

Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

B. Executive Order 12875

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

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

C. Executive Order 13084

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

13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

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

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

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 31, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

2. In § 180.418, the table in paragraph (a)(1) is amended by alphabetically adding the commodity to read as follows:

§ 180.418 Cypermethrin; tolerances for residues.

(a)(1)* * *

Commodity	Parts per million
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Onions, green	6.0
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[FR Doc. 98-24472 Filed 9-10-98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300685; FRL-6017-9]

RIN 2070-AB78

Metolachlor; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of metolachlor and its metabolites determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound in or on grass forage and grass hay. 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 grass grown for seed in Oregon. This

regulation establishes maximum permissible levels for residues of metolachlor in these feed commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire and are revoked on December 31, 1999.

DATES: This regulation is effective September 11, 1998. Objections and requests for hearings must be received by EPA on or before November 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300685], 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-300685], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #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-300685]. 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: Andrea Beard, 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) 308-9356, e-mail: beard.andrea@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 combined residues of the herbicide metolachlor and its metabolites determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, in or on grass forage at 10 part per million (ppm), and grass hay at 0.2 ppm. These tolerances will expire and are revoked on December 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

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

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

infants and children from aggregate exposure to the pesticide chemical residue. . . ."

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

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

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

II. Emergency Exemption for Metolachlor on Grass Grown for Seed and FFDCA Tolerances

Because of cancellation of several herbicide uses in recent years, a shift in weed populations and the development of resistance, plus restrictions imposed on open field burning, grass growers are no longer able to control weeds adequately with registered materials and cultural methods. The Applicants claim that if weeds are not adequately controlled, growers will incur significant economic losses due to reduced yields, and from losses due to contaminated seed, and replanting of fields that do not meet certification requirements. The Applicant proposed use of metolachlor, in conjunction with several other herbicides, to comprise a comprehensive management system to solve the current weed control problems in grass seed production. EPA has authorized under FIFRA section 18 the use of metolachlor on grass grown for seed for control of weeds in Oregon. 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 metolachlor in or on grass hay and forage. In doing so, EPA considered the new safety standard in FFDCA section

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

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether metolachlor meets EPA's registration requirements for use on grass grown for seed or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of metolachlor by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Oregon 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 metolachlor, 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 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

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

carcinogenic response and the Agency's knowledge of its mode of action.

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

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

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enactment 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 subgroups (non-nursing infants <1 year old, and children 1 to 6 years old) were 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 metolachlor and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of metolachlor and its metabolites in/on grass forage at 10 ppm, and grass hay at 0.2 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

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

1. *Acute toxicity.* EPA scientists have determined that available data do not indicate that there is potential for adverse effects after a single dietary exposure. Therefore, acute risk assessments were not conducted.

2. *Short - and intermediate - term toxicity.* For intermediate-term dermal risk assessment, the NOEL of 100 milligrams/kilogram/day (mg/kg/day) from the 21-day dermal toxicity study in rats is to be used. At the lowest effect level (LEL) of 1,000 mg/kg/day, there were dose-related increases in minor histopathological alterations of the skin, in total bilirubin (females), in absolute and relative liver weights (males), and in relative kidney weights (females). An inhalation exposure intermediate-term hazard was not identified. The EPA has determined that the available data do not indicate the potential for adverse

effects from short-term dermal or inhalation exposures.

3. *Chronic toxicity.* EPA has established the RfD for metolachlor at 0.10 mg/kg bodyweight/day (bwt/day). This RfD is based on the results from the 1-year feeding study in dogs, with a NOEL of 9.7 mg/kg/day, and an uncertainty factor of 100, based on decreased body weight gain at the LOEL of 33 mg/kg/day.

4. *Carcinogenicity.* Under the EPA Guidelines for Carcinogen Risk Assessment, metolachlor has been classified as a Group C Chemical (possible human carcinogen), based on increased incidence of adenomas and combined adenomas/carcinomas in female rats. The structural relationship of metolachlor to acetochlor and alachlor was of concern to the OPP Carcinogenicity Peer Review Committee (CPRC). However, in light of new information on the relative metabolism of these chemicals, and since there was no supportable mutagenicity concern, the CPRC recommended the MOE approach for estimation of risk, using the NOEL of 15.7 mg/kg/day from the 2-year rat feeding study.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.368) for the combined residues of metolachlor and its metabolites, in or on a variety of raw agricultural commodities ranging from 0.02 ppm in various animal commodities, to 30 ppm in peanut forage and hay. Risk assessments were conducted by EPA to assess dietary exposures and risks from metolachlor 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. EPA scientists have determined that available data do not indicate that there is potential for adverse effects after a single dietary exposure. Therefore, acute risk assessment is not required.

ii. *Chronic exposure and risk.* In conducting this chronic dietary (food only) risk assessment, OPP used percent of crop treated data for selected crops, and assumed tolerance level residues in all commodities having metolachlor tolerances. These assumptions result in an overestimate of human dietary exposure, and thus this risk estimate should be viewed as conservative; further refinement using anticipated residue levels and additional percent crop treated values would result in lower exposure estimates. Based on the given assumptions, EPA has calculated

that dietary exposure to metolachlor will utilize 1.1 % of the RfD for the overall U.S. population. The major identifiable subgroups with the highest exposure are non-nursing infants <1 year old and children 1 to 6 years old, both at 2.3 % of the RfD. This is further discussed below in the section on infants and children. EPA generally has no concern for exposure 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 metolachlor in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is reasonable certainty that no harm will result from chronic aggregate exposure to metolachlor residues.

2. From drinking water.

Environmental fate studies indicate that metolachlor appears to be moderately persistent and ranges from being mobile to highly mobile in different soils. Data collected from around the US provides evidence that metolachlor leaches into ground water, occasionally at levels that exceed the Lifetime Health Advisory (HA) level of 100 ppb. Metolachlor is not yet formally regulated under the Safe Drinking Water Act; therefore, no enforcement Maximum Contaminant Level (MCL) has been established for it. Metolachlor also has relatively high health advisory levels (1-10 day HA level of 2,000 ppb and lifetime HA level of 100 ppb). Based on available data, it appears highly unlikely that maximum or short-term average metolachlor concentrations will exceed the 1-10 day HA levels of 2,000 ppb, or that annual average metolachlor concentrations will exceed the lifetime HA of 100 ppb anywhere. Additionally, to mitigate risk, additional label restrictions are being required under the Reregistration process, designed to minimize ground and surface water contamination.

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 metolachlor 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 metolachlor 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.

Metolachlor is currently registered for use on a number of residential non-food sites including ornamental plants and grasses, highway rights of way, and recreational areas. No indoor uses are registered.

i. *Acute exposure and risk.* EPA generally will not include residential or other non-dietary exposures as a component of the acute exposure assessment. Theoretically, it is also possible that a residential, or other non-dietary, exposure could be combined with the acute total dietary exposure from food and water. However, the Agency does not believe that aggregate multiple exposure to large amounts of pesticide residues in the residential environment via multiple products and routes for a one day exposure is a reasonably probable event. It is highly unlikely that, in one day, an individual would have multiple high-end exposures to the same pesticide by treating their lawn and garden, treating their house via crack and crevice application, swimming in a pool, and be maximally exposed by the food and water consumed. Additionally, the concept of an acute exposure as a single exposure does not allow for including post-application exposures, in which residues decline over a period of days after application. Therefore, the Agency believes that residential exposures are more appropriately included in the short-term exposure scenario discussed below.

ii. *Short- and intermediate-term exposure and risk.* There are residential uses of metolachlor and EPA acknowledges that there may be short and intermediate-term non-occupational exposure scenarios. The EPA has identified a toxicity endpoint for intermediate-term residential risks. However, no acceptable reliable exposure data to assess the potential risks are available at this time. Based on

the high level of the intermediate-term toxicity endpoint (NOEL of 100 mg/kg/day, and LOEL of 1,000 mg/kg/day), the Agency does not expect the intermediate-term aggregate risk to exceed the level of concern. A short-term non-dietary toxicity endpoint was not identified for metolachlor.

iii. *Chronic exposure and risk.* The Agency has concluded that a chronic residential exposure scenario does not exist for non-occupational uses of metolachlor.

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

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

1. *Acute risk.* The available data for metolachlor do not indicate the potential for adverse effects from acute dietary exposures. Therefore, an acute aggregate risk assessment was not conducted.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to metolachlor from food will utilize 1.1 % of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants <1 year old, and children 1 to 6 years old, both at 2.3 % of the RfD; this is further discussed below. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to metolachlor 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 from aggregate exposure to metolachlor residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Based on the low percentage of the RfD occupied by the chronic dietary exposure (<3% for all population subgroups) and the high level of the intermediate-term toxicity endpoint (NOEL and LOEL of 100 and

1,000 mg/kg/day, respectively), in the best scientific judgment of EPA, the intermediate-term aggregate risk will not exceed the Agency's level of concern. Despite the potential for exposure to metolachlor in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD. Since a short-term toxicity endpoint was not identified for metolachlor, a short-term aggregate risk assessment was not conducted.

D. Aggregate Cancer Risk for U.S. Population

Based on the CPRC recommendation that the MOE approach be used to assess cancer risk, a quantitative cancer risk assessment was not performed. Based on the aggregate chronic dietary analysis (food only), the calculated MOEs for the U.S. population and infants/children are 15,000 and 6,800, respectively. Other than dietary exposure, no chronic exposure scenarios have been identified from registered uses of metolachlor. The EPA believes that the potential additional exposure in drinking water would not significantly lower the chronic dietary MOEs. The EPA has not yet established what an adequate MOE should be for chemicals having a non-linear mechanism for carcinogenicity. At this time, and for the purpose of this action only, the Agency concludes that the MOEs given above are adequate to ensure that there is a reasonable certainty that no harm to the U.S. population or to infants and children, will result from aggregate exposure to residues of metolachlor. When the Agency reaches a conclusion on the science policy issue of adequate MOEs for non-linear carcinogens, it is possible that the risk assessment for metolachlor may need to be revised.

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 metolachlor, 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 maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the

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

ii. *Developmental toxicity studies.* In the rat developmental study, the maternal NOEL was 300 mg/kg/day; mortality, increased salivation, lacrimation, convulsions, reduced body weight gain, and reduced food consumption were observed at the LEL of 1,000 mg/kg/day. The developmental NOEL was also 300 mg/kg/day, with reduced mean fetal body weight, reduced number of implantations, and a slight increase in resorptions, seen at the LEL of 1,000 mg/kg/day. In the rabbit developmental study, the maternal NOEL was 120 mg/kg/day, with lacrimation, miosis, reduced food consumption, and decreased body weight gain seen at the LEL of 360 mg/kg/day. No developmental effects were observed at the levels tested, and therefore the developmental NOEL was greater than 360 mg/kg/day (the highest dose tested (HDT)).

iii. *Reproductive toxicity study.* In the two-generation rat reproductive study, the reproductive/developmental toxicity NOEL of 23 mg/kg/day was less than the parental (systemic) toxicity NOEL of >76 mg/kg/day (HDT). The reproductive/developmental NOEL was based on decreased pup body weight during late lactation.

iv. *Pre- and post-natal sensitivity.* Based on current toxicological data requirements, the database for metolachlor relative to pre- and post-natal toxicity is complete. The developmental toxicity NOELs of 300 mg/kg/day (in rats) and >360 mg/kg/day (HDT tested in rabbits) demonstrate that there is not increased sensitivity to metolachlor by the developing fetus (pre-natal) in the presence of maternal toxicity. There was developmental toxicity in rats at 1,000 mg/kg/day (but

not in rabbits). The developmental NOELs are more than 30- and 37-fold higher in the rats and rabbits, respectively, than the NOEL of 9.7 mg/kg/day from the 1-year feeding study in dogs, which is the basis of the RfD. In the two-generation reproductive toxicity study in rats, the reproductive/developmental toxicity NOEL of 23 mg/kg/day was less than the parental (systemic) toxicity NOEL of >76 mg/kg/day. The reproductive/developmental NOEL was based on decreased pup body weight during late lactation and the NOEL occurred at a level which is below the NOEL for parental toxicity (>76 mg/kg/day). This finding suggests that pups are more sensitive to metolachlor than adult animals. For purposes of this Section 18 only, an additional 3-fold uncertainty factor was added to the RfD for infants and children.

v. Conclusion. The TMRC value for the most highly exposed infant and children subgroups (non-nursing infants <1 year old, and children 1 to 6 years old) occupies 6.9% of the RfD for both groups (with the additional 3-fold safety factor). This estimate should be viewed as conservative, since it is based on percent of crop treated data for selected crops and tolerance level residues for all commodities. Refinement of the dietary risk assessment by using additional percent crop treated and anticipated residue data would reduce dietary exposure estimates. Therefore, this risk assessment is an over-estimate of dietary risk.

2. Acute risk. The available data for metolachlor do not indicate the potential for adverse effects from acute dietary exposures. Therefore, no acute risk assessment was conducted.

3. Chronic risk. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to metolachlor from food ranges from 6.9 % for non-nursing infants <1 year old, down to 1.8 % for nursing infants <1 year old (using an additional three-fold safety factor). 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 metolachlor 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 metolachlor residues.

4. Short- or intermediate-term risk. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. A short-term non-dietary toxicity endpoint was not identified for metolachlor. Using the conservative exposure assumptions described above, EPA has concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of metolachlor is 6.9 % (using an additional 3 fold safety factor) for non-nursing infants <1 year old and children 1 to 6 years old (the most highly exposed population subgroups). Based on the low percentage of the RfD occupied by the chronic dietary exposure and the high level of the intermediate-term toxicity endpoint (NOEL = 100 mg/kg/day and LOEL = 1,000 mg/kg/day), in the best scientific judgment of EPA, the intermediate-term aggregate risk will not exceed the Agency's level of concern. Despite the potential for exposure to metolachlor in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants and animals is adequately understood. Tolerances for residues of metolachlor in or on food/feed commodities are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor ([2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide]) and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound (40 CFR 180.368)].

B. Analytical Enforcement Methodology

Adequate methods for purposes of data collection and enforcement of tolerances for metolachlor residues are available. Methods for determining the combined residues of metolachlor and its metabolites, as the derivatives CGA-37913 and CGA-49751, are described in PAM, Vol. II, as Method I (plants; Gas Chromatography (GC) with Nitrogen Phosphorus Detection(NPD)) and Method II (animals; GC-Mass Spectroscopy).

C. Magnitude of Residues

Residues of metolachlor are not expected to exceed 10 ppm in/on forage and 0.2 ppm in/on the hay of grass

grown for seed, as a result of this section 18 use. Secondary residues in animal commodities are not expected to exceed existing tolerances as a result of this section 18 use.

D. International Residue Limits

There are no established CODEX, Canadian, or Mexican residue limits for metolachlor on grass commodities.

E. Rotational Crop Restrictions

Fields in which certified grass seed is grown are not normally rotated to other crops; rotational crop restrictions are not required for this use.

VI. Conclusion

Therefore, the tolerance is established for combined residues of metolachlor and its metabolites, each expressed as the parent compound in grass forage and grass hay at 10 ppm and 0.2 ppm, respectively.

VII. Objections and Hearing Requests

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

Any person may, by November 10, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the

material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

VIII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300685] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia

address in "ADDRESSES" at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

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

B. Executive Order 12875

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

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

C. Executive Order 13084

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

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

In addition, since these tolerances and exemptions that are established under FFDCA section 408 (l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the

Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 14, 1998.

Arnold E. Layne,

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. In § 180.368, in paragraph (b), by alphabetically adding the following commodities to the table to read as follows:

§ 180.368 Metolachlor; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
Grass forage	10	12/31/99
Grass hay	0.2	12/31/99
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[FR Doc. 98-24471 Filed 9-10-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300701; FRL-6024-2]

RIN 2070-AB78

Bacillus Sphaericus; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the *Bacillus sphaericus* in or on all food commodities when applied/used in or on all food crops. Abbott Laboratories submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus sphaericus*.

DATES: This regulation is effective September 11, 1998. Objections and requests for hearings must be received by EPA on or before November 10, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300701], 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) 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-300701], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of

electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic 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 electronic objections and hearing requests must be identified by the docket number [OPP-300701]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Willie H. Nelson, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: 9th fl., Crystal Mall #2 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)308-8682 e-mail: Nelson.Willie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 22, 1997 (62 FR 44687) (FRL-5737-8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide tolerance petition by Abbott Laboratories, Sheridan Road, North Chicago, Illinois, 60064. This notice included a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus sphaericus*.

There were no comments received in response to the notice of filing, the data submitted in the petition and all relevant material have been evaluated.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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