Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994); or 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 section 408(d) of FFDCA, such as the tolerance 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 section 408(n)(4) of FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

IX. Congressional Review Act

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: February 7, 2005.

Lois Rossi,

Director, Registration Division, 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), 346a and 371.

■ 2. Section 180.441 is amended by adding alphabetically the following commodities to the table in paragraph (a)(1) and (a)(3) to read as follows:

§ 180.441 Quizalofop-ethyl; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
Bean, dry	0.4
Bean, succulent	0.25
Beet, sugar, roots	0.1
Beet, sugar, tops	0.5
Cowpea, forage	3.0
Cowpea, hay	3.0
Pea, dry	0.25
Pea, field, hay	3.0
Pea, field, vines	3.0≤
Pea, succulent	0.3
* * * * *	

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(3) * * *

Commodity	Parts per million
Beet, sugar, molasses	0.2 ppm
* * * * *	

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[FR Doc. 05–2982 Filed 2–15–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0026; FRL–7697–9]

Syrups, Hydrolyzed Starch, Hydrogenated; 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 syrups, hydrolyzed starch, hydrogenated (CAS Reg. No. 68425–17–2) when used as an inert ingredient in pesticide products. Grain Processing Corporation and SPI Polyols submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of syrups, hydrolyzed starch, hydrogenated.

DATES: This regulation is effective February 16, 2005. Objections and requests for hearings must be received on or before April 18, 2005.

ADDRESSES : To submit a written objection or hearing request follow the detailed instructions as provided in Unit XI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a

docket for this action under docket identification (ID) number OPP–2005–0026. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; e-mail address: *boyle.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

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

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Electronic Documents and Other Related Information?

In addition to using EDOCKET at *http://www.epa.gov/edocket/*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of October 23, 2002 (67 FR 65115) (FRL–7276–8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 2E6503) by Grain Processing Corporation, 1600 Oregon St, Muscatine, Iowa 52761 and SPI Polyols, 321 Cherry Lane, New Castle, Delaware 19720.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of hydrogenated starch hydrolysate (CAS Reg. No. 68425–17–2). Hydrogenated starch hydrolysate is intended to be used as an inert ingredient in pesticide products. That notice included a summary of the petition prepared by the petitioner. One comment was submitted. The Agency's response to this comment is in Unit X.

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

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

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Description of Syrups, Hydrolyzed Starch, Hydrogenated

Syrups, hydrolyzed starch, hydrogenated (also known as hydrogenated starch hydrolyzate or HSH) is a generic term for various hydrogenated syrups. These are also known by the terms sugar alcohols, polyhydric alcohols, or polyols. According to the Food and Drug Administration (FDA), sugar alcohols are ''not technically considered artificial sweeteners, . . . are slightly lower in calories than sugar and do not promote tooth decay or cause a sudden increase in blood glucose. They include sorbitol, xylitol, lactitol, mannitol, and maltitol and are used mainly to sweeten sugar-free candies, cookies, and chewing gums.''

Syrups, hydrolyzed starch, hydrogenated (CAS Reg. No. 68425–17–2) are typically prepared by hydrolyzing a starch (such as corn starch) and then hydrogenating the hydrolysis product. Starch is a polymer composed of repeating glucose units that are linked by glucosidic bonds. Hydrolysis is the process by which these bonds are broken. Given that starch is a complex polysaccharide, hydrolysis of a starch yields a complex mixture of various chemicals, that retain the basic configuration of saccharides, but can have different functional groups. This complex mixture is then hydrogenated. Both the starting material (the type of starch), and the method of hydrolysis (heat, acid and/or enzymatic) can impact the hydrolyzed starch product that would then be hydrogenated.

Syrups, hydrolyzed starch, hydrogenated contain various amounts

of maltitol, sorbitol and higher order polyols or polysaccharides. Higher-order polyols can be considered to be somewhat polymerized. Syrups, hydrolyzed starch, hydrogenated do not contribute nutrition to the human diet, are often used in reduced-calorie products, and by many are considered useful in the diets of persons with diabetes.

V. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by syrups, hydrolyzed starch, hydrogenated are discussed in this unit.

A. Review by JECFA

The Joint Expert Committee on Food Additives (JECFA) is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). In Food Additive Series 20, JECFA conducted a review of hydrogenated glucose syrups (see *http://www.inchem.org/documents/jecfa/jecmono/v020je13.htm).* JECFA defined these syrups as follows: ''Hydrogenated glucose syrups (HGS) are a mixture of polymers of glucose obtained from starch by hydrolysis which, upon hydrogenation, results in chemical reduction of the end-group glucose molecule to sorbitol. HGS consists primarily of maltitol and sorbitol, with lower portions of hydrogenated oligo- and polysaccharides.'' The toxicity data base included metabolism studies; several mutagenicity studies; a multigeneration reproduction toxicity study; a developmental study; and various acute, short-term, and long-term toxicity studies. JECFA's conclusions are extracted directly from that document:

- HGS or its major component maltitol produced significantly lower blood-glucose levels and more stable insulin levels than glucose or sucrose due to slow metabolism of maltitol.
- The results from the *in vitro* assays, with and without metabolic activation, suggest that HGS does not induce a mutagenic, clastogenic, genotoxic, or neoplastic transformation response. No *in vivo* clastogenic effects were observed.
- Acute and short-term animal studies indicate that HGS is not toxic after single or repeated oral administration of large doses. In rats, no evidence of toxic effects of prolonged feeding of up to 15–20% of the diet was observed. A 90–day study in dogs showed no evidence of adverse effects, except for diarrhea, at a level of 4.95 grams/kilogram body weight per day (g/kg bwt day).
- A multigeneration reproduction study in rats, in which HGS was administered in drinking water as an 18% aqueous solution, did not reveal any toxicologically significant effects.

In humans, an effect of concern for all polyols is a laxative effect. Available information indicates that a laxative effect can occur at intake levels of 30–50 g/day.

WHO/JECFA also reviewed an oral long-term toxicity/carcinogenic study in the rat conducted with a test substance that was approximately 87% maltitol. No adverse effects were observed in the toxicity study. A slightly increased incidence of mammary gland adenocarcinomas was observed in female rats at the two highest dose levels. However, based on historical control data, these increases were not considered to be related to treatment (see *http://www.inchem.org/documents/jecfa/jecmono/v32je08.htm).*

In 1998, JECFA conducted another review of Maltitol Syrup (see *http://www.inchem.org/documents/jecfa/jecmono/v040je07.htm).* This evaluation examined the metabolic fate of maltitol and higher-order polyols using both *in vitro* and *in vivo* studies. The results indicated that the higher-order polyols were readily hydrolyzed to glucose and maltitol. Glucose would be readily absorbed by the mammalian body; however, the rate of absorption is slower than that of directly ingested glucose. Maltitol would be further degraded through fermentation by intestinal flora. The amounts of maltitol that are absorbed are quickly excreted in the urine with little evidence of metabolism.

JECFA's review of several animal toxicity studies indicated that no treatment-related toxicity was seen in rats or dogs fed a typical syrups, hydrolyzed starch, hydrogenated product at dose levels of 18 and 43 g/kg bwt day, respectively, for 90 days.

In 1999, JECFA conducted a review of the food additive polyglycitol syrup (see *http://www.inchem.org/documents/jecfa/jecmono/v042je13.htm).* In this review, JECFA stated that their previous evaluation of maltitol syrup was applicable to polyglycitol syrup. Maltitol syrup differs from polyglycitol syrup only in the relative proportions of sorbitol, maltitol and higher-order polyols. For this 1999 review, a short-term toxicity study in rats given material with a high-order polyol content of 78% was reviewed.

Doses of a polyglycitol syrup, equal to 13 g/kg bwt per day, in the diets of rats for 13 weeks, ''was not associated with adverse effects. The only effects observed--increased weight of the empty caecum and increased urinary calcium excretion in the absence of elevated serum calcium--were considered to be the consequence of the accumulation of poorly absorbed material in the caecum and to be of no toxicological significance.''

On the basis of the information reviewed at both the 1998 and the 1999 meetings, JECFA allocated a group acceptable daily intake (ADI) of ''not specified'' to materials conforming to the specifications for polyglycitol syrup and maltitol syrup. Thus, based on its review of the available data, polyglycitol syrups do not, in the opinion of JECFA, represent a hazard to health and the establishment of an acceptable daily intake (a specific limit on the average daily intake) expressed in numerical form is not needed.

B. Information Supplied by the Petitioner

In an acute oral toxicity study, using a test substance described only as an hydrogenated starch hydrolyzate, the lethal dose $(LD)_{50}$ was >2,500 mg/kg (Toxicity Category III).

C. Conclusion

Syrups, hydrolyzed starch, hydrogenated is a generic term for a range of chemical substances that contain various sugar alcohols (sorbitol, maltitiol, and higher-order polyols) in varying proportions. WHO/JECFA has over a period of some years reviewed an extensive toxicity data base. The studies were conducted using similar mixtures of sugar alcohols. Generally, the studies did not reveal any toxicologically significant effects even at dose levels in the grams per kilogram body weight per day range. The human body has a demonstrated ability to metabolize this type of substance. The most noted effect in humans is a potential laxative effect.

VI. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including

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

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

A. Dietary Exposure

1. *Food.* To the best of the Agency's knowledge, products similar to syrups, hydrolyzed starch, hydrogenated have been used in food manufacture for approximately 20 years. In the food processing industry, these syrups are used as sweetening (flavoring) agents, humectants, texturizers, stabilizers, bulking agents and surface-finishing agents. According to information on the internet, various syrups, hydrolyzed starch, hydrogenated products are used in the manufacture of sugar-free soft and hard candies, and chewing gum. The SPI Polyol website advocates for use of its products in hard candies at levels up to 40%.

Given the widespread occurrence of all the various hydrogenated syrups or sugar alcohols in the existing food supply, the amount of syrups, hydrolyzed starch, hydrogenate in the food supply that could result from use in a pesticide product would not be expected to significantly increase the existing amounts in the food supply. The EPA-regulated uses as an inert ingredient in a pesticide product would be considerably less than all of the existing food additive non-nutritive sweetener uses.

2. *Drinking water exposure.* According to information on the internet, various syrups, hydrolyzed starch, hydrogenated products are soluble in water. It is expected that dissolving these chemicals in water would result in a thick syrupy solution depending on the percent of the syrups, hydrolyzed starch, hydrogenated in solution.

The Agency has used a surrogate chemical, sorbitol, to model the behavior of syrups, hydrolyzed starch, hydrogenated in the environment. Degradation via chemical reactions without the participation of organisms, or abiotic degradation of these chemicals would not be expected to be an important fate process. Chemicals such as syrups, hydrolyzed starch, hydrogenated will tend to have very low sorption coefficients; thus, migration to ground water and surface water via dissolution in water is highly likely. Volatilization from water would be minimal. Biodegradation is expected to be rapid. Degradation will proceed to mineralization, the formation of carbon dioxide and water, in a matter of hours to days thus mitigating the likelihood of leaching and runoff in substantial quantities to sources of drinking water.

B. Other Non-Occupational Exposure

Syrups, hydrolyzed starch, hydrogenated are also used in dental products since they do not contribute to tooth decay.

VII. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular chemical's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticide chemicals for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to syrups, hydrolyzed starch, hydrogenated and any other substances, and syrups, hydrolyzed starch, hydrogenated does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that syrups, hydrolyzed starch, hydrogenated has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VIII. Safety Factor for Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. The JEFCA committee has evaluated a multigeneration reproductive toxicity study in rats in which HGS (hydrogenated glucose syrup), a substance very similar to syrups, hydrolyzed starch, hydrogenated was administered in drinking water as an 18% aqueous solution. JECFA's review and evaluation did not reveal any toxicologically significant effects, and found no indication of increased susceptibility. Based on the reviews and evaluations conducted by WHO/JECFA, EPA has not used a safety factor analysis to assess the risk of syrups, hydrolyzed starch, hydrogenated. For the same reasons the additional tenfold safety factor is unnecessary.

IX. Determination of Safety for U.S. Population and Infants and Children

The JECFA Committee reviewed and evaluated over a period of some years toxicity studies performed on various sugar alcohol chemicals. As a result of their review and evaluation, JECFA determined an ADI (Acceptable Daily Intake) of ''not specified.'' The only concern was for the potential laxative effect at high intakes. Based on the available information, EPA finds that exempting syrups, hydrolyzed starch, hydrogenated (CAS Reg. No. 68425–17–2) from the requirement of a tolerance will be safe for the general population including infants and children.

X. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect. . . .'' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing syrups, hydrolyzed starch,

hydrogenated for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Exemptions

There are no existing tolerances or tolerance exemptions for syrups, hydrolyzed starch, hydrogenated.

D. International Tolerances

Various syrups, hydrolyzed starch, hydrogenated are used as food additives in several countries. The Agency is not aware of any country requiring a tolerance for syrups, hydrolyzed starch, hydrogenated nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

E. List 4A (Minimal Risk) Classification

The Agency established 40 CFR 180.950 (see the rationale in the proposed rule published January 15, 2002 (67 FR 1925) (FRL–6807–8)) to collect the tolerance exemptions for those substances classified as List 4A, i.e., minimal risk substances. As part of evaluating an inert ingredient and establishing the tolerance exemption, the Agency determines the chemical's list classification. The results of the reviews and evaluations performed by WHO/JECFA indicate a substance of lower toxicity. Therefore, syrups, hydrolyzed starch, hydrogenated (CAS Reg. No. 68425–17–2) is to be classified as a List 4A inert ingredient.

F. Public Comment

One comment was received from the Corn Allergy Support Group requesting that the Agency not grant the tolerance exemption for syrups, hydrolyzed starch, hydrogenated. The commenter believes that syrups, hydrolyzed starch, hydrogenated can cause severe allergic reactions in those individuals who are allergic to corn. It is certainly possible for an individual to be allergic to any food. However, most food allergy experts agree that the most common food allergens are: Peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat. According to the Food Allergy and Anaphylaxis Network (see *http://www.foodallergy.org/allergens.html*) these eight allergens account for 90% of all food-allergic reactions.

Generally, an allergic response occurs as a result of the body's reaction to protein. In 2001, the Agency evaluated in a White Paper the presence of protein in several of the processed foods derived from corn (see *http://www.epa.gov/oscpmont/sap/2001/july/wetmilling.pdf*). Corn can be milled by a dry milling or a wet milling process. The dry milling process produces flour, cornmeal, grits, corn bran and feed mixtures. The wet milling process uses a series of chemical reactions to produce corn syrup, corn oil and cornstarch. The steps that occur in the wet milling process are: Steeping, germ separation, fine grinding, starch separation, syrup conversion, and fermentation.

Given that corn starch can be used as the starting material for syrups, hydrolyzed starch, hydrogenated, the following parts of the discussion of the starch separation process as extracted from the White Paper are relevant here: ''Mill starch is passed through a centrifuge which allows for the gluten to be spun out. . . . At this point, the starch has only approximately one to two percent of protein remaining. The starch is diluted 8 to 14 times, rediluted and washed again. . . to remove the last trace of protein and produce high quality starch (usually greater than 99.5% pure).'' The starch is then converted to corn syrup via various refinement steps that are similar to the heat, acid and/or enzymatic processes using in producing syrups, hydrolyzed starch, hydrogenated.

Data in the White Paper demonstrate that while some very low levels of protein are present in the cornstarch, no detectable levels are present in corn syrup.

Fraction Derived from Corn Wet-Milling Process	Percent Protein
Corn starch	0.3–0.35% (high amylose corn - up to 1%)
Corn syrup (made from corn starch)	Not detectable

Given the similarities of the starting materials and the processes used, the Agency believes that the above data can be used to demonstrate the absence of protein in syrups, hydrolyzed starch, hydrogenated.

In response to the comment received, Grain Processing Corporation, the petitioner, submitted an opinion paper prepared by Dr. Steve L. Taylor of the Food Allergy Research & Resource Program at the University of Nebraska. The opinion paper dated February 9, 2000, is titled, *Allergenicity of Corn-Derived Maltodextrin and Corn Starch*. The abstract of Dr. Taylor's opinion is as follows:

No convincing evidence exists to support the existence of allergic reactions to corn-derived maltodextrin and corn starch. Corn, the primary source from which maltodextrins are derived, is rarely allergenic. The allergenicity of corn is likely due to specific protein allergens in corn, although these allergens have not been identified. Corn-derived maltodextrins and corn starch contain little, if any, protein. Reports of allergic reactions to corn-derived maltodextrins and corn starch in the medical literature are based upon controversial diagnostic approaches and/or anecdote. These reports have not been confirmed through double-blind, placebo-controlled challenge trials. The few clinical studies that have been conducted on corn-allergic individuals using more rigorous clinical approaches have failed to document allergic reactions to corn starch, corn syrup, or corn-derived maltodextrins.

Given the above data and an analysis of the information provided, EPA believes that there is a reasonable certainty that the tolerance exemption for syrups, hydrolyzed starch, hydrogenated would not contribute to allergic individuals' exposure to allergens. The protein that would provoke the allergic reaction is no longer present.

X. Conclusions

Based on the reviews and evaluations performed by JECFA which included the establishment of an acceptable daily intake (ADI) of ''not specified'' for polyglycitol syrups, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of syrups, hydrolyzed starch, hydrogenated. Accordingly, EPA finds that exempting syrups, hydrolyzed starch, hydrogenated (CAS Reg. No. 68425–17–2) from the requirement of a tolerance will be safe.

XI. 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old FFDCA sections 408

and 409 of the FFDCA. 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 ID number OPP–2005–0026 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 April 18, 2005.

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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit XI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0026, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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).

XII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). 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 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); or 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 section 408(d) of the FFDCA, 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal

Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIII. Congressional Review Act

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: February 7, 2005.

Lois Rossi,

Director, Registration Division, 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), 346a and 371.

■ 2. In § 180.950, the table in paragraph (e) is amended by adding alphabetically the following entry to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(e) * * *

Chemical Name	CAS No.
* * *	* *
Syrups, hydrolyzed starch, hydrogenated	CAS Reg. No. 68425–17–2
* * *	* *

[FR Doc. 05–2981 Filed 2–15–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0400; FRL–7695–7]

Avermectin B_1 and its delta-8,9-isomer; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for the combined residues of the insecticide/miticide avermectin B_1 (a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-O-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-O-demethyl-25-de (1-methylpropyl)-25-(1-methylethyl) avermectin A_1)), and its delta-8,9-isomer, in or on avocado at 0.020 ppm; food products in food handling establishments (other than those already covered by higher tolerances as a result of use on growing crops, and other than those already covered by tolerances on milk, meat, and meat byproducts) at 0.01 ppm; herbs, subgroup 19A (except chives) at 0.030 ppm; meat and meat byproducts of goat, hog, horse, poultry, and sheep at 0.02 ppm; mint at 0.010 ppm; plum at 0.010 ppm; plum, prune, dried at 0.025 ppm; vegetable, fruiting, group 8 at 0.020 ppm; and vegetable, leafy, except Brassica, group 4 at 0.10 ppm. These tolerances were requested under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA) in petitions filed by Syngenta Crop Protection, Inc. (formerly Novartis Crop Protection, Inc.), Interregional Research Project Number 4, and Whitmire Micro-Gen Research Laboratories, Inc.

DATES: This regulation is effective February 16, 2005. Objections and requests for hearings must be received on or before April 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP–2004–0400. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Thomas C. Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 308–9423; e-mail address: *harris.thomas@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.