(3) Description of incident.
(4) Date producer became aware of incident.
(5) Date of incident.
(6) Location of incident.
(d) Mail reports and questions to: Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460 or deliver reports and questions to: Crystal Mall #2, Room 910, 1921 Jefferson Davis Hwy., Arlington, VA.

Subparts E—F [Reserved]

Subpart G—Labeling [Reserved]

Subpart H—Data Requirements [Reserved]

Subpart I—[Reserved]

Subpart J—Good Laboratory Practices [Reserved]

Subpart K—Export Requirements [Reserved]

Subparts L—T [Reserved]

Subpart U—Experimental Use Permits [Reserved]

Subpart V—[Reserved]

Subpart W–Tolerances and Tolerance Exemptions

§ 174.451 Scope and purpose.

This subpart lists the tolerances and exemptions from the requirement of a tolerancefor residues of plant-incorporated protectants in or on raw agricultural commodities, in food, andin animal feeds.

Subpart X—List of Approved Inert Ingredients

§ 174.480 Scope and purpose.

This subpart lists the inert ingredients that have been exempted from FIFRA andFFDCA section 408 requirements and may be used in a plant-incorporated protectant listed insubpart B of this part.

§ 174.485 Inert ingredients from sexually compatible plant.

An inert ingredient, and residues of the inert ingredient, are exempt if all of the following conditions are met:
(a) The genetic material that encodes the inert ingredient or leads to the production of the inert ingredient is derived from a plant sexually compatible with the recipient food plant.
(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.
(c) The residues of the inert ingredient are not present in food from the plant at levels that are injurious or deleterious to human health.

Subparts Y—Z [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[OPP–300371B; FRL–6057–5]

RIN 2070–AC02

Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues of Nucleic Acids that are Part of Plant-Incorporated Protectants (Formerly Plant-Pesticides)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The substances plants produce for protection against pests, and the genetic material necessary to produce these substances, are pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if humans intend to use these substances for ''preventing, destroying, repelling or mitigating any pest.'' These substances, produced and used in living plants, along with the genetic material necessary to produce them, are also ''chemical pesticide residues'' under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA calls these substances along with the genetic material necessary to produce them, ''plant-incorporated protectants.'' In this final rule, EPA exempts from the FFDCA section 408 requirement of a tolerance, residues of nucleic acids that are part of a plant-incorporated protectant. Nucleic acids are ubiquitous in all forms of life, have always been present in human and domestic animal food and are not known to cause any adverse health effects when consumed as part of food. EPA believes there is a reasonable certainty that no harm will result from aggregate exposure to residues of nucleic acids that are part of a plant-incorporated protectant.

DATES: This regulation is effective September 17, 2001. Objections and requests for hearings must be received by EPA on or before September 17, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by regular mail, electronically, or in person. Follow the detailed instructions for the regular mail and in person methods in Unit II. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: By mail: Philip Hutton, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs (7511C), Environmental Protection Agency, 1921 Jefferson Davis Highway, Arlington, VA 22202; telephone number: (703) 308–8260; e-mail address: hutton.phil@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Document Apply to Me?

You may be potentially affected by this action if you are a person or company involved with agricultural biotechnology that may develop and market plant-incorporated protectants. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Pesticide manufacturers	32532	Establishments primarily engaged in the formulation and preparation of agricultural and household pest control chemicals
Seed companies	111	Establishments primarily engaged in growing crops, plants, vines, or trees and their seeds

Categories	NAICS codes	Examples of potentially affected entities
Colleges, universities, and professional schools	611310	Establishments of higher learning which are engaged in development and marketing of plant-incorporated protectants
Establishments involved in research and development in the life sciences	54171	Establishments primarily engaged in conducting research in the physical, engineering, or life sciences, such as agriculture and biotechnology

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 above could also be affected. The North American Industrial Classification System (NAIC) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicable provisions of 40 CFR part 174. 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/. To access information about the EPA's program for biopesticides go directly to the Home Page for the Office of Pesticide Programs at http://www.epa.gov/pesticides/biopesticides.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–300371B. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, 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.

C. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the Food Quality Protection Act (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(e) 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–300371B 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 September 17, 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 II., 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–300371B, 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).

III. Under What Authority is EPA Issuing this Final Rule?

This exemption from the requirement of a tolerance is being issued under the authority of section 408(c) of the FFDCA (21 U.S.C. 346a(c)). Under FFDCA section 408, EPA regulates pesticide chemical residues by establishing tolerances limiting the amounts of residues that may be present in or on food, or by establishing exemptions from the requirement of a tolerance for such residues. Food includes articles used for food or drink by humans or other animals. A food containing pesticide residues may not be moved in interstate commerce without an appropriate tolerance or an exemption from the requirement of a tolerance.

Section 408 of the FFDCA applies to all ''pesticide chemical residues'' which are defined as residues of either a ''pesticide chemical'' or ''any other added substance that is present on or in a commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical'' (21 U.S.C. 321(q)(2)). The FFDCA defines ''pesticide chemical'' as: ''any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide.'' (21 U.S.C. 321(q)(1)). FIFRA section 2(u) defines ''pesticide'' as: ''(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer'' (7 U.S.C. 136(u)). Under FIFRA section 2(t), the term ''pest'' includes ''(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other microorganism'' with certain exceptions (7 U.S.C. 136(t)).

Under FFDCA section 408(c), EPA can establish an exemption from the requirement of a tolerance for a ''pesticide chemical residue'' only if EPA determines that granting such an exemption is ''safe'' (21 U.S.C. 346a(c)(2)(A)(i)). The FFDCA 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'' (21 U.S.C. 346a(c)(2)(A)(ii)). This includes exposure through drinking water, and residential and other indoor uses, but does not include occupational exposure. In establishing an exemption from the requirement of a tolerance, FFDCA section 408(c) does not authorize EPA to consider potential benefits associated with use of the pesticide chemical in determining whether the pesticide chemical may be exempted.

FFDCA section 408 requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption 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'' (21 U.S.C. 346a(b)(2)(C)(ii)(I) and (c)(2)(B)). FFDCA section 408(b)(2)(D) specifies other general factors EPA must consider in establishing an exemption. FFDCA section 408(c)(3) prohibits an exemption unless there is either a practical method for detecting and measuring levels of pesticide chemical residue in or on food or there is no need for such a method, requiring EPA to state the reason for this determination (21 U.S.C. 346a(c)(3)).

IV. Context

A. What Role Does this Final Exemption Play in EPA's Approach toPlant-Incorporated Protectants?

The substances plants produce for protection against pests are pesticides under the FIFRA definition of pesticide, if humans intend to use these substances for ''preventing, destroying, repelling or mitigating any pest.'' These substances, produced and used in living plants, along with the genetic material necessary to produce them, are designated ''plant-incorporated protectants'' by EPA.

To understand the pivotal role this exemption plays in EPA's approach to plant-incorporated protectants, the two following considerations must be understood. First, the role nucleic acids

play in the concept of plant-incorporated protectant and how this exemption from the FFDCA requirement of a tolerance relates to this role. Second, how this exemption relates to the exemption from the FFDCA requirement of a tolerance published elsewhere in a companion document in this issue of the **Federal Register** for residues of the substance portion of plant-incorporated protectants derived through conventional breeding from sexually compatible plants.

1. *What role do nucleic acids play in the concept of plant- incorporated protectant and how does this role relate to this exemption?* The genetic material necessary for the production of a pesticidal substance is included in the definition of plant-incorporated protectant because the genetic material meets, in and of itself, the FIFRA section 2 definition of pesticide. A thorough discussion of why the genetic material is included in the definition of plant-incorporated protectant can be found in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants.

As noted in Unit III., section 408 of FFDCA applies to residues of pesticides in or on food or feed. (Hereafter, EPA will use the term ''in food'' in the preamble to represent the concept of ''in or on food or feed.'') Under section 408 of the FFDCA, the term residue is applied broadly to include residues of the pesticide itself and residues that are present in the food as a result of the metabolism or other degradation of the pesticide. EPA anticipates that for plant-incorporated protectants, the residues will consist of the pesticidal substance and any inert ingredient as defined for plant-incorporated protectants (e.g., any selectable marker), and the genetic material necessary for production of the pesticidal substance and any inert ingredient. In instances where the pesticidal substance is a nucleic acid (e.g., satellite RNA from plant viruses), EPA anticipates these residues will be the nucleic acid functioning as the pesticidal substance and the nucleic acid comprising the genetic material necessary for the production of the pesticidal substance (as well as any inert ingredient and the genetic material necessary to produce the inert ingredient). For anti-sense technology, EPA anticipates that these residues will consist of the the anti-sense RNA, and the DNA encoding the anti-sense RNA (as well as any inert ingredient and the genetic material necessary to produce the inert ingredient).

In developing its approach to plant-incorporated protectants, EPA recognized that nucleic acids are ubiquitous in all forms of life, including food plants. There is a long history of consumption by humans of nucleic acids in food and the Agency knows of no instance where nucleic acids have been associated with any toxic effects related to the consumption of food. It is therefore appropriate to exempt residues of nucleic acids that are part of a plant-incorporated protectant from the FFDCA section 408 requirement of a tolerance.

For EPA to exempt any residue of a pesticide, including any residue of a plant-incorporated protectant, from regulation under FFDCA section 408(e), EPA must find that there is a reasonable certainty that no harm will result from aggregate exposure to the residues, including all anticipated dietary exposures and all other exposures, for which there is realiable information. EPA is exempting in this action residues of nucleic acids that are part of plant-incorporated protectant active and inert ingredients, because it has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the residues, including all anticipated dietary exposures and all other exposures for which there is reliable information. This exemption from the requirement of a tolerance applies to the nucleic acid portion of all plant-incorporated protectants.

2. *How does this exemption relate to the exemption from the FFDCA requirement of a tolerance for the substance portion of plant-incorporated protectants derived through conventional breeding from sexually compatible plants?* This exemption can be paired with EPA's decision, published elsewhere in a companion document in this issue of the **Federal Register**, to exempt residues of pesticide chemical residues derived through conventional breeding from sexually compatible plants.

Because of these actions, all residues of plant-incorporated protectants derived through conventional breeding from sexually compatible plants are exempt from FFDCA section 408 requirements.

B. Does this Final Rule Have Any Relevance to Other Types of Pesticides?

Nonviable plant tissues, organs or parts that are used as pesticides, will not be covered by this exemption. Residues of such pesticides are subject to the regulations found in 40 CFR parts 177 through 180 rather than 40 CFR part 174. An example of this type of pesticide would be the powder, produced by drying and grinding cayenne pepper, dusted on plants to protect them from pests.

Residues of substances that are isolated from a plant's tissues and then applied to plants and/or to food for pest control will not be covered by this exemption. Residues of these types of pesticides in formulations such as those for foliar application are subject to regulations found in 40 CFR parts 177 through 180 rather than 40 CFR part 174. An example of this type of pesticide would be pyrethrum isolated from chrysanthemum plants, formulated with other ingredients for foliar application, and sprayed onto other plants for pest control.

Residues of substances that are synthesized will not be covered by this exemption. Residues of such pesticides are subject to regulations found in 40 CFR parts 177 through 180 rather than 40 CFR part 174. An example of this type of pesticide is the herbicide atrazine.

C. What is the History of this Final Rule?

This final rule is an additional step in fully implementing the ''Coordinated Framework for Regulation of Biotechnology'' of the United States of America which was published in the **Federal Register** by the Office of Science and Technology Policy (OSTP) on June 26, 1986 (51 FR 23302).

EPA sponsored, or cosponsored with other Federal agencies, three conferences dealing with plant related issues: On October 19–21, 1987, a meeting on ''Genetically Engineered Plants: Regulatory Considerations'' at Cornell University, Ithaca, New York; on September 8-9, 1988, a ''Transgenic Plant Conference'' in Annapolis, Maryland; on November 6–7, 1990, a conference on ''Pesticidal Transgenic Plants: Product Development, Risk Assessment, and Data Needs'' in Annapolis, Maryland. Information from these conferences has been incorporated as appropriate in development of this final rule.

In developing its approach to plant-incorporated protectants, EPA requested the advice of two scientific advisory groups in three meetings. On December 18, 1992, pursuant to section 25 of FIFRA, a subpanel of the FIFRA Scientific Advisory Panel (SAP) was convened to review a draft policy on plant-pesticides (now called plant-incorporated protectants) and to respond to a series of questions posed by the Agency primarily on EPA's approach under FIFRA. On July 13, 1993, EPA requested the advice of a subcommittee of the EPA Biotechnology Science Advisory Committee (BSAC) on a series of scientific questions dealing with approaches to plant-pesticides under FFDCA. On January 21, 1994, a

joint meeting of the subpanel of the SAP and the BSAC Subcommittee was held and EPA asked advice on EPA's approach to plant-pesticides under both statutes. Advice from these scientific advisory groups was considered in finalizing this final rule.

EPA published in the November 23, 1994 **Federal Register**, a package of five separate documents (59 FR 60496, 60519, 60535, 60542 and 60545) (FRL–4755–2, FRL–4755–3, FRL–4755–4, FRL–4755–5, FRL–4755–8) which described EPA's policy and proposals for plant-pesticides under FIFRA and FFDCA.

On July 22, 1996, EPA published a supplemental document in the **Federal Register** (61 FR 37891) (FRL–5387–4) on one aspect of its November 23, 1994, **Federal Register** document, i.e., how the concept of inert ingredient related to plant-pesticides.

In August of 1996, Congress enacted the FQPA which amended FFDCA and FIFRA. On May 16, 1997, EPA published in the **Federal Register** a supplemental document (62 FR 27132) (FRL–5717–2) to provide the public with an opportunity to comment on EPA's analysis of how certain FQPA amendments to FFDCA and FIFRA apply to the proposed exemption from the requirement of a tolerance for residues of nucleic acids that are part of a plant-pesticide.

On April 23, 1999, EPA published a supplemental document (64 FR 19958) (FRL–6077–6) in the **Federal Register** soliciting comment on whether to change the name of this type of pesticide.

The documents and the reports of the meetings described above are available in the official record for the rulemaking as described in Unit X.

V. What are the Key Features of the Proposed Exemption?

The development of this exemption consists of a proposed rule that appeared in the November 23, 1994, **Federal Register** (59 FR 60542) and two supplemental documents; one document that appeared in the July 22, 1996, **Federal Register** (61 FR 37891) and a second document that appeared in the May 16, 1997, **Federal Register** (62 FR 27142).

A. November 23, 1994, **Federal Register** *Proposed Rule*

In the November 23, 1994, **Federal Register** document, EPA proposed at 40 CFR 180.1138 to exempt residues of nucleic acids that are part of a plant-pesticide (now called a plant-incorporated protectant) from the requirement of a tolerance (59 FR 60542). Specifically, EPA proposed that ''residues of nucleic acids produced in living plants as part of a plant-pesticide active or inert ingredient, including both deoxyribonucleic and ribonucleic acids,'' would be exempt from the requirement of a tolerance. ''Nucleic acids'' were described as ''ribosides or deoxyribosides of adenine, thymine, guanine, cytosine, and uracil and the polymers of these ribosides and deoxyribosides and does not apply to nucleic acid analogues.''

''Active ingredient,'' when referring to plant-incorporated protectants only, was described as ''a pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant.''

''Inert ingredient,'' when referring to plant-incorporated protectants only, was described as ''any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient.''

The proposal to exempt nucleic acids that are part of a plant-incorporated protectant from the requirement of a tolerance was based on the ubiquity of nucleic acids in human and domestic animal food and the consumption of food containing nucleic acids without observed adverse health effects. Nucleic acids are widespread in foods and as part of a balanced diet, do not have toxic or pathogenic effects on animals or humans.

EPA also addressed in the proposal the status of nucleic acids used in anti-sense technology. In the proposal, EPA stated its belief that nucleic acids involved in this technology would qualify for the proposed exemption. The rationale used in the proposal to support exemption of naturally-occurring nucleic acids applies to nucleic acids used in anti-sense technology, as the anti-sense RNA and DNA are composed of the same naturally-occurring nucleic acids commonly found in living cells (ribosides or deoxyribosides of cytosine, guanine, adenine, thymine, and uracil).

In 1994, the Agency clearly stated that it was not proposing to exempt nucleic acid analogues from the requirement of a food tolerance. Certain nucleic acid analogues are being developed as therapeutic agents for human diseases (e.g., dideoxycytidine) and nucleic acid analogues could conceivably be developed and used as pesticides. These analogues are not naturally-occurring and those used as therapeutic agents frequently have significant toxicity associated with their use. The intent of EPA's 1994 proposal was to exempt only the naturally-occurring nucleic acids (ribosides or deoxyribosides of cytosine, guanine, adenine, uracil, and thymine) and polymers of such substances commonly found in living cells that serve as the mechanism of encoding traits associated with pesticidal substances produced by plants. The risk assessment supporting exemption for naturally-occurring nucleic acids does not support exemption of nucleic acid analogues (e.g., dideoxycytidine), or polymers containing such analogues.

B. What Issues Were Discussed in the Supplemental Documents?

1. *July 22, 1996.* On July 22, 1996, EPA published a supplemental document in the **Federal Register** (61 FR 37891) on one aspect of its November 23, 1994, **Federal Register** document, i.e., how the concept of inert ingredient related to plant-incorporated protectants.

2. *May 16, 1997.* In August of 1996, FFDCA and FIFRA were amended by the FQPA. On May 16, 1997, EPA published in the **Federal Register**, a supplemental document (62 FR 27142) to provide the public with an opportunity to comment on EPA's analysis of how certain FQPA amendments to FFDCA and FIFRA affect the proposed exemption from the requirement of a tolerance for residues of nucleic acids that are part of a plant-incorporated protectant.

EPA stated in the May 16 document its belief that most of the substantive factors that the FFDCA now requires EPA to consider in evaluating pesticides were considered when it proposed the exemption (59 FR 60542, November 23, 1994). EPA, thus, in the supplemental document, specifically sought comment only on its evaluation of the requirements imposed by FQPA that the Agency had not addressed in the proposal. EPA sought comment on the following five considerations. First, EPA's conclusion that there are no substances outside of the food supply that may have a cumulative toxic effect with residues of nucleic acids produced in plants as part of a plant-incorporated protectant. Second, EPA's conclusion that there are no additional substances outside the food supply that are related, via a common mechanism of toxicity, to residues of nucleic acids produced in plants as part of a plant-incorporated protectant, for which EPA must consider exposure in aggregate with

nucleic acids. Third, commenters who possess information on nucleic acids causing estrogenic effects were requested to send such information to EPA. Fourth, EPA described in greater detail the rationale supporting the statement made in the 1994 **Federal Register** document (59 FR at 60513) that ''plant-pesticides are likely to present a limited exposure of pesticidal substances to humans. In most cases, the predominant, if not the only route of exposure will be dietary. Significant respiratory and dermal exposures will be unlikely.'' No comments were received on this statement during the first comment period for the proposal. The public was given the opportunity to comment on EPA's more detailed rationale supporting the statement. Fifth, EPA also described in greater detail how the rationale presented in the 1994 **Federal Register** document (59 FR at 60538, November 23, 1994) concerning the safety for human consumption of food containing residues of nucleic acids produced in plants as part of a plant-incorporated protectant applies to infants and children. The public was given the opportunity to comment on EPA's more detailed rationale addressing infants and children as part of the larger human population.

VI. What are the Key Features of the Final Rule?

In this final rule, EPA exempts residues of nucleic acids that are part of a plant-incorporated protectant. The following language is added to 40 CFR 174.475:

> Residues of nucleic acids that are part of a plant-incorporated protectant are exempt from the requirement of a tolerance.

Definitions at 40 CFR 174.3 relevant to the language at 40 CFR 174.475 include:

''Nucleic acids'' means ribosides or deoxyribosides of adenine, thymine, guanine, cytosine and uracil; polymers of the deoxyribose-5'-monophosphates of thymine, cytosine, guanine, and adenine linked by successive 3'-5'-phosphodiester bonds (also known as deoxyribonucleic acid); and polymers of the ribose-5'-monophosphates of uracil, cytosine, guanine and adenine linked by successive 3'-5'-phosphodiester bonds (also known as ribonucleic acid). The term does not apply to nucleic acid analogues (e.g., dideoxycytidine), or polymers containing nucleic acid analogues.

Other definitions, relevant for plant-incorporated protectants only, can be found at 40 CFR 174.3 and are discussed in a companion document on FIFRA regulations published elsewhere in this issue of the **Federal Register**.

In this final rule, ''plant'' means an organism classified using the 5-kingdom classification system of Whittaker (Ref. 1) in the kingdom, Plantae. Therefore, the term ''plant'' includes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns, gymnosperms such as conifers, and angiosperms such as most major crop plants.

This exemption applies to the residues of genetic material necessary for the production of pesticidal substances in living plants, to residues of the genetic material necessary to produce any inert ingredient, to residues of nucleic acids used as the pesticidal substance (e.g., satellite RNA from plant viruses), and to residues of nucleic acids used in anti-sense technology. This exemption applies to naturally-occurring nucleic acids regardless of the sequence of the nucleic acid, the source of the sequence, or the function (e.g., template for a protein, or a regulatory element such as a promotor) the sequence encodes.

This final rule exempts only naturally-occurring nucleic acids, i.e., ribosides or deoxyribosides of adenine, guanine, cytosine, thymine, and uracil; polymers of the deoxyribose-5'-monophosphates of thymine, cytosine, guanine, and adenine linked by successive 3'-5'-phosphodiester bonds (also known as deoxyribonucleic acid); and polymers of the ribose-5'-monophosphates of uracil, cytosine, guanine and adenine linked by successive 3'-5'-phosphodiester bonds (also known as ribonucleic acid). It does not apply to nucleic acid analogues (e.g., didioxycytidine) or polymers containing nucleic acid analogues.

VII. How Do the Proposed Rule and Final Rule Differ?

This exemption from the requirement of a tolerance is adopted with a few changes from the proposed rule published in 1994 (59 FR 60545). EPA has changed the name of this type of pesticide from ''plant-pesticide'' to ''plant-incorporated protectant,'' as described in the companion document on FIFRA regulations for plant-incorporated protectants published elsewhere in this issue of the **Federal Register**.

Some modifications have been made to the text of the exemption and to associated definitions, for purposes of clarification. The definition of the term ''nucleic acids'' was modified to provide greater technical clarity; this modification does not change the scope of the exemption. These modifications are discussed in this document. A discussion of modifications to other relevant definitions, including an analysis of comments on those definitions, can be found in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants.

When EPA proposed this exemption at 40 CFR 180.1138 from the requirement of a tolerance in 1994, it also stated its intention (59 FR at 60520) to establish a new 40 CFR part 174 specifically for plant-incorporated protectants. This new 40 CFR part 174 is being established in a companion document published elsewhere in this issue of the **Federal Register**. EPA adds this exemption from the requirement of a tolerance in § 174.475, subpart W, rather than adding it to 40 CFR part 180 as proposed.

VIII. Discussion of Final Rule and Public Comments

In this unit, EPA discusses the final rule and summarizes the comments it received on the November 23, 1994, proposed rule and subsequent supplemental documents. EPA reviewed and considered all comments received on the proposed rule and the supplemental documents and prepared detailed responses to these comments, which can be found at appropriate points in this preamble in its discussion of the final rule and the statutory finding.

In addition to being addressed in this preamble, comments are also addressed in the Agency's summary of public comments and EPA's response on issues associated with plant-incorporated protectants (Ref. 2).

A. From Whom Did EPA Receive Comment?

In response to the package of documents published in the **Federal Register** in 1994, EPA received letters from industry, academia, professional and trade associations, government agencies, state regulatory authorities, public interest groups and private citizens. Some of the commenters sent separate letters for each of the five dockets associated with the 1994 **Federal Register** documents. Other commenters sent a single letter addressing all five dockets. On July 22, 1996, EPA published a supplemental document seeking comment on the concept of inert ingredient with regard to plant-incorporated protectants. EPA received comments on this supplemental document. On May 16, 1997, EPA published a supplemental document to provide the public an

opportunity to comment on EPA's analysis of how certain amendments to FFDCA and FIFRA by the FQPA affected this proposed exemption. EPA received comments on the supplemental document. Copies of all comments received are available in the official record for this final rule as described in Unit X.

B. Exemption of Residues of Nucleic Acids that are Part of a Plant-Incorporated Protectant

On November 23, 1994 (59 FR 60542), EPA proposed to exempt from the FFDCA requirement of a tolerance, residues of nucleic acids (i.e., deoxyribonucleic acid and ribonucleic acid) produced in plants as part of a plant-incorporated protectant active or inert ingredient.

During the comment period for the 1994 proposal, EPA received 17 comments. Almost all of these comments supported the proposed exemption. Commenters agreed that nucleic acids are abundant in all plants and that humans have been and are routinely exposed to large amounts of nucleic acids as a normal part of their diet. One commenter stated that EPA's proposed exemption from the requirement of a tolerance for nucleic acids is consistent with the position of the Food and Drug Administration (FDA) with regard to nucleic acids.

In response to the July 22, 1996, supplemental document, EPA received 14 comments on the concept of inert ingredient with regard to plant-incorporated protectants. None of these comments addressed the issue of inert ingredient with regard to this exemption. (Comments on other aspects of the concept of inert ingredient are discussed in a companion document published elsewhere in this issue of the **Federal Register** on FIFRA regulations for plant-incorporated protectants).

In response to the May 16, 1997, supplemental document, EPA received four comments. All four comments supported the exemption. One of the four commenters indicated they knew of no information on substances, having cumulative effects or common mechanisms of toxicity with residues of nucleic acids, that would have a bearing on this exemption from the requirement of a tolerance. No comments were received on the other considerations raised by EPA in the supplemental document.

C. What is the Language of the Exemption?

No comments on the language of the proposed exemption were received. EPA modified the language of the proposed exemption and the proposed definition of nucleic acids, however, for greater clarity. In this unit, EPA discusses those changes. EPA also discusses what ''nucleic acids'' means in the context of this exemption, and how EPA's decision on inert ingredients for plant-incorporated protectants affects this exemption.

1. *What does the term ''nucleic acid'' mean?* Genetic material, including genetic material necessary for the production of the pesticidal substance, is composed of nucleic acids. Chemically, there are two types of nucleic acids: Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) (Ref. 3). DNA is a polymer of purine and pyrimidine base deoxyribonucleoside monophosphates (also called deoxynucleotides) that are commonly referred to by the names of purine and pyrimidine bases: Adenine (A), cytosine (C), guanine (G), and thymine (T). A deoxynucleotide is made up of a sugar, a phosphate, and one of the four bases. In the DNA polymer, the sugars and phosphates of the deoxynucleotides are hooked together to form the ''backbone.'' One base is attached to each sugar in the sugar-phosphate backbone. RNA polymers are formed of similar linkages. RNA is a polymer of purine and pyrimidine base riboside monophosphates (also called nucleotides). The RNA nucleotides are also referred to by their base names: Adenine (A), cytosine (C), guanine (G), and uracil (U). In the RNA polymer, the sugar and phosphate moieties are also hooked together to form a backbone, with one base attached to each sugar moiety in the backbone. The information encoded in nucleic acids (either DNA or RNA) is determined by the sequence in which the bases are attached to the sugar-phosphate backbone (Ref. 3, 4). Nucleic acids encode all of the information necessary for the functioning of an organism. When a nucleic acid encoding a pesticidal substance is stably integrated into a plant, that plant and its progeny will, in most cases, have the potential to produce the pesticidal substance.

The ''nucleic acids'' of this exemption refer to the nucleic acids encoding the information for making polypeptides (proteins) which are the pesticidal substances or inert ingredients (e.g., selectable markers), or alternatively, encoding for proteins necessary for making (anabolizing) these substances. There may also be instances wherein nucleic acids may serve as the pesticidal substance. For example, satellite RNA of plant viruses may be used in strategies to control viral diseases in plants. In this situation, the RNA may be the pesticidal substance intended to control the pest. This exemption also applies to such RNA. This exemption for nucleic acids also applies to the DNA and RNA used in ''anti-sense'' technology, when this technology is used for pest resistance in plants. ''Anti-sense'' technology is used to block the production of a targeted enzyme or cellular component. In this technology, a segment of DNA encoding an RNA complementary (anti-sense) to the RNA necessary to produce the targeted enzyme or cellular component is introduced into the plant. For example, a company might wish to shut down an enzyme essential for pathogenesis by an agent that can cause disease in plants. To do so, the company would introduce into the genetic material of the plant, DNA encoding the anti-sense version of the RNA necessary to produce the targeted enzyme. The anti-sense version would bind to the normal version of the RNA necessary to produce the targeted enzyme. The normal (''sense'') version of the RNA would then no longer be available for processing in the cell, and, thus, the enzyme necessary for pathogenesis would not be produced. Because the essential enzyme cannot be produced, the disease-causing agent is not able to carry out one of the functions necessary for pathogenesis.

2. *What modifications were made to the language of the exemption?* In 1994, EPA proposed that residues of ''nucleic acids produced in living plants as part of a plant-pesticide active or inert ingredient, including both deoxyribonucleic and ribonucleic acids, are exempt from the requirement of a tolerance.'' In this final rule, EPA removes from the language of the exemption the phrase ''produced in living plants'' as this concept is part of the definition of plant-incorporated protectant. EPA was concerned that use of the phrase in the language of the exemption might cause some confusion because of this redundancy of concept. EPA also removed from the language of the proposed exemption, the phrase ''including both deoxyribonucleic and ribonucleic acids,'' also because of redundancy as the phrase appears in the definition of nucleic acids. Finally, EPA spelled out for greater technical clarity in the definition at 40 CFR 174.3 what substances are included in the concept of ''nucleic acids'' for plant-incorporated protectants, and what substances are excluded from the concept.

3. *How does the concept of inert ingredient relate to this exemption?* In the November 23, 1994, **Federal Register** document, EPA stated that an inert ingredient for plant-incorporated

protectants would be ''any substance, such as a selectable marker, other than the active ingredient, and the genetic material necessary for the production of the substance, that is intentionally introduced into a living plant along with the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient'' (59 FR 60521). In a companion document published elsewhere in this issue of the **Federal Register**, EPA describes its consideration of inert ingredients in light of existing regulations and comments received in response to both the November 23, 1994, **Federal Register** document (59 FR 60534) and the 1996 supplemental document (61 FR 37891, July 22, 1996) discussing the Agency's treatment of selectable markers as inert ingredients for plant-incorporated protectants. In the companion document published elsewhere in this **Federal Register**, EPA describes its determination that it will apply the concept of inert ingredients to plant-incorporated protectants consistent with the 1994 proposal.

The preamble discussion in the 1994 **Federal Register** document (59 FR at 60544) of the rationale supporting the proposed rule to exempt residues of nucleic acids from the requirement of a tolerance addressed the nucleic acids necessary to produce any substance, such as a selectable marker, used to confirm or ensure the presence of the active ingredient. The exemption at 40 CFR 174.475 contains language indicating the exempt status of residues of the genetic material necessary for the production such substances.

IX. Statutory Finding

A. What Methodology Did EPA Use to Assess these Residues?

For most pesticides (e.g., chemical pesticides), EPA's dietary risk evaluation relies on data generated by testing in laboratories using representative animal models to estimate acute, subchronic, or chronic hazard end-points (e.g., acute toxicity, carcinogenicity, developmental toxicity). Conclusions from animal models are used to assess dose-response and describe such endpoints for potential human hazard. Other information, including residue data and information generated by use of mathematical models, are used to develop human exposure estimates. These exposure and hazard components are combined to quantify the potential risk associated with the pesticide's use. Uncertainty factors are often used in the risk assessment to account for extrapolation from animal models to human toxicity and from limited studies using humans to the larger population. The data requirements describing the types of information to be generated and other guidance for assessing dietary risk are detailed in 40 CFR part 158.

The questions posed as part of the risk assessment in evaluating residues of most pesticides (e.g., chemical pesticides) can also be posed for pesticide chemical residues that are the subject of this exemption, and 40 CFR part 158 can be used as guidance in evaluating these substances for hazard end-points (including, for example, acute toxicity, carcinogenicity, and developmental toxicity). To address the hazard endpoints described in 40 CFR part 158 for residues of nucleic acids that are part of a plant-incorporated protectant, EPA relied on a very large body of information found for the most part in the public scientific literature. A very large body of experience with actual human dietary consumption, over hundreds if not thousands of years, exists for the substances that are the subject of this exemption. And thus, a large and varied amount of information developed through systematic scientific study exists in the literature that can be used for assessing the risk of exempting nucleic acids. For example, there are numerous epidemiological studies on humans on foods containing nucleic acids (Refs. 5, 6, 7, 8, 9, 10, 11, 12, and 13), as well as a large literature on constituents of food from plants accumulated by a century of systematic study (Ref. 4).

EPA also considered other information in the literature in evaluating the potential for exposure to residues of nucleic acids that are part of a plant-incorporated protectant. Plant-incorporated protectants are produced within the living plant itself and the pesticidal substance is used *in situ* in a living plant to protect against pests, in contrast to most other pesticides which must be applied to the plant or the area around the plant (Ref. 14). Because a plant-incorporated protectant is produced and used within the plant, physiological constraints limit the amount of residue produced by the plant (Ref. 14). Because a plant-incorporated protectant is within the plant, routes by which other organisms may be exposed to the plant-incorporated protectant may be more limited; e.g., dietary exposure is likely to be the predominant route of exposure.

EPA relied on data in the area of plant genetics to provide information and knowledge on the genetic material that is necessary for the production of the pesticidal substances (Ref. 3). The Agency used experimental data derived from the science of phytopathology to characterize the disease and pest resistance mechanisms known to occur in plants (Ref. 15). EPA also considered information from the field of plant physiology regarding plant metabolism, particularly the metabolism of nucleic acids in plants (Refs. 3 and 17). EPA also used information from the fields of biochemistry, microbial ecology and ecology (Refs. 3, 15, 17, and 21).

For this exemption, EPA's risk assessment was based primarily on information in the publically available scientific literature as well as through experience with breeding and growing agricultural plants, and preparing and consuming food from such plants. Such food contains nucleic acids, as nucleic acids are ubiquitous in nature and in the food supply (Ref. 4). In exempting residues in food of nucleic acids that are part of a plant-incorporated protectant from the requirement of a tolerance, EPA considered health risks to the general population, including infants and children. Infants and children have always and currently consume food containing nucleic acids. There is no evidence that nucleic acids, as components of food, present a different level of dietary risk for infants and children than they would for the adult population. EPA's risk assessment also included subgroups as part of the general population, (i.e., differences in diet due to the influence of culture), and allowed for consumption pattern differences of such subgroups.

EPA believes human experience in consuming food containing nucleic acids combined with the numerous epidemiological and other studies and the knowledge of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding are the appropriate considerations in evaluating the potential risks of residues of nucleic acids that are part of a plant-incorporated protectant. All of these bases of knowledge and experience were integral to EPA's assessment of exposures and hazards associated with residues of nucleic acids that are part of a plant-incorporated protectant.

B. What Factors Has EPA Considered in Making the Findings Required by 408(c) of the FFDCA?

FFDCA section 408(c)(2)(B) requires EPA to consider several factors in determining whether to exempt a pesticide from the requirement of a tolerance. Information relevant to EPA's consideration of these factors with regard to this exemption is contained in this document, as well as in other

documents in the record for this final rule as described in Unit X.

1. *Validity, completeness and reliability of available data.* As noted in Unit IX.A., EPA's risk assessment was based primarily on an analysis of human experience with breeding and growing agricultural plants, and preparing and consuming food from such plants, and associated epidemiological studies, nutritional assessments with human volunteers and animal model testing (Refs. 5, 6, 7, 8, 9, 10, 11, 12, 13). EPA combined this information with knowledge from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding (Refs. 3, 15, 17, and 21, for example) to evaluate the potential risks of residues of nucleic acids that are part of a plant-incorporated protectant. EPA considered the validity, completeness and reliability of all available information. EPA concluded that this information was valid, complete and reliable, and adequately addressed the issues of hazard and exposure with regard to residues of nucleic acids in food.

2. *Nature of toxic effect.* EPA considered the nature of any toxic effects shown by this information to be caused by residues of nucleic acids that are part of a plant-incorporated protectant active or inert ingredient. Nucleic acids are widespread in foods (Ref. 4) and are not associated with toxic effects on animals or humans (Ref. 4, 18). Neither nucleic acids nor the substances of which nucleic acids are composed are known to be acute toxicants, but like proteins and other normal constituents of food, may cause indirect, adverse metabolic effects if consumed exclusively at high doses over a long period of time in the absence of a balanced diet. A person consuming food from plants containing residues of nucleic acids would not be consuming nucleic acids exclusively, and nucleic acids do not occur at these high doses in food plants. Consumption of nucleic acids in food has not been associated with any toxic effects (Ref. 18). Thus, because the residues of nucleic acids that are part of a plant-incorporated protectant are no different than other nucleic acids, including those that have been safely consumed, consumption of food containing residues of nucleic acids that are part of a plant-incorporated protectant are not expected to present a toxic effect. Simiarly, the nucleic acids in food from plants have not been associated with pathogenic effects on humans or other animals (Ref. 16), and residues in food of nucleic acids that are part of a plant-incorporated protectant are not expected to have pathogenic effects on humans or other animals.

3. *Relationship of studies to humans.* EPA considered the available information concerning the relationship of this information on nucleic acids in foods to human risk. The effect of nucleic acids on humans was assessed in light of the known presence of nucleic acids in all foods (Refs. 3 and 4) and the long history of human consumption of plant food containing nucleic acids, i.e., food derived from crop plants and from animals that consume forage and other crops containing nucleic acids. The epidemiological studies supply data generated on humans and thus are directly applicable to humans. Information from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry (including studies on the constituents of food) and plant breeding can be used to predict effects on humans. Nucleic acids in foods do not have a toxic effect and cause no adverse effects to humans. Because information on human consumption of food containing nucleic acids was available and adequately addressed the issues of hazard and exposure, EPA relied primarily on the epidemiological and other information generated directly from humans rather than relying on data generated in the laboratory through animal testing.

4. *Dietary consumption patterns.* EPA considered the available information on the varying dietary consumption patterns of consumers and major identifiable consumer subgroups as it pertains to residues of nucleic acids that are part of a plant-incorporated protectant in food. Issuance of this exemption from the requirement of a tolerance is not expected to alter the current consumption pattern of nucleic acids by consumers or major identifiable consumer subgroups. Nucleic acids are ubiquitous in all living organisms and in the food supply; thus, no subgroup is likely to receive a greater exposure nor a different exposure than any other subgroup.

5. *Available information concerning cumulative effects of the pesticide chemical residue and other substances that have a common mechanism of toxicity.* EPA has examined the available information as described in Unit IX.A. and Unit IX.B.1., on the cumulative effect of residues in food of nucleic acids that are part of a plant-incorporated protectant, and other substances that may have a common mechanism of toxicity. Nucleic acids are widespread in food (Ref. 4) and have not been associated with direct toxic effects to animals or humans (Ref. 18). Because nucleic acids in foods have no human toxicity, no cumulative effects can be identified for residues of nucleic acids that are part of a plant-incorporated protectant. The FQPA also directs the Agency to examine whether there are other substances that have a common mechanism of toxicity with nucleic acids that are part of a plant-incorporated protectant. Based on available information which indicates that nucleic acids in food have no human toxicity, EPA is not aware of any other substances that might have a common mechanism of human toxicity with residues of nucleic acids that are part of a plant-incorporated protectant.

The four comments EPA received on the May 16, 1997, supplemental document all supported the exemption. One of the four commenters indicated they knew of no information on substances, having cumulative effects or common mechanisms of toxicity with residues of nucleic acids, that would have a bearing on the exemption from the requirement of a tolerance.

EPA is not aware of any substances outside of the food supply that may have a common mechanism of toxicity with nucleic acids that are part of a plant-incorporated protectant since nucleic acids in food are not toxic. EPA has identified nucleic acid analogues (e.g., dideoxycytidine, zidovudine, dideoxyinosine) as substances having some level of toxicity (Ref. 19, 20). However, the mechanisms of toxicity of such analogues are not cumulative with that of residues of naturally-occurring nucleic acids.

6. *Aggregate exposure of consumers including non-occupational exposures.* EPA considered the available information on the aggregate exposure level of consumers to residues of nucleic acids that are part of a plant-incorporated protectant and to other related substances including nucleic acids that are not part of a plant-incorporated protectant. This included a consideration of exposures from dietary sources as well as from other non-occupational sources. Plant-incorporated protectants and their residues are likely to present a limited exposure to humans.

Nucleic acids produced in living plants are part of the metabolic cycles of plants. They are biotic and thus subject to the processes of biodegradation and decay that all biotic materials undergo (Ref. 21). Biotic materials are broken down to constituent parts through the enzymatic processes of living organisms, and these constituent parts used as the building

blocks to make other biotic substances. Because of these characteristics, the potential for exposures to the residues to occur, beyond direct physical exposure to the plant, is limited.

The residues that are the subject of this exemption are biodegradable to their constituent elements through catabolism by living organisms (Ref. 21). Because of their biodegradable nature, residues of nucleic acids do not bioaccumulate (bioaccumulation occurs when a substance is taken into the body through processes such as eating, and as the body is unable to either break the substance down or eliminate it, the substance accumulates in the tissues) or biomagnify in the tissues of living organisms (biomagnification occurs when a substance bioaccumulates in the bodies of organisms lower in the food chain, and as predators higher in the food chain consume organisms lower in the food chain, more and more of the substance accumulates in the bodies of organisms higher in the food chain). Humans ingesting the nucleic acids in food are likely to quickly degrade them and use their constituent elements as nutrients.

In most cases, the predominant exposure route will be dietary. Exposure through other routes is unlikely because the substances are in the plant tissue and thus are found either within the plant or in close proximity to the plant. This is particularly true for residues of nucleic acids that are part of a plant-incorporated protectant, because large polymers are susceptible to rapid degradation. EPA expects non-dietary exposure (i.e., non-food oral, dermal and inhalation) in non-occupational settings to be negligible.

i. *Dietary exposure*. EPA considered dietary exposure to nucleic acids that are part of a plant-incorporated protectant. Nucleic acids are widespread in foods (Ref. 4), and all foods consumed by humans contain nucleic acids. As nucleic acids are ubiquitous in food, EPA concluded that all humans are exposed to nucleic acids throughout their lives as part of their diet. As described in Unit IX.A. and Unit IX.B.1., a large base of experience exists, including information on human dietary exposure, for foods that undoubtedly contain nucleic acids. Nucleic acids in food are not toxic and there is no evidence that consumption of nucleic acids in food leads to any harm.

ii. *Dermal exposure*. Residues of nucleic acids that are part of a plant-incorporated protectant may in some cases be present in sap or other exudates from the plant or the food, and, thus, may present some limited opportunity for dermal exposure to persons coming physically into contact with the plant or raw agricultural food from the plant. Individuals preparing meals are those most likely to experience dermal contact with the residues on a non-occupational basis. However, on a per person basis, the potential amounts involved in these exposures are likely to be negligible in comparison to potential exposure through the dietary route. Moreover, nucleic acids as they occur in food are unlikely to cross the barrier provided by the skin (Refs. 22 and 23). This is particularly true for residues of nucleic acids that are part of a plant-incorporated protectant as these nucleic acids, for the most part, exist in the plant as polymers (Refs. 22 and 23).

iii. *Inhalation exposure*. Residues of nucleic acids that are part of a plant-incorporated protectant may be present in pollen, and some individuals (e.g., those near enough to farms, nurseries or other plant-growing areas to be exposed to wind-blown pollen, or visiting such areas) may be exposed, through inhalation, to the pollen. On a per person basis, the potential amounts of pollen involved in these exposures are likely to be negligible in comparison to potential exposure through the dietary route. It is unlikely that exposure to the pollen is equivalent to exposure to residues of nucleic acids that are part of a plant-incorporated protectant. In pollen, residues of nucleic acids will likely be integrated into the tissue of the pollen grain. Pollen grains are solid, insoluble particles of sufficiently large diameter that they are filtered out in the nasopharynx or in the upper respiratory tract (Refs. 23 and 24). Pollen grains containing residues that are the subject of this exemption are unlikely to cross the barrier provided by the mucous membrane of the respiratory tract (Refs. 23 and 24) and thus exposure through this route is not likely to be additive to dietary exposure of nucleic acids (Refs. 23 and 24).

iv. *Drinking water*. EPA also evaluated potential non-occupational exposures in drinking water. Residues of nucleic acids that are part of a plant-incorporated protectant are produced inside the plant itself. Nucleic acids, and residues of nucleic acids, are an integral part of the living tissue of the plant. When the plant dies or a part is removed from the plant, microorganisms colonizing the tissue immediately begin to degrade it, using the components of the plant tissue (including residues of nucleic acids that are part of a plant-incorporated protectant) as building blocks for making their own cellular components or for fueling their own metabolisms (Ref. 21). Nucleic acids that are part of a plant-incorporated protectant are subject to the same processes of biodegradation and decay that all biotic materials undergo (Ref. 21) . This turnover of biotic materials in nature through a process of biodegradation occurs fairly rapidly. In addition, nucleic acids are, for the most part, highly unstable outside of the cellular environment and are usually very quickly broken down (Refs. 3 and 21). Because of the very rapid turnover of these residues, even if they reach surface waters (e.g., through plant parts falling into bodies of water), they are unlikely to present anything other than a very negligible exposure in drinking water drawn either from surface or ground water sources.

v. *Residential exposure*. EPA is not aware of any residential uses of plant-incorporated protectants that might result in exposure to residues of nucleic acids that are part of a plant-incorporated protectant.

7. *Sensitivities of subgroups*. EPA considered available information on the sensitivities of subgroups as it pertains to residues of nucleic acids that are part of a plant-incorporated protectant. As nucleic acids are ubiquitous in food, are not known to cause any adverse health effects when consumed in food and are not toxic, EPA does not expect that one subgroup would be more sensitive than another to residues of nucleic acids that are part of a plant-incorporated protectant.

8. *Estrogenic or other endocrine effects*. Based on available information concerning their structure and mode of action, plus the fact that nucleic acids are ubiquitous in foods and have no known adverse effects when consumed as part of the diet, EPA does not expect residues of nucleic acids that are part of a plant-incorporated protectant to cause estrogenic or other endocrine effects. No comment was received indicating that nucleic acids might have estrogenic or other endocrine effects in response to the specific request for such information in the May 16, 1997, supplemental document (62 FR 27142). If EPA becomes aware of a potential for estrogenic or endocrine effects from exposure to nucleic acids that are part of a plant-incorporated protectant, the Agency will reexamine this tolerance exemption in light of that information.

9. *Safety factors*. EPA did not rely solely on available animal data in reaching its determination that residues of nucleic acids that are part of a plant-incorporated protectant can be exempted from the requirement of a tolerance. There is a long history of safe human consumption of nucleic acids in

food derived from plants and from animals that consume forage and other crops (e.g., corn and other grains) containing nucleic acids. EPA thus was able to rely on epidemiological studies on humans (Refs. 5, 6, 7, 8, 9, 10, 11, 12, and 13) and a century of systematic scientific study of the constituents of food available in the public literature (Ref. 4). EPA also relied on knowledge in plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding. EPA believes that long-term evidence of human consumption and the associated information base (Refs. 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13), with a more limited reliance on animal experimentation data, are the appropriate information base for this exemption. Because the EPA was able to rely on data from humans, the Agency concluded that a safety factor designed to account for uncertainties in extrapolating from animal data would not be necessary. Because the available epidemiological and other information generated on humans was based on studies employing very large numbers of individuals, the Agency concluded that aten-fold safety factor to account for uncertainties in analyzing the human data would not be necessary.

10. *Infants and children*. EPA considered available information on consumption patterns of infants and children, including special sensitivity, cumulative effects of residues of nucleic acids that are part of a plant-incorporated protectant with other substances that may have a common mechanism of toxicity with these residues, and the need for a margin of safety for infants and children.

i. *Dietary consumption patterns*. EPA considered available information on the dietary consumption pattern of infants and children as it pertains to residues in food of nucleic acids that are part of a plant-incorporated protectant. The range of foods consumed by infants and children is in general more limited than the range of foods consumed by adults. Most newborns rely on milk products for nutrition, although some infants are fed soy-based products. Infants begin as early as four months of age to consume specific types of solid foods. Subsequent to four months of age, apart from processing to facilitate swallowing, the diets of infants begin to be based on foods consumed by the general adult population albeit in different proportions. As infants and children mature, more and more of the foods normally consumed by adults become part of their diets, and the relative proportions of the different types of food consumed changes to more closely resemble an adult diet. All foods consumed by infants and children, including milk and soy-based products, contain nucleic acids as do all foods consumed by adults. Since nucleic acids are ubiquitous in food, from the products infants consume after birth through the changing diets children consume as they mature, EPA concluded that infants and children have been, and are, exposed to nucleic acids as part of their diet. Although the diets of humans change from infancy through childhood and into adulthood, there is no evidence that such changes are likely to result in disproportionately high consumption of residues of nucleic acids, among infants and children in comparison to the general population. Nucleic acids in food are not toxic and there is no evidence that exposure to nucleic acids in food, including changes in exposure because of changes in the relative proportions of the different types of food consumed from infancy through childhood and into adulthood, leads to any harm.

ii. *Special susceptibility*. EPA considered available information on the potential for special susceptibility of infants and children, including pre-natal and post-natal toxicity, to residues of nucleic acids that are part of a plant-incorporated protectant. Nucleic acids in food are not toxic and there is no scientific evidence that nucleic acids as a component of food would have a different effect on children, in light of neurological differences between infants and children and adults, than they would on the adult population.

iii. *Cumulative effects of residues with other substances with a common mechanism of toxicity*. EPA examined the available information on the cumulative effect of residues of nucleic acids that are part of a plant-incorporated protectant as well as other substances in food that may have a common mechanism of toxicity. The Agency's consideration of the effects of the residues of nucleic acids that are part of a plant-incorporated protectant on the general population also included consideration of effects on infants and children. Nucleic acids are not toxic when consumed as part of the diet, and EPA is not aware of substances that might have a common mechanism of toxicity with nucleic acids. There is no evidence indicating that adverse effects on infants and children due to aggregate exposure to residues of nucleic acids and other substances could occur.

iv. *Margin of safety*. In determining whether the residues of nucleic acids that are part of a plant-incorporated protectant are safe, FFDCA section 408(b)(2)(C) directs EPA to apply a tenfold margin of safety for the residues and other sources of exposure to infants and children to account for potential prenatal and postnatal toxicity and completeness of data on threshold effects with respect to exposure and toxicity to infants and children, unless a different margin will be safe. For residues of nucleic acids that are part of a plant-incorporated protectant, EPA has determined that a tenfold margin of safety is not necessary to protect infants and children. EPA reaches this determination based on reliable, valid and complete information. As noted in other sections of Unit IX., EPA based its assessment of exposure and toxicity upon the long history of safe human consumption of food containing nucleic acids from plants, and other animals that consume plants containing nucleic acids, and other substances in food that may have a common mechanism of toxicity (Ref. 4), and associated epidemiological and other studies (Refs. 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13). EPA also relied upon information from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding. Based on all of this information, EPA concludes that nucleic acids in food are not toxic and may be safely consumed, including by infants and children. There is no evidence that exposure to nucleic acids in food, including changes in exposure because of differences in the relative proportions of the different types of food consumed from infancy through childhood and into adulthood, leads to any harm. Thus, on the basis of valid, complete and reliable information, EPA has concluded that nucleic acids in food are safe for infants and children, and that a margin of safety need not be applied for residues in food of nucleic acids that are part of a plant-incorporated protectant.

11. *Analytical methods*. EPA has decided that even though methodology exists to detect and measure the amount of nucleic acids in food and to detect and measure the residues of nucleic acids that are part of a plant-incorporated protectant (Ref. 4), there is no need to employ a practical method for detecting and measuring the levels of such residues. The effect of nucleic acids on humans was assessed in light of the known presence of nucleic acids in all foods (Refs. 3 and 4), the long history of safe human consumption of plant food containing nucleic acids, i.e., food derived from crop plants and from animals that consume forage and other crops containing nucleic acids, and associated epidemiological and other studies (Refs. 4, 5, 6, 7, 8, 9, 10, 11, 12,

and 13). EPA combined this information with knowledge from the disciplines of plant genetics, plant physiology, phytopathology, microbial ecology, ecology, biochemistry and plant breeding. Nucleic acids in foods do not have a toxic effect and cause no adverse effects to humans. There is no reason to believe that nucleic acids that are part of a plant-incorporated protectant would behave any differently than all of the other nucleic acids in food. There is a reasonable certainty that no harm will result from exposure to any amount of residues of nucleic acids that are part of a plant-incorporated protectant in food. Because these residues may be present in food at any level without causing harm, EPA has concluded that an analytical method is not required for detecting and measuring the levels in food of the residues of nucleic acids that are part of a plant-incorporated protectant. EPA consulted with the Department of Health and Human Services (DHHS) in developing the proposed exemption and in issuing this final rule for residues of nucleic acids that are part of a plant-incorporated protectant.

C. Determination of Safety for United States Population, and Infants and Children

Based on the information discussed in this document and that discussed in the 1994 **Federal Register** documents and the supplemental documents and the record as described in Unit X., EPA concludes that there is a reasonable certainty that no harm will result to the United States population in general, and to infants and children in the United States, from aggregate exposure to residues of nucleic acids that are part of a plant-incorporated protectant, including all anticipated dietary exposures and all other exposures for which there is reliable information. Under this exemption from the requirement for a tolerance, EPA exempts residues of nucleic acids that are part of a plant-incorporated protectant. Nucleic acids are normally a component of food from plants. Extensive use and experience show the safety of foods containing nucleic acids. The many years of human experience with the growing, preparing and consuming food from plants containing nucleic acids and information generated through years of study of the food supply (Refs. 4, 5, 6, 7, 8, 9, 10, 11, 12, and 13), indicate that adverse effects due to aggregate exposure through the dietary, non-food oral, dermal and inhalation routes are highly unlikely.

X. Documents in the Official Record

As indicated in Unit I.B.2., the official record for this final rule has been established under docket control number OPP–300371B, the public version of which is available for inspection as specified in Unit I.B.2.

A. References

The following books, articles and reports were used in preparing this final rule and were cited in this document by the number indicated:

1. Whittaker, R. H. 1969. New concepts of kingdoms of organisms. Science, 163:150–160.

2. Environmental Protection Agency (EPA). 2000. Summary of public comments and EPA response on issues associated with plant-incorporated protectants (formerly plant-pesticides) for dockets OPP–300371 and OPP–300371A.

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16. Principles and Practice of Infectious Diseases. 1979. Edited by G. L. Mandell, R. G. Douglas, Jr. and J. E. Bennett. John Wiley and Sons, New York.

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24. Environmental Protection Agency. 1997. Exposure Factors Handbook. Volume 1. National Center for Environmental Assessment. EPA/600/P-95/002Fa.

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B. Additional Information

The complete official record for this rulemaking includes:

The docket identified by the docket control number OPP–300370 for the document entitled ''Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act'' (59 FR 60496, November 23, 1994) (FRL–4755–2).

The docket identified by the docket control number OPP–300369 for the document entitled ''Plant-Pesticides Subject to the Federal Insecticide, Fungicide and Rodenticide Act; Proposed Rule'' (59 FR 60519, November 23, 1994) (FRL–4755–3).

The docket identified by the docket control number OPP–300368 for the document entitled ''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act'' (59 FR 60535, November 23, 1994) (FRL–4758–8).

The docket identified by the docket control number OPP–300371 for the document entitled ''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants'' (59 FR 60542, November 23, 1994) (FRL–4755–5).

The docket identified by the docket control number OPP–300367 for the document entitled ''Plant-Pesticides; Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Protein Produced in Plants'' (59 FR 60545, November 23, 1994) (FRL–4755–4).

The docket identified by the docket control number OPP–300370A for the document entitled ''Plant-Pesticide Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act; Reopening of Comment Period'' (61 FR 37891, July 22, 1996) (FRL–5387–4).

The docket identified by the docket control number OPP–300368A for the document entitled ''Plant-Pesticides; Supplemental Notice of Proposed Rulemaking'' (62 FR 27132, May 16, 1997) (FRL–5717–2).

The docket identified by the docket control number OPP–300371A for the document entitled ''Plant-Pesticides; Nucleic Acids; Supplemental Notice of Proposed Rulemaking'' (62 FR 27142, May 16, 1997) (FRL–5716–7).

The docket identified by the docket control number OPP–300367A for the document entitled ''Plant-Pesticides; Viral Coat Proteins; Supplemental Notice of Proposed Rulemaking'' (62 FR 27149 May 16, 1997) (FRL–5716–6).

The docket identified by the docket control number OPP–30069A for the document entitled ''Plant-Pesticides, Supplemental Notice of Availability of Information'' (64 FR 19958 April 23, 1999) (FRL–6077–6).

The docket identified by the docket control number OPP–300368B for the companion document entitled ''Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues Derived Through Conventional Breeding From Sexually Compatible Plants of Plant-Incorporated Protectants (Formerly Plant-Pesticides)'' (FRL–6057–6) published elsewhere in this issue of the **Federal Register**.

The docket identified by the docket control number OPP–300369B for the document entitled ''Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides)'' (FRL–6057–7) published elsewhere in this issue of the **Federal Register**, and the docket identified by the docket control number OPP–300370B for the document entitled ''Plant-Incorporated Protectants; Supplemental Notice of Availability of Information'' (FRL–6760–4).

Also included in the complete official public record are:

1. Public comments submitted in response to the proposals and supplemental documents cited in the above paragraph.

2. Reports of all meetings of the Biotechnology Science Advisory Committee and the FIFRA Science Advisory Panel pertaining to the development of this final rule.

3. The Economic Analysis (EA) on FIFRA regulations for plant-incorporated protectants, and documents supporting the EA (Ref. 25).

4. Support documents and reports.

5. Records of all communications between EPA personnel and persons outside EPA pertaining to the final rule. (This does not include any inter-agency and intra-agency memoranda, unless specifically noted in the Indices of the dockets).

6. Published literature that is cited in this document.

7. The response to comments document pertaining to the development of this final rule (Ref. 2).

XI. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408 and does not impose any other regulatory requirements. As such, 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 action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

This action does not require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), nor does it 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).

This action does not impose any enforceable duty or contain any unfunded mandate, and will not otherwise significantly or uniquely affect small governments as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).This rule does not significantly or uniquely affect the communities of Indian trial governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084, entitled *Consultation and Coordination with*

Indian Tribal Governments (63 FR 27655, May 19, 1998), do not apply to this rule. Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), which took effect on January 6, 2001, revokes Executive Order 13084 as of that date. EPA developed this rulemaking, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084. For the same reasons stated for Executive Order 13084, the requirements of Executive Order 13175 do not apply to this rule either. For the same reasons, this rule does not have any 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* (64 FR 43255, August 10, 1999). This 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).

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The Agency's determination is based on the fact that an exemption from the requirement of a tolerance under FFDCA section 408, such as that contained in this rule, will not adversely affect any small businesses. Additional information about the Agency's determination may be found in the small entity impact analysis prepared as part of the economic analysis for the FIFRA rulemaking, which is available in the public version of the official record (Ref. 25). The Agency has also previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a general matter, that there is no adverse economic impact associated with these actions. See 46 FR 24950, May 4, 1981.

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

XII. 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 174

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

Dated: July 12, 2001.

Christine T. Whitman,

Administrator.

Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y and 21 U.S.C. 346a and 371.

2. Section 174.475 is added to subpart W to read as follows:

§ 174.475 Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance.

Residues of nucleic acids that are part of a plant-incorporated protectant are exempt from the requirement of a tolerance.

[FR Doc. 01–17982 Filed 7–16–01; 11:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[OPP–300368B; FRL–6057–6]

RIN 2070–AC02

Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Residues Derived Through Conventional Breeding From Sexually Compatible Plants of Plant-Incorporated Protectants (Formerly Plant-Pesticides)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The substances plants produce for protection against pests, and the genetic material necessary to produce these substances, are pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if humans intend to use these substances for ''preventing, destroying, repelling or mitigating any pest.'' These substances, produced and used in living plants, along with the genetic material necessary to produce them, are also ''pesticide chemical residues'' under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA calls these substances, along with the genetic material necessary to produce them, plant-incorporated protectants. In this final rule, EPA exempts from the FFDCA section 408 requirement of a tolerance, residues of the pesticidal substance portion and residues of any inert ingredient of any plant-incorporated protectant derived through conventional breeding from a plant sexually compatible with the recipient food plant. EPA has determined that there is a reasonable certainty that no harm will result from aggregate exposure to these residues.

DATES: This rule is effective September 17, 2001. Objections and requests for hearings must be received by EPA on or before September 17, 2001.

ADDRESSES: Objections and hearing requests may be submitted by regular mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit II. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: By mail: Philip Hutton, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington DC 20460; telephone number: (703)