

PROTECTION OF CONFIDENTIAL INERT INGREDIENT INFORMATION IN A WORLD OF DISCLOSURE

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Pesticide inert ingredient information has long been protected by federal law. The balance that Congress has set – between the importance of making information available to facilitate informed decisions on the one hand and the protection of proprietary rights and promotion of innovation on the other – is embedded in many of our laws. The application of these laws has been stable for some years. We hope this article provides useful information about how the laws generally operate, and also helpful information about the U.S. Environmental Protection Agency's recent request for input as it considers options for increasing the public availability of inert ingredient information.

FIFRA Protects Most Inert Ingredient Information as Confidential Business Information

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides strong protections for inert information. There is no statutory requirement for public disclosure of all inert ingredient information. Instead, FIFRA requires that the “total percentage of all inert ingredients” in a pesticide must be listed on the label. FIFRA §2(n)(1). Congress and EPA historically have protected the identities and individual concentrations of inert ingredients as Confidential Business Information (CBI), primarily to protect proprietary rights of inert suppliers and pesticide registrants and to promote innovation. Under FIFRA, an applicant or registrant may designate as CBI information that it considers to be a trade secret or commercial or financial information. FIFRA §10(a).

EPA generally may not disclose CBI, however, the Agency has the responsibility to evaluate a CBI claims to determine if the information qualifies for protection. FIFRA §10(b). In addition, FIFRA sets limits on CBI and requires EPA to disclose certain types of information. In particular, EPA must make available safety and efficacy information from tests or experiments on a registered pesticide or its separate ingredients, impurities, or degradation products. FIFRA §10(d)(1). However, this requirement does not authorize the disclosure of “the identity or percentage quantity of any deliberately added inert ingredient of a pesticide” from such tests or experiments. FIFRA §10(d)(1)(C). EPA may disclose this information only if it first determines that disclosure is “necessary to protect against an unreasonable risk of injury to health or the environment.” FIFRA §10(d)(1).

FIFRA Does Not Prohibit EPA from Disclosing All Inert Ingredient Information

FIFRA § 10(d)(1)(C) provides substantial protections against disclosure of inert ingredient information, however, it does not provide a complete prohibition on the disclosure of all inert ingredient information. The language quoted above is strong, but a federal court and EPA have interpreted FIFRA § 10(d)(1)(C) only to prohibit the mandatory disclosure of inert ingredient identities and quantities as part of the required disclosure of safety and efficacy data. See *Northwest Coalition for Alternatives to Pesticides (NCAP) v. Browner*, 941 F. Supp. 197, 201 (D.D.C. 1996); see also 74 Fed. Reg. 68,215, 68,217 (Dec. 23, 2009). According to this interpretation, FIFRA § 10(d)(1)(C) says only that when EPA must disclose safety and efficacy information related to registered pesticides and their ingredients, the Agency is not required to release inert ingredient identities or quantities as part of that disclosure.

Under this relatively narrow interpretation, inert ingredient information does not receive absolute protection under FIFRA § 10(d)(1)(C). Rather, an applicant or registrant may claim CBI for the identities and quantities of the inert ingredients in its product, and the information is protected from disclosure only if it qualifies as a confidential trade secret or commercial or financial information like any other confidential business information. Based on the court’s decision in *NCAP*, commercial information is confidential “if disclosure is likely to cause substantial harm to the competitive position of the person from whom the information was obtained.” *NCAP v. Browner*, 941 F. Supp. at 201. Under this “substantial harm test,” a company claiming confidentiality “need not demonstrate actual harm but must show: (1) actual competition and (2) a likelihood of substantial competitive injury.” *Id.* A company submitting inert ingredient information is not required to demonstrate that it satisfies this test when it submits the information, but may need to do so if EPA requires the company to substantiate a CBI claim, as described below.

Confidential Business Information Is Similarly Protected Under FFDCA and FOIA

The Federal Food, Drug, and Cosmetic Act (FFDCA) and the Freedom of Information Act (FOIA) also provide protections for inert ingredient information, essentially to the same extent as FIFRA. FFDCA requirements apply to inert ingredients used in food pesticides. If a pesticide product or inert ingredient will be used on a food crop, the applicant must obtain a tolerance or tolerance exemption for that product. FFDCA §408; §§ 201(q)(1), (2). FFDCA specifically states that data and information submitted to support a tolerance or tolerance exemption are entitled to protection to the same extent provided by FIFRA § 10, as described above (as well as FIFRA § 3’s provisions on exclusivity and compensability of data). FFDCA §408(i)(1).

FOIA applies broadly to all federal government records, and it requires the disclosure of records unless they fall within specific statutory exemptions. 5 U.S.C. §552(a)(3). FOIA protects CBI under “Exemption 4,” which prohibits disclosure of “trade secrets and commercial or financial information obtained from a person [that are] privileged or confidential.” 5 U.S.C. §552(b)(4). FOIA Exemption 4 uses effectively the same definition of CBI as FIFRA section 10(b), and thus protects essentially the same information.

Applicants Should Identify CBI Up Front When Making Submissions to EPA

EPA has general confidentiality regulations that implement FOIA and prohibit the disclosure of claimed CBI, including inert ingredient information. *See* 40 C.F.R. Part 2, Subpart B. Generally, EPA may not disclose information claimed as CBI unless it reviews the information and formally determines that it is not entitled to confidentiality. CBI should be identified “at the time it is submitted to EPA.” 40 C.F.R. §2.203(b); *see also* 40 C.F.R. §158.33 (requiring all CBI in Part 158 submissions to be claimed as CBI when submitted). Information may be claimed as CBI after it has been submitted, but there is of course a risk that it could be released in the interim. EPA “will make such efforts as administratively practicable” to keep the information confidential, “[h]owever, EPA cannot assure that such efforts will be effective.” 40 C.F.R. §2.203(c). EPA will review information before disclosing it, though, and may protect information if it is of the type that submitters normally want to keep confidential. *See* 40 C.F.R. §2.204(c)(2).

FIFRA’s CBI requirements apply to all inert ingredient information submitted to EPA, including in the Confidential Statement of Formula (CSF). There are safeguards against disclosure, as discussed above, and as the name states, CSFs are intended to be “confidential.” To help ensure the intended protection, however, submitters should specifically claim CBI in CSFs just as with other documents (*e.g.*, marking the CSF “Confidential Business Information” and submitting the CBI separately from other required information. FIFRA §10(a)).

EPA Reviews the Confidentiality of Inert Ingredient Information Under EPA’s Confidentiality Regulations

EPA will review CBI to determine if it qualifies for confidentiality protection if EPA receives a FOIA request for the information, desires to determine whether the information is entitled to confidentiality, or believes a future disclosure request is likely. 40 C.F.R. §2.204(a). In practice, due to limited resources, EPA most commonly reviews CBI claims in the context of FOIA requests. If EPA initiates a review, it will give the company claiming the CBI an opportunity to substantiate the confidentiality claim. 40 C.F.R. §2.204(e)(1). The company usually will have fifteen business days to respond to EPA’s request. 40 C.F.R. §2.204(e)(2). EPA has a standard set of questions that it asks in these circumstances, and has developed some specific questions to ask when the substantiation involves an inert ingredient.

EPA reviews substantiations on a case-by-case basis and makes a final decision, either agreeing with the CBI claim or providing notice of its denial or partial denial. *See* 40 C.F.R. §2.205. An EPA notice of denial must “state the basis for the determination” and that the decision is final agency action subject to judicial review. 40 C.F.R. §2.205(f)(2). If EPA denies a CBI claim, for most matters EPA will not disclose the information until the 10th day after the affected business’ receipt of the denial, to allow the company to go to court to seek injunctive relief. *Id.* However,

for FIFRA information, EPA's regulations provide a longer period to go to court – it will not disclose the information until the 31st day. 40 C.F.R. § 2.307(e)(3); *see also* FIFRA §10(c).

A company submitting inert ingredient information has several opportunities to protect that information from disclosure – by claiming it as CBI, substantiating the CBI claim if requested, and even defending the CBI claim in court if necessary. These several layers of protection provide relatively strong protection against the disclosure of confidential inert ingredient information. However, companies should be aware that there is not absolute confidentiality for all inert ingredient information submitted to EPA.

EPA Must Continue to Protect Confidential Business Information as It Attempts to Increase Inert Ingredient Disclosure

As mentioned above, EPA announced last December that it is interested in increasing the public availability of inert ingredient information. It initiated a process for obtaining public input with the publication of an Advanced Notice of Proposed Rulemaking. EPA, *Public Availability of Identities of Inert Ingredients in Pesticides*, 74 Fed. Reg. 68,215 (Dec. 23, 2009) (Inert Ingredient Disclosure ANPR). Any member of the public who is interested is invited to comment. The deadline for doing so is April 23, 2010. *See* EPA, *Public Availability of Identities of Inert Ingredients in Pesticides; Extension of Comment Period*, 75 Fed. Reg. 7,560 (Feb. 22, 2010).

EPA believes that inert ingredient disclosure should be greatly increased, and it initiated the rulemaking process to try to achieve this goal. In working on a new rule, however, EPA must of course balance its desire for greater disclosure with its statutory obligations to protect inert ingredient information that is CBI. In other words, a new EPA rule cannot override the statutory protections of CBI included in FIFRA, FFDCA, and FOIA. In the Inert Ingredient Disclosure ANPR, EPA acknowledges the tension between the statutory protections for CBI and EPA's intended proposal to disclose inert ingredient information. However, EPA is considering ways that it can amend its regulations to increase disclosure without violating the statutes. 74 Fed. Reg. at 68,220.

EPA has proposed two possible approaches to inert disclosure. The first approach would require identities of "potentially hazardous" inert ingredients to be listed on pesticide labels. The second approach would go much farther and require all or most inert ingredients to be listed on pesticide labels. EPA is soliciting input to help the Agency assess these approaches and find the appropriate balance between confidentiality and disclosure. EPA requests comments on its proposed approaches generally and on a number of specific legal and practical issues related to disclosure, such as whether the Agency should require each inert identity to be claimed as confidential and whether the Agency should require substantiation of CBI claims upon submission. 74 Fed. Reg. at 68,220-21.

All companies with an interest in the confidentiality of inert ingredient information should consider commenting on the Inert Ingredient Disclosure ANPR to provide useful practical and legal information that is pertinent to possible changes in EPA's regulations. EPA is required to take into account such public comments in considering any new regulations or changes to its regulations.