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 OPP–30524 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, 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), OPP, Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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 OPP–30524. 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 listed 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. Offer alternative ways to improve the registration activity.

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

8. 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. Registration Application

EPA received an application as follows to register a pesticide product containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of this application does not imply a decision by the Agency on the application.

Product Containing Active Ingredients not Included in any Previously Registered Products

File Symbol: 70051–TA. *Applicant*: Thermo Trilogy Corporation, 9145 Guilford Road, Suite 175, Columbia, MD, 21046. *Product name*: Olive Fly Attract and Kill (A and K) Target Device. *Type of product*: Pheromone/attractant. *Active ingredients*: Ammonium bicarbonate at 12.8% and 1,7-dioxaspiro-(5,5)-undecane (Spiroketal) at 0.2%. *Proposed classification/Use*: An attractant that is used in an attract and kill device that is used to attract and kill the Olive Fruit Fly in olive orchards.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: March 14, 2002.

Janet L. Andersen,

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

[FR Doc. 02–7496 Filed 3–27–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1077; FRL–6829–1]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the amendment of a pesticide petitions 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–1077, must be received on or before April 29, 2002.

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–1077 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja Brothers, Registration Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number (703) 308–3194; and e-mail address: brothers.shaja@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 codes	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing

Categories	NAICS codes	Examples of potentially affected entities
	32532	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–1077. 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–1077 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, 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–1077. 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 listed 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 an amended pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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 support 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: March 15, 2002.

Richard P. Keigwin, Jr.,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioner and represent the views of the petitioner. 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.

Interregional Research Project Number 4 (IR-4)

PP 2E6355, 2E6367, 2E6368

EPA has received pesticide petitions (2E6355, 2E6367, 2E6368) from the Interregional Research Project Number 4 (IR-4), 681 US Highway #1 South, North Brunswick, NJ 08902-3390 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 180.371 by establishing tolerances for combined residues of thiophanate-methyl, (dimethyl [(1,2-phenylene)-bis(iminocarbonothioyl)] bis[carbamate]), its oxygen analogue dimethyl-4,4-o-phenylenebis(allophonate), and its benzimidazole-containing metabolites (calculated as thiophanate-methyl) in or on the following raw agricultural commodities:

1. Pesticide Petition (PP) 2E6355 proposes a tolerance for pistachio at 0.2 parts per million (ppm).

2. PP 2E6367 proposes a tolerance for potato at 0.05 ppm.

3. PP 2E6368 proposes a tolerance for canola at 0.1 ppm.

This notice includes a summary of the petition prepared by Cerexagri, Inc., 2000 Market Street, Philadelphia, PA 19103. EPA has determined that the petitions contain 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 support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of thiophanate-methyl in plants is well understood.

2. *Analytical method*. An adequate method for purposes of enforcement of the proposed thiophanate-methyl tolerances is available. The method uses a HPLC system employing column-switching capabilities. It consists of reverse phase HPLC with UV detection, and is capable of analyzing for residues of thiophanate-methyl and its metabolite, MBC.

3. *Magnitude of residues*. The magnitude of residues for pistachio, potato, and canola are adequately understood for the proposed tolerances.

B. Toxicological Profile

1. *Acute toxicity*. Technical thiophanate-methyl is practically non-toxic (Toxicity Category III) after administration by the oral, dermal and respiratory routes. Thiophanate-methyl is a skin sensitizer.

2. *Genotoxicity*. Thiophanate-methyl has been tested in the Salmonella typhimurium reverse mutation assay with and without activation, the Chinese hamster V79 gene mutation assay with and without activation, the Chinese hamster ovary cell chromosomal aberration assay with and without activation, a primary rat hepatocyte unscheduled DNA synthesis assay, and a mouse dominant lethal assay. All these tests were negative. Thiophanate-methyl is not genotoxic.

3. *Reproductive and developmental toxicity*. At non-maternally toxic doses, thiophanate-methyl induced no teratogenic or fetotoxic effects in rats or rabbits. Even at doses well above maternally toxic levels, thiophanate-methyl caused only minor reversible effects in fetuses and even these effects may not have been compound related. In addition, thiophanate-methyl showed no developmental effects. In rat developmental studies, no abnormalities were observed at gavage doses up to 1,000 mg/kg/day or in a dietary study of doses up to 163 mg/kg/day. Furthermore, increased offspring sensitivity was not observed in the reproductive toxicity studies at doses up to 172 mg/kg/day.

4. *Subchronic toxicity*. Thiophanate-methyl was administered dermally to male and female New Zealand white rabbits 6/hours/day, 5 days/week for 21 days at 100, 300, and 1,000 mg/kg/day. Slight dermal irritation was noted in all the treatment groups during the second week of the study. Decreased food consumption was observed in males at 1,000 mg/kg/day. A systemic NOAEL of 100 mg/kg/day was established. A systemic LOAEL of 300 mg/kg/day was established based on significant decreases in food consumption in female rabbits.

Thiophanate-methyl was evaluated in a 90 day rat feeding study. The effects of treatment were anemia, follicular hyperplasia and hypertrophy of the thyroid, hepatocellular swelling and lipofuscin, fatty degeneration of the adrenal cortex and glomerulonephrosis. The LOAEL was 2,200 ppm (155 mg/kg/day). Based on these results, a NOAEL of 200 ppm (15.7 mg/kg/day) was established for both males and females.

Dogs were fed thiophanate-methyl for 90 days. Based on the occurrence of follicular hypertrophy of the thyroid gland in both sexes and decreased serum glutamic pyruvic transaminase (SGPT) activity in females the LOAEL was determined to be 50 mg/kg/day. No NOAEL was established. (The NOAEL for the one year chronic study was 8 mg/kg/day.)

5. *Chronic toxicity*. Thiophanate-methyl was administered by capsule to beagle dogs for 1 year. Based on the decreased body weight gain in both sexes, decreased T4 levels in males and increased thyroid-to-body weight ratio and hypertrophic histologic changes in the thyroid gland in both sexes, the LOAEL for thiophanate-methyl is 40 mg/kg/day and the NOAEL is 8 mg/kg/day.

A combined chronic/carcinogenicity feeding study was performed in rats at dosages of 0, 75, 200, 1,200 and 6,000 ppm thiophanate-methyl for two years. No clinical signs attributable to thiophanate-methyl were noted in the first 52 weeks. It was concluded that the effects of the treatment with thiophanate-methyl included growth depression, anemia, morphological and functional changes in the thyroid and pituitary, hepatocellular hypertrophy with lipofuscin, accelerated nephropathy and lipidosis of the adrenal cortex. The maximally tolerated dose (MTD) was determined to be 1,200 ppm for both males and females. At 6,000 ppm, approximately five times the MTD, an increase in thyroid follicular cell adenomas was observed in males. Thyroid hyperplasia and hypertrophy were observed only at or above the MTD. These effects are considered to be related to the treatment related changes in hormonal homeostasis of the pituitary-thyroid axis. The NOAEL is 200 ppm (8.8 mg/kg/day in males and 10.2 mg/kg/day in females) when fed for 104 weeks.

In a 2–year feeding study in F344 rats, females receiving up to 334.7 mg/kg/day thiophanate-methyl showed no increase in carcinomas but did show a slight increase in benign adenomas at the highest dose. Male rats showed a dose related increase in benign adenomas and three animals at the highest dose (281 mg/kg/day) had carcinomas. However, the MTD was exceeded for both male and female rats at the highest dose tested. In males, the MTD was exceeded, as demonstrated by the severity of toxicity seen in various organs and excessive mortality (2/55 survivors at study end vs. 37/50 controls). In the highest dose females, net body weight gain was only 69% ($p < 0.001$) of the control value at the end of the study.

In an 18-month feeding study in CD-1 mice, males receiving 3,000 ppm (468

mg/kg/day) showed an increased incidence of hepatocellular hypertrophy and a small, but statistically significant, decrease in body weight (<8%). Transient increases in serum thyroid stimulating hormone (TSH) and in absolute and relative thyroid weights were also observed in males. At the highest dose tested (7,000 ppm) both males and females showed increased mortality and increased liver weight at both weeks 39 and 78. Females at 7,000 ppm (1329 mg/kg/day) showed a statistically significant decrease in body weight (<8%), decreased serum thyroxine (T4) at week 39, and increased heart weight at weeks 39 and 78. A dose-related statistically significant increase in the incidence of hepatocellular adenomas was observed in both sexes at 3,000 and 7,000 ppm. Two hepatocarcinomas and one hepatoblastoma were found. The systemic NOAEL is 150 ppm (23.7 mg/kg/day in males and 28.7 mg/kg/day in females). The LOAEL is 640 ppm based on an increased incidence of hepatocellular hypertrophy in females.

6. *Animal metabolism*. The metabolism of thiophanate-methyl in animals is well understood.

7. *Metabolite toxicology*. There are two primary metabolites of thiophanate-methyl: MBC and 2-AB. The metabolite that has been extensively evaluated for toxicity is MBC. The toxicity of MBC is well understood and documented in the report of the International Programme on Chemical Safety (Environmental Health Criteria 149).

8. *Endocrine disruption*. No effects were observed that would indicate that the endocrine system is disrupted with regard to the reproductive system (i.e., is anti-estrogenic, estrogenic, androgenic, or anti-androgenic). Thiophanate-methyl does alter thyroid function through the thyroid stimulating hormone.

C. Aggregate Exposure

1. *Dietary exposure*. Dietary exposure is the primary route of exposure to thiophanate-methyl. Tolerances have been established for the residues of thiophanate-methyl in or on a variety of raw agricultural commodities.

i. *Food*. For the purposes of assessing the potential dietary exposure for these existing and pending tolerances, Cerexagri, Inc. conducted exposure estimates using the Lifeline software version 1.1 from The Lifeline Group, results from field trials and processing studies, monitoring data, consumption data from the 1994-1996, 1998 USDA Continuing Surveys of Food Intakes by Individuals (CSFII), and information on the percentages of the crops treated (where available) with thiophanate-methyl were utilized.

ii. *Drinking water*. Thiophanate-methyl is not expected to be found in water. The half-life of thiophanate-methyl is very short in soil and water. When metabolized or chemically converted to MBC, none is expected to leave the soil. In dissipation studies neither thiophanate-methyl nor MBC was found below the top layer of the soil (0-8 cm or 0-6 inches). Little to no thiophanate-methyl exposure is expected in drinking water.

2. *Non-dietary exposure*. Thiophanate-methyl has turf use patterns. The primary use is commercial (golf course, turf sale). Based on the limited use of the product on golf courses, and the low dermal toxicity, little to no contribution to the thiophanate-methyl risk cup is expected through non-occupational exposure.

D. Cumulative Effects

Benomyl (marketed until recently), MBC, thiabendazole, and thiophanate-methyl have been evaluated for similar toxicity patterns because of the potential structure-activity relationship. Thiophanate-methyl, although displaying some similarities to each of the other benzimidazoles, is also very different. These benzimidazoles do not share a toxicity profile that would indicate there is common mode of action. The difference in toxicity patterns is apparent in the recent HED Revised Preliminary Risk Assessment for thiophanate-methyl. In this assessment, none of the NOAELs for thiophanate-methyl are based on liver effects, while both subchronic and chronic NOAELs for MBC are based on liver effects. In acute studies, MBC has testicular effects, while thiophanate-methyl induce tremors at high doses. The main overlap in toxicity profiles between thiophanate-methyl and MBC are non-specific effects such as reduced food consumption and body weights in dietary studies.

In addition, for subchronic and chronic exposures, thiophanate-methyl toxicity primarily involves the thyroid. In contrast, no disruption of the thyroid-pituitary-liver axis is documented in either the carbendazim or the benomyl studies. Secondary effects on the liver could be seen in common, but these too are very different. If driven by MBC alone, thiophanate-methyl should have a dose effect much higher than MBC. In fact, it is two to three times higher. Reproductive, developmental and genetic toxicity are also different between thiophanate-methyl and MBC. Likewise, thiabendazole is different than thiophanate-methyl. It does not metabolize to MBC and shows significant differences from thiophanate-methyl in the type of toxicities observed. Therefore, there is no scientific basis for aggregating this class of fungicides, due to a lack of common mechanisms of toxicity.

E. Safety Determination

1. *U.S. population*. For both the general population and all specific subpopulations, there is a reasonable certainty of no harm associated with all exposure assessments. Non-cancer and cancer risks are lower than have been previously calculated by EPA because: (i) PDP data were used where appropriate rather than field trial data, (ii) updated usage data lowered the estimates of the percent of crop treated for some key commodities, such as stone fruit, and (iii) a consumer washing factor of 0.07 was used for smooth skinned fruits (apples, blueberries, and strawberries). Note that two separate Lifeline analyses were conducted and submitted to EPA, one on October 3, 2001, and a second on October 19, 2001. The second analysis used actual MBC residues to calculate MBC and 2-AB residues, rather than estimating them based on thiophanate-methyl residues. The use of actual MBC data provided a more accurate assessment of exposure.

2. *Infants and children*. The rabbit study indicated that even at twice the maternal LOAEL, thiophanate-methyl induced only two effects of questionable significance, increase in supernumerary ribs (a reversible condition) and a reduction in fetal weight that was not statistically significant and was likely related to maternal toxicity. The rat developmental study showed no teratogenic or fetotoxic effects at any dose tested.

The thiophanate-methyl 2-generation reproduction study showed thyroid and liver effects in both the parental and first generation pups. The effects were greater in the parental animals than in subsequent generations. This would indicate that there is no greater sensitivity for infants and children to thiophanate-methyl than the general population.

F. International Tolerances

There are no Codex Alimentarius Commission tolerances for canola, pistachios, or potatoes. The European Union tolerances for each of the three commodities is 0.1 ppm (lower limit of analytical determination).

[FR Doc 02–7497 Filed 3–27–02; 8:45 a.m.]

BILLING CODE 6560–50–S