requirements of State or local laws or regulations.)

(n) *Director, OCHAMPUS.* The Director, OCHAMPUS, may establish other rules and procedures for the administration of the TRICARE Selected Reserve Dental Program.

Dated: May 12, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97–12871 Filed 5–15–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300490; FRL–5718–1]

RIN 2070-AB78

Emamectin Benzoate; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the insecticide emamectin benzoate: 4″-epi-methylamino-4″-deoxyavermectin B1 benzoate in or on the raw agricultural commodities head and Napa (chinese) cabbage in connection with EPA's granting an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on head and Napa cabbage in Hawaii. The tolerance will expire and is revoked on December 31, 1998.

DATES: This regulation becomes effective May 16, 1997. Objections and requests for hearings must be received by EPA on or before July 15, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300490], 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–300490], must be submitted to: Public Information and Records Integrity Branch, Information Resources and Services 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–300490]. 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: Olga Odiott, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA. (703) 308-6418, e-mail: odiott.olga@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: The regulations governing section 18 require that the Agency publish a notice of receipt in the **Federal Register** and solicit public comment on an application for a specific exemption proposing the use of an unregistered chemical [40 CFR 166.24]. Emamectin benzoate is an active ingredient not currently found in any registered product. Accordingly, a notice of receipt of this request was published in the **Federal Register** on April 11, 1997. One comment was received regarding the requirement for a groundwater monitoring study. EPA is not requiring such study under section 18. Based on the available environmental fate data, the Agency has determined that the use proposed by this emergency exemption will not cause unreasonable adverse effects on the environment. 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 insecticide 4″-epi-methylamino-4″-deoxyavermectin B1 benzoate, also referred to in this document as emamectin benzoate, in or on head and Napa cabbage at 0.025 part per million (ppm). This tolerance will expire and be revoked by EPA on December 31, 1998. After December 31, 1998, 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.* Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under 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 tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Emamectin Benzoate on Head and Napa Cabbage and FFDCA Tolerances

The Hawaii Department of Agriculture has requested a specific exemption for the use of emamectin benzoate on head and Napa cabbage to control the diamondback moth (*Plutella xylostella*). The Applicant states that although there are numerous insecticides registered for use against the diamondback moth (DBM) on cabbage in Hawaii, these pesticides do not provide effective control. DMB has become resistant to most of these insecticides and label restrictions on others render their control inadequate for this pest. Growers using these products have experienced significant yield reductions due to feeding damage by DBM larvae. *Bacillus thuringiensis* (Bt) based insecticides were once very effective, but in 1990 scientists at the University of Hawaii documented DBM resistance to first generation Bt products; more recently these same scientists have documented a 20-fold resistance to Bt toxin CryIC. Based on these trends, it is expected that the DBM will quickly develop resistance to these second generation Bt products if they are overused. Alternative control practices include the use of tolerant cabbage varieties, natural enemy augmentation, and the application of overhead irrigation. Management programs incorporating these practices have been adopted by many cabbage growers; however the growers continued to experience moderate to excessive yield losses due to DBM injury. Thus, without an effective control such as emamectin benzoate, cabbage growers in Hawaii will likely suffer severe economic losses. EPA has authorized under FIFRA section 18 the use of emamectin benzoate on cabbage for control of the DBM. After having reviewed the submission, EPA concurs that emergency conditions exist for this state.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of emamectin benzoate in or on cabbage. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. This tolerance will permit the marketing of head and Napa cabbage treated in accordance with the provisions of the section 18 emergency exemption. 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 December 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on head and Napa cabbage after that date will not be unlawful, provided the pesticide is applied during the term of, and in accordance with all the conditions of, section 18 of 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.

EPA has not made any decisions about whether emamectin benzoate meets EPA's registration requirements for use on head and Napa cabbage or whether a permanent tolerance for this use would be appropriate. This tolerance does not serve as a basis for registration of emamectin benzoate 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 Hawaii 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 emamectin benzoate, 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% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

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

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. 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.

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.

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 emamectin benzoate are discussed below.

1. *Acute toxicity.* The Agency has determined that the NOEL of 0.075 mg/kg/day from a 15-day feeding study in mice should be used to evaluate acute dietary risk. At the lowest effect level (LEL) of 0.10 mg/kg/day, there were clinical signs of tremors and histological evidence of degenerative effects in the sciatic nerve. This acute dietary risk assessment evaluates neurological risks to all population subgroups.

2. *Short- and intermediate-term dermal and inhalation toxicity.* The Agency has determined that a NOEL of 2.4 mg/kg/day from a 21-day dermal toxicity study in rabbits should be used to assess risks from short and intermediate-term dermal toxicity. At the LEL of 6.0 mg/kg/day, there were axonal degenerative lesions in the sciatic nerve and spinal cord. For the short- and intermediate-term inhalation toxicity, the Agency has determined that a NOEL of 0.075 mg/kg/day from the 15-day feeding study in mice [same study used in the acute dietary risk assessment] should be used to assess risks for occupational scenarios since no suitable inhalation toxicity study is available. At the LEL of 0.10 mg/kg/day, there were tremors, and histological degenerative effects in the sciatic nerve.

3. *Chronic risk.* The Agency has established a provisional RfD for emamectin benzoate at 0.000083 mg/kg/day. The provisional RfD was based on one-year and 90-day feeding studies in dogs with a NOEL of 0.25 mg/kg/day and an uncertainty factor of 3000 based on severe neurological effects, the steep dose response in the dog studies, data gaps in the chronic studies in mice and rats, and the extra-sensitivity for infants and children which was seen in the developmental neurotoxicity study. At the LEL of 0.50 mg/kg/day, effects in both sexes consist of axonal degeneration in the pons; medulla, sciatic, sural, and tibial; whole body tremors; stiffness of hind legs; spinal cord axonal degeneration; and muscle fiber degeneration in females. At the highest dose tested, 0.75 mg/kg/day, males were sacrificed after 7 weeks, and additional effects were mydriasis, cellular degeneration of retina, axonal degeneration of optic nerve, decreased body weight gain and decreased food consumption.

The Agency has also determined that a non-dietary chronic toxicity endpoint does not exist for emamectin benzoate and a chronic risk assessment is not required for occupational exposures.

4. *Cancer risk.* The carcinogenicity studies for emamectin benzoate have not been fully evaluated, therefore a cancer risk assessment is not possible at this time.

B. Exposures and Risks

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). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

1. *From food and feed uses.* Emamectin benzoate is not currently registered for food uses and no tolerances have been established. Risk assessments were conducted by EPA to assess dietary exposures and risks from emamectin benzoate as follows:

i. *Acute 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.

Since emamectin benzoate is not currently registered for food uses, the use proposed by this Section 18 is the only commodity considered in the acute dietary risk assessment. In conducting this risk assessment, the Agency used the tolerance value of 0.025 ppm and assumed 100% crop treated. Thus, the acute dietary risk estimates are considered conservative and therefore protective of any acute exposure scenario. The acute dietary risks from this proposed Section 18 use do not exceed the Agency's level of concern. The resulting MOEs for the different population subgroups ranged from 150 to 540. Further refinement using anticipated residue values and percent crop-treated data would result in lower acute dietary risk estimates.

ii. *Chronic risk.* For the chronic dietary risk assessment, the Agency used the tolerance value of 0.025 ppm, and assumed that all cabbage consumed in the U.S. will contain residues at the tolerance level. Thus, in making a safety determination for this tolerance, EPA is taking into account a conservative exposure assessment. With this Section 18 use of emamectin benzoate on cabbage, the TMRC estimates

represented 0% to 4% of the RfD (all TMRCs were <0.00001 mg/kg/day). The EPA has therefore concluded that the chronic dietary risks from the proposed Section 18 use do not exceed our level of concern.

2. *From drinking water.* No Maximum Concentration Level has been established for residues of emamectin benzoate in drinking water. No Health Advisory Levels for emamectin benzoate 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 (RfD's or acute dietary NOEL's) 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 exposure from contaminated water, the ranges the Agency is continuing to examine are all below the level that would cause emamectin benzoate to exceed the RfD if the tolerance being considered in this document is granted. The Agency has therefore concluded that the potential exposures associated with emamectin benzoate 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.* Emamectin benzoate is not currently registered for non-food uses.

C. 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 emamectin benzoate has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that emamectin benzoate has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* For the U.S. population, the calculated dietary (food only) MOE value is 250. This MOE value does not exceed the Agency's level of concern for acute dietary exposures. Despite the potential for exposure to emamectin benzoate from drinking water, EPA does not expect the aggregate acute risk (food + water) to exceed the Agency's level of concern.

2. *Chronic risk.* Using the conservative TMRC exposure assumptions described above, EPA has concluded that exposure to emamectin benzoate from food will utilize 1% of the RfD for the U.S. population. 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 emamectin benzoate 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 emamectin benzoate residues.

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

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 margin of exposure/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 margin of exposure/safety factor.

In assessing the potential for additional sensitivity of infants and children to residues of emamectin benzoate, EPA considered data from developmental toxicity studies in rats and rabbits, developmental neurotoxicity studies in rats, and a two-generation reproductive toxicity study in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during prenatal development. Reproduction studies provide information relating to pre- and post-natal effects from exposure to the

pesticide, information on the reproductive capability of mating animals, and data on systemic toxicity.

1. *Developmental toxicity studies.*—a. *Developmental toxicity study in rats.* The maternal (systemic) NOEL was 2 mg/kg/day, based on decreased weight gain at the lowest observed effect level (LOEL) of 4 mg/kg/day. The developmental (fetal) NOEL was 4 mg/kg/day, based on altered growth and extra ribs at the LOEL of 8 mg/kg/day.

b. *Developmental neurotoxicity study in rats.* The maternal (systemic) NOEL was 2.5 mg/kg/day. The developmental (pup) NOEL was 0.10 mg/kg/day [lowest dose tested], based on neurotoxicity findings at the LOEL of 0.60 mg/kg/day.

c. *Developmental study in rabbits.* The maternal (systemic) NOEL was 3 mg/kg/day, based on decreased weight gain and neurotoxicity at the LOEL of 6 mg/kg/day. The developmental (fetal) NOEL was 6 mg/kg/day [highest dose tested].

2. *Reproductive toxicity studies.*—a. *Reproductive toxicity study in rats.* The parental (systemic) NOEL was 0.6 mg/kg/day, based on neurological lesions and decreased weight gain at the LOEL of 1.8 mg/kg/day. The developmental (pup) NOEL was 0.6 mg/kg/day, based on neurological effects at the LEL of 1.8 mg/kg/day.

The reproductive NOEL was 0.8 mg/kg/day, based on decreased fecundity and fertility indices at the LEL of 1.8 mg/kg/day.

3. *Pre- and post-natal sensitivity.* Based on the results of the developmental neurotoxicity study for emamectin benzoate, the developmental findings [neurotoxicity], which may be due to pre- or/and post-natal extra-sensitivity, occurred in the absence of maternal effects. These results indicate extra-sensitivity for infants and children and an additional uncertainty factor of 3 was added to the provisional RfD due to these results.

Based on the reproductive toxicity study discussed above, for emamectin benzoate there does not appear to be a special sensitivity for post-natal effects. The NOELs and LOELs for both parental animals and offspring occur at the same doses of 0.6 and 1.8 mg/kg/day, respectively.

4. *Acute risk.* The acute dietary (food only) MOE for infants (< 1 year) was calculated to be 150, and that for children (1-6 years) was calculated to be 150. The acute dietary (food only) MOE for females 13+ years old (accounts for both maternal and fetal exposure) is 420. These MOE calculations are based on the NOEL (0.075 mg/kg/day) from a 15-day feeding study in mice. This risk assessment also assumed 100% crop-treated with tolerance level residues on all treated crops consumed, resulting in an over-estimate of dietary exposure. Despite the potential for exposure to emamectin benzoate in drinking water, EPA does not expect the aggregate acute exposure (food + water) to result in an MOE of less than 100. The large acute dietary MOE calculated for females 13+ years old provides assurance that there is a reasonable certainty of no harm for both females 13+ years and the pre-natal development of infants.

5. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that the percent of the RfD that will be utilized by dietary (food only) exposure to residues of emamectin benzoate ranges from 0% for non-nursing infants less than one year old, up to 1% for non-nursing infants (<1 year old), children (1-6 years old), and children (7-12 years old). Despite the potential for exposure to emamectin benzoate in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to emamectin benzoate residues.

V. Other Considerations

A. Metabolism in Plants and Animal

Plant metabolism studies for emamectin benzoate on cabbage, head lettuce, and sweet corn have been submitted to the Agency, however, the studies have not been fully evaluated to determine the residue(s) of concern. For the purposes of this Section 18, the regulated residues of concern are the parent compound emamectin benzoate (including the 4″hylamino-4″-deoxyavermectin B1A and the 4″-epi-methylamino-4″-deoxyavermectin B1B components), its delta-8,9-isomer, and the degradation products 4″-deoxy-4″-epi-(N-formyl)-avermectin B1, 4″-deoxy-4″-epi-(N-formyl-N-methyl)-avermectin B1, and 4″-deoxy-4″-epi-amino avermectin B1.

B. Analytical Enforcement Methodology

There is a practical analytical method for detecting and measuring levels of emamectin benzoate in or on cabbage with a limit of detection that allows monitoring of food with residues at or above the level set in this tolerance. The method has undergone succesful independent laboratory validation, but has not been forwarded to the EPA Analytical Chemistry Laboratory pending EPA's determination of emamectin benzoate regulable residues of concern.

C. Magnitude of Residues

Regulable residues of emamectin benzoate are not expected to exceed 0.025 ppm in/on cabbage as a result of this Section 18 use. Secondary residues are not expected in animal commodities as no feed items are associated with this Section 18 use.

D. International Residue Limits

No CODEX, Canadian, or Mexican maximum residue limits/tolerances have been established for emamectin benzoate at this time.

VI. Conclusion

Therefore, a tolerance in connection with the FIFRA section 18 emergency exemptions is established for residues of emamectin benzoate in or on head and Napa cabbage at 0.025 ppm.

VII. Objections and Hearing Requests

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

Any person may, by July 15, 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 control number [OPP–300490]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 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 (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. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations 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).

List of Subjects in 40 CFR Part 180

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

Dated: May 8, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR Chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.505 is added to read as follows:

§ 180.505 Emamectin benzoate; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* A time-limited tolerance is established for residues of the insecticide emamectin benzoate: 4″-epi-methylamino-4″-deoxyavermectin B1 benzoate in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance will expire and is revoked on the date specified in the following table.

Commodity	Parts per million	Expiration/ Revocation Date
Cabbage (head and Napa)	0.025	December 31, 1998.

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

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

[FR Doc. 97–12787 Filed 5–15–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300487; FRL–5716–8]

Carbon Disulfide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the nematicide, insecticide, and fungicide, carbon disulfide (Chemical Code Number 16401 and CAS Number 75–15–0), in or on the food commodities almond nutmeat, almond hulls, peaches, and plums (fresh prunes) from the application of sodium tetrathiocarbonate (Chemical Code Number 128904 and CAS Number 7345–69–9). Entek Corporation submitted a petition to EPA under the