Inquiry from private citizens affected by the use of Ge-68 in Ge-68/Ga-68 generators critical in medical imaging for certain cancers, and from some private companies involved in the manufacture of products for medical purposes. Responses from commenters focused on concerns such as pricing, monopolies, and discontinuation of isotope availability in the event of foreign or domestic supply disruption. A private U.S. company, Mallinckrodt Pharmaceuticals Inc., supplied a substantial amount of information in support of the Department's withdrawal from commercial production and distribution of Ge-68. The concerns and interests expressed by private citizens and affected industry are precisely those which comprise the factors the Department has evaluated to ensure there would be no adverse impacts in the event of DOE withdrawal from production.

While DOE is currently the only domestic producer of Ge-68, there are foreign producers of Ge-68 that distribute the radioisotope in the U.S. through U.S. distributors. Mallinckrodt has an existing facility in the U.S. that currently produces radioisotopes, with the capability to produce Ge-68 for domestic distribution. The information supplied by Mallinckrodt indicates it has a long history as a strong market participant in the production and sales of radioisotopes. Further, Mallinckrodt was judged to have the facilities, expertise, and management and financial resources necessary to produce sufficient quantities of Ge-68 to meet domestic demand. Production and distribution of radioisotopes is the core of the Mallinckrodt's business and Ge-68 is the latest product that they have developed to generate near-term sales and capture a share of a long-term growth market. Mallinckrodt has demonstrated capability to commercially produce Ge-68.

The Department has determined that there is sufficient evidence to conclude that, upon the Department's withdrawal from the production and distribution of Ge-68, Mallinckrodt would continue production of Ge-68, based upon the investments it's made in developing production capability, the fact that it has built a worldwide capability to engage in isotope production and distribution, and that such activities are at the core of their business. The Department has further concluded that if it were to withdraw from the market, Mallinckrodt would establish the price for the Ge-68 isotope on a fair and reasonable basis and within a range of the prices the Department currently charges. While Mallinckrodt did not explicitly state the price it would charge, its intention to maintain pricing consistent with the market suggests that there would not be catastrophic price changes if the Department withdraws from the market. With multiple private sector suppliers, pricing more likely than not would be controlled by market forces obviating the need for any Department mandate.

In light of the information provided by Mallinckrodt, input from private industry, and other information available to the Department, the Department intends to withdraw from the market for Ge-68 for the manufacture of PET calibration sources. The Department has concluded that Mallinckrodt has the capability and intent to meet market demand, and because there are multiple suppliers of Ge-68 suitable for use in the manufacturing of PET calibration sources (as well as multiple companies engaging in source fabrication), the Department has further concluded that the demand for the Ge-68 for calibration source manufacturing will be met and maintained at reasonable market-based pricing.

The Department has concluded that it will not withdraw from the market for Ge-68 for the manufacture of generators, however, because it has determined that there are no suppliers of bulk Ge-68 qualified for use in Ge-68/Ga-68 generators. This issue involves several concerns. First, if the Department were to exit the market, it appears that there would be no domestic producers of Ge-68 presently qualified for use in Ge-68/Ga-68 generators. These generators provide Ga-68 which is incorporated as a positron source in radiopharmaceuticals used in PET imaging medical applications currently under development. Qualification of other Ge-68 suppliers to serve the generator market would take time (in addition to potentially lengthy product testing, producers may have to change their production processes to provide Ge-68 that can be used on a generator for Ga-68 use in humans) and could impact researchers' achievement of Food and Drug Administration (FDA) approval for Ga-68-based medical imaging. Second, there is only one known foreign supplier of Ge-68/Ga-68 generators, which the Department does not believe is a dependable supply source for the U.S. market. The foreign supplier's production data does not provide adequate assurance the U.S. generator market would be adequately supplied by foreign suppliers. In the absence of a Department supply of Ge-68 for the manufacture of generators, Mallinckrodt would be the only immediate domestic source for generators, but only when or if the Mallinckrodt develops its own generator or its Ge-68 is qualified for use by other generator manufacturers. A single foreign supplier represents a risk that one domestic company, Mallinckrodt, could be the sole reliable domestic supplier of Ge-68 for generators and this could be problematic for the U.S. market for generators. If generator manufacturers were able to qualify Mallinckrodt's Ge-68 for use in generators, the Department's withdrawal from production would provide Mallinckrodt with a monopoly position in the marketplace for Ge-68 use in the manufacture of generators and other generator manufacturers would eventually be in a position of having to buy Ge-68 from their competitor.

In light of these circumstances, the Department has concluded that there is not effective competition in the market for Ge-68 for use in Ge-68/Ga-68 generators, and therefore it will continue to serve that segment of the Ge-68 market to provide competition. The Department's participation in that segment of the market will serve to reduce the potential for impediments to research and development leading to FDA approval of Ga-68 radiopharmaceuticals.

To help provide assurance of supply of Ge-68 for calibration source purposes, DOE proposes to maintain production capability, but not engage in sales to the marketplace, such that production would resume in a timely manner if Mallinckrodt and other suppliers are not be able to adequately serve the market or if private supplier pricing substantially increases and has a negative impact on the development and utilization of Ge-68 products.

Issued in Washington, DC, on April 2, 2014.

Jehanne Gillo,

Director, Facilities and Project Management Division, Office of Nuclear Physics, Office of Science.

[FR Doc. 2014–07865 Filed 4–8–14; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2014–0212; FRL–9908–82]

Pesticide Experimental Use Permit; Receipt of Application, Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's receipt of an application 8917–EUP–R from J.R. Simplot Company requesting an experimental use permit (EUP) for the *Rpi-vnt1 gene* that expresses the VNT1 protein in Innate™ 2.0 branded potato varieties. The Agency has determined that the permit may be of regional and national significance. Therefore, because of the potential significance, EPA is seeking comments on this application.

DATES: Comments must be received on or before May 9, 2014.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2014–0212, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC) (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8097; email address: *bacchus.shanaz@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What action is the Agency taking?

Under section 5 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land, or one acre or more of water.

Pursuant to 40 CFR 172.11(a), the Agency has determined that the following EUP application may be of regional and national significance, and therefore is seeking public comment on the EUP application:

Submitter: J.R. Simplot Company, 5369 West Irving Street, Boise, ID 83706, (8917–EUP–R).

Pesticide Chemical: Rpi-vnt1 gene that expresses the VNT1 protein in Innate™ 2.0 branded potato varieties.

Summary of Request: Simplot is proposing an experimental program to allow planting for the evaluation of the plant-incorporated protectant (PIP) *Rpi-vnt1 gene* that expresses the VNT1 protein in Innate™ 2.0 branded potato varieties. Simplot asserts that this plant trait confers resistance to the plant pathogen *Phytophthora infestans* (commonly known as late blight). Planting is expected to occur from spring 2014 through October 2014 on a total of 96.75 acres; testing will occur in 10 states: Idaho, Michigan, Nebraska, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Washington, and Wisconsin. The total amount of material expected to be used is 0.0088 pounds of VNT1 protein in 239,375 pounds of potatoes.

A copy of the application and any information submitted is available for public review in the docket established for this EUP application.

Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

List of Subjects

Environmental protection, Experimental use permits.

Dated: March 27, 2014.

Robert McNally,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2014–07819 Filed 4–8–14; 8:45 am]

BILLING CODE 6560–50–P