more pieces prepared in 5-digit or 3-digit packages, under 3.2. When SCF sacks are prepared, required origin/optional entry 3-digit sacks must not be prepared and required origin/optional entry SCF sacks must be prepared.

* * * * *

3.0 Periodicals

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3.2 Sack Preparation

[Redesignate current 3.2c and 3.2d as 3.2d and 3.2e respectively; add new 3.2c to read as follows:]

Sack size, preparation sequence, and Line 1 labeling:

* * * * *

c. Optional SCF: required at 24 pieces (no minimum for required origin/optional entry SCF), optional with one six-piece package minimum except under 1.7; for Line 1, use L002, Column C.

* * * * *

An appropriate amendment to 39 CFR 111.3 will be published to reflect these changes.

Neva R. Watson,

Alternative Liaison.

[FR Doc. 98–8 Filed 1–2–98; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300596; FRL–5762–4]

RIN 2070–AB78

Dicloran; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of dicloran, 2,6-dichloro-4-nitroaniline in or on peanuts. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on peanuts. This regulation establishes a maximum permissible level for residues of dicloran in this food commodity 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 tolerance will expire and is revoked on October 31, 1999.

DATES: This regulation is effective January 5, 1998. Objections and requests for hearings must be received by EPA on or before March 6, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300596], 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–300596], 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. 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 5.1/6.1 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–300596]. 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: Virginia Dietrich, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9359, e-mail: dietrich.virginia@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 a tolerance for residues of the fungicide, dicloran, 2,6-dichloro-4-nitroaniline, in or on peanuts at 3 part per million (ppm) for peanuts and 6 ppm for peanut oil. This tolerance will expire and is revoked on October 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerance 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 Exemption for dicloran on peanuts and FFDCA Tolerances

The Oklahoma Department of Agriculture requested a specific exemption for the use of dicloran on peanuts due to the high rainfall and corresponding high fungal disease incidence in Oklahoma this year. After having reviewed the submission, EPA has authorized under FIFRA section 18 the use of dicloran on peanuts for control of *Sclerotinia* blight in Oklahoma.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of dicloran in or on peanuts. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance 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 this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on October 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on peanuts after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether dicloran meets EPA's registration requirements for use on peanuts or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of dicloran by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Oklahoma to use this pesticide 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 exemption for dicloran, 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% 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 hundredfold MOE is based on the same rationale as the hundredfold 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 three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

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

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

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

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 less than 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 dicloran and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of 2,6-dichloro-4-nitroaniline on peanuts at 3 ppm for peanuts and 6 ppm for peanut oil. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

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

1. *Acute toxicity*. No acute dietary toxicity (risk) endpoints have been identified at this time for Dicloran (dichloronitroaniline; DCNA). Therefore, this assessment is not required.

2. *Short - and intermediate - term toxicity.* No short- or intermediate-term toxicity end points were found to be appropriate by the Agency's Ad Hoc Toxcity Endpoint Selection Committee (AHTESC).

3. *Chronic toxicity*. For dietary risk, EPA has established the Reference dose (RfD) for dicloran at 0.025 milligrams/kilogram/day (mg/kg/day). This RfD is based on a 2–year feeding study in dogs with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. The lowest observed effect level (LOEL) is based on increased liver weights and histological changes at 75.0 mg/kg/day. The Agency also determined that a chronic toxicity endpoint and risk assessment for dicloran is not required since the use of dicloran on a short-term basis for this emergency exemption does not present a chronic occupational exposure scenario.

4. *Carcinogenicity*. Dicloran has not been classified by the Cancer Peer Review Committee. However, no cancer risks have been identified in either the mouse or the rat study by the Agency's Ad Hoc Toxicity Endpoint Selection Committee.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.200) for the residues of 2,6-dichloro-4-nitroaniline, in or on a variety of raw agricultural commodities at levels ranging from 0.1 ppm in cottonseed to 20 ppm in several fruits. Risk assessments were conducted by EPA to assess dietary exposures and risks from dicloran 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. After reviewing data available on the acute toxicity of dicloran, the Agency concluded that no such toxicological endpoint of concern was demonstrated. The Agency further concluded that a risk assessment for this endpoint was not necessary.

ii. *Chronic exposure and risk*. In conducting this chronic dietary risk assessment, the Agency has made

conservative assumptions -- 100% of the peanuts treated. For most other commodities having Dicloran tolerances, anticipated residues from monitoring data were utilized. For several crops where it appears that no registrations exist, tolerance levels were used even though zero may have been more appropriate. Even though monitoring data were used for a number of commodities, the risk assessment still results in an overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, the Agency is taking into account this conservative exposure assessment.

The existing Dicloran tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

Subgroups	Percentage of RFD
U.S. Population (48 States)	2.6
Nursing Infants (< 1 year old) ..	7.1
Non-Nursing Infants (< 1 year old)	11.3
Children (1–6 years old)	5.6
Children (7–12 years old)	3.7

2. *From drinking water.* Based on information in the Agency's files, Dicloran is persistent and somewhat mobile. There are no established Maximum Contaminant Levels for residues of Dicloran in drinking water. No health advisory levels for Dicloran in drinking water have been established.

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 well below the level that would cause Dicloran to exceed the RfD if the tolerance being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with Dicloran 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 tolerance is granted.

3. *From non-dietary exposure.* Dicloran currently has no registered uses on residential non-food sites. Therefore, there is no residential non-food exposure.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

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

EPA does not have, at this time, available data to determine whether dicloran 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, dicloran 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 dicloran has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* The Agency's Ad Hoc Toxicity Selection Committee (TESC) did not identify an acute dietary end point for dicloran and determined that this risk assessment is not appropriate.

2. *Chronic risk.* Using the ARC exposure assumptions described above, EPA has concluded that aggregate exposure to dicloran from food will utilize 2.6% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants which is 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 dicloran 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 dicloran residues.

3. *Short- and intermediate-term risk.* The ad hoc TESC determined that there are no short term or intermediate term toxicological endpoints. Additionally, the ad hoc TESC has determined that there are no non-dietary, non-occupational, i.e. residential uses registered for Dicloran. Therefore no short term or intermediate term aggregate exposure assessments were conducted.

D. Aggregate Cancer Risk for U.S. Population

The Cancer Peer Review Committee has not reviewed or classified Dicloran

as to its cancer potential. However, no carcinogenicity potential has been identified in either the long term mouse or rat studies.

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 dicloran, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a 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, the maternal (systemic) NOEL was 100 mg/kg/day, based on CNS depression at the LOEL of 200 mg/kg/day. The developmental (fetal) NOEL was 100 mg/kg/day, based on decreased body weight, skeletal variations and visceral variations at the LOEL of 200 mg/kg/day. In the developmental (feeding) toxicity study in rabbits, the maternal (systemic) NOEL was 1,000 ppm which was equivalent to 30 mg/kg/day, the highest dose tested. The developmental (pup) NOEL was 30 mg/kg/day. The reproductive (pup) NOEL was 30 mg/kg/day, the highest dose tested.

iii. *Reproductive toxicity study.* In the 3 generation (single dose) reproductive toxicity study in rats, the maternal (systemic) NOEL was 100 ppm which was equivalent to 5.0 mg/kg/day. The developmental (pup) NOEL was 5.0 mg/kg/day. The reproductive (pup) NOEL was 5.0 mg/kg/day.

iv. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating pre- and post-natal toxicity for DCNA is not complete with respect to the current data requirements. However, there are no pre- or post-natal toxicity concerns for infants and children, based on the results of the available rat and rabbit developmental toxicity studies and the three generation rat reproductive study. The NOEL for maternal and developmental toxicity are at the same dose level in rat and rabbit. This indicates no extra pre-natal sensitivity for infants and children. The request for a rabbit gavage study to replace the dietary developmental study does not suggest any extra pre-natal sensitivity is present in the current study but is required to fulfill current guideline requirements. The current three generation rat reproduction study demonstrated no additional pre- or post-natal extra sensitivity for infants and children since the maternal reproductive and developmental NOELs occurred at the same dose levels. The replacement study is being requested to fulfill current guideline requirements (e.g. for the reproduction study, a study testing two generations and three doses is being conducted). Based on the developmental and reproductive studies discussed above for DCNA there does not appear to be an extra sensitivity for pre- and post-natal effects.

v. *Conclusion.* Based on the above EPA concludes that the available data support use of the standard hundredfold margin of exposure/uncertainty factor and that an additional factor/margin of safety is not needed to protect infants and children.

2. *Acute risk.* The ad hoc TESC did not identify an acute dietary end point for DCNA and determined that this risk assessment is not required. Therefore no aggregate acute risk assessment was performed.

The Agency acknowledges the potential for exposure to Dicloran in drinking water, but does not expect that exposure would result in aggregate MOEs (food plus water) that would exceed the Agency's level of concern for acute dietary exposure.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to dicloran from food will utilize from 11.3% for non-nursing infants less than 1 year old, to 5.6% for children 1–6 years old 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 dicloran 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 dicloran residues.

4. *Short- or intermediate-term risk.* The Agency's ad hoc TESC determined that there are no short term or intermediate term toxicological endpoints. Additionally, the ad hoc TESC has determined that there are no non-dietary, non-occupational, i.e. residential, uses registered for Dicloran. Therefore no short term or intermediate term aggregate exposure assessments were conducted.

V. Other Considerations

A. Metabolism In Plants and Animals

For this section 18 request only, the nature of the residue in plants is adequately understood. The residue of concern is the parent compound 2,6-dichloro-4-nitroanaline as specified in 40 CFR 180.200.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available in PAM II to enforce the tolerance expression.

C. Magnitude of Residues

Residues of Dicloran are not expected to exceed 3.0 ppm in/on peanuts or 6.0 ppm in its processed byproducts peanuts, oil as a result of this section 18 use. A time-limited tolerance should be established at this level. Secondary residues are not expected in animal commodities as no feed items are associated with this section 18 use.

D. International Residue Limits

There are no CODEX, Canadian or Mexican limits for Dicloran on peanuts.

E. Rotational Crop Restrictions.

The planting of spinach is restricted as a follow-up crop to onions, garlic and shallots, and the planting of tomatoes is restricted as a follow-up crop to sweet potatoes.

VI. Conclusion

Therefore, the tolerance is established for residues of 2,6-dichloro-4-

nitroaniline in peanuts at 3 ppm for peanuts and 6 ppm for peanut oil.

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 March 6, 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–300596] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis 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

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

In addition, under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency 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 General Accounting Office

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

List of Subjects in 40 CFR Part 180

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

Dated: December 17, 1997.

James Jones

Acting Director, 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 § 180.200, by revising the section heading, designating the existing text as paragraph (a), adding a paragraph heading, designating the text following the heading as paragraph (a)(1),

designating the text following the table as paragraph (a)(2), and by adding paragraph (b), and by adding and reserving paragraphs (c) and (d) with headings to read as follows:

§ 180.200 Dicloran; tolerances for residues.

(a) *General.* (1) * * *

(2) * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for combined residues of the fungicide, dicloran, 2,6-dichloro-4-nitroaniline in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/Revocation Date
Peanut, oil	6.0	10/31/99
Peanuts ...	3.0	10/31/99

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

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

[FR Doc. 98–73 Filed 1–2–98; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[FCC 97–419]

Procedure for Designation of Eligible Telecommunications Carriers Pursuant to Section 214(e)(6) of the Communications Act

AGENCY: Federal Communications Commission.

ACTION: Rules of agency procedure and practice.

SUMMARY: This action establishes the procedures the Commission will use in implementing Public Law 105–125 (enacted December 1, 1997), which added subsection (e)(6) to section 214(e) of the Communications Act of 1934, as amended (the Act). New section 214(e)(6) provides for the designation of eligible telecommunications carriers by the Federal Communications Commission (Commission) in certain limited circumstances for common carriers that are not subject to the jurisdiction of a state commission.

DATES: Effective January 5, 1998.

ADDRESSES: One original and five copies of all petitions and comments must be sent to Magalie Roman Salas, Secretary, Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554. Three copies also should be sent to Sheryl Todd, Universal Service Branch, Accounting and Audits Division, Common Carrier Bureau, 2100 M Street, N.W., 8th Floor, Washington, D.C. 20554. One copy must be sent to the Commission's contractor, International Transcription Service, 1231 20th Street, N.W., Washington, D.C. 20037, (202) 857–3800. 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, N.W., Washington, DC 20554. See the **SUPPLEMENTARY INFORMATION** section for electronic filing addresses.

FOR FURTHER INFORMATION CONTACT: Valerie Yates, Legal Counsel, Common Carrier Bureau, (202) 418–1500, or Cheryl Leanza, Common Carrier Bureau, (202) 418–7400. For additional information concerning the information collections contained in this Public Notice contact Judy Boley at 202–418–0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This information collection has been approved by OMB 3060–0810, expiration date of May 31, 1998. This Public Notice establishes the procedures the Commission will use in implementing Public Law 105–125 (enacted December 1, 1997), which added subsection (e)(6) to section 214(e) of the Communications Act of 1934, as amended (the Act). Public Law 105–125, 111 Stat. 2540 (1997). Section 214(e)(1) of the Act provides that common carriers designated as ''eligible telecommunications carriers'' are eligible to receive universal service support in accordance with section 254 of the Act. 47 U.S.C. secs. 214(e)(1) and 254; *see* Federal-State Joint Board on Universal Service, CC Docket No. 96–45, *Report and Order*, 62 FR 32862, June 17, 1997 (*Universal Service Order*). Section 214(e)(2) of the Act provides that state commissions shall designate eligible telecommunications carriers. *See* 47 U.S.C. sec. 214(e)(2). For purposes of the designation requirement, ''state commission'' is defined in section 3(47) of the Act as a ''commission, board, or official (by whatever name designated) which under the laws of any State has regulatory jurisdiction with respect to intrastate operations of carriers.'' 47 U.S.C. sec. 3(47). Until its recent amendment, section 214(e) did not address how common carriers not subject to the jurisdiction of a state commission would be designated. New section 214(e)(6) provides for the designation of eligible telecommunications carriers by the Federal Communications Commission (Commission) in certain limited circumstances for common carriers that are not subject to the jurisdiction of a state commission. *See* 143 Cong. Rec. S12,568 (daily ed. Nov. 13, 1997) (stating that the amendment was intended to correct an ''oversight'' in the statute regarding certain carriers, such as tribally owned common carriers, that may fall outside the jurisdiction of a state commission and that the amendment ''does nothing to alter the existing jurisdiction that state commissions have over local exchange carriers or providers of commercial mobile radio services.''). We set forth herein the procedures that carriers must use in requesting such designation from the Commission. Any carrier that is able to be or has already been designated as an eligible telecommunications carrier by a state commission is not required to receive such designation from the Commission. We delegate to the Chief, Common Carrier Bureau, the authority to designate carriers as eligible telecommunications carriers, pursuant to section 214(e)(6).

Carriers seeking designation from the Commission pursuant to section 214(e)(6) must demonstrate that they fulfill the requirements of section 214(e)(1). Accordingly, carriers seeking designation from the Commission are instructed to file a petition that sets forth the following information:

1. A certification and brief statement of supporting facts demonstrating that the petitioner is ''not subject to the jurisdiction of a state commission''.

2. A certification that the petitioner provides all services designated for support by the Commission pursuant to section 254(c). To meet the requirements of section 214(e)(1) of the Act, a carrier must offer all of the services designated for support by the Commission pursuant to section 254(c). 47 U.S.C. sec. 214(e)(1)(A). The Commission has designated the following services for support: single-party service; voice grade access to the public switched network; Dual Tone Multifrequency (DTMF) signalling or its functional equivalent; access to emergency services including, in some circumstances, access to 911 and Enhanced 911 (E911); access to operator services; access to interexchange service; access to directory assistance; and toll limitation services for qualifying low-income consumers. *See Universal Service Order,* 62 FR 32862, June 17, 1997.

a. If the petitioner seeks an extension of time in order to implement the Commission's requirements to offer single-party service, access to E911, or toll-limitation services for