any significant contamination of potential drinking water sources.

Therefore, Zeneca concludes that potential exposures from residues of fomesafen in drinking water added to the current dietary exposure will not present significant risk to the U.S. population.

4. *Non-dietary exposure*. Since fomesafen is not registered for residential or turf uses, exposures from other than dietary or occupational sources are extremely unlikely. At this time there are no reliable data to assess the potential risk from non-dietary sources.

D. Cumulative Effects

Fomesafen is a diphenyl ether class of chemicals. At this time, EPA has not made a determination that fomesafen and other compounds have a common mechanism of toxicity resulting in cumulative effects. Therefore, aggregate exposure is evaluated on the uses of fomesafen only.

E. Safety Determination

1. *U.S. population*. The Reference Dose (RfD) for fomesafen has not been established by the Agency's. For purposes of this action, the RfD is calculated at 0.0025 mg/kg of body weight/day. The RfD is based on a NOEL of 0.25 mg/kg/day from the rat feeding/carcinogenicity study and an uncertainty factor of 100. The ARC for the overall U.S. population from established tolerances and the proposed tolerance for snap beans utilizes 1.4% of the RfD. EPA generally has no concern for exposures below 100% of the RfD.

The upper-bound carcinogenic risk from established tolerance on soybeans and the proposed tolerance for snap beans is calculated at 1.56×10^{-6} for the U.S. population, based on the available market share data. The upper-bound carcinogenic risk from the proposed use on snap beans is calculated at 1.4×10^{-6}. Therefore, Zeneca believes that the potential cancer risk from residues of fomesafen resulting from the combined established tolerance on soybeans and the proposed tolerance for snap beans is negligible.

2. *Infants and children*. Zeneca noted that the potential for additional sensitivity for infants and children to residues of fomesafen have been considered based on the three-generation reproductive study in rats and the developmental toxicity studies in rat and rabbit. Zeneca concluded that fomesafen showed no evidence of reproductive toxicity and caused no developmental toxicity in the rabbit or in the rat.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete for fomesafen. Zeneca AG Products concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to fomesafen.

F. International Tolerances

There are no Codex Maximum Residue Levels established for fomesafen residues.

[FR Doc. 97–24692 Filed 9–16–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–763; FRL–5742–9]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.
DATES: Comments, identified by the docket control number PF–763, must be received on or before October 17, 1997.
ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7506C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Beth Edwards, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 206, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–5400; e-mail: edwards.beth@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions 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 Comestic 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–763] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [pf–763] and appropriate petition number. Electronic comments on this notice may be filed

online at many Federal Depository Libraries.

List of Subjects

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

Dated:September 8,1997

James Jones, Acting

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 petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them 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.

E.I. duPont de Nemours & Co.

PP 7F4859

EPA has received a pesticide petition (PP 7F4859) from E.I. duPont de Nemours & Co.(DuPont), P.O. Box 80038, Wilmington, DE 19880–0038, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of esfenvalerate, (Asana XL Insecticide), ((*S*)-cyano-(3-phenoxyphenyl)methyl (*S*)-4-chloro-alpha-(1-methylethyl) benzeneacetate in or on the raw agricultural commodity, pistachios. The enforcement analytical method for determining residues is gas chromatography with nitrogen phosphorus detection. 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*. The metabolism and chemical nature of residues of fenvalerate in plants is adequately understood. The fate of fenvalerate has been extensively studied using radioactive tracers in plant and animal metabolism/nature of the residue studies previously submitted to the Agency. These studies have demonstrated that the parent compound is the only residue of toxicological significance.

2. *Analytical method*. There is a practical analytical method utilizing electron-capture gas chromotography (MRID No. 43567101) available for enforcement with a limit of detection that allows monitoring food with residues at or above tolerance levels.

3. *Magnitude of residues*. Current tolerances are based on the sum of all isomers of fenvalerate. Fenvalerate is a racemic mixture of four isomers (about 25% each). This product was registered as Pydrin. However, since 1992, an *S,S*-isomer enriched formulation, Asana (esfenvalerate), has been the only fenvalerate formulation sold in the U.S. Since the *S,S*-isomer is the insecticidally active isomer, the use rate for Asana is 4 times lower than that for Pydrin. A petition is pending (PP–34F4329), to convert tolerances based on the use rates for Asana (still to be expressed as the sum of all isomers). Bridging studies have shown Asana residues to be 3–4 times lower than Pydrin residues.

A magnitude of residue study on pistachio was conducted at 5 sites in California where climate, soil type, and other conditions are typical of those found where Asana may be used on pistachio nuts for insect control. At each site, Asana was applied 2 times at 0.10 lb ai/A by foliar broadcast spray, 7 days apart, for a maximum rate of 0.20 lb ai/A/season. Treatments were also made at twice the maximum proposed label rate at each site. Pistachio samples were collected 0 and 1 day after the last application. The mean esfenvalerate residue found at the proposed label rate of 0.20 lb ai/A/season with a PHI of 1 day was 0.031 ppm +/- 0.012 ppm. These results support the proposed tolerance of 0.10 ppm.

Since there are no processed commodities of pistachios, processing studies were not conducted. In addition, pistachios are not an animal feed item and, therefore, secondary residues will not be an issue.

B. Toxicological Profile

The following studies have been submitted to EPA:

1. *Acute toxicity*. A rat acute oral study on esfenvalerate technical with an LD_{50} of 87.2 mg/kg (MRID 00144973). A rabbit acute dermal study on esfenvalerate with an LD_{50} of >2000 mg/kg (MRID 00156508). Acute inhalation on technical grade a.i. waived due to negligible vapor pressure. A primary eye irritation test using esfenvalerate in the rabbit which showed mild irritation (conjunctivitis) that cleared by day 7 (MRID 00156509). A primary dermal irritation test using esfenvalerate in the rabbit which showed minimal irritation that reversed within 72 hours after treatment (MRID 00156510). A dermal sensitization test on esfenvalerate in guinea pigs which showed no sensitization (MRID 41215203).

2. *Genotoxicity*. Esfenvalerate was not mutagenic in reverse mutation assays *in Salmonella* and *E. Coli* (MRID 413163010) or in HGPRT *in vitro* assay in Chinese hamster lung cells (MRID 41316302). Esfenvalerate did not induce chromosome aberrations in an *in vitro* assay in Chinese hamster ovary cells (MRID 41215204). Esfenvalerate did not induce micronuclei in bone marrow of mice given up to 150 mg/kg intraperitoneally (MRID 41316303). Esfenvalerate did not induce unscheduled DNA synthesis in HeLa cells (MRID 41316304).

3. *Reproductive and developmental toxicity*. A pilot developmental study in the rat with doses of 0, 1, 2, 3, 4, 5, and 20 mg/kg/day esfenvalerate (MRID 43211502). The maternal NOEL was 3 mg/kg/day based on maternal clinical signs of abnormal gait or mobility at 4 mg/kg/day and above. A developmental study in the rat with doses of 0, 2.5, 5, 10, and 20 mg/kg/day esfenvalerate by gavage (MRID 43211504). There was no maternal NOEL but a maternal NOEL was established in the pilot study. Maternal signs observed at 2.5 mg/kg/day were erratic jerking and extension of forelimbs, rapid side-to-side head movement and excessive grooming. There were no fetal or developmental effects in either study at 20 mg/kg/day, the highest dose tested. Therefore, the fetal/developmental NOEL was >20 mg/kg/day.

A pilot developmental study in the rabbit with doses of 0, 2, 3, 4, 4.5, 5, and 20 mg/kg/day esfenvalerate by gavage (MRID 43211501). The maternal NOEL was 2 mg/kg/day based on excessive grooming at 3 mg/kg/day and above. A developmental study in the rabbit with doses of 0, 3, 10, and 20 mg/kg/day esfenvalerate by gavage (MRID 43211503). There was no maternal NOEL but a maternal NOEL was established in the pilot study. There were no fetal or developmental effects in either study at the highest dose tested. Therefore, the fetal/developmental NOEL was >20 mg/kg/day.

A 2–generation feeding study with esfenvalerate in the rat at dietary levels of 0, 75, 100, or 300 ppm. The high

dietary concentration was lowered to 150 ppm for the second generation. Very mild body weight effects and sores at 75 ppm in both generations were considered secondary effects caused by scratching related to skin stimulation from dermal exposure. Therefore 75 ppm (4.2 mg/kg/day for first generation parental males, 5.6 mg/kg/day for first generation parental females, 6.0 mg/kg/day for second generation parental males, and 7.3 mg/kg/day for second generation parental females) was considered an NOAEL for both adult rats and their offspring. Effects were observed in adults and pups of both generations at 100 ppm and above. Pups were no more sensitive than adult animals (MRID 43489001).

4. *Subchronic toxicity*. A 90–day feeding study in rats conducted at 0, 75, 100, 125, and 300 ppm esfenvalerate with a NOEL of 125 ppm (6.3 mg/kg/day). This study provided intermediate dose levels to supplement a 90–day feeding study in rats conducted at 0, 50, 150, 300 and 500 ppm esfenvalerate with a NOEL of 50 ppm (2.5 mg/kg/day) based on jerky leg movements at 150 ppm (7.5 mg/kg/day) and above (MRID 00151030).

A 90–day feeding study in mice conducted at 0, 50, 150, and 500 ppm esfenvalerate and 2,000 ppm fenvalerate with a NOEL of 50 ppm esfenvalerate (10.5 mg/kg/day) based on lower glucose and triglycerides at 150 ppm. Neurologic symptoms were observed with 500 ppm esfenvalerate and 2,000 ppm fenvalerate (MRID 41359701).

Three month subchronic study in dogs is satisfied by 1–year oral study in dogs, in which the NOEL was 200 ppm (5 mg/kg/day) (MRID's 00265247, 403375601, and 40799501).

A 21–day dermal study in rabbits with fenvalerate conducted at 100, 300, and 1,000 mg/kg/day of fenvalerate with an NOEL of 1,000 mg/kg/day fenvalerate (MRID 42325101).

5. *Chronic toxicity*. A 1–year study in which dogs were fed 0, 25, 50, or 200 ppm esfenvalerate with no treatment related effects at any dietary level. The NOEL was 200 ppm (5 mg/kg/day). (MRID's 00265247, 40375601, 40799501). An effect level for dietary administration of esfenvalerate for dogs of 300 ppm had been established earlier in the 2–week pilot study used to select dose levels for the chronic dog study (MRID 40376501).

A 20–month study with fenvalerate in mice fed 0, 10, 30, 100, and 300 ppm fenvalerate. The NOEL was 30 ppm (6mg/kg/day) based on red blood cell effects and granulomatous changes at 100 ppm. Fenvalerate was not carcinogenic at any concentration (MRID 00093662).

An 18–month study with esfenvalerate in mice fed 0, 35, 150, and 350 ppm esfenvalerate. Mice fed the 350 ppm dose were sacrificed within the first 2 months of the study, after excessive morbidity and mortality due to self-trauma induced by pharmacological effects on dermal sensory nerves. Therefore, data collected from the 350 ppm group were not used in the evaluation of the oncogenic potential of esfenvalerate. The NOEL was 35 ppm (4.29 and 5.75 mg/kg/day for males and females, respectively) based on lower body weight and body weight gain at 150 ppm. Esfenvalerate was not carcinogenic at either the 35 ppm or 150 ppm concentrations (MRID 44260601).

A 2–year study with fenvalerate in rats fed 1, 5, 25, and 250 ppm. A 1,000 ppm group was added to establish an effect level. The NOEL was 250 ppm (12.5 mg/kg/day). At 1,000 ppm, hind limb weakness, lower body weight, and higher organ-to-body weight ratios were observed. Fenvalerate was not carcinogenic at any concentration (MRID's 00079877, 00082007).

6. *Animal metabolism*. After oral dosing, fenvalerate was eliminated from rats within 5 days after dosing. The metabolic pathway involved cleavage of the ester linkage followed by hydroxylation, oxidation, and conjugation of the acid and alcohol moieties.

7. *Metabolite toxicology*. The parent molecule is the only moiety of toxicological significance which needs regulation in plant and animal commodities.

8. *Other potential toxicology considerations - endocrine effects*. Estrogenic effects have not been observed in any studies conducted on fenvalerate or esfenvalerate. In subchronic or chronic studies there were no lesions in reproductive systems of males or females. In the recent reproduction study with esfenvalerate, full histopathological examination of the pituitary and the reproductive systems of males and females was conducted. There were no compound-related gross or histopathological effects. There were also no compound-related changes in any measures of reproductive performance including mating, fertility, or gestation indices or gestation length in either generation.

C. Aggregate Exposure

1. *Dietary exposure*. For purposes of assessing dietary exposure, chronic and acute dietary assessments have been conducted using all existing and pending tolerances for esfenvalerate. The toxocological endpoints used in both dietary assessments are derived from maternal NOEL's of 2.0 mg/kg/day from rat and rabbit teratology studies. There were no fetal effects.

2. *Food*. A chronic dietary exposure assessment using anticipated residues and assuming that 100% of all crops are treated, found the percentages of the Reference Dose (RfD) utilized by the two most sensitive sub-populations to be 44% (Non-Nursing Infants <1 yr.) and 48% (Children 1–6 yrs.). This assessment also included all food tolerances for incidental food handling establishments which were set at 0.05 ppm (the limit of quantitation) since there were no detectable residues. The results have been adjusted from the study previously submitted (MRID 43639301) to reflect the new Reference Dose (RfD) selected by EPA.

The Tier 3 acute dietary assessment has been rerun to incorporate current EPA thinking on processing studies and secondary residues that has arisen since the original study was submitted (MRID 44197701). The most sensitive sub-populations were determined to be: Non-Nursing Infants (< 1 yr.) with a Margin of Exposure (MOE) of 914 at the 95th percentile of exposure and an MOE of 254 at the 99th percentile of exposure; and Children (1–6 yrs.) with an MOE of 698 at the 95th percentile of exposure and 321 at the 99th percentile. The MOE's for the general population were 1,803 at the 95th percentile of exposure and 676 at the 99th percentile. This analysis used field trial residue data and market share data for the percent of crop treated. It also used Monte Carlo sampling and applied appropriate processing factors for apple juice and apple juice concentrate. Monte Carlo distribution was also used for meat and milk residues. Food handling establishment commodities were not included in the analysis because EPA methodology does not include them in Tier 3 exposure modeling.

3. *Drinking water*. Esfenvalerate is immobile in soil and, therefore, will not leach into groundwater. Additionally, due to the insolubility and lipophilic nature of esfenvalerate, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore not contributing to potential dietary exposure from drinking water. In addition, a screening evaluation of leaching potential of esfenvalerate has been conducted using DuPont's Tier 1 Ground Water Exposure Model (TIGEM, Version 12/30/96) which is based on results from EPA's Pesticide Root Zone Model (PRZM, Version 2.0). Based on this screening

assessment, the potential concentrations of esfenvalerate in shallow ground water are judged to be negligible.

4. *Non-dietary exposure*. Dietary exposure is the only significant route of chronic non-occupational exposure to esfenvalerate. However, esfenvalerate is registered for non-crop uses including spray treatments in and around commercial and residential areas, treatments for control of ectoparasites on pets, home care products including foggers, pressurized sprays, crack and crevice treatments, lawn and garden sprays, and pet and pet bedding sprays. For the non-agricultural products, the very low amounts of active ingredient they contain, combined with the low vapor pressure (1.5 x 10–9 mm Mercury at 25° C.) and low dermal penetration, would result in minimal inhalation and dermal exposure.

D. Cumulative Effects

The potential for cumulative effects of esfenvalerate and other pyrethroid insecticides that have a common mechanism of toxicity must also be considered. While risk assessment methodology has not been developed to estimate cumulative exposure to multiple pyrethroids, their similar insecticidal efficacy results in the substitution of one pyrethroid for another, rather than addition of pyrethroids. Because of the breadth of exposures included in the assumptions for esfenvalerate risk assessment, it is unlikely that there will be significant additive exposure to other pyrethroids.

These issues are extremely complex and require an extensive evaluation of a wealth of proprietary and published data across a broad range of pyrethroid insecticides in order to provide a scientifically sound interpretation upon which to base any regulatory judgments. The Pyrethroid Working Group is currently awaiting guidance from the Agency on cumulative effects. They anticipate having some preliminary evaluation data available for the Agency by August, 1997. For any interim decisions, the Agency should take into consideration the relatively benign toxicological profiles of pyrethroid insecticides and their long history of safe use.

E. Safety Determination

Both the chronic and acute toxicological endpoints are derived from maternal NOEL's of 2.0 mg/kg/day in developmental studies in rats and rabbits. There were no fetal effects. Therefore, the safety factor used for protection of adults is fully appropriate for the protection of infants and children; no additional safety factor is necessary.

1. *U.S. population*. A chronic dietary exposure assessment using anticipated residues and assuming that 100% of all crops are treated, found the percentage of the Reference Dose (RfD) utilized by the General Population to be 16%. There is generally no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, there is a reasonable certainty that no harm will result from aggregate exposure to esfenvalerate residues.

A Tier 3 acute dietary exposure assessment found the General Population to have MOE's of 1,803 at the 95th percentile of exposure and 676 at the 99th percentile of exposure. These values were generated using actual field trial residues and market share data for percentage of crop treated. These results depict an accurate exposure pattern at an exaggerated daily dietary exposure rate. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to esfenvalerate residues.

2. *Infants and children*. The chronic dietary assessment using the same assumptions described above, found the two most sensitive sub-populations to be non-nursing infants (<1 yr.) and children (1–6 yrs.) utilizing 44% and 48% of the RfD, respectively. In the Tier 3 acute dietary assessment that was rerun using the assumptions described above, non-nursing infants were found to have an MOE of 914 at the 95th percentile of exposure and an MOE of 254 at the 99th percentile. Children (1–6 yrs.) were determined to have an MOE of 698 at the 95th percentile and 321 at the 99th percentile. Therefore, there is a reasonable certainty that no harm will result from aggregate exposure to esfenvalerate residues.

F. International Tolerances

Codex maximum residue levels (MRL's) have been established for residues of fenvalerate on a number of crops that also have U.S. tolerances. Several of these MRL's are different than the proposed U.S. tolerances for esfenvalerate. Therefore, some harmonization of these maximum residue levels is still needed.

[FR Doc. 97–24691 Filed 9–16–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

(FRL–5893–1)

Draft Report of the National Performance Measures Strategy (''Measures Strategy'')

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of the draft report of the National Performance Measures Strategy and request for comment.

SUMMARY: The Environmental Protection Agency (EPA), Office of Enforcement and Compliance Assurance (OECA) announces the availability of and requests for comment on, the Draft Report of the National Performance Measures Strategy (''Measures Strategy''). The Measures Strategy was initiated by OECA in January of 1997 ''to develop and implement an enhanced set of performance measures for EPA's enforcement and compliance assurance program.'' Since January, public meetings and roundtable sessions, consultations with experts, and reviews of studies and articles have occurred. Ideas were offered by representatives of regulated industries or companies, national and local environmental organizations, environmental justice advocates, state environmental protection agencies and associations, state Attorneys General offices, federal oversight and management agencies, federal regulatory and law enforcement agencies, environmental policy institutes, Congressional staff, academic experts, DOJ representatives, and EPA regional and headquarters managers and staff. EPA has reviewed the ideas and suggestions that have been offered from these sources, and from that review a proposed set of performance measures has been developed.

The report describes the need for enhanced measures, key ideas from interested parties, general findings about performance measurement, a proposed measurement framework, and a set of performance measures and possible implementation steps. Stakeholders are invited and encouraged to offer comment on the draft report through written submission. EPA will review these comments, revise the report and the proposed measures (if necessary), and distribute a final report by the end of October with the performance measures OECA intends to implement. In some cases, EPA may initiate further steps to study alternative measures that require more analysis or