OVERVIEW OF FOOD SAFETY REGULATION IN THE UNITED STATES

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I INTRODUCTION

The regulation of food safety in the United States is somewhat fragmented in the sense that no one agency has control over all food establishments. Instead a number of government agencies play a key role in food safety, each having jurisdiction over a portion of the food industry. In addition, the regulation of cleaners and sanitizers used in food establishments falls under the jurisdiction of a few government agencies.

This session will address the jurisdiction of these various agencies in terms of which type of food establishments they regulate as well as which agencies have jurisdiction over certain key sanitizers and cleaners.

In so defining matters, it is our goal to provide you with an overview of how food safety is regulated in the U.S. so that you can identify the key "regulatory players" and place matters in their proper context.

II REGULATION OF FOOD ESTABLISHMENTS

Food related establishments such as meat and poultry processing plants and retail food operations are regulated by different government agencies. This section will identify the major agencies that play a role in food safety and identify their jurisdiction.

A. U.S. Department of Agriculture, Food Safety and Inspection Service.

1. Has authority over domestic and imported meat and poultry and related products, such as meat or poultry containing stews, pizzas and frozen foods.

2. Authority over processed egg products (generally liquid, frozen, and dried pasteurized egg products).

3. Inspects meat and poultry slaughter and processing plants.

4. Establishes production standards including plant sanitation and other processes.

5. Oversees food recalls by meat and poultry processors of unsafe products.

B. U.S. Food and Drug Administration.

1. Has authority over all domestic and imported food sold in interstate commerce, including eggs in the shell, but not meat and poultry.

2. Authority over bottled water, and wine beverages with less than 7% alcohol.

3. Inspects food production establishments and food warehouses for physical, chemical and microbial contamination.

4. Develops model codes, ordinances, etc. such as the Model Food Code and works with local governments to encourage their adoption.

5. Works with states and local authorities in regulating milk, shellfish and retail food establishments.

6. Establishes good food manufacturing practices and other production standards such as plant sanitation.

7. Recall of unsafe products.

8. Review of food additives

C. U.S. Environmental Protection Agency

1. Establishes safe drinking water standards.

2. Assists states in monitoring quality of drinking water and finding ways to prevent contamination of drinking water.

3. Determines safety and efficacy of sanitizers such as those used on inanimate surfaces that come into contact with food.

D. Center for Disease Control and Prevention

1. Investigates with local, state and federal officials sources of food-borne disease outbreaks.

2. Maintains a nationwide system of food-borne disease surveillance.

3. Trains local and state food safety personnel.

4. Conducts research to help prevent food-borne policies.

E. U.S. Department of Commerce, National Marine Fisheries Service

1. Through a voluntary program, it oversees fish and seafood products.

2. Through its fee-for-service Seafood Inspection Program, it inspects and certifies fishing vessels, seafood processing plants, and retail facilities to ensure the quality and safety of seafood. (Note: Mandatory regulation of seafood processing is under the jurisdiction of FDA.)

F. U.S. Department of the Treasury, Bureau of Alcohol, Tobacco and Firearms

1. Oversees alcoholic beverages except wine beverages containing less than 7% alcohol.

2. Enforces food safety laws governing production and distribution of alcoholic beverages.

G. State and Local Governments

1. General oversight over all foods within their jurisdictions.

2. Work with FDA and other appropriate federal agencies to implement food safety standards for fish, seafood, milk, and other foods produced within their borders.

3. Inspect restaurants, cafeterias, grocery stores and other retail food establishments, as well as dairy farms and milk processing plants, grain mills and food manufacturing plants within local jurisdictions.

4. Adopt food safety regulations for the purpose of regulating retail food operations. In this regard, FDA has encouraged local jurisdictions to adopt the Model Food Code. To date, over 30 jurisdictions have adopted the Model Food Code in one form or another.

H. HACCP Based Regulations.

While the regulation of food establishments in the United States is fragmented, a unifying thread runs through most, if not all, regulatory authorities. There is a general movement to adopt regulations based on the principles of Hazard Analysis and Critical Control Points (HACCP) Systems. The following is a brief summary of some of the food establishments that operate under HACCP based regulations:

1. Meat and poultry processing establishments.

2. Fruit and vegetable juice processors.

3. Seafood processors

4. Dairy plants (voluntary program).

5. Retail food operations (i.e., those establishments that sell food that is ready to eat). (HACCP included in Model Food Code.)

6. Growing number of establishments have adopted HACCP on a voluntary basis.

7. Adoption of HACCP based regulations speaks to a different philosophy in the regulation of food safety.

a) HACCP based regulations represent a move away from the traditional command and control style of regulation.

b) Traditional command and control regulations were very prescriptive and told the food related establishments what they had to do every step of the process.

c) Command and control style is best exemplified by the old FSIS regulations which addressed every detail of running a meat and poultry processing establishment including which cleaning products to use, when and how to clean, etc.

d) HACCP regulations are performance oriented. They provide "bottom line" requirements, and require food establishments to take responsibility for the particulars on how to arrive at the bottom line.

e) HACCP regulations have removed the government "crutch" and require food establishments, such as meat and poultry establishments, to make decisions on their own.

f) Without the assistance of command and control style regulations, many food related establishments are not comfortable or confident in their decisions, and need assistance in this regard.

III REGULATION OF FOOD-USE CLEANERS AND SANITIZERS

A. Antimicrobial Products.

In general, antimicrobial products used in a food context have been regulated by both EPA and FDA. However, the Food Quality Protection Act and the Antimicrobial Regulation Technical Corrections Act of 1998 modified the definitions of "food additive" and "pesticide chemical" in the Federal Food, Drug and Cosmetic Act. These changes had a significant impact upon the regulatory authority for many antimicrobial products that are used in food-contact applications. This section summarizes the regulatory

jurisdiction, any registration requirements, and the type of clearance required based on the intended use of the antimicrobial product.

1. Treatment of Permanent or Semi-Permanent Food Contact Surfaces

a) Jurisdiction: EPA

b) EPA registration required

c) Clearance: Tolerance

2. Pre- and Post-Harvest Field Wash of Raw Agricultural Commodities (antimicrobial applied directly to RAC or to process water)

a) Jurisdiction: EPA

b) EPA registration required

c) Clearance: Tolerance

3. Treatment of Raw Agricultural Commodities in a Food Processing Facility—whether applied directly or applied to process water

a) Jurisdiction: EPA and FDA

b) EPA registration required

c) Clearance: Food Additive Regulation

4. Consumer Treatment of Raw Agricultural Commodities—whether applied directly to RAC or applied to process water

a) Jurisdiction: EPA

b) EPA registration required

c) Clearance: None

5. Process Water Treatment of Processed Food or Direct Treatment of Processed Food

a) Jurisdiction: FDA

b) No registration required

c) Clearance: Food Additive Regulations

6. Process Water Treatment in a Food Processing Facility to Control a Pest in the Water.

a) Jurisdiction: EPA and FDA

b) EPA registration required

c) Clearance: Food Additive Regulations

7. Treatment of Animal Drinking Water

a) Jurisdiction: EPA

b) EPA registration required

c) Clearance: Tolerance

8. Production of Food Packaging Materials

a) Jurisdiction: EPA and FDA

b) EPA registration required

c) Clearance: Food Additive Regulations

9. Production of Food Contact Articles with an Intended Antimicrobial Effect on the Surface of the Finished Article (i.e., provides a bacteria free surface)

a) Jurisdiction: EPA

b) EPA registration required

c) Clearance: Tolerance

10. Production of Food Contact Articles with no Intended Antimicrobial Effect on the Surface of the Article (i.e., treated with an antimicrobial agent to extend the useful life of the product, but does not protect the user against food borne bacteria)

a) Jurisdiction: FDA

b) No registration required

c) Clearance: Food Additive Regulations

11. Dual Jurisdiction. In situations where both EPA and FDA have jurisdiction, both agencies assess the dietary risk, which may result in some complications in the approval of new products and ingredients.

a) FDA grants a clearance pursuant to the Food Additive Regulations

b) EPA reassesses the dietary risk prior to approving the product registration for a food use.

c) By law EPA's risk assessment must meet the safety standards of the tolerance provisions of the Federal Food, Drug and Cosmetic Act.

- FFDCA tolerance provisions require an additional 10-fold margin of safety for infants and children.

- EPA must assess based on aggregate exposure including all anticipated dietary exposures and all other exposures for which there is reliable information.

d) While FDA has provided for an "expedited review" of food additive petitions for substances designed to decrease the risk of foodborne illness. However, EPA's risk assessment process is lengthier and may result in the delay or denial of the product registration.

12. Key Terms. The following sets forth definitions for certain key terms used above.

a) Food Processing Facility—Includes those facilities where food is subject to activities that constitute processing. The term includes slaughtering or manufacturing facilities for meat, poultry, seafood and produce; retail facilities such as restaurants, grocery stores, and institutions.

b) Raw Agricultural Commodity—Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. RACs do not become processed food merely by the fact that it may be present in a food processing facility. Rather it becomes a processed food only if it is subjected to processing activities.

c) Processed Food—Processed food includes any food that is subjected to the following activities: canning, freezing, cooking, pasteurization or homogenization, irradiation, milling, grinding, chopping, slicing, cutting, or peeling. By contrast, the following activities do not constitute processing: washing, coloring, waxing, hydro-cooling, refrigeration,

shelling of nuts, ginning of cotton and the removal of leaves, stems and husks.

B. Non-Antimicrobial Cleaners

1. USDA/FSIS: Cleaning compounds and sanitizers must be safe and effective under the conditions of use. Documentation substantiating the safety of a product's use in a food processing environment must be available to FSIS inspectors.

2. FDA: Cleaning compounds and sanitizers shall be safe and adequate under the conditions of use.