

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA-2013-N-0888]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D₂ and Vitamin D₃

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulations to expand the safe uses of vitamin D₂ as a nutrient supplement in edible plant-based beverages intended for use as milk alternatives and in edible plant-based yogurt alternatives and vitamin D₃ as a nutrient supplement in milk at levels higher than those currently permitted. We are taking this action in response to a food additive petition filed by Dean Foods Company and WhiteWave Foods Company.

DATES: This rule is effective July 18, 2016. See section VIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by August 17, 2016. The Director of the Federal Register approves the incorporation by reference of certain publications listed in the rule as of July 18, 2016.

ADDRESSES: You may submit objections and requests for a hearing as follows:

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on <http://www.regulations.gov>.

- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-0888 for "Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D₂ and Vitamin D₃ Final Rule." Received objections will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of

comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Judith Kidwell, Center for Food Safety and Applied Nutrition (CFSAN) (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1071.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of August 16, 2013 (78 FR 49990), FDA announced that Dean Foods Company (Dean Foods) and WhiteWave Foods Company (WhiteWave), c/o Hogan Lovells US LLP, Columbia Square, 555 13th Street NW., Washington, DC 20004, had jointly filed a food additive petition (FAP 3A4801). The petition proposed to amend 21 CFR 172.379 to provide for the safe use of vitamin D₂ as a nutrient supplement in edible plant-based food products intended for use as alternatives to milk and milk products and to amend 21 CFR 172.380 to provide for the safe use of vitamin D₃ as a nutrient supplement in milk at levels higher than those currently permitted. After the notice of filing published, the petitioners amended the petition to limit the proposed use of vitamin D₂ to only edible plant-based beverages intended as alternatives to milk (e.g., soy-, rice-, almond-, coconut-based beverages) and edible plant-based yogurt alternatives. This final rule is a complete response to the petition.

Dean Foods/WhiteWave have requested that we amend § 172.379 to authorize the use of vitamin D₂ as a nutrient supplement at levels not to exceed 84 International Units (IU) per 100 grams (g) in edible plant-based beverages intended for use as milk alternatives and not to exceed 89 IU per 100 g in edible plant-based yogurt alternatives. Dean Foods/WhiteWave requested that the proposed use of 84 IU vitamin D₂ per 100 g in edible plant-based beverages replace the current allowable maximum use of 50 IU per 100 g in soy beverages authorized under

§ 172.379(c). Specifically, Dean Foods/WhiteWave requested that we amend § 172.379(c) to eliminate the “soy beverages” category, and instead create a new category of food that may be supplemented with vitamin D₂. This category, “edible plant-based beverages intended for use as milk alternatives”, would include soy beverages intended as milk alternatives, and would have a maximum allowable use of 84 IU vitamin D₂ per 100 g. This category would also include other edible plant-based beverages made from rice, almond, and coconut, among other foods, that are intended as milk alternatives. Dean Foods/WhiteWave also requested that we amend § 172.380 to allow for the addition of vitamin D₃ as a nutrient supplement in milk at levels not to exceed 84 IU per 100 g milk. For milk with more than the amount of vitamin D provided for in the milk standard of identity in 21 CFR 131.110(b)(2), the milk would be required to be named by use of a nutrient content claim and a standardized term in accordance with 21 CFR 130.10.

Vitamin D comprises a group of fat-soluble seco-sterols and comes in many forms. The two major physiologically relevant forms are vitamin D₂ and vitamin D₃. Vitamin D without a subscript represents either vitamin D₂ or vitamin D₃ or both. Vitamin D is affirmed as generally recognized as safe (GRAS) for use in food as a nutrient supplement in accordance with 21 CFR 184.1950(c)(1) and 21 CFR 184.1(b)(2), with the following specific limitations:

Category of food	Maximum levels in food (as served)
Breakfast cereals	350 IU/100 grams (g).
Grain products and pasta	90 IU/100 g.
Milk	42 IU/100 g.
Milk products	89 IU/100 g.

Additionally, under § 184.1950(c)(2) and (3), vitamin D is affirmed as GRAS for use in infant formulas and margarine, respectively. Under § 172.380, vitamin D₃ is approved for use as a food additive as a nutrient supplement in calcium-fortified fruit juices and fruit juice drinks, meal replacement and other type bars, soy protein-based meal replacement beverages represented for special dietary use in reducing or maintaining body weight, certain cheese and cheese products, meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight, and foods represented for use as

a sole source of nutrition for enteral feeding.

Under § 172.379, vitamin D₂ is approved for use as a food additive as a nutrient supplement in soy beverages, soy beverage products, soy-based butter substitute spreads, and soy-based cheese substitutes, and soy-based cheese substitute products.

Under § 172.381, vitamin D₂ bakers yeast is approved for use as a food additive as a source of vitamin D₂ and as a leavening agent in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods.

Vitamin D is essential for human health. The major function of vitamin D is the maintenance of blood serum concentrations of calcium and phosphorus by enhancing the absorption of these minerals in the small intestine. Vitamin D deficiency can lead to abnormalities in calcium and bone metabolism, such as rickets in children or osteomalacia in adults. Excessive intake of vitamin D elevates blood plasma calcium levels (hypercalcemia) by increased intestinal absorption and/or mobilization from the bone.

To ensure that vitamin D is not added to the U.S. food supply at levels that could raise safety concerns, FDA affirmed vitamin D as GRAS with specific limitations as listed in § 184.1950. Under § 184.1(b)(2), an ingredient affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use of the ingredient, and level of use. Any addition of vitamin D to food beyond those limitations set out in § 184.1950 requires either a food additive regulation or an amendment of § 184.1950.

To support their petition, Dean Foods/WhiteWave submitted dietary exposure estimates of vitamin D from the proposed uses of vitamin D₂ and vitamin D₃, as well as all dietary sources from naturally occurring sources of vitamin D and uses in accordance with our approved food additive regulations (§§ 172.379, 172.380, and 172.381) and our GRAS affirmation regulation (§ 184.1950). They also included dietary supplements in their estimates and compared these intake estimates to the Tolerable Upper Intake Level (UL) for vitamin D established by the Institute of Medicine (IOM) of the National Academies. Dean Foods/WhiteWave also submitted a number of publications pertaining to human clinical studies on vitamin D. Based on this information, Dean Foods/WhiteWave concluded that the proposed uses of vitamin D₂ in edible plant-based beverages intended

as alternatives to milk, edible plant-based yogurt alternatives, and vitamin D₃ in milk are safe.

II. Evaluation of Safety

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, we consider the projected human dietary exposure to the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us. We compare the estimated daily intake (EDI) of the additive from all food sources to an acceptable daily intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all food sources of the additive. We commonly use the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.

A. Acceptable Daily Intake Level for Vitamin D

In 2011, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board at the IOM conducted an extensive review of relevant published scientific literature on vitamin D to update current dietary reference intakes and ULs for vitamin D. Based on this information, the IOM revised the ULs for vitamin D and developed a report on their findings (Ref. 1). In their 2011 assessment of vitamin D, the IOM established a UL of 1,000 IU per day (IU/p/d) for infants 0 months to 6 months of age and a UL of 1,500 IU/p/d for infants 6 months to 12 months of age. For children 1 year to 3 years of age, the IOM established a UL of 2,500 IU/p/d; for children 4 years to 8 years of age, the IOM established a UL of 3,000 IU/p/d. For children 9 years to 18 years of age and adults, the IOM established a UL of 4,000 IU/p/d.

The IOM considers the UL as the highest average daily intake level of a nutrient that poses no risk of adverse effects when the nutrient is consumed over long periods of time. The UL is determined using a risk assessment model developed specifically for nutrients. The dose-response assessment, which concludes with an estimate of the UL, is built upon three toxicological concepts commonly used in assessing the risk of exposures to chemical substances: No-observed-adverse-effect level, lowest-observed-effect level, and application of an uncertainty factor. We considered the ULs established by the IOM relative to

the intake estimates as the primary basis for assessing the safety of the petitioned uses of vitamin D₂ and vitamin D₃. We also reviewed scientific articles on the safety of vitamin D submitted in the petition, as well as other relevant published studies available to FDA.

B. Estimated Daily Intake for Vitamin D

For the proposed uses of vitamin D₂ and vitamin D₃, Dean Foods/WhiteWave provided dietary intake estimates of vitamin D for 11 population groups, assuming maximum levels of vitamin D in all foods that could be fortified (except for one scenario where typical fortification levels in infant formula were used), as well as in the petitioned foods. They also included exposure from dietary supplements as reported in the 2003–2008 National Health and Nutrition Survey (NHANES) 30-day dietary supplement use data (<http://wwwn.cdc.gov/nchs/nhanes/search/datapage.aspx?Component=dietary>) and from naturally occurring food sources.

The exposure estimates performed by Dean Foods/WhiteWave are appropriate. However, there are some exposure parameters that have changed since the estimates were completed in 2013. In particular, Dean Foods/WhiteWave provided estimates that included vitamin D exposure from fortification of edible plant-based dairy analogs other than edible plant-based yogurt alternatives, which they are no longer seeking to fortify. Dean Food/WhiteWave also included fortification of meal replacement bars at a level of 500 IU/40 g in anticipation of the approval of FAP 2A4788 (Abbott Laboratories); however, this use was subsequently withdrawn from the petition before the final rule issued (see 79 FR 46993, August 12, 2014). In addition, more recent 24-hour recall dietary supplement data from the 2009–2012 NHANES (<http://wwwn.cdc.gov/nchs/nhanes/search/datapage.aspx?Component=dietary>) have become available that may better represent current vitamin D exposure from dietary supplements than the 30-day dietary supplement use data from the 2003–2008 NHANES used by Dean Foods/WhiteWave. Moreover, a recent published study suggests that it may be appropriate to include dietary sources of the vitamin D metabolite, 25-hydroxyvitamin D (25(OH)D), in vitamin D exposure estimates to take into account discrepancies seen between dietary intake and blood serum levels of vitamin D (Ref. 2). The foods that were identified in the study as sources of 25(OH)D were beef, pork, chicken, turkey, and eggs. The study also indicated that 25(OH)D may have a

potency five times that of vitamin D. For these reasons, we have used the 2009–2012 NHANES data to estimate dietary exposure to vitamin D from: (1) The petitioned uses in milk, edible plant-based beverages intended as milk alternatives, and edible plant-based yogurt alternatives; and (2) cumulative exposure from all current sources of vitamin D (*i.e.*, naturally occurring sources, approved fortified sources, and dietary supplements), the petitioned uses of vitamin D in milk, edible plant-based beverages intended as milk alternatives, and edible plant-based yogurt, and exposure from sources of 25(OH)D, which have been adjusted to account for the difference in potency between 25(OH)D and vitamin D.

For the overall U.S. population 1 year of age and older, the cumulative exposure at the 90th percentile from all food sources of vitamin D, including the proposed uses, dietary supplements, and 25(OH)D, was estimated to be 2,000 IU/p/d. The cumulative exposure for infants 0 to 6 months of age and infants 6 to 12 months of age from all food sources of vitamin D, including the proposed uses, dietary supplements, and 25(OH)D, was estimated to be 948 IU/p/d and 988 IU/p/d, respectively, for the 90th percentile consumer (Ref. 3).

C. Safety of the Petitioned Uses of Vitamin D₂

We reviewed and evaluated the information submitted by Dean Foods/WhiteWave regarding the safety of the dietary intake of vitamin D from the proposed uses in milk, edible plant-based beverages intended as milk alternatives, and edible plant-based yogurt alternatives. Dean Food/WhiteWave submitted reports of scientific studies published subsequent to the 1997 IOM report and issuance of the final rule (79 FR 46993) authorizing the use of vitamin D₃ in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and in foods represented for use as a sole source of nutrition for enteral feeding. Dean Food/WhiteWave concluded that these publications support a conclusion that the proposed use of vitamin D is safe.

We reviewed the published reports of scientific studies on vitamin D submitted by Dean Food/WhiteWave, as well as other relevant published studies available to us since our previous evaluations of six food additive petitions for fortifying a variety of foods with vitamin D (77 FR 52228, August 29, 2012; 74 FR 11019, March 16, 2009; 70 FR 69435, November 16, 2005; 70 FR 37255, June 29, 2005; 70 FR 36021, June

22, 2005; 68 FR 9000, February 27, 2003). These studies did not raise any new safety concerns regarding the current or proposed uses of vitamin D. The most recent food additive petition resulted in our amendment of the food additive regulations in § 172.380 to allow for the safe use of vitamin D₃ in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and in foods represented for use as a sole source of nutrition for enteral feeding (79 FR 46993). The six earlier food additive petitions also resulted in amendments of the food additive regulations to allow for the safe use of vitamin D as a nutrient supplement in certain foods.

We considered the ULs established by the IOM relative to the intake estimates as the primary basis for assessing the safety of the petitioned uses of vitamin D. Depending on the age group, the IOM UL for vitamin D for the U.S. population 1 year of age and older ranges from 2,500 IU/p/d to 4,000 IU/p/d. The estimated dietary exposure to vitamin D from all food sources, including the proposed uses, at the 90th percentile for the U.S. population (1 years of age and older) is estimated to be 2,000 IU/p/d, which is below the lowest IOM UL of 2,500 IU/p/d in the range of ULs for the overall U.S. population (1 year of age and older). Estimated exposure to vitamin D from all food sources, including the proposed uses, for infants 0 months to 6 months of age at the 90th percentile is 948 IU/p/d; for infants 6 months to 12 months of age, estimated exposure to vitamin D is 988 IU/p/d. Both of these estimates are below the IOM UL of 1,000 IU/p/d for infants 0 months to 6 months of age and 1,500 IU/p/d for infants 6 months to 12 months of age. Because the 90th percentile EDI of vitamin D from all current and proposed food sources for each population group is less than the corresponding IOM UL for that population group, we conclude that dietary intake of vitamin D₂ from the proposed use as a nutrient supplement in edible plant-based beverages intended as milk alternatives and edible plant-based yogurt alternatives and the proposed increased maximum permitted level of vitamin D₃ in milk are safe (Ref. 4).

III. Incorporation by Reference

FDA is incorporating by reference two monographs from the Food Chemicals Codex 9th Edition (FCC 9), which was approved by the Office of the **Federal Register**. You may purchase a copy of the material from the United States Pharmacopeial Convention, 12601

Twinbrook Pkwy., Rockville, MD 20852, 1–800–227–8772, <http://www.usp.org/>.

The current regulation for the use of vitamin D₃ in food (§ 172.380) indicates that the additive must meet the specifications in the FCC 8. The more current FCC is the 9th Edition. The current regulation for vitamin D₂ (§ 172.379) indicates the additive must meet the specifications in the 7th edition of the FCC (FCC 7). Because the specifications for vitamin D₂ and vitamin D₃ in FCC 9 are identical to those in FCC 7 and FCC 8, respectively, Dean Foods/WhiteWave requested that the respective regulations be updated to reference the specifications in FCC 9. Therefore, we are amending §§ 172.379 and 172.380 by adopting the specifications for vitamin D₂ and vitamin D₃ in FCC 9 in place of FCC 7 and FCC 8, respectively.

IV. Conclusion

Based on all data relevant to vitamin D that we reviewed, we conclude that the petitioned uses of vitamin D in milk and edible plant-based beverages intended as milk alternatives and edible plant-based yogurt alternatives within the limits proposed by Dean Food/WhiteWave are safe. Consequently, we are amending the food additive regulations as set forth in this document.

V. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), we will delete from the documents any materials that are not available for public disclosure.

VI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the August 16, 2013, **Federal Register** document of petition for FAP 3A4801. We stated that we had determined, under 21 CFR 25.32(k), that this action “is of a type that does not individually or cumulatively have a significant effect on the human environment” such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget

under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IX. Section 301(l) of the Federal Food, Drug, and Cosmetic Act

Our review of this petition was limited to section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348). This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(l) of the FD&C Act (21 U.S.C. 331(l)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(l)(1) to (4) of the FD&C Act applies. In our review of this petition, FDA did not consider whether section 301(l) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered

for introduction into interstate commerce, would not violate section 301(l) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(l) of the FD&C Act applies.

X. References

References marked with an asterisk (*) are on display at the Division of Dockets Management (see **ADDRESSES**), under Docket No. FDA–2013–N–0888, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. References without asterisks are not on display; they are available as published articles and books.

1. Committee to Review Dietary Reference Intakes for Vitamin D and Calcium, Food and Nutrition Board, Institute of Medicine, “Dietary Reference Intakes for Calcium and Vitamin D,” National Academies Press, Washington, DC, 2011.
2. Taylor, C., K. Patterson, J. Roseland, et al., “Including Food 25-Hydroxyvitamin D in Intake Estimates May Reduce the Discrepancy Between Dietary and Serum Measures of Vitamin D Status,” *Journal of Nutrition*, 144:654–659, 2014.
- *3. FDA Memorandum from D. Folmer, CFSAN Chemistry Review Group, Division of Petition Review, to J. Kidwell, Regulatory Group I, Division of Petition Review, January 27, 2016.
- *4. FDA Memorandum from T. Tyler, CFSAN Toxicology Team, Division of Petition Review, to J. Kidwell, Division of Petition Review, February 10, 2016.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

- 1. The authority citation for part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

- 2. Amend § 172.379 by revising the first sentence in paragraph (b) and revising the table in paragraph (c) by removing the entry for “Soy beverages” and adding entries for “Edible plant-

based beverages intended as milk alternatives” and “Edible plant-based yogurt alternatives” in alphabetical order to read as follows:

§ 172.379 Vitamin D₂.

* * * * *

(b) Vitamin D₂ meets the specifications of the 2015 Food Chemical Codex, 9th edition (through Third Supplement), effective December 1, 2015, pp. 1260–1261, which is incorporated by reference. * * *

(c) * * *

Category of food	Maximum levels in food (as served)
Edible plant-based beverages intended as milk alternatives.	84 IU/100 g.
Edible plant-based yogurt alternatives.	89 IU/100 g.
* * * * *	

■ 3. Amend § 172.380 by revising the first sentence in paragraph (b) and by adding paragraph (c)(8) to read as follows:

§ 172.380 Vitamin D₃.

* * * * *

(b) Vitamin D₃ meets the specifications of the 2015 Food Chemical Codex, 9th edition (through Third Supplement), effective December 1, 2015, pp. 1261–1262, which is incorporated by reference. * * *

(c) * * *

(8) At levels not to exceed 84 IU per 100 g (800 IU/quart) in milk that contains more than 42 IU vitamin D per 100 g (400 IU/quart) and that meets the requirements for foods named by use of a nutrient content claim and a standardized term in accordance with § 130.10 of this chapter.

Dated: July 11, 2016.

Susan Bernard,
Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2016–16738 Filed 7–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9777]

RIN 1545–BG41; RIN 1545–BH38

Arbitrage Guidance for Tax-Exempt Bonds

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations on the arbitrage restrictions under section 148 of the Internal Revenue Code (Code) applicable to tax-exempt bonds and other tax-advantaged bonds issued by State and local governments. These final regulations amend existing regulations to address certain market developments, simplify certain provisions, address certain technical issues, and make existing regulations more administrable. These final regulations affect State and local governments that issue tax-exempt and other tax-advantaged bonds.

DATES: *Effective Date:* These final regulations are effective on July 18, 2016.

Applicability Date: For dates of applicability, see §§ 1.141–15, 1.148–11, 1.150–1(a)(2)(iii), and 1.150–2(j).

FOR FURTHER INFORMATION CONTACT: Spence Hanemann, (202) 317–6980 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–1347. The collection of information in these final regulations is in § 1.148–4(h)(2)(viii), which contains a requirement that the issuer maintain in its records a certificate from the hedge provider. For a hedge to be a qualified hedge, existing regulations require, among other items, that the actual issuer identify the hedge on its books and records. The identification must specify the hedge provider, the terms of the contract, and the hedged bonds. These final regulations require that the identification also include a certificate from the hedge provider specifying certain information regarding the hedge.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information

unless it displays a valid control number.

Books and records relating to a collection of information must be retained as long as their contents might become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) on the arbitrage investment restrictions under section 148 of the Code and related provisions. On June 18, 1993, the Department of the Treasury (the Treasury Department) and the IRS published comprehensive final regulations in the **Federal Register** (TD 8476, 58 FR 33510) on the arbitrage investment restrictions and related provisions for tax-exempt bonds under sections 103, 148, 149, and 150, and, since that time, those final regulations have been amended in certain limited respects (the regulations issued in 1993 and the amendments thereto collectively are referred to as the Existing Regulations).

A notice of proposed rulemaking was published in the **Federal Register** (72 FR 54606; REG–106143–07) on September 26, 2007 (the 2007 Proposed Regulations). The 2007 Proposed Regulations proposed amendments to the Existing Regulations. Comments on the 2007 Proposed Regulations were received and a public hearing was held on January 30, 2008.

Another notice of proposed rulemaking was published in the **Federal Register** (78 FR 56842; REG–148659–07) on September 16, 2013 (the 2013 Proposed Regulations). The 2013 Proposed Regulations proposed additional amendments to the Existing Regulations (the 2007 Proposed Regulations and the 2013 Proposed Regulations collectively are referred to as the Proposed Regulations). Comments on the 2013 Proposed Regulations were received and a public hearing was held on February 5, 2014. The 2013 Proposed Regulations addressed the definition of issue price, among other topics.

A partial withdrawal of notice of proposed rulemaking and notice of proposed rulemaking was published in the **Federal Register** (80 FR 36301; REG–138526–14) on June 24, 2015, re-proposing amendments to the definition of issue price. After consideration of all the comments, the remaining portions of the Proposed Regulations are adopted as amended by this Treasury decision (the Final Regulations).