



MEMORANDUM

Via E-Mail

DATE: April 9, 2007

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Proposes to Exempt Food Packaging Materials Treated with Pesticides from the Definitions of Pesticide Chemical and Pesticide Chemical Residue

On April 6, 2007, the U.S. Environmental Protection Agency (EPA) published a proposed rule that would exempt the components of food packaging material (*e.g.* paper and paperboard, coatings, adhesives, and polymers) that are treated with a pesticide from the definitions of “pesticide chemical” and “pesticide chemical residue” under Section 201(q) of the Federal Food, Drugs, and Cosmetic Act (FFDCA). The regulatory text of the April 6, 2007, proposed rule is identical to that in EPA’s December 6, 2006, direct file rule, which EPA withdrew on January 25, 2007, due to adverse comments. Under the proposed rule, ingredients in food packaging treated with a pesticide would be exempt from regulation by EPA under FFDCA Section 408 as pesticide chemical residues. Further, a food that bears or contains such ingredients would not be not subject to enforcement by the Food and Drug Administration (FDA) under FFDCA Section 402(a)(2)(B) since the ingredients would no longer be pesticide chemical residues. Instead, such ingredients would be subject to regulation by the FDA as food additives under FFDCA Section 409. Comments on the proposed rule are due **April 23, 2007**.

FDA generally regulates such food additives in food packaging as food contact substances under FFDCA Section 409(h). The proposed rule would expand the scope of the provision in 40 C.F.R. Section 180.4 that currently applies only to food packaging impregnated with an insect repellent. EPA states that the proposed rule, as with the rule it would amend, applies only to the food packaging materials themselves; it would not otherwise limit EPA’s FFDCA jurisdiction over pesticides or limit FDA’s jurisdiction over substances subject to FDA regulation as food additives. According to the proposed rule, EPA, in consultation with FDA, and FDA believe the proposed rule “would eliminate the duplicative FFDCA jurisdiction and economize federal government resources while continuing to protect human health and the environment.” Even after the final rule is promulgated, under the Federal Insecticide, Fungicide,



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and Rodenticide Act (FIFRA), EPA would continue to regulate the food packaging as an inert ingredient of the pesticide product and regulate the pesticide active ingredient in the treated food packaging under both FIFRA and the FDCA.

In the proposed rule, EPA states: “It is important to understand that this proposed rule would only apply to a very small subset of food packaging materials: pesticide-treated food packaging that is distributed or sold with the purpose of controlling pests.” Food packaging that is not distributed or sold to control pests is not a pesticide, and would not be subject to this rule. As an example, the proposed rule says that “packaged products that are simply treated with pesticides by food distributors, retailers or homeowners solely to control pests on site do not themselves become pesticides simply as a result of such applications. Rather, the product itself must be distributed with the purpose of providing pest control to become a pesticide.” The treated packaging materials addressed in the proposed rule are those sold for the express purpose of providing ongoing protection from pests that may contaminate the products made with the treated packaging.

The proposed rule notes that the comments EPA received on the direct final rule all appeared to oppose the rule principally because the commenters were concerned about the inclusion of pesticides in food packaging and did not believe EPA should either be permitting or relinquishing any authority to regulate that activity. According to EPA, it appears that the commenters either misunderstood the nature of the amendment to 40 C.F.R. Section 180.4 or chose to submit comments to EPA on matters not specifically addressed by the direct final rule. EPA states: “In any case, nothing in the withdrawn direct final rule or in today’s proposal relieves EPA of the obligation to regulate pesticides in food packaging, nor does today’s action serve to approve the use of any pesticides in food packaging. Accordingly, these comments are not relevant to the action EPA is today proposing to take.” Because EPA previously provided a 30-day comment period on the withdrawn direct final rule, and the text of the proposed rule is identical to the withdrawn direct final rule, EPA is providing only a 15-day comment period on the proposed rule.

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We hope this information is helpful. As always, please call if you have any questions.