

## DUAL REGULATION OF ANTIMICROBIAL FOOD CONTACT USES IN THE U.S.

The U.S. Food and Drug Administration regulates certain antimicrobial uses pursuant to § 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) as either indirect or secondary direct food additives. In addition, the U.S. Environmental Protection Agency (EPA) regulates these same antimicrobial uses pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). FDA promulgates a regulation or issues a letter of authorization permitting such use. However, the antimicrobial product may not be marketed for the FDA-approved use until EPA registers the antimicrobial for the same use. Examples of the uses subject to dual FDA/EPA regulation are: **components of food packaging; papermill slimicides used for food-contact paper; preservatives for coatings and adhesives used with indirect food contact; antimicrobials used in sugar processing and cane mills, and antimicrobials used in or on raw agricultural commodities (RACs) and in processing water in food processing facilities.**

EPA's Office of General Counsel (OGC) has asserted EPA jurisdiction over uses subject to FDA regulation under § 409 and that EPA must perform risk assessments under FFDCA § 408 for these antimicrobials uses, in addition to FDA's § 409 clearances. FFDCA § 408 was amended by the Food Quality Protection Act (FQPA) in 1996, and, as currently interpreted by EPA, has resulted in the cancellation of many pesticide active ingredients or particular pesticide uses. OGC has interpreted FIFRA § 2(bb)(2), which states, "[t]he term 'unreasonable adverse effects on the environment' means . . . (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under [FFDCA] section 408 . . .," as requiring the additional EPA risk assessments. Risk assessment factors under § 408 involve determining (1) the special sensitivities of infants and children and (2) the cumulative effects of pesticides and other substances with a common mechanism of toxicity to (3) ensure there is a reasonable certainty of no harm from aggregate exposure from all uses of a pesticide (active or inert) substance, including possibly non-pesticide exposures.

It is worth noting that antimicrobials used as sanitizers or disinfectants on food-contact surfaces are **not** subject to FDA jurisdiction. These uses are regulated solely by EPA and are subject to the tolerance and tolerance exemption requirements of FFDCA § 408, not the food additives requirements of FFDCA § 409.

Currently, EPA's Antimicrobial Division (AD) is required to conduct independent reviews using FFDCA § 408 risk assessment factors of antimicrobial uses that have been cleared by FDA under FFDCA § 409. AD has conducted only a few § 408-type risk assessment to date. There is continuing uncertainty about data requirements and the methodology for conducting FQPA risk assessments, especially the aspect of including non-pesticide exposures in the risk assessments, is yet to be finally decided. AD also is required to conduct worker and possibly ecological risk assessments for the antimicrobials, which are not considered by FDA in its review.

It appears that EPA's management is considering the policy issues that must be addressed with regard to the overlapping jurisdiction on dietary exposures for these antimicrobial uses. Dual dietary risk assessments for the exact same uses are obviously expensive and create a drain on already strained government resources. Moreover, each dual dietary risk assessment creates an opportunity for two different federal agencies to arrive at different, even conflicting, regulatory opinions.

It is important to note, however, that even if the issue of overlapping jurisdiction for dietary exposures is addressed and resolved, many food-contact antimicrobials still will be subject to review and approval by both FDA and EPA prior to

marketing. Manufacturers and formulators of antimicrobials used in food-contact applications must factor the requirements of both agencies into their pre-marketing regulatory planning.

#### How can Steptoe & Johnson LLP help?

Steptoe has extensive expertise in the regulation of antimicrobials as food additives and pesticides. We assist companies in developing and implementing testing and regulatory strategies in order to minimize efforts, effectively coordinate obtaining approvals from both FDA and EPA, and realizing commercial goals promptly.

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