

Inert Ingredient Disclosure

Overview

On December 23, 2009, EPA published an Advance Notice of Proposed Rulemaking (ANPR) that solicits public comments on a range of issues related to disclosure of potentially “hazardous” (undefined) inert ingredients and all or most other inert ingredients in pesticides. Of particular concern is EPA’s restatement of its position that (i) non-hazardous inert ingredients are not categorically excluded from disclosure under FIFRA §10(d)(1)(C) from the mandatory §10(d)(1) disclosure of safety and efficacy data, and (ii) all excluded information must first meet the §10(b) standard for trade secrets and confidential or privileged commercial or financial information. EPA also confirmed that its guiding principle for disclosure is transparency that “will assist consumers and users of pesticides in making informed decisions and will better protect public health and the environment.” Therefore, confidential business information (CBI) claims will be closely scrutinized to remove the historical disclosure protection afforded many non-hazardous inerts. On February 10, 2010, EPA granted a 60-day extension of the comment period in response to CPDA’s and CLA’s separate requests for a 90-day extension.

Update

Working through the Inerts Steering Committee, CPDA and CLA jointly developed comments on a number of disclosure issues and responses to certain questions set forth in the ANPR, and then separately submitted similar comments on April 23, 2010. The comments focus on three core objections to the ANPR:

- EPA’s reliance on the premise of market failure has occurred due to registered products that are “more hazardous than is efficient” and, therefore, regulatory action is needed to correct the market and provide a net social benefit. The premise is wholly unsupported, and CPDA noted that the Agency must conduct a Regulatory Flexibility Analysis to identify market imperfections that necessitate regulatory action, and possibly a regulatory impact analysis under EO 12291 if the action is economically significant;
- EPA’s claim that FIFRA §10 provides only limited disclosure protection for inerts, a position that is clearly contrary to Congress’ balanced approach for protection of CBI and public access to health and safety information. This broad disclosure initiative appears to be an effort to increase “transparency” through rulemaking without clear statutory authority; and
- EPA’s position that disclosure of inerts can be required under FIFRA on the basis of “hazard” rather than risk. The Agency must first develop criteria to classify an inert ingredient as “hazardous” and then develop criteria for evaluating the ingredient in a FIFRA risk assessment.