Landfill Gas Emissions From Existing Municipal Solid Waste Landfills

§ 62.10628 Identification of sources.

The plan applies to existing municipal solid waste landfills for which construction, reconstruction, or modification was commenced before May 30, 1991, that accepted waste at any time since November 8, 1987, or that have additional capacity available for future waste deposition, as described in 40 CFR part 60, subpart Cc.

[FR Doc. 98–33481 Filed 12–17–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300750; FRL–6040–5]

RIN 2070–AB78

Harpin; Temporary/Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a temporary/time-limited tolerance exemption for residues of the biological pesticide Harpin in or on all food commodities when applied for the broad spectrum control of various bacterial, fungal, and viral plant diseases. EDEN Bioscience Corporation submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) requesting the temporary/time-limited tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of Harpin. The tolerance exemption will expire on October 31, 2000.

DATES: This regulation is effective December 18, 1998. Objections and requests for hearings must be received by EPA on or before February 16, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300750], 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–300750], 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 (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 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300750]. 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: Diana M. Horne, 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) 308–8367, e-mail: Horne.Diana@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 1998 (63 FR 50903) (FRL–6026–1), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e) announcing the filing of a pesticide tolerance petition (PP 8F4975 and subsequently changed to 9G5043). 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 FQPA of 1996. The petition requested that 40 CFR part 180 be amended by establishing a temporary/time-limited tolerance exemption for residues of Harpin.

Two comments were received urging the issuance of the Experimental Use Permit (69834–EUP–1) and temporary tolerance exemption for Harpin protein. An additional commenter raised questions regarding whether adequate field testing has been done to justify the acreage requested in the EUP; the nature of Harpin protein and the inert ingredients used in the formulation; the nature, if any, of consequences to beneficial microflora and potential impacts on the development of pathogen resistance; and whether degradation data support the contention that residues are expected to be negligible. The Agency has received summaries on a subset of approximately 200 field trials conducted by the registrant on a broad range of crops in the United States, Mexico, and the Peoples Republic of China. Harpin proteins are generally heat stable, glycine-rich and, in nature, elicit defense mechanisms within the host plant. While specific inert ingredients utilized in pesticide formulations are considered confidential business information (CBI), those used in Harpin formulations are food grade materials, or contained in lists of inert ingredients cleared for food use by the Agency. Regarding the mechanism of action of Harpin protein on plant disease organisms, evidence has been presented which suggests no direct antimicrobial activity. Instead, the protein has been described in the published literature as inducing systemic acquired immunity, a coordinated cascade of defense reactions, within the host plant. Thus, Harpin has extremely limited potential for direct toxicity to pathogens or beneficial microorganisms, or for the development of pathogen resistance. Finally, environmental fate studies submitted in support of this temporary tolerance exemption indicate that the protein is UV-labile, and subject to degradation by proteases produced by ubiquitous microflora on leaf surfaces and in water. Degradation studies indicate a half-life of less than 48 hours where Harpin was applied at 30–40 times the proposed field rate. Moreover, using current detection methodology, the active ingredient was undetectable immediately following foliar application at standard rates.

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 exemption is ''safe.'' Section 408(c)(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. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide us in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of the 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.

Harpin is a naturally occuring protein derived from the plant pathogenic bacterium *Erwinia amylovora* (*E. amylovora*) , the causative agent for fire blight disease. Because of its role in plant host-parasite relationships, Harpin is presumed to have been present in *E. amylovora* for as long as the bacterium has been involved in the fire blight disease. As such, Harpin protein has been constantly produced and secreted by *E. amylovora* in or on edible fruits such as apple and pear with no apparent adverse effects on humans.

EDEN has conducted studies to evaluate the mammalian toxicology of the Harpin protein. The results of these studies indicate that Harpin is a Toxicity Category III substance and that it poses no significant human health risks. No toxicity was observed in either of the acute oral toxicity studies conducted with the Harpin technical grade active ingredient (TGAI) or a concentrated Harpin TGAI. Acute oral LD_{50} values for both Harpin protein technical and concentrated Harpin protein technical were greater than 2,000 mg/kg in the rat (Toxicity Category III based on the maximum dose administered). The 4–hour LC_{50} for Harpin was determined to be greater than 2 mg/L in an acute inhalation study with rats. EDEN has not observed any incidents of Harpin-induced hypersensitivity in individuals exposed to Harpin during research, production, and/or field testing. The Harpin end product produced minimally and mildly irritating results in the eye irritation and dermal irritation studies, respectively.

The proteinaceous nature of Harpin, in combination with its lack of acute toxicity, lends an additional measure of safety because when proteins are toxic, they are generally known to act via acute mechanisms and at very low dose levels. Therefore, because no significant adverse effects were observed, even at the limit doses, Harpin is not considered to be an acutely toxic protein.

III. Aggregate Exposures

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

A. Dietary Exposure

1. *Food*. Residues of Harpin protein were virtually undetectable within 3–10 days following application to treated plant surfaces and in water. Based on these preliminary studies and other submitted information, it is unlikely that appreciable Harpin residues would accumulate in the environment. Because of the low rate of application and rapid degradation of Harpin in the environment, residues of Harpin in or on treated raw agricultural commodities are expected to be negligible. Moreover, because Harpin exhibits no mammalian toxicity, any dietary exposure, if it occurred, would not be harmful to humans.

2. *Drinking water exposure.* Residues of Harpin are unlikely to occur in drinking water, due to the low application rate of the product and its rapid degradation in soil and water and on foliar surfaces.

B. Other Non-Occupational Exposure

The use pattern and acreage proposed for turf application may increase exposure to Harpin; however, with the demonstrated lack of mammalian toxicity and rapid environmental degradation of this protein, such exposure will not be harmful to humans.

IV. Cumulative Effects

Consideration of a common mode of toxicity is not appropriate, given that there is no indication of mammalian toxicity of Harpin protein and no information that indicates that toxic effects would be cumulative with any other compounds. Moreover, Harpin does not exhibit a toxic mode of action in its target pests or diseases.

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

Harpin's lack of toxicity has been demonstrated by the results of acute toxicity testing in mammals in which Harpin caused no adverse effects when dosed orally and via inhalation at the limit dose for each study. Thus, the aggregate exposure to Harpin over a lifetime should pose negligible risks to human health. Based on lack of toxicity and low exposure, there is a reasonable certainty that no harm to adults, infants, or children will result from aggregate exposure to Harpin residue. Exempting Harpin from the requirement of a tolerance should pose no significant risk to humans or the environment.

VI. Other Considerations

A. Endocrine Disruptors

Neither the Agency nor EDEN Bioscience Corporation has any information to suggest that Harpin will adversely affect the endocrine system.

B. Analytical Method(s)

An analytical method for residues is not applicable, since the petitioner has requested a temporary exemption from the requirement of a tolerance.

C. Codex Maximum Residue Level

There are no tolerances, exemptions from tolerance, or Maximum Residue Levels issued for Harpin outside of the United States.

VII. Objections and Hearing Requests

The new section 408(g) of the FFDCA 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)and 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 governs 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 February 16, 1999, 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.

VIII. Public Record and Electronic Submissions

A record has been established for this rulemaking under docket control number [OPP–300750]. 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 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 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 requests, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in ADDRESSES at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA 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 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 additions, since tolerance 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.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (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 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 to 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 officials 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.

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 the rule in the **Federal Register**. This is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: December 1, 1998.

Stephen L. Johnson

Deputy Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I, part 180 is amended as follows:

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

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

2. Section 180.1204 is added to read as follows:

§ 180.1204 Harpin protein; exemption from the requirement of a temporary tolerance.

The biological pesticide Harpin is exempted from the requirement of a temporary tolerance when applied under the terms of Experimental Use Permit 69834–EUP–1, for the broad spectrum control of various bacterial, fungal, and viral plant diseases when used on all food commodities. The exemption from the requirement of a tolerance will expire on October 31, 2000.

[FR Doc. 98–33629 Filed 12–17–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300766; FRL–6049–4]

RIN 2070–AB78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of the insecticide tebufenozide, benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl) hydrazide in or on eggs; grass, forage; grass, hay; hogs, fat; hogs, kidney; hogs, liver; hogs, meat; hogs, mbyp; peanuts; peanut, hay; peanuts, meal; peanut, oil; poultry, fat; poultry, meat; poultry, mbyp; rice, bran; rice, grain; rice, hulls; rice, straw; and sweet potatoes. 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 pasture land, peanuts, rice, and sweet potatoes. This regulation establishes maximum permissible levels for residues of tebufenozide in these food 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. These tolerances will expire and are revoked on December 31, 2000.

DATES: This regulation is effective December 18, 1998. Objections and requests for hearings must be received by EPA on or before February 16, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300766], 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–300766], 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 (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–300766]. 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: Barbara Madden, 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: CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6463, e-mail: Madden.barbara@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 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 tolerances for residues of the insecticide, tebufenozide in or on eggs at 0.01 part per million (ppm); grass, forage at 5 ppm; grass, hay at 18 ppm; hogs, fat at 0.1 ppm; hogs, kidney at 0.02 ppm; hogs, liver at 1 ppm; hogs, meat at 0.02 ppm; hogs, mbyp at 0.1 ppm; peanuts at 0.05 ppm; peanut, hay at 5 ppm; peanut, meal at 0.15 ppm; peanut, oil at 0.15 ppm; poultry, fat at 0.1 ppm; poultry, meat at 0.01 ppm; poultry, mbyp 0.05 ppm; rice, bran at 0.8 ppm; rice, grain at 0.1 ppm; rice, hulls at 0.5 ppm; rice, straw at 6 ppm; and sweet potatoes at 0.25. These