



## MEMORANDUM

### Via E-Mail

DATE: April 6, 2007

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Considers Revising FIFRA Regulations for PIPs

On April 4, 2007, the U.S. Environmental Protection Agency (EPA) published an Advance Notice of Proposed Rulemaking (ANPR) announcing possible revisions to the current pesticide establishment and production regulations for producers of plant-incorporated protectants (PIP). According to EPA, it is considering amending the regulations because of the differences between PIPs and other types of pesticides. In the ANPR, EPA defines PIPs as “pesticidal substances that are intended to be produced and used in a living plant, or the produce thereof, and the genetic material necessary for the production of such a pesticidal substance, and also include any inert ingredient contained in the plant, or the produce thereof.” EPA states that, given these characteristics, PIPs may not be produced in the manner contemplated when the current establishment and production regulations were promulgated for other types of pesticides. In the ANPR, EPA provides a list of the general regulatory provisions applicable to PIPs that EPA is considering amending and requests comment on the completeness of the list and the scope of any potential changes to these regulations. EPA intends to solicit stakeholder input through two public meetings during the comment period of the ANPR. Comments are due **June 13, 2007**.

In the ANPR, EPA notes that the existing regulations were written for pesticides that are generally produced and used in a more traditional manner, *e.g.*, spraying or dusting onto plants. PIPs are produced and used in a living plant, however, which raises questions regarding how EPA should regulate their “production.” In general, according to the ANPR, EPA’s experience with PIPs is that they present different and potentially lower risk situations compared to chemical pesticides. EPA needs to ensure that appropriate PIP production data are available to manage any potential risk a PIP might pose, however, and thus it is considering revising the regulations.

Under FIFRA Section 7, pesticide producers register the establishments where they produce pesticides and report the amount of pesticide produced. EPA says that, in its



Memorandum to Firm Clients and Friends  
April 6, 2007  
Page 2

experience, the existing regulations may need to be better tailored to address PIPs. For example, existing regulations require producers to report pesticide production quantities in terms of volume or weight (gallons or pounds), measurements that are not useful when considering a pesticidal substance produced within a plant. Other questions concern the manner in which PIPs are increased within a living plant. Because the increase occurs at many stages, from product development through use, questions arise concerning where pesticide production occurs, and what establishments must register and report their production. EPA states that clarification of this matter would help to ensure that appropriate persons comply with production related requirements, and that other persons do not face unnecessary regulatory burden. To that end, EPA is reviewing the existing regulations in 40 C.F.R. Chapter I, Subchapter E, and considering potential regulatory changes to address the apparent differences between PIPs and other types of pesticides.

EPA is considering amending the following existing regulations related to pesticide establishment and production to better address PIPs and PIP production:

- *Registration of establishments where PIPs are produced* (FIFRA Section 7 and 40 C.F.R. Section 167.20). Current regulations require any producer of a pesticide to register the production site with EPA. The statutory and regulatory definitions of produce include several activities, including manufacturing, preparing, compounding, propagating, or processing any pesticide or packaging, repackaging, labeling, and relabeling the container of any pesticide.
- *Reporting by registered production establishments* (FIFRA Section 7 and 40 C.F.R. Section 167.85). Current regulations require a producer operating a producing establishment to report annually the types and amount of each pesticidal product that was produced, sold, or distributed the previous year, and to estimate the amount that will be produced during the current year.
- *Recordkeeping and inspection authority* (FIFRA Sections 8 and 9, and 40 C.F.R. Sections 169.2 and 169.3). EPA's statutory authority under FIFRA Section 8, and the regulations promulgated there under, require pesticide producers, registrants, and applicants for registration to maintain certain records related to pesticide production, and to provide these records upon request to appropriately credentialed inspectors. FIFRA Section 8 also provides authority for appropriately credentialed inspectors to conduct inspections to access such information. Furthermore, under FIFRA



Memorandum to Firm Clients and Friends  
April 6, 2007  
Page 3

Section 9, appropriately credentialed inspectors have the authority to conduct inspections at pesticide producing establishments or other places where pesticides are being held for distribution or sale for the purpose of inspecting and obtaining samples.

- *Labeling on PIP containers* (FIFRA Section 2 and 40 C.F.R. Section 156.10). The statute and current regulations provide requirements for labeling of pesticides, including name of the product, identity of the producer, net content, product registration number, establishment registration number, ingredient statement, hazard and precautionary statements, directions for use, and use classification. Currently, PIPs are labeled only for FIFRA Section 5 experimental use permits (EUP) and FIFRA Section 3 seed increase registrations.
- *EUPs for field testing of unregistered PIPs* (FIFRA Section 5 and 40 C.F.R. Part 172). FIFRA allows for field testing of unregistered pesticides under an EUP. Any pesticide production activity related to an EUP, either the production of a pesticide for use in an EUP or by being produced as a result of an EUP, is subject to FIFRA production establishment and recordkeeping requirements.
- *Production of unregistered PIPs for export* (FIFRA Section 17 and 40 C.F.R. Sections 168.65-168.85). FIFRA exempts pesticides intended solely for export from certain FIFRA requirements, including product registration requirements. Products intended for export only are therefore not subject to the product safety evaluation required of products intended for domestic distribution and sale. They must still comply with the producer establishment registration, reporting, and recordkeeping requirements of FIFRA Sections 7 and 8, however, and are subject to certain labeling requirements.

EPA requests public comment on the completeness of its list of regulations that need to be reviewed for applicability to PIPs and PIP producers, and asks for related information to use in reviewing these regulations and developing its proposed rules. EPA seeks specific comments in response to the following questions:



Memorandum to Firm Clients and Friends  
April 6, 2007  
Page 4

- *Registration of establishments.* Given that PIPs by definition are intended to be produced and used in a living plant, what activities should EPA consider to be part of “production” as that term is defined in FIFRA, and what establishments should be registered to help EPA manage any potential risks associated with PIPs? What other types of facilities, if any (e.g., growers involved in seed production), involved in the development of PIP-containing varieties should be subject to these requirements?
- *Production reporting.* What production reporting, by whom, and in what units (e.g., volume, weight, number of seeds, etc.) would be appropriate? Should reporting units be dependent on the reproductive methodology of the crop (e.g., seeds, bulbs, or tubers)? What types of production reporting would provide EPA with information valuable for compliance assurance purposes and for managing any potential risks associated with a violation?
- *Recordkeeping and inspection.* What establishments or other locations are appropriate to be inspected for records and samples, and what records would be appropriate for producers of PIPs to maintain?
- *Labeling.* Please comment on current labeling practices for PIPs. Are current labeling practices sufficient? For example, do grower agreements offer sufficient information and compliance assurance to ensure registered PIPs are used in a manner that protects human health and the environment? Are there circumstances where labeling different from that currently in practice for PIPs may be appropriate?
- *EUPs.* Are there aspects of production in association with PIP EUPs that are different from production associated with other types of pesticides used in EUPs? If there are differences, how should they be addressed for PIP EUPs?
- *Production for export.* What conditions would ensure that a PIP is intended for export only, and what would be necessary for such a PIP to meet the requirements of FIFRA?



Memorandum to Firm Clients and Friends  
April 6, 2007  
Page 5

- Are there other characteristics not described in the ANPR unique to PIPs that may affect the application of the existing regulations associated with pesticide establishments and pesticide production to PIP producers?
- Are there additional sections of FIFRA implementing regulations related to pesticide establishment and production regulations that should be modified to more effectively address the unique characteristics of PIPs?

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