



Chemical Producers & Distributors Association

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VIA EPA Docket

Jeff Kempter
Antimicrobials Division (7510P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

RE: Pesticides; Draft Guidance for Pesticide Registrants on False or Misleading Pesticide Product Brand Names; 75 Fed. Reg. 28012 (May 19, 2010); Docket ID No. EPA-HQ-OPP-2010-0282.

Dear Mr. Kempter:

The Chemical Producers & Distributors Association (“CPDA”) appreciates this opportunity to comment on the above-referenced draft guidance for pesticide registrants. CPDA is the primary advocate on federal legislative and regulatory issues for generic pesticide registrants, adjuvant and inert ingredient manufacturers, and product formulators and distributors. We represent over \$7 billion worth of pest control products used on food, feed and fiber crops, and in non-crop segments of the pesticide industry. CPDA appreciates and supports the ongoing efforts of the U.S. Environmental Protection Agency

(“EPA” or “Agency”) to implement FIFRA¹ fairly and efficiently. However, we are concerned that this effort to provide “clarifying guidance” on the Agency’s regulatory interpretation of FIFRA’s prohibition against false or misleading labeling has resulted in an unclear draft guidance document (“PR Notice 2010-X” or “Notice”) that, in practice, is likely to be implemented as an enforceable legislative rule. Moreover, we believe EPA underestimates the impact of the Notice on registrants and ignores the likelihood of unwarranted restrictions on the constitutional right of registrants to describe their products in the marketplace. The following comments address these concerns and several other aspects of PR Notice 2010-X.

The Notice is a *de facto* Legislative Rule

In the Notice and the related Federal Register notice, and in the Agency’s responses to comments on the draft 2002 notice (“Responses to Comments”),² EPA describes the Notice as “guidance,” “guidance document,” “clarifying guidance,” “general guidance,” etc., and repeatedly affirms that the Notice is not binding on either EPA or registrants.³ Furthermore, the Agency asserts that the notice is only guidance and, therefore, has “no binding effect on any pesticide registrations [, and]... does not constitute a rule.”⁴ CPDA disagrees with this characterization of the Notice because EPA is effectively amending an existing legislative rule (i.e., 40 C.F.R. §156.10(a)(5)) and, accordingly, the Agency must comply with the rulemaking provisions of section 553 of the Administrative Procedure Act (“APA”).⁵

First, the Notice, in effect, amends current registration regulations by cautioning registrants and distributors that they may face enforcement actions if, after the effective date of the Notice, they release for shipment products that are not in compliance with the Notice. Moreover, EPA expressly states that it intends to “begin a more thorough review

¹ Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”); 7 U.S.C. §§ 136 *et seq.*

² EPA, Office of Pesticide Programs (OPP), *Responses to Comments Received Concerning “Draft Guidance for Pesticide Registrants on False or Misleading Names”* (Federal Register: March 28, 2000; Vol. 67, No. 60, pp. 14941-3 (5/2/10 DRAFT)).

³ See, e.g., Notice at p. 10 (“[T]his policy is not binding on either EPA or any outside parties, and the EPA may depart from the guidance where circumstances warrant and without prior notice.”).

⁴ Responses to Comments, p. 37.

⁵ 5 U.S.C. §§ 500-596 (2010).

of existing products for compliance problems” after the effective date.⁶ This establishes a de facto enforceable requirement. Therefore, the purported “non-enforceable” guidance document would be used to improperly amend an enforceable legislative rule each time EPA enforces its determination that a specific brand name is false or misleading under FIFRA labeling regulations.⁷

Second, the Notice does not provide the clarity and certainty that EPA presumes it does. For many years, the Agency has used internal “evergreen lists” in making regulatory decisions under various programs, including one for “false or misleading” words and statements. These evergreen lists have appeared from time-to-time in PR Notices, and the Agency has recently been adding words, such as “professional” and “pro,” to the false or misleading list, even though these words have long-been approved for brand names on labels. Importantly, EPA has cited no information to support its concerns about these and other words, which the Agency claims “could bias a customer’s selection” of products or “mislead” users in ways that they “may not obtain optimal pest control results” or may believe “the product is ‘safe’ and not follow use directions “as carefully as they otherwise might.”⁸

The federal pesticide registration system simply cannot function equitably if some prohibited words are listed in an enforceable legislative rule and others on an amorphous evergreen list of words and phrases that could be subject to the same enforcement, particularly when EPA has previously authorized use of the words now being added to the evergreen list in the Notice. EPA must provide much greater clarity by using many examples of why words are false or misleading, including the acceptable and unacceptable contexts used to make false or misleading determinations. If the Agency, under threat of enforcement, intends to require registrants to make important and costly decisions about “words, phrases, company names, or trademarks that are like”⁹ the words in Table 1 of the Notice, then it should provide maximum clarity on what words are unacceptable (emphasis added). It is unreasonable to require registrants to alter brand names in the marketplace

⁶ Responses to Comments, p. 42.

⁷ 40 C.F.R. §156.10(a)(5).

⁸ Notice, p. 4.

⁹ Notice, p.5.

based on their uninformed decisions about what the Agency perceives as being “like” the words in Table 1 means, particularly since those words may be only “potentially” false or misleading.

Therefore, CPDA recommends that EPA develop a comprehensive list of words, statements, and phrases that the Agency would always, or would highly likely consider false or misleading in brand names under FIFRA, based on rationale and supporting information consistent with FIFRA requirements. Those that are always false or misleading should then be added to section 156.10(a)(5) pursuant to APA requirements. For words that are highly likely to be false or misleading, EPA should provide examples in related guidance of the contexts in which the words would be false or misleading. EPA currently lists in 40 C.F.R. §156.10(a) multiple words and phrases that provide unambiguous notice of safety related and other labeling words and phrases prohibited under the misbranding requirements of FIFRA.¹⁰ Unlike the evergreen list approach EPA is fostering with the Notice, registrants and distributors would have the certainty they need to avoid using prohibited words when submitting registration applications involving brand names, and much greater understanding of when and why those words on the “highly likely” list would not be acceptable. This approach would be significantly more equitable to pesticide registrants and distributors and would provide the stability needed to justify the considerable costs associated with introducing and maintaining a pesticide product in the marketplace.

EPA Understates the Economic Impact of the Notice on Registrants and Distributors

EPA consistently minimizes the potential economic impacts of the Notice on registrants and distributors without providing credible supporting information. For instance, in its responses to comments on the 2002 draft notice, EPA states “[t]he Agency believes that only a small percentage of federally registered products bear names that may be potentially false or misleading and does not expect the guidance will affect numerous registrants.”¹¹ EPA has neither enumerated how many labels contain potentially false or

¹⁰ FIFRA §(q)(1)(A).

¹¹ Responses to Comments, p. 3.

misleading brand names, nor identified all words it considers potentially false or misleading. CPDA's quick search of NPIRS¹² revealed that there are more than a thousand labels alone with "professional" or "pro" in the product name. This indicates that registrants and distributors may incur much greater costs to comply with the Notice than EPA assumes. Consequently, EPA should reassess its assumptions about the number of products affected by the Notice and the fundamental purpose of the Notice.

On page 10 of the Notice, EPA asserts that information collection activities associated with the Notice "are already approved by the Office of Management and Budget (OMB)," citing a 2008 Information Collection Request ("ICR") (based on 2006 data) that provides the annual reporting and recordkeeping burden for three types of registration activities. Unfortunately, this ICR is not specific to the Notice, so the burden estimates in the ICR are not relevant to the Notice. Moreover, EPA has not considered the significant actual costs registrants and distributors will incur if they abandon or modify brand names, including the costs to revise and relabel products, deal with existing inventory, undertake new marketing and advertising strategies, file for new trademarks, etc. In addition, EPA has ignored the costs associated with new state registrations, which could easily exceed \$10,000 per product label if a product is distributed in most or all states, and the associated delays in processing applications due to inadequate staffing and funding levels in many states.

The Notice Would Improperly Restrict Protected Commercial Speech

EPA's proposed actions under the Notice are clearly directed at perceived market-related inequities and seek "to bring all product names, which may include trademarked company names or brand names, into compliance with FIFRA and its regulations, thereby protecting both consumers and competitors that 'play by the rules' with respect to product names."¹³ Such an undertaking, in certain instances, would improperly restrict the constitutionally protected commercial speech of registrants and distributors.¹⁴ As noted

¹² National Pesticide Retrieval System (Purdue University).

¹³ Notice, p. 3.

¹⁴ CPDA is aware of the Agency's position on this issue, i.e., the Notice "is not intended to prohibit any particular brand name and thus does not abridge any commercial speech protection." (Response to Comments, p. 35).

above, the Agency proposes to restrict and/or prohibit use of words in brand names, which will involve numerous product names, including those that have been approved by EPA and marketed for many years. However, nowhere in the Notice does the Agency demonstrate that those words render a brand name false or misleading under FIFRA. They simply appear in a table along with several other words identified as “potentially” false or misleading to notify registrants that thousands of currently approved pesticide product brand names containing those words¹⁵ should be evaluated for possible removal or modification or face FIFRA enforcement actions.

Before EPA can restrict use of these words or any other words in brand names, particularly those already approved and in use, the Agency must comply with specific judicially imposed requirements to demonstrate that its restrictive actions are constitutionally valid. In essence, the Agency must demonstrate that (i) a word or phrase in question is unlawful (i.e., misleading under FIFRA), (ii) the Agency has a substantial interest in regulating the word, (iii) the actions required by the Notice directly advance the asserted Agency interest, and (iv) the Agency uses the least restrictive means of advancing the asserted interest.¹⁶

EPA’s justification for the Notice is that it “continues to receive occasional requests for acceptance of federal and state pesticide product brand names that appear to be false or misleading” (emphasis added).¹⁷ The Agency has provided neither rationale nor cited any compelling reason or circumstances that would justify the costly commercial disruption of revising labels and loss of brand names. Having to “occasionally” address registration applications that may involve words that are “potentially” false or misleading does not appear to warrant this likely broad restriction on protected commercial speech. EPA has provided no evidence that the use of the words in Table 1 in brand names has resulted in unreasonable adverse effects on the environment, or that consumers and users have been misled or deceived, or that the Notice will directly and materially advance a significant Agency interest. The fact that EPA took 8 years to issue a revision of the 2002

¹⁵ NPIRS.

¹⁶ See generally, Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557 (1980).

¹⁷ Notice, p. 4.

draft notice indicates instead that the Agency lacks a compelling and substantial interest that must be addressed by the Notice.

Annual Consistency Review

Regardless of the final form of guidance issued to clarify EPA's decision-making on false or misleading decisions about brand names, there must be some procedure in place to ensure that independent Agency staff decisions are consistent and in accordance with the guidance and law. These decisions will be extremely important to registrants, and must be as uniform as possible. Therefore, CPDA recommends that EPA organize a team to conduct yearly consistency reviews to assess the degree to which staff decisions are consistent with the guidance and applicable legal requirements across PM Teams and others, such as the "cross-divisional advisory group," that are involved in false or misleading determinations.

CONCLUSIONS

CPDA appreciates the opportunity to comment on this guidance document, but has significant concerns about the need for the guidance and EPA's failure to more thoroughly identify unacceptable words and phrases. We believe the Agency should amend section 156.10(a)(5) to add words and phrases determined to be false or misleading in brand names under any circumstances. Registrants need clarity and certainty when developing and selecting products for the marketplace. Requiring them to reevaluate approved existing brand names to comply with an ever-changing guidance list is an unwarranted, disruptive, and costly burden that can be minimized in the future through rulemaking. Moreover, related guidance in the form of a list of highly likely false or misleading words and related detailed examples of use contexts for false or misleading determinations should be developed to provide additional clarity on this issue. Finally, we urge the Agency to reassess the rationale for and approach to implementing this guidance for conformance with judicially imposed requirements for protecting commercial speech under the First Amendment.

Michael C. White, Ph.D., J.D.
Director of Regulatory Affairs