APPENDIX A: SUMMARY OF ACCEPTABLE DECISIONS

[Aerosol Propellants]

ODS being replaced	Substitute	Decision	Comments
CFC–11, CFC–12, CFC–114, HCFC–22, HCFC–142b as aerosol propellant.	HFC–227ea	Acceptable	Despite the relatively high global warming potential of this compound, the Agency has listed this substitute as acceptable since it meets a specialized application in MDIs where other substitutes do not provide acceptable performance.

[FR Doc. 98–13125 Filed 5–21–98; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300658; FRL–5790–1]

RIN 2070–AB78

Hydroxyethylidine Diphosphonic Acid; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of hydroxyethylidine diphosphonic acid (HEDP), when used as an inert ingredient (stabilizer/ chelator) in antimicrobial pesticide formulations applied in or on raw agricultural commodities. Ecolab, Inc. requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170).

DATES: This regulation is effective May 22, 1998. Objections and requests for hearings must be received by EPA on or before July 21, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300658], 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–300658], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300658]. 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: Amelia M. Acierto, Registration Division (7505W), 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) 308–8377, e-mail: acierto.amelia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 17, 1997 (62 FR 66091) (FRL–5760–5), 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 petition (PP 7E4922) for a tolerance exemption by Ecolab Inc., 370 N. Wabasha Street, St. Paul, Minnesota 55102. This notice included a summary of the petition prepared by Ecolab Inc., the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(c) be amended by establishing an exemption from the requirement of a tolerance for residues of the inert ingredient hydroxyethylidine diphosphonic acid (HEDP), when used as an inert ingredient (stabilizer and chelator) in antimicrobial pesticide formulations used in or on raw agricultural commodities.

I. Risk Assessment and Statutory Findings

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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This hundredfold MOE is based on the same rationale as the hundredfold uncertainty factor.

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

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

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

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of the Food Quality Protection Act, 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 percent of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

II. 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 HEDP and to make a determination on aggregate exposure, consistent with section 408(b)(2), for an exemption from the requirement of a tolerance for residues of HEDP when used as an inert ingredient in antimicrobial pesticide formulations applied to raw agricultural commodities. EPA's assessment of the dietary exposures and risks associated

with establishing the tolerance exemption 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 HEDP are discussed below.

1. *Acute toxicity*. A rat acute oral study with an LD_{50} of 2,400 mg/kg.

2. *Genotoxicity*. HEDP was reported to be non-mutagenic in a *Salmonella*/ Mammalian microsome test or in a L5178Y TK mouse lymphoma cell point mutation assay, with and without mammalian microsomal activation.

3. *Subchronic toxicity*— i. *Dogs*. In a subchronic feeding study in beagle dogs (4 dogs/sex/dose), HEDP was administered at doses of 0, 1,000, 3,000, or 10,000 ppm for 90 days. The NOEL was 3,000 ppm (75 milligrams/ kilogram/day (mg/kg/day)) and the Lowest Observed Effect Level (LOEL) was 10,000 ppm (250 mg/kg/day based on decreased weight gain in females, and decreased testicular weight accompanied by evidence of bilateral focal degeneration of the testicular germinal epithelium in males.

ii. *Rats*. In a subchronic feeding study in rats, Sprague-Dawley strain rats were fed HEDP at dietary concentrations of 0, 3,000, 10,000 and 30,000 ppm for 90 days. The NOEL was 10,000 ppm (approximately 500 mg/kg/day) and the LOEL was 30,000 ppm (approximately 1,500 mg/kg/day) based on decreased body weight, decreased food consumption, slight anemia, and decreased heart, liver, and kidney weights.

4. *Developmental toxicity study*. In a developmental toxicity study, rabbits were administered HEDP at doses of 0, 25, 50 and 100 mg/kg/day, either incorporated into feed or by intubation with water. The NOEL for both systemic and developmental effects was 50 mg/ kg/day and the LOEL was 100 mg/kg/ day gavage dose based on decreased maternal weight gain/ food consumption and decreased fetal body weights.

5. *Reproductive toxicity study*. In a combined two-generation reproduction/ developmental toxicity study, rats (22 rats/sex/dose) were administered HEDP at doses of 0, 0.1, and 0.5 percent in the diet. The NOEL for developmental and reproductive findings was 50 mg/kg/day (0.1 percent in the diet) and the LOEL was 250 mg/kg/day (0.5 percent in the diet) based on reduced litter size in the first litter (F1a) and an increase in stillborn pups in the second liter (F1b). These effects occurred in the absence of maternal toxicity and were seen in both reproductive litters of the first generation.

B. Toxicological Endpoints

1. *Acute toxicity*. An acute dietary risk assessment is not required because no significant treatment-related effects attributable to a single exposure (dose) were seen in the oral studies conducted with HEDP.

2. *Short - and intermediate - term toxicity*. A short- and intermediate-term risk assessment is not required for HEDP since significant short- and intermediate- term exposures are not expected as a result of the proposed use pattern.

3. *Chronic toxicity*. EPA has established the RfD for HEDP at 0.05 mg/kg/day. This RfD is based on a reproductive/developmental toxicity study in rats with a NOEL of 50 mg/kg/ day. An uncertainty factor of 1,000 was used in the calculation of the RfD to account for intraspecies variability (tenfold uncertainty factor), interspecies extrapolation (tenfold uncertainty factor), lack of chronic toxicity/ carcinogenicity data (threefold uncertainty factor), and the additional sensitivity of infants and children (threefold uncertainty factor). The product of these four individual uncertainty factors results in an overall uncertainty factor of 1,000.

4. *Carcinogenicity*. A survey of the open literature has not revealed any studies as to the carcinogenicity of HEDP. Since HEDP has been determined to be nonmutagenic in genotoxicity testing and no preneoplastic lesions have been noted in any of the available animal or human test data, it is expected that the use of an additional threefold uncertainty factor in the chronic risk assessment of HEDP to account for the lack of carcinogenicity data should be protective of any possible cancer risk.

C. Exposures and Risks

1. *From food and feed uses*. Risk assessments were conducted by EPA to assess dietary exposures and risks from HEDP as follows:

i. *Acute exposure and risk*. Since there are no acute toxicological concerns for HEDP, an acute dietary risk assessment was not required.

ii. *Chronic exposure and risk*. For the purpose of assessing chronic dietary exposure from HEDP, EPA considered the proposed use of HEDP as a component of an antimicrobial pesticide formulation at a concentration not to exceed 1 percent of the formulation and a maximum use rate of the antimicrobial formulation used in fruit and vegetable wash water of 1 ounce/16.4 gallons of water. There are no established U.S. tolerances for HEDP, and there are no other registered uses for HEDP on food or feed crops in the United States. In conducting this exposure assessment, EPA assumed that residues of 1 part per billion (ppb) of HEDP would be present in all raw agricultural commodities, resulting in a large overestimate of dietary exposure and protective of any chronic dietary exposure scenario. (Limted data provided by the petitioner and prior estimations of dietary intake made by the U.S Food and Drug Administration (FDA) for the use of HEDP in antimicrobial applications to processed foods indicate that residues of HEDP in the treated commodities would be unlikely to exceed 1 ppb.) Based on the assumption that residues would be present at 1 ppb in all items consumed in the diet, it is estimated that the resultant dietary exposure would be 0.00004 mg/kg/day for adults (U.S. population) and 0.0001 mg/kg/day for children.

2. *From drinking water*— i. *Acute exposure and risk*. Since there are no acute toxicological concerns for HEDP, an acute drinking water risk assessment was not required.

ii. *Chronic exposure and risk*. For the purposes of assessing chronic exposure in drinking water, EPA has considered the current use of HEDP as an antiscalant in municipal drinking water treatment systems at a maximum concentration of 25 ppb in consumed water. Based on a typical average daily consumption of 2 liters of water/ day by adults and 1 liter water/day by children. The exposure to HEDP from drinking water exposure would not be expected to exceed 0.0007 mg/kg/day for adults and 0.0025 mg/kg/day for children.

3. *From non-dietary exposure*. Since there are no acute toxicological concerns for HEDP, an acute nondietary risk assessment was not required.

Chronic exposure and risk. While non-dietary exposure to HEDP as a result of its use in antimicrobial pesticide formulations applied to raw agricultural commodites is unlikely other uses of HEPD for which non-dietary exposure may result include its use in various personal care and over-the-counter pharmaceutical products. It is expected that the exposures associated with these uses would not exceed 0.0049 mg/kg/day for adults and 0.0204 mg/kg/day for children.

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

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

Using the extremely conservative exposure assumptions described above, EPA has concluded that aggregate exposure to HEDP from all pesticide and nonpesticide uses will not exceed 0.006 mg/kg/day for adults (12 percent of the RfD) and 0.023 mg/kg/day for children (46 percent of the RfD. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA does not expect the aggregate exposure to exceed 100 percent of the RfD. EPA therefore concludes that there is a reasonable certainty that no harm will result from aggregate exposure to HEDP residues.

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

Safety factor for infants and children. In assessing the potential for additional sensitivity of infants and children to residues of HEDP, 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 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. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the NOEL in the animal study appropriate to the particular risk assessment. This hundredfold uncertainty (safety) factor/MOE (safety) is designed to account for inter-species extraoplation and inter-species variability. EPA believes that reliable data support using the hundredfold margin/factor, rather than the thousandfold margin/factor, when EPA has a complete data base under existing guidleines, and when the severity of the effect in infants or children, the potency or unusual toxic properties of a compound, or the quality of the exposure data do not raise concerns regarding the adequacy of the standard margin/factor.

The following factors support retention of a tenfold uncertainly factor: (i) The reproductive effects were observed at dose levels in which there was no apparent maternal toxicity, (ii) the study was not conducted in accordance with OPP's Subdivision F (Hazard Evaluation: Humans and Domestic Animals) Pesticide Assessment Guidelines, and (iii) a prenatal developmental toxicity study of HEDP in rats conducted via the gavage route of administration was not available (the dietary developmental toxicity study in rats which was conducted as part of the reproductive study did not completely meet Subdivision F Pesticide Assessment Guideline requirements. However, the noted reproductive effects (decreased average number of live fetuses and increases in stillborn pups) were seen as separate, single litter events of the first generation but not of the second generation which would render less significance to a finding of a treatment-related effect. Taking into account that in this case there are study deficiencies not absent studies, the evidence of a reproductive effects in the absence of maternal toxicity is equivocal, and developmental effects were observed in rabbits at dose levels in which maternal toxicity was not observed, EPA has concluded that the tenfold uncertainty factor for infants and children should be reduced to a threefold uncertainty factor.

III. Other Considerations

A. Analytical Enforcement Methodology

The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for HEDP.

B. International Residue Limits

No Codex maximum residue levels have been established for HEDP.

IV. Conclusion

Therefore, an exemption from the requirement of a tolerance is established for residues of HEDP when used as an inert ingredient (stabilizer/ chelator) in antimicrobial pesticide formulations applied to raw agricultural commodites at a level not to exceed 1 percent of the antimicrobial pesticide formulation.

V. 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 21, 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.

VI. Public Docket and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300658] (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.

VII. Regulatory Assessment Requirements

This final rule establishes an exemption from the requirement of a tolerance 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).

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

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

List of Subjects in 40 CFR Part 180

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

Dated: May 8, 1998.

Peter Caulkins,

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 § 180.1001, in paragraph (c), the table is amended by alphabetically adding the inert ingredient ''hydroxyethylidine diphosphonic acid (HEDP)'' to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert ingredients	Limits	Uses
* * *	* * *	*
Hydroxyethylidine diphosphonic acid (HEDP) (CAS Reg. No. 2809–21–4).	For use in antimicrobial pesticide formulations at not more than 1 percent.	Stabilizer, chelator
* * *	* * *	*

* * * * *

[FR Doc. 98–13603 Filed 5–21–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300659; FRL–5790–3]

RIN 2070–AB78

Bacillus Thuringiensis Subspecies tolworthi Cry9C Protein and the Genetic Material Necessary for its Production in Corn; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule amends an exemption from the requirement of a tolerance for resid ues of the insecticide, *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein and the genetic material necessary for its production in corn for feed use only; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed. Plant Genetic Systems (America), Inc. submitted a petition to the EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996 requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this plant-pesticide in or on corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed.

EFFECTIVE DATE: This regulation is effective May 22, 1998. Objections and requests for hearings must be received by EPA on or before July 21, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300659], 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–300659], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may 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 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300659]. 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: Mike Mendelsohn, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location, telephone number, and e-mail: Room CS15–W29, 2800 Jefferson Davis Highway, Arlington, VA, 703–308–8715, e-mail: mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Plant Genetic Systems (America), Inc., 7200 Hickman Road, Suite 202, Des Moines, IA 50322 has requested in pesticide petition (PP 7F4826) the establishment of an exemption from the requirement of a tolerance for residues of the insecticide *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein and the genetic material necessary for its production in corn in or on all raw agricultural commodities. A notice of filing (FRL–5739–9) was published in the **Federal Register** (62 FR 49224, September 19, 1997), and the notice announced that the comment period would end on October 20, 1997; no comments were received. Plant Genetic Systems (America), Inc. submitted an amendment to their petition on April 24, 1998 to request the establishment of an exemption from the requirement of a tolerance for residues of the insecticide *Bacillus thuringiensis* subspecies *tolworthi* Cry9C protein and the genetic material necessary for its production in corn only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed. This exemption from the requirement of a tolerance will permit the marketing of feed corn containing the plant-pesticide; as well as meat, poultry, milk, or eggs resulting from animals fed such feed. The data submitted in the petition and all other relevant material have been evaluated. Following is a summary of EPA's findings regarding this petition as required by section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as recently amended by the Food Quality Protection Act (FQPA), Pub. L. 104–170.