§ 52.222 Negative declarations.

(a) * * *

(6) * * *

(iv) Pharmaceuticals and Cosmetic Manufacturing Operations submitted on March 28, 2000 and adopted on January 18, 2000.

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(b) * * *

(4) * * *

(iii) Nitric Acid Units submitted on March 28, 2000 and adopted on January 18, 2000.

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[FR Doc. 00–27659 Filed 11–2–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301043; FRL–6740–9]

RIN 2070–AB78

Sodium *o*-nitophenolate, sodium *p*-nitrophenolate, sodium 5-nitroguaiacolate, and the End–Use Product Atonik® Exemption From the Requirement of a Tolerance and Temporary 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 the active ingredients (a.i.) sodium *o*-nitophenolate, sodium *p*-nitrophenolate, sodium 5-nitroguaiacolate, on all food commodities when used as Plant Growth Regulators on growing crops. These three a.i. comprise the end–use product ATONIK®, ASAHI Manufacturing Company, Ltd., c/o Chemical Consultants International, Inc., West 98th Terrace, Suite 100, Overland Park, KS, 66212, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium *o*-nitophenolate, sodium *p*-nitrophenolate, and sodium 5-nitroguaiacolate and reassess the three existing tolerances for those three a.i..

DATES: This regulation is effective November 3, 2000. Objections and requests for hearings, identified by docket control number OPP–301043, must be received by EPA on or before January 2, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301043 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Richard King, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8052; e-mail address: king.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301043. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of July 8, 1998 (63 FR 36901) (FRL–5791–6), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by the FQPA (Public Law 104–170) announcing the filing of a pesticide tolerance petition by ASAHI Manufacturing Company, Ltd., c/o Chemical Consultants International, Inc., West 98th Terrace, Suite 100, Overland Park, KS, 66212. This notice included a summary of the petition prepared by the petitioner ASAHI Manufacturing Company, Ltd. There were no comments received in response to the notice of filing.

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....'' Additionally, section 408(b)(2)(D) 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.

III. 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.

The Biopesticide and Pollution Prevention Division (BPPD) has reviewed submitted data to assess the potential hazards and exposures that might result from the proposed use of ATONIK® in or on all food commodities. The plant growth regulator will be formulated into an End–Use product containing a mixture of 0.6% a.i. sodium 5-nitroguaiacolate (1%), sodium *o*-nitophenolate (0.2%), and sodium *p*-nitrophenolate (0.3%) by weight and applied to all crops at rates of less than 20 grams a.i. (g a.i.) per acre. Based on the review of submitted information, dose levels and toxicity end–points were evaluated for the use of exposure estimates to characterize potential risks.

The Tier I data was submitted on the end–use product, ATONIK®, each of the three a.i., sodium *o*-nitrophenolate, sodium *p*-nitrophenolate, sodium 5-nitoguaiacolate, and a manufacturing use product (a mixture of the components). No toxicity endpoints for dietary, occupational or non–occupational risk charaterizations were indicated because:

1. The no–observed–adverse–effect levels (N0AEL) from dietary administration of the a.i. are 5–6 times higher than that of the developmental toxicity study (1,589 and 1,723 milligrams/kilograms/day (mg/kg/day) for males and females compared with 300 mg/kg/day in pregant rats).

2. The acute toxicity of the end–use product is classified into Toxicity Category IV for the oral (LD_{50} > 5,000 mg/kg) and inhalation (LC_{50} > 5.8 mg/L) routes and Toxicity Category III for the dermal route (LD_{50} > 2,000 mg/kg).

3. No developmental effects were noted at dose up to 600 mg/kg/day highest dose tested (HDT).

4. Studies on the three components of the manufacturing use product (MUP) showed no mutagentic activity.

5. The low concentration of the a.i. in the end use product (0.6%).

6. There is a low application rate (< 20 g a.i. per acre).

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

A. Dietary Exposure

No toxicity endpoints for dietary, occupational or non–occupational risk characterizations were indicated in subchronic toxicity, developmental toxicity or mutagenicity studies on ATONIK® or its three a.i.. The application rate is so low (< 20 g/acre) that negligible or nonexistent residues would be available for risk characterization. Therefore, considering the lack of toxicity and low exposure no risk characterizations have been conducted for ATONIK®.

1. *Food*. The end–use product, ATONIK®, contains three a.i. (sodium 5-nitroguaiacolate, sodium *o*-nitophenolate, and sodium *p*-nitrophenolate) in very low concentrations. At the application rates employed, the level of each a.i. which may be present in any of the food or feed items would be far below the levels which demonstrated any effects in the subchronic oral feeding study, the developmental toxicity study or the mutagenicity studies. It can be shown that in order to reach a dose rate comparable to the LOAEL of 1,600 mg/kg/day obtained in the subchronic oral feeding study, a person weighing 50 kg (100 lbs.) would have to consume all of the produce from 4 acres of crop every day.

Further, due to the rapid uptake and metabolism of the three a.i. in plants, it is unlikely that any of the residue would be available for potential exposure.

2. *Drinking water exposure*. Similarly, exposure to humans from consumption of water would be equally unlikely.

B. Other Non-Occupational Exposure

Using the previously mentioned criteria, the Agency believes that non–occupational exposures via other routes would be highly unlikely. There is no allowed use of the product containing the three a.i. on lawns, rights–of–way, golf courses, or other areas where human exposure is likely to occur. Therefore, for all practical purposes, exposure from these areas would be non–existent.

V. Cumulative Effects

Exposure through other pesticides and substances with the same mode of toxicity is not likely. What little toxicity that was observed is only detected at extremely high concentrations of these a.i..

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

The three a.i. in the End–Use Product, ATONIK®, are all classified as biochemicals. The low toxicity of each of these alone and in combination, as discussed above, demonstrates that these chemicals, at the rates established, will not pose any known risk to human health, either as children or as adults. These three a.i. are already exempted from the requirement of a tolerance for use on cotton, rice, and soybeans.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For

pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, sodium *o*-nitrophenolate, sodium *p*-nitrophenolate, and sodium 5-nitoguaiacolate, may be subjected to additional screening an/or testing to better characterize effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system–related effect have been identified.

B. Analytical Method(s)

Adequate data for the end–use product, ATONIK®, and each of the three components: sodium *o*-nitrophenolate, sodium *p*-nitrophenolate, and sodium 5-nitoguaiacolate, were submitted with the initial registration and petition for tolerances.

C. Tolerance Reassessment

The foregoing is a reassessment of the tolerances for § 180.1139 Sodium 5-nitoguaiacolate, and § 180.1140 Sodium o-nitrophenolate, and § 180.1141 Sodium p-nitrophenolate. This reassessment revises these tolerances to include all food commodities when used as plant growth regulators.

D. Codex Maximum Residue Level

No known international tolerances have been granted for this pesticide. Therefore, based on the completeness and reliability of the toxicity data from the published literature and conservative exposure assessment, the Agency concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of ATONIK® including all anticipated dietary exposure and all non–occupational exposures.

VIII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new 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 FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301043 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before January 2, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). 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). 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.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301043, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp–docket@epa.gov. Please use an ASCII file format and avoid 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 6.1/8.0 file format or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

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).

IX. 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* October 4, 1993 (58 FR 51735). 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) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* May 19, 1998 (63 FR 27655); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* February 16, 1994 (59 FR 7629); or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* April 23, 1997 (62 FR 19885). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d)(15 U.S.C. 272 note). 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* August 10, 1999 (64 FR 43255). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final 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: October 6, 2000.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division.

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. 321(q), 346(a) and 374.

2. In subpart D §180.1139, 180.1140, and 180.1141 are revised to read as follows:

§ 180.1139 Sodium 5-nitroguaiacolate; exemption from the requirements of a tolerance.

The biochemical sodium 5-nitroguiacolate is exempted from the requirement of a tolerance when used as a plant growth regulator in end–use products at a concentration of 0.1% by weight and applied at an application rate of 20 g of a.i. per acre or less per application, in or on all food commodities.

§ 180.1140 Sodium *o*-nitrophenolate; exemption from the requirement of a tolerance.

The biochemical sodium *o*-nitrophenolate is exempted from the requirement of a tolerance when used as a plant growth regulator in end–use products at a concentration of 0.2% by weight and applied at an application rate of 20 g of a.i. per acre or less per application, in or on all food commodities.

§ 180.1141 Sodium *p*-nitrophenolate; exemption from the requirement of a tolerance.

The biochemical sodium *p*-nitrophenolate is exempted from the requirement of a tolerance when used as a plant growth regulator in end–use product at a concentration of 0.3% by weight and applied at an application rate of 20 g of a.i. per acre or less per application, in or on all food commodities.

[FR Doc. 00–28277 Filed 11–2–00; 8:45 am]
BILLING CODE 6560–50–S

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA–D–7503]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the base (1% annual chance) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base flood elevations for new buildings and their contents.

DATES: These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) (FIRMs) in