

test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects in humans. In 1996, EPA chartered a scientific advisory committee, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), under the authority of the Federal Advisory Committee Act (FACA) to advise it on establishing a program to carry out Congress' directive. EDSTAC recommended a multi-step approach including a series of screens (Tier I Screens) and tests (Tier II Tests) for determining whether a chemical substance may have an effect similar to that produced by naturally occurring hormones. EPA adopted many of EDSTAC's recommendations in the program that it developed, the EDSP, to carry out Congress' directive.

EDSTAC also recognized that there currently are no validated testing systems for determining whether a chemical may have an effect in humans that is similar to an effect produced by naturally occurring hormones. Consequently, EPA is in the process of developing and validating the screens and tests that EDSTAC recommended for inclusion in the EDSP. In carrying out this validation exercise, EPA is working closely with, and adhering to the principles of the Interagency Coordinating Committee for the Validation of Alternate Methods (ICCVAM). EPA also is working closely with the Organization for Economic Cooperation and Development's (OECD) Endocrine Testing and Assessment Task Force to validate and harmonize endocrine screening tests of international interest.

Finally, to ensure that EPA has the best and most up-to-date advice available regarding the validation of the screens and tests in the EDSP, EPA recently chartered EDMVS of the NACEPT. EDMVS provides independent advice and counsel to the Agency through NACEPT, on scientific and technical issues related to validation of the EDSP Tier I screens and Tier II tests, including advice on methods for reducing animal use, refining procedures involving animals to make them less stressful, and replacing animals where scientifically appropriate.

EDMVS has met five times since its establishment in September 2001.

The objectives of the October 2001 meeting (docket control number OPPTS-42212D) were for EPA to provide:

1. An overview of EPA's EDSP.
2. Background information on test protocol validation and approaches.

3. For the EDMVS to develop a clear understanding of their scope, purpose and operating procedures.

4. For the EDMVS and the EDSP to determine the next steps.

The objectives of the December 2001 meeting (docket control number OPPTS-42212E) were for the EDMVS to provide input and advice on:

1. EDMVS's mission statement and work plan.
2. The *in utero* through lactation assay detailed review paper.
3. The pubertal assay study design for the multi-dose and chemical array protocols.
4. The mammalian 1-generation study design.

The objectives of the March 2002 meeting (docket control number OPPTS-42212F) were for the EDMVS to provide input and advice on:

1. EDSP's implementation process and practical aspects of validation.
2. The *in utero* through lactation assay protocol.
3. The fish reproduction assay detailed review paper.
4. Special studies on fathead minnow assays, vitellogenin assay, and avian dosing protocol.

5. The steroidogenesis detailed review paper.

6. The aromatase detailed review paper.

7. A proposed standard suite of chemicals for testing in the Tier I screening assay.

8. The current efforts related to evaluating the relevance of animal data to human health.

9. EPA's approach to addressing low-dose issues.

The objective of the June 2002 teleconference meeting (docket ID number OPPT-2002-0020) was for the EDMVS to provide input and advice on the steroidogenesis detailed review paper.

The objectives of the July 2002 meeting (docket ID number OPPT 2002-0029) were:

1. To review criteria, recommended by EDSTAC and adopted by EDSP for screens.

2. To receive an update on the NICEATM estrogen and androgen receptor binding efforts.

3. To discuss and provide advice on general dose setting issues, and to provide comments and advice on:

- A pubertals—special study—restricted feeding.
- A mammalian 2-generation—draft PTU special study.
- An amphibian metamorphosis detailed review paper.
- An invertebrate detailed review paper.

### III. Meeting Objectives for the December 2002 Teleconference Meeting

The objective of the December 2002 teleconference meeting (docket ID number OPPT-2002-0059) is for the EDMVS to provide input and advice on the Tier II fish lifecycle assay detailed review paper.

A list of the EDMVS members and meeting materials are available on our Web site (<http://www.epa.gov/scipoly/oscpendo/edmvs.htm>), and in the EPA Docket.

#### List of Subjects

Environmental protection, Endocrine disruptors.

Dated: November 4, 2002.

#### Joseph Merenda,

Director, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. 02-28910 Filed 11-13-02; 8:45 am]

BILLING CODE 6560-50-S

### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0294; FRL-7279-3]

#### Alpha-cyclodextrin, Beta-cyclodextrin, and Gamma-cyclodextrin; Notice of Filing a Pesticide Petition to Establish an Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin in or on various food commodities.

**DATES:** Comments, identified by docket ID number OPP-2002-0294, must be received on or before December 16, 2002.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Treva Alston, Minor Use, Inerts, and Emergency Response Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8373; e-mail address: [alston.treva@epa.gov](mailto:alston.treva@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 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 Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP-2002-0294. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgrstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment

system, EPA dockets. You may use EPA dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic

public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

*C. How and To Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2002-0294. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID number OPP-2002-0294. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID number OPP-2002-0294.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2002-0294. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

#### *D. How Should I Submit CBI To the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI, and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does

not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket 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.**

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

#### **II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### **List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 4, 2002.

**Debra Edwards,**

*Director, Registration Division, Office of Pesticide Programs.*

#### **Summary of Petition**

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the Wacker Biochem Corporation and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

*PP 2E6514*

#### **Summary of Petitions**

EPA has received a pesticide petition (2E6514) from Wacker Biochem Corporation, 3301 Sutton Road, Adrian, MI 49221-9397 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.950 to establish an exemption from the requirement of a tolerance for alpha-cyclodextrin (CAS No. 10016-20-3), beta-cyclodextrin (CAS No. 7585-39-9), and gamma-cyclodextrin (CAS No. 17465-86-0) in or on raw agricultural commodities resulting from the use of alpha-, beta-, and gamma-cyclodextrin as ingredients in pesticide formulations used in accordance with good agricultural practices. Alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin are naturally occurring compounds derived from the degradation of starch by the glucosyltransferase enzyme (CGTase). D-glucose molecules that are formed by the digestion of starch are joined "head-to-tail" to form alpha-, beta-, and gamma-cyclodextrin which are ring-shaped molecules. Alpha-, beta-, and gamma-cyclodextrin are comprised of six, seven and eight D-glucose units, respectively. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### *A. Residue Chemistry*

1. *Plant metabolism.* While no studies have been conducted to evaluate the metabolism of alpha-, beta-, and gamma-cyclodextrin in plants, the metabolic products in plants are anticipated to be

ubiquitous, naturally occurring simple sugars and CO<sub>2</sub>. The anticipated plant metabolites are not of toxicological concern.

2. *Analytical method.* An analytical method is not required for enforcement purposes since Wacker Biochem is requesting the establishment of an exemption from the requirement of a tolerance without any numerical limitation.

#### B. Toxicological Profile

Alpha-cyclodextrin: The Food & Agriculture Organization/World Health Organization (FAO/WHO) Joint Expert Committee on Food Additives (JECFA) has evaluated alpha-cyclodextrin and in 2001 allocated an acceptable daily

intake (ADI) of "not specified." This is the most desirable ADI allocation issued by JECFA.

Beta-cyclodextrin: A GRAS (generally recognized as safe) petition was submitted by Roquette America Inc/American Maize-Products Co. for use as a formulation aid in the production of dry flavoring mixes (February 3, 1992) and for use as a flavor protectant (September 20, 1996). A self-affirmation of beta-cyclodextrin as a flavor carrier in foods was completed by Cerestar USA on February 4, 1998. Wacker Biochem Corporation has submitted to the FDA an independent GRAS determination for beta-cyclodextrin for use as a flavor carrier or protectant in baked goods

prepared from dry mixes, breakfast cereal, chewing gum, compressed, candies, gelatins and puddings, flavored coffee and tea, processed cheese products, dry mix for beverages, flavored savory snacks and crackers, dry mixes for soups (GRAS Notice No. 74). FDA has not yet completed its review of the self-affirmation.

Gamma-cyclodextrin: Wacker Biochem Corporation has determined that gamma-cyclodextrin is generally recognized as safe (GRAS) when used as a stabilizer, emulsifier, carrier and formulation aid in foods.

The toxicology and metabolism data relevant to the proposed tolerance exemption are summarized in Table 1.

TABLE 1.—TOXICITY AND METABOLISM

Study	Cyclo-dextrin	Result
Acute oral toxicity	Alpha-	LD <sub>50</sub> >10,000 mg/kg (rat)
	Beta-	LD <sub>50</sub> >12,000 mg/kg (rabbit)
	Gamma-	LD <sub>50</sub> >8,000 mg/kg (rat)
Acute dermal toxicity		No data are available
Acute inhalation toxicity		No data are available
Primary eye irritation	Alpha-	Crystalline form: Eye irritant, but not corrosive 50% suspension: Non-irritant
	Beta-	Slight irritant
	Gamma-	Non-irritant
Primary dermal irritation	Alpha-	Non-irritant
	Beta-	Non-irritant
Dermal sensitization	Alpha-	Non-sensitizer
	Beta-	Non-sensitizer
	Gamma-	Non-sensitizer
28-Day feeding study: rodent	Alpha-	NOEL = 5% in the diet
	Beta-	NOEL = 5% in the diet
90-Day feeding study: rat	Alpha-	NOAEL = 20% in diet highest dose tested (HDT)
	Beta-	NOAEL = 400 mg/kg/day by gavage
	Gamma-	NOAEL = 20% in diet HDT
90-Day feeding study: dog	Alpha-	NOAEL = 20% in diet HDT
	Beta-	NOEL = 2.5% in diet LOEL = 5% in diet. Hematology and clinical chemistry effects observed indicated slight toxicity
	Gamma-	NOAEL = 20% in diet HDT

TABLE 1.—TOXICITY AND METABOLISM—Continued

Study	Cyclo-dextrin	Result
Subchronic dermal toxicity		No data are available
Chronic feeding and oncogenicity	Beta-	1-year dog NOAEL = 1% in diet = 350 mg/kg/day LOAEL = 2.5% in diet = 925 mg/kg/day Increased levels of protein were observed in urine 2-year rat: NOEL for oncogenicity = 6% in diet Small percentage is absorbed by the intestinal walls and causes kidney damage. Beta-cyclodextrin is not degraded in the small intestine. In the large intestine, it undergoes bacterial degradation, leading to gas generation and diarrhea
Teratology study: rodent	Alpha-	Not teratogenic, embryotoxic or fetotoxic at doses up to 20% of diets in both rats and rabbits HDT
	Beta-	Not teratogenic, embryotoxic or fetotoxic at 5,000 mg/kg/day in rats HDT and at 1,000 mg/kg/day in rabbits HDT
	Gamma-	Not teratogenic, embryotoxic or fetotoxic at doses up to 20% of diets in both rats and rabbits HDT
2-Generation reproduction	Beta-	NOAEL in rats = 1% in diet = 700 mg/kg/day LOAEL in dams and offspring = 2.5% in the diet
Gene mutation test	Alpha-	Negative Ames test
	Gamma-	Negative Ames test
Structural chromosomal aberration test	Beta-	Negative in rats at dose of 2% in diet
Other genotoxic effects	Alpha-	Negative micronucleus test
	Gamma-	Negative micronucleus test
Metabolism (oral dosing)	Alpha	Absorption: 2% dose absorbed Distribution: Liver (>0.05% dose) and kidney (>0.01% dose) Metabolism: Extensively and predominantly metabolized to CO <sub>2</sub> by intestinal flora Excretion: 60% dose expelled as CO <sub>2</sub> 26–33% dose incorporated 7–14% dose excreted in urine and feces
	Beta-	Absorption: No significant absorption as intact molecule. Absorption as sugars is similar to that of glucose; occurs via passive transport Distribution: Max. 0.9% in GI tract 60 hours after dosing Metabolism: Hydrolysis to open chain dextrans and glucose occurs in the large intestine by intestinal flora Excretion: 66.8% dose as CO <sub>2</sub> in expired air within 23 hours of dosing. 0.6% to 4% in feces within 60 hours of dosing
	Gamma-	Absorption: >0.1% as intact molecule Metabolism: Rapid and total degradation to glucose in the upper intestinal tract by intestinal flora Excretion: 60% dose expelled as CO <sub>2</sub> 37% dose incorporated 3% dose excreted in urine and feces

1. *Metabolite toxicology.* Alpha-, beta-, and gamma-cyclodextrin are metabolized to simple sugars and CO<sub>2</sub>. These metabolites are also metabolites of the digestion of carbohydrates in the diet and have no significant toxicity.

2. *Endocrine disruption.* Based upon the available data, alpha-, beta-, and gamma-cyclodextrin are not anticipated to disrupt the endocrine system.

*C. Aggregate Exposure*

1. *Food.* Alpha-cyclodextrin, beta-cyclodextrin, and gamma-cyclodextrin are

naturally occurring compounds and are used as food additives.

Alpha-cyclodextrin food additive uses include: Carrier; encapsulating agent for food additives, flavorings and vitamins; stabilizer; and absorbent. The ADI is “not specified.”

Beta-cyclodextrin is used as a flavor carrier or protectant. See Table 2 for a detailed list of uses and the maximum concentrations.

TABLE 2.—MAXIMUM CONCENTRATION OF BETA-CYCLODEXTRIN IN FOODS

Beta-Cyclodextrin Use	Maximum Concentration
Baked goods prepared from dry mixes compressed candies	2%
Gelatins and puddings flavored coffee and tea dry mix for beverages	1%
Flavored savory snacks and crackers	0.5%
Dry mixes for soups	0.2%

Gamma-cyclodextrin is used in foods such as bread spreads, frozen dairy desserts, ready to eat dairy desserts, desserts prepared from dry mixes, fruit fillings, cheese and cream fillings, chewing gum, dietary supplements. See Table 3 for a complete list of uses and the maximum concentrations.

TABLE 3.—MAXIMUM CONCENTRATION OF GAMMA-CYCLODEXTRIN IN FOODS

Gamma-Cyclodextrin Use	Maximum Use Concentration
Carrier for flavors, sweeteners and colors	<1%
Dry mixes for beverages	<1%
Dry mixes for soups	<1%
Dry mixes for dressings, gravies, and sauces	<1%
Dry mixes for puddings, gelatins, and fillings	<1%
Instant coffee and instant tea	<1%
Coffee whiteners	<1%
Compressed candies	<1%
Chewing gum	<1%
Breakfast cereals (ready-to-eat)	<1%
Savory snacks and crackers	<1%
Spices and seasonings	<1%
Carrier for vitamins	<1%
For use in dry food mixes and dietary supplements	<90% <sup>1</sup>
Carrier for polyunsaturated fatty acids	
For use in dry food mixes and dietary supplements	<80% <sup>1</sup>
Flavor modifier	
Soya milk	<2%
Stabilizer	
Bread spreads (fat-reduced)	<20%
Frozen dairy desserts	<3%
Baked goods (excl. bread, but incl. dough and baking mixes)	<2%
Bread	<1%
Fruit-based fillings	<3%
Fat-based fillings	<5%

TABLE 3.—MAXIMUM CONCENTRATION OF GAMMA-CYCLODEXTRIN IN FOODS—Continued

Gamma-Cyclodextrin Use	Maximum Use Concentration
Processed cheese	<3%
Dairy deserts (ready-to-eat and prepared from dry mixes)	<3%

<sup>1</sup>Percent by weight of gamma-cyclodextrin relative to the nutrient for which gamma-cyclodextrin is used as a carrier.

The proposed use of alpha-, beta-, and gamma-cyclodextrin as ingredients in pesticide formulations is anticipated to result in no significant additional dietary exposure to alpha-, beta-, and gamma-cyclodextrin.

2. *Drinking water.* Any alpha-, beta-, and gamma-cyclodextrin in drinking water sources is anticipated to degrade to simple sugars and CO<sub>2</sub> that will be used by plants as building blocks for the plant's growth. No significant exposure of alpha-, beta-, and gamma-cyclodextrin via drinking water is anticipated.

3. *Non-dietary exposure.* Cyclodextrins are used extensively in the cosmetic industry. Alpha-, beta-, and gamma-cyclodextrin are too large to be absorbed through the skin, so no significant systemic exposure is anticipated to result from the cosmetic use or other residential uses of alpha-, beta-, and gamma-cyclodextrin.

#### D. Cumulative Effects

Alpha-, beta-, and gamma-cyclodextrin have no significant toxic effects for consideration of cumulative effects.

#### E. Safety Determination

1. *U.S. population.* Alpha-, beta-, and gamma-cyclodextrin are low toxicity, naturally occurring compounds that are used as food additives. The D-glucose building blocks of alpha-, beta-, and gamma-cyclodextrin are also the result of digestion of starchy foods such as bread, rice, potatoes and pasta. Alpha-, beta-, and gamma-cyclodextrin are part of the current U.S. diet, and the proposed new uses of alpha-, beta-, and gamma-cyclodextrin as ingredients in pesticide formulations is not anticipated to contribute significantly to the amount of alpha-, beta-, and gamma-cyclodextrin in the U.S. diet. The proposed new use of alpha-, beta-, and gamma-cyclodextrin for use as an inert ingredient in pesticide formulations has a reasonable certainty of no harm to the U.S. population.

2. *Infants and children.* Alpha-, beta-, and gamma-cyclodextrin have no significant toxic effects that are specific to infants or children. The proposed new uses of alpha-, beta-, and gamma-cyclodextrin as ingredients in pesticide

formulations has a reasonable certainty of no harm to infants or children.

#### F. International Tolerances

Alpha-cyclodextrin: The FAO/WHO JECFA has evaluated alpha-cyclodextrin and in 2001 allocated an ADI of "not specified." This is the most desirable ADI and is limited to low toxicity compounds.

*Beta-cyclodextrin:* A request was submitted to the CODEX Alimentarius Commission for additive clearance in the General Standard on Food Additives (INS No. 459) at a maximum level of 50,000 milligrams/kilogram (mg/kg) in food category 5.3, for chewing gum. A new monograph for beta-cyclodextrin has been published in the First Supplement to the Fourth Edition of the Food Chemicals Codex. Beta-cyclodextrin is published in Annex V of the Official Journal of the European Communities-Food Additives as a carrier only for food additives up to 1 gram/kilogram food. An ADI of 5 mg/kg body weight was established at the February 1995 joint FAO/WHO meeting of the expert committee on food additives and is published in WHO Food Additive Series 35.

Gamma-cyclodextrin: The FAO/WHO JECFA has evaluated alpha-cyclodextrin and in 2,000 (53rd meeting) allocated an ADI of "not specified." This is the most desirable ADI and is limited to low toxicity compounds.

[FR Doc. 02-28909 Filed 11-13-02; 8:45 am]

BILLING CODE 6560-50-S

### FEDERAL COMMUNICATIONS COMMISSION

#### Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

November 7, 2002.

**SUMMARY:** The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Pub. L. 104-13. An agency may not conduct or sponsor a collection

of information unless it displays a current valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

**DATES:** Written comments should be submitted on or before January 13, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all comments to Les Smith, Federal Communications Commission, Room 1-A804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to [lesmith@fcc.gov](mailto:lesmith@fcc.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection(s) contact Les Smith at 202-418-0217 or via the Internet at [lesmith@fcc.gov](mailto:lesmith@fcc.gov).

#### SUPPLEMENTARY INFORMATION:

*OMB Control Number:* 3060-0960.

*Title:* Application of Network Non-Duplication, Syndicated Exclusivity, and Sports Blackout Rules to Satellite Retransmissions of Broadcast Signals.

*Form Number:* N/A.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Businesses or other for-profit entities.

*Number of Respondents:* 1,407.

*Estimated Time per Response:* 0.5 to 1.0 hours.

*Frequency of Response:* On occasion reporting requirements; Third party disclosure.

*Total Annual Burden:* 63,992 hours.