Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

Appendix 1: Known or Reasonably Foreseeable Hazards ("Potential Hazards")

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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Table 2O: Known or reasonably foreseeable ("potential") food-related chemical hazards for Spices and Herbs

Table 2P: Known or reasonably foreseeable ("potential") food-related chemical hazards for Food Sweeteners (Nutritive and Non-Nutritive)

A1.1 Purpose of Appendix 1

The guidance in Appendix 1 is intended to help you identify known or reasonably foreseeable biological, chemical, and physical hazards for each type of food manufactured, processed, packed, or held at your facility. Identifying known or reasonably foreseeable hazards is one step in determining, through your hazard analysis, which hazards require a preventive control. (See 21 CFR 117.130(a)(1).) Throughout this guidance:

- We use the term "potential hazard" as a synonym for "known or reasonably foreseeable hazard" for the following reasons:
  - Some users of this Appendix 1 could be more familiar with the term "potential hazard" because "potential hazard" is used in food safety systems such as HACCP that are similar to, but not the same as, the system of hazard analysis and risk-based preventive controls in part 117;
  - "Potential hazard" is a term that is used in some training materials to help emphasize during training that a known or reasonably foreseeable hazard is still being evaluated to determine whether it is a hazard requiring a preventive control for a food; and
  - Form 2-B in Appendix 2 of this guidance (Hazard Analysis) uses the term "potential hazard" as a shorthand for "known or reasonably foreseeable hazard" due to space limitations.[2]
- With the exception of Form 2-B, when appropriate, in this guidance we use[3] the combined term "known or reasonably foreseeable hazard ("potential hazard")" (or, depending on context, "known or reasonably foreseeable ("potential") hazard") so that this guidance:
  - consistently uses the term used in the regulatory text of part 117 to unambiguously direct you to the regulatory requirements that are the subject of this guidance;
  - consistently uses a term that could be more familiar to some users of this guidance; and
  - consistently reminds you that a known or reasonably foreseeable hazard is still being evaluated to determine whether it is a hazard requiring a preventive control for a food.

A1.2 Terms, Abbreviations, and Resources

See the following sections in the Introduction of this guidance for terms, abbreviations, and resources as follows:

- Section III.A: Glossary of terms that are used in this guidance and are defined in 21 CFR 117.3;
- Section III.B: Glossary of terms that are defined for use in this guidance but are not defined in 21 CFR 117.3;
- Section IV: Table of Abbreviations that are used in this guidance; and

[2] We intend to modify Form 2-B to explain that it uses "potential hazard" as a synonym for "known or reasonably foreseeable hazard."
[3] We intend to modify chapters already available as draft guidance to consistently use both terms.

- Section VI: Resources that could be useful in developing and implementing your food safety plan.

We organized the resources in section VI in the Introduction of this guidance in a series of tables as shown in Table A1-1:

Table A1-1 Resource Tables in Section VI in the Introduction of This Guidance

Table No. in Section VI of the Introduction	Table Title
3	FDA Compliance Policy Guides Cited as a Resource in this Guidance
4	FDA Guidance for Industry Cited as a Resource in this Guidance
5	FDA Compliance Programs and Import Alerts Cited as a Resource in this Guidance
6	Codex Standards, Codes of Practice, and Guidelines Cited as a Resource in this Guidance
7	Resources for Designing Validation Studies
8	Additional Resources Cited in this Guidance

When we cite a resource that is listed in one of the tables in section VI of the Introduction of this guidance, we refer you to the applicable Table in the Introduction for information on how to access the resource. For example, if we cite to "CPG Sec. 555.400 Aflatoxins in Human Food: Guidance for FDA Staff," we refer you to Table 3 in section VI of the Introduction.

These resources are available as of the date that we make this guidance available. We have verified the website addresses listed for these resources, as of the date that we make the Introduction of this guidance available, but websites are subject to change over time. In addition, the policies, recommendations, and information in these resources can change over time. We recommend that you periodically review websites listing FDA's CPGs, FDA's Guidance for Industry, FDA's Compliance Programs and Import Alerts, and Codex Standards, Codes of Practice, and Guidelines for new or modified policies, recommendations, and information.

A1.3 Requirement for a Hazard Analysis

Part 117 defines and uses three terms (i.e., "hazard," "known or reasonably foreseeable hazard," and "hazard requiring a preventive control") to establish a tiered approach to the requirements for hazard analysis and risk-based preventive controls. The term "hazard' is the broadest of these three terms – e.g., any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. To conduct your hazard analysis:

- You start with the universe of all hazards that are relevant to food safety.
- Through the "hazard identification" phase of your hazard analysis, you then narrow this universe of all hazards relevant to food safety to those hazards that are "known or reasonably foreseeable hazards" ("potential hazards") for each type of food manufactured, processed, packed, or held at your facility – i.e., those biological, chemical (including

radiological), and physical hazards that are known to be, or have the potential to be, associated with your facility or your food. These "known or reasonably foreseeable hazards" ("potential hazards") are the hazards that you evaluate in your hazard analysis.

- Through the "hazard evaluation" phase of your hazard analysis, you then determine the subset of those known or reasonably foreseeable hazards ("potential hazards") that are hazards requiring a preventive control – i.e., those known or reasonably foreseeable hazards for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

(See the definitions of "hazard," "known or reasonably foreseeable hazard," and "hazard requiring a preventive control" in 21 CFR 117.3 and the discussion of the term "potential hazard" in section A1.1 of this Appendix 1. See the requirement for a hazard analysis in 21 CFR 117.130.)

Chapter 2 of this guidance:

- provides an overview of the requirements for hazard analysis and recommendations for steps to take before beginning a hazard analysis;
- describes a "Hazard Analysis Worksheet" that is a resource that you can use in conducting your hazard analysis; and
- provides recommendations for a step-by-step approach to conducting the hazard identification and hazard evaluation phases of the hazard analysis to determine those known or reasonably foreseeable hazards ("potential hazards") requiring a preventive control. To do so, Chapter 2:
    - includes a series of questions you can ask during the hazard identification phase required by 21 CFR 117.130(b) to help narrow the universe of hazards that are relevant to your facility and your food products to the known or reasonably foreseeable hazards ("potential hazards");
    - provides recommendations for conducting the hazard evaluation phase required by 21 CFR 117.130(c) to determine which known or reasonably foreseeable hazards ("potential hazards") require a preventive control through consideration of the severity of the illness or injury if the hazard were to occur, an evaluation of environmental pathogens in certain circumstances, and an evaluation of a series of factors and their effects on the safety of the finished food for the intended consumer; and
    - briefly discusses the types of preventive controls (e.g., process controls, food allergen controls, sanitation controls, and supply-chain controls) that could be applied when the outcome of the hazard evaluation phase of the hazard analysis is that a known or reasonably foreseeable hazard ("potential hazard") requires a preventive control.

Chapter 3 of this guidance is an in-depth resource that provides background information about the most relevant biological, chemical, and physical hazards that could be associated with a facility or a food. For example, Chapter 3 includes several "Quick Reference Guides" that help

you to identify common sources of biological, chemical, and physical hazards. However, Chapter 3 does not provide an exhaustive compendium of biological, chemical, and physical hazards or all known details about each biological, chemical, or physical hazard that Chapter 3 discusses.

We recommend that you use the information in Chapters 2 and 3 to help you determine which hazards that we identify in the **Tables** in this Appendix as known or reasonably foreseeable hazards ("potential hazards") for specific types of food products are hazards requiring a preventive control for your food products. See also the notes in sections A1.6.1 (regarding food-related biological hazards), A1.6.2 (regarding food-related chemical hazards), and A1.7 (regarding process-related hazards and facility-related hazards).

A1.4 How We Developed Appendix 1

The PCHF requirements apply to a broad array of food products. To develop guidance on hazards that could be known or reasonably foreseeable hazards ("potential hazards") for specific types of food products, we consulted subject matter experts (SMEs) within CFSAN. We also contracted with a third-party consultant tasked to identify and retain recognized SMEs within the food industry and academia to provide input during this process.

We consulted with CFSAN's SMEs, and the consultant worked with its SMEs to identify 16 **Food Groups** and Food Categories and Food Subcategories within each **Food Group**. The consultations with these SMEs included their recommendations on the most relevant hazards that should be identified as known or reasonably foreseeable hazards ("potential hazards") for subsequent hazard evaluation by each facility that produces food products in the Food Subcategories to determine which hazards require a preventive control as appropriate to the facility and its food products. Resources that SMEs used for this purpose included scientific publications (including information from the books of the International Commission on Microbiological Specifications for Foods and publications from the Centers for Disease Control and Prevention), published data from the FDA Recalls, Market Withdrawals, & Safety Alerts Website (Table 8 in section VI of the Introduction of this guidance), published FDA databases (such as the Pesticide Residue Monitoring Program Reports and Data (Table 8 in section VI of the Introduction of this guidance)) and unpublished FDA databases (such as the database used to store reports to the Reportable Food Registry[4] and FDA surveillance databases) available to CFSAN SMEs.

In 2016, we first made Appendix 1 available as draft guidance for public comment (81 FR 57816, August 24, 2016). The 2016 draft Appendix 1 included three sets of **Tables** of known or reasonably foreseeable hazards ("potential hazards") – one for biological hazards, one for chemical hazards, and one for process-related biological, chemical, and physical hazards. After considering public comments, we revised Appendix 1 and are making this revised Appendix 1 available as a revised draft guidance for public comment. This revised Appendix 1 only includes two sets of **Tables** of known or reasonably foreseeable hazards ("potential hazards") – one for biological hazards and one for chemical hazards. This revised Appendix 1 no longer includes a table of known or reasonably foreseeable hazards ("potential hazards") for process-related biological, chemical, and physical hazards, because process-related hazards generally are unique to each facility based on its operations and processes. Instead, section A1.7 recommends that each facility identify known or reasonably foreseeable ("potential") process-

[4] Aggregate information is available to the public from the FDA-TRACK: Reportable Food Registry Data Dashboard (Table 8 in section VI of the Introduction of this guidance).

related hazards for its products based on its knowledge, experience, and history of hazards associated with its operations, using the recommendations provided in Chapter 2 of this guidance in combination with the information provided in Chapter 3 of this guidance. Similarly, section A1.7 recommends that each facility identify known or reasonably foreseeable ("potential") facility-related hazards for its products based on its knowledge, experience, and history of hazards associated with its facility, using the recommendations provided in Chapter 2 of this guidance in combination with the information provided in Chapter 3 of this guidance.

Although Appendix 1 is comprehensive, it is not exhaustive and only reflects data and information available as of 2022. New information about hazards that could be associated with certain types of food products could become available in the future. In addition, Appendix 1 does not address specialty ingredients such as seaweed (other than seaweed extracts such as carrageenan), proteins extracted from plants (e.g., protein extracted from peas), proteins produced through microbial fermentation (e.g., egg-white protein produced through yeast fermentation), and microorganisms (e.g., *Bifidobacterium* spp. and *Lactobacillus* spp.). Information that you could use to evaluate known or reasonably foreseeable ("potential") hazards in such ingredients includes technical data sheets provided by the supplier, and specifications that are established in the Food Chemicals Codex or an FDA regulation or that are described in FDA's response to a GRAS notice.[5] If you do not find readily available information about known or reasonably foreseeable ("potential") hazards in an ingredient, you could check with the supplier of the ingredient.

While Appendix 1 is a comprehensive starting point, each facility has the ultimate responsibility to identify the hazards relevant to food manufactured, processed, packed, or held at that facility, such as hazards that are associated with its facility-specific history even though they are not identified as known or reasonably foreseeable ("potential") hazards in the tables.

A1.5 Organization of Appendix 1

A1.5.1 Food Groups Addressed by Appendix 1

We organized Appendix 1 around 16 **Food Groups**, identified as **Food Groups A** through **P**:

- **Food Group A**: Bakery Items
- **Food Group B**: Beverage items
- **Food Group C**: Food Additives, Color Additives, and GRAS Substances
- **Food Group D**: Chocolate and Candy
- **Food Group E**: Dairy
- **Food Group F**: Dressings, Condiments, and Dips
- **Food Group G**: Egg and Egg Products
- **Food Group H**: Fruits and Vegetables
- **Food Group I**: Game Meat Products

[5] For information about GRAS notices and FDA's response to GRAS notices, see our website (Table 8 in section VI of the Introduction of this guidance).

- **Food Group J**: Grains, Pulses, Flours, and Starches
- **Food Group K**: Nuts and Seeds
- **Food Group L**: Oils and Oil Products
- **Food Group M**: Snack Foods
- **Food Group N**: Soups and Sauces
- **Food Group O**: Spices and Herbs
- **Food Group P**: Food Sweeteners (Nutritive and Non-Nutritive)

A1.5.2 Tables of Known or Reasonably Foreseeable Hazards ("Potential Hazards")

We organized the information regarding known or reasonably foreseeable hazards ("potential hazards") in Appendix 1 as follows:

- Section A1.10 includes **Tables 1A** through **1P**, which list the most relevant[6] food-related biological hazards in Food Subcategories in the 16 **Food Groups**. These **Tables** are marked (with an "X") for those food-related biological hazards that SMEs recommended be identified as known or reasonably foreseeable hazards ("potential hazards") for subsequent hazard evaluation by a facility that produces food products in those Food Subcategories to determine which hazards require a preventive control, as appropriate to the facility and its food products.
- Section A1.11, which lists the most relevant food-related chemical hazards, is organized around the same 16 **Food Groups** as those addressed in section A.1.10.
    - In 12 of these 16 **Food Groups, Tables 2B, 2C, 2D, 2E, 2G, 2H, 2I, 2J, 2K, 2L, 2O, and 2P** list the most relevant food-related chemical hazards in Food Subcategories. These **Tables** are marked (with an "X") for the most relevant[7] food-related chemical hazards that SMEs recommended be identified as known or reasonably foreseeable hazards ("potential hazards") for subsequent hazard evaluation by a facility that produces food products in those Food Subcategories to determine which hazards require a preventive control as appropriate to the facility and its food products.
    - In four of these 16 **Food Groups** (i.e., Bakery Items; Dressings, Condiments, and Dips; Snack Foods; and Soups and Sauces)**,** the known or reasonably foreseeable ("potential") chemical hazards depend on the ingredients used. To maintain the overall organization associated with the 16 **Food Groups,** section A1.11 includes an entry for that **Food Group** (i.e., **Food Groups 2A, 2F, 2M, and 2N)** and recommends that you refer to the **Tables** most applicable to the ingredients you use.

[6] In determining the most relevant biological hazards to list in the **Tables**, we first selected 12 of the major pathogens identified as being associated with foodborne illness in the United States. (Scallan et al., 2011.) As discussed in section A1.6.1.2.2, we subsequently deleted *Shigella* spp. from the relevant biological hazards listed in the **Tables**.

[7] For information on factors that we considered in determining the most relevant chemical hazards to list in the **Tables**, see section A1.6.2.

For more information about the hazards in these **Tables**, see chapter 3 and section A1.6.

A1.5.3 Organization of Each Table in Appendix 1

Each **Table** in Appendix 1 represents one **Food Group**, which is identified in the title of the **Table**. Below, we describe the elements of these **Tables**.

- Food Category: The main subdivision within each of the 16 individual **Food Groups**
- #: A code (with a number or a number/letter combination) assigned to each Food Subcategory
- Food Subcategory: Descriptive details to distinguish food items within the Food Category. See section A1.5.4 for more information about the Food Subcategories. The Food Subcategories may not include "niche" food products, raw materials, or ingredients that result from an evolution of food products over time.
- Storage Conditions: The **Tables** for most (but not all) **Food Groups** specify storage conditions for Food Subcategories in that **Food Group**. For example, the **Tables** for Bakery Items identify three storage conditions (e.g., refrigerated storage, frozen storage, and ambient storage) that apply to specific subcategories of Bakery Items.
- Hazards: See Chapter 3 for detailed information about the hazards that are most relevant to food safety. An "X" marks those hazards that SMEs recommended be identified as known or reasonably foreseeable hazards ("potential hazards") for subsequent hazard evaluation by a facility that produces food products in those Food Subcategories to determine whether these are hazards that require a preventive control as appropriate to the facility and its food products. For help in determining which of these recommendations apply to your food product and might be hazards requiring a preventive control as appropriate to your facility and your food, see Chapter 2 and Chapter 3 and the discussion in section A1.8.
- Comments: In general, your knowledge of your food product (e.g., ingredients, intended use, and storage conditions) should enable you to identify the Food Category and Food Subcategory that best represents it. However, although some products obviously fall into a Food Category and Subcategory, others may not. For example, "chocolate chip cookies" obviously fall into the Food Category Brownies/Cookies, but it may not be obvious that the **Tables** consider biscotti to be a "cookie." Therefore, the Comments provide examples of products that may not obviously fall into a Food Category and Subcategory.

Importantly, the food products in a Food Subcategory, and the sources of food ingredients in the Food Subcategories, are diverse. As a result, the recommendations of SMEs in the **Tables** in Appendix 1 may not always apply to all food products in that Food Subcategory. See the recommendations in section A1.8 regarding how to use the **Tables** in this Appendix, including discussion that hazards that SMEs recommended be identified as known or reasonably foreseeable hazards ("potential hazards") might not apply to all food products in a Food Subcategory; each facility determines, through its hazard analysis, those known or reasonably foreseeable hazards ("potential hazards") that require a preventive control.

Food products evolve and, thus, over time there will be food products that are not addressed in the **Tables** of potential hazards. If you identify a Food Subcategory that has characteristics of your food product, you may still be able to use the **Tables** in Appendix 1 to help you identify known or reasonably foreseeable hazards ("potential hazards") that warrant evaluation to determine whether they are hazards requiring a preventive control for your food product.

A1.5.4 The Food Subcategories in the Tables in Appendix 1 Address Raw Materials, Other Ingredients, and Multi-Component Foods

Most foods contain multiple raw materials and other ingredients. Although many of the foods in the **Tables** are multi-component foods, it is not practical to include all multi-component foods in the tables, because the ingredients and processing methods can vary widely (e.g., entrées, side dishes, sandwiches). To assess the biological and chemical hazards for these multi-component foods, you should consider the hazards associated with the individual raw materials/ingredients, as well as the hazards that may arise from the processing methods used in making them.

Some **Tables**, such as the "Food Additives, Color Additives, and GRAS Substances" **Food Group Table**, address food materials that are almost exclusively used as ingredients in the production of other foods. Examples of foods in the "Food Additives, Color Additives, and GRAS Substances" **Food Group** are emulsifiers, stabilizers and thickeners, enzymes, colors, flavors, and other ingredients (such as antimicrobials and preservatives).

Other **Tables** address **Food Groups** with Food Categories and Food Subcategories that are both commonly used as **raw materials or other ingredients** in the production of multi-component foods and commonly consumed as finished foods. When using these **Tables**, the known or reasonably foreseeable hazards ("potential hazards") that you should consider for an ingredient that you use in manufacturing/processing one of these food products could depend on how you use the ingredient. For example:

- Food products that are in the "Whole, Grains" Food Subcategory in **Table 1J** (e.g., barley, quinoa) are commonly sold both to manufacturers/processors for use as an ingredient in multi-component foods and to consumers. Multi-component foods manufactured/processed using whole grains as an ingredient can be dry foods (such as dry mixes that consumers use in cooking) or high-moisture foods (such as cooked grain bowls and cooked grain-based side dishes) in which the whole grains are hydrated during manufacturing/processing. You should consider *Bacillus cereus* as a known or reasonably foreseeable hazard ("potential hazard") when you use the whole grains to manufacture/process a cooked high-moisture product (where *B. cereus* could grow), but not when you distribute dry whole grains to consumers or use the dry whole grains to manufacture/process a dry mix that consumers will cook.
- Food products that are in the "Dry Mixes, Powders" Food Subcategory in the "Soups, Sauces, Gravies" Food Category in **Table 1N** are commonly sold both to manufacturers/processors for use as an ingredient in multi-component foods (such as refrigerated or frozen meals) and to consumers (e.g., for use in an entrée prepared at home by rehydration followed by cooking). You should consider pathogenic sporeformers such as *B. cereus* and *C. perfringens* as known or reasonably foreseeable hazards ("potential hazards") when you use a dry mix or powder as an ingredient of a sauce that you use to manufacture/process a frozen meal, but not when you use the dry mix or powder to manufacture/process a dry sauce mix packaged for retail sale to consumers.
- Food products that are in the "Dried, Ground, Cracked, or Whole" Food Subcategory in the "Spices" Food Category in **Table 1O** are commonly sold both to manufacturers/processors for use as an ingredient in multi-component foods (such as high-moisture dips, sauces, and refrigerated and frozen meals) and to consumers (e.g., for use in an entrée prepared at home). You should consider pathogenic sporeformers such as *B. cereus* and *C. perfringens* as known or reasonably foreseeable hazards ("potential hazards") when you use a product

in this Food Subcategory to manufacture/process high-moisture foods such as dips, sauces, and refrigerated and frozen meals (where high moisture could allow growth of pathogenic sporeformers), but not when you use a dry product in this Food Subcategory to manufacture/process a dry spice mix.

Some Food Categories and Food Subcategories could apply to more than one **Table**. For example, oil-based flavor extracts from plants appear in the oil-based liquid Subcategory of the Flavor Category in **Table 1C** (Miscellaneous Food Additives, Color Additives, and GRAS Substances) as well as in the essential oil Subcategory in the Seasonings Category in **Table 1O** (Spices and Herbs). As another example, the category/subcategory of dairy-based ready-to-drink beverages appear in **Table 1B** (Beverage Items) as well as in the cultured milk products subcategory of the milk and butter category in **Table 1E** (Dairy Products).

A1.5.5 Food Categories/Food Subcategories that Are LACF

The PCHF requirements do not apply with respect to activities that are subject to the LACF regulations (21 CFR part 113) for the control of biological hazards and, thus, LACF foods are not covered by the Food Categories/Food Subcategories in **Tables 1A** through **1P** (Food-Related Biological Hazards). (See 21 CFR 117.5(d).) *C. botulinum* would be the biological hazard associated with an LACF used as an ingredient; the hazard would be controlled by the supplier.

The PCHF requirements do apply to chemical and physical hazards that could be associated with an LACF food. The **Tables** in section A1.11 address chemical hazards that you should consider for LACF. For example, for the known or reasonably foreseeable ("potential") chemical hazards associated with a canned vegetable, you should look at **Table 2H**, which addresses the **Food Group** Fruits and Vegetables.

A1.5.6 Infant Formula and Other Foods for Infants and Toddlers

Infant formula is a specialized, multi-component food. The Food Categories/Food Subcategories in the **Tables** in Appendix 1 do not list infant formula. When you manufacture/process an infant formula, you should consider whether there are known or reasonably foreseeable biological or chemical hazards ("potential biological or chemical hazards") associated with the ingredients of that infant formula.

The Food Categories/Food Subcategories in the **Tables** in Appendix 1 do not specifically identify "baby food," such as pureed fruits and vegetables intended for consumption by infants and toddlers. When you manufacture/process a food intended for consumption by infants or toddlers, you should look for a broader term applicable to that food. For example, for "baby food" that contains fruit, you could look at the Heat-Treated Fruit Products Subcategory or any of the other fruit-related Subcategories in **Tables 1H** and **2H**. For "baby food" that contains a vegetable, you could look at any of the vegetable-related Subcategories in **Tables 1H** and **2H**.

See also the discussion of known or reasonably foreseeable ("potential") biological hazards in infant formula and other foods for infants and toddlers in section A1.6.1.5 and the discussion of known or reasonably foreseeable ("potential") chemical hazards in infant formula and other foods for infants and toddlers in section A1.6.2.5.

A1.6 Tables of Known or Reasonably Foreseeable Hazards ("Potential Hazards") in Appendix 1

A1.6.1 Food-Related Biological Hazards

A1.6.1.1 The most relevant food-related biological hazards

Chapter 3 of this guidance provides background information (e.g., characteristics of microorganisms that can contaminate food and potential sources of these microbial contaminants) for the following food-related biological hazards that are most relevant to food safety:

- *Bacillus cereus*
- *Clostridium botulinum*
- *Clostridium perfringens*
- *Brucella spp.*
- *Campylobacter spp.*
- *Pathogenic E. coli*
- *Salmonella spp.*
- *Listeria monocytogenes*
- *Shigella spp.*
- *Staphylococcus aureus*
- Parasites
- Viruses

As discussed in section A1.3, Chapter 3 does not provide an exhaustive compendium of biological, chemical, and physical hazards. Likewise, **Tables 1A** through **1P** do not include an exhaustive list of known or reasonably foreseeable ("potential") biological hazards. For example, **Tables 1A** through **1P** do not list the biological hazard *Cronobacter* spp. (including *C. sakazakii*) because *Cronobacter* spp. (including *C. sakazakii*) is largely a hazard for powdered infant formula rather than a hazard applicable to foods for the general population.[8] However, **Table 1E** (for the **Food Category** Dairy) notes that the SMEs recommend considering *Cronobacter* spp. (including *C. sakazakii*) as a known or reasonably foreseeable ("potential") biological hazard in powdered milk intended for use in infant formula.

Many RACS that are raw materials or ingredients in food products could be contaminated with multiple known or reasonably foreseeable ("potential") biological hazards. In many cases, processing to control the most common of these known or reasonably foreseeable ("potential") biological hazards for a Food Subcategory would also control biological hazards that are less common. For example, the most common known or reasonably foreseeable ("potential")

[8] The draft Chapter 3 that we made available for public comment in 2016 did not discuss *Cronobacter* spp. When we finalize that chapter, we intend to add a discussion of *Cronobacter* spp. and applicable references.

biological hazard for raw cocoa beans is *Salmonella*. Processing to control *Salmonella* would also control less common known or reasonably foreseeable ("potential") biological hazards for raw cocoa beans (such as *L. monocytogenes* and pathogenic *E. coli*). Therefore, **Table 1D** only identifies *Salmonella* as a known or reasonably foreseeable ("potential") biological hazard for raw cocoa beans.

A1.6.1.2 Note about viruses, parasites, and *Shigella* spp.

In food establishments subject to part 117, contamination of food with biological hazards that are viruses (e.g., norovirus and hepatitis A virus), parasites (e.g., *Cryptosporidium* spp., *Cyclospora cayetanensis*, and *Giardia intestinalis*) or the bacterial pathogen S*higella* spp. by food handlers generally is addressed by following the CGMPs such as those relevant to worker hygiene and disease control. (See 21 CFR 117.10.) Likewise, when an entity that supplies produce to a food facility for use as an ingredient in a food product is subject to our produce safety regulation entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (21 CFR part 112), that supplier addresses biological hazards that are viruses, parasites, or S*higella* spp. by following provisions such as the standards for Health and Hygiene in part 112, subpart D. For waterborne viruses and parasites and for *Shigella* spp. (which can be present due to fecal contamination), a supplier of produce that is subject to 21 CFR part 112 would also follow the standards for Agricultural Water in part 112, subpart E[9].

A1.6.1.2.1 Viruses and parasites

There are very few Food Subcategories in which the SMEs identified viruses or parasites as known or reasonably foreseeable ("potential") biological hazards for subsequent hazard evaluation to determine whether they are hazards requiring a preventive control. In the "Fruits and Vegetables" **Food Group** (see **Table 1H**), these Food Subcategories are:

- "Whole RAC" Food Subcategory in the "Fruits" Food Category;
- "Fresh-cut" Food Subcategory in the "Processed Fruits" Food Category;
- "Whole or Cut" (Frozen) Food Subcategory in the "Processed Fruits" Food Category; and
- "Whole RAC" Food Subcategory in the "Vegetables" Food Category.

Note that footnotes in **Table 1H** identify specific foods for which the SMEs identified viruses or parasites as known or reasonably foreseeable ("potential") biological hazards for subsequent hazard evaluation within the Food Category.

In the "Game Meat" **Food Group** (see **Table 1I**), the SMEs identified the parasite *Toxoplasma gondii* as associated with wild boar, deer and elk and considered that *Trichinella* spp. is primarily a problem with wild game such as wild boar, bear and walrus. This guidance does not address hazards associated with wild game meat, only farm-raised game meat. Thus, **Table 1I**

[9] In 2019, FDA extended the dates for compliance with the provisions of part 112, subpart E for covered produce other than sprouts (84 FR 9706, March 18, 2019). The compliance dates range from January 26, 2022, through January 26, 2024, depending on the size of a covered farm. In 2021, FDA proposed to amend the agricultural water provisions of the produce safety regulation that covered farms have found complex and challenging to implement (86 FR 69120, December 6, 2021). In that proposed rule, FDA announced its intent to exercise enforcement discretion for these subpart E requirements while pursuing a targeted compliance date rulemaking, with the goal of completing the rulemaking as quickly as possible.

only identifies *Toxoplasma gondii* as a known or reasonably foreseeable ("potential") biological hazard for deer and elk that are farmed for commercial meat distribution.

A1.6.1.2.2 *Shigella* spp.

Outbreaks of foodborne shigellosis have been associated with contaminated raw vegetables such as lettuce salads, shredded cabbage, green onions and parsley (Beuchat, 1996; Long et al., 2002; Naimi et al., 2003), and the SMEs identified *Shigella* spp. as known or reasonably foreseeable ("potential") biological hazards for subsequent hazard evaluation for these raw vegetables in the "Fruits and Vegetables" **Food Group**. The SMEs also identified *Salmonella* and/or pathogenic *E. coli* as known or reasonably foreseeable ("potential") biological hazards for these raw vegetables in the "Fruits and Vegetables" **Food Group**. If you identify *Salmonella* and/or pathogenic *E. coli* as a hazard requiring a preventive control, a preventive control that you establish and implement to significantly minimize or prevent *Salmonella* or pathogenic *E. coli* generally would also significantly minimize or prevent *Shigella* spp. Therefore, we decided that it was not necessary to separately identify *Shigella* spp. as a known or reasonably foreseeable ("potential") biological hazard for subsequent hazard evaluation in any **Food Group,** and none of the **Tables** in section A1.10 list *Shigella* spp. as a known or reasonably foreseeable ("potential") biological hazard.

A1.6.1.3 Note about biological hazards in food subcategories manufactured using exceptionally lethal processes

Some food products can only be produced using exceptionally lethal processes that adequately control biological hazards. If the processing is not conducted in a way that adequately controls biological hazards, the product would not be suitable for distribution. Due to the exceptional lethality of the processes used to manufacture these food products, in some instances the SMEs did not identify any known or reasonably foreseeable ("potential") biological hazards for these foods (e.g., sugar confections in **Table 1D** and crackers in **Table 1M**). In other instances, the tables indicate known or reasonably foreseeable ("potential") biological hazards, but a facility could determine these are not hazards requiring a preventive control because they are produced using an exceptionally lethal process (e.g., soups, sauces and gravies, where some of the products receive an exceptionally lethal process but other products do not).

For example:

- A process of making caramel by boiling ingredients such as sugar, butter, and sweetened condensed milk for several minutes to about 240°F (116°C) would provide exceptional lethality for biological hazards (e.g., *Listeria monocytogenes*); without boiling for several minutes, the ingredients will not result in a chewy caramel when cooled. Thus, the SMEs did not identify any known or reasonably foreseeable ("potential") biological hazards associated with the "Sugar Confections" Food Subcategory (e.g., caramels) in the "Chocolate and Confectionery Products" Food Category (**Table 1D**).
- A process of making jam, jelly, or chutney by a process that includes boiling would provide exceptional lethality for biological hazards (e.g., pathogenic *E. coli, Salmonella* species (spp.), and *Listeria monocytogenes*); without boiling these products will not thicken to the desired consistency. Thus, the SMEs did not identify any known or reasonably foreseeable ("potential") biological hazards associated with the "Jams, Jellies, Chutneys" Food Subcategory in the "Processed Fruits" Food Category (**Table 1H**).

- A process of making a shelf-stable acid or acidified fruit cocktail would provide exceptional lethality for biological hazards (e.g., pathogenic *E. coli, Salmonella* spp.*,* and *Listeria monocytogenes*). The process for making the fruit cocktail that can be stored at ambient temperatures is designed to inactivate certain non-pathogenic sporeformers that could cause spoilage; these sporeformers have much greater heat resistance than the vegetative pathogens that are the biological hazards in the ingredients. The SMEs identified several known or reasonably foreseeable ("potential") biological hazards associated with the Subcategory "Heat-Treated Fruit Products" in the "Processed Fruits" Food Category (**Table 1H**) but noted that some of these foods may receive an exceptionally lethal process.
- A process of making a gravy by boiling or cooking down a liquid sauce to thicken it would provide exceptional lethality for vegetative pathogens such as *E. coli* O157:H7, *Salmonella* spp. and *Listeria monocytogenes*, and, if one of these is the pertinent pathogen in an ingredient, you may not need to consider it as a known or reasonably foreseeable ("potential") biological hazard. (Alternatively, your PCQI could identify vegetative pathogens such as *E. coli* O157:H7, *Salmonella* spp. or *Listeria monocytogenes*, as known or reasonably foreseeable ("potential") biological hazards for ingredients used in making gravy, but determine that they do not require a preventive control because the process is exceptionally lethal.) The SMEs identified several known or reasonably foreseeable ("potential") biological hazards associated with the Subcategories in the "Soups, Sauces, Gravies" Food Category (**Table 1N**) but noted that some of these foods may receive an exceptionally lethal process.
- A baking process (e.g., 482°F (250°C) for 4.5 min.) used in the manufacture of snack crackers would provide exceptional lethality for vegetative pathogens such as *E. coli* O157:H7, *Salmonella* spp. and *Listeria monocytogenes*; without this high temperature process, the baked and cooled product would not have or retain the characteristic texture desired for this snack item. Thus, the SMEs did not identify any known or reasonably foreseeable ("potential") biological hazards associated with the "Baked, Unfilled, Unseasoned or Seasoned" Food Subcategory in the "Crackers" Food Category (**Table 1M**).

A1.6.1.4 Note about biological hazards in products produced in establishments that are under the jurisdiction of USDA

The production of certain meat products (but not game meat products), poultry products, and processed egg products (e.g., pasteurized liquid whole egg) is subject to regulation by USDA's FSIS under the statutes it administers (i.e., the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.). None of the **Food Groups** in Appendix 1 is directed to products while under the sole jurisdiction of USDA's FSIS. However, some FSIS-regulated products are sometimes used as ingredients in food products that are subject to our regulation under the FD&C Act and produced in accordance with the requirements of part 117. For example, in the **Food Group** "Egg and Egg Products" the Food Category "Further Processed Egg Products" subcategory "Cooked Egg Products" includes products such as egg patties (which can be an ingredient in breakfast sandwiches) that can be made with liquid whole egg, an FSIS-regulated food. If you use a food product that is produced under the jurisdiction of USDA's FSIS as an ingredient in your food product, you should determine, through your hazard analysis, whether a hazard you identify as a known or reasonably foreseeable ("potential") biological hazard in that ingredient is a hazard requiring a preventive control.

In the *Federal Register* of October 29, 2020 (85 FR 68640), FSIS published a final rule to apply the egg products regulations to egg substitutes (e.g., egg whites) and freeze-dried products (e.g., freeze-dried breakfast items for outdoor recreation) and require inspection of these products. The final rule is effective October 30, 2023. The **Food Group** "Egg and Egg Products" no longer includes egg substitutes and freeze-dried products.

A1.6.1.5 Note about biological hazards in infant formula and other foods for infants and toddlers

As discussed in section A1.5.6, the Food Categories/Food Subcategories in the **Tables** in Appendix 1 do not list infant formula or other foods for infants or toddlers. When you manufacture/process an infant formula or other food for infants or toddlers, you should consider whether there are known or reasonably foreseeable ("potential") biological hazards associated with the ingredients in that infant formula or other food for infants and toddlers.

Importantly, the controls to prevent adulteration from microorganisms in our infant formula regulations in 21 CFR part 106[10] specify criteria for when a powdered infant formula that contains *Cronobacter* spp. or *Salmonella* spp. will be deemed adulterated under sections 402(a)(1), 402(a)(4), and 412(a)(3) of the FD&C Act. You must comply with these microbiological criteria when you manufacture/process powdered infant formula. (See 21 CFR 106.55(e).)

A1.6.1.6 Note about biological hazards in food products produced using ingredients that are pasteurized or otherwise treated to control biological hazards

Many biological hazards that could be in ingredients are controlled by pasteurization or other treatment that is performed by the supplier of those ingredients. For example, in many circumstances your supplier would control known or reasonably foreseeable ("potential") biological hazards in milk-based ingredients used to make products such as dairy-based beverages, cream, cultured milk products, and cheese, or in egg-based ingredients used to make products such as some condiments. **Tables 1A** through **1P** list the known or reasonably foreseeable ("potential") biological hazards that could be in a food product due to the ingredients in the food product regardless of whether the outcome of the hazard analysis is that a hazard that requires a preventive control is controlled by you (e.g., by a process control) or by your supplier.

A1.6.1.7 Note about biological hazards in food products that consumers cook

In some cases, the outcome of your hazard analysis for foods such as uncooked fruit pies could be that known or reasonably foreseeable ("potential") biological hazards will be controlled by consumer cooking rather than by a preventive control.

[10] Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications

A1.6.2 Food-Related Chemical Hazards

A1.6.2.1 The most relevant food-related chemical hazards

Chapter 3 of this guidance provides background information[11] (e.g., characteristics of chemicals that can contaminate food and potential sources of these chemical contaminants) for the following food-related chemical hazards that are most relevant to food safety:

- drug residues in milk, honey, and game meat;
- environmental contaminants (e.g., dioxins and PCBs);
- food allergens and substances associated with a food intolerance or food-related disease (e.g., sulfites, gluten);
- toxic elements[12] in or on produce ingredients;
- mycotoxins[13] in commodities such as grains, apples, peanuts, and tree nuts;
- natural toxins (such as hypoglycin A in ackee and cyanogenic glycosides in cassava (yuca)[14]);
- pesticides in or on produce RACs[15];
- radiological hazards; and
- unapproved food or color additives.

The **Tables** in section A1.11 address drug residues, toxic elements, mycotoxins/natural toxins, and pesticides. As discussed in sections A1.6.2.2 through A1.6.2.4, these **Tables** do not

[11] A reference that we did not include in draft Chapter 3 of this guidance is the European Union's Rapid Alert System for Food and Feed (RASFF) (Table 8 in section VI of the Introduction of this guidance). RASFF enables information to be shared efficiently between its members when risks to public health are detected in the food chain. The RASFF portal features an interactive searchable online database. It gives public access to summary information about the most recently transmitted RASFF notifications as well as the ability to search for information on any notification issued in the past. When we finalize Chapter 3, we intend to identify RASFF as a resource for you to use in determining whether a chemical hazard is a known or reasonably foreseeable ("potential") hazard requiring a preventive control.

[12] The discussion in the draft Chapter 3 that we made available for public comment in 2016 focused on the toxic elements that are heavy metals. When we finalize that chapter, we intend to discuss toxic elements more broadly, consistent with the discussions of toxic elements in FDA's "Closer to Zero" action plan (Table 8 in section VI of the Introduction of this guidance). Import Alert 99-42 (Table 5 in section VI of the Introduction of this guidance) covers specific firms that have offered foods with levels of heavy metals that may render a product injurious to health and that may be detained without physical examination in accordance with the guidance in FDA's Regulatory Procedures Manual Chapter 9-8 (Table 8 in section VI of the Introduction of this guidance).

[13] FDA's Import Alert 23-14 identifies mycotoxins associated with certain food types (Table 5 in section VI of the Introduction of this guidance).

[14] The draft Chapter 3 that we made available for public comment in 2016 did not identify cyanogenic glycosides as a natural toxin. When we finalize that chapter, we intend to include cyanogenic glycosides as a natural toxin.

[15] See Liang et al., 2021 and FDA's Pesticide Residue Monitoring Program Reports and Data for commodities associated with pesticides (Table 8 in section VI of the Introduction of this guidance).

address food allergens, substances associated with a food intolerance or food-related disease, radiological hazards, dioxins, and unapproved food or color additives.

As discussed in Chapter 3, the PCHF requirements specify that you must consider, as part of your hazard identification, known or reasonably foreseeable hazards that may be intentionally introduced for purposes of economic gain (21 CFR 117.130(b)(2)(iii)) and recommends that you focus on circumstances where there has been a pattern of such adulteration in the past. Chapter 3 includes a quick reference guide (Table 3-8) that lists circumstances where there has been a pattern of such adulteration in the past and identifies additional resources that you can use for this purpose. The **Tables** in section A1.11 do not further address known or reasonably foreseeable hazards that may be intentionally introduced for purposes of economic gain.

A1.6.2.2 Note about food allergen hazards and substances associated with a food intolerance or food-related disease

See the discussion of food allergen hazards in Chapter 3.[16] The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) amended the FD&C Act and defined the following eight foods and any ingredients that contain protein derived from these eight foods (with certain exemptions noted in section 201(qq)(2) of the FD&C Act (21 U.S.C. 321(qq)(2)), including highly refined oils) as major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. In 2021, the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER) amended the definition of "major food allergen" to add sesame to that definition, effective for food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023.

A food allergen hazard can occur due to an undeclared food allergen in your food product or in raw materials or other ingredients that you receive from a supplier. A food allergen hazard also can occur due to unintended allergen presence[17] that can occur during production of your food product or during production of raw materials or other ingredients that you receive from a supplier. As a result, a food allergen hazard could be identified as a known or reasonably foreseeable (“potential”) chemical hazard for a majority of food products. Rather than identifying food allergen hazards as known or reasonably foreseeable (“potential”) chemical hazards for most food subcategories, the **Tables** of food-related chemical hazards do not address food allergen hazards.

As discussed in Chapter 3, for some consumers, certain substances can cause hypersensitivity reactions. Like food allergens, these substances are lawfully used in food. Also, like food allergens, some of these substances are subject to labeling requirements. For example, some sulfiting agents must be listed on the ingredient label unless they are added to food as an “incidental substance”; sulfiting agents are considered to be incidental only if they have no technical effect in the finished food and are present at less than 10 parts per million (ppm) (21 CFR 101.100(a)(4)). Because such substances generally are intentionally added to food (rather than be contaminants that could be unintentionally added to food), the **Tables** of food-related chemical hazards do not address these substances.

[16] For information on controlling food allergen hazards, see Chapter 11 of this guidance.
[17] We use the term “unintended allergen presence” to mean the presence of an allergen due to allergen cross-contact.

A1.6.2.3 Note about radiological hazards, dioxins, PCBs, and toxic elements

See the discussion of radiological hazards in Chapter 3. Radiological hazards rarely occur in the food supply. There are two primary sources of radiological hazards:

- water: the primary source of water that could be contaminated with radiological hazards is well water in specific areas in the United States where high concentrations of some radionuclides, such as radium-226, radium-228, and uranium, have been detected in well water; and
- accidental contamination, e.g., contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster.

Radiological hazards that result from contaminated well water or from accidental contamination can affect almost any Food Subcategory. Rather than identify radiological hazards as known or reasonably foreseeable ("potential") chemical hazards for all food subcategories, the **Tables** of food-related chemical hazards do not address radiological hazards. We recommend that you consider the information in Chapter 3 regarding radiological hazards when conducting your hazard analysis for your food products.

See also the discussion of dioxins and PCBs, which are environmental contaminants[18], in Chapter 3. Because dioxins and PCBs rarely occur in the food supply and are largely associated with accidental contamination, the **Tables** of food-related chemical hazards do not address dioxins or PCBs.

Table 3-1 in Chapter 3 identifies four heavy metals (which we now refer to as "toxic elements") as chemical hazards that can contaminate food: arsenic, cadmium, lead, and mercury. This Appendix does not address mercury, which is principally a hazard in seafood products that are not covered by this guidance.

Water is an ingredient in many food products. If you source a water-containing food from a geographic area in which water has been contaminated with toxic elements, you may need to consider whether a toxic element is a known or reasonably foreseeable ("potential") hazard for your food product (Keurig Dr Pepper, 2019; see also FDA Import Alert 99-42 in Table 5 in section VI of the Introduction of this guidance).

A1.6.2.4 Note about unapproved food and color additives

See the discussion of food additives, color additives, and GRAS substances in Chapter 3, including the statutory framework applicable to substances that are added to food. An unapproved food or color additive that results from use of a substance that is not lawful for use in food can affect almost any Food Subcategory. Rather than identify unapproved food or color additives as known or reasonably foreseeable ("potential") chemical hazards for all food

[18] The draft Chapter 3 that we made available for public comment in 2016 did not discuss perchlorates and per- and polyfluoroalkyl substances (PFAS), which can result from industrial contamination. When we finalize that chapter, we intend to include perchlorates and PFAS as examples of environmental contaminants.

subcategories, the **Tables** of food-related chemical hazards do not address unapproved food and color additive hazards.

A substance that is GRAS under the conditions of its intended use is not subject to the premarket review and approval requirements applicable to food and color additives. Although some GRAS substances are listed in our regulations, other GRAS substances are lawfully used in food without being listed in our regulations.

Some food and color additives are specifically prohibited from use in food because we have determined that the chemical additive poses a potential risk to public health (see 21 CFR part 189 and 21 CFR 81.10). Examples of such food and color additives are coumarin (21 CFR 189.130), safrole (21 CFR 189.180), and FD&C Red No. 4 ("Red No. 4") (21 CFR 81.10(d)). We consider a prohibited food additive or color additive to be an unapproved food additive or color additive for the purposes of the PCHF requirements and, thus, to be a chemical hazard.

We recommend that you consider the information in Chapter 3 to reduce the potential for an unapproved food or color additive in your food products. We intend to update Chapter 3 to highlight the following resources:

- Food and color additive regulations. The most relevant regulations are in:
  - 21 CFR part 73: Listing of Color Additives Exempt from Certification
  - 21 CFR part 74: Listing of Color Additives Subject to Certification
  - 21 CFR part 172: Food Additives Permitted for Direct Addition to Food for Human Consumption
  - 21 CFR part 173: Secondary Direct Food Additives Permitted in Food for Human Consumption
- The Color Additive Status List and the Food Additive Status List (Table 8 in section VI of the Introduction of this guidance)
- Lists of substances that are used in food under the GRAS provisions of the FD&C Act, including:
  - 21 CFR part 182: Substances Generally Recognized as Safe
  - 21 CFR part 184: Direct Food Substances Affirmed as Generally Recognized as Safe
  - GRAS Notice Inventory (Table 8 in section VI of the Introduction of this guidance)

A1.6.2.5 Note about toxic element hazards in foods for infants and toddlers, including infant formula

As discussed in section A1.5.6, the Food Categories/Food Subcategories in the **Tables** in Appendix 1 do not list infant formula or other foods for infants and toddlers. When you manufacture/process an infant formula or other food for infants or toddlers, you should consider whether there are known or reasonably foreseeable ("potential") chemical hazards associated with the ingredients in that infant formula or other food for infants or toddlers.

FDA's "Closer to Zero" action plan (Table 8 in section VI of the Introduction of this guidance) identifies actions we will take to reduce exposure to toxic elements from foods eaten by babies

and young children. We have prioritized babies and young children because their smaller body sizes and metabolism make them more vulnerable to the harmful effects of these contaminants. The “Closer to Zero” action plan follows a four-stage iterative approach that includes research, regulatory, and outreach efforts to lead to the development of action levels for certain toxic elements in categories of baby foods (e.g., cereals, pureed fruits and vegetables) and other foods commonly eaten by babies and young children.

This guidance does not identify specific action levels for any toxic element hazards in foods for infants and toddlers. Instead, we identify action levels or other recommendations for reducing toxic elements in foods for infants and toddlers in more specific guidance such as Compliance Policy Guides (Table 3 in section VI of the Introduction of this guidance) and Guidance for Industry (Table 4 in section VI of the Introduction of this guidance). For example, as of the date of publication of this Appendix, our Guidance for Industry addresses arsenic in rice cereal, arsenic in juice, lead in juice, lead in food intended for babies and young children, and lead in candy likely to be consumed frequently by small children (Table 4 in section VI of the Introduction of this guidance). You should check our "Closer to Zero: Action Plan for Baby Foods” website (Table 8 in section VI of the Introduction of this guidance), and our websites listing Compliance Policy Guides and Guidance for Industry, for such action levels on a regular basis, because the action plan’s iterative approach can lead to adjustments in any announced action levels on an ongoing basis.

A1.6.2.6 Note about mycotoxin hazards

As discussed in Chapter 3 and in our Compliance Program[19] 7307.001 (Mycotoxins in Domestic and Imported Foods) (Table 5 in section VI of the Introduction of this guidance), mycotoxins are a common group of natural toxins that include aflatoxin, fumonisin, deoxynivalenol (vomitoxin), ochratoxin, and patulin. Mycotoxins are toxic metabolites produced by certain fungi (i.e., molds) that can infect and proliferate on agricultural commodities (e.g., grains such as wheat and corn, peanuts, fruits, and tree nuts) in the field and during storage. Specific mycotoxins are most commonly associated with certain commodities as follows:

- aflatoxin: peanuts, dried corn, tree nuts, and some edible seeds[20] (melon seeds, pumpkin seeds, and sunflower seeds);
- ochratoxin: cocoa, coffee, raisins, dried figs, cereal grains;
- fumonisins: dried corn;
- deoxynivalenol (vomitoxin): wheat, barley; and
- patulin: apples

[19] FDA's Compliance Programs (Table 5 in section VI of the Introduction of this guidance) provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the FD&C Act and other laws administered by FDA. Compliance Programs are made available to the public under the Freedom of Information Act.

[20] The draft Chapter 3 that we made available for public comment in 2016 did not discuss aflatoxins in edible seeds. When we finalize that chapter, we intend to reference the information in our Compliance Program 7307.001 (Mycotoxins in Domestic and Imported Foods; Table 5 in section VI of the Introduction of this guidance).

When a **Table** of known or reasonably foreseeable ("potential") chemical hazards broadly identifies the chemical hazard "mycotoxin," a footnote in the **Table** also identifies the applicable mycotoxin.

A1.7 Process-related Hazards and Facility-related Hazards

As discussed in Chapter 2 of this guidance, when conducting your hazard analysis, you consider those known or reasonably foreseeable hazards ("potential hazards") originating from processes (process-related hazards), and the food-production environment (facility-related hazards) (21 CFR 117.130(c)(2)). Because each facility is unique in its products, operations, processes, and physical plant, process-related hazards and facility-related hazards can be specific to each facility. Therefore, this Appendix 1 does not identify known or reasonably foreseeable ("potential") process-related hazards or facility-related hazards. Instead, we recommend that each facility identify known or reasonably foreseeable ("potential") process-related hazards or facility-related hazards for its products based on its knowledge, experience, and history of hazards associated with its operations. The recommendations provided in Chapter 2 of this guidance and the information provided in Chapter 3 of this guidance are resources for facilities to do so. For your convenience, we list the most relevant biological, chemical, and physical hazards that are process-related or facility-related (as discussed in Chapter 3) in sections A1.7.1 and A1.7.2.

For examples of known or reasonably foreseeable ("potential") process-related hazards and facility-related hazards that could be associated with certain operations, see sections A1.7.1 through A1.7.3.

A1.7.1 The Most Relevant Process-related and Facility-related Biological Hazards

Sections 3.3.4 and 3.3.5 in Chapter 3 of this guidance provide background information for the following process-related and facility-related biological hazards that are most relevant to food safety:

- Bacterial Pathogens – Presence / growth / toxin production due to survival of a lethal treatment. (Section 3.3.4.1)
    - For example, a heat treatment that is not properly delivered (e.g., the temperature is too low, or the heating time is insufficient) could allow a pathogen to survive; in some cases, the surviving pathogens could subsequently grow and produce toxin.
- Bacterial Pathogens - Growth and/or toxin production due to poor time/temperature control. (Sections 3.3.4.2.1 and 3.3.4.2.2)
    - For example, a cooling mechanism that does not function as intended could allow a small number of microbial pathogens to increase in number.
- Bacterial Pathogens - Growth and/or toxin production due to poor formulation control. (Section 3.3.4.2.3)
    - For example, if insufficient acid is added to reduce the pH sufficiently in an acidified food, pathogenic sporeformers could grow and produce toxin.
- Bacterial Pathogens - Growth and/or toxin production due to reduced oxygen packaging (ROP). (Section 3.3.4.2.4)

  - For example, reduced oxygen packaging that is used to increase shelf life could create an environment that supports the growth of *C. botulinum*.

- Bacterial pathogens - Presence due to ingredients added after process controls. (Section 3.3.4.3)
- Bacterial Pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity. (Section 3.3.4.4)
  - For example, if a container is not properly sealed and it is cooled in water, water containing pathogens can be drawn into the container.
- Environmental Pathogens – Presence due to recontamination from the processing environment. (Section 3.3.5.1)
  - For example, equipment that is difficult to clean or is prone to damage could increase the risk for environmental pathogens to contaminate the product post-processing.
  - As another example, facility traffic patterns can transfer environmental pathogens from one process area to another.

See also Chapters 6 through 10 of this guidance. These chapters address process controls that are heat treatments, time/temperature controls, formulation, drying/dehydrating, and sanitation controls, respectively, applicable to process-related and facility-related biological hazards that require a preventive control.

A1.7.2 The Most Relevant Process-related Chemical Hazards

Section 3.4.2 in Chapter 3 of this guidance provides background information for the following process-related chemical hazards that are most relevant to food safety:

- Undeclared food allergens – Incorrect label (Sections 3.4.2.1.2 and 3.4.2.1.3). For example:
  - An incorrect label can result if you change the product formulation to include a food allergen but do not update the product label to declare that food allergen.
  - If the product label is pre-printed on the product package, an incorrect label can result if the wrong packaging is brought to the production line.
  - If you apply the product label to the package after the package has been filled, an incorrect label can result if the wrong label is brought to the production line.
- Unintended food allergen presence – allergen cross-contact (Section 3.4.2.1.4). For example:
  - Allergen cross-contact can result if equipment that is difficult to clean or is prone to damage is used to produce foods that contain ingredients from different food allergen sources.
  - Allergen cross-contact can result from the unintentional addition of the wrong ingredient to a food.
- Chemical hazards due to mis-formulation (e.g., sulfites, yellow #5) (Section 3.4.2.2.2)
  - For example, mis-formulation can occur if you manufacture/process some products with added sulfites and other products without sulfites, and if you unintentionally add sulfites to a product that does not include sulfites in the product recipe.
- Process-contaminant hazards in certain plant-based foods (Section 3.4.2.3)

- For example, some chemical hazards (such as acrylamide in certain plant-based foods and 3-monochloropropane-1,2-diol esters (3-MCPDEs) and glycidyl esters (GEs) (developed in some refined oils)) have the potential to form during food production, particularly at high temperature.[21] See our website regarding 3-MCPDEs and GEs (Table 8 in section VI of the Introduction of this guidance) and the Codex Code of Practice CXC 79-2019 in Table 6 in section VI of the Introduction of this guidance.[22]

See also Chapters 11 and 12 of this guidance; these chapters address food allergen controls and preventive controls for chemical hazards, respectively, applicable to process-related chemical hazards that require a preventive control.

As discussed in section 3.4.3 of Chapter 3 of this guidance, this guidance does not discuss preventive controls for facility-related chemical hazards such as cleaning chemicals and the leaching of heavy metals from containers or utensils, because such hazards are usually addressed through CGMPs.

A1.7.3 The Most Relevant Process-related Physical Hazards

Section 3.5 in Chapter 3 of this guidance provides background information for the following process-related and facility-related physical hazards that are most relevant to food safety:

- Metal (Section 3.5)
  - For example, a process that uses a metal chopping blade could introduce metal fragments if the blade breaks.
- Glass (when product is packed in glass) (Section 3.5)
  - For example, a product packaged in glass containers could introduce glass fragments if a container breaks.
- Hard plastic (Section 3.5)
  - For example, hard plastic can be introduced into food when tools and equipment such as scoops, paddles, buckets or other containers develop fatigue, crack, and break as they wear, or when plastic sieves and screens deteriorate.

As discussed in section 3.5 in Chapter 3 of this guidance, in general there is overlap between facility-related physical hazards and process-related physical hazards and, in evaluating the potential for physical hazards in your food products, it does not matter whether you consider physical hazards to be facility-related or process-related.

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[21] The Codex Alimentarius Commission, in which FDA participates, has developed recommendations for industry on reducing 3-MCPDE and GE in refined oils and foods, particularly when a refined oil is used in infant formula (Codex Code of Practice CXC 79-2019, Table 6 in section VI of the Introduction of this guidance). FDA has focused its testing efforts on infant formula because infants are a vulnerable population, infant formula contains relatively large amounts of oil (about 25-30%) to support infants' nutritional needs, and, for some infants, infant formula is a sole food source. Because of the combined efforts of industry and FDA, average 3-MCPDE and GE levels in infant formula in the U.S. have declined over the last several years.

[22] The draft Chapter 3 that we made available for public comment in 2016 did not discuss 3-MCPDE and GE that can form during the production of refined oils. When we finalize that chapter, we intend to include information about these process-related chemical hazards.

See also Chapter 13 of this guidance, applicable to process-related and facility-related physical hazards that require a preventive control.

A1.8 How to Use the Tables in Appendix 1

A1.8.1 Appendix 1 Reflects a Tiered Approach to the Requirements for Hazard Analysis

As discussed in section A1.3, part 117 establishes a tiered approach to the requirements for hazard analysis. This tiered approach considers three levels of hazards:

- The universe of hazards most relevant to food safety;
- Known or reasonably foreseeable hazards ("potential hazards"); and
- Hazards requiring a preventive control.

Under this tiered approach, you conduct your hazard analysis by first broadly considering the universe of all hazards relevant to food safety and then, through the process of hazard identification, narrowing that broad list of hazards to those hazards that are known or reasonably foreseeable hazards ("potential hazards") for your food products. You then determine, through the process of hazard evaluation, the subset of those known or reasonably foreseeable hazards ("potential hazards") that are hazards requiring a preventive control. For additional help in determining which known or reasonably foreseeable hazards ("potential hazards") require a preventive control, see Chapters 2 and 3.

The columns in the **Tables** in Appendix 1 list the most relevant hazards[23], among the universe of hazards for food safety, for 16 **Food Groups**. Hazards marked with an X for a Food Subcategory are hazards that SMEs recommended be identified as known or reasonably foreseeable hazards ("potential hazards") for subsequent hazard evaluation by each facility that produces food products in those Food Subcategories.

A1.8.2 Hazards that SMEs Recommended Be Identified as Known or Reasonably Foreseeable Hazards ("Potential Hazards") Might Not Apply to All Food Products in a Food Subcategory

The food products in a Food Subcategory, and the sources of food ingredients in the Food Subcategories, are diverse. As a result, the recommendations of SMEs in the **Tables** in Appendix 1 may not always apply to all food products in that Food Subcategory. For example, a hazard marked with an X could:

- Be a known or reasonably foreseeable ("potential") hazard only for some products in a Food Subcategory. For example:
    - **Table 1O** (Spices and Herbs) identifies *Cyclospora* as a known or reasonably foreseeable ("potential") biological hazard for some, but not all, herbs in two Food Subcategories (2b and 3a).

[23] For information on how we identified the most relevant biological and chemical hazards to address in this Appendix, see sections A1.5.2, A1.6.1, and A1.6.2.

- **Table 1C** (Food Additives, Color Additives, and GRAS Substances) identifies *Salmonella* as a known or reasonably foreseeable ("potential") biological hazard for Flavors in Subcategory 5e (Ambient or Refrigerated Other Flavor Enhancer) because the SMEs recommended that *Salmonella* be considered for one food product in this subcategory (i.e., hydrolyzed vegetable protein), even though other food products in this subcategory (such as monosodium glutamate) do not have a known or reasonably foreseeable ("potential") *Salmonella* hazard;

- Only be a known or reasonably foreseeable ("potential") hazard when a food ingredient is sourced from a specific geographic location (e.g., for chemical hazards such as toxic elements and pesticides sourced from locations where there has been a history of such contamination); or
- Only be a known or reasonably foreseeable ("potential") hazard when a food ingredient is used in a food that changes its characteristics (e.g., *B. cereus* in cooked (hydrated) rice but not dried rice).

See the recommendation in Chapter 2 for you to record the reasons that led to the conclusions of your hazard evaluation (i.e., the Yes/No conclusions listed in column 3 of Form 2-B). Explaining your reasons for a "No" conclusion can be just as important as explaining your reasons for a "Yes" conclusion. To be thorough and to have readily available answers to questions about your hazard analysis, you may find it useful to take a conservative approach by listing in Column 2 several known or reasonably foreseeable ("potential") hazards even though they clearly do not require a preventive control (especially when there has been significant debate over whether something is actually a known or reasonably foreseeable ("potential") hazard for the facility), and explain the reasons for your "No" conclusion. This can be useful both during your own review of your food safety plan and during review of your food safety plan by others – e.g., if an inspector or auditor questions whether a particular hazard was considered.

A1.8.3 Each Facility Determines, Through Its Hazard Analysis, Those Known or Reasonably Foreseeable Hazards ("Potential Hazards") That Require a Preventive Control

Each facility has the responsibility to determine, through its complete hazard analysis, whether known or reasonably foreseeable hazards ("potential hazards") are hazards that require a preventive control as appropriate to the facility and its food products. For example, a hazard marked with an X in the **Tables** could be a hazard that does not require a preventive control if it has a low probability of occurring in your food product in light of your facility and your food due to:

- a process control that has exceptional lethality[24] for biological pathogens (e.g., when your food product is caramel);
- the effectiveness of your CGMP practices in addressing the hazard (such as the effectiveness of your CGMP hygiene procedures and policies in reducing the potential for sick or infected employees to contaminate food); or

[24] We intend to discuss processes that have "exceptional lethality" in our discussion of process validation (Chapter 9). For example, processes that include boiling for several minutes might be considered processes that provide "exceptional lethality" in that such boiling can provide a high level of reduction of vegetative pathogens such as *E. coli* O157:H7, *Salmonella* spp. and *L. monocytogenes*.

- likely preparation and handling steps before consumption (e.g., if your product is not an RTE food (as defined in 21 CFR 117.3) and your product label provides the end user with cooking instructions adequate to significantly minimize biological hazards).

A1.9 References

Section VII in the Introduction of this guidance includes all references cited in this guidance, including any references cited in this Appendix. When a reference listed in section VII of the Introduction of this guidance includes a website address, FDA has verified the website address, as of the date that the Notice of Availability for the Introduction of this guidance publishes in the *Federal Register*, but websites are subject to change over time.

A1.10 Tables of Known or Reasonably Foreseeable ("Potential") Food-Related Biological Hazards

Tables 1A through **1P** list the most relevant food-related biological hazards for 16 **Food Groups**. The food-related biological hazards marked with an X for a Food Subcategory are the food-related biological hazards that SMEs recommended be identified as known or reasonably foreseeable ("potential") biological hazards for subsequent hazard evaluation by each facility that produces food products in those Food Subcategories to determine which of these biological hazards require a preventive control as appropriate to the facility and its food products. As discussed in section A1.1 of this Appendix, this guidance, including **Tables 1A** through **1P**, consistently uses a combined term (e.g., "known or reasonably foreseeable ("potential") biological hazard") to describe the output of the **Tables** to consistently use both the term used in the regulatory text of part 117 and a term that could be more familiar to some users of this guidance.

Tables 1A through **1P** do not identify any hazards requiring a preventive control in any Food Subcategory. It is the responsibility of the owner, operator, or agent in charge of each food facility to determine, through hazard analysis, whether a biological hazard identified in **Tables 1A** through **1P** as a known or reasonably foreseeable ("potential") biological hazard is a hazard requiring a preventive control in the facility's food product.

Table 1A: Known or reasonably foreseeable ("potential") food-related biological hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Bread, Biscuits, Rolls, Brownies, Cookies, Pizza, Pie Crust	1	- Unbaked Bakery Items - Ready-To-Bake (RTB) Dough - RTB Crust - With or Without Inclusions[1]	Refrigerated or Frozen						X	X	X				Includes bagels, croissants, puff pastry, phyllo
Bread, Whole/Pre-sliced	2a	- Fully-Baked - With or without Pre-Bake Added Filling or Inclusions[1] - Without Post-Bake Added Frosting/Topping	Ambient, Refrigerated or Frozen						X	X	X				Includes biscuits, bagels, rolls, croissants
Bread, Whole/Pre-sliced	2b	- Fully-Baked - With or without Pre-Bake Added Filling or Inclusions[1] - With Post-Bake Added Filling, Frosting, and/or Topping	Ambient, Refrigerated or Frozen						X	X	X	X			Includes bread with drizzles/ frosting

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Brownies / Cookies	3a	- Fully-Baked - With or without Pre-Bake Added Filling or Inclusions[1] - Without Post-Bake Added Frosting/ Topping	Ambient						**X**	**X**	**X**				Includes biscotti; fruit filled bars/wafers
Brownies / Cookies	3b	- Fully-Baked - With or without Pre-Bake Added Filling or Inclusions[1] - With Post-Bake Added Filling, Frosting, and/or Topping	Ambient						**X**	**X**	**X**	**X**			Includes fruit-, cream- or chocolate-filled bars/ wafers
Cakes/Muffins/ Quick Breads	4a	- Fully-Baked - With or without Pre-Bake Added Filling or Inclusions[1] - Without Post-Bake Added Frosting/ Topping	Ambient, Refrigerated, or Frozen						**X**	**X**	**X**				- Includes all flavors and densities - Includes all fillings added before baking

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Cakes/Muffins/ Quick Breads	4b	- Fully-Baked - With or without Pre-Bake Added Filling or Inclusions[1] - With Post-Bake Added Filling, Frosting, and/or Topping	Ambient, Refrigerated or Frozen						**X**	**X**	**X**	**X**			Includes tortes and products with post-bake added cream, nuts, confectionery and dried fruits and layer cakes with fillings or frosting
Croutons/Bread Crumbs	5	Other Bakery Products	Ambient						**X**	**X**	**X**				Includes unseasoned and seasoned products
Custard Pies	6	- Unbaked Bakery Items - Ready-To-Bake (RTB) Crust and Filling	Frozen						**X**	**X**	**X**				Includes pies with egg- and milk-derived ingredients
Custard/Cream[2]/ Crème Pie/ Cheesecake	7a	- Fully-Baked/ Cooked - With or Without Pre-Cook Added Fillings - Without Post-Bake Added Frosting/Topping	Ambient, Refrigerated or Frozen	**X**[3]	**X**[3]				**X**	**X**	**X**				Includes cheesecake and pies with egg- and milk-derived ingredients

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Custard/Cream[2]/ Crème Pie/ Cheesecake	7b	- Fully-Baked/ Cooked - With Post-Bake Added Frosting/ Topping	Ambient, Refrigerated or Frozen	X[3]	X[3]				X	X	X	X			Includes cheesecake and pies with whipped cream topping
Dry Mixes	8	Other Bakery Products	Ambient						X	X	X				Includes mixes for breads, quick breads, pancakes, cookies, cakes, brownies, biscuits, breading, pie crust
Fruit Pies/Cobblers	9a	Unbaked Bakery Items	Frozen						X	X	X				Includes all fruits and fruit mixtures
Fruit Pies/Cobblers	9b	- Fully-Baked - With or Without Pre-or Post- Bake Added Fillings, Frosting, and/or Topping	Ambient, Refrigerated, or Frozen						X	X	X				Includes all fruits and fruit mixtures
Ice Cream Cones	10	Other Bakery Products	Ambient						X	X	X				Includes plain and sugar cones

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Liquid Batter	11	Unbaked Bakery Items	Refrigerated	X[3]	X[3]				X	X	X	X			Includes batters for pancakes, brownies, waffles, doughnut
Other Pastry Products	12a	- Fully-Baked - With or Without Pre-Bake Added Filling - Without Post-Bake Added Frosting/Topping	Refrigerated or Frozen						X	X	X				Includes several breakfast items, such as French toast, pancakes, waffles
Other Pastry Products	12b	- Fully-Baked - With Post-Bake Added Filling, Frosting and/or Topping	Ambient, Refrigerated or Frozen						X	X	X	X			Includes Danishes, éclairs, cream puffs, cannoli, doughnuts, toaster pastries, turnovers
Tortillas, Soft Shell/Hard Shell	13	Other Bakery Products	Ambient or Refrigerated						X	X	X				Includes tortillas made with corn, wheat, rice, quinoa

[1] If your food product includes an inclusion, your hazard analysis should also consider known or reasonably foreseeable ("potential") biological hazards associated with the inclusion (e.g., hazards for nuts, chocolate chips, fruit). The other tables in section A1.10 are resources that could be applicable to the inclusion.

[2] In a cream/crème pie, the crust is baked and then a cooked filling is added to the baked crust. In a custard pie, the filling is poured into the crust and then the filling and crust are baked at the same time.

[3] The SMEs noted that whether these pathogenic sporeformers are known or reasonably foreseeable ("potential") biological hazards that could require time/temperature controls depends on the product (e.g., pH, water activity) and the process used to make the product.

Table 1B: Known or reasonably foreseeable ("potential") food-related biological hazards for Beverage Items

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Non-dairy Cocoa/ Chocolate	1a	Ready-to-Drink	Refrigerated	X[1]	X[1]					X					Includes plant-based chocolate/ cocoa-flavored drinks
Non-dairy Cocoa/ Chocolate	1b	Powdered Beverages	Ambient							X					Includes plant-based chocolate/ cocoa-flavored products
Coffee	2a	- Roasted Beans - Whole or Ground	Ambient							X					Includes flavored, non-flavored, and single serve
Coffee	2b	- Ready-to-Drink - Unflavored and Flavored	Refrigerated	X[1]	X[1]					X					Includes brewed coffee and espresso-style coffee
Coffee	2c	- Powdered - Freeze Dried	Ambient							X					Includes instant coffees, cappuccino mix
Coffee	2d	Concentrated Liquid Base Mixes	Refrigerated	X[1]	X[1]					X					Includes plain and flavored

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Dairy-Based	3	Ready-to-Drink	Refrigerated	**X**[1]	**X**[1]				**X**	**X**	**X**				Includes flavored and unflavored fluid milk from multiple species, yogurt drinks, kefir
Non-Dairy[2]	4a	- Ready-to-Drink Milk Substitutes - Plain and Flavored	Refrigerated	**X**[1]	**X**[1]				**X**	**X**	**X**				Includes plant-based beverages and non-dairy liquid creamer
Non-Dairy	4b	Powdered Coffee Creamer	Ambient							**X**					Includes plain and flavored
Juice-Based[2]	5	Ready-to-Drink (not 100% juice)	Ambient[3] or Refrigerated	**X**[1]	**X**[1]				**X**	**X**					All fruit drinks with some juice content
Tea and Tea Substitutes	6a	Loose Leaf and Bagged	Ambient						**X**	**X**					Includes flavored and non-flavored teas and herbal teas

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Tea and Tea Substitutes	6b	- Instant - Powdered	Ambient						**X**	**X**					Includes flavored and non-flavored teas and herbal teas
Tea and Tea Substitutes	6c	Ready-to-Drink	Ambient[3] or Refrigerated						**X**	**X**					Includes flavored and non-flavored teas and herbal teas
Tea and Tea Substitutes	6d	Concentrated Liquid Base Mixes	Ambient[3] or Refrigerated						**X**	**X**					Includes plain and flavored and herbal teas
Carbonated Beverages	7	- Ready-to-Drink - Carbonated	Ambient												Bottled drinking water is subject to the processing and bottling requirements of 21 CFR part 129 and the microbiological criteria in 21 CFR 165.110(b)

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Uncarbonated Beverages	8	- Ready-to-Drink - Uncarbonated Waters	Ambient												Bottled drinking water is subject to the processing and bottling requirements of 21 CFR part 129 and the microbiological criteria in 21 CFR 165.110(b)
Sports and Energy Beverages	9	Ready-to-Drink	Ambient[3] or Refrigerated							**X**[3]					All varieties
Beverage Concentrates/ Base Mixes[2]	10a	Liquid	Ambient[3] or Refrigerated												Includes bases for carbonated beverages and syrups for flavored drinks

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Beverage Concentrates/ Base Mixes	10b	Dry Powdered	Ambient												Includes powdered flavors
Adult Beverage Mixers[2]	11	Mixes intended for alcoholic beverages (liquid and powders)	Ambient[3] or Refrigerated	**X**[1]	**X**[1]					**X**					All varieties
Ground Coffee Substitutes	12	Dry Powdered	Ambient						**X**[4]	**X**[4]					Includes chicory root powder, roasted grains

[1] The SMEs noted that whether these pathogenic sporeformers are known or reasonably foreseeable ("potential") biological hazards that could require time/temperature controls depends on the product (e.g., pH, water activity) and the process used to make the product.

[2] Depending on the ingredients there could be other hazards. Refer to other tables for the ingredients.

[3] There may not be any known or reasonably foreseeable ("potential") biological hazard applicable to shelf-stable products. Shelf-stable products that are LACF products are not subject to the requirements for biological hazards in 21 CFR Part 117. Shelf-stable non-LACF products generally are produced using an exceptionally lethal process. (See the discussion of exceptionally lethal processes in section A1.6.1.3.)

[4] The SMEs identified this as a known or reasonably foreseeable ("potential") biological hazard applicable only when the beverage includes an herb.

[5] See **Table 1J** for the known or reasonably foreseeable ("potential") biological hazards associated with the applicable roasted grain.

Table 1C: Known or reasonably foreseeable ("potential") food-related biological hazards for Miscellaneous Food Additives, Color Additives, and GRAS Substances

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Emulsifiers	1	Emulsifiers	Ambient or Refrigerated							**X**[3]					Includes substances such as lecithin (from soy, safflower, or corn oil or from egg) mono- and diglycerides, polysorbates, sorbitan monostearate
Stabilizers and Thickeners	2a	Firming Agents	Ambient												Includes substances such as calcium chloride, calcium lactate
Stabilizers and Thickeners	2b	Humectants	Ambient												Includes substances such as glycerin, sorbitol
Stabilizers and Thickeners	2c	Leavening Agents	Ambient							X[3]					Includes substances such as baking soda, monocalcium phosphate, calcium carbonate, dried yeast

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Stabilizers and Thickeners	2d	Stabilizers, Thickeners, Binders, Texturizers	Ambient							**X**					Includes substances such as gelatin, pectin, carrageenan, modified starches, acacia gum, guar gum, xanthan gum
Stabilizers and Thickeners	2e	Dough Strengtheners and Conditioner	Ambient												Includes substances such as ammonium sulfate, azodicarbonamide, and l-cysteine
Stabilizers and Thickeners	2f	Anti-caking Agents	Ambient												Includes substances such as calcium silicate, iron ammonium citrate, silicon dioxide
Enzymes	3	Bakery, Proteolytic, Starch/Sugar Liquefication, Cheese-making	Refrigerated							**X**					Includes substances such as amylases, chymosin, lactase, lipase, papain, proteases, xylanase

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Colors	4a	Certified Colors	Ambient												Includes FD&C colors listed in 21 CFR part 74, subpart A
Colors	4b	Colors Exempt from Certification	Ambient or Refrigerated												Includes colors listed in 21 CFR part 73, subpart A
Flavors	5a	Liquid: Oil-Based[1, 2]	Ambient or Refrigerated												Includes a variety of oil-based flavor extracts from plants
Flavors	5b	Liquid: Aqueous	Ambient												Includes a variety of non-oil-based flavor extracts from plants
Flavors	5c	Powdered: Natural Flavor	Ambient or Refrigerated												Includes a variety of powdered flavor extracts from plants
Flavors	5d	Artificial: Synthetic Flavor	Ambient or Refrigerated												Includes a variety of synthetic flavors

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Flavors	5e	Other: Flavor Enhancer	Ambient or Refrigerated							X					Includes substances such as monosodium glutamate, autolyzed yeast extract, hydrolyzed vegetable proteins, disodium guanylate, inosinate
Flavors	5f	Flavor Paste	Ambient or Refrigerated						X	X	X				Includes a variety of plant-based flavor pastes
Other Chemical Ingredients	6a	Processing Chemicals	Ambient												Includes substances such as potassium hydroxide, potassium bicarbonate, sodium chloride, hydrochloric acid, sodium hydroxide, calcium carbonate, calcium lactate, mineral oil
Other Chemical Ingredients	6b	Organic Acids	Ambient												Includes substances such as acetic acid, citric acid, lactic acid, fumaric acid

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Other Chemical Ingredients	6c	Antioxidants	Ambient or Refrigerated												Includes substances such as butylated hydroxy toluene (BHT), d-alpha-tocopherol acetate (TOCO)
Other Chemical Ingredients	6d	Antimicrobials and Preservatives	Ambient or Refrigerated												Includes substances such as nisin, potassium sorbate
Other Chemical Ingredients	6e	Processing Aid Gases	Ambient												Includes gases such as nitrogen, carbon dioxide
Other Chemical Ingredients	6f	Soluble Fiber	Ambient												Includes substances such as inulin, fructan

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Nutrients	7	Vitamins, Minerals, and Vitamin/Mineral Premixes	Ambient or Refrigerated												Includes substances such as thiamine hydrochloride, riboflavin, niacin, niacinamide, folate or folic acid, beta carotene, potassium iodide, iron or ferrous sulfate, alpha tocopherols, ascorbic acid, Vitamin D, magnesium sulfate

[1] Although the SMEs identified known or reasonably foreseeable ("potential") biological hazards in the source plant of some of these oils (e.g., sesame, almond), such hazards have not been found in the oils.
[2] See also Category 3b (Essential oils) in Table 1O (Spices and Herbs).
[3] *Salmonella* has been isolated from soy lecithin (Food Navigator.co, 2006; and The Brussels Times, 2022a and b) and dried yeast (Wilson et al., 1975).

Table 1D: Known or reasonably foreseeable ("potential") food-related biological hazards for Chocolate and Candy

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Chocolate Industrial Products	1a	Raw Cocoa Beans	Ambient							X					Cocoa Beans
Chocolate Industrial Products	1b	Roasted Cocoa Beans and Nibs	Ambient							X					Beans and Nibs
Chocolate Industrial Products	1c	Chocolate/Cocoa Products for Baking	Ambient							X					Includes chocolate products with varying sweetness and includes bulk solid (blocks), bulk molded (chips), bulk powder, and bulk liquid
Confectionary Industrial Products	2a	Other Products for Baking	Ambient							X					Includes bulk molded (e.g., peanut butter chips, caramel chip) and bulk liquid
Confectionary Industrial Products	2b	Chocolate Coating for Enrobing	Ambient							X					Includes bulk solid and bulk liquid products
Chocolate and Confectionery Products	3a	Chocolate Confections	Ambient							X					Includes bars, chips, morsels, fudge, bonbons

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Chocolate and Confectionery Products	3b	Chocolate Confections - With Inclusions[1]	Ambient												Includes chocolate covered nuts/ fruit/ caramel/ mints, biscuits, nougats; chocolate candy bar with nuts or fruit; chocolate with crisped rice; fudge with nuts
Confectionery Products	3c	Sugar Confections[2]	Ambient												Includes caramels, gummy gel candies, fruit chews, licorice, marshmallows, soft jellied candy, gel cups candy, maple creams, fondant, pastilles, rock candy, hard candy
Confectionery Products	3d	Sugar Confections with inclusions[1]	Ambient												Includes nut brittles (peanut brittle, almond brittle), nut clusters, candy with fruit pieces
Confectionery Products	3e	Sugar Confections Specialties	Ambient							**X**					Includes candy coated popcorn, cereal confection, marzipan, coconut roll, peanut butter fudge, cotton candy[2], pastes

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Toppings/ Frosting	4	Toppings and Frosting (Non-Fruit/Nut)	Ambient							**X**[3]					All flavors and varieties

[1] With the exception of inclusions (e.g., nuts, chocolate chips, fruit) added after the cooking process for the chocolate confection is complete, the SMEs did not identify any known or reasonably foreseeable ("potential") biological hazards for products found in this Food Subcategory because the products are processed by an "exceptionally lethal process." (See the discussion of exceptionally lethal processes in section A1.6.1.3.) If your food product includes an inclusion added after the cooking process for the chocolate confection, your hazard analysis should also consider known or reasonably foreseeable ("potential") biological hazards associated with the inclusion (e.g., hazards for nuts, chocolate chips, fruit). The other tables in section A1.10 are resources that could be applicable to the inclusion.

[2] The SMEs did not identify any known or reasonably foreseeable ("potential") biological hazards for products found in this Food Subcategory or identified in the comment box because the products are processed by an "exceptionally lethal process." (See the discussion of exceptionally lethal processes in section A1.6.1.3.)

[3] The SMEs identified a known or reasonably foreseeable ("potential") *Salmonella* hazard only if the product contains ingredients for which *Salmonella* is a known or reasonably foreseeable ("potential") hazard. See the applicable **Table** for any known or reasonably foreseeable ("potential") hazards associated with the ingredients of your food product.

Table 1E: Known or reasonably foreseeable ("potential") food-related biological hazards for Dairy

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Raw[1] Milk	1	Liquid Milk for Processing	Refrigerated	X[2]	X[2]		X	X	X	X	X	X			Raw fluid milk
Milk and Butter	2a	Liquid Milk products	Ambient[3] or Refrigerated	X[2]	X[2]				X	X	X				Includes flavored and unflavored fluid milk from multiple species (cow, goat, sheep), ultra-pasteurized milks, milk-based creamer
Milk and Butter	2b	Cream products	Refrigerated	X[2]	X[2]				X	X	X				Includes heavy, light, whipping creams and half-and-half
Milk and Butter	2c	Butter products	Refrigerated						X	X	X	X			Includes butter spreads and blends
Milk and Butter	2d	Cultured milk products	Refrigerated						X	X	X				Includes buttermilk, sour cream, yogurt, yogurt drinks, kefir
Milk and Butter	2e	Dry milk products[4]	Ambient	X[5]					X	X	X				Includes dried products extracted from milk, such as whey powder and dried milk products used in dried dips

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Milk-Based Products	3a	Ice cream, regular and low fat (with and without inclusions)[6]	Frozen						X	X	X				All flavors
Milk-Based Products	3b	Sherbets	Frozen						X	X	X				All flavors
Milk-Based Products	3c	Frozen Novelty Items	Frozen						X	X	X				Includes ice cream cakes/bars/ sandwiches, frozen yogurt
Cheese and Cheese Products – Whole	4a	Extra Hard Cheese (low pH, low water activity)	Ambient or Refrigerated						X	X	X	X			Includes Parmesan, Asiago, Romano, Sbrinz
Cheese and Cheese Products – Whole	4b	Hard Cheese	Refrigerated						X	X	X	X			Includes Cheddar, Colby, Swiss, Gruyere
Cheese and Cheese Products – Whole	4c	Semi-soft Cheese	Refrigerated						X	X	X	X			Includes Monterey, Provolone, Oaxaca, Monterey Jack, Edam, Havarti, Paneer, Raclette

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Cheese and Cheese Products – Whole	4d	Soft, Ripened Cheese	Refrigerated						X	X	X	X			Includes Brie, Camembert, Taleggio
Cheese and Cheese Products – Whole	4e	Soft, Unripen Cheese/ Fresh Cheese	Refrigerated						X	X	X	X			Includes Cottage Cheese, Cream Cheese, Ricotta, Queso Fresco, Cheese Curd, Mozzarella
Cheese and Cheese Products - Sliced, Shredded, or Grated	5a	Hard and Extra Hard Cheese	Ambient or Refrigerated						X	X	X	X			Includes Parmesan, Asiago, Romano, Cheddar
Cheese and Cheese Products - Sliced, Shredded, or Grated	5b	Semi-soft Cheese	Refrigerated						X	X	X	X			Includes Monterey, Provolone, Oaxaca, Monterey Jack
Cheese and Cheese Products - Sliced, Shredded, or Grated	5c	Pasteurized Process Cheese	Ambient[7] or Refrigerated												Includes Process American Cheese

[1] Milk and cream, and butter made from them, in this Table are considered "pasteurized" under 21 CFR 1240.61 and the Pasteurized Milk Ordinance. Raw milk is only used in certain cheeses that are aged for at least 60 days. *Brucella* spp. and *Campylobacter* spp. are not identified as known or reasonably foreseeable ("potential") hazards for Food Categories other than Raw Milk because processes targeting the principal pathogens associated with dairy products will also address these pathogens and they generally are not reintroduced into milk after it has been pasteurized.

[2] The SMEs noted that whether these pathogenic sporeformers are known or reasonably foreseeable ("potential") biological hazards that could require time/temperature controls depends on the product (e.g., pH, water activity) and the process used to make the product.

[3] Excludes LACF (shelf-stable) products (including evaporated and sweetened and condensed milk products), which are not subject to the requirements for biological hazards in 21 CFR Part 117.

[4] We recommend that you also consider *Cronobacter* spp. (including *C. sakazakii*) as a known or reasonably foreseeable ("potential") biological hazard when milk powders are destined for use in dry blended powdered infant formula products. A facility that manufactures/processes powdered infant formula is subject to the microbiological criteria in 21 CFR 106.55(e) for when a powdered infant formula that contains *Cronobacter* spp. will be deemed adulterated under sections 402(a)(1), 402(a)(4), and 412(a)(3) of the FD&C Act.

[5] The SMEs identified this as a known or reasonably foreseeable ("potential") biological hazard applicable only when the food is used as an ingredient in another product where the dried milk becomes hydrated.

[6] If your food product includes an inclusion, your hazard analysis should also consider known or reasonably foreseeable ("potential") biological hazards associated with the inclusion (e.g., hazards for nuts, chocolate chips, fruit). The other tables in section A1.10 are resources that could be applicable to the inclusion.

[7] Excludes LACF (shelf-stable) pasteurized process cheese products (e.g., jars of cheese spreads), which are not subject to the requirements for biological hazards in 21 CFR Part 117.

Table 1F: Known or reasonably foreseeable ("potential") food-related biological hazards for Dressings, Condiments, and Dips

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Condiments	1a	Mayonnaise	Ambient or Refrigerated						X	X	X				Includes regular and "lite" products and flavored products
Condiments	1b	Mustard	Ambient or Refrigerated						X	X	X				Includes all varieties
Condiments	1c	Ketchup	Ambient						X	X	X				Includes all varieties
Condiments	1d	Vinegar	Ambient												Includes all varieties
Condiments	1e	Other Condiments	Ambient												Includes soy sauce, Worcestershire sauce, prepared horseradish, steak sauce, Tabasco sauce
Salad Dressings	2a	Dressings, salad (prepared)	Ambient or Refrigerated						X	X	X				Includes all varieties
Salad Dressings	2b	Dry mixes	Ambient						X	X					Includes all varieties

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Dips	3a	Dips and spreads	Ambient[1] or Refrigerated	**X**	**X**				**X**	**X**	**X**	**X**			Includes dips and spreads such as guacamole, salsa, dairy-based dips, bean dips, sesame-based dips (e.g., hummus, tahini, vegetable dips, taco Dip, 7-layer dip
Dips	3b	Dips and spreads, dry	Ambient	**X**[2]	**X**[2]				**X**	**X**		**X**			Dry dips, dry dairy-based dips (e.g., vegetable dip seasoning, toasted onion dip mix)

[1] Excludes LACF (shelf-stable) products which are not subject to the requirements for biological hazards in 21 CFR Part 117.

[2] The SMEs identified known or reasonably foreseeable ("potential) biological hazards for sporeformers that would apply only when these products are rehydrated and/or used as an ingredient in a product where pH would permit growth.

Table 1G: Known or reasonably foreseeable ("potential") food-related biological hazards for Egg and Egg Products

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Shell Eggs	1	Shell Eggs	Refrigerated							X					Includes raw and pasteurized in-shell
Further Processed Egg Products	2a	Eggs Hard Cooked	Refrigerated							X	X				Includes eggs in shell or shelled
Further Processed Egg Products	2b	Cooked Egg Products	Refrigerated or Frozen							X	X				Includes cooked products such as omelets, egg patties, scrambled eggs
Further Processed Egg Products	3	Egg-based products and egg substitutes (not fully cooked)[1]	Refrigerated or Frozen								X				For use as an ingredient

1 As discussed in section A1.6.1.4, the production of certain processed egg products (e.g., pasteurized liquid whole egg) is subject to regulation by USDA's FSIS under the Egg Products Inspection Act. However, these processed egg products could be used as ingredients in foods subject to FDA's jurisdiction.

Table 1H: Known or reasonably foreseeable ("potential") food-related biological hazards for Fruits and Vegetables

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Fruits	1	Whole RAC	Ambient or Refrigerated						X	X	X		X[1]	X[2]	All whole RAC fruits
Processed Fruits	2a	Fresh-cut	Refrigerated						X	X	X		X[1]	X[2]	All fresh-cut fruit, including individual fruit and mixed fruit
Processed Fruits	2b	Whole or Cut	Frozen						X	X	X		X[1]	X[2]	All frozen fruit
Processed Fruits	2c	Heat Treated Fruit Products	Ambient[3,4] or Refrigerated						X	X	X				Includes individual and mixed fruit (e.g., fruit and mixed fruit in juice or syrup)
Processed Fruits	2d	Dried/ Dehydrated Fruit Products	Ambient						X	X	X				All dried/ dehydrated fruits
Processed Fruits	2e	Jams, Jellies, Chutneys[4]	Ambient												All varieties

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Processed Fruits	2f	Coated Fruits[5]	Refrigerated								**X**				All coated fruits (e.g., caramel apples with inserted stick, chocolate covered strawberries)
Vegetables	3	Whole RAC	Ambient or Refrigerated	**X**[6]	**X**				**X**	**X**	**X**		**X**[7]		All whole RAC vegetables
Processed Vegetables	4a	Fresh-cut	Refrigerated	**X**[6]	**X**				**X**	**X**	**X**				All fresh-cut vegetables
Processed Vegetables	4b	Whole or Cut	Frozen						**X**	**X**	**X**				All frozen vegetables
Processed Vegetables	4c	Whole or cut, Heat treated	Refrigerated	**X**	**X**				**X**	**X**	**X**				All heat-treated, refrigerated vegetables, such as mashed potatoes and roasted vegetables
Processed Vegetables	4d	Acidified Products	Ambient	**X**	**X**				**X**	**X**	**X**				All ambient acidified vegetables and vegetable mixtures (such as in salsas)

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Processed Vegetables	4e	Dried/ Dehydrated Products	Ambient	X[8]	X[8]				X	X	X				All dried/ dehydrated vegetables
Processed Vegetables	4f	Fermented Products	Ambient	X	X				X	X	X				Includes sauerkraut, pickles, kimchi
Processed Fruits or Vegetables	5	Acid Pureed Products	Ambient						X	X	X				Includes applesauce, apple butter, tomato paste

[1] The SME identification of the parasite *Cyclospora* as a known or reasonably foreseeable ("potential") biological hazard in this subcategory primarily applies to berries and berry-containing products that have not been heat treated sufficiently to inactivate *Cyclospora*, but could also apply to other produce from areas where *Cyclospora* has been determined to be present, e.g., in the water supply.

[2] The SME identification of viruses (such as norovirus and hepatitis A) as known or reasonably foreseeable ("potential") biological hazards is limited to berries, pomegranates (the arils), and any fresh, refrigerated, or frozen products containing berries or pomegranate.

[3] Excludes LACF (shelf-stable) products such as heat-treated canned mangoes, which are not subject to the requirements for biological hazards in 21 CFR Part 117.

[4] The SMEs did not identify any known or reasonably foreseeable ("potential") biological hazards for shelf-stable products found in this Food Subcategory because the products are processed by an "exceptionally lethal process." (See the discussion of exceptionally lethal processes in section A1.6.1.3.)

[5] Your hazard analysis should also consider known or reasonably foreseeable ("potential") biological hazards associated with the coating (e.g., hazards for chocolate) and the specific fruits being coated. The other tables in section A1.10 are resources that could be applicable to the coating.

[6] See the discussion, in Chapter 3 of this guidance, of the potential for reduced oxygen packaging (ROP) to create a process-related biological hazard. When we finalize Chapter 3, we intend to emphasize that this risk may not apply to all fresh and fresh-cut produce RACs (e.g., we are not aware of reports of botulism associated with commercially available fresh-cut leafy greens packaged in ROP). We also intend to emphasize the importance of evaluating whether ROP presents an increased risk from sporeforming pathogens in your specific food product when deciding whether to use ROP.

[7] The SME identification of parasites (such as *Cyclospora*) as a known or reasonably foreseeable ("potential") biological hazard in this subcategory primarily applies to fresh herbs (such as basil and cilantro) and uncooked foods containing these herbs, but could also apply to other produce from areas where *Cyclospora* has been determined to be present, e.g., in the water supply.

[8] The SMEs identified known or reasonably foreseeable ("potential") biological hazards only when the food is used as an ingredient in another product where the dehydrated vegetable becomes hydrated.

Table 1l: Known or reasonably foreseeable ("potential") food-related biological hazards for Game Meat Products[1]

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Raw Game Meat	1a	Intact (Not Ground) Game Meat	Refrigerated or Frozen			X		X	X	X			X[2]		Intact meat from all game species (e.g., bison, deer, elk, rabbit, and birds (such as pheasant, grouse, quail))
Raw Game Meat	1b	Ground Game Meat	Refrigerated or Frozen			X		X	X	X	X		X[2]		Ground meat from all game species
Game Meat Products	2a	Processed Game Meat Products	Ambient			X		X	X	X	X				Processed products such as jerky
Game Meat Products	2b	Processed Game Meat Products	Refrigerated			X		X	X	X	X				Processed products such as sausages, patties, frankfurters, salami

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Game Meat Products	2c	Processed Game Meat Products	Frozen			**X**		**X**	**X**	**X**	**X**				Processed products such as sausages, patties, frankfurters, salami

[1] The SMEs identified known or reasonably foreseeable ("potential") biological hazards in the broad category "Game Meat Products" but did not differentiate between species (e.g., bison, deer, rabbit).
[2] *Toxoplasma gondii* is associated with deer and elk.

Table 1J: Known or reasonably foreseeable ("potential") food-related biological hazards for Grains, Pulses, Flours, and Starches

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Grains	1	Whole, grains	Ambient	X[1]	X[1]				X	X	X				All whole grains
Grains, Milled Products	2a	Flours (other than rice flour, corn flour, and root flour)	Ambient	X[1]	X[1]				X	X	X				All flours from grains (except as noted in the subcategory); includes gluten
Grains, Milled Products	2b	Rice and rice products	Ambient	X[1]		X[1]				X					Includes all varieties of rice and rice-based noodles
Grains, Milled Products	2c	Malt	Ambient							X					Includes all malted grain products
Grains, Milled Products	2d	Corn	Ambient	X[1]						X					Cornmeal, corn flour
Grain-based Cereal Products	3a	Cereal Product: Ready-to-Eat	Ambient							X					Includes cereal products with and without inclusions[2]
Grain-based Cereal Products	3b	Breakfast food, dried	Ambient	X[1]						X					Includes products such as oatmeal, farina, oat bran, cream of wheat, grits
Grain-based Pasta Products	4a	Unfilled Pasta	Refrigerated or Frozen	X[1]	X[1]				X	X	X				All varieties

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Grain-based Pasta Products	4b	Filled Par-boiled Pasta	Refrigerated or Frozen	X[1]	X[1]				X	X	X				All varieties
Grain-based Pasta Products	4c	Dried Pasta	Ambient	X[1]	X[1]	X[1]				X					All varieties
Other Milled Products	5a	Root flours	Ambient	X[1]						X					All root flours (e.g., from potatoes, cassava)
Other Milled Products	5b	Starch products	Ambient	X[1]						X					Cornstarch, Potato Starch, Wheat Starch
Pulses[3]	6a	Whole, dried	Ambient	X[1]	X[1]	X[1]			X	X					Includes all pulses
Pulses[3]	6b	Cooked pulses	Ambient,[4] Refrigerated or Frozen	X	X	X			X	X	X				Includes bean paste

[1] The SMEs identified this as a known or reasonably foreseeable ("potential") biological hazard applicable only when the food becomes hydrated to an a_w that allows growth or is used as an ingredient in another product where the grains/pulse/flour/starch become hydrated to an a_w that allows growth.

[2] If a cereal product contains one or more inclusions (such as nuts or chocolate), your hazard analysis should also consider known or reasonably foreseeable ("potential") biological hazards associated with the inclusion (e.g., hazards for nuts, chocolate chips, fruit). The other tables in section A1.10 are resources that could be applicable to the inclusion.

[3] Pulses are the dried, edible, pod-grown seed from produce (such as peas, beans, or lentils) within the legume family. Pulses include commodities such as bambara beans; chickpeas; cowpeas; dry beans (such as adzuki, black, flageolet, great northern, kidney, lima, mung, navy, pink, pinto, and tepary beans); dry broad beans; dry peas; lentils; and pigeon peas.

[4] Excludes LACF (shelf-stable) products such as canned pulses or bean pastes, which are not subject to the requirements for biological hazards in 21 CFR Part 117.

Table 1K: Known or reasonably foreseeable ("potential") food-related biological hazards for Nuts and Seeds

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Nuts	1a	Peanuts, Raw	Ambient						X	X	X				Peanuts
Nuts	1b	Peanuts Roasted or Boiled	Ambient						X	X	X				Peanuts
Nuts	1c	Tree Nuts, Raw	Ambient						X	X	X				Includes all tree nuts
Nuts	1d	Tree Nuts, Roasted	Ambient						X	X	X				Includes all tree nuts
Nuts	1e	Nut Butters	Ambient						X	X	X				Includes product from peanuts and tree nuts
Edible Seeds	2a	Raw	Ambient						X	X	X				Includes edible seeds from flax, melon, pumpkin, sesame, sunflower
Edible Seeds	2b	Roasted	Ambient						X	X	X				Includes edible seeds from flax, melon, pumpkin, sesame, sunflower
Other Nut and Seed Products	3a	Nut and Seed Pastes	Ambient						X	X	X				Includes pastes from peanuts, tree nuts, and seeds, seeds
Other Nut and Seed Products	3b	Nut and Seed Flours	Ambient						X	X	X				Includes flour from peanuts, tree nuts, and seeds

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Other Nut and Seed Products	3c	Coconut Products	Ambient, Refrigerated, or Frozen						X	X	X				Includes shredded, flaked, and toasted products

Table 1L: Known or reasonably foreseeable ("potential") food-related biological hazards for Oils and Oil Products

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Oil Products	1a	Cooking Oils	Ambient												Includes single oils and oil blends
Oil Products	1b	Margarines and other spreads	Ambient or Refrigerated												Includes all varieties
Oil Products	1c	Shortening	Ambient												Includes varieties considered as imitation/ substitute and includes partially and fully hydrogenated vegetable oils
Oil Products	1d	Infused Oils	Ambient		**X**[1]										Includes oils infused with acidified or non-acidified ingredients
Oil Products	1e	Cocoa Butter and Cocoa Butter Substitutes	Ambient												Includes cocoa butter and cocoa butter substitutes (e.g., from coconut oil, palm kernel oil, or both oils (21 CFR 172.861) or primarily from palm oil or primarily from high-oleic safflower or sunflower oil (21 CFR 184.1259)

[1] The SMEs only identified *C. botulinum* as a known or reasonably foreseeable ("potential") hazard for oils infused with an ingredient that has not been acidified.

Table 1M: Known or reasonably foreseeable ("potential") food-related biological hazards for Snack Foods[1]

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Bread Snacks	1a	Baked or Fried	Ambient						X	X					Includes unseasoned and seasoned[2] varieties
Bread Snacks	1b	Baked with Filling	Ambient						X	X					Includes unseasoned and seasoned[2] varieties
Chips and Crisps	2a	Fried Fruit/ Vegetable	Ambient						X	X					Includes unseasoned[3] and seasoned[2] varieties
Chips and Crisps	2b	Baked Fruit/ Vegetable	Ambient						X	X					Includes unseasoned[3] and seasoned[2] varieties
Chips and Crisps	2c	Dehydrated Fruit/ Vegetable	Ambient						X	X					Includes unseasoned[3] and seasoned[2] varieties
Crackers and Biscuits	3a	- Baked - Unfilled	Ambient[3]												Includes unseasoned and seasoned[2] varieties

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Crackers and Biscuits	3b	- Baked - Filled[4]	Ambient												Includes unseasoned and seasoned[2] varieties
Puffed Snacks	4	Baked or Fried	Ambient						X	X					Includes unseasoned[3] and seasoned[2] varieties
Snack Food Bars	5	- Cold Pressed/ Formed - With or without coating	Ambient or Refrigerated						X	X					Includes bars made with nuts, fruit, seeds, chocolate chips[4]
Snack Mix	6	Mixed/ Coated Fruits, Nuts, and Pretzels	Ambient						X	X					Includes all varieties and coatings[4]
Pudding and Gelatin Products	7a	Dry Mixes	Ambient						X	X					Includes all varieties[4]
Pudding and Gelatin Products	7b	Prepared	Ambient[5] or Refrigerated	X	X				X	X	X				Includes all varieties[4]
Frozen Novelties	8a	Non-Dairy	Frozen							X	X				Includes all varieties and coatings[4]

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Frozen Novelties	8b	Flavored Ices	Frozen												Includes all varieties and flavors

[1] See other Food Groups such as Bakery, Confectionary, Dairy, Grains, Pulses, Flours, and Starches, and Nuts and Seeds for additional Snack Categories such as cookies, candy, ice cream dairy novelties, mixed nuts, sunflower seeds, and instant noodles.

[2] If the product is seasoned after baking or frying, see also **Table 1O** for known or reasonably foreseeable ("potential") hazards in spices and herbs that could be used in the seasoning.

[3] The SMEs did not identify any known or reasonably foreseeable ("potential") biological hazards for shelf-stable products found in this Food Subcategory because the products are processed by an "exceptionally lethal process." (See the discussion of exceptionally lethal processes in section A1.6.1.3.)

[4] If the product contains ingredients addressed by other **Tables**, see the applicable **Table** as well.

[5] Excludes LACF (shelf-stable) products, which are not subject to the requirements for biological hazards in 21 CFR Part 117.

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Table 1N: Known or reasonably foreseeable ("potential") food-related biological hazards for Soups and Sauces

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Soups, Sauces, Gravies	1a	Dry Mixes, Powders	Ambient	X[1]	X[1]	X[1]			X[2]	X[2]	X[2]				Includes all varieties
Soups, Sauces, Gravies	1b	Base pastes	Ambient	X[1]	X[1]	X[1]			X[2]	X[2]	X[2]				Includes all varieties
Soups, Sauces, Gravies	1c	Full Strength Liquid or Condensed	Refrigerated or Frozen	X	X	X			X[2]	X[2]	X[2]				Includes all varieties

[1] The SMEs identified known or reasonably foreseeable ("potential") biological hazards for sporeformers that would apply only when these products are rehydrated and/or used as an ingredient in a high-moisture food.

[2] In some cases, for vegetative cells of pathogens the cooking step for a product in this Food Subcategory is an exceptionally lethal process. (See the discussion of exceptionally lethal processes in section A1.6.1.3.) Because some products in this Food Subcategory are produced using processing that is not an exceptionally lethal process, the SMEs recommended that the vegetative pathogen hazards marked with an X be identified as known or reasonably foreseeable ("potential") biological hazards. If the processing step is an exceptionally lethal process, the outcome of the hazard analysis could be that the listed known or reasonably foreseeable ("potential") biological hazard does not require a preventive control. Check

other tables for the major ingredients, because, depending on the ingredients, there may be other hazards, and some of the hazards listed here may not apply to all products in a Food Subcategory.

Table 1O: Known or reasonably foreseeable ("potential") food-related biological hazards for Spices and Herbs

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Spices	1	Dried, Ground, Cracked, or Whole	Ambient	X[1]	X[1]	X[1]				X[2]					Includes cinnamon, cardamom, turmeric, paprika, pepper (black, white, red), cayenne powder, paprika, chili powder, cumin, coriander, mustard, fenugreek, horseradish, fennel seeds, caraway, allspice, nutmeg, ginger, garlic (minced or powder), onion (minced or powder), oregano, celery seed
Herbs	2a	Dried	Ambient	X[1]	X[1]	X[1]				X[2]					Includes basil, oregano, thyme, sage, parsley, bay leaf, dill, rosemary, cilantro, mint, kaffir lime, chives, peppermint
Herbs	2b	Fresh	Ambient or Refrigerated							X[2]			X[3]		Includes basil, oregano, thyme, sage, parsley, bay leaf, dill, rosemary, cilantro, mint, kaffir lime, chives, peppermint

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Seasonings	3a	Pastes	Ambient or Refrigerated	X[1]	X[1]	X[1]				X[2]			X[3]		Includes varieties made from a single spice or herb or from multiple spices or herbs
Seasonings	3b	Essential Oils	Ambient												Includes essential oil extracted from any spice or herb
Seasonings	3c	Spice and seasoning mixtures, Dry or Liquid Blends	Ambient	X[1]	X[1]	X[1]				X[2]					Includes all varieties
Seasonings	4	Salt	Ambient												Includes all varieties

[1] The SMEs identified this as a known or reasonably foreseeable ("potential") biological hazard applicable only when these products are rehydrated and/or used as an ingredient in a high-moisture food.
[2] The SMEs identified *Salmonella* spp., but not pathogenic *E. coli*, as a known or reasonably foreseeable ("potential") biological hazard in this subcategory based on a 2022 FAO/WHO report (FAO/WHO 2022b).
[3] The SME identification of the parasite *Cyclospora* as a known or reasonably foreseeable ("potential") biological hazard in this subcategory primarily applies only to certain herbs (e.g., basil and cilantro), but could also apply to other herbs from areas where *Cyclospora* has been determined to be present, e.g., in the water supply.

Table 1P: Known or reasonably foreseeable ("potential") food-related biological hazards for Food Sweeteners (Nutritive and Non-Nutritive)

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Food Sweeteners (Nutritive and Non-Nutritive)	1a	Sugars (Dry)	Ambient												Includes all varieties
Food Sweeteners (Nutritive and Non-Nutritive)	1b	Syrup/Molasses (Liquid)	Ambient												Includes all varieties
Food Sweeteners (Nutritive and Non-Nutritive)	1c	Honey (Liquid)	Ambient		**X**[1]										Includes all varieties and forms (e.g., comb, strained, whipped)
Food Sweeteners (Nutritive and Non-Nutritive)	1d	Imitation Syrup/Molasses (Liquid)	Ambient												Includes all flavors/ varieties
Food Sweeteners (Nutritive and Non-Nutritive)	1e	Sugar Substitutes (Nutritive)	Ambient												Includes sugar alcohols, isomalt, tagatose

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Food Sweeteners (Nutritive and Non-Nutritive)	1f	Sugar Substitutes (Non-nutritive)	Ambient												Includes aspartame, saccharin, acesulfame K, neotame, stevia, sucralose

[1] The SMEs identified this as a known or reasonably foreseeable ("potential") biological hazard applicable only if honey is used as an ingredient in infant foods.

A1.11 Tables of Potential Food-Related Chemical Hazards

For consistency with the **Tables** of Known or Reasonably Foreseeable ("Potential") Food-Related Biological Hazards (**Tables 1A** through **1P**), we organized this section around the same 16 **Food Groups** as those addressed by **Tables 1A** through **1P**. However, in most circumstances a chemical hazard requiring a preventive control is addressed through a supply-chain program on ingredients used in a food product rather than through process controls applied during production of the food product. Therefore, we focused the **Tables** in this section on the food categories and subcategories containing food products that could be consumed as an ingredient of other food products; in some cases (e.g., Fruits and Vegetables) these food products also might be consumed as a finished food product. For example, for the purpose of considering biological hazards, **Table 1G** (Known or reasonably foreseeable ("potential") food-related biological hazards for Egg and Egg Products) lists 5 food categories, including shell eggs. However, for the purpose of considering chemical hazards **Table 2G** (Known or reasonably foreseeable ("potential") food-related chemical hazards for Egg and Egg Products) lists only one of those 5 food categories – i.e., shell eggs; shell eggs would be the source ingredient of the remaining 4 food categories that are listed in **Table 1G** for food-related biological hazards.

For 12 of the 16 **Food Groups**, **Tables 2B, 2D, 2E, 2G, 2H, 2I, 2J, 2K, 2O**, and **2P** list the most relevant food-related chemical hazards and mark with an X for a Food Subcategory the most relevant food-related chemical hazards that SMEs recommended be identified as known or reasonably foreseeable hazards ("potential hazards") for subsequent hazard evaluation by each facility that produces food products in those Food Subcategories to determine which hazards require a preventive control as appropriate to the facility and its food products. As discussed in section A1.1 of this Appendix, this guidance, including the **Tables** of Known or Reasonably Foreseeable ("Potential") Food-Related Chemical Hazards, consistently uses the combined term "known or reasonably foreseeable hazard ("potential hazard")" to describe the output of the **Tables** to consistently use both the term used in the regulatory text of part 117 and a term that could be more familiar to some users of this guidance.

For four of the 16 **Food Groups** (i.e., Bakery Items; Dressings, Condiments, and Dips; Snack Foods; and Soups and Sauces) the chemical hazards depend on the ingredients used. To maintain the overall organization associated with the 16 **Food Groups**, for these **Food Groups** we include an entry for that "**Food Group**" (i.e., **Food Groups 2A, 2F, 2M, and 2N)** and advise you to address known or reasonably foreseeable chemical hazards ("potential chemical hazards") that might be in the ingredients you use to produce foods in that **Food Group**.

For three **Food Groups** (i.e., **Tables 2H, 2L, and 2O** for Fruits and Vegetables, Oils and Oil Products, and Spices and Herbs, respectively), we organized the information in the **Table** around the hazards rather than around the food categories and food subcategories. For example, **Table 2H** for Fruits and Vegetables has separate rows directed to pesticides, cadmium, lead, and mycotoxins/other natural toxins. We organized the information this way because some chemical hazards (such as pesticides in the Fruits and Vegetables **Food Group**) broadly apply to many foods in a **Food Group**, whereas other chemical hazards (such as toxic elements and mycotoxins) more narrowly apply to a subset of foods in a **Food Group.**

The **Tables** of Known or Reasonably Foreseeable ("Potential") Food-Related Chemical Hazards do not identify any hazards requiring a preventive control in any Food Subcategory. It is the responsibility of the owner, operator, or agent in charge of each food facility to determine, through hazard

analysis, whether a chemical hazard identified in these Tables as a known or reasonably foreseeable ("potential") chemical hazard is a hazard requiring a preventive control for the facility's food product.

Food Group 2A: Known or reasonably foreseeable ("potential") food-related chemical hazards for Bakery Items

This Appendix does not include a Table of known or reasonably foreseeable ("potential") food-related chemical hazards for Bakery Items. Instead, for known or reasonably foreseeable ("potential") food-related chemical hazards for Bakery Items, you should see the Table(s) associated with the ingredients in your Bakery Item. For example:

- If your Bakery Item contains chocolate, you should consult Table 2D regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Chocolate and Candy.
- If your Bakery Item contains eggs, you should consult Table 2G regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Egg and Egg Products.
- If your Bakery Item contains wheat flour, you should consult Table 2J regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Grains, Pulses, Flours, and Starches.
- If your Bakery Item contains fruit, you should consult Table 2H regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Fruits and Vegetables.

Table 2B: Known or reasonably foreseeable ("potential") food-related chemical hazards for Beverage Items

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Non-dairy Cocoa/ Chocolate	1	- Ready-to-Drink - Powdered	Ambient and Refrigerated			X	X	X[1]		Includes plant-based chocolate/ cocoa flavored products
Coffee	2	- Raw and Roasted Beans/ Whole or Ground - Single Serve - Ready-to-Drink - Powdered - Freeze-Dried	Ambient					X[1]		Includes flavored and unflavored varieties
Tea	6	- Loose Leaf and Bagged - Tea and Tea Substitutes	Ambient						X	Includes plain and flavored teas and herbal teas
Carbonated Beverages	7	Ready-to-Drink / Carbonated Plain and Flavored	Ambient		X					Includes plain and flavored varieties
Ground Coffee Substitutes	12	Dry Powdered	Ambient					X[2]		Includes chicory root powder, roasted grains

[1] The applicable mycotoxin is ochratoxin. (See FDA Compliance Program 7307.001 (in Table 5 in section VI of the Introduction of this guidance) and Codex Code of Practice CAC/RCP 69-2009 and CAC/RCP 72-2013 (in Table 6 in section VI of the Introduction of this guidance).)

[2] The applicable mycotoxin depends on the grain. For the applicable mycotoxin for a specific grain, see **Table 1J.**

Table 2C: Food Additives, Color Additives, and GRAS Substances

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Nutrients	7	Vitamins, Minerals, and Vitamin/Mineral Premixes	Ambient or Refrigerated		X[1]		X[1]			The specific vitamin or mineral that could be contaminated with arsenic or lead is not yet identified.

[1] Bair, EC, 2022.

Table 2D: Known or reasonably foreseeable ("potential") food-related chemical hazards for Chocolate and Candy

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Chocolate Industrial Products	1a	Raw Cocoa Beans	Ambient			**X**	**X**	**X**[1]		Cocoa Beans
Chocolate Industrial Products	1b	Roasted Cocoa Beans and Nibs, Cocoa Butter, Cocoa Powder	Ambient			**X**	**X**	**X**[1]		Beans and Nibs

[1] The applicable mycotoxin is ochratoxin. (See FDA Compliance Program 7307.001 (in Table 5 in section VI of the Introduction of this guidance) and Codex Code of Practice CAC/RCP 72-2013 (in Table 6 in section VI of the Introduction of this guidance).)

Table 2E: Known or reasonably foreseeable ("potential") food-related chemical hazards for Dairy

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
All	1, 2, 3, 4, 5	All	Ambient, Refrigerated, and Frozen	**X**						Includes all products described in **Table 1E,** as well as shelf stable and aseptically processed and packaged milk and milk products that are produced in accordance with our LACF regulation in 21 CFR part 113

Food Group 2F: Dressings, Condiments, and Dips

This Appendix does not include a Table of known or reasonably foreseeable ("potential") food-related chemical hazards for Dressings, Condiments, and Dips. Instead, for known or reasonably foreseeable ("potential") food-related chemical hazards for Dressings, Condiments, and Dips, you should see the Table(s) associated with the ingredients in your Dressing, Condiment or Dip Item. For example:

- If your Dressing, Condiment, or Dip contains dairy ingredients, you should consult Table 2D regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Dairy.
- If your Dressing, Condiment, or Dip contains eggs, you should consult Table 2G regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Egg and Egg Products.
- If your Dressing, Condiment, or Dip contains flour or a pulse such as chickpeas, you should consult Table 2J regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Grains, Pulses, Flours, and Starches.
- If your Dressing, Condiment, or Dip contains a fruit or vegetable, you should consult Table 2H regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Fruits and Vegetables.

Table 2G: Known or reasonably foreseeable ("potential") food-related chemical hazards for Egg and Egg Products

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Shell Eggs	1	Shell Eggs - Raw and Pasteurized in Shell	Refrigerated	**X**						Includes all shell eggs

Table 2H: Known or reasonably foreseeable ("potential") food-related chemical hazards for Fruits and Vegetables[1]

Category	#[1]	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated						**X**	All fruits and vegetables
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated			**X**				Includes spinach, lettuce, potatoes, beets
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated				**X**			Includes sweet potatoes, carrots, spinach, dried plums (prunes), potatoes, mushrooms, garlic
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated					**X**[2]		Includes apple products, dried fruits, dried beans and peas

[1] Known or reasonably foreseeable ("potential") chemical hazards generally apply to a raw agricultural commodity regardless of whether and how it is processed. Therefore, each row in **Table 2H** applies to "fruits and vegetables," regardless of whether they are whole RACs or processed as described in **Table 1H** regarding known or reasonably foreseeable ("potential") biological hazards. The difference between each row is the chemical hazard that is listed as a known or reasonably foreseeable ("potential") chemical hazard.

[2] For apples and apple products, the applicable mycotoxin is patulin. For dried fruits the applicable mycotoxins are aflatoxin (dried figs) (FDA Import Alert 23-14; see Table 5 in section VI of the Introduction of this guidance) or ochratoxin A (raisins, dried figs) (FDA Compliance Program 7307.001; see Table 5 in section VI of the Introduction of this guidance). For dried vegetable (beans and peas) the applicable mycotoxin is ochratoxin A (FDA Compliance Program 7307.001; see Table 5 in section VI of the Introduction of this guidance).

Table 2l: Known or reasonably foreseeable ("potential") food-related chemical hazards for Game Meat Products

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Raw Game Meat	All	Ground and Not Ground Game Meat	Refrigerated or Frozen	X[1]						Bison Steak, Deer Shoulder, Rabbit, and Birds (Pheasant, Grouse, Quail)

[1] The SMEs identified known or reasonably foreseeable ("potential") drug residue hazards in the broad category "Game Meat Products" but did not differentiate between species (e.g., bison, deer, rabbit). You can search for drug approvals by species using the advanced search feature on our website at https://animaldrugsatfda.fda.gov/. (See Table 8 in section VI of the Introduction of this guidance.) You can find tolerances for approved animal drugs in 21 CFR Part 556.

Table 2J: Known or reasonably foreseeable ("potential") food-related chemical hazards for Grains, Pulses, Flours, and Starches

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Grains, Non-Rice	1	Whole and milled grains (e.g., flour and bran)	Ambient					X[1]	X	Wheat, Rye, Sorghum, Oats, Barley, Triticale, Buckwheat, Corn, Amaranth, Millet, Quinoa (RACs and milled grain products)
Rice, Milled Rice Products	2b	Rice (whole and milled) and rice products	Ambient		X	X		X[2]	X	White or Brown Rice, Rice protein, Sticky/sweet Rice, Basmati Rice, Jasmine Rice, Arborio rice, Rice-based noodles, Rice-based cereal
Other Milled Products	5a	Root flours	Ambient					X[3]		Potato flour, Cassava flour
Other Milled Products	5a	Root flours	Ambient						X	Sweet potato flour, yam flour
Pulses	6a	Whole (dried) or processed	Ambient					X[4]	X	Soybean, Kidney, Pinto, Navy, Azuki, Mung, Black Gram, Dried Peas; Chickpea; Cowpea/Black-eyed Pea; Lentil; Winged Bean

[1] The applicable mycotoxins are ochratoxin A (oats, wheat, barley), aflatoxin (dried corn), fumonisins (dried corn), and deoxynivalenol/ vomitoxin (wheat, barley) (See CPG Sec. 555.400 (in Table 3 in section VI of the Introduction of this guidance); Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed (in Table 4 in section VI of the Introduction of this guidance); FDA Compliance Program 7307.001 (in Table 5 in section VI of the Introduction of this guidance); and Import Alert 23-14 (in Table 5 in section VI of the Introduction of this guidance).)

[2] Aflatoxin is the applicable mycotoxin (only for raw brown rice).

[3] Cassava contains cyanogenic glycosides that produce cyanide. Depending on the level of cyanogenic glycosides, cassava is detoxified by heat processing alone, or by a combination of heat processing and food preparation techniques such as peeling, soaking, sun-drying, and scraping off the outer layer to leach out the cyanide (Canadian Food Inspection Agency, 2019).

[4] The applicable mycotoxin is ochratoxin A for dried peas and beans. (See FDA Compliance Program 7307.001 (in Table 5 in section VI of the Introduction of this guidance).)

Table 2K: Known or reasonably foreseeable ("potential") food-related chemical hazards for Nuts and Seeds

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Nuts	1a	Peanuts, Raw and treated	Ambient					X[1]	X	Peanuts
Nuts	1c	Tree Nuts, Raw and treated	Ambient					X[1]		All tree nuts
Nuts	1c	Tree Nuts, Raw and treated	Ambient						X	Cashews and pecans
Edible Seeds	2a	Raw and treated	Ambient					X[1]	X	Melon, Pumpkin, Sunflower
Edible Seeds	2a	Raw and treated	Ambient			X				Sunflower

[1] The applicable mycotoxin is aflatoxin. (See CPG Sec. 570.200, CPG Sec. 570.375, and CPG Sec. 570.500 in Table 3 in section VI of the Introduction of this guidance.)

Table 2L: Known or reasonably foreseeable ("potential") food-related chemical hazards for Oils and Oil Products

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Oil products	1a 1d	Highly refined cooking oils and infused oils	Ambient							See the discussion in section A1.7.2 that the chemical hazards 3-monochloropropane-1,2-diol esters (3-MCPDEs) and glycidyl esters (GEs) have the potential to form in refined oils during food production, particularly at high temperature.
Oil products	1a	Cooking oils that are not highly refined (e.g., produced through cold pressing)	Ambient						**X**	Includes olive oil
Oil products	1a 1d	Cooking oils and infused oils that are not highly refined (e.g., produced through cold pressing)	Ambient					**X**[1]		Includes cold-pressed oil and flavored oils from peanuts, tree nuts, sesame, sunflower, and melon

[1] The applicable mycotoxin is aflatoxin (Einolghozati et al., 2021; Sahin et al., 2022; and **Table** 2K).

Food Group 2M: Known or reasonably foreseeable ("potential") food-related chemical hazards for Snack Foods

This Appendix does not include a Table of known or reasonably foreseeable ("potential") food-related chemical hazards for Snack Foods. Instead, for known or reasonably foreseeable ("potential") food-related chemical hazards for Snack Foods, you should see the Table(s) associated with the ingredients in your Snack Food. For example:

- If your Snack Food contains chocolate, you should consult Table 2D regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Chocolate and Candy.
- If your Snack Food contains a fruit or vegetable, you should consult Table 2H regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Fruits and Vegetables.
- If your Snack Food contains wheat flour, you should consult Table 2J regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Grains, Pulses, Flours, and Starches.
- If your Snack Food contains peanuts or tree nuts, you should consult Table 2K regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Nuts and Seeds.

Food Group 2N: Known or reasonably foreseeable ("potential") food-related chemical hazards for Soups and Sauces

This Appendix does not include a Table of known or reasonably foreseeable ("potential") food-related chemical hazards for Soups and Sauces. Instead, for known or reasonably foreseeable ("potential") food-related chemical hazards for Soups and Sauces, you should see the Table(s) associated with the ingredients in your Soup or Sauce. For example:

- If your Soup or Sauce contains a dairy item, you should consult Table 2E regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Dairy.
- If your Soup or Sauce contains a fruit or vegetable, you should consult Table 2H regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Fruits and Vegetables.
- If your Soup or Sauce contains wheat flour, you should consult Table 2J regarding known or reasonably foreseeable ("potential") food-related chemical hazards for Grains, Pulses, Flours, and Starches.

Table 2O: Known or reasonably foreseeable ("potential") food-related chemical hazards for Spices and Herbs

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Spices	1	Dried, Ground, Cracked, or Whole	Ambient						X	Includes capsicums (which include cayenne, chili, paprika), cumin
Spices	1	Dried, Ground, Cracked, or Whole	Ambient		X					Includes chili powder, cumin, oregano
Spices	1	Dried, Ground, Cracked, or Whole	Ambient			X				Includes chilis/chili powder, cumin, oregano
Spices	1	Dried, Ground, Cracked, or Whole	Ambient				X[1]			Includes aniseed, chili powder, cinnamon, coriander, cumin, curry, ginger, five spice, red hot pepper, turmeric
Spices	1	Dried, Ground, Cracked, or Whole	Ambient					X[2]		Includes capsicums (which include cayenne, chili, paprika), ginger, nutmeg, turmeric
Herbs	2a	Fresh and Dried	Ambient						X	Includes basil, bay leaves, tarragon, thyme

[1] See Ishida et al. 2022.

[2] The applicable mycotoxins are aflatoxin and ochratoxin A. (See Compliance Program 7307.001 in Table 5 in section VI of the Introduction of this guidance; Iha and Truckness, 2019; and Kabak and Dobson, 2017.)

Table 2P: Known or reasonably foreseeable ("potential") food-related chemical hazards for Food Sweeteners (Nutritive and Non-Nutritive)

Category	#	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mercury	Mycotoxins/ Natural toxins	Pesticides	Comments
Food Sweeteners (Nutritive and Non-Nutritive)	1c	Honey (Liquid)	Ambient	**X**						**X**	Includes all varieties and forms (e.g., comb, strained, whipped)

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