would be significantly lower if anticipated residues were utilized rather than tolerance values. Therefore, AgrEvo concludes that there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to propamocarb residues.

I. International Tolerances

The Codex Alimentarius Commission (Codex) has established tolerances (MRLs) for propamocarb in the following raw agricultural commodities:

Commodity	Part per million
Beetroot	0.2 ppm
Brussels sprouts	1.0 ppm
Cabbage, head	0.1 ppm
Celery	0.2 ppm
Cucumber	2.0 ppm
Cauliflower	0.2 ppm
Lettuce, head	10.0 ppm
Pepper, sweet	1.0 ppm
Radish	5.0 ppm
Strawberry	0.1 ppm
Tomato	1.0 ppm

The FAO/WHO/JMPR have recommended an Acceptable Daily Intake (ADI) of 0.1 mg/kg/day.

J. Conclusions

AgrEvo USA believes that the proposed use of propamacarb on potatoes would not pose a significant risk to human health, including that of infants and children, and is in compliance with the requirements of the Food Quality Protection Act of 1996. Moreover, the proposed tolerances for propamocarb in potato commodities, meat and milk, of 0.05 ppm, should be established.

II. Public Record

Interested persons are invited to submit comments on this notice of filing. Comments must bear a notation indicating the docket control number, [PF–716]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8:30 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice under docket control number [PF–716] 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 public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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

Electronic comments must be submitted as ASCII file avoiding the use of special characters and any form of encryption.

The official record for this notice, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Authority: 21 U.S.C. 346a.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping.

Dated: February 26, 1997.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–5681 Filed 3–11–97; 8:45 am]
BILLING CODE 6560–50–F

[PF–712; FRL–5587–7]

The Cryolite Task Force; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing regulations establishing tolerances for residues of the insecticidal fluorine compounds cryolite and/or synthetic cryolite (sodium aluminum fluoride or sodium aluminofluoride) in or on potatoes and in processed potato waste. This notice includes a summary of the petition that was prepared by the petitioner, The Cryolite Task Force.

DATES: Comments, identified by the docket control number [PF-712] must be received on or before April 11, 1997.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide 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 22202.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted either in ASCII format (avoiding the use of special characters and any form of encryption) or in WordPerfect in 5.1 file format. All comments and data in electronic form must be identified by the docket control number [PF-712]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. The official record for this rulemaking, as well as the public version described above, will be kept in paper form. Additional information on electronic submissions can be found in Unit II. of this document.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information so marked will not be

disclosed except in accordance with procedures set forth in 40 CFR part 2. No CBI should be submitted through e-mail. 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.

FOR FURTHER INFORMATION CONTACT: William Jacobs, Acting, Product Manager 14, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 219, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. (703) 305-6600; e-mail: jacobs.william@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition from The Cryolite Task Force c/o Gowan, P.O. Box 5568, Yuma, AZ 85366. The petition proposes, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend 40 CFR 180.145 to renew the regulations that established tolerances for the insecticidal fluorine compounds cryolite and/or synthetic cryolite in or on potatoes at 2.0 parts per million (ppm) and processed potato waste at 22 ppm.

EPA has determined that the 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.

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act (FQPA) (Pub. L. 104-170), The Cryolite Task Force included in the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of The Cryolite Task Force; EPA is in the process of evaluating the petition. As required by section 408(d)(3), EPA is including the summary as a part of this notice of filing. EPA may have made minor edits to the summary for purposes of clarity.

I. The Cryolite Task Force's Petition Summary

This petition is submitted by the Cryolite Task Force (Consortium No. 62569), under section 408 of the FFDCA, as most recently amended by the FQPA.

This submission amends petitions PP 9F3739 and FAP 1H5604 by providing the additional information specified by the FQPA. A permanent tolerance is proposed for residues of the insecticide sodium aluminofluoride (cryolite and/or synthetic cryolite) in or on the raw agricultural commodities (RAC) potatoes, as provided by the new FFDCA section 408. In addition, the petitioner proposes that EPA establish a permanent tolerance for residues of cryolite in processed potato waste, as provided under the new FFDCA section 408.

Time-limited tolerances for residues of sodium aluminofluoride (cryolite and/or synthetic cryolite) in/on potatoes and processed potato waste were initially granted on May 5, 1993. These tolerances expired on May 6, 1996. A time limitation was required initially for these regulations because a chronic dog feeding study and a two-generation rat reproduction study were outstanding. These two studies were submitted and were found acceptable in reviews dated April 13, 1994 (chronic dog) and February 24, 1995 (rat reproduction). In the Federal Register of May 8, 1996 (61 FR 20781) (FRL–5362–6), EPA proposed establishing permanent tolerances of 2 ppm and 22 ppm for residues of cryolite in/on potatoes and processed potato waste, respectively. A 30–day comment period was specified by the Agency for these proposed regulations. However, prior to publication of final regulations, the FQPA specified additional requirements for tolerance petitions. This submission amends PP 9F3739 and FAP 1H5604 by providing the additional information specified.

A. Residue Data

1. *Name, identity, and composition of the residue.* Cryolite (sodium aluminofluoride, sodium hexafluoroaluminate or sodium aluminum fluoride) is a fluorine-containing insecticide which is found in naturally occurring mineral deposits and also is produced synthetically.

Empirical Formula: Na3AlF6

Molecular Weight: 209.97

CAS Registry No.: 15096-52-3

OPP Chemical Code: 075101

A Reregistration Eligibility Decision (RED) was issued for cryolite in August 1996. As documented in the May 8, 1996 Federal Register and reiterated in the RED, the Agency has determined that plant residues are inorganic surface residues of cryolite, measured as total fluoride; and that the residue of concern in animals also is total fluoride.

Provisions in the FQPA which are relevant to degradates or metabolites of pesticide chemical residues are not applicable to elemental fluorine.

2. *Magnitude of the residue in plants.* As documented in the May 8, 1996 Federal Register and reiterated in the RED, the Agency has concluded that complete and acceptable crop residue data are available to support the proposed tolerance of 2 ppm in or on potatoes.

Data previously reviewed by EPA show background levels of fluoride in untreated potatoes ranging from 0.14 ppm to 0.31 ppm. Levels of fluoride found in treated potatoes ranged from 0.18 ppm to 0.94 ppm.

3. *Magnitude of the residue in processed food/feed.* As documented in the May 8, 1996 Federal Register and reiterated in the RED, EPA has concluded that an acceptable potato processing study supports the proposed tolerance of 22 ppm in or on processed potato waste. This study indicates that cryolite residues concentrated 11x in potato peels/potato waste processed from potatoes treated at a 6.7x exaggerated rate. Residues did not concentrate in potato chips, flakes, or granules.

4. *Directions for use.* Labeling has been approved for foliar application to potatoes at up to 11.5 lbs. active ingredient (a.i.) per acre, with a maximum seasonal application of 92 lbs. a.i. per acre.

5. *Analytical method.* EPA concluded in the May 8, 1996 Federal Register and reiterated in the cryolite RED that adequate methodology is available for data collection and tolerance enforcement. Methods for both plant residues and animal tissues have undergone successful Agency validation and will be published in PAM, Vol. II. Using these methods, total fluoride is determined using a pH/ion meter with a fluoride-specific electrode. The limit of quantitation is 0.05 ppm. The residue analytical method does not distinguish between naturally occurring fluoride and fluoride resulting from agricultural use of cryolite. Current FDA multi-residue screening protocols are not appropriate for inorganic fluoride residues.

6. *Practical methods for removing residues.* Plant residues are inorganic surface residues of cryolite. Data previously submitted in FAP 1H5604 show that washing and peeling are effective methods of removing these residues.

7. *Plant metabolism.* EPA concluded in the May 8, 1996 Federal Register and reiterated in the cryolite RED that the qualitative nature of the residue in plants is understood and that plant residues are inorganic surface residues

of cryolite which are measured as fluoride.

8. *Animal metabolism*. EPA concluded in the May 8, 1996 Federal Register and reiterated in the cryolite RED that cryolite metabolism in animals manifests itself as free fluoride, that the qualitative nature of the residue is understood and that total fluoride is the residue of concern.

9. *Magnitude of the residue in meat, milk, poultry and eggs*. EPA concluded in the May 8, 1996 Federal Register and reiterated in the cryolite RED that there is no reasonable expectation of finite fluoride residues in ruminant or poultry tissues as a result of livestock ingestion of cryolite.

B. Toxicological Data

The cryolite RED concluded that the toxicological data base was adequate for a reregistration eligibility decision for numerous crop uses, including potatoes. No additional toxicology requirements were specified in the RED. The cryolite residue of toxicological concern is fluoride; and health effects identified for fluoride in humans and animals are skeletal and dental fluorosis. Dental fluorosis (mottling of tooth enamel) is not considered to be an adverse effect.

Further, the Agency has determined that although fluoride accumulation is demonstrated in a number of studies, the accumulation itself is not considered an adverse effect.

1. *Acute toxicity*. A rat acute oral toxicity study (MRID 00138096) showed an LD_{50} greater than 5,000 milligrams/kilograms (mg/kg). A rabbit acute dermal toxicity study (MRID 00128107) demonstrated an LD_{50} of 2,100 mg/kg. An LC_{50} > 2.06 mg/L and < 5.03 mg/L was seen in an acute inhalation study with rats (MRID 00128107). Technical cryolite is a moderate eye irritant in rabbits (MRID 00128106). Cryolite is not a skin irritant to rabbits (MRID 00128106) and is not a dermal sensitizer to guinea pigs (MRID 00138097).

2. *Subchronic toxicity*. Cryolite was tested in a 28-day range-finding feeding study in rats (MRID 00128109) at dose levels of 0, 250, 500, 1,000, 2,000, 4,000, 10,000, 25,000, and 50,000 ppm in the diet (representing approximately 0, 25, 50, 100, 200, 400, 1,000, 2,500 and 5,000 mg/kg/day). The only compound related effect seen in this study was a change in coloration and physical property of the teeth. A no observed effect level (NOEL) was not determined in this study. The lowest observed effect level (LOEL) is 250 ppm (25 mg/kg/day) based on dental fluorosis.

In a 90–day rat feeding study (MRID 00158000), cryolite was tested at dose levels of 0, 50, 5,000, and 50,000 ppm (corresponding to 0, 3.8, 399.2, and 4,172.3 mg/kg/day in males and 0, 4.5, 455.9, and 4,758.1 mg/kg/day in females). The NOEL was 50 ppm (3.8 mg/kg/day) for effects other than fluoride accumulation. The LOEL was 5,000 ppm (399.2 mg/kg/day) based on lesions observed in the stomach. Fluoride accumulated at all dose levels in this study. Cryolite was tested in a 90–day dog feeding study (MRID 00157999) at dose levels of 0, 500, 10,000, and 50,000 ppm (corresponding to 0, 17,368, and 1,692 mg/kg/day). The NOEL was 10,000 ppm (368 mg/kg/day). The LOEL was 50,000 ppm (1,692 mg/kg/day) for effects other than fluoride accumulation. Fluoride accumulation occurred at all dose levels.

A 21–day subchronic dermal toxicity study in rabbits (MRID 41224801) is considered invalid because it is likely that cryolite was ingested by the test animals during the study. For this reason, the systemic dermal NOEL and LOEL could not be determined from this study. EPA noted in the RED that an additional subchronic dermal study is not necessary, because based on its chemical/physical properties, cryolite would not be absorbed through the skin to any appreciable extent.

3. *Genotoxicity*. Cryolite was negative in an Ames reverse mutation test (MRID 41838401) using *Salmonella typhimurium* with and without activation at dose levels of 167, 500, 1,670, 5,000, 7,500, and 10,000 µg/plate. Cryolite was tested in an *in vitro* chromosome aberration assay (MRID 41838402) using human lymphocytes at 100, 500, and 1,000 µg/ml, with and without activation. The results were negative. Cryolite also was negative in an unscheduled DNA synthesis study (MRID 41838403) with rat hepatocytes at dose levels up to and including 50 µg/ml.

4. *Chronic toxicity*. The Agency concluded in the May 8, 1996 Federal Register and reiterated in the cryolite RED that the available information does not support the regulation of cryolite insecticides as carcinogens. The Agency has classified cryolite as a Group D chemical (not classifiable as to human carcinogenicity. Further, EPA has noted that fluoride has been the subject of a comprehensive review by the National Research Council (National Academy of Sciences Subcommittee of Health Effects of Ingested Fluoride) who concluded that ''. . .the available laboratory data are insufficient to demonstrate a carcinogenic effect of fluoride in animals'' and that ''. . .the weight of evidence from more that 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans.'' As stated in the May 8, 1996 Federal Register and reiterated in the cryolite RED, the Agency is in agreement with the conclusions reached by the National Academy of Science (NAS).

The following specific chronic/oncogenicity studies are included in the cryolite toxicology data base:

A 2–year bioassay in B6C3F1 mice (HED DOC No. 009682) was conducted by the National Toxicology Program (NTP) using sodium fluoride as the test material at dose levels of 0, 25, 100, and 175 ppm, in water, representing 0, 2.4, 9.6, and 16.7 mg/kg/day in males and 0, 2.8, 11.3, and 18.8 mg/kg/day in females. The NOEL was less than 25 ppm (2.4 mg/kg/day). The LOEL was 25 ppm (2.4 mg/kg/day) based on attrition of the teeth in males, discoloration and mottling of the teeth in males and females, and increased bone fluoride in both sexes. NTP considered that there was no evidence of carcinogenic activity in male and female mice.

A 2–year bioassay in F344/N rats (HED DOC No. 009682) also was conducted by the NTP using sodium fluoride as the test material at dose levels of 0, 25, 47, 100, and 175 ppm, in water, representing 0, 1.3, 5.2, and 8.6 mg/kg/day in males and 0, 1.3, 5.5, and 9.5 mg/kg/day in females. Osteosarcoma of the bone was observed only in 1 male of 50 (1/50) in the 100 ppm group and in 3 of 80 (3/80) males in the 175 ppm group. The NOEL was less than 25 ppm (1.3 mg/kg/day). The LOEL was 25 ppm (1.3 mg/kg/day) based on mottling of teeth, dentine incisor dysplasia, increased serum, urine and bone fluoride levels in males and females and incisor odontoblast and incisor ameloblast degeneration in males. NTP considered that there was ''equivocal evidence'' of carcinogenic activity in male rats in this study and ''no evidence'' of carcinogenic activity in female rats.

EPA concluded in the May 8, 1996 Federal Register and reiterated in the cryolite RED that the NTP studies utilizing sodium fluoride in lieu of cryolite satisfy the guideline study requirements for both the rodent chronic feeding study and the rat carcinogenicity study. Fluoride has been identified as the residue of toxicological concern in cryolite and synthetic cryolite and these compounds act as free fluoride. It should be noted that the NTP studies, which utilized freely soluble NaF represent a worst-case toxicological scenario on a ppm basis compared to what would be expected with cryolite *per se*, from which fluoride ion dissociation is much more limited.

A 1-year chronic dog feeding study (MRID 42575101) was conducted with cryolite at dose levels of 0, 3,000, 10,000, and 30,000 ppm, representing 0, 95, 366, and 1,137 mg/kg/day in males and 0, 105, 387, and 1,139 mg/kg/day in females (in terms of fluoride, the doses are 0, 51, 198, and 614 mg F/kg/day for males and 0, 57, 209, and 615 mg F/kg/day for females). The NOEL was less than 3,000 ppm (95 mg/kg/day in males and 105 mg/kg/day in females). The LOEL was 3,000 ppm based on increases in emesis, nucleated cells in males, renal lesions, and a decrease in urine-specific gravity in females.

5. *Reproductive toxicity.* A two-generation rat reproduction study (MRID 43387501) was conducted with cryolite at dietary dose levels of 0, 200, 600, and 1,800 ppm (representing 0, 14, 42, and 128 mg/kg/day for males and 0, 16, 49, and 149 mg/kg/day for females, respectively, during premating). The systemic toxicity NOEL was not determined. The LOEL for systemic toxicity was 200 ppm (15 mg/kg/day) based on dental fluorosis. The NOEL and LOEL for reproductive toxicity were 600 and 1,800 ppm, respectively (46 and 138 mg/kg/day) based on decreased pup body weights.

The National Research Council (NRC) has reviewed the potential for reproductive effects from fluoride *per se*. In the report Health Effects of Ingested Fluoride, the NRC concluded that:

> There have been reports of adverse effects on reproductive outcomes associated with high levels of fluoride in many animal species. In most of the studies, however, the fluoride concentrations associated with adverse effects were far higher than those encountered in drinking water. The apparent threshold concentration for inducing reproductive effects was 100 mg/L in mice, rats, foxes and cattle; 100-200 mg/L in minks, owls and kestrels; and over 500 mg/L in hens. Based on these findings, the subcommittee concludes that the fluoride concentrations associated with adverse reproductive effects in animals are far higher than those to which human populations are exposed. Consequently, ingestion of fluoride at current concentrations should have no adverse effects on human reproduction.

6. *Developmental toxicity.* A developmental toxicity study was performed with cryolite in rats (MRID 00128112) at dose levels of 0, 750, 1,500, and 3,000 mg/kg/day (gavage). The NOEL for both developmental and maternal toxicity was 3,000 mg/kg/day. At this dose level, the only observation was whitening of the teeth of dams. A developmental toxicity study was conducted in female mice (MRID 42297902) with cryolite at dose levels of 0, 30, 100, and 300 mg/kg/day (gavage). The NOEL for maternal toxicity was 30 mg/kg/day and the LOEL was 100 mg/kg/day based on a single mortality in this group. Fetuses at 300 mg/kg/day exhibited bent ribs and bent limb bones. The NOEL for developmental toxicity was 100 mg/kg/day. The LOEL was 300 mg/kg/day based on an increase in bent ribs and bent limbs. A range-finding developmental toxicity study in female rabbits (MRID 42297901) tested cryolite at dose levels of 0, 10, 30, 100, 300, and 1,000 mg/kg/day (gavage). The NOEL for maternal toxicity was determined to be 10 mg/kg/day and the LOEL was 30 mg/kg/day based on an increased incidence of soft stool and dark colored feces and decreased defecation and urination. The NOEL for developmental toxicity was 30 mg/kg/day. The developmental LOEL could not be assessed due to excessive maternal toxicity at dose levels of > 30 mg/kg/day.

7. *Metabolism/metabolite toxicity.* As noted in the May 8, 1996 Federal Register and reiterated in the RED, cryolite behaves toxicologically as free fluoride. That is, dissociation produces free fluoride ions which are assimilated into bone. There are numerous references in the open literature concerning the metabolism of cryolite and other fluoride salts. The National Research Council concluded in their 1993 comprehensive report entitled ''Health Effects of Ingested Fluoride'' that fluoride is readily absorbed by the gut and rapidly becomes associated with teeth and bones. The remaining fluoride is eliminated almost exclusively by the kidneys with the rate of renal clearance related directly to urinary pH.

8. *Endocrine effects.* The two-generation rat reproduction study, the rat, rabbit and mouse developmental studies and the dog chronic studies summarized above did not demonstrate any effects with cryolite that are similar to those produced by naturally occurring estrogens, or other endocrine effects. No endocrine effects were determined in the rat and mouse NTP studies.

In addition, it should be noted that national and international regulatory organizations (U.S. EPA Office of Water, U.S. DHHS, the Canadian Government, and the World Health Organization) have assessed potential health risks from exposure to fluoride. EPA has concluded that the endpoints and estimated effect levels documented by these organizations are similar and that the health effects of fluoride in animals and humans include dental and skeletal fluorosis. Endocrine effects have not been recognized as toxicological endpoints for fluoride by any worldwide regulatory authority.

C. Aggregate Exposure

1. *Dietary exposure-food.* As noted in the May 8, 1996 Federal Register and reiterated in the RED, the Agency has estimated dietary exposure to cryolite using reassessed tolerances for all crops (including the proposed tolerances for potatoes) and percent of crop treated assumptions. In the RED, EPA estimated dietary exposure to cryolite from all crops to be approximately 0.020 mg/kg/day for the U.S. population, 0.024 mg/kg/day for children 1-6, 0.015 mg/kg/day for children 7-12, and 0.028 mg/kg/day for nursing females 13+ years. For the highest exposed subgroup (females 20 years old and over), the Agency estimated exposure of 0.038 mg/kg/day (61 FR 20781). The Agency estimated dietary exposure resulting from the specific use of cryolite on potatoes to be approximately 0.00016 mg/kg/day. The Task Force believes that these exposure estimates in fact overstate actual dietary exposure since cryolite tolerance levels, rather than residues actually present at the consumer level were used by EPA in the exposure assessments.

2. *Dietary exposure- drinking water.* In the Environmental Fate Assessment conducted for the RED, the Agency concluded that the use of cryolite should have negligible impacts on fluoride levels in ground and surface water. For this reason, the contribution of cryolite to potential exposure to fluoride from drinking water need not be considered in the aggregate risk assessment.

However, fluoride is intentionally supplemented to drinking water for prevention of dental caries and may also be present at natural background levels. The U.S. Public Health Service recommends an optimal fluoride concentration of 0.7 to 1.2 mg/L to prevent dental caries and minimize dental fluorosis.

Fluoride levels in public drinking water are regulated under the Safe Drinking Water Act. A Maximum Concentration Limit (MCL) of 4.0 mg/L (0.114 mg/kg/day) has been established. EPA has previously estimated that levels of fluoride in/on food from the agricultural use of cryolite plus fluoride levels in U.S. drinking water supplies results in a daily dietary intake of fluoride of approximately 0.095 mg/kg/day. This is substantially less than the Maximum Concentration Limit (MCL) of 4.0 mg/L (0.144 mg/kg/day), a level which provides no known or anticipated adverse health effect as determined by the Surgeon General.

As noted in the May 8, 1996 Federal Register and reiterated in the RED, the Agency has concurred with the findings

of the Surgeon General that adverse health effects have not been found in the U. S. population below 8 mg F/L (0.23 mg/kg/day).

3. *Non-dietary exposure*. Cryolite is used almost exclusively as an agricultural crop protection insecticide. Conceivably, cryolite also could be used in outdoor homeowner/residential sites for insect control in ornamentals and shade trees. Cryolite is not registered for either lawn or crack and crevice treatments. EPA concluded in the RED that a post-application exposure assessment for cryolite (including both occupational and residential exposure) was not appropriate since no toxicological endpoints relevant to non-dietary exposure have been identified for cryolite. The Task Force concludes that non-dietary exposure represents a negligible component of potential aggregate exposure to cryolite and need not be considered in the aggregate risk assessment.

D. Cumulative Effects

The residue of toxicological concern in cryolite is fluoride. Although fluoride supplements in drinking water are not considered to be pesticidal substances, the dietary contribution of drinking water to overall fluoride exposure has been discussed elsewhere in this summary. Current tolerances for insecticidal fluorine-containing compounds are limited to cryolite and synthetic cryolite. For this reason, consideration of potential cumulative effects of residues from pesticidal substances other than sodium aluminofluoride with a common mechanism of toxicity are not applicable.

E. Safety Determination

1. *U.S. population*. As discussed above, non-dietary exposure to cryolite is negligible. For dietary exposure, EPA has concluded that rather than establishing a traditional Reference Dose (RfD), a weight-of-the-evidence risk assessment is a more appropriate approach for cryolite. The toxicological endpoint of concern for dietary exposure to cryolite is skeletal fluorosis. EPA has approximated that total dietary fluoride levels in food plus drinking water is 0.095 mg/kg/day. Of this total exposure, the dietary (food) contribution is about 0.020 mg/kg/day for the U.S. population, and 0.038 mg/kg/day for the highest exposed subgroup (females 20 years old and over). The proposed potato tolerances have been estimated by EPA to contribute approximately 0.00016 mg/kg/day to total dietary exposure. These exposure estimates likely overstate actual dietary exposure, since marketbasket residue levels for cryolite have not been considered. As noted above, the Agency has concurred with the findings of the Surgeon General that adverse health effects (skeletal fluorosis) have not been found in the U.S. population below 8 mg F/L (0.23 mg/kg/day).

2. *Infants and children*. EPA has concluded previously that in rats, the developmental NOEL for cryolite is 3,000 mg/kg/day (1,584 mg/kg/day F), that in mice, the developmental NOEL is 100 mg/kg/day (52.8 mg/kg/day F), and that in rabbits, the developmental NOEL is 30 mg/kg/day (15.8 mg/kg/day F). The NOEL for reproductive toxicity of cryolite determined in a 2-generation rat reproduction study was determined by the Agency to be 46 mg/kg/day (24.3 mg/kg/day F).

These data show clearly that no additional margin of safety is required for exposure of infants and children to cryolite. The developmental NOEL ranges from more than 166x (rabbit) to more than 16,000x (rat) for the maximum combined exposure of infants and children to residues of fluoride from all agricultural uses of cryolite plus drinking water. The reproductive NOEL is about 256x greater than maximum combined exposure of infants and children to residues of fluoride.

F. International Tolerances

No Codex, EC or other international tolerances are in effect for cryolite; thus, potential dietary exposure to fluoride from the agricultural use of cryolite on crops would not include imported foodstuffs.

II. Public Record

A record has been established for this notice under docket control number [PF–712] (including comments and data submitted electronically as described below). A public version of the 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 public record is located in Room 1132 of the Public Response and Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 24, 1997.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97–6015 Filed 3–11–97; 8:45 am]

BILLING CODE 6560–50–F

[PF–715; FRL–5589–6]

Zeneca Ag Products; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the initial filing of three pesticide petitions proposing the establishment of tolerances for residues of azoxystrobin (not accepted by ANSI) in or on raw agricultural commodities of grape (pesticide petition (PP) 5F4541), pecan (PP 6F4642), and tomato, peach, banana, peanut, and wheat (PP 6F4762). This notice includes a summary of the petitions that was prepared by the petitioner, Zeneca Ag Products.

DATES: Comments, identified by the docket control number [PF–715], must be received on or before, April 11, 1997.

ADDRESSES: By mail, submit written comments to Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. S.W., Washington, DC 20460. In person, bring comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: 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.