CSPA®
Consumer Specialty Products Association

June 11, 2007

James B. Gulliford
Assistant Administrator
US EPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Mail Code 7101M
Washington, DC 20460

Re: Petition to Modify EPA's Exemption from FIFRA Regulation for Minimum Risk Pesticides under 40 C.F.R. § 152.25(f) (filed March 15, 2006)

Dear Mr. Gulliford:

The Consumer Specialty Products Association (CSPA) understands and applauds the fact that you have recently focused on the merits of CSPA's above-referenced Petition to require Agency review of product efficacy for those minimum risk pesticides claiming to control health pests. This letter provides procedural recommendations to the Agency on implementing CSPA's proposed amendment to the above-referenced regulation in order to bring such exempt products quickly into compliance with the Agency's product performance standards, while at the same time being fair to those marketers who have relied upon the exemption to sell pesticides claiming to control public health pests.

Specifically, CSPA urges the Agency to enlist the cooperation of the U.S. Department of Agriculture (USDA) and the Scientific Advisory Panel (SAP) to reduce the statutory time periods for their review of new regulations and then to issue an "interim final" rule that requires every marketer of an exempt pesticide claiming to control a public health pest to satisfy two conditions: (1) within one month, identify and certify its intention to register each such pesticide; and (2) within nine months, apply for registration together with the necessary supporting efficacy and stability data required by 40 C.F.R. § 158.640 and 158.190. Any marketer who is currently relying on the exemption to sell a pesticide intended to control a public health pest and who is unwilling to make the required certification would have one year after issuance of the interim final rule in which to sell off existing stocks.

Background

The Agency invited public comments on CSPA's Petition by November 13, 2006 and then extended this deadline until January 5, 2007 and during this comment period received overwhelmingly supportive comments, especially from state regulators and public health authorities such as the Association of American Pest Control Officials and the Centers for Disease Control and Prevention. Such broad-based support is not surprising since CSPA's Petition rests upon the unassailable proposition that all pesticides, whether conventional or nonconventional, claiming to control public health pests should meet the same performance standards and undergo the same Agency review because of their significance to public health.

Opposition to CSPA's Petition surfaced largely from nonconventional pesticide proponents and manufacturers who erroneously conflate the requested Agency review of product efficacy and stability data with the larger testing burdens of full registration under FIFRA. Full registration is not at issue here since CSPA does not question the Agency's underlying finding that exempt products pose "little or no risk" from a toxicological standpoint. Rather, the critical issue is one of product performance. While taking steps to require competing pesticides with public health pest claims to meet a common performance standard properly levels the commercial playing field, CSPA's overarching concern is to protect the consumer against insect and tick-borne diseases. The Agency has an important responsibility to assure the public that all pesticides claiming to control public health pests are in fact effective, and similarly the public is clearly entitled to Agency assurance because the public's health is at stake.

In short, the real issue before the Agency is not the merits of CSPA's Petition, which are compelling, but rather the procedures for implementing responsive rulemaking: Specifically, how to bring the heretofore exempt public health pesticides under Agency review promptly, without unduly penalizing marketers of such pesticides who are relying on the minimum risk pesticide exemption. This letter proposes an appropriate process to this end.

FIFRA and APA Rulemaking Procedures

FIFRA § 25 requires the Agency to give USDA and the FIFRA SAP at least 60 days to review proposed and 30 days to review final regulations. Nevertheless, both USDA and FIFRA SAP can agree to waive these statutory time periods. *See* FIFRA § 25(a)(2)(C) & (d)(1). Hence, the Agency can avoid the 60 day review of proposed rules

and, in addition, can reduce or eliminate the 30-day review period for final rules by obtaining waivers from these two bodies, if EPA elects to proceed through interim final rulemaking because of the important public health concerns at stake.

In the past, EPA has used the "good cause" exemption from standard notice-and-comment rulemaking under the Administrative Procedure Act (APA) to institute interim final rulemaking when standard rulemaking is "impractical, unnecessary, or contrary to the public interest." U.S.C. § 553(b)(B). *See* e.g., 40 C.F.R. § 721.160(c)(5) (EPA Procedures for Issuing Significant New Use Rules under TSCA). Where, as here, a public health problem will persist for a considerable time after a remedial rule becomes final and effective, interim final rulemaking is not only useful but necessary and appropriate. Furthermore, the Agency already has afforded ample opportunity for, and received the benefit of, extensive public comment on CSPA's Petition.

An interim final rule becomes effective immediately upon publication but also affords the public 30 days to submit comments, which the Agency will consider in developing the final rule. Interim final rules issued under this procedure, although immediately effective, automatically expire 180 days after publication unless within that period EPA issues a final rule in the Federal Register. Thus, the Agency could receive and consider further public comments even while it addresses proactively the ongoing public health problem created by unregistered and (we believe) largely untested pesticides marketed under the 152.25(f) exemption with claims to control public health pests.

Interim Final Rule Content

CSPA proposes that the Agency issue an interim final rule requiring every marketer who relies on the exemption to sell products claiming to control public health pests to satisfy two conditions: First, within 30 days of publication every marketer must notify the Agency of each such pesticide which it is currently marketing under the exemption and, in addition, must certify its intention to apply for registration within 9 months of publication, supported by the required product efficacy and stability data for each such product. In other words, the rule would expressly condition each marketer's right to continued reliance on the exemption upon timely filing of this notification/certification.

Consequently, the interim final rule will start the process of removing from the market any exempt product whose marketer will not commit to registration. Those

marketers who notify the Agency of their exempt pesticide but do not certify their intention to apply for registration of such pesticide would need to cease manufacture within 30 days and, thereafter, would have one year from publication to sell off existing inventory. EPA could take immediate enforcement action against any marketer that continues to sell an exempt public health pesticide without having filed the required notification. By requiring certification of intent to register within 9 months, the rule will give marketers sufficient time to undertake any required efficacy and stability testing, if not already completed, and will enable the Agency to plan its forthcoming registration reviews based on the number of certified products.

Second, within 9 months of publication the marketer of an affected pesticide must apply for registration, supported by the product performance and stability data required in 40 C.F.R. § 158.640 & 158.190. In keeping with the Agency's finding underlying the 152.25(f) exemption, namely that these exempt products have little or no toxicity, the rule would expressly waive the requirement for submitting toxicity data with the application. During its initial screening of each such application, EPA can identify and deny those applications which obviously lack the requisite performance and stability data. These products would receive a short sell-off period of 6 months.

Thereafter, EPA can and should streamline its review of these currently unevaluated pesticides with claims for controlling public health pests since they will remain on the market pending EPA's registration decision. CSPA recognizes that guideline test methods often may not be appropriate for evaluating pesticides, conventional and nonconventional alike, with unique modes of action and, therefore, that EPA needs to be flexible in its choice of test methods for measuring the performance of particular products. Nevertheless, performance standards should be the same for both conventional and nonconventional pesticides to ensure protection of the public health. Since the Agency's review will focus solely on the efficacy and stability data and related product claims, however, EPA should be able to complete its review of these applications within the applicable deadlines under the Pesticide Registration Improvement Act for new products undergoing non-fast track review of product chemistry and public health pest efficacy, namely 6 months. 65 Fed. Reg. 12,772, 12,776 (2004).

Conclusion

Since CSPA filed its March 15, 2005 Petition on these exempt public health pesticides, the 2006 use season has passed, and now consumers are well within the second (2007) use season. Unless the Agency takes prompt and appropriate action to

implement CSPA's Petition, these unevaluated and, we believe, largely untested pesticides making public health pest claims under section 152.25(f) will remain on the market, where they will continue to pose an indeterminate public health risk. If EPA acts promptly to publish an interim final rule, any such currently exempt pesticides would be discontinued promptly and sold off within a year, if the marketer does not immediately commit to register them. If the marketer does commit to register them, these exempt pesticides would undergo registration review during the next (2008) use season and, thereafter, either could continue on the market under a valid EPA registration or would be removed from the market because their registration was denied.

Unless the Agency acts promptly and aggressively to implement CSPA's Petition through interim final rulemaking, the public will remain at risk from these unevaluated public health pesticides for many years to come.

Very truly yours,

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