Subpart R—Kansas

3. Subpart R is amended by adding an undesignated center heading and paragraph § 62.4177 to read as follows:

Emissions From Existing Municipal Waste Combustors With the Capacity To Burn Greater than 35 Megagrams Per Day of Municipal Solid Waste

§ 62.4177 Identification of plan—negative declaration.

Letter from the Kansas Department of Health submitted April 26 1996, certifying that there are no municipal waste combustors in the state of Kansas subject to part 60, subpart Cb of this chapter.

Subpart AA—Missouri

4. Subpart AA is amended by adding an undesignated center heading and paragraph § 62.6356 to read as follows:

Emissions From Existing Municipal Waste Combustors With the Capacity To Burn Greater than 35 Megagrams Per Day of Municipal Solid Waste

§ 62.6356 Identification of plan—negative declaration.

Letter from the Air Pollution Control Program of the Department of Natural Resources submitted June 3, 1996, certifying that there are no municipal waste combustors in the state of Missouri subject to part 60, subpart Cb of this chapter.

Subpart CC—Nebraska

5. Subpart CC is amended by adding an undesignated center heading and paragraph § 62.6912 to read as follows:

Emissions From Existing Municipal Waste Combustors With the Capacity To Burn Greater than 35 Megagrams Per Day of Municipal Solid Waste

§ 62.6912 Identification of plan—negative declaration.

Letter from the Air Quality Section of the Nebraska Department of Environmental Quality submitted May 13, 1996, certifying that there are no municipal waste combustors in the state of Nebraska subject to part 60, subpart Cb of this chapter.

[FR Doc. 97–20475 Filed 8–1–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300526; FRL–5735–6]

RIN 2070–AB78

Bacillus Cereus Strain BP01; 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 biological pesticide *Bacillus cereus* strain BP01 for use on cotton. Micro Flo Company, acting through their agent SRA International, submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus cereus* strain BP01 on growing crops.

DATES: This regulation is effective August 4, 1997. Objections and requests for hearings must be received by EPA on or before October 3, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300526], 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–300526], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may 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 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300526]. 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: James J. Boland, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: 5th fl., CS #1 2800 Crystal Drive, Arlington, VA 22202, (703) 308–8728, e-mail: boland.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 25, 1997 (62 FR 34277)(FRL–5727–1) EPA issued a notice pursuant to section 408(d), of the Federal Food Drug & Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition by SRA International, 1850 M Street NW., Suite 290, Washington DC, 20036, on behalf of the Micro Flo Company, P.O. Box 5948, Lakeland Florida 33807–5948. The notice contained 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 the biological pest control agent *Bacillus cereus* strain BP01 on growing crops.

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

The data submitted in the petition and other material have been evaluated. The toxicology data requirements in support of this exemption from the requirement of a tolerance were satisfied.

I. Risk Assessment and Statutory Findings

New section 408(c)(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(c)(2)(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(c)(2)(B) 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. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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. Additionally, 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.'' All available information indicates that *Bacillus cereus* strain BP01 when used in cotton will have no human toxicity based upon the lack of mammalian toxicity of this product and the lack of exposure with the cotton growth regulator use pattern. All mammalian toxicology data requirements have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.740 for microbial pesticides for food, non-food, domestic outdoor and forestry uses. The mammalian toxicology data base includes acute toxicity studies. To date, none of the active microbial pesticidal ingredients registered by the Agency have required subchronic or chronic exposure studies. Also, for food uses of microbial pesticides, the acute toxicity/pathogenicity studies have allowed for the conclusion that an exemption from the requirement of a tolerance is appropriate and adequate to protect human health, including that of infants and children. The results of testing done on *Bacillus cereus* and the end use product Mepichlor/BP01 4-2 agree with this.

III. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure*— a. *Food*. While the proposed use pattern will result in dietary exposure with possible residues on food and feed, negligible risk is expected for both the general population and infants and children. Submitted acute toxicology tests confirm that based upon the use sites, use patterns, application method, use rates, low exposure, and lack of significant toxicological concerns, the potential risks, if any, to humans are considered negligible and an exemption from the requirement of a tolerance is warranted. Acute exposure could occur from the proposed outdoor use sites but would be very low because of the low applications rates. The application rate is 2 to 24 fl.oz./A based on growth stage of the crop and previous application history. In considering health risk from microbial pesticides, it is important to recognize the ubiquitous nature of microorganisms. Most microorganisms are considered to be non-pathogenic for humans, despite the continual exposure to high numbers of a myriad of airborne, waterborne, food and soil associated microorganisms as well as human and mammalian commensal microbes on a daily basis. *Bacillus cereus* has been implicated in nosocomial infections in rare instances and in food poisoning incidents. The quality control procedures have ensured that the diarrheal enterotoxin is not present in this product. In summary, the Agency believes that the potential aggregate exposure, derived from dermal and inhalation exposure via mixing, loading and applying *Bacillus cereus*, the oral dietary exposure drinking water containing *B. cereus* strain BP01, should fall well below the currently tested microbial safety levels. There have been no confirmed reports of immediate or delayed allergic reactions to despite significant oral, dermal and inhalation exposure to the microbial product. Therefore, the lack of toxicity associated with *Bacillus cereus* strain BP01, data relating to the post application die-off of *B. cereus* species v background soil population counts of naturally occurring microbes provides a scientific rationale for exempting *B. cereus* strain BP01 from the requirement of a tolerance.

b. *Drinking water exposure*. The microorganism *Bacillus cereus* is ubiquitous in many soils throughout the world. *Bacillus cereus* is not known as an aquatic bacterium and therefore is not expected to proliferate in aquatic habitats. Although the potential exists for a minimal amount of the *B. cereus* strain BP01 which is applied to enter ground water or other drinking water sources, the amount would in all probability be undetectable or more than several orders of magnitude lower than those levels which were tested and are considered necessary for safety. Moreover, *Bacillus cereus* strain BP01 is not considered to be a risk to drinking water. Drinking water is accordingly not being screened for *B. cereus* as a potential indicator of microbial contamination or as a direct pathogenic contaminant. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to *B. cereus* strain BP01 through drinking water. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent.

2. *Other non-occupational exposures.* All mammalian toxicology data requirements have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.740 for microbial pesticides for food, non-food, domestic outdoor and forestry uses. The mammalian toxicology data base includes acute toxicity studies. Based on the use sites, use patterns, application method, use rates, low exposure, and lack of significant toxicological concerns, as demonstrated in the submitted toxicology studies, the potential risks, if any, to humans are considered negligible.

a. *Dermal exposure*. Exposure via the skin would be the primary route of exposure for mixer/loader applicators. Since unbroken skin is a natural barrier to microbial invasion of the human body, dermal absorption could occur only if the skin were cut, if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed. Based on the application methods, the potential for dermal

exposure exists for pesticide handlers and applicators. The Agency is requiring the appropriate signal word and statements of precaution.

b. *Inhalation Exposure*. Inhalation would be the primary route of exposure for mixer/loader applicators. The pulmonary study showed no adverse effects; the risks anticipated for this route of exposure are considered minimal.

IV. Safety Factors

The toxicity of *Bacillus sp*. is well established. No tolerance is needed since the proposed uses do not include food/feed uses. The information submitted to support the acute toxicity waiver requests, supplemented by available public data, indicate category IV for acute oral toxicity, category III for acute dermal toxicity, category III for primary eye irritation, category IV for primary dermal irritation, and that *Bacillus cereus* strain BP01 is not a dermal sensitizer. *Bacillus cereus* has been implicated in nosocomial infections in rare instances and in food poisoning incidents. The quality control procedures have ensured that the diarrheal enterotoxin is not present in this product.

V. Infants and Children

Consistent with section 408(b)(2)(C) of the FFDCA, EPA has assessed the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. A battery of acute toxicity/pathogenicity studies is considered sufficient by the Agency to perform a risk assessment for microbial pesticides. To date, none of the active microbial pesticidal ingredients registered by the Agency have required subchronic or chronic exposure studies. Also, for food uses of microbial pesticides, the acute toxicity/pathogenicity studies have allowed for the conclusion that an exemption from the requirement of a tolerance is appropriate and adequate to protect human health, including that of infants and children. The results of testing done on *B. cereus* strain BP01 and Mepichlor/BP01 4-2 agree with this. Quality control procedures in place during manufacturing ensure that harmful levels of contaminating microorganisms are prevented and the mammalian enterotoxin is not present. In considering health risk from microbial pesticides, it is important to keep the ubiquitous nature of microorganisms in mind. Most microorganisms are considered to be non-pathogenic for humans, despite the continual exposure to high numbers of a myriad of airborne, waterborne, food and soil associated microorganisms, as well as human and mammalian commensal microbes, on a daily basis.

VI. Other Considerations

1. *Endocrine disrupters*. There is no known metabolite that acts as an ''endocrine disrupter'' produced by this microorganism. As expected from non-pathogenic microorganism, the submitted toxicity/pathogenicity studies in the rodent (required for microbial pesticides) indicate that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. Therefore, no adverse effects to the endocrine or immune systems are known or expected. The Agency is not requiring information on the endocrine effects of this biological pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

2. *Analytical method*. The Agency proposes to establish 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 *Bacillus cereus* strain BP01.

VII. Determination of Safety for U.S. Population, Infants and Children

For the U.S. population, including infants and children, the Agency has not identified any subchronic, chronic, immune, endocrine, dietary, or nondietary exposure issues as they may affect infants and children and the general population. Risks to applicators are mitigated when the product is used according to label directions. Therefore, EPA concludes that there is reasonable certainty that no harm will result to the U.S. population from aggregate exposure to residues of *Bacillus cereus* BP01 microbial plant growth regulator including all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for *Bacillus cereus* strain BP01. Thus, a tolerance for *Bacillus cereus* strain BP01 is not necessary to protect the public health. Therefore, 40 CFR part 180 is amended as set forth below.

VIII. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) 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 October 3, 1997, 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 under the ''Addresses'' section (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(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (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 a 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(s) 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.

IX. Public Docket

A record has been established for this rulemaking under docket control number [OPP–300526]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Electronic comments can 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, is kept in paper form. Accordingly, in the event there are objections and hearing request, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in Addresses at the beginning of this document.

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement 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 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 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.

XI. 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: July 30, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

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

2. Section 180.1181 is added to read as follows:

§ 180.1181 Bacillus cereus strain BP01; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial plant regulator *Bacillus cereus* strain BP01 in or on cottonseed.

[FR Doc. 97–20561 Filed 8-1-97 ; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 74

Miscellaneous Amendments

AGENCY: Department of Health and Human Services, (HHS).

ACTION: Final rule.

SUMMARY: This final rule will remove appendixes I and J, which contain the text of Office Management and Budget (OMB) Circulars A–128 and A–133, from 45 CFR part 74. It will also update several items to conform them to the Federal Acquisition Streamlining Act of 1994 and correct a confusing statement which resulted from two typographical errors in that portion of OMB Circular A–110 upon which this statement is based.

EFFECTIVE DATE: This rule is effective September 3, 1997.

FOR FURTHER INFORMATION CONTACT: Charles Gale, Director, Office of Grants Management, 202–690–6377; for the hearing impaired only: TDD 202–690–6415.

SUPPLEMENTARY INFORMATION: Pursuant to the President's Regulatory Reform Initiative, we have identified appendixes I and J of 45 CFR part 74 as unnecessary. These appendixes are being removed because they simply repeat the texts of Circulars A–133 (an out-of-date version of the Circular) and A–128 respectively. In addition, various references to appendixes I and J are also being removed.

Copies of Circulars A–128 and A–133 are widely available electronically; they may also be obtained from OMB and from the HHS Office of Grants Management.

We are also making the following non-substantive changes and corrections:

1. We are updating the definition of ''small awards'' in section 74.2 and changing ''small purchase'' threshold to ''simplified acquisition'' threshold everywhere that it appears. These actions are to conform these terms to the Federal Acquisition Streamlining Act of 1994 (FASA) (108 Stat. 3243).