shortened its abbreviation to "RA" to establish the distinction that the risk assessment is qualitative rather than quantitative.

III. Peer Reviewer Comments and FDA Response

Below, we provide the text of each peer reviewer's feedback and responses to the specific charge questions verbatim without attribution to the specific reviewer. FDA considered and used this information to edit, clarify, supplement and improve the draft RA. FDA responded and/or commented in reply to the peer reviewers in instances when doing so was deemed warranted and appropriate but did not respond or comment in all instances.

A. General Impressions

Reviewer #1

This reviewer believes that the information in the report is accurate and the conclusions are sound. The report could be shortened and more reader-friendly. In some places a table could be used to list or compare items as a way to reduce the repetition of some long phrases in the text. The authors try hard to completely and accurately state the information, but in many cases parts of the report must be re-read because sentences are too lengthy.

Reviewer #2

The document is well sourced for the conclusions drawn by the authors. Particularly, the Hazard Identification and Risk Characterization sections are well referenced and all pertinent conclusions are drawn from literature. However, the authors were not clear when presented information in this Qualitative Risk Assessment was inside or outside the scope of the risk assessment. Since an assessment was conducted by the FDA to identify activity/animal food combinations as described in the paragraph starting at line 508, divulging the information and including the information in this publication would allow reviewers to better judge the accuracy and thoroughness of the report, along with a more complete boundary of the scope of investigation.

The risk assessment was not uniform in the clarity of information presented. The Hazard Identification and Hazard Characterization sections are appropriately referenced and conclusions are readily drawn by the information presented. The individual sections of the Qualitative Risk Assessment that lacked clarity and logical flow of information are discussed in the Specific Observations section below. The document varied between citing specific sections of law or code to more general references to the FD&C Act and the FSMA. It would help to follow the authors' logic more fully if specific citations were included with every reference to regulations in the document. In addition, examples presented in the presentation did generally not add to understanding the point originally set out to explain. The document would benefit from specific and clear examples instead of "i.e." statements where the original point is expanded upon with more verbiage. Elevating the importance of the information presented in the paragraph starting at line 548 would eliminate many questions as the remainder of the document is read.

The conclusions set forth in the document are appropriate for the animal food and activity combinations identified within this Qualitative Risk Assessment. Some additional interventions may be appropriate for minimizing and preventing hazards.

Reviewer #3

In general, I found the document to be somewhat difficult to interpret and understand but am willing to accept the fact that I am not accustom to reading "government speak." If I understand the primary purpose of the document correctly, it is to guide the FDA in determining when and if a specific facility falls within the definition of a "farm" on which the farm's RACs are used in the manufacture of livestock feed that would be consumed on that farm and would NOT be introduced into commerce outside the farm. The underlying assumption is that those activities and use of the farm's RACs would likely constitute a "low risk" activity and the farm would be exempt from registration requirements under the FSM Act. In addition to manufacturing and processing, it is likely that the farm would hold (store) certain ingredient components that might have been produced on the farm to be used in production of that livestock feed to be fed on the farm. Again, assuming proper management of that storage process, the activity would likely be considered "low" risk and the farm would be exempt from registration requirements under the act. It seems like the document is unnecessarily verbose. Why not plain and clear language that can be understood by the average stakeholder who is to be regulated by the act?

In addition, the document seems to have nearly total missed two of the most important "processes" used in the manufacture of livestock feed and that is "weighing" and "mixing." I found a single mention of weighing (line 1076) used to describe the proportioning of ingredients in the manufacture of livestock feed and that was regarding the exact weighing of certain additives that could be toxic at excessive levels. Likewise, "mixing" was mentioned several times, however, the importance of proper mixing of ingredients was not emphasized at all. For example, one can start with a perfect formula for a specific animal, accurately weigh all the necessary ingredients into the feed but, if the feed is not properly mixed, it is possible to offer a ration (daily aliquot) to the animal that contains a toxic level of some additive that is in a "super" concentration. If appropriate background had been provided for weighing and mixing, it is my belief that Question 5 (Line 1401) could have been answered differently. With improper mixing or weighing, "Nutrient Imbalance" is a more likely risk but, if done properly, is an inherent control that could significantly minimize or prevent a hazard that is reasonable likely to occur. In fact, Table 12 implies that "Mixing/blending for the purpose of making a processed animal food" can result in nutrient imbalance which could cause serious adverse health consequences or death. That finding would seem to counter the answer shown in Question 5.

While I did find the document difficult to understand and interpret, I feel that the appropriate background information is established and, once I got to the answers to the questions to be addressed in the QRA (lines 1349-1540), the purpose of the document became clearer and more easily understood.

Reviewer #4

The purpose of the QRA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low-risk. Whereas much of the document has reasonable assumptions for management purposes, there is some lack of clarity into what the QRA actually is addressing. What precisely is an activity/animal food? From the document itself animal feed is a major portion, but products derived from animals and animals themselves are also mentioned. Because definitions are mentioned in several parts of the document and only some well-expressed in Table 1, a glossary of terms could be added as an annex, e.g., lines 540-541; 1152-1153j.

On-farm and Off-farm activities are spelled out in detail, e.g., Table 3, and should cover all or most of the activities encountered (there are always exceptions encountered once the real world is involved). The risk analysis framework, being based on Codex Alimentarius, is acceptable in principle; however, since this is a qualitative assessment, there are no models to follow – this is an in-house assessment that does not have apparent precedents, at least in the literature. In the document, it indicates that the Secretary determines what is a low risk activity and by extension to the CVM agency level.

The hazard identification section is weak because there are limited data to identify hazards in animal food. The authors rely on the Reportable Food Registry and the Recall Enterprise System, and by their own admission these have their limitations and underreport, such as recalls not reflecting the true degree of animal food contamination since hazards can be detected by processors before an animal food is processed and a recall process initiated. Tables 5, 6 and 7 show the hazards used in the assessment. *Salmonella* is the pathogen that is the main biological agent of concern, being present in many types of ingredients of animal feed and food. *Pseudomona*s is mentioned in Table 6 but not explored any further. Other pathogens should be described and rationales given why or why not they should be included in the assessment. Under the response to the Charge Questions some examples are given including other enteric bacteria and parasites. *C. botulinum* is listed under chemical, but, in fact, traditionally this is a pathogen that should be listed under microbiological because the factors that allow the toxin to develop in food or feed impact the organism not the toxin itself, such as anaerobic atmosphere, time and temperature.

In the Biological Hazards section both human and animal diseases are mentioned but this section could be improved by more clearly separating human and animal illnesses, e.g., certain strains of *Salmonella* affect animals worse than others, so the reader is clear what the assessment does in the Risk Characterization, since both human and animal effects are noted (see Table 8). In my opinion, the assessment should be carried out separately for animals exposed to food and feed, and for humans that may have eaten food from animals exposed to these hazards. Also, the low, medium, high characterizations for frequency, severity and exposure have no supporting data; these could be put into an annex. Broad assumptions are made such as *Salmonella* is severe for humans but low for animals. What is high or low severity? Most assessments for human foodborne disease would put *B. cereus/S. aureus* as low; *Salmonella, Campylobacter* as moderate, and *C. botulinum* and *Listeria monocytogenes* as high (these are only examples, not a complete listing). Some animals are severely affected by certain strains of *Salmonella* such as *S. Cholera-suis* in pigs, *S. Newport/S. Dublin* in cattle, or *S. Enteritidis/S. Pullorum* in poultry. Dioxins, I suspect, are included because any amount can trigger a recall, but the risk to human health is very low; it's more a regulatory thing. I understand cattle and other food animals in free range like to suck, chew or eat anything in their reach, whether a lead container, a discarded PPB or PCB-containing piece of equipment, dioxin-containing edible oil, or a sharp object like glass or metal, but these are unlikely to be identified quickly as any farmer would remove these from animal or human access if they were found. Pesticide levels are typically very low in crops and other products destined for animal feed unless the farmer or a neighboring farmer has not been delivering them according to GAPs. Mycotoxin levels are most likely to vary even within crop depending on local moisture, humidity, temperature and heterogeneous presence of fungal spores, and therefore the farmer has to be vigilant about inspecting his crops during the growing

season (in large fields comingling of grains, some contaminated and some not, will occur unless any infected grain heads are removed before harvest). Thus, this is one hazard that is going to be in varying amounts depending on weather and farmer vigilance, and fumonisins and other mycotoxins can be in crops. However, today very little aflatoxin and other mycotoxins get into the human food chain though contaminated animal products in domestically-produced crops (meat and milk should be excluded from the assessment). DON can cause human illness but not in the US and the authors cite FAO as saying that conclusive evidence for the role of mycotoxins in diseases is lacking. Areas not included so far are antibiotics and AMR. These have the potential to be long-term high risk factors for disease in both animals and humans, as well as supplying short term cures; at least these should be discussed as whether they should be included or not and reasons given why.

Aquaculture is within FDA's mandate but is not mentioned at all in this assessment. Within the document, it is stated that "farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both." Therefore, there should be a short discussion on the classification of aquaculture feed and products arising into low or high risk farm and off-farm groupings. Typically, aquaculture is carried out for processing of fish and crustaceans for consumption beyond the farm and should not be considered low risk. Feed would be obtained from outside sources unless the operation is very small, where food waste as direct fish food or manure and discarded animal parts used to stimulate algal growth for use as feed could be from within a farm.

I found it strange that horses are mentioned quite a few times in the document, as an animal that can be severely affected by botulism, salmonellosis, fumonisin poisoning from silage, and GI effects from ingestion of physical objects. Since horses rarely enter the human food supply, I wonder why they are included? I can understand that a veterinary assessment would want to consider all animals, but how do horses relate to FSMA? Pet food, milk and milk products and animal-derived tissue are excluded from the assessment by definition as covered under separate legislation. Yet, products from food animals are covered and meat-producing animals and pet food are mentioned many times in the text or in tables. Can some clarity be given to what is in the assessment and what is not?

Reviewer #5

The report is a very detailed description of the process and conclusions that FDA used to evaluate the risk of particular on-site activities that are not really farming. FDA carefully adheres to the generally accepted methods for risk assessment of Hazard Identification and Characterization, Exposure Assessment and Risk Characterization. They seem to have considered the key hazards and understood the intent of Congress, regarding the need for QRA.

The methods and conclusion of FDA, as shown in this report, appear to be sound, reliable, and science-based. However, I cannot be totally sure. The organization, particularly the headings make it difficult to discern the topic for many of the sections. For this type of document to be useful, it needs to be clearer.

The Executive Summary needs more information about the purpose of the QRA and methods. Particularly, the risk management questions need to be identified.

In summary, due to difficulties in understanding some of the reports organization, I cannot be sure that I have TOTALLY comprehended all of FDA's methods. Therefore, if this report were a scientific paper, I would recommend: reorganization and re-review.

B. Peer Reviewer Response to Charge Questions

Charge Question #1. Are the risk analysis framework and the risk management approach appropriate for the intended purpose of the QRA?

Reviewer #1
Yes, but the discussion may be too complicated to be understood by some of the intended audience.

FDA Response:
In revising the risk assessment we have deleted the risk analysis framework section (although we did follow the Codex approach, since it is internationally accepted).

Reviewer #2
Yes, for the identified risks presented in the QRA, the hazards, their characterization, exposure assessment, and risk characterization were able to produce a well thought out Risk Characterization for animal food/activity combinations.

Reviewer #3
Yes, using the Codex definitions are familiar to most stakeholders and are most useful in defining what a "risk" is and how it should be managed. The "Risk Management Approach" seems reasonable; however, many of the terms and the language used are not commonly used outside of government and left me wondering exactly what is being said. Sentences that go on for six or seven lines are confusing. For example, the authors could use one or two examples of what is meant by the term "activity" (line 385).

FDA Response:
In revising the draft RA, we attempted to shorten the long sentences. This was particularly possible where we could substitute an acronym for a long phase such as "SAHCODHA" for "serious adverse health consequences or death to humans or animals." The draft RA has been re-organized such that Table 1 provides a list of many common manufacturing, processing, packing and holding activities that may be conducted on farm.

Reviewer #4
There are no standards for qualitative risk assessments and, therefore, each has to be evaluated on its own merits. The framework follows the definitions of Codex Alimentarius, which is consistent with previous US and international risk assessment approaches. As the authors point out, it is not clear whether the requirement of section 103(c)(1)(C) of FSMA to conduct a science-based risk analysis was intended to encompass all three components of risk analysis which creates a degree of uncertainty about the process. The authors tentatively conclude that the analysis required by section 103(c)(1)(C) "should be limited to an assessment of the risk of specific types of on-farm activity/animal food combinations for the purposes of making the risk management decisions required by section 103(c)(1)(D)." Could someone not ask for clarification rather than state ambiguity in a guidance document that will eventually become public, or at least confirm this is indeed what is requested? Also, as the authors discover when they actually look at some of the practical aspects of low and high risk farm activity/animal food

combination, there are recognized and likely unrecognized complications. This makes the framework reasonable in a general approach but risk management has to take into consideration other aspects than the pure science.

FDA Response:
In revising the draft RA, the Agency removed the discussion about the risk analysis framework and consequently, the discussion concerning whether the analysis should be limited to an assessment of risk. While the document no longer references the Codex Alimentarius, the Agency continued to follow that approach, which advocates separation of assessment and management functions.

Reviewer #5
Yes. This section might better be termed "Scope and Assumptions" (e.g., Sec F). If that change is made, then the heading II QRA (line 468) should be moved to line 572.

The section I.C. RA Framework is a very good discussion about the main objective of the QRA and the questions FDA hopes to address, especially lines 334-336.

I suggest deleting "tentatively." The points made in lines 334-336 and 366-370 are key to the whole document. They explain the "target" or purpose of this QRA, therefore they should be emphasized in the Executive Summary and at the conclusion. They essentially answer the question, "Why did we do this QRA?"

I am not sure FDA used the term "risk management" correctly (lines 379ff). Calling this section "Approach" gives me the impression that some methods will be described. Actually it seems like assumptions regarding which RM options are "on the table" or not. The discussion and assumptions in this section are appropriate, but the "considerations" should be labeled as "assumptions."

I do agree with FDA "tentative conclusion" on lines 336-339:

> "We therefore tentatively conclude that the analysis required by section 103(c)(1)(C) should be limited to an assessment of the risk of specific types of on-farm activity/animal food combinations for the purposes of making the risk management decisions required by section 103(c)(1)(D)."

I think it was good idea to look at activity/animal food combination (AAC).

FDA Response:
In revising the RA document, an explanation of why we did this RA was moved to the first section, Background and Purpose. The Approach section has been abbreviated; it provides the rationale for evaluating activity/animal food combinations and no longer discusses risk management options.

Charge Question #2. Are the definitions of "low-risk activity" and "low-risk activity/animal food combination" reasonable?

Reviewer #1
Yes, but lengthy. The phrase "low-risk activity/(animal) food combination" could be replaced with "low-risk activity for animal food" or "animal food low-risk activity."

FDA response:
The Agency agrees that the phrase is lengthy. However, the suggested replacements would not be adequate because they could be misconstrued as indicating that an activity is low-risk across all animal foods, and a primary message of the RA is that the same activity may be low-risk when performed on one animal food but not low-risk when performed on another.

Reviewer #2
The only problem with this definition is lack of the authors' insight in to what they define as reasonable. Insights into population risk of health consequences or death by Epidemiological analysis such as Cohort Studies to look at the Relative Risk of the activity/food combinations. The authors should investigate if data exist, and how to quantify acceptable risk.

FDA response:
A section on data limitations has been added to the RA. Data for estimation of relative risks of activity/food combinations is sparse even for human food and human outcomes; it is extremely so for animal food and animal health outcomes.

Reviewer #3
Yes, however, it takes careful reading of the description several time to truly understand what the author is intending to say. That is simply because the phrases are not that common or familiar to me nor are they in common usage.

Reviewer #4
Determining how low a low risk is, or what activities and foods constitute a low risk, will always be subjective. Any risk, no matter how low, has the potential to cause a contamination and possible illness. Even if this is a very rare occasion, or some other unforeseen activity occurs that increases the risk, such an event will eventually happen, and CVM needs a plan to be able to respond to any criticism that follows. It is like *E. coli* in leafy greens; both the industry and government know there are risks because it is impossible to prevent contamination and controls are not totally effective. Recalls and occasional illnesses do occur, but there are plans in place to minimize both the risk and adverse publicity. This is partly covered by the statement: "Any classification of an activity/animal food combination as "low risk" should not be interpreted to suggest that facilities engaged in these activities do not have an obligation to ensure the safety of the food they manufacture, process, pack, or hold and to comply with requirements of the FD&C Act and its implementing regulations, including any applicable CGMP requirements." The authors seem to pick up on this when they write the following sentence with words like "not reasonably" and "does not significantly minimize or prevent such a hazard." ".... low-risk activity to mean an activity that is not reasonably likely to introduce a hazard for which there is a reasonable probability that use of, or exposure to, the animal food will cause serious adverse health consequences or death to animals or humans and that does not significantly minimize or

prevent such a hazard that is reasonably likely to occur." This wording uses reasonably and significantly in a very general sense and seems to anticipate unforeseen issues.

FDA response:
In addition to drafting the preventive control regulations as a means to reduce the occurrence of incidents, the Agency has been working to develop systems to support rapid response to unforeseen incidents when they do occur, which also minimizes the likelihood that hazards will cause adverse health consequences.

Reviewer #5
Yes, the definitions are reasonable.

They largely reflect common sense about on-farm practices, which begs the question why such an extensive QRA is required.

I suggest FDA define the hazard as done in lines 425-428, then find a "shorthand" way to reference it in the remainder of document. Inclusion of this three line description in other sections dilutes the meaning of any sentence in which it is used.

FDA Response:
The Agency revised the discussion of the definitions of low-risk activity and low-risk activity/food combination to improve readability. The Agency substituted the acronym "SAHCODHA" for the long phase "serious adverse health consequences or death to humans or animals."

Charge Question #3. Is the approach for determining food types and activity/animal food combinations that we considered outside the scope of the draft QRA and those that were included in the draft QRA reasonable given the purpose of the QRA? If not, how might this be revised?

Reviewer #1
The approach is appropriate. "Labeling" as an activity is not described until Tables 9 and 11. Readers of this document may not understand why labeling is included.

FDA Response:
In the revised RA, Table 1, and the text below it, lists all activities, including labeling, that are considered in the risk assessment.

Reviewer #2
The paper should first be revisited to make it clear what food and activity/animal food combinations are outside the QRA and provide clear justifications for exclusions. For example, I.(F.) excludes animal-derived foods from low risk categories as being always high risk, then is listed in Table 4 as an activity conducted on a Farm-Mixed-type Facility, and is also excluded from the QRA by the paragraph starting at line 548 as remaining within the farm definition. When looking at a common animal feed such as Dairy Herd & Beef Calf Milk Replacer, would it be classified as a high risk animal food? For example, I.(D.) Considerations #3&#4, we would assume milk replacer to be a hazard because we dismiss the existing regularity framework for safety (#3), the components of the milk replacer required time and temperature control for safety

(#4). However milk replacer has been shown to be a safer and more efficient animal food than raw milk produced on the farm.

This might be revised to classify food types and activity/animal food combinations that have been scientifically proven to cause lower disease incidence than RACs produced on the farm where the animals are housed to be low risk.

***FDA Response*:**
In revising the RA, FDA emphasized that the RA is related to manufacturing, processing, packing, and holding activities for animal food when such activities are conducted on farm-mixed facilities. The Agency's understanding is that production of animal-derived foods for use in animals, such as meat and bone meal, and the production of calf milk replacers are not likely to be on-farm activities. Risk of the use of products such as meat and bone meal or milk replacers on farm for feeding animals on the farm is not assessed because consumption of product on farm does not cause a farm to be considered a farm-mixed facility.

Reviewer #3
I would suggest reconsideration of the statement that these products require one or more preventative controls. It is indicated later in the document that bringing certain ingredients (non-farm RACs) onto the farm for the purpose of manufacturing a complete animal feed on the farm from farm-produced RACs does not trigger registration and the associated regulatory oversight. For example, dried non-fat skimmed milk (DSM) and properly processed animal protein products (e.g.-meat and bone meal-MBM) do not require preventative controls and are acceptable ingredients to be blended into complete animal feeds. DSM is widely used in blending calf/baby pig milk replacer and MBM is a common ingredient used in the preparation of swine feeds. Certainly if these products are produced on a farm, preventative controls are necessary but I cannot imagine a "farm" being engaged in those kinds of activities.

FDA Response:
The Agency agrees with the reviewer that production of these products is not likely to be done on-farm and that use of these products to feed animals on the farm does not require preventive controls. However, it is important to recognize that changes in availability of technology or raw product might alter the pattern of activities likely to be done on-farm. Therefore, the Agency felt it valuable to acknowledge the hazards of activities performed on these animal foods but not currently likely to be conducted on-farm.

Reviewer #4
Yes, reasonable, but probably not complete; only after putting the RA into practice will other points and questions emerge. Here are some thoughts.

Are there fruits and vegetables that could be used for animal food, not just those that are culled? Pumpkins, squash, and apples may not be just culls but would supplement feed for chickens, especially if pulped or added to other ingredients like straw. Also, some tropical fruits, not consumed by people but which could be used as animal feed, include the Chalum (*Inga* spp.) and some Cucurbitaceae; others contain seeds with a high oil and protein content, such as Jícara (*Crescentia alata*). Maybe these are extremely unlikely for most US farms but not so farfetched for Hawaii and the tropical island territories. Nuts not normally eaten by humans can be eaten

with relish by pigs (not just shells). For instance, in Europe and some parts of North America, pork fed on oak mast, chestnut mast or beech mast has a reputation for producing exceptional finished meat, and Spanish and Virginian acorn-fed cured hams are specialties. Would recycled food waste be considered both for on-farm use and processed if for a wider distribution? As the environmental "green" interest for recycling increases by both public and municipalities, this could be an increasingly important part of the food supply with risks such as *Salmonella,* if simply composted.

FDA Response:
The reviewer raises the question of animal food ingredients not specifically described in the risk assessment, some of which are not commonly found in the continental US. Unless the Agency becomes aware of issues with the use of particular fruits and vegetables, the Agency considers the use of the generic other plants and other plant by-products to cover the activity/animal food combinations referred to in the comments. Rendering to produce recycled animal tissue products was considered out of the scope of the RA because of the requirement for temperature controls. Additionally, this activity is not likely to be done on farm. Processing of other food waste on farm for wider distribution was not listed in the RA because FDA did not find information to support current on-farm production of food waste for commercial distribution.

Reviewer #5
Not outside scope. I felt the need for more information on why these were chosen, like did you look at all activities, and then throw some out?

Who were the experts utilized?

***FDA Response*:**
FDA developed a matrix that listed all activities associated with animal food as defined in the literature, including the *Official Publication* (OP) of the American Association of Feed Control Officials (AAFCO), in rows and all major animal food groups as columns. The Agency consulted with the experts within CVM, members of the feed industry, state regulators, and extension service personnel who provided input on which activities are performed on which animal foods and whether the activities are likely to be performed on-farm. In many cases, the experts offered their opinions as to whether the activity/animal food combinations were low risk.

Charge Question #4. Are the scope and purpose of the QRA clearly identified? If not, what additional information should be provided?

Reviewer #1
Yes.

Reviewer #2
Clear examples of farm mixed-type facilities should be included to introduce the reader to the concept of what could occur on these facilities and what would be the activity that would need registration with the FDA. The input gained from the survey discussed in the paragraph starting at line 508 should be more clearly discussed and defined.

FDA Response:
Examples of activities and how they would be classified is now included as an Appendix to the RA. The information from experts about on-farm activity/animal food combinations is described in the revised RA in Scope section, before Table 1, and in response to Reviewer #5 concerning Charge Question #3.

Reviewer #3
Yes, the scope statement is sufficiently clear.

Reviewer #4
Composting is not mentioned anywhere (silage is a type of this and is mentioned); are there situations where composted food could be used as animal feed? For instance, from below it is not clear how much would be used as direct animal food and what the risks could be, but it seems there is some market for direct animal feed from recycled and composted waste food:

> "*...farmers can receive free compost feed stock by setting up a system of picking it up from businesses and institutions or having them deliver it to the farm site. Some operations may pay the farmer to pick it up or drop it off for disposal of their waste. Farmers can adapt to the scale that best fits their agricultural system. Larger inputs of food waste may be composted and sold off farm. Agricultural systems may include manures, crop residues, and other organic farm waste as feedstock to the compost, if desired.*" "*Hog producers may want to use cooked food waste as an animal feed or as a feed supplement.*" "*It may be worthwhile to contact your county agricultural extension agent or the University of Georgia for information on obtaining lab analysis of the feedstocks in your compost mix.*" "*The market for compost is one of increasing demand. Supermarkets, restaurants, and schools produce 16 million tons of commercial organic waste that may be composted. Source separated food scrap compost is generally higher in nutrient value and lower in contamination than most other types of compost, thus making it more valuable in the market. Composts from source-separated feedstocks have the highest average revenue per ton at nearly $40. Compost from yard trimmings has a value of $32 a ton and municipal solid waste compost has a value of $3 a ton.*"

(Mark Risse and Britt Faucette, 2012, Food Waste Composting: Institutional and Industrial Applications. University of Georgia Extension)

FDA Response:
CVM acknowledges the comment and is aware of growing interest in the use of commercial human food waste in animal food. In conducting this RA, the Agency did not find information to support current on-farm use of commercial human food waste in the production of animal food for commercial distribution. Processing of animal tissue-derived products was determined to be out of the scope of the risk assessment because it requires controls and thus, would not be considered low risk if it were to occur. Commercial human food waste consisting of plants and plant byproducts would fall within the scope of the RA and risk determinations for activities associated with this group of animal foods were made.

Reviewer #5
Yes, but hard to "see it" due to organizational challenges in the document.

Consideration/assumption #3 is unclear to me (lines 390-400). There may be some "FDA speak" in the second half of the paragraph (lines 395-400).

Charge Question #5: Are the questions to be addressed in the QRA appropriate, given the scope and purpose of the QRA? If not, what changes would you suggest?

Reviewer #1
Generally, yes. Question 4 asks to identify hazards that have a reasonable probability of causing serious health consequences. Question 6 asks about interventions to prevent a hazard that is reasonably likely to occur and cause serious health consequences. These questions appear to refer to the same hazards. The answer for Question 4 is *Salmonella*, mycotoxins and nutrient imbalance. The answer for Question 6 considers these and additional hazards- *Clostridium botulinum*, heavy metals and physical hazards. The hazards discussed in Questions 4 and 6 should be similar.

FDA Response:
The reviewer is correct. The *C.botulinum* organism was found to have a control during composting. The heavy metals and physical hazards were not found to be reasonably likely to cause SAHCODHA to humans or animals due to low likelihood of occurrence. The Agency made revisions to the RA document to correct this inconsistency.

Reviewer #2
A specific question should be asked to state what food types and activity/animal food combinations are outside the QRA, so readers can then focus on what is inside the QRA. For example, the reader should know approximately what is not covered, what is low risk, and what is high risk after reading the document.

FDA Response:
The Agency made a series of revisions to improve the description of what is included, what is not covered, what is low risk, and what is not low risk.

Reviewer #3
If properly answered, the questions posed are sufficient.

Reviewer #4
Yes, reasonable but probably not complete; only after putting the RA into practice will other points and questions emerge.

Reviewer #5
Yes.

Section IIA (line 470) should become part of Section I.
Line 477 should be labeled "Risk management questions to be addressed in QRA." I feel this change is very important as it indicates to risk managers the areas in which they must engage and

provide input. The 2009 report by NAS, "Science and Decisions," faulted failure of engagement by managers as a chief reason that risk analysis is not functioning well to inform decision makers.

While I agree with the items listed in Table 4, I am unclear how that list was developed. Lines 539-541 mention use of "experts." I don't think that process was described in this document. Who are the experts, how did FDA extract their opinions on Table 4?

FDA Response:
FDA disagrees that line 477 should be labeled "Risk management questions to be addressed in the QRA," because not all of the questions listed are risk management questions. FDA encourages risk managers, as members of the public, to review and provide comment on the entire draft RA.

See our response to Reviewer #5 for Question 3 above for an explanation of FDA's process for gathering information from experts.

Charge Question #6. Does the QRA adequately cover the activity/animal food combinations that are not within the farm definition and that would be conducted by farm mixed-type facilities? If not, what other activity/food combinations should be included?

Reviewer #1
Yes.

Reviewer #2
In the case of calf feeding operations, animal food might be obtained in the form of waste milk from area dairy farms, or the youngstock farm may be a separate legal entity from the parent dairy farm. Consumption of milk fed to calves, whether raw, heat treated, or pasteurized, should be addressed by the QRA.

FDA Response:
Activities to make milk products were excluded from the scope of the RA because they require temperature controls. By definition, if heating is needed to control a hazard, the activity would not be considered low-risk. In the scenario described by the reviewer, if the farm providing the milk is providing raw milk, that farm remains within the farm definition because they are selling their raw agricultural commodity (RAC). The farm that receives the milk may choose to heat treat it but remains within the farm definition because the milk is being fed to animals that they are raising.

Reviewer #3
I assume that the covered activity/animal food combinations covered are primarily those listed in Table 4 (lines 531-534). If so, the listing is sufficiently exhaustive. However, the discussion following the table seems to exclude extruding and pelleting as activities not found associated with farm feed manufacturing. There are certainly instances where small extruders are used on-farm to produce full-fat soybean meal that could/would be used in site-manufactured feeds. In addition, though rare, some very large hog operations would likely consider pelleting on-site, to take advantage of the nutritional benefits of that process.

FDA Response:
FDA appreciates receipt of information about small extruders. A key to determining whether a facility doing the extruding and pelleting on-farm would be subject to the requirements of 415 and 418 is whether the processed animal food is being fed to animals on that farm or is being distributed into commerce.

Reviewer #4
See comments under #7.

Reviewer #5
Yes, more than adequately.

The section on definitions, from lines 249-271, was appropriate and necessary. However, the details about definitions relative to additional rulemaking, as noted in lines 273-279, were a distraction. Certainly, I see how these relate to the QRA, but they almost look like they are part of the QRA. FDA might consider placing Table 2 and 3 in an appendix. If the "full discussion" is published as part of a different rule (line 277), then it should not take up much space here.

Part of the confusion may be the use of the term "organizing principles." That term is inconsistent with normal RA methods and is also a distraction.

FDA Response:
The text about rulemaking was moved to an appendix.

Charge Question #7. Considering the scope and purpose of the QRA, are the approaches to hazard identification, hazard characterization, exposure assessment, and risk characterization appropriate?

Reviewer #1
Yes, but some discussion should be shortened. The Exposure Assessment section is 7 pages long. This section could be reduced by focusing on hazards that are identified as reasonably likely to occur.

FDA Response:
The Exposure Assessment section provides information on the factors that influence the likelihood of the hazard to be present in the animal food during or following an activity. Prior to examining all the influencing factors, it is not possible to determine which hazards are reasonably likely to occur.

Reviewer #2
Yes.

Reviewer #3
Yes, however, I think the list of chemical hazards should be expanded to include nitrate toxins in hay and forage products. This is an unusual year, but we are seeing a very large percentage of dry hay and baled forage samples with levels of nitrates that are well above the toxic level (in some cases 3X or 4X) for many ruminants. Most of these forages are fed directly to livestock but some will be chopped/ground and blended into farm manufactured feeds.

FDA Response*:*
The Agency will consider the reviewer's recommendation for possible inclusion in the final RA.

Reviewer #4
The issue of some fruits, vegetables and nuts being considered has already been discussed but not whether they are high or low hazards. Pumpkins, squash, and apples as pulp certainly could contain pathogens like *Salmonella* or *E. coli*. The risks of tropical fruits could be similar to apples but also there could be natural toxic compounds present that would need to be avoided or eliminated. Nut mast like nut shells could have mycotoxins present. Food waste, whether composted or not, could contain pathogens like *Salmonella*. Ensiled material is likely to contain *Listeria monocytogenes*, but it is not clear whether animals ingesting this pathogen could then be an increased source of the organism for humans when the meat or products from these animals are used as food, since the pathogen is a frequent environmental contaminant. There is certainly an increased risk of the animals being infected and causing adverse veterinary conditions including abortions.

Horses are mentioned several times in this document. Either these should be excluded as a food animal or included, as horse meat may be consumed by humans. If the latter is valid, then *Trichinella* is a major concern, both for on-farm use and for any form of processing. An ARS research project by Fayer, Jenkins, Miska and Santin-Duran from 2005-2010 showed that parasites in food animals could present problems for food prepared from these animals: "4 new species of *Cryptosporidium* were discovered and named including a widespread zoonotic species found in food animals; *Cryptosporidium* oocysts were found to strongly attach to fresh leafy greens and apples and resist removal by normal washing procedures; 6 new genotypes of the zoonotic microsporidian parasite *E. bieneusi* were discovered and gene sequences deposited in GenBank; developed an international consensus paper on taxonomy of zoonotic microsporidia; antibodies to Giardia proteins associated with attachment to host cells blocked experimental attachment; the human pathogen *Blastocystis* was found in cattle in the U.S.; in cooperation with APHIS zoonotic parasites were identified in cow-calf operations in 20 states." Note also that the *Cryptosporidium* oocysts were found to strongly attach to fresh leafy greens and apples and resist removal by normal washing procedures, which would be a concern from the produce industry.

There is one other pathogen that should be a concern for farm growing, harvesting and processing environments: *Clostridium difficile*. Recent studies have isolated *C. difficile* from retail foods intended for human consumption in the United States, Canada, and Europe and from meat products intended for consumption by pets. In their study, Gould and Limbago (2010) summarize the available data on *C. difficile* in animals and food and discuss data gaps that must be addressed to clarify whether foodborne transmission of this pathogen might occur, and if so, whether this route might be important in the epidemiology of *C. difficile* infections (CDI). "CDI is recognized as a cause of epidemic disease in piglets, and *C. difficile* is also commonly found in

other food animals, including cattle and chickens. Some of the *C. difficile* strains most commonly identified in food animals appear to be emerging as causes of disease in humans, especially among humans with community-associated CDI. Although a link between *C. difficile* carriage in animals and disease in humans has not been adequately defined, some investigators have suggested that food animals may play an important role in the expansion of pathogenic *C. difficile* clones and in transmission to humans through food." Gould and Limbago continue, "If transmission indeed occurs from animals to humans, it will be essential to characterize the dynamics of this transmission, including whether transmission occurs though direct animal-to-human contact or though indirect means, such as consumption of contaminated foods. Increasingly, foods such as produce have been recognized as vehicles for pathogen transmission in outbreaks. In many of these outbreaks, a contaminated environment (e.g., soil or irrigation water) appears to be responsible for delivery of bacteria to the food plants. In some instances, pathogens are internalized by the plant during growth, limiting the efficacy of control measures based on sanitation or washing. *C. difficile* has also been isolated from produce and can be recovered from a wide variety of environmental sources, including soil, sea water, and fresh water. Thus, it is possible that humans and animals are frequently exposed to *C. difficile* spores from multiple sources. Whether, when, and how frequently this exposure leads to disease is a critical question for improved control of CDI."

The researchers add that additional studies are needed to develop consensus best-practice methods to test meats and other foods for *C. difficile*, as well as to understand surface decontamination on *C. difficile* spores in and on meat and other food products and, if foodborne transmission proves to be a mechanism, to evaluate other possible approaches to limit transmission by this route. They note, "It is reasonable to assume that the general public is and has been often exposed to low numbers of potentially infectious *C. difficile* spores. There is currently limited epidemiologic evidence to support or refute the hypothesis that *C. difficile* is transmitted by the foodborne route; the presence of *C. difficile* on retail foods suggests but does not prove that some proportion of infections is acquired this way. The food supply may thus serve as a source of new strains causing human infections; alternatively, food could be another constant and normally innocuous exposure. It is very clear that more research is needed to better understand the dynamics of and risk factors for development of CDI among persons in the community, including the relevance and possible importance of foodborne transmission."

Curry et al. (2012) studied the prevalence of *Clostridium difficile* in retail meat samples. A total of 102 ground meat and sausage samples from 3 grocers in Pittsburgh, PA, were cultured for *C. difficile*. Brand A pork sausages were resampled between May 2011 and January 2012. Two out of 102 (2.0%) meat products initially sampled were positive for *C. difficile*; both were pork sausage from Brand A from the same processing facility (Facility A). On subsequent sampling of Brand A products, 10/19 samples from processing Facility A and 1/10 samples from 3 other facilities were positive for *C. difficile*. The isolates recovered were inferred ribotype 078, comprising 6 genotypes. From these data, when contamination occurs, it may be related to events at processing facilities.

Whether or not *C. difficile* should be listed as a hazard for the QnRA is up to the Agency, but certainly more research should be done to help farmers and processors avoid or eliminate this pathogen.

Gould, L. H., and B. Limbago. 2010. *Clostridium difficile* in food and domestic animals: a new foodborne pathogen? *Clinical Infectious Diseases* 51:577–582.

Scott R. Curry, Jane W. Marsh, Jessica L. Schlackman, and Lee H. Harrison. 2012. Prevalence of *Clostridium difficile* in uncooked ground meat products from Pittsburgh, Pennsylvania..*Appl. Environ. Microbiol*. 78(12) 4183-4186.

FDA Response:
FDA agrees that more research would help to understand the sources and control procedures for parasites and *C. difficile*. Concerning the comments about food animals and horses, CVM understood our task to be to assess animal food safety risk for food for any animal species if that food is produced at a farm-mixed facility. The purpose of the RA was to determine low risk activity/animal food combinations for activities that would be conducted by a farm-mixed facility. Because food for horses may be produced at a farm-mixed facility without needing preventive controls to significantly minimize or prevent a hazard that is reasonably likely to cause serious adverse health consequences or death, it was included in the RA.

Reviewer #5
Yes, very well done section.

However, I have some question about line 637.

Also, I think a critical biological hazard has been omitted. *Listeria* is a significant hazard in feedstuffs that are improperly ensiled. This is the chief source of encephalitis.

From the Merck Veterinary Manual:
http://www.merckvetmanual.com/mvm/index.jsp?cfile=htm/bc/51400.htm
I bolded the key words.

> **ETIOLOGY**
> The **natural reservoirs** of *L. monocytogenes* appear to be **soil and mammalian GI tracts**, both of which contaminate vegetation. **Grazing animals ingest the organism** and further contaminate vegetation and soil. **Animal-to-animal** transmission occurs via the **fecal-oral** route.
>
> Listeriosis is primarily a winter-spring disease of feedlot or housed ruminants. The less acidic pH of spoiled silage enhances multiplication of *L. monocytogenes*. Outbreaks may occur ≥10 days after **feeding poor-quality silage**. Removal or change of silage in the ration often stops the spread of listeriosis; feeding the same silage months later may result in new cases.

Regarding the chemical hazard of aflatoxin, line 718 is describing acute illness, but then mentions liver cirrhosis. I may be wrong, but cirrhosis is usually a chronic condition.

I have a question/concern about the exposure route of "contact with animal food" (lines 865, 874). The report needs to be more convincing there is a hazard of risk that would occur to humans or animals from contacting (I assume through skin or inhalation) the feedstuff.

Characterization: This section has important findings that clearly present the results of the QRA. However, in Table 8 row 5, Chemical (nutrient imbalance), there seems to be a conflict. Column 4 reports "low" risk of single eating occasion; comment section reports "superpotent may require a single eating occasion." Maybe a footnote is needed.

I think lines 1239-1242 explain why microbial hazards (not low risk) are not shown in Table 9, but they should be better listed anyway. If I have misunderstood this paragraph, FDA should take that evidence that it needs to be reworded.

Sections G and H are a good summarization of the QRA's conclusions.

FDA Response:
The Agency will consider whether *Listeria monocytogenes* is a hazard that is reasonably likely to occur in animal food. The table, formerly Table 8 and now Table 9, has been revised to note that the "low" risk of a single eating occasion is associated with subpotent foods which require multiple exposures to elicit a response while a single eating occasion may be sufficient to elicit a response from a superpotent food. The former Table 9 has been split into multiple tables and microbial hazards are included in Tables 5, 6, and 7 where activities that affect their growth and survival are described.

Charge Question #8. Is the report written in a transparent and clear manner? Does the report adequately address the questions and stated objectives? If not, how might the report be revised?

Reviewer #1
Generally, yes. Some comments above and below suggest some revisions to make the report clearer. Some long phrases are repeated too often and these may need to be read two or three times for comprehension.

Reviewer #2
Examples presented in the presentation did generally not add to understanding the point the authors originally set out to explain. The document would benefit from specific and clear examples instead of "i.e." statements where the original point is expanded on with more verbiage. Elevating the importance of the information presented in the paragraph starting at line 548 would eliminate many questions as the remainder of the document is read.

FDA Response:
The Agency revised the draft RA to move an extensive regulatory background to an Appendix. The Agency believes that doing so improves the readability of the early sections of the draft RA.

Reviewer #3
As I've stated earlier, many of the terms used (e.g., "activity/animal food combination") were created for this document and are not in common usage among regulated stakeholders. That leads

to an unnecessary level of confusion. I understand that, to a certain extent, the purpose of the document is to interpret and translate the language in the FSM Act and it does so. However, the use of more acceptable and commonly used terms and language would be greatly appreciated.

FDA Response:
The Agency revised the draft RA to move an extensive regulatory background to an Appendix. The Agency also revised the risk characterization section of the document to first present the risk characterization of activity/food combinations without the overlay of the applicable statutory and regulatory framework. Doing so focuses the risk characterization on the risk of the activity/food combinations themselves. In Appendix 2, the Agency added the regulatory overlay and characterized the risk of activity/food combinations in groups shaped by the applicable regulatory factors and the resulting activity classifications.

Reviewer #4
See comments under the General Impressions and Specific Observations.

Reviewer #5
No. Yes.

As mentioned, the organization, as well as the excruciating detail, makes it difficult to discern the simple message from this QRA.

Charge Question #9. Do you have any additional comments that might improve the document?

Reviewer #1
Yes, see below.

The term "animal food" should be defined. The product you refer to as "animal food" is more commonly discussed as "animal feed." The term "animal food" can be interpreted as food from animals rather than food for animals.

The document has many long sentences that require re-reading to fully understand. Some phrases are repeated too often and could be replaced by a defined abbreviation or a table. For example, the phrase "RACs grown or raised on a farm not under the same ownership" is abbreviated as a "farm's own RACs." Another example of a phrase that is repeated too often is "hazard that can result in serious adverse health consequences or death." In some parts of the document, a table could be used to discuss or compare groups or attributes so that long text phrases do not need to be repeated so often. Additionally, a phrase such as "hazard for which there is a reasonable probability that use of, or exposure to, the animal food will cause serious adverse health consequences or death to animals or humans" could be re-defined as "serious hazard" so that the long phrase would not be repeated so often.

In the risk management approach, Consideration #5 is not clear. This can be interpreted as you are trying to compare hazards to each other. Also, if you are evaluating a hazard to determine if serious health consequences are possible, then when those adverse effects occur (single vs. cumulative exposure) is not relevant. The hazard has serious health consequences either way.

FDA Response:
The Agency has revised the RA and the risk management considerations have not been included in the revised document. In revising the RA the Agency attempted to find ways to shorten sentences, such as by the use of the SAHCODHA acronym described in an earlier response.

Reviewer #2
The impact of storing, processing, and feeding animal foods that were classified as out of the scope of the QRA should be addressed, as they are a common activity in the production of animal food in animal feeding operations. The concept of processing "purchased components to produce a finished food for consumption by the farm's own animals" remaining within the farm definition, and then later in the document the "improper blending of feed as a hazard for nutrient imbalance" should be further explored.

FDA Response:
In revising the document, the Agency placed more emphasis on the goal of the risk assessment to define low risk activity/animal food combinations being conducted by farm-mixed facilities. The hazards associated with mixing/blending a complete animal food are the same regardless whether the animal food will be fed to animals on the farm or to animals on a farm that bought the animal food. However, when the mixing/blending of a complete animal food is being done by a farm-mixed facility for distribution into commerce, the activity falls outside of the farm definition.

Reviewer #3
No.

Reviewer #4
See comments under the General Impressions and Specific Observations.

Reviewer #5
None, other than realize that decision makers hope to use this document and, therefore, have a need to understand it. Consider a "laymen's" version and an analyst's. I have seen too many risk managers ignore technically good RA because they were difficult to understand.

C. Specific Observations

The specific observations provided by the peer reviewers are presented in their entirety in this section. Many of the observations tended to be editorial comments. In revising the RA document editorial changes suggested by the reviewers were made where appropriate; some suggested revisions were no longer applicable due to re-organization of the document. For the most part, comments that were not editorial in nature repeated themes the reviewers presented in response to the charge questions to which FDA responded above.

Table 1: Specific Observations by Reviewer #1

Line	Comment	FDA Response
227-231	The information in this paragraph is repeated in lines 240-243.	Editorial
350	Delete one of the phrases "in food-producing animals."	Editorial
351-352	Delete "as a general matter."	Editorial
539	Change "Table X" to "Table 4"?	Editorial
585	Insert "(Table 5 and 6)" after "with animal food."	Editorial
613	The stand-alone sentence "No radiological hazards reports have been received." can be inserted at the end of Table 5 with a zero in the middle and right column.	We added a zero line for radiological hazards to the RES reports table
Table 6, L 3	Move "339" up one line and delete "Total."	Editorial
Table 6, L 7	Move "1324" up one row and delete "Total."	Editorial
646-647	The phrase "which could be a contaminant in virtually any food category" is not needed.	Editorial
646-650	This paragraph should be deleted. The reason that Table 7 does not include physical hazards, nutrient imbalance hazards and radiological hazards is that they are not biological and chemical hazards.	The table (now Table 4) was meant to associate all types of hazards to animal food categories. It happened that only the biological and chemical are prevalent enough to warrant the table. The name of the table has been changed to reflect the original intention and the paragraph is required to explain the absence of the other hazards.
844-845	This sentence can be added to the paragraph above it.	The sentence was separated because it describes the impact of the hazard on humans while the paragraph above it is about the impact on animal health.
850	Change "Table 8" to "Table 7."	Document was re-organized and table numbers have been changed.

Line	Comment	FDA Response
1177 & 1178	Should "X" be replaced with a number?	A number was inserted.
Table 8	Column 4 (single eating ….) can be moved to the left of the "Frequency" column. Column 5 (Reasonable probability….) can be moved to left of the "severity" column.	The table was revised
1231 & 1240	Change "Table 12" to "Table 9."	Document was re-organized and table numbers have been changed.
1289, 1296, 1325	Remove the word "such," otherwise the phrase that follows "such" appears to apply only to the first phrase of these sentences.	Risk tables 10 and 11 and the text surrounding them have been completely revised.
1287, 1288	The use of "neither" and "nor" may be correct, but this makes the sentence hard to understand. I suggest replacing "neither" with "not" and replace "nor" with "and is not."	Risk tables 10 and 11 and the text surrounding them have been revised.
1294	No cell in Tables 10 or 11 has the letter "O," so you should just state that there are no activity/animal food combinations that fit the category.	Risk tables 10 and 11 and the text surrounding them have been revised.
1291-1310	This information is repeated in the section headings, text, and table footnotes between lines 1312 and 1346.	Risk tables 10 and 11 and the text surrounding them have been revised.
Table 12	These activities should be included in Table 11.	The activities that were not found to be low risk have now been incorporated into the risk determination tables, 10 and 11.

Line	Comment	FDA Response
1396	"Radiological hazards" does not need to be on this list. The document clearly states in some places that radiological hazards are not present, but in other places radiological hazards are discussed as a concern.	In providing the response to Question 3, we are indicating all the hazards that the RA covered. Radiological hazards were determined to be not very likely to cause serious adverse health consequences and are not provided in the response to Question 4.
1419, 1423	Remove "that that."	Editorial
1429	"preservatives" is too vague. Should remove this or specify the chemicals.	According to the definitions of low-risk and not low-risk used in the RA, the risks for processes requiring addition of preservatives would be evaluated the same, regardless of the specific chemicals used.
1430, 1438	Should specify the target water activity (<0.88, for example).	The body of the RA has been revised and provides an $a_w < 0.94$ as preventive of *Salmonella* growth.
1440-1443	Delete these lines.	Editorial. This section has been revised.
1447	Delete "under."	Editorial. Section has been revised.
1481	Separate the three processes by commas, rather than slashes.	The term activity/animal food combinations was adopted and used throughout the RA. Packing, holding, processing, and manufacturing refer to the broad classification of activities used in regulation.
1485	Delete "to foods to foods."	Editorial. Duplication removed.

Table 2: Specific Observations by Reviewer #2

Line	Comment	FDA Response
430	Reasonable should be described in the context of risk.	In this document, a hazard that has a reasonable likelihood or reasonable probability of causing serious adverse health consequences or death to humans
430	The "i.e." statement does not add clarity and should be rewritten.	The text has been revised and the definition of low-risk activity/animal food combination is now found in Section I.E.
394	Sentence starting with "If a hazard…" is unclear. The point is important and seems like it needs a few more sentences to be fully thought out.	Document has been revised and the regulatory overlay is separated into an appendix where it is discussed in detail.
548	The concept of processing "purchased components to produce a finished food for consumption by the farm's own animals" remaining within the farm definition, and then later in the document the improper blending of feed as a hazard for nutrient imbalance should be further explored.	The document has been re-organized and the regulatory overlay that distinguishes between mixing of animal food for consumption on the farm and mixing of animal food for distribution into commerce is now provided in the Appendix
548	Why include a partial list of food categories that remain within the farm definition? This adds to confusion when it is placed with little context in this form.	See response above.
1075	Care should also be taken to avoid too little of required nutrients.	The document has been revised to use the term nutrient imbalance to encompass both sub- and super-potent cases.
1200	The "Single Eating…" column should list "single" or "cumulative."	The table (now Table 9) was revised in response to this comment and the one above.
1237	The use of wire to tie bales is too antiquated to be a good example in the context of this QRA. Better examples would be harvesting, feeding, or housing equipment in poor repair.	The revised RA does not use the example of baling wire.

Line	Comment	FDA Response
1267	Have you considered spray dried eggs or milk powders?	Processing of animal products to produce spray dried eggs or milk powders has been determined to be outside the scope of the RA because such processes require temperature controls and are therefore, by definition, not low risk. Mixing this type of product into a finished animal food is within the scope of the RA. We have modified the discussion of processing that is considered outside the scope of the RA to make this distinction clearer.
1349	Look over this list to standardize formatting of bullet points and remove extra bullets with no text.	Editorial
1432	Duplicate bullets.	Editorial
1453	Suggested additions: Use of metal detector in forage harvesting equipment (common in silage choppers) and magnets in feeding equipment (common on TMR mixer discharges).	The document now includes mention of these controls.

Table 3: Specific Observations by Reviewer #3

Line	Comment	FDA Response
260	In Table 1, §1.227(b)(6), the word "formulating" should be replaced with the terms "weighing and proportioning." Formulating means creating a balanced formula to meet the nutrient needs of an animal	This wording comes from the regulations implementing the registration requirement in section 415 of the FD&C Act.
539	Where the heck is "Table X"?	Editorial. The placer holder was replaced by the correct table number.
548-553	The words "…farms processing rendered…" are confusing. Why not "…farms using rendered...?" Generally, ingredients brought onto the farm are used "as is" and not processed in any fashion. In addition, the listing of ingredients that would likely be purchased and used in farm-feed manufacturing should include oil seed meals, grain by-products and many other ingredients. Why not just give a few examples and indicate that there are many more that could be used?	The document has been revised and references to ingredients purchased to be mixed with RACs to make animal food for consumption by animals are provided only as examples.
733-740	There are vast differences between food animal species as to the effect of mycotoxins on different species. That should be briefly discussed.	In discussing health consequences, the revised document describes different severities of effects for different species and more than one mycotoxin.
806-817	The concept of "available" phosphorus should be discussed. The use of phytase to enhance the availability of natural phosphorus has become very prevalent and should be mentioned in the context of this paragraph.	We consider phytase to be one of the other ingredients purchased and used on farm discussed in the reviewer's comment two lines above.

Line	Comment	FDA Response
1034-1043	There are no references cited in this paragraph, but the statement that silage should be "aerated while fermenting and during storage" is simply wrong and should be reconsidered. Ensiling is properly done under anaerobic conditions.	The document has been revised to clarify that anaerobic conditions are required for proper ensiling.
1067	…is likely to *be* pronounced…	Editorial.
1073	…minerals *and other micro-ingredients* to…	This section states that people knowledgeable in nutritional requirements, in nutritional composition of animal food, and in adequate mixing techniques need to be responsible for the production of animal food with proper nutritional balance. It was not our purpose to provide an exhaustive list of ingredients to achieve nutritional balance and that is why we limited it to well-known, very basic categories of purchased ingredients.
1128	…hogs and pigs… I thought they were the same thing.	This is the terminology used in the USDA 2007 Census of Agriculture in listing the number of animals in the inventory in 2007 and 2002 (Ref. 75 of the draft RA).
1267-1268	The list shown in this paragraph is far short of exhaustive. There are hundreds of ingredients that could be brought onto the farm for the purpose of manufacturing feed. I suggest deleting the statement denying identification of other types of animal food that could be brought onto the farm.	The document has been revised. The statement described has been deleted. Where lists are given they are typically short and intended to provide examples rather than to be exhaustive because of the many ingredients available.
1466-1477	Shouldn't drying and dehydration be included in the listing?	Drying and dehydration were added to the list of activities.

Table 4: Specific Observations by Reviewer #4

Line	Comment	FDA Response
Lines 94, 199, 233,	To whom does “We”refer?	“We” refers to the Agency, FDA.
Table 3	mostly clear. However, what about the activities of sampling and testing? I assume still within a farm definition but the analysis may lead to a processing step like cooking or destruction like landfill (probably still on farm). Is pulping of fruits and vegetables like pumpkins similar to processing even if mainly used on farm? What about loading onto a tanker for liquids or grain or live animals to a slaughterhouse for further action off farm? I assume the material/animals are considered on-farm until the purchaser drives it away.	The document has been revised so that the risk assessment now focuses only on the animal food and activity combinations. The regulatory overlay which distinguishes between activities conducted on-farm to produce animal food to be consumed on the farm (or one under the same ownership) and activities conducted on-farm to produce animal food for distribution into commerce has been moved to the Appendices to separate it from the risk assessment.
Line 322	can someone not ask for clarification rather than state ambiguity in a public document?	The statement of ambiguity is not included in the revised document.
Line 363	define CGMP	CGMP is now defined in appendix 3. The document also uses the phrase “general principles of good manufacturing” to refer to the general sense of good manufacturing practices rather than to particular regulatory requirements.
Line 390	Consideration #3 first sentence is a little convoluted and too long to understand	Editorial
Lines 429-434	Is there too much duplication of thought here?	Editorial

Line	Comment	FDA Response
Lines 447-449	should seafood be in or out	The document has been revised to clarify the activities that are outside the scope of the risk assessment and those that are within. Processing of animal products including seafood to make an animal food ingredient such as shrimp meal is outside the scope of the RA. Use of products such as shrimp meal in the on-farm manufacture of an animal food is within the scope of the RA.
Line 517	how does animal-derived tissue - line 447- and meat products relate to each other - is the former a broader definition?	The RA document has been revised as described above to clarify what is meant by animal-derived tissue and distinguish it from the resultant processed animal products that may be used in the manufacture of a finished animal food.
Line 524	others' RACs [should be other RACs? or RACs from other farms]	By "others' RACs" we mean RACs from other farms.
Table 4	I find this table somewhat confusing as to why they are excluded from on-farm as the footnote indicates, like grading and weighing	In the revised RA document this table is now Table 1 and refers to the Appendix for explanation of those activities that are within the farm definition and those that are not.
Line 539-541	this is the first time small or very small farms are mentioned, should not some discussion of size of farms come earlier?]	The Executive Summary, which appears at the beginning of the document, states that the RA is to be considered "in determining whether to exempt small or very small businesses" engaged in certain on-farm activities involving certain animal foods.

Line	Comment	FDA Response
Lines 590-593	Are these meant to be definitions within the context of the Assessment to clearly distinguish a chemical hazard from a chemical contaminant? Perhaps these could be written better if that is the intention. Table 5 does not quite use these terms	The table (now 2) lists both chemical contaminants and chemical nutrient imbalance under the column heading "Hazard".
Table 6	Pseudomonas is interesting because that is not usually considered pathogen by ingestion - what was the issue here?	The reviewer is correct. The issue was not a food issue; the line was included in the table in error and has been removed.
Line 654	Can we get some details of the botulinal toxin issues, rather unusual	Editorial. Changed to botulinum.
Table 7	is it not botulinum or botulinal rather than botulism	Changes made.
Lines 667-668	Add "main", since you do list other microbial hazards	Current Table 4 title includes "That are Reasonably Likely to Be Associated" and the numbers in the previous tables indicate strong association only with Salmonella, the one listed in Table 4.
Lines 672-687	This section could be improved by separating human and animal illnesses more clearly and as mentioned below that typhoid is a very severe human disease, but not transmitted through animals. Certain strains of *Salmonella* affect animals worse than others, e.g., *S*. Kentucky is very common in broilers but not a human concern because of the high infections dose; *S*. Dublin, Newport, Entertidis and other serovars can cause severe infections in animals, as well as humans. Salmonellae can be transmitted to both humans and animals through the environment	We revised the hazard characterization section for biological hazards according to the recommendation to separate out human and animal serotypes.

Line	Comment	FDA Response
Lines 690-698	I note more than food animals are covered here including pets and horses, fine, but they are excluded from this Assessment	The subject matter of the RA is the activities used in animal food production on-farm. Certain processes on animal food were considered outside the scope of the RA because they require heat or refrigeration as preventive controls and could not therefore be considered low risk. This included pet food manufacturing. Since horse food can be made on-farm without requirements for preventive controls, it was not excluded from the RA.
Lines 767-769	Any bot cases with food animals, rather than horses, more important for this Assessment?	Botulism in other animals is described in the hazard characterization section.
Lines 782-786	accidental or deliberate (dioxin) poisoning only, such as contaminated cooking oil; chloracne is a very rare event that needs to be stated and probably never from the domestic food supply	Document says that large amounts are required to see chloracne and that most exposures are to low levels.
Line 787	some examples would be good here to show how inadvertent action like fumes containing the compound getting into oil can result in a recall because of regular testing	All contamination scenarios in the RA are assumed to be the result of inadvertent actions or natural events. Intentional contamination is not covered in the RA. Regular testing is part of a preventive control program that serves to keep contaminated product from being distributed, regardless of the root cause of the contamination.

Line	Comment	FDA Response
Line 844-845	do you want to discuss glass, metal filings, bone and teeth fragments, grease, etc., which come from some form of processing in feed and food? These are mentioned in Tables 5 and 6	Glass, metal, and plastic were reported in (now) Tables 2 and 3. Bone and teeth fragments and grease will be hazards encountered in the processing of animal tissue that was determined to out of the scope of the RA.
Line 971	you discuss molds here and under chemical elsewhere - where we have a biological agent producing a toxin, we have to put it into one category or the other. Typically, mycotoxins are treated as chemicals, and seafood toxins and microbial toxins under biological on the basis of acute or chronic disease	We revised the document to include C. *botulinum* under biological hazards because the control of the toxin production is the control of the bacteria. As stated in the comment, the mycotoxins are treated as chemicals.
Line 1002	Somewhere antibiotics and AMR need to be discussed. These can impact the growth of pathogens and their severity in causing disease. For instance, a food animal given antibiotics to treat a disease or for growth promotion can result in resistant *Salmonella* strains contaminating a carcass and subsequent undercooking or cross contamination can result in severe human illnesses. Although animal tissues are excluded from the Assessment, it seems these sections are broader in their scope. Even if these are not to be considered further, at least the issue of AMR should be raised and stated it is a major issue but dealt with under other Assessments	The revised draft RA document does not include an explanation that AMR is dealt with under other assessments but we will keep this comment under consideration in the development of the final RA.
Line 1034	you have chosen to put bot toxin under chemical, more typically under microbial - see above- for discussion on this	See above for response to this.

Line	Comment	FDA Response
Line 1145-1146	the reader is left hanging what this example is - a little more detail is required like the range found	Ranges for the prevalence and the concentration levels have been provided in the revised draft RA.
Line 1153	this definition (small and very small) should come earlier	The definition of small and very small is in the process of being
Line 1176	are these RFR, or all reports including reports of illnesses?]	In the revised draft RA, the description has been clarified to include frequency of Class I recalls in addition to RFR entries.
Table 8, line 1	but some (animals) can be severely affected *S*. Cholerae-suis, *S*. Newport, *S*. Enteritidis, etc	This is now acknowledged in the Comment column of Table 9.
Table 8, line 2	not sure why just pet food mentioned since excluded, what about almonds, melons, spices, peanuts, etc.? with respect to human contact]	The question is asking about human contact with human food while the subject matter of (now) Table 9 is animal food.
Table 8, line 3	very low for mycotoxins and pesticides and rare for dioxin	While any given lot of animal food may have low levels of mycotoxins or pesticides, the revised draft RA notes that grain and oilseeds comprise about 75% of animal diets. Therefore we do not consider the likelihood of exposure to be very low.
Table 8, line 4	to affect animals	In the revised document this is revised to clarify subpotent food requires multiple exposures but we did not add “to affect animals” because nutrient imbalance was defined as a hazard for animals only.

Line	Comment	FDA Response
Line 1218-1219	somewhere, probably earlier, it should be mentioned that pathogens are able to survive and growth under anaerobic, microaerophilic and oxidative conditions but pH, a_W and competition have a greater impact on their growth and survival. Molds however, do need air to grow and produce toxins	This discussion is found in the section of the revised draft RA concerning the impact of pH on the growth of bacterial pathogens.
Table 9, line 1	The fermenting and other microbial reactions also removes oxygen to limit mold growth.	This is discussed in the section of the revised draft RA concerning the interaction of factors that impact the growth of foodborne pathogens.
Table 9, line 1	infestation is not the right word, perhaps invasion or growth	The text has been changed.
Table 9, line 3	plastic was mentioned earlier	Editorial
Table 10	the way I read this Table is that all activities are low or not applicable - perhaps we do not need the table	In the revised draft RA the risk calculations have been refined and both low and not low risk activities are included in the tables.
Table 11	again this Table only indicates no or low risk which could be summarized differently	See above.
Table 12, line 1	Earlier stated that pesticide residues are considered extremely low in US crops and therefore cannot be significantly minimized, lines 780-781	These two statements are not in conflict. The earlier statement is that levels of pesticide in the U.S. food supply are in compliance with EPA's tolerances. That the levels are low in the food supply may be, at least in part, because the crops have been carefully aspirated and cleaned.
Line 1430	Add "and high acidity"	High acidity as an intervention was conveyed in the draft RA as "reducing pH".

Line	Comment	FDA Response
Line 1440	Add “For silage, fermentation and low oxygen content will also help”	In the revised draft RA, Question 6 is now answered only for those hazards which the RA considered to have a reasonable probability of causing serious adverse health consequences in response to Question 4. Because silage was not included in response to Question 4, an intervention for hazards in silage is not required in answer to Question 6.
Line 1457	Animals will also ingest many objects they are curious about both in the field or in the stall	The revised draft RA has been revised as indicated directly above. Physical hazards were not included as a response to Question 4 and interventions for physical hazards were not required in answer to Question 6. While we agree with the reviewer’s comment, we would not have used this fact in describing interventions for physical hazards found in animal food.

Table 5: Specific Observations by Reviewer #5

Line	Comment	FDA Response
105	Label "group 1" with shorthand version of lines 96-98	In the Executive Summary of the revised draft RA, the activity/animal food combinations are no longer grouped. Groups appear in the Appendix where they are more completely described.
123	Label "group 2" ditto	See above.
164	As mentioned the heading "approach" suggests that materials and methods will follow	The contents of the section labeled "Approach" has been significantly revised in draft RA to describe the method used in conducting the RA. Discussion of the regulatory aspects of conducting the risk assessment has been moved to an introductory section and to the Appendices.
247	Change "clarification" to "definitions"	Section I.E. of the revised draft RA is entitled "Definitions of Low-Risk Activity and Low-Risk Activity/Animal Food Combination."
252-254	Sentence is very unclear	Discussion of the relevance of Section 415, Registration of Food Facilities, and FSMA requirements to clarify definitions in Section 415 has been moved to an Appendix where it does not interrupt the flow of the RA.
273 – 279	Introduction of another rule making process is confusing here	See above.
282	"organizing principles" is not normal part of QRA methods	The organizing principles were for the proposed revisions to definitions in Section 415. These were moved to the Appendix of the document. See above.

Line	Comment	FDA Response
299	Agree and appreciate FDA's challenge	No response necessary.
334	Delete "tentative" after this review	Tentative has been removed.
334-336, 359-370	Key information that needs to be in Exec Summary	We decided to confine the Executive Summary to a brief statement of the mandate to conduct the assessment and the findings of the assessment.
374	As stated above, I think these are RAM assumptions, not "considerations"	The document was revised substantially and the considerations were deleted and replaced by a three-part definition of low-risk activity and a risk management assumption that activities that require temperature controls cannot be low-risk.
395-399	Unclear	This section concerns the impact on preventive control requirements of having other regulatory frameworks at play such as Juice or Seafood HACCP rules, a topic more relevant for the draft Human Food Preventive Control Rule than for the Animal Food Preventive Control Rule. For this reason and other reasons, the discussion was moved to the Appendix where the regulatory overlay was applied.
468	Move this heading to later in the doc	Risk Characterization became Section VI in the revised draft RA.

Line	Comment	FDA Response
477	Change to "Specific RM questions to ….	We chose not to adopt this suggestion because the questions define a sequence of steps needed to assess the risk. The risk management question was really the final one, "Which activity/animal food combinations are low risk?".
539 and elsewhere	I am sure correct Table numbers will be inserted	Table numbers were inserted.
637	Sentence is confusing	It is difficult to provide both accuracy and clarity when accuracy requires phrases such as "manufactured, processed, packer or held on a farm mixed-type facility." Hopefully the columns and row in the (now) Table 4 will help to clarify the meaning of the sentence.
662	Consider adding Listeria as a bio hazard (see above)	The Agency will consider whether *Listeria monocytogenes* is a hazard that is reasonably likely to occur in animal food.
718	Cirrhosis is usually chronic	The statement in the draft RA was as in the Williams reference.
865, 874	I question if contact with feedstuff is a hazard	We know contact to be an issue with pet food. As *Salmonella* are frequently found in other animal foods, we kept the contact exposure as a possibility.
1239	Explain meaning of #3 here	It is unclear what this comment is about. There is no #3 in the area around line 1239.

IV. External Peer Reviewers

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Dr. Behnke is an expert in animal food processing, having produced an extensive body of research on the effects of various food processing conditions on animal food quality and safety. He served as a member of an Institute of Medicine/National Regulatory Council committee charged with reviewing FDA effectiveness and capabilities in monitoring food safety. The resulting book by the National Academies Press is entitled Enhancing Food Safety: The Role of the Food and Drug Administration and was published in 2010. Dr. Behnke's role was to represent the animal feed industry's interest in food safety, to provide input about how FDA should be interacting with that segment of agriculture, and involved assessment of risks in the animal food safety system.

Joseph D. Eifert
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Dr. Eifert's research efforts focus on ways to reduce foodborne pathogens on food surfaces or methods to improve sampling techniques and analytical methodology for optimizing the quantitative recovery of pathogenic microorganisms from foods, food contact surfaces, and food processing environments. He has received numerous grants to study these methods in poultry and seafood plants as well as in juice and dairy tanker trucks. He has also developed training curriculum on Good Manufacturing Practices and a variety of other regulatory and technical workshops that he provides as Extension Specialist to the Virginia poultry processing industry to enhance their ability to produce safe, quality products and to comply with evolving regulations.

H. Scott Hurd
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Director, World Health Organization Collaborating Center for Risk Assessment and Hazard Identification in Foods of Animal Origin

Dr. Hurd is a veterinarian and a Ph.D. epidemiologist. He has held a number of positions in the United States Department of Agriculture including as lead epidemiologist, developing the National Animal Health Monitoring System (NAHMS) with the Animal and Plant Health Inspection Service (APHIS) and the National Animal Disease Center of the Agricultural Research Service (ARS), and most recently, as Deputy Undersecretary for Food Safety, Food Safety and Inspection Service (FSIS). He has published a number of food safety risk assessments, including articles on factors influencing levels of Salmonella on pork and on the risk from antimicrobial resistant bacteria harbored by animals. He recently served on the Healthy Animals, Healthy Canada expert panel on Approaches to Animal Health Risk of the Council of Canadian Academies.

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Mr. Leuer is an inspector for the Minnesota Department of Agriculture and is credentialed for performing contract inspections for the FDA. He inspects commercial feed manufacturers, distributors, renderers, and transporters in enforcing both state and federal feed laws. His research and experience is in dairy management and calf feeding and health.

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Dr. Todd is recognized internationally for his work on foodborne disease and its surveillance and costs, developing microbial risk assessments, the impact of seafood toxins on disease, and detection of pathogens in foods. He has developed methods to detect pathogens, such as *E. coli* 0157 and *Salmonella.* He has been active in developing and preparing microbial risk assessments in collaboration with mathematical modelers. For instance, he headed a team from Health Canada and the Canadian Food Inspection Agency to produce a risk assessment for *Salmonella* Enteritidis in shell eggs in Canada. He has conducted other risk assessments including two on *Listeria monocytogenes* in chopped cabbage and *E. coli* 0157:H7 in shredded lettuce.