Commodity	Parts per million	Expiration/Revocation Date
Sheep, liver	7	9/30/98
Sheep, kidney	32	9/30/98
Sheep, meat	2.5	9/30/98

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

PART 185—[Amended]

2. In part 185:

i. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 348.

§ 185.3900 [Removed]

ii. Section 185.3900 is removed.

[FR Doc. 97–31553 Filed 12–4–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300586; FRL–5756–5]

RIN 2070–AB78

Fluorine Compounds; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the insecticidal fluorine compounds cryolite and/or synthetic cryolite (sodium aluminum fluoride) in or on the raw agricultural commodity (RAC) potatoes and in the processed animal feed commodity, potato waste. A petition requesting these tolerances was submitted by The Cryolite Task Force under the Federal Food Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170). The tolerance will expire on November 21, 2001.

DATES: This regulation is effective December 5, 1997. Objections and requests for hearings must be received by EPA on or before February 3, 1998.

ADDRESSES: Written objections and hearing requests, identified by the document control number, OPP–300586, must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the document control number, [OPP–300586], must be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: OPP-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300586]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Jacqueline Mosby, Environmental Scientist, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-6792, e-mail: mosby-romney.jackie2epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued notices as follows regarding petitions for pesticide tolerances for insecticidal fluorine compounds in or on potatoes and in the processed animal feed, potato waste.

1. March 23, 1989 (54 FR 12009); PP 9F3739; filing notice;

2. April 3, 1991 (56 FR 13643); PP 1F3959 and FAP 1H5604; filing notice.

3. May 5, 1993 (58 FR 26687); PP 9F3739 and FAP 1H5604; final rule for time-limited tolerances.

4. May 8, 1996 (61 FR 20781) (FRL–5362–6); PP 9F3739 and FAP 1H5604); proposed rule for permanent tolerances.

The Agency did not publish a final rule establishing permanent tolerances prior to the enactment of the Food Quality and Protection Act (FQPA) of 1996. Because of new procedures under FQPA, The Cryolite Task Force, c/o Gowan Company, P.O. Box 5569, Yuma, AZ 85336 was required to submit a notice of filing requesting issuance of these tolerances in compliance with FQPA.

In the **Federal Register** of March 12, 1997 (62 FR 11437) EPA issued a notice of filing pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) for tolerance by The Cryolite Task Force. This notice contained a summary of the petition prepared by The Cryolite Task Force.

The petition requested that 40 CFR 180.145 be amended by establishing tolerances for residues of the insecticidal fluorine compounds cryolite and synthetic cryolite in or on potatoes at 2.0 parts per million (ppm) and processed potato waste at 22.0 ppm. These tolerances will expire on November 21, 2001.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical

residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all 3 sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established

tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of cryolite and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of cryolite on potatoes at 2.0 ppm, and processed potato waste at 22.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by cryolite are discussed below.

1. *Acute toxicity studies*. Oral, dermal, and inhalation studies place cryolite in toxicity category III, for acute dermal and in category IV for acute oral, and inhalation. No effects are observed in a skin irritation study, the eye irritation study shows it to be a moderate irritant to the eyes; and results of the dermal sensitization study shows it to be a non-sensitizer.

2. *Subchronic toxicity studies*. i. A 28-day range-finding feeding study conducted with cryolite in rats 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 milligrams/kilograms/day) (mg/kg/day) with the only compound related effect being a change in coloration and physical property of the teeth.

The NOEL was not determined. The LOEL is 250 ppm (25 mg/kg/day) based on dental fluorosis.

ii. A 90-day rat feeding study conducted with cryolite at dose levels of 0, 50, 5,000, and 50,000 ppm (corresponding to 0, 3.8, 399.2 and 4172.3 mg/kg/day in males and 0, 4.5, 455.9 and 4758.1 mg/kg/day in females).

The NOEL is 50 ppm (3.8 mg/kg/day) for effects other than fluoride accumulation. The LOEL is 5,000 ppm (399.2 mg/kg/day) based on lesions observed in the stomach. Fluoride accumulated at all dose levels.

iii. A 90-day dog feeding study conducted with cryolite at dose levels of 0, 500, 10,000, and 50,000 ppm (corresponding to 0, 17, 368 and 1692 mg/kg/day).

The NOEL is 10,000 ppm (368 mg/kg/day). The LOEL is 50,000 ppm (1,692 mg/kg/day) for effects other than fluoride accumulation. Fluoride accumulation occurred at all dose levels.

3. *Chronic/carcinogenicity studies*. i. A 2-year rat bioassay 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, 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 only observed in one male in the 100 ppm group and in three males in the 175 ppm group. NTP considers this to be equivocal evidence of carcinogenicity in male F344/N rats. The NOEL is less than 25 ppm (1.3 mg/kg/day). The LOEL is 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. There was ''equivocal evidence'' of carcinogenic activity in male rats and ''no evidence'' of carcinogenic activity in female rats.

The NTP study utilizing sodium fluoride as the test material in lieu of cryolite or synthetic cryolite satisfies the guideline study requirement 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 the available data show that these compounds act as free fluoride.

ii. A 2-year mouse bioassay conducted by the NTP utilizing 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 is less than 25 ppm (2.4 mg/kg/day). The LOEL is 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. There was ''no evidence'' of carcinogenic activity in male and female mice.

This study utilizing sodium fluoride in lieu of cryolite or synthetic cryolite as the test material satisfies the guideline study requirement for a mouse carcinogenicity study for the reason described above under item 3.i.

iii. A 1-year chronic dog feeding study 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 (in terms of Cryolite) is less than 3,000 ppm (95 mg/kg/day in males and 105 mg/kg/day in females). The LOEL is 3,000 ppm (95 mg/kg/day) based on increases in emesis, nucleated cells in males, renal lesions and a decrease in urine specific gravity in females.

4. *Other studies/documents*. i. Mutagenicity studies including an Ames test (negative) at dose levels of 167, 500, 1670, 5,000, 7,500 and 10,000 ug/plate; an *in vitro* assay in human lymphocytes (negative) at 100, 500, and 1,000 μg/ml; and an unscheduled DNA synthesis study in rat hepatocytes (negative) at dose levels up to and including 50 μg/ml.

ii. Drinking water Criteria Document on Fluoride. Fluoride has been identified as the residue of toxicological concern in cryolite and synthetic cryolite and the available data show that these compounds which are approximately 52.8% fluoride, act as free fluoride.

The EPA Office of Drinking Water issued a Drinking Water Criteria Document on Fluoride (October 21, 1985) which presents summaries of experimental and clinical data on the health effects of fluoride in animals and humans. In general, the health effects of fluoride (F) include dental fluorosis and skeletal fluorosis.

B. Toxicological Endpoints

1. *Acute toxicity*. Based on the available toxicity data, EPA has determined that cryolite does not exhibit any adverse health effects occurring as a result of a one day or single dietary or non-dietary exposure.

2. *Short and intermediate-term toxicity*. Based on the available data, EPA has determined that cryolite does not exhibit any adverse heath effects occurring as a result of short- or intermediate-term dietary and non-dietary exposure.

3. *Chronic toxicity*. Rather than the establishment of the traditional Reference Dose (RfD), a weight-of-the-evidence risk assessment was determined by the Agency to be a more appropriate approach for the assessment of the dietary exposure to fluoride residues as a result of agricultural uses of cryolite for the following reasons:

i. 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. The endpoints and estimated effect levels documented by these organizations are similar.

ii. The U.S. Surgeon General (Koop, 1984 and Elders, 1994) has recommended a guideline level of exposure that should provide an adequate ''margin of safety'' based on a large amount of human data, including epidemiology studies.

iii. Animal data considered in evaluating the proposed regulations are consistent with human data with respect to dose related skeletal effects.

4. *Carcinogenicity*. 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 than 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans.'' EPA is in agreement with the conclusions reached by the National Academy of Science (NAS).

The available information does not support the regulation of cryolite as a carcinogen and it has been classified as a Group D chemical (not classifiable as to human carcinogenicity).

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.145) for the residues of cryolite In or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from cryolite as follows:

i. *Acute exposure and risk*. Based on the available acute toxicity data, EPA has determined that cryolite does not pose any acute dietary risk.

ii. *Chronic exposure and risk*. The weight-of-the-evidence dietary risk assessment was conducted utilizing the following factors. All calculations are based on 2 L/day water consumption and 70 kg adult.

a. There exists no directly applicable scientific documentation of adverse medical effects at levels of fluoride below 8 mg/L 0.23 mg/kg/day. (U.S. EPA. 1985. National Primary Drinking Water Regulations; Fluoride. Proposed Rulemaking. May 14, 1985, 50 FR 20166).

b. Less than 0.4% of the U.S. population (on public water supplies) is exposed to greater than 2 mg/L fluoride 0.057 mg/kg/day in the public water supply. (U.S. EPA. 1985. drinking Water Criteria Document on fluoride. U.S. EPA Office of Drinking Water, Washington, DC TR-832-5. pg. IV-3, Table IV-1.)

The dietary exposure estimates used reassessed tolerances and percent of crop treated. These exposure estimates are conservative since average residues were not calculated and monitoring data were not used to refine residue estimates.

Section 408(b)(2)(F) allows the Agency to use data n the actual percent of crop treated when establishing a tolerance only where the Agency can make the following findings:

(a) That data used are reliable and provided a valid basis for showing the percentage of food derived from a crop that is likely contain residues.

(b) That the exposure estimate does not underestimate the exposure for any significant subpopulation.

(c) Where data on regional pesticide use and food consumption are available, that the exposure estimate does not understate exposure for any regional population. In addition, the Agency must provide for periodic evaluation of any estimates used.

Percent of crop treated estimates are derived from federal and market survey data. EPA considers these data reliable. Typically a range of estimates are supplied and the upper end of this range is used for the exposure assessment. By using this upper end estimate of percent crop treated, EPA is reasonably certain that exposure is not underestimated for any significant subpopulation. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Review of this regional data allows EPA to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by EPA. EPA has made these findings when appropriate with respect to the proposed tolerance. EPA has not provided for periodic reevaluation of the data on percent crop treated because this tolerance has a time-limitation.

2. *From drinking water*— i. *Acute exposure and risk*. Based on the available acute toxicity data, EPA has determined that fluoride does not pose any acute dietary risk.

ii. *Chronic exposure and risk*. Fluoride levels in public drinking water are regulated under the Safe Drinking Water Act. EPA has established a Maximum Concentration Limit (MCL) at 4.0 mg/L 0.114 mg/kg/day to protect against crippling skeletal fluorosis (April 2, 1986) (51 FR 11396). The MCL established on April 2, 1986 finalizes interim regulations set in the **Federal Register** of November 14, 1985 (50 FR 47142), and proposed in the **Federal Register** of May 14, 1985 (50 FR 20164). In addition, these **Federal Register** notices established a Secondary Maximum Contaminant Level (SMCL) at 2.0 mg/L 0.057 mg/kg/day for cosmetic effects (objectionable dental fluorosis) which are not considered to be adverse health effects by the Surgeon General.

As described above, less than 0.4% of the U.S. population (on public water supplies) is exposed to greater than 2 mg/L fluoride 0.057 mg/kg/day in the public water supply.

3. *From non-dietary exposure.* Cryolite is registered for use on ornamentals, a use which could result in residential, non-occupational exposure. It is not registered for indoor use. EPA has not estimated non-dietary or residential exposure from registered ornamental uses of cryolite because

i. There are no toxicological endpoints identified for cryolite.

ii. Fluoride occurs naturally in the environmental background and there would not be significant exposure to fluoride from the use of cryolite.

iii. It would not be appropriate since the available information regarding solubility and degradation indicates that there would likely be no appreciable dermal absorption. The Agency does not anticipate significant non-dietary exposure from the use of cryolite.

4. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of

toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether cryolite has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cryolite does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cryolite has a common mechanism of toxicity with other substances. For the purpose of this time-limited tolerance, the Agency has considered risks from cryolite and from fluoride in intentionally fluoridated water.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* Based on the available acute toxicity data, EPA has determined that cryolite does not pose any acute dietary risk.

2. *Chronic risk.* Fluoride is ubiquitous and may be present at low levels in air, soils and in foodstuffs that have not been treated with cryolite and/or synthetic cryolite as well as in drinking water. The atmospheric levels of fluoride and incidental dietary exposures to fluoride as a toothpaste additive or as a dental treatment contribute relatively little to the average level of dietary fluoride exposure and are not further considered in the exposure estimate.

Dietary exposure estimates using reassessed tolerance/including the subject tolerance for potatoes (which is estimated as approximately 0.00016 mg/kg/day) and percent of crops treated are approximately 0.020 mg/kg/day for the U.S. population and 0.028 mg/kg/day for the highest exposed subgroup (females 13 years old and over, nursing). These exposure estimates are conservative since average residues were not calculated and monitoring data were not used to refine residue estimates.

Therefore, it can be concluded that levels of fluoride in/on food from the agricultural use of Cryolite plus fluoride levels in U.S. drinking water supplies (0.057 mg/kg/day) results in a high-end daily dietary intake of fluoride of approximately 0.085 mg/kg/day. This is less than the Maximum Concentration Limit (MCL) of 4.0 mg/L 0.114 mg/kg/day, a level which provides no known or anticipated adverse health effect as determined by the Surgeon General.

Due to the fact that fluoride naturally occurs at low levels in food and air as well as drinking water, there is a low percentage of the population (0.4%) exposed to levels above the secondary Maximum Contaminant Level (2 mg/L) and below the MCL, dietary exposure from agricultural uses is low (typically much less than ca. 66% of the levels found in intentionally fluoridated water), and aggregate high-end exposure is estimated to be below the MCL, EPA concludes there is a reasonable certainty that no harm will result from aggregate exposure to fluoride residues.

3. *Short-and intermediate -term risk.* Short-and intermediate-term risk aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. As explained above, EPA does not anticipate significant non-dietary (residential) exposure from the use of cryolite.

E. Aggregate Cancer Risk for U.S. Population

As described above, the available information does not support the regulation of cryolite as a carcinogen and it has been classified as a Group D chemical (not classifiable as to human carcinogenicity).

F. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of cryolite, EPA considered data from oral developmental toxicity studies in the rat and mouse; and a range-finding study in the rabbit as well as data from a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies.* A developmental toxicity study conducted with cryolite in rats at dose levels of 0, 750, 1,500, and 3,000 mg/kg/day (gavage) in which 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 conducted in female mice with Cryolite at dose levels of 0, 30, 100 and 300 mg/kg/day (gavage) in which the NOEL for maternal toxicity was 30 mg/kg/day and the LOEL was 100 mg/kg/day based on the occurrence of dark red contents of the stomach. Fetuses at the highest dose tested, 300 mg/kg/day exhibited bent ribs and bent limb bones.

A range-finding developmental toxicity study conducted in female rabbits with Cryolite at dose levels of 0, 10, 30, 100, 300 and 1,000 mg/kg/day (gavage) which showed only severe maternal effects at all doses. There were no developmental findings in the fetuses up to 30 mg/kg/day. At doses greater than 30 mg/kg/day, developmental findings were not observed due to the severe maternal toxicity.

A new rabbit developmental study is not required at this time since there are two acceptable rodent developmental studies (rat and mouse) showing no specific adverse developmental effects. In addition, the National Academy of Sciences (NAS) report supports this decision. It is unlikely that an additional rabbit developmental study would alter the risk evaluation for cryolite.

The rabbit range-finding study suggested that severe maternal toxicity occurred at lower doses than external developmental toxicity. However, following an extensive literature evaluation, the National Research Council (National Academy of Sciences Subcommittee of Health Effects of Ingested Fluoride) (NAS) determined that:

> There have been reports of adverse effects on reproductive outcomes associated with high levels of fluoride intake 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. ...
>
> 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.

iii. *Reproductive toxicity study.* A 2-generation reproduction study conducted with Cryolite in the diet of rats at 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) in which the LOEL for systemic toxicity was 200 ppm (15 mg/kg/day) based on dental fluorosis. The NOEL for decreased pup body weight was 46 mg/kg/day and, at the lowest dose tested (8 mg/kg/day) there was parental toxicity. Therefore, there was pup toxicity only in the presence of parental toxicity.

iv. *Pre- and post-natal sensitivity.* Based on current data requirements, the database relative to pre- and post-natal toxicity is complete. These data taken together suggest minimal concern for developmental or reproductive toxicity and do not indicate any increased pre- or post-natal sensitivity.

v. *Conclusion.* Therefore, EPA concludes that reliable data support use of the weight-of-the-evidence risk assessment approach for the assessment of risks to infants and children associated with the use of cryolite and that an additional safety factor is not needed.

2. *Acute risk.* As described above, based on available acute toxicity data, EPA has determined that cryolite does not pose any acute dietary risk.

3. *Chronic risk.* The high end dietary exposure estimate for infants and children using reassessed tolerances and percent of crops treated is 0.024 mg/kg/day. This is lower than the exposure estimate of 0.028 mg/kg/day which was used in the Agency's determination of safety for the U.S. population described above.

EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fluoride residues.

4. *Short- or intermediate- term risk.* As described above, EPA has determined that cryolite does not exhibit any adverse health effects occurring as a result of short- or intermediate-term dietary and non-dietary exposure.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of the subject insecticides in plants and animals is adequately understood.

Open literature studies show that human and animal metabolism of cryolite and/or synthetic cryolite manifests itself as normal free fluoride metabolism. That is, dissociation occurs, producing free fluoride ions which are assimilated into bone. The residue of concern in animals is total fluoride.

Plant residues are inorganic surface residues of cryolite which are measured as total fluoride. Uptake and translocation of cryolite residues from soil is unlikely due to the low water solubility of cryolite.

B. Analytical Enforcement Methodology

An adequate analytical method (fluoride specific electrode) is available for enforcement purposes for plant and animal residues. The limit of quantitation is 0.05 ppm. Because cryolite is an inorganic ionic compound, the requirement for data using the multi-residue protocols in the Pesticide Analytical Manual (PAM) Vol. I is not applicable.

Because of the long lead time from establishing these tolerances, to publication of the enforcement methodology in the PAM Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from; Calvin Furlow, Public Information Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW.,Washington, DC 20460. Office location and telephone number; Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., VA 22202, (703)-305-5232.

C. Magnitude of Residues

It has been determined that residues of cryolite are not expected to exceed 2.0 ppm in potatoes and 22.0 ppm in processed potato waste.

Data submitted in support of the subject petition show background levels of fluoride in untreated potatoes ranged from 0.14 ppm to 0.31 ppm and are consistent with the ranges reported in the open literature. Levels of fluoride found in the treated potatoes ranged from 0.18 ppm to 0.94 ppm. The residue analytical method used for enforcing the subject tolerance and regulation cannot distinguish between the naturally occurring fluoride and the fluoride resulting from use of cryolite and/or synthetic cryolite.

A potato processing study showed that cryolite residues did not concentrate in potato chips, flakes or granules. Therefore, tolerances on these commodities are not required.

There is no reasonable expectation of finite fluoride residues in ruminant or poultry tissues as a result of livestock ingestion of cryolite and this situation falls under 40 CFR 180.6 (a)(3). Therefore, tolerances for cryolite residues in meat, milk, poultry, and eggs are not required.

D. International Residue Limits

No Codex Maximum Residue Limits (MRLs) for fluorine compounds (cryolite) exist. Therefore, there are no questions of compatibility with respect to Codex MRLs and U. S. tolerances.

E. Rotational Crop Restrictions

The residue available to rotational crops is expected to be negligible with

respect to the amount of free fluorine occurring naturally in soil.

F. Endocrine Effects

No evidence of such effects were reported in the toxicology studies described above. There is no evidence at this time that cryolite causes endocrine effects.

IV. Conclusion

Therefore, the tolerance is established for residues of cryolite in or on potatoes at 2.0 ppm and in potato waste from processing at 22.0 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by February 3, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential 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. A copy of the information 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.

VI. Public Docket

A record has been established for this rulemaking under docket control number [OPP–300586] (including any comments and data submitted electronically). 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 Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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 any copies of objections and hearing requests 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 Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of this rule in today's **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 21, 1997.

Linda A. Travers,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

a. The authority citation for part 180 continues to read as follows:

Authority : 21 U.S.C. 346a and 371.

b. In § 180.145:

i. By designating paragraph (a) as paragraph (a)(1), by adding paragraph (a)(2), and by adding a heading to paragraph (a).

ii. By removing paragraph (c) and redesignating paragraph (b) as new paragraph (c) and adding a heading.

iii. By adding and reserving new paragraphs (b) and (d) with headings.

The amendments to § 180.145 read as follows:

§ 180.145 Fluorine compounds: tolerances for residues.

(a) *General.* * * *

(2) Time-limited tolerances are established for residues of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminum fluoride) in or on the commodities as follows:

Commodity	Parts per million	Expiration/revocation date
Potatoes	2.0	11/21/2001
Potatoes, waste from processing	22.0	11/21/2001

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* * * *

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–31920 Filed 12–4–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Parts 205, 232, 233, 235, 250, 251, 255, 256, and 257

RIN 0970–AB84

Repeal of Obsolete Title IV–A and IV–F Program Rules

AGENCY: Administration for Children and Families (ACF), HHS.

ACTION: Final rule; removal.

SUMMARY: This document removes regulations governing certain programs repealed or eliminated under the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, including: Emergency Assistance; Job Opportunities and Basic Skills Training; and three child care programs authorized under title IV–A of the Social Security Act. It also repeals some administrative rules of the AFDC program, because the program was repealed effective July 1, 1997.

DATES: Effective date is December 5, 1997.

FOR FURTHER INFORMATION CONTACT: Mack Storrs, Director, Division of Self-Sufficiency Programs, Office of Family Assistance, ACF, at 202–401–9289.

SUPPLEMENTARY INFORMATION: On August 22, 1996, President Clinton signed The Personal Responsibility and Work Opportunity Reconciliation Act of 1996—or PRWORA—into law. This law replaced the nation's largest public assistance program, known as Aid to Families with Dependent Children, and affiliated programs, with a new block grant to States. It also made substantial changes to the Federal child care programs that served welfare recipients and other low-income families.

This legislation made a number of our existing regulations obsolete, effective July 1, 1997, or earlier. The purpose of this rulemaking is to remove many of the obsolete rules. Thus, this rulemaking reflects ACF's continuing commitment to the Administration's regulatory reinvention initiative. In particular, it responds to the first directive in the President's strategy—to ''cut obsolete regulations.'' Through this rulemaking, we are eliminating approximately 82 pages of obsolete rules from the Code of Federal Regulations.

Aid to Families With Dependent Children and Emergency Assistance

Section 103(a) of PRWORA (Pub. L. 104–193) repealed the provisions in the existing part A of title IV of the Social Security Act and replaced them with provisions governing the new welfare block grant. Under section 116 of PRWORA, this change took effect on July 1, 1997, except in States that chose to implement their new welfare programs at an earlier date. The provisions that were repealed governed the existing programs of Aid to Families with Dependent Children (AFDC) and Emergency Assistance (EA).

The regulations for the Emergency Assistance program are found at 45 CFR 233.120. This rulemaking would remove this section of the regulation in its entirety.

The regulations for the AFDC program are found throughout Chapter II of Title 45 in the Code of Federal Regulations.

In this rulemaking we are removing only a limited number of administrative rules. They are those AFDC rules that address the AFDC Quality Control System (authorized under section 408 of the Social Security Act, as in effect under prior law), some provisions related to child support requirements and fraud control, and certain provisions related to financial penalties against the States under prior law.

We will make other conforming changes to the AFDC regulations at a later date. We must exercise care in repealing the AFDC rules because: (1) eligibility for other programs, such as title IV–E (Foster Care) and title XIX (Medicaid), retain a direct connection to the AFDC rules in effect prior to PRWORA; and (2) many of the AFDC provisions are intertwined with provisions for other assistance programs that were not repealed. (The most notable example of this latter problem is the overlap between the AFDC rules and the rules for the adult programs operated by the Territories under titles I, X, IV, and XVI of the Social Security Act.) To address these more sensitive and complicated conforming changes, we need to engage in additional analysis and consult with other Federal agencies and other interested groups. Thus, most of the conforming changes to the AFDC regulations will be reserved for future rulemaking efforts.

The IV–A Child Care Programs

Section 103(c) of PRWORA eliminated the child care provisions that were in title IV–A of the Social Security Act at the time of enactment. Under section 116(c) of PRWORA, the elimination of those provisions took effect on October 1, 1996. The new child care provisions in title VI of PRWORA took effect that same day.

The programs eliminated by PRWORA were: child care for AFDC recipients and JOBS participants under section 402(g) of the Act, transitional child care for former AFDC recipients under section 402(g) of the Act, and child care for at-risk families under