result in unreasonable adverse effects to man and the environment.

III. Conditionally Approved Application

EPA issued a notice, published in the **Federal Register** of April 27, 1998 (63 FR 20629) (FRL–5785–6), which announced that Bio-Care Technology Pty Ltd., c/o U.S. Agent: Ms. Amy Roberts, Technology Sciences Group Inc., 1101 17th St., NW., Suite 500, Washington DC 20036–4704, had submitted an application to conditionally register the pesticide product, NOGALL, Microbial Biocontrol Agent/Bacterial Inoculant (EPA File Symbol 62388–R), containing *Agrobacterium radiobacter* strain K1026 at 0.25% an active ingredient not included in any previously registered product.

The application was conditionally approved on September 28, 1999, for an end-use product listed below:

NOGALL (EPA Registration Number 62388–1) containing 0.25% *Agrobiacterium radiobacter* strain K1026) is used as a biological control agent for the prevention of crown gall disease caused by the infection of nursery stock by many virulent strains of *Agrobacterium tumefaciens* and *A. rhizogenes* on non-food and non-bearing plants only.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: February 16, 2000.

Janet L. Andersen,

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

[FR Doc. 00–4423 Filed 2–24–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–920; FRL–6494–2]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–920, must be received on or before March 27, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–920 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Fungicide Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9354; e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production. Animal production. Food manufacturing. Pesticide manufacturing.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–920. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–920 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3.*Electronically.* You may submit your comments electronically by e-mail to: *''opp-docket@epa.gov,''* or you can submit a computer disk as described

above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–920. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 17, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Tomen Agro, Inc. and Bayer Corporation, Agriculture Division

7F4890

EPA has received an amendment to pesticide petition (7F4890) from the TM–402 Fungicide Task Force comprised of Tomen Agro, Inc., 100 First Street, Suite 1610, San Francisco, CA 94105 and Bayer Corporation, Agriculture Division, 8400 Hawthorn Road, P.O. Box 4913, Kansas City, MO 64120–0013 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerances for residues of N-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexanecarboxamide (TM–402 or fenhexamid) in or on the raw agricultural commodities almond nutmeat at 0.02 parts per million (ppm), almond hulls at 2.0 ppm, and stone fruit at 5.0 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. A lactating goat was dosed at 10 milligrams (mg) ^{14}C–TM–402 per killograms/bodyweight (kg/bwt) on 3 consecutive days at 24-hour intervals. TM–402 was rapidly and almost completely absorbed and was rapidly distributed and eliminated (24.9% in urine, 38.6% in feces, and 0.03% in milk). The half-life of biliary-fecal elimination (primary pathway) was 0.5 hours. The primary residues in tissues were unreacted TM–402, its glucuronide derivative and the 4-hydroxy derivative. Since almond and stone fruit commodities are not significant poultry feeds, discussion of nature-of-the residue in the hen is not required. The nature-of-the-residue in crops was determined to be primarily unreacted TM–402 in apples, grapes, and tomatoes.

2. *Analytical method*. An adequate method for purposes of enforcement of the proposed TM–402 tolerances in plant commodities is available. Bayer AG Analytical Method No. 00362 was used by Tomen Agro to determine magnitude of TM–402 residues in almond nutmeat, almond hulls, cherries, peaches, and plums. This method has been independently validated for grapes. The limit of quantitation (LOQ) was determined to be 0.02 ppm in almond nutmeat.

3. *Magnitude of residues*. The maximum TM–402 residues in almond nutmeat permitted by the proposed label is 0.02 ppm. TM–402 residue in all almond nutmeat samples resulting from treatment of growing almonds was < 0.02 ppm (< the level of detection (LOD). The maximum TM–402 residue in almond hulls permitted by the proposed label is 2.0 ppm. The average TM–402 residues for almond hulls resulting from the treatment of growing almonds permitted by the proposed label are 0.7 ppm. The maximum TM–402 residue for fresh stone fruit permitted by the proposed label is 5.0 ppm. The average TM–402 residue resulting from the proposed treatment of growing stone fruit was 1.9 ppm in cherries, 1.3 ppm in peaches, and 0.10 ppm in plums. Calculated TM–402 residues in meat and milk are

significantly below < 0.01 ppm. Since no aquatic uses are proposed, magnitude of the residue data in fish and irrigated crops are not required.

B. Toxicological Profile

1. *Acute toxicity*. Data from a complete battery of acute toxicity studies for TM–402 technical are available. The acute oral toxicity study resulted in an LD_{50} of > 5,000 mg/kg for both sexes. The acute dermal toxicity in rats resulted in an LD_{50} of greater than 5,000 mg/kg for both sexes. The acute inhalation was investigated in two studies in rats. Inhalation by aerosol at the maximum technically possible concentration of 0.322 milligram/liter (mg/L) resulted in no deaths or symptoms (LC_{50} > 0.322 mg/L). A dust inhalation study resulted in an LC_{50} > 5.057 mg/L. TM–402 was not irritating to the skin or eyes after a 4-hour exposure period. The Buehler dermal sensitization study in guinea pigs indicated that TM–402 is not a sensitizer. Based on these results TM–402 technical is placed in toxicity Category IV and does not pose any acute dietary risks.

2. *Genotoxicty*. The potential for genetic toxicity of TM–402 was evaluated in six assays including two Ames tests, an HGPRT forward mutation assay, a unscheduled DNA synthesis (UDS) assay, an *in vitro* chromosomal aberration assay in chinese hamster ovary (CHO) cells, and a micronucleus test in mice. The compound was found to be devoid of any mutagenic activity in each of these assays including those tests that investigated the absence or presence of metabolic activating systems. The weight of evidence indicates that TM–402 technical does not pose a risk of mutagenicity or genotoxicity.

3. *Reproductive and developmental toxicity*. TM–402 has been tested for reproductive toxicity in rats and developmental toxicity in both rats and rabbits.

i. In a 2-generation reproduction study (one mating per generation), 30 Sprague-Dawley rats per sex per dose were administered 0, 100, 500, 5,000, or 20,000 ppm of TM–402 in the diet. The reproductive toxicity no observed adverse effect level (NOAEL) was 20,000 ppm. The neonatal NOAEL was 500 ppm, and the lowest observed adverse effect level (LOAEL) was 5,000 ppm based on decreased pup body weight. The parental toxicity NOAEL was 500 ppm based on lower adult pre-mating body weights at 5,000 and 20,000 ppm, lower gestation body weights at 20,000 ppm, lower lactation body weights at 5,000 and 20,000 ppm, and statistically significant changes in clinical chemistry parameters, terminal body weights, and organ weights at 5,000 and 20,000 ppm. Based on this study, it is clear that the only toxic effects in the neonates occurred at parentally toxic doses.

ii. In rats, TM–402 was administered by gavage at doses of 0 or 1,000 mg/kg for gestation days 6–15. No maternal toxicity, embryotoxicity, fetotoxicity, or teratogenic effects were observed at the limit dose of 1,000 mg/kg/day. Therefore, the NOAEL for maternal and developmental toxicity was 1,000 mg/kg/day.

iii. In rabbits, TM–402 was administered by gavage at doses of 0, 100, 300, and 1,000 mg/kg for gestation days 6–18. Body weight gain and feed consumption of the dams were reduced at the two top doses. One abortion occurred in each of the top two dose groups and two total resorptions occurred in the top dose group. The placental weights were slightly decreased at 300 mg/kg/day and above. In the 1,000 mg/kg/day group, slightly decreased fetal weights and a slightly retarded skeletal ossification were observed. All other parameters investigated in the study were unaffected. Therefore, the NOAELs for maternal and developmental toxicity were 100 mg/kg/day in this study.

Based on the 2-generation reproduction study in rats, TM–402 is not considered a reproductive toxicant and shows no evidence of endocrine effects. The data from the developmental toxicity studies on TM–402 show no evidence of a potential for developmental effects (malformations or variations) at doses that are not maternally toxic. The NOAEL for both maternal and developmental toxicity in rats was 1,000 mg/kg/day, and for rabbits the NOAEL for both maternal and developmental toxicity was 100 mg/kg/day.

4. *Subchronic toxicity*. The subchronic toxicity of TM–402 has been evaluated in rats, mice, and dogs.

i. TM–402 was administered in the diet to rats for 13 weeks at doses of 0, 2,500, 5,000, 10,000, and 20,000 ppm. The NOAEL was 5,000 ppm (415 mg/kg/day in males and 549 mg/kg/day in females). Reversible liver effects were observed at 10,000 ppm.

ii. TM–402 was administered in the diet to mice for approximately 14 weeks at doses of 0, 100, 1,000, and 10,000 ppm. The NOAEL was 1,000 ppm (266.6 mg/kg/day in males and 453.9 mg/kg/day in females). Increased feed and water consumption and kidney and liver effects were observed at 10,000 ppm.

iii. TM–402 was administered in the diet to beagle dogs for 13 weeks at doses of 0, 1,000, 7,000, and 50,000 ppm. The NOAEL was 1,000 ppm (33.9 mg/kg/day in males and 37.0 mg/kg/day in females). Increased Heinz bodies were observed at 7,000 ppm.

5. *Chronic toxicity*. The chronic toxicity of TM–402 has been evaluated in a 1-year dog study and a 2-year chronic toxicity/oncogenicity study in rats.

i. TM–402 was administered in the feed at doses of 0, 500, 3,500, or 25,000 ppm to 4 male and 4 female beagle dogs per group for 52 weeks. A systemic NOAEL of 500 ppm (an average dose of 17.4 mg/kg/day over the course of the study) was observed based on decreased food consumption and decreased body weight gain at 25,000 ppm, decreased erythrocyte, hemoglobin and hematocrit values at 25,000 ppm, increased Heinz bodies at 3,500 ppm and above, and a dose-dependent increase of alkaline phosphatase at 3,500 ppm and above. There were no treatment related effects on either macroscopic or histologic pathology.

ii. A combined chronic/oncogenicity study was performed in Wistar rats. Fifty animals/sex/dose were administered doses of 0, 500, 5,000, or 20,000 ppm for 24 months in the feed. A further 10 animals/sex/group received the same doses and were sacrificed after 52 weeks. The doses administered relative to body weight were 0, 28, 292, or 1,280 mg/kg/day for males and 0, 40, 415, or 2,067 mg/kg/day for females. The NOAEL in the study was 500 ppm (28 mg/kg/day for males and 40 mg/kg/day for females) based on body weight decreases in females at 5,000 ppm and above, changes in biochemical liver parameters in the absence of morphological changes in both sexes at 5,000 ppm and above, and caecal mucosal hyperplasia evident at 5,000 ppm and above.

The NOAEL in the chronic dog study was 17.4 mg/kg/day based on body weight, hematology and clinical chemistry effects. The lowest NOAEL in the 2-year rat study was determined to be 28 mg/kg/day based on body weight, clinical chemistry parameters in the liver, and caecal mucosal hyperplasia.

6. *Oncogenicity*. The oncogenic potential of TM–402 has been in a 2-year oncogenicity study in mice and a 2-year chronic toxicity/oncogenicity study in rats.

i. In mice, TM–402 was administered to 50 sex/group in their feed at concentrations of 0, 800, 2,400, or 7,000 ppm for 24 months. These concentrations resulted in a compound intake of 247.4, 807.4, or 2,354.8 mg/kg/

day in males and 364.5, 1,054.5, and 3,178.2 mg/kg/day in females. A further 10 mice/sex/group received the same concentrations and were sacrificed after 12 months. There was no treatment effect on mortality, feed consumption, the hematological system or on the liver. Water consumption was increased in both sexes, and body weights were 8% lower in males at the highest dose of 7,000 ppm. At 7,000 ppm, elevated plasma creatinine concentrations, decreased kidney weights, and an increased occurrence of morphological lesions indicated a nephrotoxic effect of the compound. There was no shift in the tumor spectrum with treatment, and therefore, TM–402 was not oncogenic in this study.

ii. In the 2-year rat chronic/oncogenicity study described above, there was no indication of an oncogenic response. There was no indication of an oncogenic response in the 2-year rat and mouse studies on TM–402.

7. *Neurotoxicity*. The possibility for acute neurotoxicity of TM–402 was investigated. TM–402 was administered by gavage in a single dose to 12 Wistar rats/sex/group at doses of 0, 200, 630, 2,000 mg/kg. There was no evidence of neurotoxicity at any level tested.

8. *Endocrine disruption*. TM–402 has no endocrine-modulation characteristics as demonstrated by the lack of endocrine effects in developmental, reproductive, subchronic, and chronic studies.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Dietary exposure to TM–402 are limited to the established tolerances for residues of TM–402 on grapes at 4.0 ppm, raisins at 6.0 ppm, and strawberries at 3.0 ppm, and the proposed tolerances in the current submission which are as follows: almond nutmeat 0.02 ppm; almond hulls 2.0 ppm, and stone fruit 5.0 ppm.

ii. *Drinking water*. Review of the environmental fate data indicates the TM–402 is relatively immobile and rapidly degrades in the soil and water. TM–402 dissipates in the environment via several processes. Therefore, a significant contribution to aggregate risk from drinking water is unlikely.

2. *Non-dietary exposure*. There is no significant potential for non-occupational exposure to the general public. The proposed uses are limited to agricultural and horticultural use.

D. Cumulative Effects

Consideration of a common mechanism of toxicity is not appropriate at this time since there is no significant toxicity observed for TM–402. Even at toxicology limit doses, only minimal toxicity is observed for TM–402. Therefore, only the potential risks of TM–402 are considered in the exposure assessment.

E. Safety Determination

1. *U.S. population*. Based on the most sensitive species, Tomen Agro has calculated an appropriate reference dose (RfD) for TM–402. Using the NOAEL of 17.4 mg/kg/day in the 1-year dog study and an uncertainty factor (UF) of 100 to account for interspecies and intraspecies variability, an RfD of 0.174 mg/kg/day is recommended.

A chronic dietary risk assessment which included all tolerances was conducted on TM–402 using U.S. EPA's Dietary Risk Evaluation System (DRES). The theoretical maximum residue contribution (TMRC) for the U.S. population (48 contiguous States) is 0.0031 mg/kg/day and this represents 1.7% of the proposed RfD. The most highly exposed subgroup was non-nursing infants (< 1-year old) where the TMRC was 0.017 mg/kg/day, representing only 9.6% of the proposed RfD. For nursing infants (< 1-year old) the TMRC was 0.0088 mg/kg/day (5.0% of the RfD). For children (1–6 years old) the TMRC was 0.0078 mg/kg/day (4.4% of the RfD), and for children 7–12 years old the TMRC is 0.0040 mg/kg/day (2.3% of the RfD). If these calculations consider the average of anticipated residue values instead of assuming ''tolerance level'' residues, the values are reduced to approximately one-forth of those listed above. Even under the most conservative assumptions, the estimates of dietary exposure clearly demonstrate adequate safety margins of all segments of the population.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of TM–402, the available developmental toxicity and reproductive toxicity studies and the potential for endocrine modulation by TM–402 were considered. Developmental toxicity studies in two species indicate that TM–402 does not impose additional risks to developing fetuses and is not a teratogen. The 2–generation reproduction study in rats demonstrated that there were no adverse effects on reproductive performance, fertility, fecundity, pup survival, or pup development at non-maternally toxic levels. Maternal and developmental NOAELs and LOAELs were comparable, indicating no increase in susceptibility of developing organisms. No evidence of endocrine effects was noted in any study. It is therefore, concluded that TM–402 poses no additional risk for infants and children and no additional uncertainty factor is warranted.

F. International Tolerances

There are no established maximum residue levels established for fenhexamid by the Codex Alimentarius Commission.

[FR Doc. 00–4421 Filed 2–24–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50866; FRL–6492–1]

Experimental Use Permit; Cry1F Bt Corn Receipt of Amendment/Extension Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application 68467–EUP–2 from Mycogen c/o Dow Agrosciences LLC requesting an experimental use permit (EUP) for the *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999) in corn plants. The Agency has determined that the application may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on this application.

DATES: Comments, identified by docket control number OPP–50866, must be received on or before March 27, 2000.

ADDRESSES: Comments and data may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–50866 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8715; and e-mail address: mendelsohn.mike@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be