PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:


§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6002 Class E Surface Area Airspace.

* * * * *

ASO TN E2 Knoxville, TN [Amended]
Knoxville Downtown Island Airport, TN
(Lat. 35°57′30″ N, long. 83°52′25″ W)
University of Tennessee Medical Center Heliport, TN
(Lat. 35°56′30″ N, long. 83°56′38″ W)
Within a 4.5-mile radius of Knoxville Downtown Island Airport, excluding that airspace within a 1.0-mile radius of University of Tennessee Medical Center Heliport.

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

ASO TN E5 Knoxville, TN [Amended]
McGhee-Tyson Airport, TN
(Lat. 35°48′34″ N, long. 83°59′43″ W)
Gatlinburg-Pigeon Forge Airport, TN
(Lat. 35°51′28″ N, long. 83°31′43″ W)
Knoxville Downtown Island Airport, TN
(Lat. 35°57′30″ N, long. 83°52′25″ W)

That airspace extending upward from 700 feet above the surface within a 15.4-mile radius of McGhee-Tyson Airport, and within a 13-mile radius of Gatlinburg-Pigeon Forge Airport, and from the 080° bearing from Gatlinburg-Pigeon Forge Airport clockwise to the 210° bearing extending from the 13-mile radius southeast to the 33-mile radius centered on Gatlinburg-Pigeon Forge Airport, and within an 8-mile radius of Knoxville Downtown Island Airport.

ASO TN E5 Madisonville, TN [New]
Monroe County Airport, TN,
(Lat. 35°32′43″ N, long. 84°22′49″ W)
That airspace extending upward from 700 feet above the surface within an 8.5-mile radius of Monroe County Airport.

Issued in College Park, Georgia, on September 24, 2018.

Ryan W. Almasy,
Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

BILLY M. MILLER III, Acting Administrator.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573


Food Additives Permitted in Feed and Drinking Water of Animals; 25-Hydroxyvitamin D₃

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of 25-hydroxyvitamin D₃ as a source of vitamin D₃ activity for layer and breeder chickens and turkeys. This action is in response to two food additive petitions filed by DSM Nutritional Products.

DATES: This rule is effective October 2, 2018. See section V of this document for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by November 1, 2018.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before November 1, 2018. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 1, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions
Submit electronic objections in the following way: Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to https://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 https://www.regulations.gov.

Written/Paper Submissions
Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper objections submitted to the Dockets Management Staff, 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–F–1540 (for submissions related to FAP 2277) or FDA–2014–F–0296 (for submissions related to FAP 2279) for “Food Additives Permitted in Feed and Drinking Water of Animals; 25-hydroxyvitamin D₃.” Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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 in 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 objections. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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 objections 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: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper objections received, go to https://www.regulations.gov and insert the appropriate docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carissa Doody, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–228), Rockville, MD 20855, 240–402–6283, carissa.doody@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In documents published in the Federal Register of December 23, 2013 (78 FR 77384) and March 26, 2014 (79 FR 16698), FDA announced that we had filed two food additive petitions (animal use) (FAPS 2277 and 2279) submitted by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. The petitions proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of 25-hydroxyvitamin D₃ as a source of vitamin D₃ activity for layer and breeder chickens and turkeys and that the food additive regulations should be amended as set forth in this document. This is not a significant regulatory action subject to Executive Order 12866.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petitions and documents we considered and relied upon in reaching our decision to approve the petitions will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see ADDRESSES) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for part 573 continues to read as follows:


2. Add § 573.550 to subpart B to read as follows:

§ 573.550 25-hydroxyvitamin D₃

The food additive, 25-hydroxyvitamin D₃, may be safely used in accordance with the following prescribed conditions:

(a) The additive is used or intended for use as a source of vitamin D₃ activity in animal feed or drinking water in accordance with good manufacturing and feeding practices as follows:

(1) In feed or drinking water of layer and breeder chickens not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water.

(2) In feed or drinking water of turkeys not to exceed:

(i) 92 ppb in feed; or

(ii) In drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(b) The additive consists of not less than 94 percent 25-hydroxyvitamin D₃ (9,10-secocholesta-5,7,10(19)-triene-3,25-diol).

(c) The additive meets the following specifications:

(1) Not more than 1 percent of any individual sterol.

(2) Not more than 5 percent water.

(3) Not more than 20 parts per million (ppm) lead.

(4) Not more than 20 ppm aluminum.

(5) Not more than 1.0 percent solvents and non-detectable levels of 2', 4', 5', 7' tetraiodofluorescein.

(6) Not more than 1 ppb 1, 25-dihydroxycholecalciferol.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:

(1) The name of the additive.

(2) A statement to indicate the maximum use level of 25-hydroxyvitamin D₃ must not exceed 69 ppb in feed or 34.5 ppb in drinking water for layer and breeder chickens.

(3) A statement to indicate for turkeys the maximum use level of 25-hydroxyvitamin D₃ must not exceed 92 ppb in feed; or in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(4) Adequate use directions to ensure that 25-hydroxyvitamin D₃ (and all premixes) is uniformly blended throughout the feed or drinking water.

(5) An expiration date on all premix labeling.

(6) A statement on all premix labeling (feed and drinking water forms) that 25-
DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 658

[FHWA Docket No. FHWA–2018–0035]

RIN 2125–AF81

Truck Size and Weight

AGENCY: Federal Highway Administration (FHWA), U. S. Department of Transportation (DOT).

ACTION: Final rule; technical correction.

SUMMARY: This rule makes a technical correction to the regulations that govern Longer Combination Vehicles (LCV) for the Commonwealth of Pennsylvania and the State of Ohio. The amendments contained herein make no substantive changes to FHWA regulations, policies, or procedures.

DATES: This rule is effective November 1, 2018.

FOR FURTHER INFORMATION CONTACT: John Berg, Truck Size and Weight Program Manager, Office of Freight Management and Operations, (202) 740–4602; or William Winne, Office of the Chief Counsel, (202) 366–1397. Both are located at 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours for FHWA are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access


Background

This rulemaking makes technical corrections to the regulations in appendix C of 23 CFR part 658 that govern length and weight of trailers in Pennsylvania and Ohio. The regulations on LCV’s were frozen as of July 1, 1991, in accordance with Section 1023 of the Intermodal Surface Transportation Efficiency Act (ISTEA). A procedure to “review and correct” the accuracy of the list mandated in 23 U.S.C. 127(d)(3)(D) is provided under 23 U.S.C. 127(d)(3)(E), and implemented under 23 CFR 658.23(f). This provision requires the FHWA Administrator to review petitions to correct any errors in Appendix C. The Commonwealth of Pennsylvania and State of Ohio have petitioned the Federal Highway Administrator to make corrections to items they found to be incorrect in accordance with 23 CFR 658.23(f), and certified those provisions were in effect as of July 1, 1991.

The Pennsylvania Department of Transportation petitioned FHWA seeking to invoke the “grandfather” provisions of 23 U.S.C. 127(a)(4) to allow the operation on the Pennsylvania Turnpike of vehicles or loads with weight limitations exceeding the Federal maximums mandated in 23 U.S.C. 127(a). Pennsylvania’s claim to grandfather rights is based on State statute or enforceable regulation authorizing weight limitations exceeding the Federal maximum in existence on or before July 1, 1956. The Commonwealth seeks to correct a reporting mistake under 23 U.S.C. 127(d)(3)(A) regarding the actual lawful operation on the Turnpike of LCVs up to 100,000 pounds and no longer than 28 ½ feet for each trailer on or before, June 1, 1991. These provisions will be added to Appendix C and bring it into conformance with the Pennsylvania statutes of that time.

The Ohio Department of Transportation (ODOT) petitioned FHWA seeking to invoke the “grandfather” provisions of 23 U.S.C. 127(a)(4) to reflect that triple-trailers can operate on any “turnpike project” as defined in Ohio Revised Code (ORC) section 5537.01 and permitted by the Ohio Turnpike and Infrastructure Commission under the program authorized in ORC 5537.16 (The Ohio Turnpike Act of 1949 and as amended and effective prior to June 1, 1991). In addition, under ORC 4513.34, ODOT and local authorities are authorized to issue special permits for oversized vehicles (effective prior to June 1, 1991). These provisions will be added to Appendix C and bring it into conformance with the Ohio’s statutes of that time.

Rulemaking Analyses and Notice

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. The FHWA finds that notice and comment for this rule is unnecessary and contrary to the public interest because it will have no substantive impact and is technical in nature. The amendments to the rule are based upon the explicit language of statutes that were enacted subsequent to the promulgation of the rule. The FHWA does not anticipate receiving meaningful comments. States, local governments, motor carriers, and other transportation stakeholders rely upon the regulations corrected by this action. These corrections will reduce confusion for these entities and should not be unnecessarily delayed. Accordingly, for the reasons listed above, the agencies find good cause under 5 U.S.C. 553(b)(3)(B) to waive notice and opportunity for comment.

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), Executive Order 13771 (Reducing Regulations and Controlling Regulatory Costs), and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not a significant regulatory action within the meaning of Executive Order (E.O.) 12866 or significant within the meaning of DOT regulatory policies and procedures. This action complies with E.O.s 12866 and 13563 to improve regulation. It is anticipated that the economic impact of this rulemaking will be minimal. This rule only makes minor corrections that will not in any way alter the regulatory effect of 23 CFR part 658. Thus, this final rule will not adversely affect, in a material way, any sector of the economy. In addition, these changes will not interfere with any action taken or planned by another agency and will not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. This action complies with E.O.s 12866, 13563, and 13771 to improve regulation. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612) FHWA has evaluated the effects of this action on small entities and has determined that the action will not have a significant economic impact on a substantial number of small entities. This final rule will not make any substantive changes to our regulations or in the way that our regulations affect small entities; it merely corrects technical errors. For this reason, FHWA certifies that this action