Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

In addition, since these tolerances and exemptions that are established on the basis of a petition under FFDCA section 408 (d), such as the tolerances 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.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of the rule in the **Federal Register**. This rule 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: August 26, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In section 180.443, by adding new entries for artichokes, asparagus, and peppers (bell and non-bell) in alphabetical order to the table in paragraph (b), to read as follows:

§ 180.443 Myclobutanil; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
Artichoke	1.0	7/31/00
Asparagus	0.02	7/31/00
*	*	*
Peppers (bell and non-bell)	1.0	7/31/00
*	*	*

* * * * *

[FR Doc. 98–24845 Filed 9–15–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300699; FRL–6022–5]

RIN 2070–AB78

Propyzamide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of propyzamide (pronamide) and its metabolites containing the 3,5-dichlorobenzoyl moiety (calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide) in or on cranberries, grass hay, and grass forage. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal

Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on cranberries, and on grass grown for seed. This regulation establishes maximum permissible levels for residues of propyzamide in these food and feed commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on December 31, 1999.

DATES: This regulation is effective September 16, 1998. Objections and requests for hearings must be received by EPA on or before November 16, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300699], 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 docket control number, [OPP–300699], must also 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. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300699]. 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: Telephone numbers and e-mail addresses: For propyzamide on cranberries: Andrew Ertman, (703) 308–9367, e-mail: ertman.andrew@epamail.epa.gov; for propyzamide on grass grown for seed: Andrea Beard (703) 308–9356, e-mail: beard.andrea@epamail.epa.gov. Office location (both): Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. By mail (both): Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for combined residues of the herbicide propyzamide (pronamide) and its metabolites, in or on cranberries at 0.05 part per million (ppm), and in or on grass forage at 1 ppm and grass hay at 0.5 ppm. These tolerances will expire and are revoked on December 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemptions for Propyzamide (Pronamide) and FFDCA Tolerances

Propyzamide on Cranberries: Dodder is a serious and devastating pest in commercial cranberry production as well as many other agricultural crops. It is an obligate shoot parasite that, in order to survive, must make a successful attachment to a host plant. The body of the organism consists of thin, yellow, twining stems that produce small clusters of white flowers and can form a dense mat of ''spaghetti-like'' stems on top of infected plants. Dodder is prolific in its seed production, and produces seeds in capsules that are contained in large air spaces and are thus very buoyant. With the widespread adoption of water harvesting, dodder infestations have become practically ubiquitous in the Massachusetts production area. The detrimental impact of dodder infestations on cranberry yields have been reported widely in scientific journals, extension publications and internal memorandum. Yield losses can range from 12% in slight infestations up to 100% in severe infestations. Currently registered herbicides have not been totally effective, leading to a steady increase in dodder infestations.

Propyzamide on Grasses grown for seed: Because of cancellation of several herbicide uses in recent years, a shift in weed populations and the development of resistance, plus restrictions imposed on open field burning, grass growers are no longer able to control weeds adequately with registered materials and cultural methods. The Applicants claim that if weeds are not adequately controlled, growers will incur significant economic losses due to reduced yields, and from losses due to contaminated seed, and replanting of fields that do not meet certification requirements. The Applicant proposed use of propyzamide, in conjunction with several other herbicides, to comprise a comprehensive management system to solve the current weed control problems in grass seed production.

EPA has authorized under FIFRA section 18 the use of propyzamide on cranberries for control of dodder in Massachusetts, and on grasses grown for seed to control grassy weeds in Oregon. After having reviewed the submissions, EPA concurs that emergency conditions exist for these states.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of propyzamide in or on cranberries and grass hay and forage. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 1999, under FFDC a section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on cranberries or grass hay or grass forage after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether propyzamide meets EPA's registration requirements for use on cranberries or grasses grown for seed or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of propyzamide by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Massachusetts or Oregon to use this pesticide on the specified crops under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding these emergency exemptions for propyzamide, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

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 percent 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 dat a 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.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. 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, to pesticide residues. For this pesticide, the most highly exposed population subgroup (Non-Nursing Infants <1 year old) was not regionally based.

IV. 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 propyzamide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of propyzamide (pronamide) and its metabolites containing the 3,5-dichlorobenzoyl moiety (calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide) on cranberries at 0.05 ppm, on grass forage at 1.0 ppm, and on grass hay at 0.5 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances 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 propyzamide are discussed below.

1. *Acute toxicity.* None. For acute dietary risk assessment, EPA has determined, based on the available data, that an acute dietary endpoint was not necessary for purposes of risk assessment.

2. *Short - and intermediate - term toxicity.* EPA has not identified any toxicity endpoints for short- or intermediate-term toxicity, and has determined, based on the data, that these risk assessments are not necessary.

3. *Chronic toxicity.* EPA has established the Reference Dose (RfD) for propyzamide at 0.08 milligrams/kilogram body weight/day (mg/kg bwt/day). The RfD was established based on a 2–year feeding study in rats with a NOEL of 8.46 mg/kg/day and using an uncertainty factor of 100. The Lowest Observed Effect Level (LOEL) of 42.6 mg/kg/day was based on decreased mean body weight and decreased mean body weight gain, increased relative liver weight, increased incidences of hepatic centrilobular hypertrophy, as well as eosinophilic cell alterations and thyroid follicular cell hypertrophy in both males and females. In females there was an increased incidence of ovarian hyperplasia.

4. *Carcinogenicity.* Propyzamide has been classified as a Group B2 (probable human carcinogen) chemical. The decision was based on the finding of two types of tumors in the rat (benign testicular interstitial cell tumors and thyroid follicular cell adenomas), and one type in the mouse (liver carcinomas). The Agency recommended using the Q_1* approach (Q_1* = 0.01540) for purposes of risk assessment.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.317) for the residues of propyzamide, 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety and calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-

propynyl)benzamide) in or on a variety of raw agricultural commodities at levels ranging from 0.02 ppm in milk to 10 ppm in nongrass animal feeds. Risk assessments were conducted by EPA to assess dietary exposures and risks from propyzamide as follows:

i. *Acute exposure and risk.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. As the Agency did not identify an acute dietary endpoint, no acute risk assessment was conducted.

ii. *Chronic exposure and risk.* In conducting this chronic dietary risk assessment, EPA has made partially refined assumptions. For cranberries, the conservative assumptions of tolerance level residues and 100% crop treated were used. Refinements to other commodities included anticipated residues for lettuce, milk, eggs, and most poultry commodities; additionally, percent of crop treated figures were incorporated for small berries, grapes, cherries, stone fruits, pome fruits, lettuce, and artichokes. All other commodities were assumed to be 100% crop treated and to contain tolerance level residues.

The existing propyzamide tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in an Anticipated Residue Contributions (ARCs) that are equivalent to <1% of the RfD for all population subgroups, as shown below:

Population Subgroup	ARC (mg/kg/day)	%RFD
U.S. Population (48 States)	0.000151	0.19
Nursing Infants (<1 year old)	0.000195	0.24
Non-Nursing Infants (<1 year old)	0.000601	0.75
Children (1–6 years old)	0.000354	0.44
Children (7–12 years old)	0.000225	0.28

iii. *Cancer risk*. Propyzamide has been classified as a Group B2 (probable human carcinogen) chemical by the Agency. The decision was based on the finding of two types of tumors in the rat (benign testicular interstitial cell tumors and thyroid follicular cell adenomas), and one type in the mouse (liver carcinomas). The Agency recommended using the Q_1* approach (Q_1*=0.01540(mg/kg/day)$^{-1}$) for purposes of risk assessment. Using the partially refined exposure estimates described above, the cancer risk estimate for the U.S.population is 2.3×10^{-6}. The contribution of propyzamide exposure resulting from this section 18 use has been amortized for 5 years for the purposes of this section 18 only. Although the cancer risk estimate exceeds 1×10^{-6}, this risk analysis assumed all the beef, goat, sheep, and pork commodities contain tolerance level residues. Although the milk, turkey, poultry, and egg commodities were assumed to contain anticipated residues, the percent treated values used were 100. These commodities contribute significantly to the diet. Therefore, if anticipated residues were used for all commodities, and actual percent treated values were used for all these animal commodities, it is expected that the cancer risk estimate from food would fall below 1×10^{-6}.

2. *From drinking water.* Based on information in the Agency's files, propyzamide is persistent and not mobile. There is no established Maximum Contaminant Level for residues of propyzamide in drinking water. A lifetime health advisory level of 0.05 mg/L for propyzamide in drinking water has been established. The Agency utilized GENEEC and SCIGROW computer modeling to estimate pesticide concentrations found in surface and ground waters, respectively, thus providing a reasonable and conservative upper-bound estimate for screening purposes, for use in the human health risk assessment. For surface water, the chronic (average 56–day) value is 8.3 parts per billion (ppb). The groundwater screening concentration is 0.28 ppb.

i. *Acute exposure and risk.* Because no acute dietary endpoint was identified, no acute risk assessment was conducted.

ii. *Chronic exposure and risk.* Chronic drinking water levels of concern (DWLOC) for propyzamide were calculated based on the chronic dietary (food) exposure estimates. A human health DWLOC is the concentration in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that chemical from food, water, and non-occupational (residential) sources. It is current Agency policy that the following subpopulations be addressed when calculating drinking water levels of concern: US population (48 States), Males (13+ years), Females (13+ years), and all infants/children and if other adult populations greater than the U.S. population, the highest of them also. In conducting these calculations, default body weights are used of 70 kg (adult male), 60 kg (adult females), and 10 kg (child); default consumption values of water are used of 2 liters perday for adults and 1 liter per day for children. Using these assumptions and the levels provided by the computer models, given above, the resultant DWLOCs were calculated to be 2,800 ppb for the Overall US population and Males (13–19), 2,400 ppb for Females (13–19 yrs. old), and 790 ppb for the most highly exposed infant/children subpopulation, Non-Nursing Infants (<1 Year Old). These values are substantially higher than the residue estimates calculated. Therefore, chronic exposure to propyzamide residues in drinking water do not exceed the Agency's level of concern.

iii. *Cancer Risk.* The cancer risk estimate (food only) is not likely to exceed the Agency's level of concern. In addition, in the Agency's best scientific judgment, considering the conservative nature of the GENEEC surface water number of 8.3 ppb, EPA does not expect significant additional contribution to cancer risk from exposure to propyzamide in drinking water.

3. *From non-dietary exposure.* Propyzamide is currently registered for use on numerous ornamental plants (including woody shrubs, shade trees, and ornamental turf); there are no indoor uses registered. However, all registered residential uses of propyzamide are currently inactive, and therefore residential uses are not a contributing factor to aggregate risk at this time.

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).

Propyzamide is a member of the substituted amides class of pesticides. However, EPA does not have, at this time, available data to determine whether propyzamide 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, propyzamide 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 propyzamide has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* Because no acute dietary endpoint was identified, no acute risk assessment was conducted.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to propyzamide from food will utilize 0.19% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is Non-Nursing Infants, with 0.75% of the RfD utilized, further discussed below. EPA generally has 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. Despite the potential for exposure to propyzamide in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to propyzamide residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Because no endpoint was identified for this type of exposure, EPA did not conduct a risk assessment for short- or intermediate-term exposure.

D. Aggregate Cancer Risk for U.S. Population

As discussed in the previous section, EPA believes that if further refinement of residue and percent crop treated estimates were incorporated in to the risk assessment, the cancer risk from food would fall below 1×10^{-6}. Although the GENEEC drinking water model indicates potential for low residues of propyzamide in water, it is EPA's best scientific judgment that the total aggregate cancer risk presented from propyzamide will not exceed 1×10^{-6}, even if drinking water exposures were to occur at the extremely conservative screening levels estimated. Therefore, EPA concludes that there is a reasonable certainty that no harm in the form of cancer will result from aggregate exposure to propyzamide residues.

E. 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 propyzamide, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. 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 MOE 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.* In the developmental study in rats, there were no maternal (systemic) or developmental (fetal) adverse effects observed at the highest dose tested (160 mg/kg/day).

In the developmental toxicity study in rabbits, the maternal (systemic) NOEL was 5 mg/kg/day. The LOEL of 20 mg/kg/day was based on anorexia, vacuolated hepatocytes, and soiled anal area. The developmental (fetal) NOEL was 20 mg/kg/day. The developmental LOEL of 80 mg/kg/day was based on increased number of absorptions and abortions.

iii. *Reproductive toxicity study.* In the 2–generation reproductive toxicity study in rats, the parental (systemic) NOEL was 10 mg/kg/day (200 ppm), based on decreased body weight, and decreased feed consumption at the

LOEL of 75 mg/kg/day (1,500 ppm). The reproductive (pup) NOEL was also 10 mg/kg/day (200 ppm) based on decreased pup weight at the LOEL of 75 mg/kg/day (1,500 ppm).

iv. *Pre- and post-natal sensitivity.* The toxicological database for evaluating pre- and post-natal toxicity for propyzamide is complete with respect to current data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies as well as the 2–generation rat reproductive toxicity study.

v. *Conclusion.* Based upon the available data, outlined above, EPA scientists concluded that reliable data support the conclusion that using the standard 100–fold uncertainty factor will provide adequate protection for infants and children, and that an additional 10–fold uncertainty factor is not warranted. EPA concludes that there is reasonable certainty of safety for infants and children exposed to dietary residues of propyzamide.

2. *Acute risk.* Because no acute dietary endpoint was identified, no acute risk assessment was conducted.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to propyzamide from food will utilize from 0.24% to 0.75% of the RfD for infants and children. EPA generally has 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. Despite the potential for exposure to propyzamide in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to propyzamide residues.

4. *Short- or intermediate-term risk.* Because no endpoint was identified for short- or intermediate-term exposure, EPA did not conduct a risk assessment for this type of exposure.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood. The residues of concern are the parent compound and its metabolites containing the 3,5-dichlorobenzoyl moiety, calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide(as specified in 40 CFR 180.317) .

B. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography using electron capture detection) is available to enforce the tolerance expression. This method is published in PAM II, as method I.

C. Magnitude of Residues

Residues of propyzamide and its regulated metabolites are not expected to exceed 0.05 ppm in/on cranberries, 0.5 ppm in/on grass hay, and 1 ppm in/on grass forage, as a result of these section 18 uses. Secondary residues in animal commodities are not expected from cranberries, and secondary residues resulting form the grass use are not expected to exceed established tolerances.

D. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits for propyzamide on cranberries or grass commodities, so harmonization is not an issue for these section 18 uses.

E. Rotational Crop Restrictions

Cranberries are not a rotated crop, and thus rotational crop restrictions are not applicable. Fields in which certified grass seed is grown are not normally rotated to other crops, and rotational crop restrictions are not required for this use.

VI. Conclusion

Therefore, the tolerances are established for combined residues of propyzamide in/on cranberries at 0.05 ppm, grass hay at 0.5 ppm, and grass forage at 1 ppm.

VII. 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 November 16, 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 Confidential Business Information (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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300699] (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 119 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 Highway, Arlington, VA.

Electronic comments may 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 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.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under FFDCA section 408(l)(6). 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 58–3, 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).

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded federal mandate on State, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

In addition, since these tolerances and exemptions that are established under FFDCA section 408(l)(6), 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.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of this rule in the **Federal Register**. This rule 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: August 26, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In §180.317, by revising the heading; by adding a heading to paragraph (a) and revising the introductory text; by designating the current paragraph (b) as (c); by adding a new paragraph (b); by revising the

introductory text of newly designated (c); and by adding and reserving paragraph (d) to read as follows:

§ 180.317 Propyzamide; tolerances for residues.

(a) *General.* Tolerances are established for combined residues of the herbicide propyzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety and calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide) in or on the following raw agricultural commodities:

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the residues of propyzamide, in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Cranberries	0.05	12/31/99
Grass, forage	1.0	12/31/99
Grass, hay	0.5	12/31/99

(c) *Tolerances with regional registrations.* Tolerances with regional registration are established for the combined residues of the herbicide propyzamide and its metabolites (containing the 3,5-dichlorobenzoyl moiety and calculated as 3,5-dichloro-*N*-(1,1-dimethyl-2-propynyl)benzamide) in or on the following raw agricultural commodities:

* * * * *

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

[FR Doc. 98–24846 Filed 9–15–98; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–138, RM–8855, 8856, 8857, 8858, 8872; FCC 98–175]

Main Studio and Public Inspection File of Broadcast Stations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this *Report and Order* (''R&O''), the Commission adopts amendments to its rules governing main studio and local public inspection file requirements for broadcast licensees. The Commission relaxes the standard governing the location of the main studio to allow a station to locate within the principal community contour of any station licensed to the community of license, and requires the local public inspection file to be located at the broadcast station's main studio, wherever located. The Commission also amended the public inspection file rules to streamline the contents of the public inspection file. For additional information, *see* Supplementary Information.

EFFECTIVE DATE: These rules contain information collection requirements that are not effective until approved by the Office of Management and Budget. FCC will publish a document in the **Federal Register** announcing the effective date of this document.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Room 222, Washington, DC 20554. In addition to filing comments with the Secretary, a copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 234, 1919 M Street, NW., Washington, DC 20554, or via the Internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Victoria M. McCauley or Kim Matthews Mass Media Bureau, (202) 418–2130. For additional information concerning the information collections contained in this R&O contact Judy Boley at 202–418–0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 97–138, adopted July 27, 1998 and released August 11, 1998. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC, 20036, (202) 857–3800.

Synopsis of Report and Order on Main Studio and Public Inspection File

I. Introduction

1. With this *Report and Order,* we amend our rules regarding the main studio and local public inspection file for broadcast stations. In the *Notice of Proposed Rule Making,* 62 FR 32061 (June 12, 1997), we proposed that modification of these rules could serve the public interest. We here conclude that it is possible to grant broadcast licensees additional flexibility in locating their main studios, together with their public files, and adhere to the original purpose underlying these rules: to maintain reasonable accessibility of station facilities, personnel and information to members of the station's community of license, which enables the residents of the community to monitor a station's performance, and encourages a continuing dialogue between the station and its community. In this way, a station is better integrated into the activities of the community and can be more responsive to local community needs in its programming. In order to facilitate this interaction, this *R&O* also amends Sections 73.3526 and 73.3527 of our rules to clarify and update the required contents of the public inspection files. The actions we take today are consistent with our ongoing effort to ensure that our rules continue to serve the public interest without imposing unnecessary regulatory burdens. These modifications in no way alter the obligation of each broadcast licensee to serve the needs and interests of its community.

II. Main Studio Rule

2. *Discussion.* In the *NPRM* in this proceeding, we set forth two goals in determining whether to modify the main studio rule. Our first goal is to strike an appropriate balance between ensuring that the public has reasonable access to each station's main studio and public file and minimizing regulatory burdens on licensees. Our second goal is to adopt clear rules that are easy to administer and understand. In the *NPRM,* sought comment on the option of permitting a station to locate its main studio anywhere in the principal community contour of any station licensed to the same community, or