



BERGESON & CAMPBELL, P.C.

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MEMORANDUM

Via E-Mail

DATE: November 2, 2007

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Publishes Revised FIFRA Registration Data Requirements

On Friday, October 26, 2007, the U.S. Environmental Protection Agency (EPA) published final revised data requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registration actions for conventional, biochemical, and microbial pesticides, as well as made related technical amendments.¹ EPA has reorganized 40 C.F.R. Part 158 (Part 158) to accommodate these changes. In a separate but related publication, EPA announced on Wednesday, October 24, 2007, that it is moving the data requirements for antimicrobial pesticides as published in the 2007 version of Part 158 into a new Part 161, entitled *Data Requirements for Registration of Antimicrobial Pesticides*.² The revised regulations will be effective 60 days after their respective publication dates.

The following memorandum discusses these changes to the data requirements, as well as some recent related changes to EPA's Office of Pesticide Programs (OPP) website.

Data Requirements for Conventional Pesticides

EPA originally proposed changes to the data requirements for conventional pesticides on March 11, 2005. The proposal prompted a significant amount of comment from stakeholders, which EPA discusses in the preamble to the final rule and addresses in the

¹ 72 Fed. Reg. 60934; 72 Fed. Reg. 60988; and 72 Fed. Reg. 61025 (Oct. 26, 2007).

² 72 Fed. Reg. 60251, 60253 (Oct. 24, 2007).



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Response to Comments document.³ Consistent with its proposal, EPA has promulgated four types of changes to the codified regulations:

- Newly imposed requirements;
- Newly codified requirements;
- Revisions of existing requirements (such as changes to the number and types of species required for a particular study); and
- Elimination of requirements.

Examples of newly imposed requirements include:

- Functional immunotoxicity testing, to evaluate the potential of a chemical to affect the immune system adversely. The new study will be required for technical grade active ingredients for all food and nonfood pesticides.⁴
- Twenty-one- to 28-day dermal toxicity testing for all food use pesticides, for use in worker risk assessments. If the primary route of exposure for non-food uses is dermal, then a 90-day study will be required.⁵

In many cases, EPA states that “new” requirements are not really new, as EPA has been requiring the studies for many years, but are merely newly codified in the regulations. Examples of changes to the regulations that EPA is making to reflect what EPA characterizes as ongoing EPA practice include:

- The requirement for independent laboratory validation for chemistry methods used in the ecological and environmental fate field studies;⁶

³ EPA, *Response to Comments to Part 158 Rule Proposed March 11, 2005*, Docket ID: OPP-2004-0387, available at <http://www.regulations.gov>.

⁴ 72 Fed. Reg. 60939 and 60976 (Oct. 26, 2007) (to be codified at 40 C.F.R. § 158.500).

⁵ 72 Fed. Reg. 60940 and 60976 (Oct. 26, 2007) (to be codified at 40 C.F.R. § 158.500).

⁶ 72 Fed. Reg. at 60942 and 60948 (to be codified at 40 C.F.R. § 158.1300, Note 7); 72 Fed. Reg. at 60942 and 60948 (to be codified at 40 C.F.R. § 158.1410, Note 9).



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- The elimination of the seed germination study;⁷ and
- A change in the designation of the requirement for the photodegradation on soil study from conditionally required to required for terrestrial food crop and forestry use patterns.⁸

Examples of existing data requirements that EPA is modifying include the following:

- Revision of prenatal developmental toxicity testing to require tests on two species, instead of just one, for all non-food pesticides;⁹
- Revision of acute avian oral toxicity testing to require tests on a second avian species, a passerine species, but no longer to specify the red-winged blackbird;¹⁰
- Change in the status of the avian reproduction testing requirement from conditionally required to required for terrestrial, aquatic, forestry, and residential outdoor use patterns;¹¹
- Change in several existing post-application exposure data requirements from conditionally required to required and expanding the use sites to which these data requirements apply to include residential use sites;¹² and
- Expansion of the use sites that require specific environmental fate data, including hydrolysis for certain indoor uses where, EPA states,

⁷ 72 Fed. Reg. at 60946.

⁸ 72 Fed. Reg. at 60948 (to be codified at 40 C.F.R. § 158.1300).

⁹ 72 Fed. Reg. at 60939 (to be codified at 40 C.F.R. § 158.230).

¹⁰ 72 Fed. Reg. at 60943.

¹¹ 72 Fed. Reg. at 60943.

¹² 72 Fed. Reg. at 60947.



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“environmental exposure may be likely,” and photodegradation in air to all terrestrial, greenhouse, forestry, and residential outdoor use patterns.¹³

Finally, examples of data requirements that EPA has eliminated from the FIFRA data requirements include:

- The non-rodent chronic study (1-year dog study);¹⁴
- Bioaccumulation testing for aquatic nonfood residential and residential outdoor uses;¹⁵ and
- Honey bee subacute feeding study. This study was not proposed for elimination, but EPA states that it is removing this requirement because “the information from this test can be covered under the field study requirement.”¹⁶

EPA also has made several organizational changes to Part 158. The subparts have been reordered and sections renumbered, for example, to make the rules “more user-friendly.” A copy of the index to the revised Part 158 appears as Appendix A to this memorandum. Appendix A reflects changes made to Part 158 that apply to conventional pesticides, as well as changes to subparts U and V which apply to biochemical and microbial pesticides, respectively. Examples of other organizational changes include:

- A new regulatory subpart for the data requirements applicable to Experimental Use Permits (EUP), rather than identifying data required to support EUPs by bracketing a subset of the data requirements for registration;¹⁷

¹³ 72 Fed. Reg. at 60948.

¹⁴ 72 Fed. Reg. at 60940-41.

¹⁵ 72 Fed. Reg. at 60945.

¹⁶ 72 Fed. Reg. at 60947.

¹⁷ 72 Fed. Reg. at 60939 (to be codified at 40 C.F.R. Part 158 subpart C).



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- Presentation first of data requirements, such as product chemistry and acute mammalian toxicity, that may apply to follow-on end-use product registrants, who as a group may be less familiar with the data requirements, particularly those for new active ingredients and/or new uses, which appear in later subparts;¹⁸ and
- Deletion of Part 158, Appendix A, a compendium of pesticide use sites associated with major use patterns. EPA is placing an updated version of the information on its website, as discussed below, which EPA states will allow it to correct and update it more regularly.¹⁹

Data Requirements for Biopesticides

EPA originally proposed changes to the data requirements for biochemical and microbial pesticides (biopesticides) on March 8, 2006.²⁰ Consistent with the changes for conventional chemicals, the changes for biopesticide data requirements include newly imposed requirements, newly codified requirements, revisions to existing requirements, and deleted requirements. Among the most significant changes, EPA revises the definitions of biochemical and microbial pesticides, as discussed below. EPA also makes organizational changes and discusses a process available to registrants for assistance with the identification of applicable data requirements and bases for data waiver requests.

EPA has promulgated the following definition for biochemical pesticide as it was proposed:

A biochemical pesticide is a pesticide that:

- (i) Is a naturally-occurring substance or structurally similar and functionally identical to a naturally-occurring substance;
- (ii) Has a history of exposure to humans and the environment demonstrating minimal toxicity, or in the case of a synthetically-derived biochemical pesticide[], is equivalent to a naturally-occurring substance that has such a history; and

¹⁸ 72 Fed. Reg. at 60935.

¹⁹ 72 Fed. Reg. at 60938.

²⁰ 71 Fed. Reg. 12072.



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(iii) Has a non-toxic mode of action to the target pest(s).²¹

According to the preamble, commenters expressed concern that this definition is more restrictive than the current one. EPA states that it disagrees with this characterization and notes that of the 180 biochemicals registered since 1948, EPA has concluded that all but two would meet this definition.²² EPA also modifies the definition of pheromones to clarify that the criteria for a biochemical also apply pheromones,²³ and modifies the definition of straight chain lepidopteran pheromone to conform with the “internationally-recognized” definition.²⁴

Similarly, EPA has promulgated the following definition for microbial pesticide, with changes from the proposal:

Microbial pesticide is a microbial agent intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, that:

- i. Is a eucaryotic microorganism including, but not limited to, protozoa, algae, and fungi;
- ii. Is a procaryotic microorganism, including, but not limited to, Eubacteria and Archaeobacteria; or
- iii. Is a parasitically replicating microscopic element, including, but not limited to, viruses.²⁵

EPA states that it has added the examples of Eubacteria and Archaeobacteria in response to comments to clarify that these procaryotes are included in the definition. EPA also changed the proposed phrase “autonomous replicating microscopic element” to “parasitically replicating microscopic element” and “microorganism” to “microbial agent” to improve accuracy and consistency with language elsewhere in the regulations.²⁶

²¹ 72 Fed. Reg. at 61002 (to be codified at 40 C.F.R. § 158.2000(a)(1)).

²² 72. Fed. Reg. at 60993.

²³ 72 Fed. Reg. at 60993 (to be codified at 40 C.F.R. § 158.2000(a)(2)).

²⁴ 72 Fed. Reg. at 60993 (to be codified at 40 C.F.R. § 158.2000(a)(2)(iii)).

²⁵ 72 Fed. Reg. at 60995 (to be codified at 40 C.F.R. § 158.2100(b)).

²⁶ 72 Fed. Reg. at 60996.



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Examples of new or revised data requirements in the final rule specifically applicable to biochemical pesticides include:

- Conditional requirement for immunotoxicity data as a Tier II and Tier III data requirement;²⁷
- Addition of companion animal safety data requirement;²⁸ and
- Applicator/user exposure data if the use of the biochemical pesticide could result in exposure levels that exceed historic levels to humans or the environment.²⁹

Examples of new or revised data requirements in the final rule specifically applicable to microbial pesticides include the following changes:

- EPA eliminated the intracerebral injection assay as proposed, and clarified that pathogenicity/toxicity data for viral agents are not required because of “the difficulty of establishing the clearance endpoint for viruses”;³⁰
- EPA eliminated the mutagenicity data requirement on the whole microorganism as proposed;³¹ and
- EPA has revised the requirements for non-target ecological effects to include testing on end-use product formulations when significant non-target exposure is expected and the product may contain other ingredients that may be toxic to non-target organisms.³²

²⁷ 72 Fed. Reg. at 60994 (to be codified at 40 C.F.R. § 158.2050(d)).

²⁸ *Id.*

²⁹ *Id.*

³⁰ 72 Fed. Reg. at 60997.

³¹ *Id.*

³² 72 Fed. Reg. at 60998 (to be codified at 40 C.F.R. § 158.2150(d)).



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Consistent with the organizational change made for conventional pesticides, the data requirements for experimental use permits for biochemical and microbial pesticides have been separated from those for registration.³³

Finally, in the preamble, EPA states that it continues to encourage applicants to request pre-submission meetings with EPA to discuss the applicable data requirements and potential bases for data waivers for proposed biopesticide products. EPA also announces a post-submission process for continuing consultation and exchange of information about opportunities for citing to other existing data or information or seeking data waivers from the applicable data requirements.³⁴

New Part 161 and Other Technical Amendments

As noted above, EPA has created a new Part 161, entitled *Data Requirements for Registration of Antimicrobial Pesticides*, and has moved existing data requirements for antimicrobial pesticides from Part 158 to new Part 161, without substantive changes.³⁵ Proposed changes to the data requirements for antimicrobial pesticides were published on September 17, 1999;³⁶ EPA is expected to revisit these proposed changes in the future.

EPA also published technical changes to the regulations, largely comprising corrections to cross-references due to the reorganization of Part 158.³⁷ In its March 11, 2005, proposed rule, EPA suggested removing or revising provisions in Part 158 that directly or indirectly arise from the formulators' exemption. In the final rule, EPA states that it "believes that the formulators' exemption should properly be located" in Part 152, with other provisions concerning submission or citation of data, but that it "recognizes the value of referring to the provisions of part 152 in part 158." Accordingly, the final rule adds a new paragraph to Section

³³ 72 Fed. Reg. at 60999 (to be codified at 40 C.F.R. §§ 158.2080-158.2084, and 158.2170-158.2174).

³⁴ 72 Fed. Reg. at 60990.

³⁵ 72 Fed. Reg. 60251 (Oct. 24, 2007).

³⁶ 64 Fed. Reg. 50672 (Sept. 17, 1999).

³⁷ 72 Fed. Reg. 61025 (Oct. 26, 2007).



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158.70(a), which explains that the provisions of Part 158 should be read in conjunction with those of part 152, subpart E.³⁸

Related Additions to OPP's Website

On October 26, 2007, EPA also made revisions to its website to coincide with the published changes to Part 158. In particular, EPA added:

- A new Data Requirements web page, available at http://www.epa.gov/pesticides/regulating/data_requirements.htm, which discusses both recent and future changes to pesticide data requirements. In addition to the changes discussed above, the website states that EPA will be developing proposed rules:
 - To address product performance data requirements for conventional pesticides and biochemical and microbial pesticides; and
 - For data requirements specifically applicable to plant-incorporated protectants.
- A Pesticide Use Site Index, available at <http://www.epa.gov/pesticides/regulating/usesite/index.htm>, which replaces Part 158, Appendix A. According to EPA, the Index provides registrants with information regarding pesticide major use patterns and pesticide use sites, which in turn should aid registrants in identifying data requirements applicable for new products and new uses.

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

³⁸ 72 Fed. Reg. at 60936-37.



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Appendix A

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