FDA’s List of Low-Risk Foods

As part of the regulations to implement the Food Safety Modernization Act (FSMA), the US Food and Drug Administration (FDA) requires entities making food for human consumption to register with the agency as food ‘facilities’ and to properly apply Good Manufacturing Practices (GMPs) in producing their foods. These regulations require many facilities to implement Hazard Analysis and Risk-Based Preventive Controls (HARPC) and Supply Chain Programs (SCP), which are complex rules that add further layers of food safety management for many food businesses. Importantly, food businesses with fewer than 500 full-time equivalent employees that are located on farms and that only pack, hold or manufacture foods that the FDA has determined to be ‘low-risk’ are exempt from HARPC and SCP.

However, food businesses with less than 500 employees that are not located on farms still need to know about this Low Risk Activity/Food Combination (LRAFC) exemption if they only pack, hold or manufacture foods on FDA’s low-risk list. While these businesses are not exempt from HARPC and SCP, they can take advantage of the fact that FDA has determined the foods they produce are low-risk to dramatically reduce the paperwork and effort they invest in HARPC and SCP programs. That’s because compliance with FSMA’s GMP regulations inherently addresses the most significant food safety risks that a HARPC and SC program would need to cover in the case of low-risk foods; a business making low-risk foods that is in compliance with GMPs therefore achieves the purpose of the HARPC and SC regulations, and only requires a little extra documentation to meet those requirements.

The food processing activities that are covered under the LRAFC exemption are as follows (per 21 CFR 117.5(h)):

1. Boiling: Gums; Latexes; and Resins.

2. Chopping, coring, cutting, peeling, pitting, shredding, and slicing:
   - Acid fruits and vegetables that have a pH less than 4.2 (for example cutting lemons and limes);
   - Baked goods (for example slicing bread);
   - Dried/dehydrated fruit and vegetable products (for example pitting dried plums);
   - Dried herbs and other spices (for example chopping intact, dried basil);
   - Game meat jerky;
   - Gums/latexes/resins;
   - Other grain products (for example shredding dried cereal); and
   - Peanuts and tree nuts, and peanut and tree nut products (for example chopping roasted peanuts).

3. Coating:
   - Dried/dehydrated fruit and vegetable products (for example coating raisins with chocolate);
   - Other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (for example coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk...
activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination;  
Other grain products (for example adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens); and  
Peanuts and tree nuts (for example adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (for example adding seasonings provided that the seasonings have been treated to significantly minimize pathogens).

4. Drying/dehydrating (that includes additional manufacturing or is performed on processed foods):
Other fruit and vegetable products with pH less than 4.2 (for example drying cut fruit and vegetables with pH less than 4.2); and
Other herb and spice products (for example drying chopped fresh herbs, including tea).

5. Extracting (including by pressing, by distilling, and by solvent extraction) from:
Dried/dehydrated herb and spice products (for example dried mint);
Fresh herbs (for example fresh mint);
Fruits and vegetables (for example olives, avocados);
Grains (for example oilseeds), and;
Other herb and spice products (for example chopped fresh mint, chopped dried mint).

6. Freezing:
Acid fruits and vegetables with pH less than 4.2, and;
Other fruit and vegetable products with pH less than 4.2 (for example cut fruits and vegetables).

7. Grinding/cracking/crushing/milling:
Baked goods (for example crackers);
Cocoa beans (roasted) and coffee beans (roasted);
Dried/dehydrated fruit and vegetable products (for example raisins and dried legumes);
Other fruit and vegetable products (for example dried, pitted dates);
Dried/dehydrated herb and spice products (for example intact dried basil);
Other herb and spice products (for example chopped dried herbs);
Grains (for example oats, rice, rye, wheat) and other grain products (for example dried cereal), and;
Peanuts and tree nuts, and peanut and tree nut products (for example roasted peanuts);

8. Labeling:
Baked goods or candy that do not contain food allergens;
Roasted cocoa and coffee beans, and cocoa products that do not contain food allergens;
Game meat jerky;
Gums/latexes/resins that are processed foods;
Honey (pasteurized);
Jams/jellies/preserves;
Milled grain products that do not contain food allergens (for example corn meal) or that are single-ingredient foods (for example wheat flour, wheat bran);
Molasses and treacle;
Oils;
Other fruit and vegetable products that do not contain food allergens (for example snack chips made from potatoes or plantains);
Other grain products that do not contain food allergens (for example popcorn);
Other herb and spice products (for example chopped or ground dried herbs);
Peanut or tree nut products, (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (for example roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours));
Processed seeds for direct consumption;
Soft drinks and carbonated water;
Sugar and syrups;
Trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration);
Vinegar, and;
Any other processed food that does not require time/temperature control for safety and that does not contain food allergens (for example vitamins, minerals, and dietary ingredients (for example bone meal) in powdered, granular, or other solid form).

9. Making:
Baked goods from milled grain products (for example breads and cookies);
Candy from peanuts and tree nuts (for example nut brittles), sugar/syrups (for example taffy, toffee), and saps (for example maple candy, maple cream);
Cocoa products from roasted cocoa beans;
Dried pasta from grains;
Jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;
Molasses and treacle from sugar beets and sugarcane;
Oat flakes from grains;
Popcorn from grains;
Snack chips from fruits and vegetables (for example making plantain and potato chips);
Soft drinks and carbonated water from sugar, syrups, and water;
Sugars and syrups from fruits and vegetables (for example dates), grains (for example rice, sorghum), other grain products (for example malted grains such as barley), saps (for example agave, birch, maple, palm), sugar beets, and sugarcane;
Trail mix and granola from cocoa products (for example chocolate), dried/dehydrated fruit and vegetable products (for example raisins), other fruit and vegetable products (for example chopped dried fruits), other grain products (for example oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens; and
Vinegar from fruits and vegetables, other fruit and vegetable products (for example fruit wines, apple cider), and other grain products (for example malt).
10. Mixing:
Baked goods (for example multiple types of cookies or muffins);
Candy (for example varieties of taffy);
Cocoa beans (roasted);
Coffee beans (roasted);
Dried/dehydrated fruit and vegetable products (for example dried blueberries, dried currants, and raisins);
Dried/dehydrated herb and spice products (for example dried, intact basil and dried, intact oregano);
Honey (pasteurized);
Milled grain products (for example flour, bran, and corn meal);
Other fruit and vegetable products (for example dried, sliced apples and dried, sliced peaches);
Other grain products (for example different types of dried pasta);
Other herb and spice products (for example chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars);
Peanut and tree nut products; and
Sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (for example vitamins, minerals, and dietary ingredients (for example bone meal) in powdered, granular, or other solid form).

11. Packaging:
Baked goods (for example, bread and cookies);
Candy;
Cocoa beans (roasted);
Cocoa products;
Coffee beans (roasted);
Game meat jerky;
Gums/latexes/resins that are processed foods;
Honey (pasteurized);
Jams/jellies/preserves;
Milled grain products (for example, flour, bran, corn meal);
Molasses and treacle;
Oils;
Other fruit and vegetable products (for example, pitted, dried fruits; sliced, dried apples; snack chips);
Other grain products (for example, popcorn);
Other herb and spice products (for example, chopped or ground dried herbs);
Peanut and tree nut products;
Processed seeds for direct consumption;
Soft drinks and carbonated water;
Sugar;
Syrups;
Trail mix and granola;
Vinegar; and
Any other processed food that does not require time/temperature control for safety (for example, vitamins, minerals, and dietary ingredients (for example, bone meal) in powdered, granular, or other solid form).

12. Pasteurizing honey.

13. Roasting and toasting baked goods (for example toasting bread for croutons).

14. Salting:
Other grain products (for example soy nuts); Peanut and tree nut products; and Processed seeds for direct consumption.

15. Sifting:
Milled grain products (for example flour, bran, corn meal); Other fruit and vegetable products (for example chickpea flour); and Peanut and tree nut products (for example peanut flour, almond flour).

In addition, packing, holding, and storing the following foods is also covered under the low risk exemption (per 21 CFR 117.5(g)):

(i) Baked goods (for example, bread and cookies);
(ii) Candy (for example, hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);
(iii) Cocoa beans (roasted);
(iv) Cocoa products;
(v) Coffee beans (roasted);
(vi) Game meat jerky;
(vii) Gums, latexes, and resins that are processed foods;
(viii) Honey (pasteurized);
(ix) Jams, jellies, and preserves;
(x) Milled grain products (for example, flour, bran, and corn meal);
(xi) Molasses and treacle;
(xii) Oils (for example, olive oil and sunflower seed oil);
(xiii) Other fruit and vegetable products (for example, flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);
(xiv) Other grain products (for example, dried pasta, oat flakes, and popcorn);
(xv) Other herb and spice products (for example, chopped or ground dried herbs, herbal extracts);
(xvi) Peanut and tree nut products (for example, roasted peanuts and tree nut flours);
(xvii) Processed seeds for direct consumption (for example, roasted pumpkin seeds);
(xviii) Soft drinks and carbonated water;
(xix) Sugar;
(xx) Syrups (for example, maple syrup and agave syrup);
(xxi) Trail mix and granola;
(xxii) Vinegar; and
(xxiii) Any other processed food that does not require time/temperature control for safety (for example, vitamins, minerals, and dietary ingredients (for example, bone meal) in powdered, granular, or other solid form).

The FSMA regulations define the broad categories of foods identified above (per 21 CFR 117.3 (g)(2)):

(i) Dried/dehydrated fruit and vegetable products includes only those processed food products such as raisins and dried legumes made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(ii) Other fruit and vegetable products includes those processed food products that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. Examples also include dried fruit and vegetable products made with additional manufacturing/processing (such as dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins). This category does not include dried/dehydrated fruit and vegetable products made without additional manufacturing/processing as described in item (i) above. This category also does not include products that require time/temperature control for safety (such as fresh-cut fruits and vegetables).

(iii) Peanut and tree nut products includes processed food products such as roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.

(iv) Processed seeds for direct consumption include processed food products such as roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds.

(v) Dried/dehydrated herb and spice products includes only processed food products such as dried intact herbs made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(vi) Other herb and spice products includes those processed food products such as chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (for example, essential oils, extracts containing more than 20 percent ethanol, extracts containing more than 35 percent glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category does not include dried/dehydrated herb and spice products made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling as described in item (v) above. This category also does not include products that require time/temperature control for safety, such as fresh herb-infused oils.
(vii) Grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).

(viii) Milled grain products include processed food products such as flour, bran, and corn meal.

(ix) Baked goods include processed food products such as breads, brownies, cakes, cookies, and crackers. This category does not include products that require time/temperature control for safety, such as cream-filled pastries.

(x) Other grain products include processed food products such as dried cereal, dried pasta, oat flakes, and popcorn. This category does not include milled grain products as described in item (viii) above or baked goods as described in item (ix) above.