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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; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 507****[Docket No. FDA-2013-N-1043]****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 of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm” (the RA). The purpose of the RA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk when conducted in an animal food facility co-located on a farm. We conducted this 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: September 17, 2015.**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for electronic access to the RA.**FOR FURTHER INFORMATION CONTACT:**

Mary J. Bartholomew, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6224.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of October 29, 2013 (78 FR 64428), we announced the availability of a draft qualitative risk assessment (RA) (Ref. 1) related to manufacturing, processing, packing, and holding activities for animal food when such activities are conducted in an animal food facility co-located on a farm. Interested parties were given the opportunity to submit comments by

February 26, 2014, for us to consider on the approach used, the assumptions made, how risk was determined, the data used, and the clarity and the transparency of the RA documentation. We extended the comment period on February 3, 2014 (79 FR 6116), to March 31, 2014. We received 11 comments on the draft RA and have revised it where appropriate (Ref. 2).

The purpose of the RA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk when conducted in an animal food facility co-located on a farm. We conducted this RA to satisfy FSMA’s requirements to conduct a science-based risk analysis and to consider the results of that analysis in determining whether to exempt small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities involving specific animal food that we determine to be low risk from requirements specified in sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350g and 350j, respectively), or whether to modify such requirements for such facilities.

See 78 FR 64428 through 64429 for additional background information on FSMA, the requirements of sections 418 and 421 of the FD&C Act, the focus of the RA, the approach used, the nine specific questions addressed by the RA, and our request for comments.

Before making the draft RA available for public comment, we submitted an earlier version of the draft RA to a group of scientific experts external to FDA for peer review and revised that earlier version, 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).

Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to implement section 418 of the FD&C Act for food for animals. That final rule establishes current good manufacturing practice requirements for animal food facilities and establishes requirements for certain animal food facilities to conduct a hazard analysis and to identify and implement risk-based preventive controls. In that final rule, we use the results of the RA to exempt animal food facilities that are small or

very small businesses, co-located on a farm, from these requirements when such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the RA as low-risk activity/animal food combinations.

II. Electronic Access

The RA and our response to comments on the draft RA are available electronically at <http://www.regulations.gov>, <http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM366906.pdf>, and <http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM459595.pdf>.

III. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

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. FDA, “Qualitative Risk Assessment. Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,” 2015. Available at <http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/UCM459595.pdf>.

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: August 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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