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MEMORANDUM

Via E-Mail

DATE: November 14, 2006

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: OPP Releases Draft Inert Ingredients Document and Labeling Materials

Last week, the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) released a draft document regarding inert ingredients and materials regarding labeling consistency. The October 31, 2006, draft document on inert ingredients is entitled “Tips for Inert Ingredients.” It describes what an inert ingredient is, how to find inert ingredients that are approved for use in pesticide products, what to put on a confidential statement of formula for inert ingredients, and how to contact OPP’s Inert Ingredient Assessment Branch (IIAB). The draft document is available at <http://www.epa.gov/opprd001/inerts/tips.pdf>. The labeling consistency materials include a response to comments on “For Use Only By,” a request for comments on the issue of whether product labels can establish minimum use rates for any purpose other than risk reduction or efficacy, and a pesticide labeling consistency question and answer (Q&A) web page. The labeling documents and a link to the Q&A are available on the Internet at http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm.

Tips for Inert Ingredients

EPA’s draft document includes the following questions and answers. More information is available in EPA’s draft document.

- Q: What is an “inert ingredient”?
- A: EPA’s draft document states that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) defines an inert ingredient as “one that is intentionally added to a pesticide formulation and is not pesticidally active, such as solvents, carriers, aerosol propellants, fragrances, and dyes.” According to EPA, “[i]t is important to note that the term ‘inert’ does not imply non-toxicity.”



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Q: How can I find inert ingredients that are approved for use in pesticide products?

A: EPA states that inert ingredients can be approved for use in pesticide products applied either to:

1. Non-food sites only, such as ornamental plants, lawns, highway right-of-ways, etc.; or
2. Food sites (food and feed crops, raw agricultural commodities, or livestock used for food) and non-food sites. It is important to note that use on food requires a tolerance/exemption from the requirement of a tolerance (*e.g.*, tolerance exemption) and the use is usually limited in some fashion.

The draft document provides the following resources for additional information:

A list of inert ingredients approved for non-food uses is available on the Internet at <http://www.epa.gov/opprd001/inerts/lists.html>. The draft document states that EPA intends to post the updated list of inert ingredients in **early 2007**.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), all inert ingredients used in pesticide products applied to food sites must have a tolerance/tolerance exemption in 40 C.F.R. Part 180, and more information on food use inert ingredients is available in this Part.

Q: What do I put on my Confidential Statement of Formula (CSF) for Inert Ingredients?

A: For each inert ingredient, provide the chemical names and CAS numbers. For food use products, also identify the tolerances/tolerance exemptions that are associated with each inert. The draft document states:

Be aware that EPA will not approve product formulations that contain unapproved inert ingredients. If a new inert ingredient tolerance/tolerance exemption is needed, a petition (with data) must be submitted for new tolerance exemptions. If approval of a new non-food use inert ingredient is needed, a letter requesting an approval must be submitted along with supporting information.

Q: How do I contact the IIAB?



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A: For technical questions, such as questions about chemical nomenclatures and chemicals included in inert ingredient tolerance exemptions, please contact: Pauline Wagner, IIAB Chief, 703-308-6164, wagner.pauline@epa.gov; or Kerry Leifer, Team Leader, 703-308-8811, leifer.kerry@epa.gov.

For general information on inert ingredients, the approval status of a particular chemical, and the final revocation rules, please contact: Karen Angulo, Team Leader, 703-306-0404, angulo.karen@epa.gov.

Pesticide Labeling Consistency

“For Use Only By”

EPA posted a document entitled *Pesticide Labeling Consistency -- “For Use Only By” Issue Paper: OPP Synopsis and Discussion of Comments Received* (Response to Comments). In January 2006, EPA solicited comment on the use of label statements such as “for professional use only” and “for commercial use only” on products not classified for restricted use. According to the Response to Comments, EPA and state pesticide regulators “generally agree that these terms are not enforceable against sellers and questionable against users, because they have no definitions in law or regulation. Consequently, they are not likely to be effective as limitations on users.” The Response to Comments says that EPA’s Label Review Manual (LRM) states that “overly general, undefined terms are not appropriate, however, over time many such statements have found their way onto approved labels.” EPA intends the Response to Comments to provide feedback to the states, registrants, and organizations who commented on the 2006 issue paper. This paper includes a synopsis of the main points raised by regulators and industry groups; provides clarification of EPA positions on some of these issues; and discusses possible next steps for addressing these issues. The Response to Comments is available at <http://www.epa.gov/pesticides/regulating/labels/forusecomments.pdf>.

Minimum Application Rates

OPP posted a paper entitled *Pesticide Labeling Consistency -- Minimum Application Rates Opportunity for Public Comment*, which requests comments on the issue of whether product labels can establish minimum use rates for any purpose other than risk reduction or efficacy. OPP states that it is interested in comments on the following specific issues:

- Should EPA allow minimum use rates on products where risks associated with reduced application have not been found?



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- What is the value associated with allowing this?
- What are the problems or issues associated with allowing this?
- Would these use rates appear to be misleading statements if they do not mitigate risks?

The document is available at <http://www.epa.gov/pesticides/regulating/labels/rates.pdf>.
Comments are due **December 11, 2006**.

The response to comments on “For Use Only by” and the request for comments on “Minimum Use Rates” are both available on OPP’s Labeling Consistency website, at <http://www.epa.gov/pesticides/regulating/labels/projects.html>.

Pesticide Labeling Consistency Q&A

OPP created a web page entitled “Pesticide Labeling Questions & Answers,” which consists of questions submitted by the public to EPA regarding labeling of pesticide products and EPA’s response. The page is available on the Internet at http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm, and it includes questions on the following topics:

- Antimicrobial claims;
- Contract manufacture;
- Definitions/interpretations;
- Distributors;
- Exception to use in a manner not permitted (FIFRA Section 2(ee));
- Existing stocks;
- Miscellaneous;
- Notifications;



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- Pictures and logos;
- Pesticide exemption (FIFRA Section 25(b));
- Product names; and
- Termiticides.

According to the web page, the new Q&A topics are pictures and logos, and product names.

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We hope this information is helpful. As always, please call if you have any questions.