



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

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

Draft 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; 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/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/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. Elsewhere in this issue of the Federal Register, FDA is using the results of the draft RA to propose to exempt 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/food combinations from the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for hazard analysis and risk-based preventive controls.

DATES: Submit either electronic or written comments on the draft RA by February 15, 2013.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On January 4, 2011, FSMA (Public Law 111-353) was signed into law. Section 103 of FSMA, Hazard analysis and risk-based preventive controls, amends 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 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) or misbranded

under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). 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)-(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) to implement section 418 of the FD&C Act.

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 (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 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 part 1 (21 CFR part 1), subpart H (Registration of food facilities) (hereinafter the section 415 registration regulations).

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 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 foods; and (2) specific on-farm manufacturing and processing activities as such activities relate to specific 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 (including requirements for hazard analysis and preventive controls), and the mandatory inspection frequency in section 421, 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 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 promulgated 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/food combinations that would be considered low risk (Ref. 1). We focused on activity/food combinations that we identified as being conducted on farms, but we did not consider activity/food combinations that would be solely within the farm definition (such as growing fruits and vegetables) and, thus, are not relevant to the requirements of section 103 of FSMA. We considered the risk of activity/food combinations rather than separately considering the risk of specific food categories because doing so better enabled us to focus on whether a specific

manufacturing, processing, packing, or holding activity conducted on 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 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/food combinations to determine food types out of scope of the draft RA, and to evaluate hazards associated with foods 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 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 foods?

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

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

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

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

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 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 from consumption of these foods?

Question 9: Which activity/food combinations are low risk, i.e., what on-farm activity/food combinations are not reasonably likely to introduce hazards that are reasonably likely to cause serious adverse health consequences or death 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?

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 food being operated upon is a raw agricultural commodity (RAC) or a processed 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/food combinations without the overlay of the applicable statutory and regulatory framework. Doing so focuses the risk characterization on the risk of the activity/food combinations themselves. We then add that regulatory overlay and characterize the

risk of activity/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 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 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/food combination";
- the food types and activity/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/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 to <http://www.regulations.gov> or written comments regarding the draft RA 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 at <http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm>.

### V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, 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/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/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/default.htm>.

2. Codex Alimentarius Commission, “Codex Alimentarius Commission Procedural Manual, Twentieth Edition,” 2011.

3. 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>.

Dated: January 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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