I. Introduction

The Environmental Protection Agency (the Agency) codified twelve antimicrobial use patterns in 40 CFR part 158, subpart W (referred to as "Part 158W"). The Agency has developed an Antimicrobial Pesticide Use Site Index (USI) to provide guidance about the antimicrobial pesticide use sites associated with these antimicrobial pesticide use patterns. The USI is a guidance document to assist applicants in identifying the data that are necessary to support registration of products and to determine if labeled uses necessitate establishment of a tolerance or exemption from the requirement of a tolerance. As noted in 40 CFR Section 158.100(d), the USI will be updated periodically, as needed.

The association of a particular antimicrobial use site with an antimicrobial pesticide use pattern should be viewed as a recommendation only and is not to be construed as binding on either EPA or any outside parties. EPA may depart from the guidance where circumstances warrant and without prior notice.

Pesticide product labeling provides critical information about pesticide use sites, as well as how to safely and effectively handle and use pesticide products. In order to ensure no unreasonable adverse effects on human health or the environment, FIFRA and its regulations require, among other things, that product labeling specifically states where and how a pesticide is intended to be used. Where a pesticide is to be used is generally referred to as the "pesticide use site." For antimicrobial pesticides, the use sites are diverse and constantly evolving as new products are developed. The USI serves as a guide to the general types of use sites that are commonly listed on antimicrobial labels. It is not intended as an exhaustive list of all possible antimicrobial use sites. The use sites are organized into twelve use patterns which are used to delineate data requirements in Part 158W.

Furthermore, the use sites associated with the twelve use patterns are organized into three food use categories: direct food uses, indirect food uses, and nonfood uses. A number of the data requirements in subpart W depend on this categorization. The categorization is dependent on the context of the label and a determination of whether residues of the pesticide product have the potential to come into contact with food, either directly or indirectly. For example, within the use pattern *Residential and Public Access Premises*, the use site of *Household/Domestic Dwellings* is listed under both the indirect food use subcategory as well as the nonfood use subcategory. Specifically, there are two use sites: *Household/Domestic Dwellings (food handling areas),* listed under "indirect food," and *Household/Domestic Dwellings (non-food handling areas),* listed under "nonfood". This reflects the fact that within the use site category of *Household/Domestic Dwellings*, there is a potential for indirect food contact for some uses (e.g., if a product is labeled for use on kitchen countertops), but there are also uses within this category that would be considered nonfood (e.g., a product labeled for use as a toilet bowl disinfectant). The categorization of the use sites on the product label determines whether or not certain data requirements must be addressed.

To aid applicants, the descriptions of the food use categories, direct food, indirect food, and nonfood are listed below. Food has the same meaning as the Federal Food, Drug, and Cosmetic Act at 21 U.S.C. § 321(f): (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

Direct Food Use

A use is generally considered to be a direct food use if an antimicrobial pesticide is intended to be directly applied to food or applied to a material or article for the purpose of treating food. Use sites that fall into this category include, but are not limited to: fruit and vegetable rinses, fogging of poultry areas, and egg washing treatments. These types of uses are generally subject to a FFDCA clearance.

Indirect Food Use

A use is generally considered to be an indirect food use if the use involves application of the antimicrobial pesticide in or on a material or article that comes into contact with food and may result in residues in or on food, but the use is not intended for pesticidal treatment of food. As a result of contact with a surface and/or material that has been treated and/or impregnated with an antimicrobial pesticide, there is a potential for transfer of residues in or on food. Use sites that fall into this category include, but are not limited to: sanitization of food-contact dishes, utensils, food-processing equipment, and countertops; disinfection of food-use areas; and impregnation of cutting boards, conveyor belts, or food containers and/or packaging for a pesticidal purpose other than treating food (e.g., to protect the article itself from degradation by bacteria). These types of uses may be subject to a FFDCA clearance.

Nonfood Use

A use is generally considered to be a nonfood use if the antimicrobial pesticide is not expected to come into contact (directly or indirectly) with food as a result of its intended use and, therefore, there is no reasonable expectation of residues in/on food. Use sites that fall into this category include, but are not limited to: fuel tanks, human footwear, or nonfood areas (e.g., under the sink) of eating establishments. These types of uses are not subject to a FFDCA clearance.

II. How to Use this Use Site Index to Determine Data Requirements

The applicant should follow these basic steps for using the Use Site Index:

1. Look for use sites in the USI that are similar to your proposed uses.
2. Identify which of the use patterns applies to your proposed uses.
3. For ecological data requirements, consult the Nontarget Organism, Nontarget Plant Protection, and Environmental Fate Data Requirement Tables in Part 158W to determine data required for each use pattern. For example, Guideline Number 850.3020, Honeybee Acute Contact Data, are Required (R) for Wood Preservatives, Not Required (NR) for Industrial Processes and Water Systems and Antifoulant Paints and Coatings, but Conditionally Required (CR) for the All Other Use Pattern Categories.
4. For human health (toxicology and residue chemistry) data requirements, determine the food use category of your proposed uses by:
    a. Identifying whether your proposed use sites are characterized as “direct food”, “indirect food”, or “nonfood” based on the designation of the similar use sites listed in the USI.
    b. Applying the guidance in Section III (Figure 1. Food Use Description Flow Chart) to the proposed uses to determine whether a dietary assessment and/or tolerance/tolerance exemption is needed.
5. For exposure data requirements, consult the Antimicrobial Applicator Exposure Data Requirements table and the Antimicrobial Post-Application Exposure Data Requirements tables to determine the data required according to whether the use pattern is associated with occupational or residential exposure.

III. How to Determine Required FFDCA Clearances

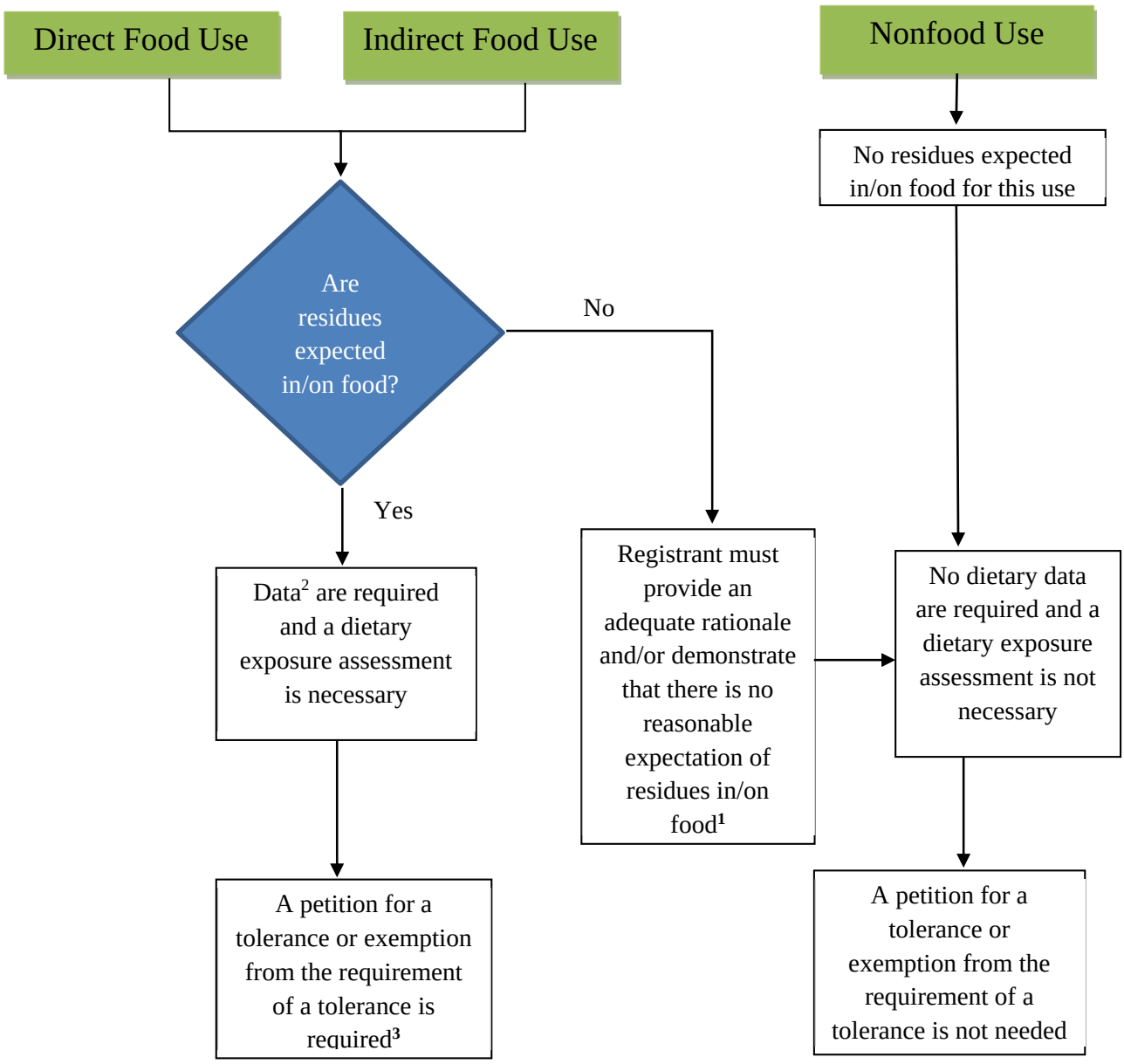
This USI provides guidance on whether a use site on a product label will necessitate establishing a tolerance or tolerance exemption (see Figure 1).

FFDCA clearances will be required where there is a reasonable expectation of residues in or on food as a result of application (either directly or indirectly) of the pesticide to food and the food moves in interstate commerce. For a substance that meets the definition of "pesticide chemical residue" under FFDCA section 201(q), a tolerance or exemption from the requirement of a tolerance will be required; for a substance that is excluded from that definition, the US Food and Drug Administration (FDA) may need to issue a food additive regulation or food contact notification. Regardless of the classification under 201(q), residues of pesticides in or on foods will cause foods to be considered adulterated and subject to seizure if appropriate FFDCA clearance(s) are not in place (i.e., a tolerance, tolerance exemption, FDA food additive regulation, and/or food contact notification (FCN)). See 21 U.S.C. §§ 334, 342, 346a, and 348.

EPA has made it a requirement of FIFRA registration that, if a pesticide bears directions for use on food or may be reasonably expected to result in residues on food which moves in commerce, all necessary FFDCA clearances must be in place. 40 C.F.R. § 152.112(g). Because direct food use pesticides, by definition, contain label directions for use on food, all necessary clearances under the FFDCA must be in place to obtain FIFRA registration. Because indirect food uses are generally considered to have a reasonable expectation for residues on food, all necessary clearances under the FFDCA also must be in place to obtain a FIFRA registration. However, EPA will not require that FFDCA clearances be obtained for indirect food uses if an applicant can demonstrate that the use(s) of a particular product do not have a reasonable expectation of resulting in residues on food. No FFDCA clearances are required for nonfood uses because there is no reasonable expectation of residues on food for these uses.

Figure 1 below assumes that a determination under FFDCA section 201(q) has been made and the residues in/on food would meet the definition of pesticide chemical residues. Therefore, EPA would have jurisdiction under FFDCA section 408 to determine if a tolerance or exemption from the requirement of a tolerance is needed. For residues that do not meet the definition of "pesticide chemical residue" and are under the jurisdiction of FDA under FFDCA section 409, EPA still must make a safety finding by conducting any appropriate dietary exposure assessments if the residues result from the use of FIFRA-registered pesticides. This flow chart is not designed to delineate jurisdiction under FFDCA between EPA and FDA.

Figure 1. Food Use Description Flow Chart



[1] Examples of rationale include but are not limited to:

- Data and/or scientific rationale used to support FDA food additive regulation or FCN;
- Theoretical high-end calculations/modeling demonstrating that there is no reasonable expectation of residues in/on food;
- Data or scientific rationale for residue removal via a potable water rinse;
- Label restrictions limiting exposure to food;
- Rationale on product chemistry and/or environmental fate characteristics (i.e., volatility, solubility); or
- Residue data

[2] In this context, the word "data" refers to any data to satisfy 40 CFR Part 158W data requirements (e.g., residue chemistry and toxicity data).

[3] Uses from strictly residential products do not require a tolerance or tolerance exemption.

IV. Use Site Index

Food Uses		Nonfood Uses
Direct Food Uses	**Indirect Food Uses**	
1. Agricultural Premises and Equipment		
–Irrigation Systems (Food crops)	–Animal Drinking Water –Animal Premises/Structures/Buildings/ Equipment (animals, food/feed, or drinking water are present during treatment) –Beehives (honey producing) –Dairy Farm Milk Handling (milking equipment and milk storage tanks) –Empty Containers or Equipment to Be Used for Raw Agricultural Commodities –Facilities/Equipment (crop harvesting and food contact surfaces) –Fish Hatchery Buildings/Areas (nonaquatic) –Food/Feed Storage Premises (unpackaged food/feed) –Greenhouses (food crops)	–Agricultural/Farm Premises/Structures/Buildings/ Equipment (animals, food/feed, and drinking water not present during treatment) –Beehives (non-honey producing, such as leaf cutter bees, alkali bees, bumble bee pollinators) –Egg Handling Equipment/Rooms/Washing/Treatments (Hatching) –Food/Feed Storage Premises (packaged food/feed, except for fumigant uses designed to penetrate the packaging) –Greenhouses (Nonfood crops) –Irrigation Systems (Nonfood crops) –Shoe Baths –Tobacco Processing Plant Premises/Equipment
2. Food Handling/Storage Establishments, Premises and Equipment		
–Egg Washing Treatments –Fruit and Vegetable Treatments	–Dairies/Cheese Processing Plant Premises/Equipment –Dishwashing Water –Eating Establishments/Equipment/Utensils/Food Handling/Serving Areas –Egg Handling Equipment/Handling Rooms/Packing Plants –Feed Mills/Food Processing Plants Premises and Equipment –Food Processing Water Systems –Transportation/Facilities/Barges/Railroad Cars/Commercial Shipping Containers	–Eating Establishments (Nonfood areas) –Food Processing Plant Premises/Equipment (Nonfood) –Hydrostatic Sterilizer Water Systems –Pasteurizer/Warmer/Cannery/Retort Water Systems
3. Commercial, Institutional and Industrial Premises and Equipment		
Not Applicable	Not Applicable	–Barber/Beauty Shop Equipment/Instruments –Commercial Transportation Vehicles/Facilities –Heating, Ventilation, and Air Conditioning (HVAC) Systems –Laundry/Laundry Equipment –Premises/Equipment –Refuse/Solid Waste Transportation Facilities/Handling Equipment
4. Residential and Public Access Premises		
Fruit and Vegetable Treatments	–Household/Domestic Dwellings (Food Handling Areas such as kitchens)	–Air Treatments –Animal Kennels/Pet Living/Sleeping Quarters –Automobiles, Taxis, Limousines, Recreational Vehicles (RVs)

Food Uses		Nonfood Uses
Direct Food Uses	**Indirect Food Uses**	
		–Bathroom Premises and Surfaces –Clothing/Laundry –HVAC Systems and Humidifiers –Public Areas Contents/Premises –Household/Domestic Dwellings Contents/Premises (non-food handling areas such as bathrooms) –Paths/Patios/Paved Areas –Public Areas Contents/Premises –Refuse/Solid Waste Containers/Equipment/Facilities/Sites –Toilets (Urinals, Latrines, Water Closets)
5. Medical Premises and Equipment		
Not applicable	Not applicable	–Air Treatments –Ambulances –Hospitals/Medical Institutions (Human/Veterinary nonfood handling areas) –Critical and Noncritical items (patient care items and noncritical environmental surfaces) –Medical Waste –Morgues/Mortuaries/Autopsy/Embalming Room Premises/Equipment –Nursing Homes/Assisted Living Facilities (nonfood handling areas)
6. Human Drinking Water Systems		
Not applicable	Not applicable	–Dental water lines –Emergency Water Systems –Individual Water Systems (e.g., private water systems/well) –Public Water Systems –Premise plumbing systems –Reverse Osmosis Water Systems (hard, non-porous surfaces) –Water Purifier Units –Water tanks (e.g., water coolers, holding tanks, pressure tanks)
7. Materials Preservatives		
Preservative of pesticide formulations applied to growing crops or crops after harvest	–Adhesives/Coatings/Caulks (with potential to contact food) –Cleaning Products (kitchen food contact surfaces) –Dispersions/Emulsions/Solutions/ Suspensions (with potential to contact food) –Paper/Paperboard (with potential to contact food) –Plastic/Rubber Products (cutting boards, counter tops)	**Arts & Crafts Materials**, such as finger paints, crayons, colored chalk, pencils **Construction Materials**, such as adhesives/paints and coatings/caulks not in contact with food, wallboard, ceiling tiles, flooring, Heating/Ventilating/Air Conditioning (HVAC) system filters and other components, pipes (non-potable), mastics, joint compounds, grouting, cements, concrete admixes **Disposable Diapers** **Industrial Matrices**, such as metal working cutting fluids (MWFs), metal cleaning fluids, inks/dyes, fuels/oils,

Food Uses		Nonfood Uses
Direct Food Uses	**Indirect Food Uses**	
		dispersions/emulsions/solutions/suspensions, slurries/pastes/gels, fuel and oil storage tanks, recovery drilling muds/packer fluids, polymers, resins, rubber, fracturing fluids, injection, well squeeze, insulation, refuse containers, moulded articles **Nonfood pesticide formulations**, such as lawns, crack and crevice pesticides, rodenticides, and human and pet treatments (e.g., fleas, lice, scabies, pet collars) **Paper and Paperboard Nonfood Contact Materials** **Plastic and Rubber Nonfood Contact Materials**, such as barrier fabric, shower curtain, cable/wire insulation, non-food containers, moulded articles **Textiles**, such as clothing, footwear, bedding, cloth diapers, fibers, cordage, tarps, tents, awnings, auxiliaries (sizing/finishing agents), leather/hides, feathers, felt, carpets and padding, canvas, drapes, filters, shower curtains, rayon, yarn, cloth, insulation, wall and floor covering
8. Industrial Processes and Water Systems		
Not applicable	–Pulp/Paper Mill Water Systems (food contact paper)	–Air Conditioner/Refrigeration Condensate Water Systems –Air Washer Water Systems –Bilge Water –Coal Slurry Systems –Commercial/Industrial Cooling Water Systems[Recirculating/Once Through] –Evaporative Condenser Water Systems –Gas/Oil Equipment/Fluids –HVAC Systems –Industrial Processing Water/Fluid Systems –Industrial Waste and Waste Water Systems –Industrial Drainage Systems –Influent Water Filtration Systems –Industrial Scrubbing System –Pulp/Paper/Textile Mill Water Systems (e.g., newspaper print, magazine print) –Reverse Osmosis Water System (Non potable water)
9. Antifoulant Paints and Coatings		
Not applicable	–Nets Used for Aquaculture	–Ballast Water Treatments –Aquatic Vessel Coatings –Aquatic Structures/Equipment –Crab/Lobster Pots

Food Uses		Nonfood Uses
Direct Food Uses	**Indirect Food Uses**	
10. Wood Preservatives		
Not applicable	Packing, transporting, or holding containers for raw agricultural commodities made from treated wood as per 21CFR178.3800	**Above Ground**, including trusses, millwork, siding and trim; furniture, decking, railings, flooring, fence pickets, and grape trellises, etc. **Ground Contact**, including fence, deck and guardrail posts, crossties, permanent wood foundations, buildings poles, posts, utility poles, ties, freshwater piling, raised garden beds **Marine Use**, including piling, bulkheads, bracing
11. Swimming Pools and Spas		
Not applicable	Not applicable	–Spa and Hot Tub Water Systems –Swimming Pool Water Systems –Water Parks Water Systems
12. Aquatic Areas		
Commercial Fishery Water Systems	Agricultural Drainage Systems Intermittently Flooded Areas/Water (rice paddies, cranberry bogs)	–Lakes/Ponds/Reservoirs –Ornamental Ponds/Aquaria –Salt Water Sites –Streams/Rivers/Channeled Water