



Confidential Business Information

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Confidentiality of Inert Ingredients

- Confidentiality of pesticide inert ingredients is protected under FIFRA, FFDCA, and FOIA.
- “[T]otal percentage of all inert ingredients” in a pesticide must be listed on the label. FIFRA § 2(n)(1)
- No additional statutory requirement for public disclosure of individual inert ingredients in a pesticide.

Reasons Congress Has Protected Inert Information

- To promote innovation.
- To protect proprietary rights of inert suppliers and pesticide registrants.

CBI Under FIFRA

- FIFRA § 10 (7 U.S.C. § 136h) – Protection Of Trade Secrets And Other Information
- An applicant or a registrant may designate as CBI information that it considers to be a trade secret or commercial or financial information. FIFRA § 10(a)

CBI Under FIFRA

- EPA has the responsibility to evaluate an applicant's or a registrant's CBI designations, but generally may not disclose trade secrets or privileged or confidential commercial or financial information. FIFRA § 10(b)

CBI Under FIFRA

- If EPA and the applicant/registrant disagree about a designation, FIFRA requires EPA to protect the information until the applicant/registrant has an opportunity to challenge EPA's evaluation in Court. FIFRA § 10(c)
- FIFRA § 10(c) contains a 30-day notice requirement to allow for such challenges.

Limitations to Protection of CBI

- FIFRA sets limits on CBI, and EPA must disclose certain designated information. FIFRA § 10(d)
- In particular, EPA must make available safety and efficacy data (with limits on others' reliance on the data for registration purposes, as discussed by other speakers). FIFRA § 10(d)(1)

Confidentiality of Inert Ingredient Information

- The availability of safety and efficacy data does not authorize disclosure of “the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.” FIFRA § 10(d)(1)(C)
- EPA may disclose this information only if it has first determined that disclosure is “necessary to protect against an unreasonable risk of injury to health or the environment.” FIFRA § 10(d)(1)(C)

CBI Under FFDCA

- If a pesticide product or inert leaves a residue in or on food, the applicant must obtain a tolerance or tolerance exemption for that product. FFDCA § 408 (21 U.S.C. 346a), §§ 201(q)(1), (2)
- Data and information submitted to support a tolerance or tolerance exemption are entitled to protection to the same extent provided by FIFRA §§ 3 and 10. FFDCA § 408(i)(1)

CBI Under FOIA

- FOIA requires disclosure of records unless they fall within specific statutory exemptions. 5 U.S.C. § 552(a)(3)
- FOIA Exemption 4 protects “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 essentially the same definition of CBI as FIFRA § 10(b).

CBI Under EPA's Confidentiality Regulations

- EPA's general confidentiality regulations, which are used to implement FOIA, also prohibit disclosure of claimed CBI. 40 C.F.R. Part 2, Subpart B.
- EPA must make a final determination that information is not entitled to confidentiality before it may disclose the information.

CBI Under EPA's Confidentiality Regulations

- CBI should be marked “at the time it is submitted to EPA.” 40 CFR § 2.203(b)
- Post-submission CBI claims may not be effective: “EPA will make such efforts as administratively practicable.... However, EPA cannot assure that such efforts will be effective” 40 CFR § 2.203(c)

CBI Under EPA's Confidentiality Regulations

- Person claiming CBI usually has the opportunity to substantiate the claim
- Usually 15 days
- EPA's 8 questions

CBI Under EPA's Confidentiality Regulations

- EPA's 8 questions:
 - 1-2: Period of time to protect and why
 - 3: Measures taken to protect
 - 4: Prior government determinations
 - 5: Other means of access
 - 6: Harm if disclose (more on *NCAP* case below)
 - 7: Whether voluntarily submitted
 - 8: Any other relevant information

CBI Under EPA's Confidentiality Regulations

- 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.
- An EPA notice of denial “shall state the basis for the determination” and that the decision is final agency action subject to judicial review. 40 CFR § 2.205(f)(2)

CBI Under EPA's Confidentiality Regulations

- 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.
- 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 CFR § 2.307(e)(3)

Interpretation of FIFRA § 10(d)(1)(C)

- What is the scope of FIFRA § 10(d)(1)(C)'s prohibition on disclosure of inert ingredients?
 - Prohibits disclosure of any inert information?
 - Prohibits disclosure of inert information that qualifies as CBI under FIFRA § 10(b)?
- EPA follows the latter, based on *Northwest Coalition for Alternatives to Pesticides (NCAP) v. Browner*, 941 F. Supp. 197, 201 (D.D.C. 1996) (copy provided in symposium notebook).

Confidential Commercial Information (*NCAP v. Browner*)

- “Commercial information is ‘confidential’ for purposes of FOIA Exemption 4 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

Confidential Commercial Information (*NCAP v. Browner*)

- “That party need not demonstrate actual harm but must show (1) actual competition and (2) a likelihood of substantial competitive injury.”
NCAP v. Browner, 941 F. Supp. at 201

Inert CBI Claims

- As for other CBI, an applicant or registrant may claim CBI for the identity of inert ingredients in its product.
- As discussed earlier, EPA may request that the claim be substantiated, including demonstrating competition and likelihood of substantial competitive injury.

Proprietary Inerts and Mixtures

- An applicant/a registrant may purchase proprietary inerts or proprietary inert mixtures for use in its product.
- Sometimes the supplier will not disclose to its customer the ingredients in a proprietary inert or mixture.
- In such cases, EPA allows the supplier to submit information about proprietary inerts or proprietary mixtures directly to EPA, without disclosure to the applicant/registrant.

Confidentiality of Proprietary Inerts and Mixtures

- A supplier may also claim CBI for its proprietary inerts and mixtures.
- Such claims are eligible for the same FIFRA and FOIA CBI protections discussed earlier for other inert ingredient information.



Thank You

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