

Antimicrobial Food Additives

Guidance

Written comments may be submitted at any time to the Dockets Management Branch, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Such comments will be considered when determining whether to amend the guidance. For questions regarding the use or interpretation of this guidance, contact Mark Hepp, (202) 418-3098, MHepp@bangate.fda.gov

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Antimicrobial Food Additives - Guidance

1. Purpose

This document is intended to clarify FDA's jurisdiction over antimicrobials that are used in or on food, including those used in or on edible food, in water that contacts edible food, and those used in the manufacture of, or in or on, food-contact articles, subsequent to the enactment of the Food Quality Protection Act of 1996 (FQPA), and the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA).¹

2. Introduction and Scope

The FQPA became law on August 3, 1996. FQPA amended both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Federal Food, Drug, and Cosmetic Act (FFDCA). Among other things, FQPA changed the definitions of "*food additive*" (sec. 201(s)) and "*pesticide chemical*" (sec. 201(q)) in FFDCA. These changes had a significant impact on the regulatory authority for many antimicrobial products that are used in food-contact applications. Specifically, under FQPA certain food-contact antimicrobials, previously regulated by FDA as food additives under section 409 of FFDCA, were to be regulated by EPA as "*pesticide chemicals*" under section 408 of FFDCA. These products included antimicrobials used in or on food packaging, such as slimicides used in the manufacture of food-contact paper, materials preservatives used in the manufacture of food packaging and other food-contact articles, and those products intended to provide a sanitizing effect on food-contact surfaces. Prior to FQPA, these products were subject to registration by EPA under FIFRA as pesticides, and subject to regulation by FDA under FFDCA as food additives. Subsequent to FQPA such products were still subject to registration as pesticides under FIFRA, but their residues in food were subject to a tolerance or exemption from tolerance established by EPA under section 408 of FFDCA, and no longer subject to regulation by FDA as a food additive.

ARTCA, enacted on October 30, 1998, amended the definition of a "*pesticide chemical*," under section 201(q), and the transitional provisions under section 408(j) of FFDCA. ARTCA in part corrected the

¹ This document represents the Agency's current thinking on FDA's jurisdiction over antimicrobial substances used in or on food or food contact substances. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

unintended transfer of regulatory authority, from FDA to EPA, that resulted from the passage of FQPA, for certain food-contact antimicrobials. Specifically, ARTCA reestablished FDA's traditional regulatory authority for certain antimicrobials that are used in or on food-contact articles. ARTCA also provided FDA with new authority to regulate, as food additives under section 409 of FFDCA, antimicrobials on certain raw agricultural commodities (RACs). Under ARTCA, EPA retains regulatory authority over most antimicrobial uses on RACs and permanent or semipermanent food-contact surfaces, and acquires all food uses of ethylene oxide and propylene oxide. Finally, ARTCA provided a transitional provision to ensure that regulations for antimicrobial substances, issued subject to EPA's regulatory authority under section 408 of FFDCA pre-ARTCA, which were transferred to FDA's regulatory authority under section 409 of FFDCA post-ARTCA, were deemed to have been issued under section 409, post-ARTCA.

This document is intended to clarify FDA's jurisdiction over antimicrobials, after passage of ARTCA, that are used in food or that may become a component of food as a result of their intended use. The food-related uses of antimicrobial products that have been specifically excluded from FDA's regulatory authority by ARTCA are also discussed. In addition, consistent with the interpretation stated in the Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances (63 FR 54541, October 9, 1998; hereafter "Notice of Policy Interpretation"²) this document provides guidance on the meaning of the term *processed food* under FIFRA, and the phrase "*preparing, packing, or holding of the food for commercial purposes*" (hereafter, the location of such activities is referred to as a "*food processing facility*") which are important in delineating the jurisdiction of FDA and EPA over antimicrobial substances. Also described is the regulatory authority relating to the inert ingredients of certain pesticide formulations which authority may be transferred, by EPA, to FDA to regulate as food additives. Finally, antimicrobial substances that are exempt from the definition of "*pesticide chemical*" but which may require pesticide registration under FIFRA are discussed.

3. FDA Jurisdiction and Authority Regarding Food Additives, General

2 Although ARTCA supersedes the Notice of Policy Interpretation with respect to FFDCA regulatory authority over antimicrobial substances used in food and as food contact substances, ARTCA does not supersede the interpretation of the term "*processed food*" in FIFRA that was addressed in the Notice.

The FFDCa prohibits the introduction, or delivery for introduction, into interstate commerce of any food that is “*adulterated*” (FFDCa section 301(a)). Food is deemed adulterated, among other reasons, “if it is, or it bears or contains, any *food additive* which is unsafe within the meaning of section 409” (FFDCa section 402(a)(2)(C)). FDA has regulatory authority over food additives under section 409 of the FFDCa. Under section 409 of the FFDCa, a substance is deemed to be an unsafe food additive unless such substance is generally recognized as safe (GRAS) under the intended conditions of use, conforms to the terms of an exemption for investigational use, conforms to a food additive regulation, is exempted from regulation as a food additive under § 170.39, or, in the case of food-contact substances (FFDCa section 406(h)), there is a notification submitted under section 409(h) that is in effect. Food additive, and other food ingredient regulations provide the identity, specifications and conditions of safe use for a substance that results or may reasonably be expected to result directly or indirectly in its becoming a component or otherwise affecting the characteristics of any food as a result of its intended use. They are listed in parts 172 to 186 of Title 21 of the Code of Federal Regulations (CFR).

The definition for “*food additive*” (FFDCa section 201(s)) specifically excludes “*a pesticide chemical*” and “*a pesticide chemical residue in or on a raw agricultural commodity or processed food*” and thus, they are excluded from regulation under section 409. Instead, pesticide chemicals and pesticide chemical residues in or on such food must conform to a tolerance, or an exemption from tolerance, as established by EPA under section 408 of the FFDCa. Pesticide tolerances or exemptions from a tolerance although established by EPA, are enforced by FDA. Such tolerances or exemptions are listed in 40 CFR 180-185. Thus, EPA and FDA have complementary responsibilities under FFDCa for pesticide chemicals and residues of such chemicals in food, i.e., EPA establishes a tolerance, or exemption from tolerance, and FDA enforces the tolerance or exemption. However, no such complementary responsibilities exist under FFDCa for antimicrobial substances that are food additives under FFDCa, where a tolerance or exemption from tolerance would not be applicable. Certain of these “*food additive*” antimicrobial substances i.e., those intended to control microorganisms on raw agricultural commodities or in water, when used in a food processing facility, may be subject to EPA’s regulatory authority under FIFRA as a “*pesticide*” and thus would be subject to pesticide registration.

4. Food Additive Uses of Antimicrobial Substances under FFDCa, as Amended by ARTCA

Antimicrobial uses that may result in residues in or on food can be divided among two categories: uses where the intended antimicrobial effects are on edible food, or in water that comes into contact with such

food, and uses of food-contact substances. At this time there are uses in both categories that fall within FDA's authority to regulate as food additives under section 409 of FFDCA and other uses that fall within EPA's authority to regulate as pesticide chemicals under section 408 of FFDCA. This section describes in detail those uses post-ARTCA that are regulated by FDA under section 409 as food additives and certain other uses that are specifically excluded from regulation as food additives.

Antimicrobials used directly in or on food

FDA's regulatory authority, under section 409 of FFDCA, over antimicrobial substances that are used to mitigate a FIFRA "pest" in or on edible food in a food processing facility, in part, is subject to the statutory exclusions to the definition of "pesticide chemical" under section 201(q)(1)(B)(i) of FFDCA, as amended by ARTCA. In addition, FDA's regulatory authority over processed food uses of such antimicrobial substances also results from EPA's current statutory and regulatory exceptions to the definition of "pest."³

Excluded from the definition of "pesticide chemical" under 201(q)(1)(B)(i) of the FFDCA, as amended by ARTCA, are antimicrobial substances applied on food, or added to water that comes into contact with the food in the preparing, packing, or holding of food for commercial purposes. Such uses are subject to regulation as food additives under section 409 of FFDCA. Under FIFRA, a microbe in or on "processed food" (within the meaning of that term in 40 CFR 152.5) is not a "pest," and therefore the antimicrobial substance used to mitigate such a microbe is not a "pesticide" under FIFRA, and consequently, not a "pesticide chemical" under FFDCA.⁴ Thus,

3 Excepted from the definition of "fungus" under section 2(k) of FIFRA, are non-chlorophyll-bearing thallophytes on or in processed food. Therefore, such microbes are excepted from the definition of "pest" under section 2(t) of FIFRA (which definition includes "fungus"). Excepted from "pest" in 40 CFR 152.5 are any fungus, bacteria, virus, or other microorganism on or in processed food. Antimicrobials that are directed against such microbes that are not "pests" are not "pesticides" under section 2(u) of FIFRA, and consequently, are not "pesticide chemicals" under section 201(q) of FFDCA.

4 An exception to this is the use of ethylene oxide and propylene oxide on processed food. Under section 201(q)(1)(A) of FFDCA, as amended by ARTCA, a FIFRA "pesticide" includes ethylene oxide and propylene oxide when such substances are applied on food. This provision expanded EPA's jurisdiction, post-ARTCA, over the use of ethylene oxide and propylene oxide on processed food, under both FIFRA as a pesticide, and FFDCA as a pesticide chemical.

antimicrobial substances that are excluded from “pesticide chemical” under section 201(q)(1)(B)(i), given EPA’s current statutory and regulatory scheme, include those antimicrobial substances that are intended to control microorganisms on raw agricultural commodities or in process water where food is prepared, packed, or held for commercial purposes.⁵

Whether a food would be subject to the statutory or regulatory exceptions to “pest” under FIFRA, would depend upon whether the food is a “processed food” under FIFRA. Moreover, an understanding of how FDA and EPA have interpreted the term “processed food,” as distinguished from the term “raw agricultural commodity,” based on whether specific food handling activities constitute “processing,” is important in ascertaining whether a food is “prepared, packed, or held for commercial purposes” within the meaning of 201(q)(1)(B)(i).⁶ ARTCA included certain applications of antimicrobial substances on raw agricultural commodities and in water that contacts such commodities within the definition of “pesticide chemical,” provided that these applications are in the field, in a treatment facility where only RACs are treated and the status of the commodity remains unchanged, and during transportation between the field and such a treatment facility. Treatments in such a facility may include washing, waxing, fumigating, or packing of RACs. Food handling activities that determine whether a food is “processed” within the meaning of 40 CFR 152.5, or “prepared, packed or held” within the meaning of 201(q)(1)(B)(i), are described in more detail below in section 7.

Food-contact substance Antimicrobials

A food contact substance is any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food, if such use is not intended to have any

5 To the extent that the intended use of the antimicrobial substance is to mitigate a “pest” (as defined under section 2(t) of FIFRA) in the water itself to which either raw agricultural commodities or processed food are added, or to mitigate a “pest” on a raw agricultural commodity, the petitioner should consult with EPA to determine whether a pesticide registration is required under FIFRA.

6 Antimicrobial substances intended to control microbes in or on processed food are not pesticides under FIFRA because such microbes are not “pests” within the meaning of FIFRA. What constitutes a processed food within the meaning of FIFRA and the regulatory exemption under 40 CFR 152.5 as the result of EPA and FDA consultations is discussed later in this guidance.

technical effect on such food. (FFDCA section 409(h)(6)). Such substances may be used as a component of cutting boards, conveyor belts, and food packaging. Under section (201(q)(B)(ii)) of ARTCA food-contact substances are excluded from the definition of a “*pesticide chemical*” in the following circumstances: 1) When the substance is included for an antimicrobial use in an object that has a food-contact surface but, a) has no intended ongoing effect on any portion of the object, or b) has an intended ongoing antimicrobial effect on a portion of the object other than the food-contact surface and; 2) when the antimicrobial is used in or on food packaging, without regard to whether the antimicrobial is intended to have an ongoing effect on any portion of the package. Such substances include production aids, materials preservatives, as well as substances that, if they are applied to or incorporated in food packaging, have a sanitizing effect.

Food-contact substances (other than components of food packaging) with no intended ongoing effect on any portion of the object.

These substances are often referred to as nonfunctional components because they are not intended to function in the finished food-contact article. Such antimicrobial products are generally production aids used to control the growth of microorganisms in the equipment and materials used to manufacture food-contact articles. Examples include papermill slimicides, and antimicrobials used as preservatives in the production of rubber latices and water-based adhesives and coatings. Generally, the finished food-contact article contains too little moisture to support microbial growth, and thus there is no need for the substance to function in the finished article. Because these substances are used in the manufacture of the food-contact article, they are unavoidably incorporated into the finished product, and thus may migrate to food. These nonfunctional food-contact substances are excluded from the definition of *pesticide chemical* and thus are regulated as food additives by FDA.

Food-contact substances (other than components of food packaging) intended to have an ongoing effect on any part of the object *except the food-contact surface*.

FDA refers to such substances as materials preservatives. Materials preservatives are sometimes incorporated into food-contact articles to protect the finished product from discoloration, degradation or decomposition due to microbiological activity. These substances differ from surface active antimicrobials, e.g., sanitizing solutions, in that they are not intended to control microorganisms contaminating the surface of the object, or possibly the food contacting the object. Substances in this category include antimicrobials incorporated into polymeric resins used to manufacture food-contact articles, or antimicrobials

incorporated into coatings applied to conveyor belts or other food-contact articles, *when they are intended only to preserve the article itself*, and not to mitigate microbes contacting the finished article. Such antimicrobial materials preservatives which have an intended ongoing effect on part of the food-contact article, but not on the surface of the article, are excluded from the definition of *pesticide chemical* and thus are regulated as food additives by FDA.

Antimicrobials included in, or applied to, food packaging without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging.

Under section 201(q)(1)(B)(ii) of FFDCFA, as amended by ARTCA, all uses of antimicrobials in or on food packaging are food additive uses. Packaging materials include bulk food storage containers, paperboard cartons, plastic or paper food wraps, jars, and bottles. Examples of antimicrobial uses include surface sanitizing solutions for milk bottles, hydrogen peroxide solutions that are used to sanitize packages used in the aseptic packing of milk and fruit juices, and antimicrobials impregnated into food packaging to protect either the package, or to extend the shelf life of the food. Antimicrobials applied to, or included in, food packaging materials are excluded from the definition of *pesticide chemical* and thus are regulated as food additives by FDA, regardless of whether the antimicrobial is intended to have an ongoing effect on any portion of the packaging.

5. Pesticide Chemical Uses of Antimicrobial Substances under FFDCFA, as Amended by ARTCA

ARTCA specifically excludes from FDA's regulatory authority, food-contact substances that are intended to exert an antimicrobial effect on the semipermanent or permanent food-contact surface, other than packaging, of an object that has such surface. This includes antimicrobial products that are applied to the surface of food-contact articles such as sanitizing solutions, as well as those incorporated into such articles to achieve an ongoing antimicrobial effect on the surface of the article.

Food-contact substances intended to exert an antimicrobial effect that are applied to a semipermanent or permanent food-contact surface, other than food packaging.

Antimicrobial solutions are often applied to counter tops, table tops, food processing equipment, cutlery, dishware or cookware, to sanitize such objects after they have been washed. Under section 201(q)(1)(B)(ii) of FFDCFA, as amended by ARTCA, such antimicrobial substances are included in the definition of "pesticide chemical" and therefore, are subject to regulation by EPA under section 408. However, any antimicrobial substances used to sanitize food packaging materials are excluded from

“pesticide chemical” under such section and therefore are food additives subject to regulation by FDA under section 409 of FFDCFA.

Food-contact substances intended to exert an ongoing antimicrobial effect on a semipermanent or permanent food-contact surface, other than the surface of food packaging.

This category of antimicrobial substances are used in cutting boards, conveyor belts and other articles that are used in the processing of food. The impregnated antimicrobial is intended to exert a sanitizing effect on the semipermanent or permanent food-contact surface of the food-contact article (other than food packaging). Under section 201(q)(1)(B)(ii) of FFDCFA, as amended by ARTCA, antimicrobials intended to control microorganisms on the semipermanent or permanent food-contact surface of food-contact articles, other than food packaging, are subject to regulation by EPA under section 408 as pesticide chemicals.

Because an inert ingredient in such a food-contact article other than food packaging is part of a pesticide formulation, such an inert ingredient would ordinarily be regarded as a “*pesticide chemical*” under section 201(q)(1)(A) of FFDCFA, as amended by ARTCA. Normally EPA would establish a tolerance or an exemption from the requirement of a tolerance under FFDCFA sec. 408 for such an inert ingredient. However, it is expected that the the food-contact article containing an impregnated antimicrobial would be manufactured by adding antimicrobial active ingredients to other ingredients (i.e. food additives) already in compliance with the applicable food additive regulations. Thus, all of the inert ingredients in such antimicrobial food-contact articles would likely already be regulated, or otherwise permitted by FDA, under FFDCFA sec. 409. Accordingly, FDA and EPA have agreed that EPA would consider, on a case-by-case basis, excepting such inert ingredients from the definition of pesticide chemical under section 201(q)(3) of FFDCFA, as amended by FQPA. If so excepted, such inert ingredients would be regulated as food additives under section 409 of FFDCFA.

6. Food additive uses subject to pesticide registration under FIFRA

By definition, a substance that is a pesticide chemical under section 201(q) is a “pesticide” within the meaning of FIFRA (section 201(q)(1)(A) of FFDCFA, as amended by ARTCA), and not a “*food additive*.” Such pesticide chemicals are subject to pesticide registration under FIFRA. As discussed earlier, there are exceptions to the definition of a “*pesticide chemical*” under section 201(q)(1)(B), which exceptions are subject to regulation as food additives under section 409. However, under section 201(q)(1)(B) of

FFDCA, as amended by ARTCA, such substances that are excepted from “*pesticide chemical*” are not excepted from the definition of a “*pesticide*” under FIFRA. Consequently, such substances that still meet the definition of a pesticide under FIFRA (even though, under FFDCA, they may be regulated as food additives), are subject to registration under FIFRA.

7. Processed Food and Food Processing facility

This section provides guidance on the terms “*processed food*” and “*food processing facility*,” terms that are important in defining the jurisdiction of FDA and EPA over antimicrobial substances. FDA and EPA have agreed that the following post-harvest activities do not constitute processing, and that food subjected to these activities would not be considered processed food: washing, coloring, waxing, hydro-cooling, refrigeration, shelling of nuts, ginning of cotton, and the removal of leaves, stems, and husks. FDA and EPA have agreed that the following activities constitute processing and that any food subjected to these activities becomes a “*processed food*,” (within the meaning of that term in 40 CFR 152.5): canning, freezing, cooking, pasteurization or homogenization, irradiation, milling, grinding, chopping, slicing, cutting, or peeling.

As stated in the Notice of Policy Interpretation, in determining which operations would be considered processing, for the purposes of delineating jurisdiction over antimicrobial substances, EPA considered how such actions or operations are categorized, either explicitly or implicitly, in FFDCA or its legislative history. For example, FFDCA defines a “*raw agricultural commodity*” as “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” (FFDCA 201(r)). This definition explicitly categorizes washing and coloring as non-processing operations and implicitly categorizes peeling as processing.

Similarly, the statute expressly lists several operations as qualifying as processing including canning, cooking, freezing, dehydration, or milling (FFDCA 201(gg)); see FFDCA section 402(a)(2)(C) (1990). From these examples, EPA extracted the following guiding principle: processing operations are those that alter the general state of the commodity, while non-processing operations, like harvesting, are designed only to isolate or separate the commodity from foreign objects or other parts of the plant.

EPA has issued a policy statement under the FFDCA interpreting the term “*raw agricultural commodity*,” and by inference “*processed food*,” for foods that have been subjected to drying (61 FR

2386, January 25, 1996) (FRL-4992-4). Briefly, the policy states that a “*raw agricultural commodity*” becomes a “*processed food*” when it is dried, unless the purpose of the drying is to facilitate transportation or storage of the commodity prior to processing. As a practical matter, this policy means that some vegetables and fruits, such as grapes, become processed food when the commodity is dried. Other commodities, such as hay, nuts, rice, beans, corn, other grasses, legumes, and grains, remain raw agricultural commodities even though they may have undergone some drying. EPA stated, in the Notice of Policy Interpretation, that it believes that the distinction set forth in this prior FFDCA interpretation is reasonable and intends to follow it in implementing the term “*processed food*” under FIFRA.

The term “*food processing facility*,” as used in this guidance, includes those facilities where food is subject to activities that constitute *processing*. When foods are subject to food handling activities that constitute *processing* such food would be processed food, within the meaning of 40 CFR 152.5(d). Consequently, an antimicrobial used in or on such processed food would not be a “*pesticide*” under FIFRA or a “*pesticide chemical*” under FFDCA and instead would be subject to regulation by FDA as a food additive. Such antimicrobials would not be subject to any exemption from “*pesticide chemical*” under section 201(q) of FFDCA. However, some foods, such as raw agricultural commodities (RACs), may be subject to certain food handling practices that would not, for purposes of this guidance, constitute “processing” activities, even though such commodities are handled in locations where food is prepared, packed or held for commercial purposes, i.e., in a “food processing facility.” Such commodities would, under section 201(q)(B)(i) of FFDCA, as amended by ARTCA, be subject to the exception to “pesticide chemical.” Consequently, the antimicrobial substances used to mitigate pests on such commodities either by adding such substances to the commodities directly or by adding such substances to water to which these commodities are added, would be subject to regulation as a food additive under section 409 of FFDCA and also subject to pesticide registration under FIFRA⁷. When RACs are subject to food

⁷ Antimicrobial substances used to mitigate microbiological organisms on processed food, by adding such substances to water to which the processed food is added, would be subject to regulation as a food additive and not be subject to regulation as a pesticide under FIFRA, to the extent that the intended use is to mitigate microbiological organisms only on the processed food and not to mitigate pests in the water itself. If the intended use of such substances is to mitigate pests in the water itself or includes the mitigation of pests in the water itself, to which processed food is added, such use is subject to regulation as a food additive, however, a manufacturer should consult with EPA to determine whether a pesticide registration is

handling practices that do not constitute “processing” activities in one of the enumerated locations under section 201(q)(1)(B) of FFDCA, as amended by ARTCA, where an antimicrobial is applied, i.e., in a field, at a treatment facility where only RACs are treated, e.g., subject to food handling practices that do not change their status as RACs, or during transportation between the field and such a treatment facility, such applications are pesticide chemical applications and are subject to a 408 tolerance or an exemption from the requirement of a tolerance under FFDCA and pesticide registration under FIFRA.

Included within the meaning of the term “*food processing facility*,” are those facilities where meat and poultry are slaughtered or otherwise processed subject to the Federal Meat Inspection Act, 21 U.S.C. 601 et seq., and Poultry Products Inspection Act, 21 U.S.C. 451 et. seq. Also included within that term are facilities where antimicrobials are used in egg washing or processing subject to the Egg Products Inspection Act, 21 U.S.C. 1301 et seq., provided that the eggs are treated in a manner that changes their status from RACs to processed food in such a facility. Finally, the term also includes fish processing operations, commercial fishing vessels, and retail food establishments.

Processing activities include most food handling activities, including those that are done to a carcass post-slaughter. Such activities include skinning, eviscerating, and quartering. Because such post-slaughter activities constitute *processing*, the meat that is subject to such activities is “processed food” within the meaning of that term in 40 CFR 152.5. Therefore, the regulatory status of antimicrobials that are used on meat after slaughter is unchanged by FQPA or ARTCA, and they remain subject to regulation by FDA as food additives. Similarly, seafood that is harvested is *processed*. Activities done post-harvest to seafood include, among other things, handling, storing, preparing, heading, eviscerating, shucking, or holding (21 CFR 123.3(k)(1)). Antimicrobials that are used in or on seafood, post-harvest, would also be subject to regulation by FDA as food additives. In summary, FDA's regulatory authority over the antimicrobial substances used on meat, poultry, and seafood remains unchanged because such uses constitute those that are on “processed food,” not raw agricultural commodities.

8. Summary

required.

ARTCA, in part, through changes to the definition of “*pesticide chemical*,” (FFDCA, sec. 201(q)), and the definition of “*food additive*” (FFDCA, sec. 201(s)), altered FDA’s and EPA’s regulatory authority over antimicrobial substances under FFDCA. The following list summarizes the antimicrobial uses that FDA regulates as food additives under FFDCA sec. 409.

Processed Food:

FDA regulates all antimicrobials used in or on *processed food* under FFDCA sec. 409, as food additives, except ethylene oxide and propylene oxide.

Raw Agricultural Commodities:

FDA regulates antimicrobial substances applied to RACs where food is prepared, packed, or held for commercial purposes.

This authority does not extend to antimicrobials applied 1) in the field, 2) at a treatment facility where RACs are the only food treated, and the treatment does not change the status of the food as a RAC (including washing, waxing, fumigating, and packing) and 3) during transportation between the field and such facility (described in 1 and 2).

Food Processing Water:

ARTCA clarifies that antimicrobials added to water in a food processing facility are subject to regulation as food additives, whether the water is to contact RACs or processed food. To the extent that the intended use of the antimicrobial substance is to mitigate a “pest” (as defined under section 2(t) of FIFRA) in the water itself to which either raw agricultural commodities or processed food are added, or to mitigate a “pest” on the raw agricultural commodity, the petitioner should consult with EPA to determine whether a pesticide registration is required under FIFRA.

Food-Contact Substances:

FDA regulates antimicrobial substances that are incorporated in objects that have a food-contact surface when the antimicrobial has no intended, ongoing effect in the finished article (nonfunctional components), and when the antimicrobial has an intended ongoing effect on part of the finished article, other than the article’s food-contact surface (materials preservatives). FDA regulates all antimicrobials incorporated in, or applied to, food packaging materials regardless of

whether the substance is intended to have an ongoing effect on any portion of the packaging.
FDA does not regulate antimicrobials that are incorporated in, or applied to, objects that have a semipermanent or permanent food-contact surface, other than food packaging, to provide a sanitizing effect on such surface.

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