DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 507

[Docket No. FDA–2013–N–1043]

Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of, and requesting comment on, a document entitled ''Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm'' (the draft RA). The purpose of the draft RA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk. FDA conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA.

DATES: Submit either electronic or written comments on the draft RA by February 26, 2014.

ADDRESSES: Submit electronic comments on the draft RA to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary J. Bartholomew, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8172.

SUPPLEMENTARY INFORMATION:

I. Background

On January 4, 2011, FSMA (Pub. L. 111–353) was signed into law. Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to create a new section 418 with the same name. Section 418 of the FD&C Act (21 U.S.C. 350g) contains requirements applicable to food facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) and mandates Agency rulemaking. Section 418(a) of the FD&C Act is a general provision that requires the owner, operator, or agent in charge of a facility to evaluate the hazards that could affect food (including animal food) manufactured, processed, packed, or held by the facility; identify and implement preventive controls; monitor the performance of those controls; and maintain records of the monitoring. Section 418(a) of the FD&C Act specifies that the purpose of the preventive controls is to prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 (21 U.S.C. 342). Section 418(b) of the FD&C Act requires that the hazard analysis identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility. Sections 418(c) to (i) of the FD&C Act contain additional requirements applicable to facilities, including requirements for preventive controls (section 418(c)), monitoring (section 418(d)), corrective actions (section 418(e)), verification (section 418(f)), recordkeeping (section 418(g)), a written plan and documentation (section 418(h)), and reanalysis of hazards (section 418(i)). Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule (the proposed preventive controls rule for food for animals) to implement section 418 of the FD&C Act. FDA is using the results of the draft RA to propose to exempt animal food facilities that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/animal food combinations from the requirements of the FD&C Act for hazard analysis and risk-based preventive controls.

Section 103(c) of FSMA requires rulemaking in two areas: (1) Clarification of the activities that are included as part of the definition of the term ''facility'' under section 415 of the FD&C Act (Registration of Food Facilities) and (2) possible exemption from or modification of requirements of section 418 and section 421 (21 U.S.C. 350j) (Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry; Annual Report) of the FD&C Act for certain facilities as FDA deems appropriate. Section 415 of the FD&C Act directs FDA to require by regulation that any facility engaged in manufacturing, processing, packing, or holding food for human or animal consumption in the United States be registered with FDA. The registration requirement in section 415 of the FD&C Act does not apply to farms. Our regulations that implement section 415 and require food facilities to register with FDA are established in 21 CFR part 1, subpart H (Registration of Food Facilities).

Section 103(c)(1)(C) of FSMA directs the Secretary of Health and Human Services (the Secretary) to conduct a science-based risk analysis as part of the section 103(c) rulemaking. The science-based risk analysis is to cover: (1) Specific types of on-farm packing or holding of animal food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific animal foods and (2) specific on-farm manufacturing and processing activities as such activities relate to specific animal foods that are not consumed on that farm or on another farm under common ownership.

Section 103(c)(1)(D)(i) of FSMA requires that the Secretary consider the results of the science-based risk analysis and exempt certain facilities from the requirements in section 418 of the FD&C Act (including requirements for hazard analysis and preventive controls) and the mandatory inspection frequency in section 421 of the FD&C Act, or modify the requirements in sections 418 or 421 of the FD&C Act, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific animal foods the Secretary determines to be low risk. Section 103(c)(1)(D)(ii) of FSMA provides, in relevant part, that the exemptions or modifications described in section 103(c)(1)(D)(i) shall apply only to small businesses and very small businesses, as defined in the regulation issued under section 418(n) of the FD&C Act.

II. Qualitative Risk Assessment

As explained in the draft RA, we conducted the qualitative risk assessment to identify activity/animal food combinations that would be considered low risk (Ref. 1). We focused on activity/animal food combinations that we identified as being conducted on farms, but we did not consider activity/animal food combinations that would be solely within the farm definition (such as growing grains) and, thus, are not relevant to the requirements of section 103 of FSMA. We considered the risk of activity/animal food combinations rather than separately considering the risk of

specific animal food categories because doing so better enabled us to focus on whether a specific manufacturing, processing, packing, or holding activity conducted on animal food on a farm warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act. In the remainder of this document, we use the term ''farm mixed-type facility'' to refer to an establishment that grows and harvests crops or raises animals and may conduct other activities applicable to farms and to animal food facilities co-located on farms.

In the draft RA, we describe the approach applied to define a low-risk activity and low-risk activity/animal food combinations to determine activities on animal food that are out of scope of the draft RA, and to evaluate hazards associated with activity/animal food combinations within the scope of the draft RA (Ref. 1). We followed the risk assessment framework of the Codex Alimentarius Commission (Ref. 2), which involves hazard identification, hazard characterization, exposure assessment, and risk characterization.

The draft RA addresses nine specific questions:

Question 1: What are the animal foods that would be manufactured, processed, packed, or held by a farm mixed-type facility?

Question 2: What are the activities that might be conducted by farm mixed-type facilities on those animal foods?

Question 3: What are the hazards reasonably likely to occur in those animal foods?

Question 4: For the purpose of determining whether an activity/animal food combination is low risk, which hazards should be considered to have a reasonable probability of causing serious adverse health consequences or death to humans or animals?

Question 5: For the purpose of determining whether an activity/animal food combination is low risk, what animal foods have inherent controls that significantly minimize or prevent a biological hazard that is reasonably likely to occur in these animal foods and that is reasonably likely to cause serious adverse health consequences or death to humans or animals?

Question 6: What interventions significantly minimize or prevent a hazard that is reasonably likely to occur in these animal foods and that is reasonably likely to cause serious adverse health consequences or death to humans or animals?

Question 7: Which of these activities are reasonably likely to introduce, or increase the potential for occurrence of, hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals and what are these hazards?

Question 8: Which of these activities are interventions to significantly minimize or prevent hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals from consumption of these animal foods?

Question 9: Which activity/animal food combinations are low risk, i.e., what on-farm activity/animal food combinations are not reasonably likely to introduce hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals or serve as preventive controls (interventions) to significantly minimize or prevent a hazard that is reasonably likely to cause serious adverse health consequences or death to humans or animals?

As discussed in the draft RA, a specific activity may have a different classification within the classes of manufacturing, processing, packing, and holding (with consequences for what regulations apply to the activity) based on whether the animal food being operated upon is a raw agricultural commodity (RAC) or a processed animal food and whether a RAC was grown or raised on the farm performing the activity or a farm under the same ownership (Ref. 1). In the draft RA, we first characterize the risk of activity/animal food combinations without the overlay of the applicable statutory and regulatory framework. Doing so focuses the risk characterization on the risk of the activity/animal food combinations themselves. We then add that regulatory overlay and characterize the risk of activity/animal food combinations in three regulatory groups shaped by the applicable regulatory factors and the resulting activity classifications:

- Regulatory Group Type 1: Low-risk packing and holding activities that might be conducted on a farm on animal food not grown, raised, or consumed on that farm or another farm under the same ownership;
- Regulatory Group Type 2: Low-risk manufacturing and processing activities that might be conducted on a farm on the farm's own RACs for distribution into commerce; and
- Regulatory Group Type 3: Low-risk manufacturing and processing activities that might be conducted on a farm on animal food other than the farm's own RACs for distribution into commerce.

We are seeking comments that can be used to improve:

- The approach used;
- The assumptions made;
- The data used; and
- The transparency of the draft RA.

Specifically we request comment on:

- The definitions of ''low-risk activity'' and ''low-risk activity/animal food combination'';
- The animal food types and activity/animal food combinations that we are considering outside the scope of the draft RA and those we are considering within the scope of the draft RA;
- The approach to characterizing the risk of an activity/animal food combination;
- The questions addressed by the draft RA; and
- The answers to those questions.

We submitted a draft RA to a group of scientific experts external to FDA for peer review and revised the draft RA, as appropriate, considering the experts' comments. A report concerning the external peer review is available for public review, and can be accessed from our Web site (Ref. 3). We will consider public comments regarding the draft RA in preparing a final version of the RA.

III. Comments

Interested persons may submit either electronic comments regarding the draft RA to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments 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.*

IV. Electronic Access

The draft RA is available electronically at *http://www.regulations.gov* and *http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366906.pdf.*

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested person between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this references section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA, ''Draft Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the

Farm Definition) Conducted in a Facility Co-Located on a Farm,'' 2012. Available at *http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366906.pdf.*

2. Codex Alimentarius Commission, ''Codex Alimentarius Commission Procedural Manual, Twentieth Edition,'' 2011.

3. FDA, ''Peer Review Report. External Peer Review of the FDA/CVM Draft Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,'' 2013. Available at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*

Dated: October 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–25124 Filed 10–25–13; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–112815–12]

RIN 1545–BK99

Mixed Straddles; Straddle-by-Straddle Identification Under Section 1092(b)(2)(A)(i)(I); Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing; correction.

SUMMARY: This document contains amendments to proposed regulations relating to guidance for taxpayers electing to establish a mixed straddle using straddle-by-straddle identification. These amendments include a change to the applicability date of the proposed regulations pursuant to which the proposed regulations would apply to transactions established after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. The amendments to the proposed regulations will affect taxpayers who elect to establish a mixed straddle using straddle-by-straddle identification.

DATES: Comments must be received by October 31, 2013. Request to speak and outlines of topics to be discussed at the public hearing scheduled for December 4, 2013, at 10 a.m. must be received by October 31, 2013.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–112815–12), room 5205, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–112815–12), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–112815–12).

FOR FURTHER INFORMATION CONTACT: Pamela Lew or Robert B. Williams at (202) 622–3950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The proposed regulations that are the subject of these amendments are under section 1092 of the Internal Revenue Code (Code). The text of temporary regulations (TD 9627), published in the **Federal Register** on Friday, August 2, 2013 (78 FR 46807), serves as the text of the proposed regulations. The proposed regulations (REG–112815–12) were published in the **Federal Register** on Friday, August 2, 2013 (78 FR 46854). The proposed regulations were proposed to apply to all identified mixed straddles established after the date of filing, August 1, 2013.

Need for amendments

The Treasury Department and the IRS received comments raising concerns about the immediate applicability date of the temporary regulations. In response to those comments, the Treasury Department and the IRS are amending the temporary regulations to limit the application of the identified mixed straddle transaction rules in § 1.1092(b)-6T to section 1092(b)(2) identified mixed straddles established after the date of publication of the Treasury decision adopting the rules as final regulations in the **Federal Register**. The text of the temporary regulations, as amended, continues to serve as the text of these proposed regulations, and this document amends the proposed regulations to conform to the changes to the temporary regulations. The Treasury Department and the IRS anticipate finalizing the regulations no later than the end of the current Priority Guidance Plan year on June 30, 2014, and will as part of that process consider all comments received.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *.

Section 1.1092(b)–6 also issued under 26 U.S.C. 1092(b)(1).

Section 1.1092(b)–6 also issued under 26 U.S.C. 1092(b)(2).* * *

■ **Par. 2.** Section 1.1092(b)–6 is amended by revising the heading to read as follows:

§ 1.1092(b)–6 Mixed straddles; accrued gain and loss associated with a position that becomes part of a section 1092(b)(2) identified mixed straddle.

* * * * *

Martin Franks,

Branch Chief, Publications & Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure & Administration).

[FR Doc. 2013–25360 Filed 10–25–13; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR part 52

[EPA–R09–OAR–2013–0663; FRL–9902–10–Region9]

Partial Approval and Disapproval of Air Quality State Implementation Plans; Nevada; Infrastructure Requirements for Lead (Pb)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to partially approve and partially disapprove State Implementation Plan (SIP) revisions submitted by the State of Nevada on October 12, 2011, July 23, 2012, and August 30, 2012, pursuant to the requirements of the Clean Air Act (CAA or the Act) for the implementation, maintenance, and enforcement of the 2008 Lead (Pb) national ambient air quality standards (NAAQS). We refer to such SIP revisions as ''infrastructure'' SIPs because they are intended to address basic structural SIP requirements for new or revised NAAQS including, but not limited to, legal authority, regulatory structure, resources, permit programs, monitoring, and modeling necessary to assure attainment and maintenance of the standards. We are taking comments on