



MEMORANDUM

Via E-Mail

DATE: September 21, 2007

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Clarifies Position on Ion-Generating Equipment

Today the U.S. Environmental Protection Agency (EPA) issued a *Federal Register* notice intended to “clarify” its position on the distinction between devices and pesticides with regard to ion-generating equipment and stating that such equipment will be regulated as pesticides. The notice states EPA’s basis for this conclusion and “invites all interested parties to collaborate” with EPA in identifying data and other information necessary to support registration of these products.

Importantly, EPA states that, through the notice, it is establishing a process and a timeline for any parties affected by the notice to come into compliance with the clarified requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). According to the notice, potentially affected equipment include, but are not limited to, “washing machines containing electrodes that emit silver, copper, or zinc ions and ion generators used in swimming pools to kill algae and as an adjunct to the chlorination process.” EPA intends the listed products to provide a “guide for readers” regarding entities likely to be affected by its clarification and notes that “[o]ther types of technology not listed in this notice could also be affected.” EPA requests information on any other type of equipment that generates ions from electrodes for pesticidal purposes that could be covered under the notice.

Background

In a November 19, 1976, *Federal Register* notice,¹ EPA consolidated and clarified the requirements applicable to pest control devices and device producers. In the notice, EPA listed the types of products that would be affected by the notice and further provided a distinction between devices and pesticides. If an article uses physical or mechanical means to trap, destroy, repel, or mitigate any pest, the notice stated that it is considered to be a device. If the article

¹ 41 Fed. Reg. 51065.



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incorporates a substance or mixture of substances to prevent, destroy, repel, or mitigate any pest, then it is considered to be a pesticide.

In September 2005, EPA staff advised a manufacturer that washing machines using silver electrodes to produce silver ions for the pesticidal purpose of killing germs are considered devices rather than pesticides, and thus do not require registration. In today's *Federal Register* notice, EPA states that it has since determined that, under the statutory interpretation set forth in its 1976 policy statement, "such ion-generating equipment would require registration as a pesticide under FIFRA."

EPA's Interpretations of "Pesticide" and "Device" Under FIFRA

In the 1976 *Federal Register* notice, EPA stated its interpretation of the statutory terms "pesticide" and "device" for the purpose of distinguishing between items that were subject to the registration requirements of FIFRA (*i.e.*, pesticides) and those that were not (*i.e.*, devices). FIFRA Section 2(h) defines "device" as "any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling or mitigating any pest." FIFRA Section 2(u) defines "pesticide" as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." In the 1976 notice, EPA stated its statutory interpretation that the primary distinction between pesticides and devices was the means by which they achieved their pesticidal purpose: "If an article uses physical or mechanical means to trap, destroy, repeal [sic], or mitigate any [pest], it is considered to be a device. If the article incorporates a substance or mixture of substances intended to prevent, destroy, repeal [sic], or mitigate any pest, it is considered to be a pesticide."

Therefore, according to EPA, the key distinction between pesticides and devices is whether the pesticidal activity of the article is due to physical or mechanical actions or due to a substance or mixture of substances. EPA states that some of the types of products that were specifically identified as devices in the 1976 notice included, but were not limited to, "ultra violet light systems, ozone generators, water and air filters (except those containing substances or mixtures of substances), and ultrasonic devices making claims to inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites." In today's notice, EPA states that, in 1976, it was not aware of equipment such as the ion-generating washing machine that was presented to EPA in 2005.

Today's notice covers articles that are ion generators that incorporate a substance (*e.g.*, silver or copper) in the form of an electrode, and pass a current through the electrode to release ions of that substance for the purpose of preventing, destroying, repelling, or mitigating a pest (*e.g.*, bacteria or algae). EPA states that, because these items incorporate a substance or



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substances that accomplish their pesticidal function, such items are considered pesticides for purposes of FIFRA, and must be registered prior to sale or distribution.

Implementation

EPA says it “is aware that there may be some confusion in the regulated community” regarding EPA’s interpretation of the distinction between pesticides and devices. EPA will work with producers of ion generators to identify what data and other information are required to support an application for registration and to obtain registrations to bring such equipment into compliance for equipment being distributed or sold in the U.S. on September 21, 2007. Any person distributing or selling such equipment on or prior to September 21, 2007, may continue the distribution or sale of such equipment until **March 21, 2008**. EPA does not speculate what becomes of entities that neglect to obtain FIFRA registration by that date, but the inference is EPA would take the position the product is an unregistered pesticide and its marketing would be susceptible to enforcement action.

Any producer or importer of such equipment who distributes or sells the equipment on or prior to September 21, 2007, and who wishes to continue that distribution or sale after **March 21, 2008**, may do so only if a prospective registrant has commenced the registration process for the equipment by submitting, at a minimum, an Application for Pesticide Registration Form (EPA Form No. 8570-1) for the equipment. The form should be submitted to EPA on or before **March 21, 2008**. EPA states that, on the form, only the following information must be provided: Section I, Item 4: Company and Product Name; Section I, Item 5: Name and Address of Applicant; Section II, check “other” and place in explanation “Ion Generator FR Notice”; and all of Section IV. The form is available on the Internet at <http://www.epa.gov/opprd001/forms/8570-1.pdf>.

Persons distributing or selling such equipment on or prior to September 21, 2007, other than the producer or importer, may continue to distribute or sell such equipment until their inventories are exhausted. Further, any producer or importer of such equipment who is distributing or selling the equipment on or prior to September 21, 2007, who wishes to continue that distribution or sale after **March 23, 2009**, may do so only if a prospective registrant has submitted to EPA a completed registration package for the equipment on or before **March 23, 2009**. Producers or importers of such equipment may continue to distribute or sell such equipment only until such time as EPA acts upon the application or the application is withdrawn. Again, EPA states, “persons distributing or selling such equipment on or prior [September 21, 2007,] other than the producer or importer may continue to distribute or sell such equipment until their inventories are exhausted.”



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