

EPA SEEKS TO DISCLOSE MORE CHEMICAL IDENTITY INFORMATION

The US Environmental Protection Agency (EPA or Agency) has begun making two important changes concerning the way the Agency intends to deal with claims of confidentiality regarding the identities of chemicals in commerce. The changes could affect companies who submit information to the Agency pursuant to the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 *et seq.* When fully implemented, the two changes will limit the extent to which information concerning chemical identities can be claimed as Confidential Business Information (CBI). The Agency is undertaking these policies to further the Administration's goals concerning "transparency," and EPA is likely to undertake additional actions to increase disclosure to the public of information concerning chemicals contained in commercial chemical products.

DISCLOSURE OF INERT INGREDIENTS UNDER FIFRA

On December 23, 2009, EPA issued an advance notice of proposed rulemaking (ANPR) to seek comment regarding significant changes to EPA's pesticide labeling requirements for inert ingredients.¹ Currently, EPA treats the disclosure of "active" and "inert" ingredients differently for labeling purposes; the Agency requires that only "active" ingredients be identified by name and percentage on the pesticide label's ingredient statement.² 40 CFR 156.10(g). After decades operating under this approach, EPA has announced that this policy interferes with the "fair and efficient" operation of the pesticide market, because consumers with more "knowledge[] about the product choices available to them...are better able to compare the products and vote with their pocketbook by selecting that product which best satisfies their needs and/or preferences." 74 Fed. Reg. 68215, 68219.³ EPA believes new labeling requirements will allow consumers

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¹ Public Availability of Identities of Inert Ingredients in Pesticides, 74 Fed. Reg. 68215 (Dec. 23, 2009) (to be codified at 40 C.F.R. pt 156).

² Section 2(a)(1) defines "active ingredient" to include any ingredient "which will prevent, destroy, repel or mitigate any pest." Section 2(m) defines an "inert ingredient" as an ingredient which is not "active."

³ EPA's recent actions appear to be driven largely by two petitions it received in August, 2006—one filed by a group of 22 non-governmental organizations (NGOs), and the other filed by the Attorney Generals of 15 US states and territories—which sought to require increased disclosure of inert ingredients. 74 Fed. Reg. 68215, 68217. EPA partially granted the petitions on September 30, 2009, and committed to initiate rulemaking to broaden the availability of inert ingredient identities. *Id.* at 68218. However, EPA exhibited a willingness to engage in a dialogue on this issue during the waning years of the Clinton Administration, when in 1999 it requested the Pesticide Program Dialogue Committee (PPDC) to establish a workgroup to advise the PPDC and EPA on ways to increase the public availability of inert ingredients contained in pesticides. See EPA Publication, Final Report to the PPDC on the Activities of the Inert Disclosure Stakeholder Workgroup, available at <http://www.epa.gov/pesticides/ppdc/inert-finalreport.html>.

to “fully express their preferences through informed purchasing,” which may “lead the market to provide more product choices that could reduce the overall exposure to potentially hazardous chemicals.” *Id.*

In its ANPR, EPA proposes two general approaches to a revised pesticide labeling rule, both of which could drastically change the way in which inert ingredients are addressed on pesticide labels: (1) EPA could require disclosure of potentially hazardous inert ingredients; or (2) EPA could require disclosure of most or all inert ingredients, regardless of hazard. With regard to the first approach, EPA has suggested three alternative methods to determine which inert ingredients would be considered potentially hazardous, and thus subject to additional disclosure on product labels. Those alternatives include requiring the disclosure of particular inert ingredients currently listed as hazardous; creating a new list of substances considered to be hazardous when used as inert ingredients in pesticides; or creating a new objective criteria to screen inert ingredients on a case-by-case basis to determine if they are hazardous as contained in a particular pesticide. With regard to its second potential approach—requiring the disclosure of all inert ingredients regardless of hazard—in order to implement such a rule, EPA must first determine that inert ingredients as a class should not be entitled to confidential treatment under FIFRA Section 10(b) and 10(d).⁴ *Id.* at 68220. Signaling a potential basis for making this determination, EPA has requested comment regarding whether current analytical techniques “have increased in accuracy and decreased in cost to the extent that essentially complete analysis of competitors’ products is now both routinely performed and successful when attempted in the pesticide industry.” *Id.* If EPA determines that confidential treatment for inert

ingredients no longer prevents such “reverse-engineering” by competitors, EPA may be willing to determine that CBI claims for inert ingredients should be eliminated completely.

Comments with regard to the ANPR must be submitted to EPA on or before April 23, 2010.⁵

DISCLOSURE REQUIREMENTS UNDER TSCA SECTION 8(e)

On January 21, 2010, EPA announced that the Agency no longer will allow parties submitting substantial risk reports under TSCA Section 8(e) automatically to claim the chemical identity to be CBI when the substance already appears on the public edition of the TSCA Inventory.⁶ Pursuant to TSCA Section 8(e), companies that manufacture, process, or distribute chemical substances must promptly alert EPA when they acquire information that reasonably supports the conclusion that a chemical substance presents a substantial risk of injury to health or the environment. It has been EPA’s practice to redact the chemical identity from public portions of TSCA Section 8(e) reports where the chemical identity is claimed as CBI, even when the chemical identity already is listed on the public portion of the TSCA Chemical Inventory. Commencing immediately, where a report submitted under Section 8(e) involves a chemical substance that already is listed on the public portion of the TSCA Chemical Substances Inventory, the chemical identity no longer will be entitled to confidential treatment. *Id.*

FUTURE REGULATION REGARDING CBI

These two actions come on the heels of other recent EPA efforts to increase public disclosure of commercial chemical product information, including EPA’s decision to release the identities of approximately 530 substances

⁴ FIFRA Section 10(b) requires that “the Administrator shall not make public information which in the Administrator’s judgment contains or relates to trades secrets or commercial or financial information obtained from a person and privileged and confidential” 10 U.S.C. § 136h(b). In addition, FIFRA Section 10(d) specifically precludes the Agency from releasing “the identity or percentage quantity of any deliberately added inert ingredient... unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.” 10 U.S.C. § 136h(d).

⁵ At the request of two submitters, EPA extended its original deadline for comment by 60 days. 75 Fed. Reg. 7560 (Feb. 22, 2010).

⁶ Claims of Confidentiality of Certain Chemical Identities Submitted under Section 8(e) of the Toxic Substances Control Act, 75 Fed. Reg. 3462 (Jan 21, 2010).

previously claimed as CBI on the TSCA Inventory.⁷ These actions reflect the Agency's commitment to increased disclosure requirements concerning chemical identities, uses, and risk-related information. This policy shift is likely to result in EPA further limiting CBI protections in the commercial chemical industry, and parties that may be affected by these changes should watch closely for future developments in this area.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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⁷ TSCA Chemical Substance Inventory Update; Changing Certain Chemical Substances' Identities from Confidential to Non-Confidential, 74 Fed. Reg. 37224 (July 28, 2009).