

Commodity	Parts per million	Expiration/Revocation Date
Sheep, fat	0.2	None
Sheep, mbyp	0.2	None
Sheep, meat	0.2	None
Soybean, hay	10.0	None
Soybeans	10.0	None
Spearmint, tops (stems and leaves)	30.0	December 31, 1998
Spinach	4.0	None
Strawberries	10.0	None
Sugar beet molasses	10.0	None
Sugar beet, roots	1.0	None
Sugar beet, tops	3.0	None
Sunflower meal	20.0	None
Sunflower seeds	7.0	None
Sweet potato	4.0	None
Tomato pomace, dried	12.0	None
Tomato products, concentrated	24	None
Tree nuts	0.2	None

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

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

registration, as defined in § 180.1(n), are established for the combined residues of the herbicide 2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-

cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the following commodities:

Commodity	Parts per million	Expiration/Revocation Date
Artichokes	3.0	None
Endive	2.0	December 31, 1998
Rhubarb	0.3	None

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

PART 185—[AMENDED]

2. In part 185:

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

Authority: 21 U.S.C. 346a and 348.

§ 185.2800 [Removed]

b. Section 185.2800 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348, and 701.

§ 186.2800 [Removed]

b. Section 186.2800 is removed.

[FR Doc. 97-9374 Filed 4-10-97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180, 185, and 186

[OPP-300470; FRL-5598-2]

RIN 2070-AC78

Norflurazon; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the herbicide norflurazon in or on the raw agricultural commodities bermudagrass hay and forage in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of norflurazon on bermudagrass in the states of Alabama, Georgia, Louisiana, Mississippi, and Texas. This regulation establishes maximum permissible levels for residues of norflurazon in these foods 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 be revoked by EPA on November 30, 1998.

DATES: This regulation becomes effective April 11, 1997. Objections and requests for hearings must be received by EPA on or before June 10, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300470], 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-300470], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, 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 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-300470]. 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: Libby Pemberton, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202, (703) 308-8326, e-mail: pemberton.libby@epamail.epa.gov.

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 residues of norflurazon on bermudagrass forage at 2 ppm and bermudagrass hay at 3 ppm. These tolerances will expire on November 30, 1998.

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) 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, 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. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the regulations be consistent with section 408(b)(2) and (c)(2) and FIFRA section 18.

Section 408(l)(6) allows EPA to establish tolerances or exemptions from the requirement for a tolerance, in connection with EPA's granting of FIFRA section 18 emergency exemptions, without providing notice or a period for public comment. Thus, consistent with the need to act expeditiously on requests for emergency exemptions under FIFRA, EPA can establish such tolerances or exemptions under the authority of section 408(e) and (l)(6) without notice and comment rulemaking.

In establishing section 18-related tolerances and exemptions during this interim period before EPA issues the section 408(l)(6) procedural regulation and before EPA makes its broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section

408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance and exemption decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development. EPA intends to act on section 18-related tolerances and exemptions that clearly qualify under the new law.

II. Emergency Exemptions for Norflurazon on Bermudagrass and FFDCA Tolerances

EPA has authorized use under FIFRA section 18 of norflurazon on bermudagrass hay meadows and pastures for control of grassy weeds. Bermudagrass requires at least 2 years to completely cover a planted area and successfully compete with annual grassy weeds. Successful establishment during the first 2 years is critically important to profitable production from a bermudagrass hay meadow. Annual grassy weed encroachment and resulting variable bermudagrass stands will reduce the quantity of hay produced and the overall quality. A hay field does not reach maximum hay production for 3 or 4 years after establishment depending on the degree of success in establishment. For the next 6 to 7 years, growers should receive maximum economic yield and return on their annual investments. The market will not accept bermudagrass hay contaminated with weeds or annual grasses. Bermudagrass stands often begin to decline after about 10 years due to diseases, insect problems, fertility imbalances, or environmental stresses. Establishment of a new stand of bermudagrass is the most cost effective way of maintaining maximum quality and quantity of hay. Atrazine and simazine, which traditionally provided control of these weeds, were voluntarily canceled in 1990 resulting in this urgent, nonroutine situation. After having reviewed their submissions, EPA concurs that emergency conditions exist.

As part of its assessment of these specific exemptions, EPA assessed the potential risks presented by residues of norflurazon on bermudagrass 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 clearly be consistent with the new safety standard and with FIFRA section 18. These tolerances for residues of norflurazon will permit the marketing of bermudagrass hay and forage treated in accordance with the provisions of the section 18 emergency exemptions.

Consistent with the need to move quickly on these emergency exemptions 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 be revoked by EPA on November 30, 1998, under FFDCA section 408(l)(5), residues of norflurazon not in excess of the amount specified in these tolerances remaining in or on bermudagrass hay and forage after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, the emergency exemptions. 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.

EPA has not made any decisions about whether norflurazon meets the requirements for registration under FIFRA section 3 for use on bermudagrass or whether permanent tolerances for norflurazon for bermudagrass hay and forage would be appropriate. This action by EPA does not serve as a basis for registration of norflurazon by a State for special local needs under FIFRA section 24(c). Nor does this action serve as the basis for any States other than Alabama, Georgia, Louisiana, Mississippi, and Texas to use this product on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for norflurazon, 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. For many of these 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.

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 margin of exposure 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.

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, and other non-occupational exposures, such as where residues leach into groundwater or surface water that is consumed as drinking water. 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. 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 percent 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.

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 these actions. Norflurazon is registered by EPA for several agricultural as well as non-agricultural uses. EPA believes it has sufficient data to assess the hazards of norflurazon and to make a determination on aggregate exposure, consistent with section 408(b)(2), for the time-limited tolerances for residues of norflurazon on bermudagrass hay and forage. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

1. *Chronic toxicity.* Based on the available chronic toxicity data, EPA's Office of Pesticide Programs (OPP) has established the RfD for norflurazon at 0.02 milligrams(mg)/kilogram(kg)/day. The RfD was established based on a NOEL (no observable effect level) of 1.53 mg/kg/day in a 6-month dog feeding study. The LEL (lowest effect level) was based on absolute and relative liver weight and increased cholesterol levels. An uncertainty factor (UF) of 100 was used to account for both inter-species extrapolation and intra-species variability.

2. *Acute toxicity.* Agency toxicologists have recommended that the developmental NOEL of 30 mg/kg/day from the rabbit developmental toxicity study be used for acute dietary risk calculations. The developmental LEL of 60 mg/kg/day is based on increased skeletal variations. The population of concern for this risk assessment is females 13+ years old.

3. *Short-term non-dietary inhalation and dermal toxicity.* OPP recommends use of the 21-day dermal toxicity study

in rabbits for short- and intermediate-term MOE calculations.

The NOEL was 375 mg/kg/day and the LEL of 1,000 mg/kg/day was based on increased absolute and relative liver weights, and increased alkaline phosphatase.

4. *Carcinogenicity.* Norflurazon is classified as a "Group C", possible human carcinogen, by the Carcinogenicity Peer Review Committee (CPRC). The CPRC recommended using the RfD approach for quantification of human risk.

B. Aggregate Exposure

Tolerances for residues of norflurazon in or on food/feed commodities are currently expressed in terms of the herbicide norflurazon (4-chloro-5-(methylamino)-2-(alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2H)-pyridazinone) and its desmethyl metabolite 4-chloro-5-(amino)-2-(alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2H)-pyridazinone (40 CFR 180.356, 185.4450, and 186.4450). Existing norflurazon tolerances for meat, milk, poultry, and eggs are not expected to be exceeded and are adequate to cover any secondary residues which might occur in animal commodities as a result of this use on bermudagrass.

For the purpose of assessing chronic dietary exposure from norflurazon, EPA assumed tolerance level residues and 100% of crop treated for the proposed use of norflurazon. These conservative assumptions result in overestimation of human dietary exposures.

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water-related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfDs or acute dietary NOELs) and assumptions about body weight and consumption, to

calculate, for each pesticide, the increment of aggregate risk contributed by consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause norflurazon to exceed the RfD if the tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with norflurazon in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerances are granted.

Based on the available studies used in EPA's assessment of environmental risk, norflurazon is persistent and mobile. The "Pesticides in Groundwater Data Base" (EPA 734-12-92-001, September 1992) reported sampling of wells for norflurazon residues in Texas and California. Texas reported 188 wells sampled, California reported 6 wells sampled. No detection of residues were reported in any of the sampled wells. There is no established Maximum Concentration Level (MCL) for residues of norflurazon in drinking water. No drinking water health advisory levels have been established for norflurazon.

Norflurazon is registered for uses, such as fencerows and around buildings, that could result in non-occupational exposure, and EPA acknowledges that there may be short-, intermediate-, and long-term non-occupational, non-dietary exposure scenarios. At this time, the Agency has insufficient information to assess the potential risks from such exposure.

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 norflurazon 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, norflurazon 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 norflurazon has a common mechanism of toxicity with other substances.

C. Safety Determinations for U.S. Population

Taking into account the completeness and reliability of the toxicity data, EPA has concluded that chronic dietary exposure to norflurazon in food from published tolerances will utilize 10 percent of the RfD for the U.S. population. EPA generally has no concern for chronic exposures below 100 percent 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. The acute dietary

exposure endpoint of concern for norflurazon is developmental. For the population of concern, females 13+ years, a MOE of 3,000 was calculated. This MOE value does not exceed the Agency's level of concern for acute dietary exposure. Dietary cancer concerns are adequately addressed by the chronic exposure analysis using the RfD. Short- and intermediate-term aggregate risk takes into account exposure from chronic dietary food and water plus indoor and outdoor residential exposure. Short- and intermediate-term MOE's for the U.S. population was calculated to be 11,000. Despite the potential for exposure to norflurazon from drinking water and outdoor residential uses, EPA does not expect the aggregate exposure to exceed 100% of the RfD or the Agency's level of concern for acute, short- and intermediate-term dietary exposure. EPA concludes that there is a reasonable certainty that no harm will result for the U.S. population from aggregate exposure to norflurazon residues.

D. Determination of Safety for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (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 exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. EPA believes that reliable data support using the standard margin of exposure (usually 100x for combined inter- and intra-species variability) and not the additional ten-fold margin of exposure 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 margin of exposure. Based on current toxicological data requirements, the data base for norflurazon relative to pre- and post-natal toxicity is complete.

The results of the rabbit developmental toxicity study required an acute dietary risk assessment be performed for additional pre-natal sensitivity due to skeletal variations. However, the MOE of 3,000 is adequate to protect against any pre-natal fetal risks. In the rabbit developmental toxicity study, the NOEL of 30 mg/kg/day was the same for both developmental and maternal toxicity. The developmental LEL of 60 mg/kg/

day was based on increased skeletal variations and decreased mean fetal weight. The maternal LEL of 60 mg/kg/day was based on decreased body weight and abortions. Although there were developmental effects at 60 mg/kg/day in rabbit fetuses, these findings only occurred in the presence of maternal toxicity. In the rat developmental toxicity study, the developmental NOEL was identified at; 400 mg/kg/day (HDT), while the maternal (systemic) NOEL was <100 mg/kg/day. The acute dietary exposure endpoint of concern for norflurazon is developmental (increased skeletal variations). For the population subgroup of concern, females 13+ years, the calculated Margin of Exposure (MOE) value is 3,000.

The results of the 2-generation reproductive toxicity study will be used to assess the potential for additional pre- and post-natal sensitivity. The parental (systemic) NOEL was 10.2 mg/kg/day and the reproductive NOEL was 50.8 mg/kg/day. The reproductive LEL of 102.5 mg/kg/day was based on increased pup deaths, increased stillborns and decreased lactation index. These effects occurred in the presence of maternal toxicity. This indicates that there is no extra post-natal sensitivity. The NOEL used to establish the RfD is approximately 10-fold lower than the pup NOEL from the reproduction study; therefore, EPA concludes that reliable data support use of the standard uncertainty factor as protecting the safety of infants and children and that an additional 10-fold margin of exposure is unnecessary.

EPA has concluded that the percent of the RfD that will be utilized by chronic dietary (food) exposure to residues of norflurazon ranges from 15% for nursing infants (<1 year old) up to 47% for non-nursing infants (<1 year old). However, this calculation assumes tolerance level residues for all commodities and is therefore an overestimate of dietary risk. Refinement of the dietary risk assessment by using anticipated residue data would reduce dietary exposure. The addition of potential exposure from norflurazon residues in drinking water is not expected to result in an exposure which would exceed the RfD. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to norflurazon residues.

V. Other Considerations

The metabolism of norflurazon in plants and animals is adequately understood for the purposes of this tolerance. There are no Codex maximum residue levels established for residues of

norflurazon and its desmethyl metabolite in or on bermudagrass hay and forage. The residue of concern, for the purposes of this tolerance, is norflurazon and its desmethyl metabolite. Adequate methods for purposes of data collection and enforcement of tolerances for norflurazon and its desmethyl metabolite are available. Methods for determining norflurazon residues are described in the Pesticide Analytical Manual, Vol. II.

VI. Conclusion

Therefore, tolerances in connection with the FIFRA section 18 emergency exemptions are established for residues of norflurazon in or on bermudagrass forage at 2 ppm and bermudagrass hay at 3 ppm. These tolerances will expire and be revoked by EPA on November 30, 1998. In addition to the new tolerance being established, since FQPA eliminates all distinctions between raw and processed food, EPA is combining the tolerances that now appear in §§ 185.4450 and 186.4450 into § 180.356. Subsequently, §§ 185.4450 and 186.4450 are removed.

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 June 10, 1997 file written objections to any aspect of this regulation (including the revocation provision) 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 Docket

A record has been established for this rulemaking under docket number [OPP-300470]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, 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. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is

not "a significant regulatory action" and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, it is not subject to review by the Office of Management and Budget.

This action does not impose any enforceable duty, or contain any "unfunded mandates" as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), entitled Enhancing the Intergovernmental Partnership, or special consideration as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because FFDCA section 408(l)(6) permits establishment of this regulation without a notice of proposed rulemaking, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 604(a), do not apply. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions adversely impact small entities and concluded, as a generic matter, that there is no adverse impact. (46 FR 24950) (May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104-121, 110 Stat. 847), EPA 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 the rule in today's **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Parts 180, 185, and 186

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

Dated: April 4, 1997.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

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

b. Section 180.356 is amended by redesignating the existing text as paragraph (a), adding a paragraph heading and adding alphabetically three new entries to the table therein to the newly redesignated paragraph (a), adding a new paragraph (b), and reserving paragraphs (c) and (d) to read as follows:

§ 180.356 Norflurazon, tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * Citrus molasses	* * * 1.0
* * * Dried citrus pulp	* * * 0.4
* * * Dried hops	* * * 3.0

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide norflurazon (4-chloro-5-(methylamino)-2-(alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2H)pyridazinone) and its desmethyl metabolite 4-chloro-5-(amino)-2-alpha, alpha, alpha-trifluoro-*m*-tolyl)-3-(2H)-pyridazinone in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances are specified in the following table. The tolerances expire and will be revoked on the date specified in the table by EPA.

Commodity	Parts per million	Expiration/Revocation Date
Grasses, Bermuda, Forage	2.0	November 30, 1998
Grasses, Bermuda, Hay	3.0	November 30, 1998

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

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

PART 185—[AMENDED]

2. In part 185:

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

Authority: 21 U.S.C. 346a and 348.

§ 185.4450 [Removed]

b. Section 185.4450 is removed.

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 342, 348 and 701.

§ 186.4450 [Removed]

b. Section 186.4450 is removed.

[FR Doc. 97-9375 Filed 4-10-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION**Coast Guard****46 CFR Part 2**

[CGD 97-001]

RIN 2115-AF41

Delegation of Authority to Officer in Charge, Marine Inspection.

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is authorizing Officers in Charge, Marine Inspection (OCMI) to redelegate signature authority for certain vessel inspection documents. Currently, the OCMI signs all vessel inspection documents. This rule will authorize redelegation of that function to reduce the number of documents OCMI must sign.

DATES: This rule is effective on April 11, 1997.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at the office of the Executive Secretary, Marine Safety Council (G-LRA/3406), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593-0001 between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267-1477.

FOR FURTHER INFORMATION CONTACT: LT Eric Christensen, Project Manager, Vessel and Facility Operating Standards Division (G-MSO-2), (202)267-1055.

SUPPLEMENTARY INFORMATION:**Background and Purpose**

The delegation of authority from the Commandant of the Coast Guard to Officer in Charge, Marine Inspection gives signature authority to the OCMI for various inspection documents. During a recent reorganization, the Coast Guard established Activity

Commands which combine OCMI, Captain of the Port (COTP), and Group functions. Activities are large units that perform a large number of tasks including many requiring the OCMI's signature. This rule will authorize redelegation of that signatory function to reduce the number of vessel inspection documents OCMI must sign personally.

Discussion and Change

The rationale for this change is that many routine documents don't require the personal attention of the OCMI, and increasing responsibilities of the OCMI will mean that the official's attention is needed more urgently elsewhere. Regulations currently require the OCMI to personally sign hundreds of inspection documents issued by each Marine Safety Office each year. In many cases, a new computer-generated Certificate of Inspection is based on an administrative change such as ownership or address and not on any substantive change in the vessel particulars. Authority to redelegate signatory authority would relieve the OCMI of a substantial paperwork burden.

The Coast Guard is proceeding directly to a final rule under section 553(b)(3)(A) of the Administrative Procedures Act (5 U.S.C. 551 *et seq.*) which excludes rulemakings relating to agency organization, procedure, or practice from the requirements of public notice and comment. These changes are administrative and will not impact the type or quality of Coast Guard services performed.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. As this rule involves internal Agency practices and procedures, it will not impose any costs on the public.

Collection of Information

This rule contains no new collection-of-information requirements under the

Paperwork Reduction Act [44 U.S.C. 3501 *et seq.*].

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this interim rule and concluded that, under § 2.B.2 of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation. This exclusion is in accordance with paragraphs 2.B.2.e.(34) (a) and (b), concerning regulations that are editorial or procedural and concerning internal agency functions or organization. A Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 46 CFR Part 2

Marine safety, Reporting and recordkeeping requirements, Vessels.

For the reasons set forth in the preamble, the Coast Guard amends 46 CFR part 2 as follows:

PART 2—VESSEL INSPECTIONS

1. The authority citation for part 2 continues to read as follows:

Authority: 33 U.S.C. 1903; 43 U.S.C. 1333; 46 U.S.C. 3306, 3703; E.O. 12334, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46; subpart 2.45 also issued under the authority of Act Dec. 27, 1950, Ch. 1155, secs. 1, 2, 64 Stat. 1120 (see 46 U.S.C. App. note prec. 1).

2. Section 2.01-30 is added to read as follows:

§ 2.01-30 Delegation of OCMI signature authority.

The OCMI may redelegate to one individual on his or her staff authority to sign documents issued under this subpart.

Dated: March 31, 1997.

J. C. Card,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 97-9409 Filed 4-10-97; 8:45 am]

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