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 § 180.442, by amending the table under paragraph (b) by revising the entry for ''Raspberries'' to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* * *	* *	* *
Raspberries	3.0	12/31/99
* * *	* *	* *

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[FR Doc. 98–18279 Filed 7–9–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300665; FRL–5794–3]

RIN 2070–AB78

Gliocladium Catenulatum Strain J1446; 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 *Gliocladium catenulatum* strain J1446 in or on all agricultural commodities. Kemira Agro Oy 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 *Gliocladium catenulatum* strain J1446.

DATES: This regulation is effective July 10, 1998. Objections and requests for hearings must be received by EPA on or before September 8, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300665], 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 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–300665], 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 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300665]. 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: Susanne Cerrelli, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location and telephone number, and e-mail address: CM #2 Rm. 902 W48, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–8077, e-mail address: cerrelli.susanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 25, 1997 (62 FR 34271)(FRL–5721–7), EPA issued a notice pursuant to section 408(d), of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance petition by Kemira Agro Oy (PP 7F4137). 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 *Gliocladium catenulatum* strain J1446. There were no comments 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 via submitted data.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all 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 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...'' Additionally, section 408(b)(2)(D)(v) requires that 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.''

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.

All available information indicates that *Gliocladium catenulatum* strain J1446 is of low toxicity. Acute oral toxicity/pathogenicity, dermal irritation and eye irritation were classified toxicity category IV. Acute oral toxicity/pathogenicity limit test and acute pulmonary toxicity/pathogenicity tests were classified category III. *Gliocladium catenulatum* strain J1446 did not survive, replicate, infect, or produce disease in test animals injected with a single high dose of this microbial agent. No mechanism of toxicity was identified for *Gliocladium catenulatum*, therefore a common mechanism of human toxicity with other agents is not indicated, so no cumulative effects are considered.

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 groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure.* (a) *Food.* The use of *Gliocladium catenulatum* strain J1446 is not expected to result in any new dietary exposure to this organism. Fungi such as *Gliocladium catenulatum* strain J1446 are ubiquitous in the agricultural environment. It is anticipated that the concentrations of *Gliocladium catenulatum* on treated plants may be elevated immediately after application but will rapidly decline to environmental background levels. The risks anticipated for dietary exposure are considered minimal because no signs of toxicity were observed in the acute oral toxicity/pathogenicity studies (Toxicity Category IV).

(b) *Drinking water. Gliocladium catenulatum* strain J1446 is a naturally-occurring fungus and is widespread in the environment throughout the world. *Gliocladium catenulatum* is not known as an aquatic fungus, and therefore is not expected to proliferate in aquatic habitats. Moreover, *Gliocladium catenulatum* is not considered to be a risk to drinking water. Drinking water is accordingly not being screened for *Gliocladium catenulatum* 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 *Gliocladium catenulatum* through drinking water. Therefore, the potential of significant transfer to drinking water is minimal to non-existent.

2. *Other non-occupational exposure.* Other non-occupational exposure of *Gliocladium catenulatum* strain J1446 via residential and indoor uses of it as a pesticide, e.g., uses around homes, parks, recreation areas, will be minimal to non-existent. The risk from non-occupational exposure is considered minimal as there is no evidence of adverse effects from oral, dermal or inhalation exposure to this microbial agent.

(a) *Dermal exposure.* The risks anticipated for this route of exposure are considered minimal because no signs of dermal toxicity or irritation were observed in the acute dermal toxicity and irritation studies (Toxicity Category IV).

(b) *Inhalation exposure.* The risks anticipated for this route of exposure are considered minimal because this microbial agent did not exhibit toxicity and pathogenicity in the acute pulmonary toxicity/pathogenicity studies. (Toxicity Category III) The anticipated risks from aggregate exposure via dermal and inhalation are a compilation of two low risk exposure scenarios and are considered negligible.

IV. Other Considerations

1. *Endocrine disrupters.* The Agency has no information to suggest that *Gliocladium catenulatum* has an effect on the immune and endocrine systems. No specific tests have been conducted with *Gliocladium catenulatum* strain J1446 to determine such effects. However, as is expected from a non-pathogenic microorganism, the submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. There are no reports indicating that *Gliocladium catenulatum* strain J1446 produces any toxins or antibiotics. Therefore, it is unlikely that this organism would have estrogenic or endocrine effects because it has demonstrated low mammalian toxicity. 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 *Gliocladium catenulatum*.

3. *Codex Maximum Residue Level.* There are no CODEX tolerances nor international tolerance exemptions established for *Gliocladium catenulatum* strain J1446 at this time.

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

Based on all available information, the Agency concludes that *Gliocladium catenulatum* strain J1446 has no significant toxicity. Further, there is no evidence which suggests that aggregate exposure of either adults or infants and children to *Gliocladium catenulatum* leads to any harm. Accordingly, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population or any significant subpopulation, including infants and children, from aggregate exposure under this exemption.

FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of exposure (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 exposure will be safe for infants and children. Margins of exposure are often referred to as uncertainty (safety) factors. In this instance, the Agency believes there is reliable data to support the conclusion that this microbial agent is practically non-toxic to mammals, including infants and children, and, thus, there are no threshold effects; therefore, EPA has not used a margin of exposure approach to assess the safety of *Gliocladium catenulatum* strain J1446. As a result, the provision requiring an additional margin of exposure does not apply.

VI. 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 September 8, 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 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.

VII. Public Docket and Electronic Submissions

A record has been established for this rulemaking under docket control number [OPP–300665]. 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 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.

VIII. 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 and 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 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.

IX. 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 the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 24, 1998.

Stephen L. Johnson,

Acting 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.S.C. 346a and 371

2. Section 180.1198 is added to read as follows:

§ 180.1198 Gliocladium catenulatum strain J1446; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the microbial pesticide, *Gliocladium*

catenulatum strain J1446 when used in or on all food commodities.

[FR Doc. 98–18277 Filed 7–9–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300678; FRL–5798–6]

RIN 2070–AB78

Myclobutanil; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of myclobutanil in or on caneberries, and in or on dried hop cones. 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 caneberries in Oregon, and use of the pesticide on hops in Idaho, Oregon, and Washington. This regulation establishes a maximum permissible level for residues of myclobutanil 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. The tolerances will expire and be revoked on December 31, 1999.

DATES: This regulation is effective July 10, 1998. Objections and requests for hearings must be received by EPA on or before September 8, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300678], 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–300678], 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–300678]. 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: David Deegan, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308–9358, e-mail: deegan.dave@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for combined residues of the fungicide myclobutanil α-butyl-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile plus its alcohol metabolite α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile (free and bound), in or on caneberries at 1.0 part per million (ppm), and in or on dried hop cones at 5.0 ppm. These tolerances will expire and be revoked on December 31, 1999. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Authority

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

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

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

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

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