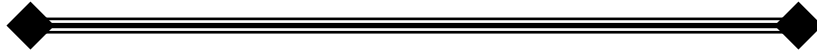


Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services



**Qualitative Risk Assessment:
Risk of Activity/Food Combinations for Activities (Outside the
Farm Definition) Conducted in a Facility Co-Located on a Farm:
Response to Public Comments**

August 2015

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I. A Summary of Key Changes in the Final Risk Assessment Compared to the Draft Risk Assessment

Table 1. A Summary of Key Changes in the Final Risk Assessment Compared to the Draft Risk Assessment

Applicable Section of the Risk Assessment	Applicable Table of the Risk Assessment	Change
I, III, VII	N/A	Asked questions and discussed hazards with respect to “known or reasonably foreseeable hazards” rather than “hazards reasonably likely to occur” because of changes in terminology and because the hazards that require a preventive control are specific to a food and a facility.
I, II	1, 18, 19	Excluded baked goods that require refrigeration for safety from the scope of the risk assessment and limited the exclusion for cut fruits and vegetables to those that are low-acid. When considering the risk of activities related to acid fruits and vegetables, we considered the risk for growth of pathogens when the pH is between 4.2 and 4.6. Excluded game meat products that require refrigeration for safety in addition to excluding game meat.
I,II	1, 18, 19	Considered information from an updated Food Processing Sector Study.
II, VI, VII	1, 18, 19	Made changes to reflect the revised farm definition, which increased the number of activities within the farm definition thereby narrowing the scope of the activity/food combinations that needed to be considered in the final risk assessment. (For example, drying/dehydrating raw agricultural commodities (RACs) without additional manufacturing/processing, such as drying grapes to make raisins, now falls within the farm definition.)
II, VI, VII	1, 18, 19	Added foods and activities as a result of comments submitted on the draft RA and on the proposed preventive controls for human food rule.
II, VI, VII	1, 18, 19	Revised the way foods were grouped, e.g., broad categories of foods were broken into smaller categories.
II, VI, VII	1, 18, 19	Included activities that encompass multiple steps (e.g., making jams, jellies and preserves may involve steps such as cutting, mashing, boiling, mixing, and canning) and grouped these steps to better identify the end product. As such, activities that are encompassed within the making of a particular product are no longer listed as separate activities within the table. (For example, because making syrup includes boiling sap, boiling sap is not listed as a separate activity.)
III	2, 3, 4, 5, and 6	Updated the foodborne illness surveillance information in Table 2. Updated the Reportable Food Registry information in Table 3 (now Tables 3, 4, 5, and 6).
III	7	Updated Table 4 (now Table 7) on the potential biological and chemical hazards likely to be associated with the food categories manufactured, processed, packed, or held on a farm mixed-type facility to include the revised food categories.
III, IV	7	Updated information in Table 4 (now Table 7) on mycotoxins and added references.

Applicable Section of the Risk Assessment	Applicable Table of the Risk Assessment	Change
IV	N/A	Deleted discussion of radiological hazards in the RA, because the preventive controls for human foods rule now considers them as a type of chemical hazard. (We have considered them as part of our consideration of chemical hazards, and we focused in the final RA on the chemical hazards most likely to require a preventive control.)
V	9	Updated Table 6 (now Table 9) on inherent controls for biological hazards to include additional foods.
V	11	Updated the examples in Table 8 (now Table 11) of activities that can introduce, or increase the potential for, biological hazards to better reflect activities relevant to the final RA (e.g., we removed washing fruits and vegetables, as this activity falls within the farm definition).
V	N/A	Deleted information on oxidation-reduction potential as not needed based on the foods included in the final RA.
VI	18	Revised and merged the two draft RA tables addressing whether an activity/food combination is low risk (Table 18 in the final RA) to reflect the revised list of foods and activities in Table 1 of the final RA.
VI	19	Revised the table describing why certain activity/food combinations are not low risk (Table 19 in the final RA) to reflect the decisions made in Table 18.
VII	N/A	Revised the answers to the questions posed in the RA and the list of low-risk activity/food combinations to reflect the outcome of the final RA.
Appendices	N/A	Deleted the draft appendices that focused on categorizing the low-risk activity/food combinations according to the regulatory framework.
Appendices	N/A	<p>Added new appendices on:</p> <ul style="list-style-type: none"> • the definitions of “farm” and activities relevant to the “farm” definition (i.e., “harvesting,” “holding,” “manufacturing/processing,” and “packing,” and • the chronology of technical and scientific reviews of the RA.
Throughout	N/A	Revised terminology for consistency with revisions to the preventive controls for human foods rule, e.g., food allergen hazards rather than allergen hazards.
Throughout	N/A	Updated several references and added additional ones.

II. Public Comments and FDA/CFSAN’s Responses

A. Comments on Activity/Food Combinations

Table 2. Comments on Activities

Public Comment: 2012 Draft Risk Assessment	FDA/CFSAN's Response
<p>Comments stated that it is not clear how certain high- or moderate-risk practices (e.g., washing), which are necessary to move product from the field, will affect exemptions. Comments state that future risk assessments should examine the impact of these practices by commodity and volume of intact fruits and vegetables marketed through small and very-small farm mixed-type facilities.</p>	<p>Washing raw agricultural commodities (RACs) is within the “farm” definition (e.g., when washing is done during harvesting or in an on-farm packinghouse on intact RACs) and is therefore out of the scope of this risk assessment. When washing is done as part of manufacturing/processing (e.g., washing fruits and vegetables as part of freezing them), it is considered in this risk assessment as part of the manufacturing/processing and not as a stand-alone activity.</p>
<p>Comments ask us to expand the list of on-farm low-risk packing and holding activities to include packing and holding of food products not expressly covered by the proposed exemption.</p>	<p>FDA modified Table 1 of the risk assessment to list more types of food categories so as to make it clearer when a particular food is encompassed within a particular activity/food combination. For example, Table 1 of the risk assessment lists food categories such as baked goods, milled grain products, and other grain products that are processed foods, in place of the original category “grain products.” We also expanded the list of foods considered in the risk assessment based on comments submitted. As a result, the list of on-farm low-risk packing and holding activities was also expanded. (See Section III of this document).</p>
<p>Comments ask us to include in the exemption a single list of low-risk manufacturing/processing activity food combinations applicable to farm mixed-type facilities conducting activities on their own RACs and farm mixed-type facilities conducting activities on others’ RACs.</p>	<p>The revised “farm” definition no longer distinguishes between activities conducted on a farm mixed-type facility’s own RACs and activities conducted on others’ RACs. As a result, the comment’s request is moot.</p>

Public Comment: 2012 Draft Risk Assessment	FDA/CFSAN's Response
Comments ask us to expand the list of activity/food combinations in the exemption.	FDA evaluated specific additional activity/food combinations provided in the comments within the qualitative risk assessment to determine whether they satisfied the criteria for a low-risk activity/food combination and added additional activity/food combinations where appropriate based on the conclusions of the risk assessment (see Section III, Table 7 and Table 8 of this document (packing and holding) and Section IV, Table 9 and Table 10 of this document (manufacturing/processing)).
Comments stated that FDA should not automatically exclude on-farm activities that require refrigeration and/or freezing for safety from the “low risk” category. Similarly, FDA should not automatically exclude activities that require measurement of cooking times from being considered “low risk”.	FDA disagrees with these comments and the risk assessment continues to consider foods requiring time/temperature control for safety to be out of scope of the risk assessment. However, in revising the risk assessment, FDA determined that freezing intact or cut fruits and vegetables with pH <4.2 is a low-risk activity/food combination. See the discussion in sections I.B, I.C, and I.E and Tables 18 and 19 of the risk assessment.
Comments stated that FDA should expand the risk assessment to consider dietary ingredients.	FDA revised the qualitative risk assessment to evaluate foods such as chopped fresh herbs, chopped or ground dried herbs, and herbal extracts, which may be used as dietary ingredients. FDA also added a category “Any other processed food that does not require time/temperature control for safety” in the list of on-farm low-risk packing and holding activities, and considered vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form as examples of such foods.

B. Comments on Hazards

Table 3. Comments on Hazards

Public Comment: 2012 Draft Risk Assessment	FDA/CFSAN's Response
Comments stated that FDA should include <i>Toxoplasma gondii</i> , <i>Cyclospora cayetanensis</i> , other pathogenic <i>E. coli</i> , as well as antibiotic residues, heavy metals and other environmental contaminants such as cadmium and lead in the list of hazards reasonably likely to occur in foods being considered.	FDA has incorporated additional text on relevant hazards in foods as they relate to risks from activity/food combinations.

C. Comments on Data and Data Sources

Table 4. Comments on Data and Data Sources

Public Comment: 2012 Draft Risk Assessment	FDA/CFSAN's Response
Comments stated that FDA should re-examine its data sources in assessing commodity-specific risks, as it is likely that many will be found to be low risk.	FDA disagrees that it should re-examine its data sources in assessing commodity-specific risks, because the risk assessment focused on the risk of activity/food combinations rather than separately considering the risk of specific food categories. See the discussion in section I.B of the qualitative risk assessment.
Comments stated that the Centers for Disease Control and Prevention should expand its data analysis effort (see Painter et al. 2013, <i>Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by Using Outbreak Data, United States, 1998-2008</i> , <i>Emerging Infectious Diseases</i> , 19:407-415).	The Painter et al. 2013 paper is the most up-to-date publication available, and more finely grained data for additional commodities are not currently available.
Comments stated that FDA should rely on more recent data on aflatoxin contamination and should consider long-term exposures.	FDA has updated the references on aflatoxins in the risk assessment and has added text on long-term exposures to aflatoxins and their potential effects.
Comments stated that FDA should consider the disproportionate impact that some of the hazards have on more susceptible populations in its risk assessment.	FDA has included text regarding the data limitations, including absence of data to conduct a dose-response assessment for specific susceptible populations.

Public Comment: 2012 Draft Risk Assessment	FDA/CFSAN's Response
<p>Comments express concern that conclusions drawn regarding risk categories, and exemptions made based on this qualitative risk assessment do not account for consumer risk from consumption of activity/food products.</p>	<p>The results of the qualitative risk assessment are based on consumer risk to the extent practicable, consistent with the inherent data limitations.</p>
<p>Comments stated that FDA should justify why certain activities are considered low-risk activities, since they provide opportunities for spread of biological hazards.</p>	<p>FDA evaluated each of the requested activity/food combinations that was within the scope of this rule within the qualitative risk assessment to determine whether it satisfied the criteria for a low-risk activity/food combination. See the description of the criteria for whether an activity/food combination is low risk in section I.E of the qualitative risk assessment and the explanation for why FDA concluded that certain activity/food combinations are not low risk in Table 19 within the risk assessment.</p>
<p>Comments stated that the risk assessment should not rely on the Food Processing Sector study but instead collect data from large-scale surveys of actual farm mixed-type facilities and their activities.</p>	<p>We revised and extended the results of our earlier Food Processing Sector study by expanding our data sources and by including representatives from USDA's Economic Research Service, USDA's Agricultural Marketing Service, and the American Farm Bureau to help oversee the revised study. To better account for farms that perform processing activities, we included Census of Agriculture data both to provide a count of total U.S. farms and to estimate the number of farms conducting food processing activities. We also included the Agricultural Resource Management Survey data. In addition, we obtained estimates from commodity specialists at trade associations, USDA, and universities with in-depth knowledge of the processing activities for specific agricultural commodities and reached out to directors of promotion and marketing boards. FDA disagrees that we need to conduct large-scale surveys to collect additional information in light of the opportunities for broad public input regarding the activity/food combinations conducted on farm and farm mixed-type facilities (see Appendix 2 of the risk assessment, Chronology of Technical and Scientific Reviews of the Qualitative Risk Assessment) and the new data sources and input provided to the Food Processing Sector study.</p>

D. Comments on Definitions

Table 5. Comments on Definitions

Public Comment: 2012 Draft Risk Assessment	FDA/CFSAN's Response
<p>Comments state that FDA should provide a definition for “low moisture food” and should take moisture levels into account more consistently in the draft risk assessment. (Comments stated that low moisture food should be defined as any food, whether in liquid, solid, or semisolid form, having a water activity lower than 0.85.)</p>	<p>We did not use the term “low-moisture food” in the qualitative risk assessment, so there is no need to provide a definition. We evaluated a number of foods that could be classified as low-moisture foods, and identified a number of low-risk activity/food combinations for such foods; however, we did not evaluate low-moisture foods as a category because there are differences in the way these foods are manufactured/processed and not all meet the criteria for low-risk activity/food combinations.</p>
<p>Comments stated that FDA needs to be more transparent when defining terms such as “hazards RLTO,” “too rare,” and criteria used to determine severity of biological hazards with respect to hospitalizations and deaths.</p>	<p>FDA has made revisions to better define terminology used in the risk assessment where appropriate. For example, we use the term “known or reasonably foreseeable hazard” (a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food) as more appropriate for the risk assessment we conducted. We did not use the term “too rare.” We explain the criteria used to determine severity of biological hazards with respect to hospitalizations and deaths in VI.B Qualitative Risk Characterization of Biological Hazards, in which we ordered information related to frequency and severity and grouped them as “low,” “medium,” and “high,” which seemed most appropriate given the data available.</p>

E. Comments on Organization

Table 6. Comments on Organization

Public Comment: 2012 Draft Risk Assessment	FDA/CFSAN's Response
<p>Comments stated that FDA should present information more clearly, particularly information intended for a public audience. Comments stated that data from Appendix 2 should be moved into the main document.</p>	<p>FDA has clarified text in the risk assessment for the intended public audience. We deleted the draft appendices because they no longer reflect the “farm” definition as a result of regulatory changes in that definition.</p>

Public Comment: 2012 Draft Risk Assessment	FDA/CFSAN's Response
<p>Comments stated that use of 3 regulatory groups to categorize different types of on-farm activities is confusing and would benefit from clarification. Comments stated that FDA should address common scenarios such as on farm processing activities for products from other farms, such as farmer owned cooperatives, food hubs, and CSA operations.</p>	<p>We deleted the draft appendices because they no longer reflect the “farm” definition as a result of regulatory changes in that definition. (See Appendix 1 in the risk assessment for the definition of “farm” and the definitions of “harvesting,” “holding,” “manufacturing/processing,” and “packing.”) These definitions do not distinguish whether activities are performed on foods from the farm conducting them or from other farms. We do not address scenarios for business types such as cooperatives, food hubs and CSA operations because the purpose of this risk assessment is to identify which activity/food combinations subject to the preventive controls rule are low-risk activity/food combinations when performed on-farm. In many cases the activities of farmer owned cooperatives, food hubs, and CSA operations will not be subject to the preventive controls rule, for example, if they fall within the farm definition.</p>

F. Comments on Opportunity for Public Comment

Table 7. Comments on Opportunity for Public Comment

Public Comment: 2012 Draft Risk Assessment	FDA/CFSAN's Response
<p>Comments stated that FDA should revise the draft risk assessment and make it available for additional public comment.</p>	<p>The draft risk assessment was subjected to peer review in accordance with the OMB Final Information Quality Bulletin for Peer Review before it was made available for a broader public comment period that exceeded 10 months. The additional iterative process recommended is not necessary and would go beyond the processes routinely applied for public input on a risk assessment.</p>

III. Packing/Holding Activities

The first column in Table 7 lists the food or food category that comments ask us to include in the exemption for on-farm, low-risk packing and holding activities. The second column lists the regulatory citation for the relevant exemption for on-farm packing and holding. Importantly, the full regulatory text of the exemption includes some limitations that were not specified in the comments, and Table 7 should not be viewed as equating the requests of the comments with the final regulatory text of the exemption. For example, § 117.5(g)(2)(ix) specifies that the food category “baked goods” includes processed food products such as breads, brownies, cakes, cookies, and crackers, but does not include products that require time/temperature control for safety (such as cream-filled pastries).

Table 8. Requested Food or Food Category and Relevant Exemption for On-Farm Low-Risk Packing and Holding Activities

Food or Food Category Requested in the Comments	Relevant Regulatory Section (§)
<ul style="list-style-type: none"> • Barley malt syrup • Barley malt extract • Other concentrated grain malt products in liquid or powder form 	<ul style="list-style-type: none"> • 117.5(g)(3)(xix)--Sugar • 117.5(g)(3)(xx)--Syrups • 117.5(g)(3)(xxii)--Vinegar • 117.5(g)(3)(xxiii)--Any other processed food that does not require time/temperature control for safety
<ul style="list-style-type: none"> • Birch sap and syrup • Cane syrup • Coconut sap and sugar • Date sugar • Palm sap and sugar • Sorghum juice and syrup • Other concentrated natural sweetener having a water activity lower than 0.85 and made with an adequate microbial reduction step 	<ul style="list-style-type: none"> • 117.5(g)(3)(xix)--Sugar • 117.5(g)(3)(xx)--Syrups
Chips	117.5(g)(3)(xiii)--Other fruit and vegetable products
<ul style="list-style-type: none"> • Crackers • Bread crumbs • Dry bread 	117.5(g)(3)(i)--Baked goods
Crude “dietary ingredient botanicals” in cut, chopped, or powdered form	<ul style="list-style-type: none"> • 117.5(g)(3)(xiii)--Other fruit and vegetable products • 117.5(g)(3)(xv) Other herb and spice products
<ul style="list-style-type: none"> • Dried cereal • Dried pasta 	117.5(g)(3)(xiv)--Other grain products
Dried herbs and spices, chopped or ground	117.5(g)(3)(xv)--Other herb and spice products
Dry legume products (e.g., chickpea flour)	117.5(g)(3)(xiii)--Other fruit and vegetable products
Dry, unsulfited, fruits and vegetables in cut, chopped, sliced, shredded, or other form	117.5(g)(3)(xiii)--Other fruit and vegetable products
Gums and resins	117.5(g)(3)(vii)--Gums, latexes, and resins that are processed foods
Herbal extracts (e.g., in solvents such as glycerin, alcohol and oil)	117.5(g)(3)(xv)--Other herb and spice products
<ul style="list-style-type: none"> • Honey infused with dried herbs or spices • Oil and/or vinegar infused with dried herbs or spices 	117.5(g)(3)(xv)--Other herb and spice products
Jerky	117.5(g)(3)(vi)--Game meat jerky
Molasses and treacle	117.5(g)(3)(xi)--Molasses and treacle
Potato starch	117.5(g)(3)(xiii)--Other fruit and vegetable products
Popcorn	117.5(g)(3)(xiv)--Other grain products

Food or Food Category Requested in the Comments	Relevant Regulatory Section (§)
Salt, baking powder	117.5(g)(3)(xxiii)--Any other processed food that does not require time/temperature control for safety
Vitamins, minerals, and processed dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form	117.5(g)(3)(xxiii)--Any other processed food that does not require time/temperature control for safety

In Table 8, we list those foods or food categories, requested by comments, that are not included in the exemption for on-farm, low-risk packing and holding activities, and explain why.

Table 9. Why Certain Requested Food Categories Are Not Included in the Exemption for On-Farm Low-Risk Packing and Holding Activities

Food or Food Category Requested in the Comments	Why the Food or Food Category is Not Listed in the Exemption
Barley malt and other grain malts	Malting increases the potential for a hazard, e.g., growth of microbial pathogens such as <i>Salmonella</i> , during the germination process. (However, the risk is mitigated when malting is done in conjunction with making sugar, syrups or vinegar.)
Crude “dietary ingredient botanicals” in whole, form	These are RACs, so packing and holding them is within the farm definition.
Dates (RACs)	These are RACs, so packing and holding them is within the farm definition.
Dried intact herbs and spices	Although these are processed foods, packing and holding them is specifically included within the farm definition.
Dried legumes	Although these are processed foods, packing and holding them is specifically included within the farm definition.
Gums, resins, and exudates in solid, powdered, granular, or paste form	Gums, resins and exudates (including latexes such as chicle) are RACs, so packing and holding them is within the “farm” definition. These products are made into processed foods in some cases, such as by boiling or cutting. The powdered, granular and paste forms from further processing are considered in the risk assessment as “any other processed food that does not require time/temperature control for safety.”

IV. Manufacturing/Processing Activities

The first column in Table 9 lists the activity/food combination that comments ask us to include in the exemption for on-farm, low-risk manufacturing/processing activity/food combinations. The second column lists the regulatory citation for the relevant exemption for an on-farm manufacturing/processing activity/food combination. Importantly, the full regulatory text of the exemption includes some limitations that were not specified in the comments, and Table 9 should not be viewed as equating the requests of the comments with the final regulatory text of the exemption. For example, § 117.5(g)(2)(ix) specifies that the food category “baked goods” includes processed food products such as breads, brownies, cakes, cookies, crackers, but does not include products that require time/temperature control for safety (such as cream-filled pastries).

Table 10. Requested Activity/Food Combinations and Relevant Exemption for On-Farm Low-Risk Manufacturing/Processing Activities

Activity/Food Combination Requested in the Comments	Regulatory Section (§) Listing the Exemption
Baking activities involving grain products	117.5(h)(3)(ix)--Making baked goods from milled grain products (e.g., breads and cookies)
Chopping, coring, cutting, peeling, pitting, shredding, and slicing: • Crackers, dry bread, bread crumbs • Dry cereal, popcorn • Gums, resins and exudates • Jerky	117.5(h)(3)(ii)--Chopping, coring, cutting, peeling, pitting, shredding, and slicing: • Baked goods • Other grain products • Gums/latexes/resins • Game meat jerky
Cooking low-moisture foods with dry heat	117.5(h)(3)(xxv)--Roasting and toasting baked goods
Drying/dehydrating cut fruits and vegetables that are immediately moved into a drying process	117.5(h)(3)(iv)--Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2, and other herb and spice products (e.g., chopped fresh herbs, including tea)
• Distilling mint • Extracting virgin olive oil • Extracting oils from seeds (e.g., sunflower seeds, flax seeds) • Making liquid botanical extracts from dry botanical raw material with solvents such as glycerin, ethanol, vinegar, honey	117.5(h)(3)(v)--Extracting (including by pressing, by distilling, and by solvent extraction) from: • Dried/dehydrated herb and spice products • Fresh herbs • Fruits and vegetables • Grains • Other herb and spice products
Grinding/milling/cracking/crushing: • Crackers, dry bread, bread crumbs • Dry cereal, dry pasta, popcorn • Dry legumes	117.5(h)(3)(vii)--Grinding/milling/cracking/crushing: • Baked goods • Other grain products • Dried/dehydrated fruit and vegetable products
Mixing • Honey infused with dried herbs or spices • Oil and/or vinegar infused with dried herbs or spices	117.5(h)(3)(xxii)—Mixing other herb and spice products
Making maple cream, maple sugar, and molded maple candy	117.5(h)(3)(x)--Making candy
Making molasses and treacle from sugarcane and sugar beets	117.5(h)(3)(xiv)--Making molasses and treacle

Activity/Food Combination Requested in the Comments	Regulatory Section (§) Listing the Exemption
<ul style="list-style-type: none"> • Making apple syrup • Making syrups from sorghum, rice • Making syrups from malted barley • Making syrups such as birch and walnut syrup 	117.5(h)(3)(xix)--Making sugar and syrup from: <ul style="list-style-type: none"> • Fruits and vegetables • Grains • Other grain products • Saps
Making vinegar, including infused and flavored vinegars	<ul style="list-style-type: none"> • 117.5(h)(3)(xxi)—Making vinegar from fruits and vegetables, other fruit and vegetable products, and other grain products • 117.5(h)(3)(xxii)—Mixing other herb and spice products
Processing tea	<ul style="list-style-type: none"> • 117.5(h)(3)(iv)--Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2, and other herb and spice products (e.g., chopped fresh herbs, including tea)

In Table 10, we list those activity/food combinations, requested by comments, that are not included in the exemption for on-farm, low-risk manufacturing/processing activity/food combinations, and explain why.

Table 11. Why Certain Requested Activity/Food Combinations Are Not Included in the Exemption for On-Farm Low-Risk Manufacturing/Processing Activities

Activity/Food Combination Requested in the Comments	Why the Activity/Food Combination is Not Listed in the Exemption
Acidifying, pickling, and fermenting low-acid fruits and vegetables made in compliance with CGMPs	Acidifying, pickling, and fermenting activities control microbial hazards and, thus, are not low-risk activities.
Cucumbers, garlic scapes, peppers, and other low-acid foods that are preserved	The production of low-acid processed foods must control the microbial hazard <i>C. botulinum</i> and, thus, is not a low-risk activity.
Drying/dehydrating tea leaves (e.g., by withering)	Drying/dehydrating tea leaves is within the “farm” definition.
Fermentation of vegetables	Fermenting activities control microbial hazards and, thus, are not low-risk activities.
Food processing conducted in compliance with relevant State regulation	It is the risk associated with the activity/food combination, not the regulatory oversight by a State, that is relevant to this exemption.
Freezing fruit juices	Fruit juices are outside the scope of the RA based on the statutory framework of FSMA.
Low-acid fruits and vegetables manufactured in compliance with CGMPs under the FD&C Act	The production of low-acid processed foods must control the microbial hazard <i>C. botulinum</i> and, thus, is not a low-risk activity.
Making pickles and salsa	The processes for making pickles and salsa must control microbial hazards and, thus, are not low-risk activities.
Roasting grains for animal feed	This activity involves the production of animal food, which is subject to the animal preventive controls rule rather than the human preventive controls rule.