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21 CFR Part 117

Qualitative Risk Assessment of Risk of Activity/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 117

[Docket No. FDA-2012-N-1258]

Qualitative Risk Assessment of Risk of Activity/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 of Risk of Activity/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/food combinations that would be considered low risk when conducted in a 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: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 16, 2013 (78 FR 3824), we announced the availability of a draft qualitative risk assessment (RA) (Ref. 1) related to manufacturing, processing, packing, and holding activities for human food when such activities are conducted in a food facility co-located on a farm. We reopened the comment period on March 13, 2013 (78 FR 15894) and also extended the comment period on April 26, 2013 (78 FR 24693). We gave interested parties an opportunity to submit comments by September 16, 2013, for us to consider on the approach used, the assumptions made, the

modeling techniques, the data used, and the clarity and the transparency of the RA documentation. We received more than two dozen comments on the draft RA and have revised it where appropriate (Refs. 2 and 3).

The purpose of the RA is to provide a science-based risk analysis of those activity/food combinations that would be considered low risk when conducted in a 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 foods 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 21 U.S.C. 350j, respectively), or whether to modify such requirements for such facilities. See 78 FR 3824 at 3825 to 3826 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. 4).

Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to implement section 418 of the FD&C Act for human food. That final rule establishes requirements for certain 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 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/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/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm>, and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm>, and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

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/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,” 2012. Available at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>. See Reference 1 to the notice of availability of the draft risk assessment.

2. FDA, “Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,” 2015. Available at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

3. FDA, “Qualitative Risk Assessment. Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm. Response to Public Comments,” 2015. Available at: <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

4. FDA, “Peer Review Report. External Peer Review of the FDA/CFSAN Draft Qualitative Risk Assessment: Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm,” 2012. Available at: <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>. See Reference 3 to the notice of availability of the draft risk assessment.

Dated: August 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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