The proposed power plant, located near the town of Burney, Shasta County, California, will have a nominal electrical output of 500 MW and will be fired on natural gas. The proposed facility will be subject to PSD for Nitrogen Oxides (NO_X), Carbon Monoxide (CO), Volatile Organic Compounds (VOC), and Particulate Matter (PM_{10}). The permit includes the following Best Available Control Technology (BACT) emission limits: NO_X at 2.5 ppmvd (based on 1-hour averaging at 15% O_2), 4 ppmvd CO (based on 3-hour averaging at 15% O_2), 2 ppmvd VOC (based on 1-hour averaging at 15% O_2), and PM_{10} at 0.0012 grain/dscf (based on 1-hour averaging at 3% CO_2). The BACT requirements include use of Selective Catalytic Reduction (SCR) for the control of NO_X emissions, an oxidation catalyst for CO and VOC emissions, and a combination of good combustion control and natural gas for the control of PM_{10} emissions. Continuous emission monitoring is required for NO_X, CO and opacity. The facility is also subject to New Source Performance Standards, Subparts AA and GG, and the Acid Rain program under title IV of the Clean Air Act.

If available, judicial review of these determinations under section 307(b)(1) of the CAA may be sought only by the filing of a petition for review in the United States Court of Appeals for the appropriate circuit within 60 days from the date on which this document is published in the **Federal Register**. Under section 307(b)(2) of this Act, this determination shall not be subject to later judicial review in any civil or criminal proceedings for enforcement.

Dated: July 30, 2001.

Jack P. Broadbent,

Director, Air Division, Region IX.

[FR Doc. 01–20661 Filed 8–15–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301129; FRL–6782–8]

RIN 2070–AB78

B-D-Glucuronidase from E. coli and the Genetic Material Necessary for its Production As a Plant Pesticide Inert Ingredient; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *B*-D-glucuronidase from *Escherichia coli* and the genetic material necessary for its production in or on all food commodities when applied/used as a plant pesticide inert ingredient. Monsanto submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *B*-D-glucuronidase derived from *E. coli* and the genetic material necessary for its production.

DATES: This regulation is effective August 16, 2001. Objections and requests for hearings, identified by docket control number (OPP–301129), must be received by EPA, on or before October 15, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number (OPP–301129) in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703–308–8733); and e-mail address: hollis.linda@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register** —Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301129. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of May 3, 2000 (65 FR 25719) (FRL–6553–2), EPA issued a notice pursuant to section 408

of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition (PP) OE6066 by Monsanto. This notice included a summary of the petition prepared by the petitioner Monsanto. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1216 be amended by establishing an exemption from the requirement of a tolerance for residues of *B*-D-glucuronidase derived from *E. coli* and the genetic material necessary for its production.

III. Risk Assessment

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Additionally, section 408(b)(2)(D) requires that the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity. ''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Several types of data are required for proteinaceous plant-pesticide ingredients to provide a reasonable certainty that no harm will result from the aggregate exposure to these proteins. The information is intended to show that a proteinaceous plant-pesticide behaves as would be expected of a typical dietary protein, is not structurally related to any known food allergen or protein toxin, and does not display any oral toxicity when administered at high doses. These data consist of an *in vitro* digestion assay, amino acid sequence homology comparisons and an acute oral toxicity test. The acute oral toxicity test is done at a maximum hazard dose using purified protein of the plant-pesticide as a test substance.

EPA believes that protein instability in digestive fluids and the lack of adverse effects using the maximum hazard dose approach in general eliminate the need for longer-term testing of Bt protein plant-pesticide ingredients. Dosing of these animals with the maximum hazard dose, along with the product characterization data should identify potential toxins and allergens, and provide an effective means to determine the safety of these protein. The adequacy of the current testing requirements was discussed at the June 7, 200 Scientific Advisory Panel (SAP) meeting.

Toxicity studies submitted in support of this tolerance exemption included the following:

Acute oral toxicity (44988–01). One hundred CD-1 albino mice divided into groups of 10 male and 10 female each were treated with 1.0 milligrams/kilograms (mg/kg), 10.0 mg/kg or 100.0 mg/kg of the test substance (GUS protein) or 100.0 mg/kg control substance (bovine serum albumin). Treatment was administered by oral gavage at 33 ml/kg body weight. Three unscheduled deaths occurred on day 5. These animals were in each of the following groups: 100.0 mg control substance, 10.0 mg or 100.0 mg test substance. Since the deaths appeared in both control and test substance groups, there were no abnormal observations upon gross necropsy of the animals that died prematurely, the deaths were not dose related and only three deaths were seen in the one hundred animals of the study, it appears that the deaths were not related to the test substance. Minor weight loss was recorded in all groups and routine, minor organ abnormalities were also seen in both the treated and control groups during gross necropsy at schedules sacrifice. Based upon the data, there were no significant adverse effects reported upon dosing mice with up to 100.0 mg/kg body weight GUS protein.

In vitro digestibility (449394–07). This study was performed on *B*-D-glucuronidase purified from *E. coli* strain K12 engineered to express the GUS protein to determine the digestive fate of the protein in simulated gastric and intestinal fluid. The data submitted indicate that the GUS protein is broken down rapidly with incubation in simulated gastric fluids but is relatively stable in simulated intestinal fluids. GUS protein enzymatic activity rapidly disappears after incubation in simulated gastric fluid (2 minutes, the first timepoint examined). GUS protein also disappears when examined immunologically by western blot as quickly as 15 seconds after incubation in simulated gastric fluid. Although still degraded, GUS protein is more stable to intestinal digestion disappearing by 240 minutes by western blot yet still being detected by enzymatic activity (decreased about 90%) at this same time point. These results suggest that the protein breaks down in the human digestive tract as expected of a dietary protein and will not likely pose a risk in foods as part of the human diet.

The *B*-D-glucuronidase which is the subject of this rule is a protein originally isolated from *E. coli* and introduced into plants to serve as a transformation marker. GUS (*B*-D-glucuronide glucouronosohydrolase; E.C.3.2.1.31) from *E. coli* is a homotetrameric enzyme with an individual monomeric weight of 68kD. Individual subunits do not have enzymatic activity. GUS has a pH optima near 7.0 and maintains enzymatic activity for approximately 2 hours at 55 degrees C but is rapidly degraded at 60 degrees C. This bacterial enzymatic activity is ubiquitous in the digestive system of humans and other vertebrates. As a protein component of the normal microflora of the intestinal tract, there will be no change in exposure from the presence of this protein as a transformation marker. In addition, other types of GUS enzyme are present in the liver, spleen, kidneys, salivary glands, breast milk and a variety of other tissues in humans, other vertebrates and a number of invertebrates. While these proteins have similar activity, the mammalian safety data generated to date has been specifically for the *E. coli* derived GUS so the present tolerance is limited to that form.

Allergenic responses are very unlikely to occur and the Agency is currently unaware of any allergic reactions to this protein. The highest activity of the mammalian GUS protein is found primarily in the liver and kidneys. However, activity has also been seen in the spleen, breast milk, adrenal gland and alimentary tract. GUS protein is also found in many other bacteria besides *E. coli* and is also present in the environment (Ref. 1). The GUS protein is used as a marker gene during the plant transformation process in the development of genetically modified plants. During the plant transformation process, the GUS protein serves as an identifier which enables the separation of transformed plant cells containing an added gene from those plant cells that have failed to take up or maintain the additional gene of interest. Thus, the GUS protein allows a cell expressing that marker gene to be readily identified.

The mammalian health and safety of the GUS protein is based on its ubiquitous presence in the digestive system of humans and other tissues (Refs. 2 and 6), as well as its presence in anaerobic bacteria (Ref. 3), and other environmental bacteria (Ref. 7). Further, the mammalian health and safety of the GUS protein is based on the long history of safe consumption of the protein in the human and domestic animal food supply (Ref. 2), and in the tissue of various plant species from which foods such as potatoes, apples, almonds, rye, sugar beets, etc., are derived (Refs. 4, 8, and 9). There have been no reports of adverse effects to humans or domestic animals from the consumption of the GUS protein. Toxicity studies conducted in support of this tolerance exemption indicated a lack of toxicity of the *E. coli* derived GUS protein in mice. Moreover, *in vitro* digestibility studies further validate earlier findings that the *E. coli* derived GUS protein is broken down under conditions in mammalian digestive fluids. Therefore, the Agency concludes that the risk to humans when consuming foods containing the GUS protein is minimal to non-existent. The lack of heat stability of the GUS protein suggests that cooking foods would eliminate the protein activity (Ref. 5). Further, the data submitted suggest that upon ingestion, the GUS protein rapidly degrades in the digestive tract thus posing no risks of adverse effects to humans.

The genetic material necessary for the production of the plant pesticide inert ingredient are the nucleic acids (DNA) which comprise genetic material encoding the protein and their regulatory regions. Regulatory regions are the genetic material that control the expression of the genetic material encoding the proteins, such as promoters, terminators, and enhancers. DNA is common to all forms of plant and animal life and the Agency knows of no adverse effects related to their consumption as a component of food. These ubiquitous nucleic acids as they appear in the subject plant pesticide inert ingredient have been adequately characterized by the applicant. The EPA concludes that no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the GUS protein.

V. Aggregate Exposures

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

A. Dietary Exposure

1. *Food*. The use of *B*-D-glucuronidase from *E. coli* and the genetic material necessary for its production as a plant pesticide inert ingredient will not result in new dietary exposure to human health or to the environment. The GUS protein is ubiquitous in the digestive tract of humans, other vertebrate, invertebrates, bacteria, in the environment and in foods in the human and domestic animal diet. Exposure from this protein has not posed any unreasonable risk or health concerns. The lack of mammalian toxicity and the rapid degradation of the protein by the stomach digestion of the GUS protein provide a scientific rationale for exempting from the requirement of a tolerance *B*-D-glucuronidase and the genetic material necessary for its production when used as a plant pesticide inert ingredient (Ref. 10). Moreover, there is no evidence indicating adverse effects due to aggregate exposure of the GUS protein through dietary, non-food oral, dermal and inhalation.

2. *Drinking water exposure*. Potential exposures in drinking water is negligible. Because GUS protein is contained within the cells of the plant and is naturally degraded upon plant senescence, the likely transfer of the GUS protein to drinking water is minimal to non-existent.

B. Other Non-Occupational Exposure

Other non-occupational exposure of *B*-D-glucuronidase via residential and indoor uses e.g., uses around homes, parks, recreation areas, athletic fields and golf courses will be minimal to non-existent as the GUS protein is contained within the plant cells.

1. *Dermal exposure*. Due to the nature of the GUS protein contained within the plant cells as part of the plant pesticide inert ingredient, exposure through any route (i.e., dermal, respiratory) other than dietary is unlikely to occur. Physical contact with the plant or raw agricultural food from the plant may present some limited opportunity for dermal exposure. However, on a per person basis, the potential amounts involved in this exposure is negligible in comparison to exposure through the dietary route.

2. *Inhalation exposure*. The occurrence of respiratory exposure of the GUS protein contained within the plant cells is negligible in comparison to potential exposure through the dietary route.

VI. Cumulative Effects

E. coli derived *B*-D-glucuronidase enzyme and its gene is present as part of a ubiquitous organism in the digestive systems of humans and other vertebrates. Based on the lack of mammalian toxicity and the long history of safe consumption of the protein in the human and domestic animal food supply and the rapid degradation of the protein in the digestive tract, no cumulative effects with other substances are expected.

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

For the U.S. population, including infants and children, *B*-D-glucuronidase from *E. coli* and the genetic material necessary for its production as a plant pesticide inert ingredient has no known or reported adverse effects. The Agency's conclusions are based on the extensive use and experience with the GUS protein including the long history of safe consumption of the protein in the human and domestic animal food supply, the lack of mammalian toxicity associated with the protein, the rapid degradation of the protein by the stomach digestion prior to passage to the intestinal tract, along with no reported adverse effects due to aggregate exposure through the dietary, non-food oral, dermal and inhalation routes. Therefore, based on all available information, the EPA concludes that there is reasonable certainty that no harm will result from aggregate

exposure of the U.S. population, including infants and children, to the GUS protein when used as a plant pesticide inert ingredient, as expressed in plants in or on all food commodities.

VIII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredient) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen-and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and to the extent that FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, *B*-D-glucuronidase from *E. coli* and the genetic material necessary for its production may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system-related effects have been identified.

B. Analytical Method(s)

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purposes for *B*-D-glucuronidase from *E. coli* and the genetic material necessary for its production.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels (MRL's) established for residues of *B*-D-glucuronidase from *E. coli* and the genetic material necessary for its production.

IX. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301140 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 October 15, 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, Ariel Rios Bldg., 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 IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket number OPP–301140, 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 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).

X. References

1. Fuchs, R.L. and Astwood, J.D. 1996. Allergenicity assessment of foods derived from genetically modified plants. *Food Technology* 50: 83–88.

2. Gilissen, L. J. W., P. L. J. Metz, W. J. Stiekema and J. P. Nap. 1998. Biosafety of *E. coli b*-glucuronidase (GUS) in plants. Trans. Res. 7:157–163.

3. Hawkesworth, G., B.S. Draser and M.J. Hill. 1971. Intestinal bacteria and the hydrolysis of glycosidic bonds. *J. Med. Microbiol.* 4:451–9.

4. Hodal, L. A. Bochardt, J.E. Nielsen, O. Mattsson, and F.T. Okk. 1992. Detection, expression and specific elimination of endogenous *b*-glucuronidase activity in transgenic and non-transgenic plants. Plant Science. 87:115–22.

5. Jefferson, R.A. and K.J. Wilson. 1991. The GUS gene fusion system. Plant Mol. Biol. Manual B14:1–33.

6. Jefferson, R. A., T. A. Kavanagh, and M. W. Bevan. 1986. *B*-Glucuronidase from *Escherichia coli* as a gene-fusion marker. *Proc. Natl. Acad. Sci. USA* 83: 8447–8451.

7. Levvy, G.A. and C.A. Marsh. 1959. Preparation and properties of *b*-glucuronidase. Adv. Carbohydrate Chem. 14:381–428.

8. Schulz, M. and G. Weissenbock. 1987. Dynamics of the tissue-specific metabolism of lutolin glucuronides in the mesophyll of rye primary leaves (*Secale cereale*) Z. Naturforsh. 43c: 187–93.

9. Wozniak, C.A. and L.D. Owens. 1994. Native *B*-glucuronidase activity in sugarbeet (*Beta vulgaris*). *Physiol. Plant.* 90: 763–771.

10. Kough, J. 2001. Note to file: Safety assessment of *B*-glucuronidase as a worker gene/inert ingredient.

XI. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104 –4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require OMB review 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 involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

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 180

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

Dated: July 11, 2001.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.1216 is added to subpart D to read as follows:

§ 180.1216 *B*-D-glucuronidase from *E. coli* and the genetic material necessary for its production as a plant-pesticide inert ingredient; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *B*-D-glucuronidase from *E. coli* and the genetic material necessary for its production when used as a plant-

pesticide inert ingredient in or on all food commodities. Genetic material necessary for the production means both: Genetic material that encodes a substance or leads to the production of a substance; and regulatory regions. It does not include non-coding, non-expressed nucleotide sequences. Regulatory region means genetic material that controls the expression of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include, but are not limited to, promoters, enhancers, and terminators.

[FR Doc. 01–20665 Filed 8–15–01; 8:45 a.m.]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL—7029–1]

Vermont: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: Vermont has applied to EPA for Final authorization of a revision to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has determined that the revision satisfies all requirements needed to qualify for Final authorization, and is authorizing the State's revision through this immediate final action. EPA is publishing this rule to authorize the revision without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we receive written comments which oppose this authorization during the comment period, the decision to authorize Vermont's revision to its hazardous waste program will take effect as provided below. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect, and the separate document in the proposed rules section of this **Federal Register** will serve as the proposal to authorize the changes.

The rulemaking for which Vermont is being authorized stems from the EPA Project XL initiative. Project XL, which stands for ''eXcellence and Leadership,'' is a national initiative that tests innovative ways of achieving better and more cost-effective public health and environmental protection. It encourages testing of cleaner, cheaper, and smarter ways to attain environmental results superior to those achieved under current regulations and policies, in conjunction with greater accountability to stakeholders.

DATES: This Final authorization will become effective on October 15, 2001 unless EPA receives adverse written comments by September 17, 2001. If EPA receives such comments, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take immediate effect.

ADDRESSES: Send written comments to Robin Biscaia, Hazardous Waste Unit, EPA New England, One Congress Street, Suite 1100 (CHW), Boston, MA 02114–2023; Phone number: (617) 918–1648. You can view and copy materials submitted by Vermont during normal business hours at the following locations: EPA New England Library, One Congress Street, Suite 1100 (LIB), Boston, MA 02114–2023; Phone number: (617) 918–1990; Business hours: 9:00 A.M. to 4:00 P.M.; or the Agency of Natural Resources, 103 South Main Street—West Office Building, Waterbury, VT 05671–0404; Phone number: (802) 241–3888; Business hours: 7:45 A.M. to 4:30 P.M.

FOR FURTHER INFORMATION CONTACT: Robin Biscaia, EPA New England, One Congress Street, Suite 1100 (CHW), Boston, MA 02114–2023; Phone number: (617) 918–1642.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

On September 12, 2000 (65 FR 59955) EPA published a final rule for the Project XL Site-Specific Rulemaking for the IBM Semiconductor Manufacturing Facility in Essex Junction, Vermont. In this rule, EPA promulgated a site-specific exemption in 40 CFR 261.4(b) for the copper metallization process at the IBM Vermont facility from the F006 hazardous waste listing description. This rule was promulgated pursuant to non-HSWA authority. Since Vermont has received authority to implement non-HSWA regulations that specifically identify hazardous wastes by listing them, the rule to modify the listing for F006 would not be effective until Vermont adopted the modification. Vermont adopted the rule on March 15, 2001 and applied for Final authorization on April 10, 2001.

B. What Decisions Have We Made in this Rule?

We conclude that Vermont's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Vermont Final authorization to operate its hazardous waste program with the changes described in the authorization application. Vermont has responsibility for permitting Treatment, Storage, and Disposal Facilities (TSDFs) within its borders and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA).

C. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that the IBM semiconductor manufacturing site, subject to RCRA, in Essex Junction, Vermont will now have to comply with the authorized State requirements in lieu of Federal requirements in order to comply with RCRA. Vermont has enforcement responsibilities under its state hazardous waste program for violations of such program, but EPA retains its full authority under RCRA sections 3007, 3008, 3013, and 7003.

This action does not impose additional requirements on the IBM Essex Junction facility because the regulation for which Vermont is being authorized by today's action is already effective under state law, and is not changed by today's action.

D. Why Wasn't There a Proposed Rule Before Today's Rule?

EPA did not publish a proposal before today's rule because we view this as a non-controversial program change and do not expect comments that oppose this approval. We are providing an opportunity for public comment now. In addition to this rule, in the proposed rules section of today's **Federal Register** we are publishing a separate document