DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[98N–0867]

ENVIRONMENTAL PROTECTION AGENCY

[OPP–300624; FRL–5773–8]

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

AGENCIES: Environmental Protection Agency (EPA) and Food and Drug Administration (FDA).

ACTION: Notice of policy interpretation.

SUMMARY: The Food Quality Protection Act of 1996 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 regulatory authority of both EPA and FDA with respect to the FFDCA's regulation of pesticide residues in or on food. This notice: (1) Sets forth legal and policy interpretations of the FFDCA as they relate to the jurisdiction of EPA and FDA over antimicrobial substances used in or on food, including food-contact articles; (2) discusses interpretations of certain terms in FIFRA and the implementing regulations relevant to the authority of the two agencies; (3) provides a description of how EPA and FDA propose to clarify the post-FQPA regulatory authority over certain antimicrobial substances; and (4) discusses how EPA and FDA plan to handle the review of petitions for antimicrobial substances that will remain under EPA's jurisdiction and for those that EPA proposes to return to FDA's regulatory authority through EPA rulemaking.

DATES: The policy set out in this notice is effective immediately. Both FDA and EPA will accept comments on this notice for 90 days from October 9, 1998.

ADDRESSES: Comments should be sent to both FDA and EPA dockets at the addresses listed below. Submit written comments identified by the appropriate docket number (for FDA 98N–0867 and for EPA OPP–300624) to:

FDA at: Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

EPA at: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to EPA: opp-docket@epamail.epa.gov. Follow the instructions under Unit VII. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Regarding EPA issues: William L. Jordan, Antimicrobials Division (7510W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (703) 308–6411.

Regarding FDA issues: Mark A. Hepp, Office of Pre-Market Approval Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St., SW., Washington, DC 20204-0002, Telephone: (202) 418–3098.

SUPPLEMENTARY INFORMATION:

Electronic Availability:

Internet

Electronic copies of this document and PR Notice 97P-1 are available from the EPA home page at the Federal Register-Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

Fax on Demand

Using a faxphone call 202–401–0527 and select item 6108 for a copy of the PR Notice and select item 6113 for a copy of this **Federal Register** notice.

EPA and FDA are issuing this joint notice to clarify, subsequent to the enactment of the Food Quality Protection Act of 1996 (FQPA), the jurisdiction over antimicrobials that are used in or on food, including those used in or on edible food, and those used in the manufacture of, or in or on, food-contact articles. In addition, the agencies are setting forth a proposed allocation of jurisdiction for these antimicrobials. Implementation of some of these decisions would require EPA rulemaking. Such rulemaking, if finalized as proposed, would reestablish FDA's regulatory authority over certain antimicrobial substances. Therefore, the agencies are presenting an interim plan to coordinate the review of petitions for the antimicrobial substances that would be affected by any proposed EPA rulemaking.

This joint notice is subject to FDA's good guidance practices (GGPs) Level 1 guidance (62 FR 8961, February 27, 1997). FDA will not solicit public input prior to implementation because the guidance presents a less burdensome policy that is consistent with the public health. This guidance does not create or confer any rights for or on any person and does not operate to bind FDA, EPA, or the public.

I. Legal Background

As described more fully below, EPA regulates the sale, distribution, and use of ''pesticides'' under FIFRA, 7 U.S.C. 136 *et seq*. Historically, EPA and FDA have shared regulatory authority under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 321 *et seq*. over the residues of such ''pesticides'' in or on food. The FQPA of 1996 amended FFDCA in ways that alter EPA's and FDA's jurisdiction over certain pesticides with antimicrobial uses.

A. EPA Jurisdiction and Authorities Under FIFRA

In general, FIFRA gives EPA authority to regulate the sale, distribution, and use of a ''pesticide.'' A ''pesticide'' is defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, . . .'' (FIFRA section 2(u)). The term ''pest'' includes ''(1) any insect, rodent, nematode, fungus, weed, or (2) any . . . virus, bacteria, or other microorganism which the Administrator declares to be a pest'' (FIFRA section 2(t)). As a result of these broad definitions, EPA regulates, as FIFRA pesticides, a wide variety of chemical substances marketed for a diverse array of uses. For example, EPA regulates, as pesticides, substances used to control weeds and fungi on crops, and microorganisms that may be present on permanent or semi-permanent surfaces, such as counter tops and food processing equipment that may come in contact with food.

It should be noted that FIFRA defines ''fungus'' as ''any non-chlorophyll-bearing thallophyte . . . as for example . . . mildew, mold, yeast, and bacteria . . .,'' but the definition specifically excludes those organisms when ''on or in processed food, beverages, or pharmaceuticals'' (FIFRA section 2(k)). Further, EPA has broadened this statutory exclusion in its FIFRA regulations at 40 CFR 152.5(d). Specifically, under this rule, an organism is not considered a ''pest'' if it is a ''fungus, bacterium, virus, or other microorganisms [sic] . . . on or in processed food or processed animal feed, beverages, drugs, . . . or cosmetics . . . .'' In applying this exclusion, EPA has historically interpreted the words ''processed food'' and ''processed animal feed'' as they are commonly understood--food that has undergone processing and is intended to be consumed immediately or after some further processing or preparation. Because the commonly understood meaning of these terms applies to edible food articles, EPA has not considered food-contact items (such as paperboard and ceramic ware) to be ''processed food'' within the meaning of that term in FIFRA and EPA's implementing regulations.[1] Thus, EPA has regarded any antimicrobial substance used in or on paper, paperboard, or other food-contact items as a ''pesticide'' under FIFRA.

With minor exceptions, no pesticide product may be sold or distributed unless EPA has licensed or ''registered'' the product (FIFRA section 12(a)(1)(A)). EPA registers products on the basis of data showing that the pesticide, when used in accordance with the terms and conditions of registration and in accordance with widespread and commonly recognized practice, will perform its intended function without causing ''unreasonable adverse effects on the environment'' (FIFRA section 3(c)(5)). Through registration, EPA regulates the composition, packaging, and labeling of pesticides. The labeling of a pesticide product includes information prescribing how a product may be used and generally contains directions specifying the sites on which the product may be used, the amount that may be applied, the frequency of application, and appropriate precautions necessary to reduce risks. It is unlawful to use a registered pesticide in a manner inconsistent with its labeling (FIFRA section 12(a)(2)(G)).

B. EPA and FDA Jurisdiction and Authorities Under FFDCA Prior to FQPA

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 a raw agricultural commodity and it bears or contains *a pesticide chemical* which is unsafe within the meaning of section 408(a); or 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)(B), (C) (emphasis added)). As discussed more fully below, prior to the enactment of FQPA, some FIFRA ''pesticides''--primarily agricultural chemicals--were ''pesticide chemicals'' under FFDCA; other FIFRA ''pesticides''--including antimicrobials--were ''food additives'' under FFDCA. Thus, pre-FQPA, both EPA and FDA had responsibilities under FFDCA for the regulation of residues in food resulting from use of substances considered ''pesticides'' under FIFRA. Each agency's pre-FQPA authority is described directly below. Section C in this unit explains the changes in each agency's authority brought about by FQPA.

1. *EPA jurisdiction and authorities.* Under Reorganization Plan 3 of 1970, which created the Environmental Protection Agency, EPA assumed the authority in FFDCA to set tolerances, and exemptions from the requirement of a tolerance, for ''pesticide chemicals'' (5 U.S.C. App. I, 84 Stat. 2086). At that time, the FFDCA defined a ''pesticide chemical,'' as ''any substance which . . . is a 'pesticide' within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u)) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities'' (FFDCA section 201(q), 21 U.S.C. 321(q) (1994) (amended 1996)). Thus, in addition to registering pesticides under FIFRA, EPA regulated the presence of the residues in food of FIFRA ''pesticides'' resulting from their use in or on raw agricultural commodities.

It is important to note that the definition of ''pesticide chemical'' in FFDCA was narrower than FIFRA's definition of ''pesticide,'' and therefore EPA had jurisdiction over residues in or on food for only some FIFRA pesticides. As a practical matter, EPA's authority under FFDCA extended only to pesticides used in agricultural production--e.g., weed killers, fungicides, growth regulators, and insecticides applied to growing crops and stored raw agricultural commodities.

In general, a ''pesticide chemical'' in or on a raw agricultural commodity was considered ''unsafe'' unless there was a tolerance or an exemption from the requirement of a tolerance for the pesticide chemical and the residue of the pesticide chemical conformed to the terms of the tolerance or exemption. See FFDCA section 408(a)(1), 21 U.S.C. 346a(a)(1) (1994) (amended 1996). A tolerance sets out the maximum amount of a residue that may legally remain on a particular food. For example, EPA established a tolerance of 0.05 parts per million (ppm) of the weed killer alachlor in peanuts. See 40 CFR 180.249. Any residue of alachlor over that amount would cause the peanuts to be adulterated. An exemption from the requirement of a tolerance represents a determination by EPA that any amount of residue of a specific pesticide chemical expected to be present in or on a raw agricultural commodity as a result of its use would be safe. For pesticides subject to a tolerance exemption, there is no numerical limit on the amount of permitted residue.

In its administration of FIFRA and FFDCA, EPA has adopted policies to ensure the coordinated application of both statutes. Specifically, EPA will not register a pesticide under FIFRA if its use is expected to result in residues in food unless such use complies fully with the FFDCA. See 40 CFR 152.112(g) and 152.113(a)(3).

2. *FDA jurisdiction and authorities.* FDA was (and remains) responsible for the regulation of ''food additives'' that are not ''pesticide chemicals.'' Prior to the FQPA, the definition of ''food additive'' included residues in food of certain FIFRA ''pesticides'' that were not FFDCA ''pesticide chemicals.'' The term ''food additive'' was defined as: ''any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized as safe . . . '' (FFDCA section 201(s) (1990) (amended 1996)). The definition of ''food additive'' specifically excluded a ''pesticide chemical in or on a raw agricultural commodity'' (FFDCA section 201(s)(1)(1990) (amended 1996)). Under this definition, the term ''food additive'' did not include pesticide chemicals in or on a raw agricultural commodity but did include pesticide chemicals in foods that were not raw agricultural commodities. EPA

[1]The discussion in the paragraph above, however, does not purport to interpret the FFDCA definition, but rather to address the meaning of the terms ''processed food'' and ''processed animal feed'' used in FIFRA and EPA's implementing regulations.

was responsible for the establishment of tolerances or food additive regulations under section 409 for pesticide chemical residues in food. FDA was responsible for the establishment of ''food additive regulations'' for all food additives except those that were also pesticide chemicals. FDA did set food additive regulations for food additives that were FIFRA pesticides, but not FFDCA pesticide chemicals.

As a practical matter, FIFRA pesticides that were regulated by FDA as food additives prior to FQPA were for antimicrobial uses. These FDA-regulated substances included products used as sanitizers and disinfectants for permanent or semi-permanent food-contact surfaces; as materials preservatives in products like adhesives, coatings, and latex solutions that could be used to manufacture food packaging materials or which could otherwise come into contact with food; and as slimicides added during the process of making paper and paperboard used to package food. In sum, for each of these categories, EPA registered antimicrobial substances as a pesticide under FIFRA for the food uses, only after FDA had made a determination that the use of the products were safe under section 409 of FFDCA.

Finally, FDA was (and remains) responsible for enforcement of all FFDCA pesticide tolerances and of food additive regulations. FDA can request seizure of a food or other enforcement action when a pesticide residue on food does not conform to an established tolerance or food additive regulation, or when there is no tolerance, exemption from the requirement of a tolerance, or food additive regulation in place.

C. Changes in EPA and FDA Authority Under FFDCA Resulting From FQPA

While FQPA made a number of changes to both FIFRA and FFDCA, this notice focuses only on changes that alter the regulatory responsibilities of EPA and FDA for establishing FFDCA section 408 tolerances, exemptions from the requirement for a tolerance, and food additive regulations with respect to antimicrobials. Specifically, this section discusses: FQPA definitions of ''pesticide chemical,'' ''pesticide chemical residue,'' and ''food additive''; the authority in FFDCA section 201(q)(3) to except substances from the definition of ''pesticide chemical''; the transition provisions in FFDCA section 408(j); and the new statutory standard in FFDCA section 408 for the establishment of a tolerance and an exemption from the requirement for a tolerance.

1. *Definitions of ''pesticide chemical,'' ''pesticide chemical residue,'' and ''food additive.''* FQPA redefined ''pesticide chemical'' in FFDCA to mean: ''any substance that is a pesticide within the meaning of FIFRA, including all active and inert ingredients of such pesticide'' (FFDCA section 201(q)(1)). Notably, this new definition eliminates the restriction in the pre-FQPA definition of ''pesticide chemical'' that the pesticide be used in the production, storage, or transportation of a raw agricultural commodity.

FQPA also amended the definition of ''food additive'' (FFDCA section 201(s)). The FQPA amendments did not affect the primary definition of ''food additive.'' As before, the term food additive is defined broadly and includes ''any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food. . . '' (FFDCA section 201(s)). However, the FQPA amendments did revise the food additive definition's exclusions. Specifically, the term ''food additive'' now excludes ''a pesticide chemical residue in or on a raw agricultural commodity or processed food'' (FFDCA section 201(s)(1)). As a result of these two changes, antimicrobial pesticides formerly regulated by FDA as ''food additives'' under section 409 of FFDCA, are now considered ''pesticide chemicals'' and regulated by EPA under section 408 of FFDCA .

FQPA also added a definition of ''pesticide chemical residue'' (FFDCA section 201(q)(2)). This term means any residue in or on food of a pesticide chemical or any other substance that results primarily from the metabolism or degradation of a pesticide chemical. This definition makes explicit the long-standing EPA interpretation that the term ''pesticide chemical'' includes the chemical compounds formed through the breakdown or metabolism of pesticidally active and inert ingredients in a pesticide formulation.

2. *Exception authority*. FQPA added a clause to the subsection defining ''pesticide chemical'' and ''pesticide chemical residue'' that gives EPA the authority, in certain circumstances, to ''except'' or exclude otherwise covered substances from these definitions (FFDCA section 201(q)(3)). Specifically, EPA may exclude a substance from the definition of a ''pesticide chemical'' or a ''pesticide chemical residue'' if EPA makes two findings: (1) The presence of the substance in a raw agricultural commodity or processed food is due primarily to natural causes or to human activities not involving the use of the substance for a pesticidal purpose in the production, storage, processing, or transportation of a raw agricultural commodity or processed food; and (2) after consultation with the Secretary of Health and Human Services, the substance is more appropriately regulated under provisions of the FFDCA other than section 402(a)(2)(B) and 408.

3. *Transition provision*. FQPA added a provision to the FFDCA to assure an orderly transition to the new regulatory system. All previously issued regulations under FFDCA section 406, 408, and 409, which authorized the presence in food of any substance that is a pesticide chemical residue, remain in effect unless modified or revoked (FFDCA section 408(j)). Thus, existing food additive regulations issued by FDA for antimicrobial substances that are pesticides remain valid, and food is not adulterated by residues of such substances that conform to the applicable food additive regulations.

4. *Statutory standard for section 408 tolerances and exemptions*. FQPA amended section 408 of FFDCA to establish a new standard for making decisions to establish tolerances or exemptions from the requirement of a tolerance for pesticide chemical residues. In order to establish or leave in effect either a tolerance or an exemption, EPA must conclude that the pesticide chemical residue in food would be ''safe'' (FFDCA section 408(b)(2)(A)(i), (c)(2)(A)(i)). ''Safe'' is further defined to mean ''a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information'' (FFDCA section 408(b)(2)(A)(ii), (c)(2)(A)(ii)). The amendments also direct EPA to consider a variety of factors in making decisions under the new standard. These factors include: the potential for greater sensitivity or exposure for infants and children to the pesticide chemical residue; and the cumulative effects of the pesticide chemical residue and other substances that have a common mechanism of toxicity. See FFDCA section 408(b)(2)(C) and (D).

5. *Summary*. The FQPA amendments have expanded the definition of ''pesticide chemical'' in FFDCA to correspond in scope to the definition of ''pesticide'' in FIFRA. As a result, so long as a substance is a ''pesticide'' under FIFRA, EPA now has jurisdiction to regulate the substance under both FIFRA and FFDCA. EPA also has the authority to ''except'' substances from

the definitions of ''pesticide chemical'' or ''pesticide chemical residue.'' Such an exception would transfer the regulatory responsibility for such substances to FDA, without yielding regulatory authority under FIFRA over the use of the pesticide. Notwithstanding these changes, all previously issued approvals that allow residues of pesticides in food remain valid under the transition provisions. All pesticides that are EPA's regulatory responsibility under FFDCA are subject to the new safety standard of FFDCA section 408.

II. Background

In addition to considering the changes to the legal framework resulting from FQPA, EPA and FDA evaluated whether the jurisdictional change brought about by FQPA for certain antimicrobial substances resulted in the most efficient regulatory outcome. The agencies took several factors into account in the deliberations and tentatively concluded that an alternative jurisdictional approach for certain antimicrobial substances would be more appropriate. Principally, the two agencies have concluded that the jurisdiction under FFDCA for antimicrobial substances should be allocated in a way that promotes protection of public health, and uses limited public resources efficiently. The factors that the agencies considered are discussed more fully in sections A and B of this unit.

A. Promotion of Public Health

In recent years, the scientific community has identified the contamination of food by pathogenic microbes as both a serious and growing problem affecting the overall safety of the food supply. The Federal government, working through multiple agencies such as FDA, EPA, and the Department of Agriculture, Food Safety and Inspection Service, is using its resources and regulatory authorities to address this problem in a concerted fashion. Some of the more significant initiatives are FDA's Hazard Analysis and Critical Control Point (HACCP) program for the seafood industry, USDA's HACCP program for the meat and poultry industry, and the possible expansion by FDA of HACCP to other segments of the food industry. HACCP starts with the preparation of a hazard analysis for each food processing facility and then a plan designed to prevent hazards from occurring in the production of food through a range of available control techniques and to respond to deviations from the prevention plan.

FDA is especially concerned with a growing problem of pathogens in fruits, vegetables, and unpasteurized juices. FDA's concern extends to both domestic and imported foods. This includes contamination of foods with *Escherichia coli* 0157:H7, which caused a serious human illness outbreak involving unpasteurized apple juice in the fall of 1996, problems associated with *Listeria monocytogenes* in cut vegetables, and others. As noted, FDA considers HACCP to be a state of the art approach to dealing with these problems. For HACCP to be effective, however, regulatory agencies must be sure that industry HACCP plans include controls that will ensure that the public is adequately protected from pathogens in foods. In order to accomplish this, FDA expects that it will, over time, establish a number of performance standards to assure the effective control of pathogens in foods.

FDA and EPA must ensure a coordinated approach if these concerns with microbial contamination are to be effectively addressed. For example, one technique for reducing microbial contamination of foods is the appropriate use of antimicrobial chemicals. Therefore, in evaluating jurisdictional alternatives, the two agencies have tentatively decided to recognize and give considerable weight to the benefits that would result from FDA having broad regulatory authority over the use of antimicrobial chemicals in food processing facilities. This coordinated approach will allow FDA to move forward in proposing, for instance, that juices sold for human consumption be subject to a process that reduces, controls, or eliminates pathogens, and therefore, will be equivalent to pasteurization in its effect. An equivalent process may include the use of antimicrobials. Antimicrobials must not only kill pathogens; assurance is needed that after antimicrobials are applied, the food meets the performance standard that FDA has determined is necessary to protect the public health. Furthermore, the food must meet the performance standard in a real world production environment.

The use of antimicrobials in food production may be a complex undertaking. For example, the use of an antimicrobial that might not be capable of meeting the performance standard by itself at one processing step can be combined with other pathogen reduction efforts at other processing steps. It is important that together, these controls achieve the desired public health objective. The total process, including the antimicrobial use, can be considered in determining whether the process is adequate to protect the public from pathogens.

FDA and EPA, after considering these situations and FDA's role and experience in dealing with pathogens in foods, have tentatively concluded that FDA should have broad regulatory authority over the use of antimicrobial substances in food processing facilities. Presently, FDA has regulatory authority over such substances when used in or on processed edible foods. However, the intended use of antimicrobial substances on certain food-contact articles and on raw agricultural commodities is within EPA's regulatory purview. Therefore, the proposed allocation of jurisdiction, described in Unit III. of this notice, would expand FDA's regulatory authority to include antimicrobial substances used on certain food-contact articles and on raw agricultural commodities in food processing facilities.

B. Efficient Use of Public Resources

Congress' amendment to the definition of ''pesticide chemical residue'' in FFDCA, which now includes such residues on processed food in addition to those residues on raw agricultural commodities, may be viewed as streamlining the regulatory system by consolidating responsibilities for regulating ''pesticides'' with antimicrobial activity in EPA. One consequence of FQPA is to allow EPA to coordinate the parallel decision-making process of registration under FIFRA and tolerance setting under FFDCA for antimicrobial substances that are ''pesticides'' under FIFRA. This is consistent with other FQPA amendments that direct EPA to streamline its registration process for non-food use antimicrobial pesticides. See FIFRA section 3(h).

The FQPA amendments did not affect the current regulatory framework in FIFRA which exempts, by statute, certain microbes in or on processed food from the definition of ''pest.'' Nor did these amendments affect the Administrator's authority to declare by regulation that certain microbes are not ''pests.'' Thus, antimicrobials directed against microbes that are in or on processed edible food remain subject to FDA's regulatory authority as food additives post-FQPA.

However, this new regulatory scheme created by FQPA differs significantly from the previous regulatory scheme in place for over 25 years for certain indirect food additives. Antimicrobial substances applied to or incorporated in food-contact articles but not used directly in or on edible processed food were regulated by FDA as food additives

because of their potential migration to food. FDA and EPA have extensive regulatory experience with this pre-FQPA jurisdictional scheme and have developed considerable understanding and experience with the policies and procedures of the respective agencies.

To the extent that the regulated community has expressed its views, it expressed a preference for retaining, to the greatest extent possible, the pre-FQPA regulatory scheme regarding antimicrobials in or on food-contact articles. Such an approach, it argued, could involve fewer delays because ongoing reviews would continue at FDA where such reviews have historically been performed. Moreover, by retaining the pre-FQPA scheme, products regulated by FDA would not be subject to the requirement in FFDCA section 408 to pay a fee.

Implementing the new statutory scheme, therefore, would involve adjustments for both the regulated industry and the Federal agencies. During the transition, decision-making would likely experience considerable delays. Moreover, during the transition both agencies would face additional, new work associated with any transfer of responsibilities. To the extent that the agencies use rulemaking to restore the pre-FQPA allocation of jurisdiction, these problems are reduced.

In conclusion, EPA and FDA weighed all of these considerations in formulating the approach set forth in Unit III. of this notice regarding the allocation of regulatory responsibility for antimicrobial substances used in food-contact articles and food packaging materials. The agencies reached decisions that they believe reflect the most appropriate balance of the competing considerations based upon currently available information. This proposed allocation of responsibilities is described more fully in Unit III. below.

III. Allocation of Regulatory Responsibilities Under FFDCA in Light of FQPA Amendments

A. Summary

EPA and FDA propose to divide the universe of antimicrobial substances regulated under the FFDCA, and potentially affected by the FQPA amendments, into the following categories. Some of these categories are the consequence of statutory provisions; others would be established through rulemaking. Sections B. through F. of this unit discuss each of the following categories in detail. Section G. of this unit provides a table summarizing the categories.

1. *Antimicrobial substances directed against microbes in or on edible food, animal drinking water, and process water that contacts edible food (see section B. of this unit).*

a. EPA: antimicrobials used in or on raw agricultural commodities, or in process water contacting such commodities, in the field, or in a facility where only one or more of the following activities occurs: washing, waxing, fumigating, and packing of raw agricultural commodities, or during transportation of such commodities between the field and such facility; antimicrobials used in or on raw agricultural commodities for consumer use; antimicrobials that are not drugs used in animal drinking water.

b. FDA: antimicrobials used in or on processed food or processed animal feed; antimicrobials used in or on raw agricultural commodities or in process water contacting such commodities (other than those described in section III.A.1.a. of this unit), in a facility where such commodities are prepared, packed, or held (hereinafter ''food processing facility'' (refer to section B. of this unit for a description of such facilities));

2. *Antimicrobial substances directed against microbes on permanent or semi-permanent food-contact surfaces (see section C. of this unit).* [Note: impregnated antimicrobials are addresssed in paragraphs 4. and 5. below.]

a. EPA: sole jurisdiction.

b. FDA: no jurisdiction.

3. *Antimicrobial substances used in the production of food packaging materials and in or on such finished materials including plastic, paper, and paperboard (see section D. of this unit).*

a. EPA: no jurisdiction.

b. FDA: sole jurisdiction.

4. *Antimicrobial substances used in production of food-contact articles, other than food packaging, for which there is no ongoing intended antimicrobial effect in the finished article (see section E. of this unit).*

a. EPA: no jurisdiction.

b. FDA: sole jurisdiction.

5. *Antimicrobial substances incorporated into food-contact articles, other than food packaging, that have an intended antimicrobial effect on the finished article itself, including the article's surface (see section F. of this unit).*

a. EPA: jurisdiction over active pesticidal ingredients.

b. FDA: jurisdiction over inert ingredients in such pesticides.

B. Antimicrobial Substances Directed Against Microbes in or on Edible Food, Animal Drinking Water, and Process Water that Contacts Edible Food

The FQPA amendments did not change FDA's and EPA's jurisdiction over antimicrobials used to control microbes on raw agricultural commodities and processed food (within the meaning of the term ''processed food'' in 40 CFR 152.5). Antimicrobial substances directed against microbes in water in which raw agricultural commodities are washed, or directed against microbes in or on raw agricultural commodities, whether the antimicrobials are added to the commodities directly, or indirectly through the addition of the antimicrobial to water in which the commodities are washed, are subject to EPA's regulatory authority as ''pesticides'' under FIFRA and ''pesticide chemicals'' under FFDCA. This category includes antimicrobial substances used in the washing of fresh fruits and vegetables. EPA also regulates antimicrobial substances added to drinking water of cattle, poultry, and other food animals.

Antimicrobial substances directed against microbes in or on processed food are not subject to EPA's regulatory authority either under FIFRA or FFDCA. This is a result of a jurisdictional division that existed both before and after the FQPA amendments. The definition of ''pest'' in EPA's implementing regulation at 40 CFR 152.5(d) specifically excludes ''microorganisms . . . on or in processed food . . . .'' See Unit II.A. of this notice. Therefore, antimicrobial substances directed against microorganisms on or in processed food are not ''pesticides'' under FIFRA. Since these substances are not pesticides under FIFRA, they are not ''pesticide chemicals'' under FFDCA. This category includes substances such as those listed in 21 CFR 172.165, 173.315, and 173.320. EPA has had, and will have, no role in the regulation of substances for these uses; they do not require registration under FIFRA nor tolerances under FFDCA section 408.

Many existing and proposed applications involve the addition, inside a food processing facility, of antimicrobial substances to process water that contacts fruits, vegtables, or other foods. According to the Memorandum of Understanding (MOU) between FDA and EPA on the jurisdiction over substances in drinking water (44 FR 42775, July 20, 1979), FDA has responsibility under FFDCA section 409 for water, and substances in water (including antimicrobials) used in food

and for food processing.[2] (44 FR 42775, July 20, 1979). Under this MOU, EPA has, in the past, refrained from regulating such antimicrobial substances under FIFRA, FFDCA, the Safe Drinking Water Act, 42 U.S.C. 300f *et seq.*, and the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.* More recently, however, EPA has exercised its authority over antimicrobials added to process water inside a food processing facility, if that water contacts a raw agricultural commodity, whether or not such raw agricultural commodity is later subjected to processing.

FQPA did not alter the regulatory framework in FIFRA that determines whether antimicrobial substances used in or on raw agricultural commodities or processed food are classified as FIFRA ''pesticides.'' Despite this fact, a more efficient allocation of jurisdiction over antimicrobials that are used in or on both raw agricultural commodities and processed food appears warranted, given FDA's interest in regulatory authority over such substances in food processing facilities.

As discussed above, under the current regulatory scheme, whether EPA or FDA has jurisdiction over an antimicrobial used on edible food depends on whether the antimicrobial substance is applied to a raw agricultural commodity or processed food. Yet it is sometimes difficult to determine whether certain activities constitute ''processing'' or are merely post-harvest treatment activities. EPA made such a distinction for dried commodities (61 FR 2386, January 25, 1996) and found that, in the legislative history of FFDCA section 408, there was ambiguity in whether certain types of drying were considered ''processing.'' Moreover, raw agricultural commodities that are treated with antimicrobials inside a food processing establishment or facility may be culled, with some of these commodities undergoing further processing and others leaving the facility without any further processing. This practice makes it difficult to determine which specific commodities will remain ''raw agricultural commodities'' and which will be processed.

The agencies believe that it makes little sense to have the same antimicrobial substance require both a section 408 tolerance and a section 409 food additive regulation when the food, whether raw or processed, is undergoing the same activity, e.g., washing. Therefore, EPA intends to propose an amendment to 40 CFR 152.5 to exclude from the definition of ''pest'' microbes that are in or on raw agricultural commodities or in process water used on such commodities in a food processing facility. Thus, antimicrobials that are both used inside a food processing facility and applied either directly to edible food, whether raw agricultural commodities or processed food, or to process water that contacts such edible food would not be FIFRA ''pesticides'' nor FFDCA ''pesticide chemicals,'' but instead would be subject to regulation as FFDCA ''food additives'' under FFDCA section 409.

1. *Facilities.* The proposed change in the allocation of jurisdiction over antimicrobials used in or on raw agricultural commodities, described in section III.A.1.b. of this unit, is limited to those commodities in ''food processing facilities.'' The term ''food processing facility'' would include those locations where food is prepared, packed, or held, except for in the field where raw agricultural commodities are subject to certain post-harvest treatments. Thus, the term includes slaughtering or manufacturing facilities for meat, poultry, seafood, and produce; retail facilities such as restaurants, grocery stores, institutions, and food vending operations; and mobile food facilities such as trains, planes, and vessels. FDA's jurisdiction over antimicrobials that are used on ''processed'' food in such locations remains unchanged by FQPA; such antimicrobials remain subject to regulation as food additives under section 409 of FFDCA.

EPA and FDA realize that certain food processing facilities are part of a farming operation where antimicrobial use on raw agricultural commodities would not constitute uses described in section III.A.1.a. of this unit. For example, egg sanitizing may occur ''on the farm'' as part of an operation with the same types of food handling activities as those that occur in other food processing facilities. Antimicrobials used in such an operation would be subject to food additive approval by FDA.

2. *Ethylene and propylene oxides.* As a result of the agreement between FDA and EPA, the allocation of regulatory jurisdiction under FFDCA over antimicrobial substances used on edible food would, for the most part, correspond to the allocation that existed prior to enactment of FQPA. As discussed, the major change would affect antimicrobial substances used on raw agricultural commodities inside food processing facilities. There is, however, an additional set of antimicrobial uses--ethylene oxide and propylene oxide use on whole and ground spices--for which the proposed allocation would represent a difference from the current regulatory scheme. All uses of ethylene oxide on spices have been regulated by EPA under FFDCA section 408. Since these uses of ethylene oxide take place inside food processing facilities, the proposed allocation would give FDA exclusive jurisdiction over these uses under FFDCA section 409. This situation is further complicated by the fact that these active ingredients also have insecticidal properties that could only be regulated by EPA under both FIFRA and FFDCA. EPA and FDA are considering, in light of the long history of regulation of this chemical and these specific uses by EPA under FFDCA section 408, whether to address the uses differently from the general approach described above. At a minimum, EPA's proposed rule will seek public comment on the implications for different regulatory schemes for these uses under FFDCA.

In summary, FDA and EPA agree that because it is difficult to ascertain whether certain food will remain a raw agricultural commodity or become a processed food when entering food processing facilities, it would be more efficient to allocate regulatory responsibility for antimicrobials that are used on raw agricultural commodities in such facilities to FDA. Moreover, it would be consistent with the promotion of public health and FDA's interest in the application of HACCP principles to food production. Thus, antimicrobials that are used inside a food processing facility, including those used in process water contacting edible food, regardless of whether the food is ''processed,'' would not be FIFRA ''pesticides'' nor FFDCA ''pesticide chemicals,'' but instead would be ''food additives'' under FFDCA section 409.

Antimicrobials that are directed against microbes in or on raw agricultural commodities, as described in section III.A.1.a. of this unit, would remain FIFRA ''pesticides'' and FFDCA ''pesticide chemicals'' and thus require pesticide registration under FIFRA and a tolerance or exemption from the requirement of a tolerance under FFDCA. Antimicrobials that are used by the consumer in or on raw agricultural commodities in the household would remain FIFRA ''pesticides'' and thus would also require FIFRA registration. Moreover, such antimicrobials would be FFDCA ''pesticide chemicals,'' but would not require a tolerance or an exemption from the requirement of a tolerance where such food is not ''held for sale'' within the meaning of FFDCA. Nonetheless, EPA will continue to

[2]Under the MOU, EPA has regulatory responsibility for substances added to a public drinking water system before the water enters a food processing establishment.

conduct the same safety evaluation of dietary exposure to antimicrobials used in consumer households as it does for tolerances issued under FFDCA section 408.

3. *Labeling of products used in retail facilities*. Historically, FDA has had limited involvement in the regulation and enforcement activities affecting retail establishments, including restaurants and grocery stores. FDA has directed its efforts toward providing technical assistance to state and local governmental agencies that, as a practical matter, have primary responsibility for regulating the retail segment of the food industry. Providing a model food code has been the central mechanism through which FDA, as a lead Federal food control agency, has promoted uniform implementation of national food regulatory policy among the several thousand Federal, state, tribal, and local agencies that carry out the primary oversight of this industry component.

Although the food code provides referenced information about the approved use of antimicrobials in or on food, EPA and FDA believe that directions for use should be included on the labeling of such substances. The labeling would ensure that a person using such a product in the retail setting will have adequate directions for use readily available. Therefore, as part of its exercise of regulatory authority over the use of those antimicrobial substances, FDA is planning to propose to require that a manufacturer provide adequate directions for use to ensure compliance with the applicable food additive regulation. These directions would include the conditions of safe use required under FFDCA section 409(c)(1). The conditions of safe use require adequate directions to achieve the intended technical effect.

Consistent with its authority under FFDCA section 409(c)(3)(B), FDA believes that a product that is intended to achieve an antimicrobial effect may require a label with adequate directions to achieve such effect so that the use of the product would not promote deception of the consumer. Specifically, section 409(c)(3)(B) prohibits FDA from approving a food additive if the proposed use would result in the misbranding of food within the meaning of FFDCA section 403(a)(1). Under section 403(a)(1) of FFDCA, a food is misbranded if its labeling is false or misleading in any particular.

Section 201(n) of the FFDCA provides context to what is meant by ''misleading'' in FFDCA section 403(a)(1). Under FFDCA section 201(n), when determining whether a product is misbranded, FDA is to take into account not only the representations made about the product, but also the extent to which the labeling fails to reveal facts material in light of such representations made or suggested in the labeling or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. See 21 CFR 1.21. FDA believes that directions to achieve an antimicrobial's intended technical effect may be a material fact with respect to the consequences which may result from the use of the antimicrobial. For example, an antimicrobial that is intended to kill pathogenic microbes and fails to provide directions to achieve such effect may result in adverse consequences to the consumer from ultimate consumption if the antimicrobial is not used appropriately. Therefore, if such labeling is required for the antimicrobial's approval for use as a food additive, the absence of such labeling would constitute misbranding under FFDCA section 403(a)(1). In general, FDA believes that the concept of ''material fact'' is one that should be applied on a case-by-case basis.

C. Antimicrobial Substances Used to Sanitize or Disinfect Permanent or Semi-Permanent Food-Contact Surfaces

Products intended for the uses in this category have the same regulatory status under FIFRA, both before and after FQPA. Because they are directed against pests, i.e., against microbes that are not excluded by FIFRA or implementing regulations from the definition of ''pest,'' antimicrobial substances used to sanitize or disinfect environmental surfaces are ''pesticides'' under FIFRA. This category includes antimicrobial substances that are used in or on equipment in food production facilities such as farm bulk tanks and milking machines; in manufacturing facilities such as meat saws/grinders, shellfish skimmers, and in-plant product conveyance systems; in retail food facilities such as slicers, cutting surfaces, dishwashing machines, and kitchen utensils and tableware; and in mobile facilities such as bulk tankers used for liquid eggs or dairy products. Such products must be registered by EPA under FIFRA prior to marketing.

The use of these products is also widely specified and referenced in FDA's model codes pertaining to the milk, retail food, and shellfish industries. These products are considered to be ''public health pesticides'' under FQPA and, therefore, EPA will coordinate with FDA as part of the PHS in determining the safe and necessary use of these products.

As explained in Unit I.A. of this notice, EPA does not regard food-contact surfaces as ''processed food'' within the meaning of FIFRA section 2(k) and the regulations at 40 CFR 152.5(d). EPA and FDA have tentatively agreed to treat substances used to disinfect reusable food packaging materials, e.g. beverage containers, differently from antimicrobial pesticides used to disinfect or sanitize environmental surfaces (refer to discussion in section D. of this unit).

Before the FQPA amendments, products used to sanitize or disinfect permanent or semi-permanent food-contact surfaces were not considered ''pesticide chemicals'' under FFDCA because they were not used in the production, storage, or transportation of raw agricultural commodities. Therefore, these products were regulated as ''food additives'' by FDA under FFDCA section 409. Food additive regulations for this category of products appear in 21 CFR 178.1010.

Under FQPA, products in this category are ''pesticide chemicals''because they are FIFRA pesticides, and thus, no longer within the scope of the term ''food additive.'' Consequently, they are regulated under FFDCA section 408 by EPA. Because of the transition provisions in FQPA, previously issued food additive regulations remain in effect for substances in this category.

FDA and EPA have agreed to propose that EPA should retain jurisdiction over these products, rather than promulgate rules that would restore the pre-FQPA regulatory scheme. Many of the products in this category have non-food uses at other sites, especially sites involving potential exposure to children or other potentially sensitive groups in the general population. As a policy matter, EPA has decided it will conduct a more extensive risk assessment of such non-food uses to take into account the aggregate exposure of sensitive population subgroups. See EPA PR Notice 97-1 and FFDCA section 408(b). As part of its assessment of aggregate exposure, EPA would also evaluate the potential dietary exposure to the antimicrobial substance. Because EPA will be routinely evaluating the non-food uses of these products, the two agencies believe it would be more efficient for EPA to regulate the food uses of these products along with the non-food uses.

D. Antimicrobial Substances Used in the Production of Food Packaging Materials and in or on Such Finished Materials

Under FIFRA, antimicrobial substances used in the production of food packaging materials, or used in or on such materials, are considered ''pesticides.'' This category of products includes slimicides used in the manufacture of food-contact paper and paperboard, and preservatives added to aqueous suspensions for adhesives or coatings. Also included are antimicrobials incorporated into polymers or finished paper and paperboard coatings to kill microbes in the final food packaging or in the food that contacts such packaging and sanitizers applied to food containers such as aseptic packaging. As discussed in Unit I.A. of this notice, none of these food packaging materials is considered a ''processed food'' under FIFRA regulations.

The FQPA amendments altered the regulatory authority over some of these products under FFDCA. Prior to FQPA, these antimicrobial substances were regulated under FFDCA section 201(s) as food additives, GRAS substances, or prior sanctioned substances. Even though many of these substances were FIFRA ''pesticides,'' they were not used in the production, storage, or transportation of raw agricultural commodities. Consequently, FDA exercised authority over these chemicals in food under FFDCA. FDA food additive regulations for some of these chemicals appear in, for example, 21 CFR 175.105, 176.170, 176.300, and 178.1005. After FQPA, many of these products in this category are considered ''pesticide chemicals'' under FFDCA, because they are ''pesticides'' under FIFRA. Because of the exclusion of a ''pesticide chemical'' from the definition of ''food additive,'' these substances are no longer ''food additives'' and are not within FDA's regulatory responsibility. Thus, EPA is now responsible for the establishment of tolerances or exemptions from the requirement of a tolerance for their residues in food under FFDCA section 408.

EPA and FDA have determined that antimicrobial substances in this category should be subject to regulation as food additives. This category includes two types of products: (1) Antimicrobial substances that are impregnated into food packaging that have an ongoing intended antimicrobial effect on the food or in or on the packaging itself, and (2) antimicrobial substances used in the production of food packaging that have no ongoing intended antimicrobial effect beyond the material production process.

For the first category, EPA plans to propose that FDA have regulatory authority over those antimicrobials impregnated in food packaging that are used against microbes on raw agricultural commodities and those used against microbes in or on the packaging itself. Antimicrobials used to kill microbes on processed food are not pesticides; therefore, FDA retains authority over food packaging impregnated with an antimicrobial that is intended to kill microbes on the packaged, processed food.

The second category includes antimicrobial substances used in the production of food packaging that have no ongoing intended antimicrobial effect in the finished materials. They are ''pesticides'' under FIFRA and therefore ''pesticide chemicals'' under FFDCA, post-FQPA. EPA intends to propose a regulatory scheme that gives FDA responsibility for this latter category of products for two reasons. First, antimicrobial substances in this category that kill microbes in materials used in the production of food packaging are part of the formulation of such materials. These substances include adjuvants and other components of the food packaging materials that are regulated as food additives by FDA. Government resources would be better used if these antimicrobial substances were regulated as food additives in conjunction with the adjuvants and other packaging components in which they are used. This approach is also more efficient for the regulated community for the same reason. The regulated community has expressed a strong preference for continuation of FDA regulation of these products under FFDCA. For both categories, the control of microbes in or on food packaging, as for example in the production of aseptically packaged food, is a very important aspect of an effective food safety program, such as HACCP. The two agencies believe that FDA will be better able to protect the public health by administering these regulatory programs--HACCP and use of antimicrobial substances in or on food packaging--than if jurisdiction were divided between EPA and FDA.

EPA intends to propose to amend the definition of ''pest'' in 40 CFR 152.5(d) to exclude microbes in or on food packaging or in materials used in the production of such packaging. As a result of such an amendment, antimicrobial substances directed against such microbes would not be ''pesticides'' under FIFRA, and thus, would not be ''pesticide chemicals'' under FFDCA. Instead, such products would be ''food additives'' subject solely to FDA's regulatory authority.

E. Antimicrobial Substances Incorporated into Food-Contact Articles, Other Than Food Packaging, with No Pesticidal Effect in the Finished Article

Antimicrobial substances incorporated into food-contact articles, other than food packaging, have historically been and are still considered by EPA as ''pesticides'' under FIFRA. This category includes a wide variety of registered pesticide products such as: preservatives used in latex solutions, adhesives and coatings intended for use in food-contact articles, and antimicrobial substances used in the manufacture of conveyer belts, cutting boards, plastic tubing, and other articles that come in contact with food during its storage, transportation, processing, or preparation. These antimicrobial substances may or may not have an ongoing antimicrobial effect in the finished food-contact article. Only those that have no intended ongoing antimicrobial effect in the finished article are discussed in this unit. Those with an ongoing pesticidal effect are considered in section F. of this unit.

Similar to products described in section D. of this unit, the regulatory status under FFDCA of antimicrobial substances incorporated into food-contact articles, other than food packaging, with no intended ongoing antimicrobial effect in the finished articles was changed by FQPA. Prior to FQPA, these products were regulated as ''food additives'' by FDA. Food additive regulations for these products appear in 21 CFR 175.300 and 177.2600, for example. After FQPA, these products are ''pesticide chemicals'' under FFDCA, and thus, within the regulatory authority of EPA.

Again, just as for antimicrobials used on or in food packaging materials, EPA and FDA have agreed that the regulatory responsibility for these antimicrobial substances should be similar to that existing before the FQPA amendments. EPA will propose to amend the definition of ''pest'' in 40 CFR 152.5(d) to exclude microbes in materials used in the production of food-contact articles, other than food packaging (which was previously discussed in section D. of this unit). The result of such a rulemaking would be that products for uses in this category would no longer be ''pesticides'' under FIFRA and would be subject to regulation as ''food additives'' under FFDCA section 409, instead of as ''pesticide chemicals'' under section 408 of FFDCA.

The reasons for this proposed action are similar to those described above for antimicrobial substances used in or on food packaging materials with no intended ongoing antimicrobial effect in the finished packaging. Again, these substances are part of the formulations of materials used to produce food-contact articles. Regulation of these substances as food additives along with the other adjuvants and components would result in a more efficient use of government resources. Further, these antimicrobial substances have no intended ongoing antimicrobial effect in the finished food-contact article. Therefore, no claims for antimicrobial activity (i.e., pesticidal effect), which would be under the jurisdiction of EPA, are made for the finished food-contact article.

F. Antimicrobial Substances Incorporated into Permanent or Semi-Permanent Food-Contact Articles, Other Than Food Packaging, With an Ongoing Antimicrobial Effect

This category covers antimicrobial substances incorporated into permanent or semi-permanent food-contact articles such as conveyer belts, cutting boards, and plastic tubing for the purpose of having a pesticidal effect during the continuing life of the product, either on the food-contact materials themselves (self-protection) or on food that contacts the treated article. Antimicrobial substances intended to control or mitigate ''pests'' are ''pesticides'' under FIFRA. Therefore products in this category are subject to EPA regulation under FIFRA to the extent that the target microorganisms are ''pests.'' It should be noted that, if the presence of the antimicrobial substance in the food-contact article is intended only to control microbes in or on ''processed food,'' such a substance would not be considered a ''pesticide'' under FIFRA because microbes in or on processed food are not ''pests.''

At present, there are no products registered as pesticides by EPA that are intended to be incorporated in permanent or semi-permanent food-contact articles for a pesticidal purpose on the food that contacts such articles. Several companies, however, have been marketing unregistered products with such claims. For example, several companies make plastic cutting boards impregnated with an antimicrobial substance and have marketed these products with claims that the presence of the pesticidal substance can kill or control specific pathogenic bacteria or germs that cause food borne illnesses. Similar products could include antimicrobial countertops, housewares, conveyer belts, gloves, shelving, and sponges. Although no company has actually applied for registration of such product, several have approached EPA concerning their interest in marketing such products.

Prior to FQPA, products in this category would have been both ''pesticides'' and ''food additives,'' but with the FQPA amendments, these products are ''pesticide chemicals'' subject only to EPA regulation. FDA and EPA have tentatively decided to leave the allocation of responsibility largely as it exists after the FQPA amendments. Under this scheme, EPA will exercise FIFRA jurisdiction over the products, as well as FFDCA jurisdiction over the pesticide active ingredients, but FDA will regulate the inert ingredients in these products. If a company seeks to market an antimicrobial food-contact product, e.g. an antibacterial cutting board, EPA would be responsible for registration of the product under FIFRA.

The primary reason for EPA retaining responsibility for these products, as contrasted with its approach to the category described in section E. of this unit, is EPA's concern about claims made for the antimicrobial efficacy of these products. EPA believes that in determining whether to register such products, it would be critical not only to evaluate potential dietary and other risks, but also to ensure that, when public health claims are made, the products actually perform as claimed. EPA has considerable experience evaluating antimicrobial efficacy and making decisions about the labeling of pesticide products with differing levels of efficacy. Therefore from both an efficiency and public health protection perspective, EPA appears to be the more appropriate agency to exercise regulatory responsibility for these products.

EPA would also propose to establish a tolerance or an exemption from the requirement of a tolerance for the active ingredient in the product, under FFDCA. EPA would further need to determine under FFDCA that the inert ingredients were allowed to be present in food because, as explained before, EPA will not register a pesticide unless all ingredients in the product have the necessary approvals. Ordinarily, because the inert ingredients are part of a pesticide product, they would be regarded as ''pesticide chemicals'' and EPA would establish a tolerance or exemption from the requirement for a tolerance for such ingredients. As a practical matter, however, EPA expects that these antimicrobial products would be manufactured by adding antimicrobial active ingredient chemicals to products already in compliance with the applicable food additive regulations. Therefore, all of the inert ingredients in such products would likely already be regulated or permitted by FDA under the FFDCA. EPA and FDA have tentatively decided that EPA would ''except'' such products from the definition of ''pesticide chemical'' on a case-by-case basis, making the inert substances ''food additives'' and subject to section 409 of FFDCA. Such exceptions would be issued under the authority of FFDCA section 201(q)(3). See Unit I.C. of this notice.

G. Summary of Jurisdictional Changes

The following table summarizes the status of FDA and EPA jurisdiction for antimicrobial substances under FFDCA both before and after FQPA. This table also summarizes the jurisdictional allocation that EPA intends to propose through rulemaking.

Table 1.—EPA and FDA Jurisdiction Under FFDCA

Product Category	Before FQPA	After FQPA	After Planned EPA Rulemaking
1. Antimicrobial substances directed against microbes in or on edible food, antimicrobials that are not drugs used in animal drinking water, and antimicrobials used in process water that contacts edible food (Unit III.B.)	EPA & FDA	EPA & FDA	EPA--antimicrobials that are not drugs used in animal drinking water and antimicrobials in or on raw agricultural commodities or process water contacting such commodities in the field, or in a facility where only one or more of the following activities occurs: washing, waxing, fumigating, and packing of raw agricultural commodities, or during transportation of such commodities between the field and such facility; and antimicrobials used in or on raw agricultural commodities for consumer use. FDA--in or on processed food or processed animal feed; in or on raw agricultural commodities or process water contacting such commodities in a food processing facility as described in Unit III.A.1.b.
2. Antimicrobial substances directed against microbes on permanent or semi-permanent food-contact surfaces (Unit III.C.)	FDA	EPA	EPA
3. Antimicrobial substances used in the production of food packaging materials and in or on such finished materials, including plastic, paper, and paperboard (Unit III.D.)	FDA	EPA	FDA
4. Antimicrobial substances used in production of food-contact articles, other than food packaging, for which there is no ongoing intended antimicrobial effect in the finished article (Unit III.E.)	FDA	EPA	FDA
5. Antimicrobial substances incorporated into food-contact articles, other than food packaging, that have an intended antimicrobial effect on the finished article itself, including the article's surface (Unit III.F.)	FDA	EPA	EPA (active ingredients) and FDA (inert ingredients)

IV. Processed Food

This section provides guidance on a term that is important in defining the categories, and the resulting jurisdiction of FDA and EPA. Specifically it addresses what qualifies as a ''processed food'' under FIFRA.

Although FQPA and the agencies' subsequent policy agreement on their proposed approach to regulation of antimicrobials largely eliminated the importance of the distinction between raw and processed food for purposes of FFDCA tolerance setting, this distinction still affects the jurisdiction of EPA and FDA under both FIFRA and FFDCA over antimicrobial substances. Three of the proposed categories (Unit III.B., D., and F. of this notice) are based, in part, on whether the antimicrobial substance is directed against microbes on an article that is a ''processed food'' within the meaning of FIFRA. As explained below, FDA and EPA have developed guidance to help in the interpretation of this FIFRA term.

EPA has tentatively decided 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. EPA has tentatively concluded that the following activities constitute processing and that any food subjected to these activities becomes a ''processed food'': canning, freezing, cooking, pasteurization or homogenization, irradiation, milling, grinding, chopping, slicing, cutting, or peeling.

In determining which operations would be considered processing, 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--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 ones 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. If EPA were writing on a clean slate, it perhaps would classify coloring differently. However, given the lack of intrusiveness involved in the coloring of certain commodities (e.g., oranges), EPA believes that categorizing coloring for such commodities as not processing is consistent with the guiding principle outlined above.

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, this 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. On the other hand, hay, nuts, rice, beans, corn, other grasses, legumes, and grains remain raw agricultural commodities even though they may have undergone some drying. EPA believes 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,'' described in Unit III.B. of this notice, would include those facilities where food is subject to activities that constitute ''processing'' unless such activities fall within the exceptions for post-harvest treatments described earlier in this section. 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.* 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(d). Therefore, the regulatory status of antimicrobials that are used on meat after slaughter is unchanged by FQPA and they are 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 is unchanged by FQPA because such uses constitute those that are on ''processed food,'' not raw agricultural commodities.

V. Implementation of Legal and Policy Interpretations of FFDCA Jurisdiction

This unit of the notice discusses how EPA and FDA propose to implement the legal and policy interpretations. Unit V.A. discusses the rulemaking being planned by EPA to implement the jurisdictional allocations discussed in Unit III. of this notice. Unit V.B. describes how EPA will handle both new and pending petitions and Threshold of Regulation (TOR) requests (see 21 CFR 170.39), that are for antimicrobial pesticides that the agencies have determined are now under EPA authority. (A petition or TOR request is considered ''new'' if it is submitted after publication of this notice.) Finally, Unit V.C. of this notice explains the regulatory status of products that are currently registered as pesticides and bear labeling directions for use against microorganisms that would no longer be ''pests'' under EPA's intended rulemaking.

A. Schedule for EPA Rulemaking to Implement Legal and Policy Interpretations

EPA and FDA have agreed that EPA will undertake rulemaking to redefine ''pest.'' If these regulations are promulgated in final as they are proposed, the result would be to exclude from FIFRA regulation as ''pesticides'' any antimicrobial substance: (1) Used in or on raw agricultural commodities in a food processing facility and in process water contacting such commodities; (2) used in the production of food packaging materials and in or on such finished materials; and (3) used in materials that are incorporated into food-contact articles, other than food packaging, that have no continuing antimicrobial effect in the finished article. The exception for processed food and processed animal feed in 40 CFR 152.5 remains intact. The practical effect of this change would provide FDA with regulatory authority over antimicrobials used in or on ''edible'' food (including both processed food and raw agricultural commodities) in a food processing facility. EPA plans to include this redefinition in the proposed rules being issued under FIFRA section 3(h) and 25(a) in response to FQPA mandate to promulgate new regulations to streamline its registration of antimicrobial pesticides. The proposed rules should be issued in 1998, and a final rule redefining ''pest'' should be published in the first half of 1999.

B. Antimicrobial Substances Regulated Completely by EPA

As discussed above, EPA has several categories of antimicrobial substances within its regulatory authority. Pursuant to the proposed allocation of jurisdiction, EPA intends to retain regulatory authority for antimicrobials that are: (1) Directed against microbes in or on raw agricultural commodities or process water contacting such commodities as described in Unit III.A.1.a. of this notice; (2) used to sanitize or disinfect food-contact surfaces, not including food packaging (Unit III.C. of this notice); and (3) incorporated into food-contact articles, except food packaging, with continuing pesticidal activity, except where the target microorganisms are in or on processed food (Unit III.F. of this notice). EPA registers such antimicrobials under FIFRA and establishes tolerances or exemptions from the requirement of a tolerance for the antimicrobials and their ingredients. In addition, EPA has current regulatory authority over the three categories of antimicrobials described in Unit V.A. of this notice, for which it intends to initiate rulemaking to propose that FDA have regulatory authority over as food additives under FFDCA section 409. This portion of the notice focuses on how new and pending petitions will be handled by EPA, both for those antimicrobial substances over which EPA plans to retain regulatory authority and for those that EPA plans to propose to allocate regulatory authority to FDA through rulemaking.

EPA staff are available to meet with petitioners to discuss the status of pending petitions and procedures for submitting a new petition. If a petitioner or any other person considering submitting a petition is interested in meeting with EPA, the petitioner should contact the appropriate Branch Chief in EPA's Antimicrobials Division to schedule a meeting. Information about how to contact EPA appears in Unit VI. of this notice.

1. *New petitions.* Any petition to establish a tolerance or an exemption from the requirement of a tolerance filed after publication of this notice for products now regulated by EPA should be submitted to EPA in the format described in 40 CFR 180.7. In addition, the petition must contain an ''FQPA Addendum.'' EPA has issued detailed guidance in PR Notice 97-1 providing direction on the format and types of information that EPA expects to be

included in the petition to address the factors required by FFDCA to be considered as part of the safety standard of FFDCA section 408. Petitioners should address these factors as they relate to the specific chemical and use pattern that are the subject of their petition. Copies of PR Notice 97-1 are available from the EPA contacts listed in Unit VI. of this notice.

In addition, each petitioner must submit a draft Notice of Filing which EPA may use as the basis for preparing a **Federal Register** Notice announcing receipt of the petition. The petitioner must include in the draft notice or provide separately a summary of the petition and the information, data, and arguments submitted in support of the petition. Generally, the summary should be no longer than five pages. This summary will be included in the Notice of Filing EPA is required to publish (FFDCA section 408(d)(3)). EPA Branch Chiefs have examples of such summaries which they will provide on request. Petitions for actions on antimicrobial substances that may ultimately be under FDA's jurisdiction, if the EPA rulemaking is finalized as it is intended to be proposed, will be under a Notice of Filing stating that the final action may be taken under FFDCA section 408 or section 409. The petition must also be accompanied by the tolerance fee required under FFDCA section 408(m) and 40 CFR 180.33.

Once EPA receives a complete, new petition, the Agency will issue a Notice of Receipt in the **Federal Register** (FFDCA section 408(d)(3)). The Notice will include the summary of petition and data, information, and arguments supporting the petition (FFDCA section 408(d)(2)(A)(i)(I)). EPA will review the petition and take final action as quickly as its resources and other, statutorily mandated, priorities allow.

2. *Pending petitions.* EPA is working with FDA to complete work, as expeditiously as possible, on a group of pending petitions. Prior to enactment of FQPA, FDA received but was unable to complete action on a number of petitions and TOR requests. FDA continued to work on these actions and made progress in these reviews. In addition, since FQPA became law, FDA has received additional petitions and TOR requests. FDA has taken no action with regard to any petition submitted after enactment of FQPA for an antimicrobial substance for which FDA questioned its jurisdiction as a result of FQPA.

EPA places a high priority on completing the review of these pending actions. Therefore, EPA is working with FDA to transfer the petitions and associated FDA evaluations to EPA, so that EPA can complete the review of these petitions as quickly as possible.

The transfer of the petitions and associated evaluations to EPA must conform to the restrictions on transfer of CBI from FDA. Petitioners should request FDA to transfer petitions and FDA evaluations to EPA. Such requests should be directed to the FDA consumer safety officer (CSO) named in the filing notice of the petition or current CSO, if changed since the filing notice. FDA will not transfer any petition or FDA evaluations to EPA until FDA has a signed consent form from the petitioner to transfer such records. FDA will provide the consent form to the petitioner after receiving the petitioner's request for a transfer of records to EPA.

Once FDA has transferred a petition and associated files to EPA, EPA will review the petition. However, companies will need to take some additional steps to allow EPA to complete its review of the petition. First, each petitioner must prepare a short summary of its petition and the data, information, and argument submitted in support of the petition. Second, each petitioner must address the specific factors EPA is required by FFDCA to consider as part of its determination of whether the safety standard in FFDCA section 408 is met. Both of these points were discussed in detail under the ''New Petitions,'' section in this unit.

EPA recognizes that the uncertainty about the jurisdiction of FDA and EPA under FFDCA over antimicrobial agents has caused delays in issuing final decisions on some of the pending petitions. EPA is taking several steps to lessen the impact of such delay. First, EPA will not require the submission of a new petition for any chemical which is the subject of a petition pending with FDA. Instead, EPA will accept the petition as it was submitted to FDA and will process it without further delay. Second, for pending petitions, EPA will waive the required tolerance fee required under FFDCA section 408(m). EPA has the authority to waive or reduce the tolerance fee when waiving the payment of the fee would be ''equitable and not contrary to the purposes of this subsection'' (FFDCA section 408(m)(1)). In this instance, EPA believes that it would be equitable to waive the required fee because it partially offsets any financial burdens resulting from the delay in taking final action on pending petitions. Finally, as noted earlier, completion of review of these petitions holds a very high priority at EPA.

C. EPA-Registered Products Which Would Cease to Be ''Pesticides'' Under FIFRA Pursuant to the Proposed Rulemaking

As discussed in Unit III. of this notice, EPA and FDA have agreed that EPA will propose a rule amending the definition of ''pest'' in 40 CFR 152.5(d). If that rule becomes final, certain antimicrobial substances would no longer be ''pesticides'' and would no longer be subject to regulation under FIFRA. On the effective date of such a final rule, EPA would discontinue registration of any products, previously registered by EPA as pesticides, and bearing labeling for use only against microorganisms that would not be pests.

Former registrants of such products should note that the Federal decision regarding what is a pesticide may not be definitive for the purposes of state regulatory schemes. Former registrants are encouraged to contact state officials to determine how such an EPA rulemaking would affect a product's regulatory status under state law.

EPA would continue to require registration for antimicrobial substances that continue to be ''pesticides'' under FIFRA, even though certain uses for such substances would be ''food additive'' uses under FFDCA. Consistent with current EPA practice, when the use of an antimicrobial substance is both a food additive and a pesticide use as, for example, a slimicide used in the production of food and non-food-contact paper, EPA would review labeling for the pesticidal use and FDA would review the non-pesticidal, i.e., food additive, use. Such a substance may be categorically excluded from the need for an environmental assessment under FDA's regulations implementing the National Environmental Policy Act (NEPA) based on the fact that the food additive use is substantially identical to the pesticide use (62 FR 40570, 40596; July 29, 1997 (citing to the categorical exclusion in 21 CFR 25.32(q))). After FDA approves a food additive that is also regulated as a FIFRA ''pesticide,'' a petitioner would need to formally request EPA to amend its pesticide registration label for the antimicrobial to include the ''non-pesticidal'' use.

VI. Agency Contacts

In the event of questions about the process, EPA and FDA staff are available to meet with petitioners to discuss the status of pending petitions and procedures for submitting a new petition. If a petitioner or any other person considering submitting a petition is interested in meeting with either agency, he or she should contact the

appropriate Branch Chief in EPA's Antimicrobials Division to schedule a meeting or the appropriate team leader in FDA's Indirect Additives Branch.

The EPA Branch Chiefs can be reached at:

Dennis Edwards, Chief, Regulatory Management Branch I, Antimicrobials Division (7510W), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (703) 308–8087, Fax: (703) 308–8481, e-mail: edwards.dennis@epamail.epa.gov.

Connie Welch, Chief, Regulatory Management Branch II, Antimicrobials Division (7510W), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Telephone: (703) 308–8218, Fax: (703) 308–6466, e-mail: welch.connie@epamail.epa.gov.

FDA can be contacted at:

Sandra L. Varner or Andrew J. Zajac, Office of Pre-market Approval Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St., SW., Washington, DC 20204-0002, Telephone: (202) 418–3075 (S. Varner) (202), 418–3095 (A. Zajac).

Mark A. Hepp, Office of Pre-Market Approval Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St., SW., Washington, DC 20204-0002, Telephone: (202) 418–3098.

VII. EPA Public Record and Electronic Submissions

The EPA official record for this notice, as well as the public version, has been established for this document under docket control number ''OPP–300624'' (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number ''OPP–300624.'' Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental Protection Agency, Food and Drug Administration, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 30, 1998.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances, Environmental Protection Agency.

Dated: August 21, 1998.

Sharon Smith Holston,

Acting Commissioner, Food and Drug Administration.

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