

Nanoscale Materials

Overview

On June 17, 2011, EPA published for comment a draft policy statement concerning pesticide products containing nanoscale materials (“defined” as an active or inert ingredient having at least one dimension that measures 1-100 nm). This policy will be used to obtain information about nanoscale materials present in currently registered pesticide products and for treating all registration applications for such materials as applications for “new” ingredients. Applicants can rebut this newness presumption by submitting data/information demonstrating “substantial similarity” to a registered non-nanoscale or nanoscale material. To obtain information about active and inert ingredient nanoscale materials in registered pesticide products, EPA proposes to use FIFRA section 6(a)(2), which authorizes the Agency to obtain information about “adverse effects” related to registered products.

CPDA Comments

On August 17, 2011, CPDA submitted comments on the proposed policy statement that urged EPA not to use section 6(a)(2) to obtain information about nanoscale materials because nanotechnology is a new technology, especially for pesticide products, and using that provision of FIFRA (i.e., “adverse effects” reporting) could unnecessarily stigmatize the nanotechnology industry generally and the pesticide industry in particular. CPDA recommended that the Agency use instead a more targeted approach under section 3(c)(2)(B) authority (i.e., data call in), which would remove the stigma concerns and minimize the information collections burdens on EPA and registrants. Rather than requiring all registrants to respond to a section 6(a)(2) notice, this case-by-case approach could focus on pesticide classes that are known to, or most likely to, contain nanoscale materials to provide the currently available “presence,” “process,” and “type” information EPA seeks. CPDA also expressed its concern that the proposed newness presumption for all nanoscale materials would effectively require all pesticide registrants and those seeking approval of inerts to incur higher PRIA fees and data submission burdens, potentially creating a barrier to development and use of nanoscale active and inert ingredients in pesticide products. CPDA recommended that EPA not implement the presumption policy at this time, and instead focus on developing specific data requirements and testing protocols for these materials.