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MEMORANDUM

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Re: **FSMA Implementation Update: "Solely Engaged" Draft Guidance, Animal Food cGMP Guidance, Sanitary Food Transportation Training for Carriers, and Compliance Dates**

FDA is continuing to release resources intended to assist industry with implementation of the FDA Food Safety Modernization Act (FSMA). This memorandum discusses four such documents that were released recently. First, FDA released Draft Guidance explaining the meaning of the phrase "solely engaged," which is used in the regulations to establish several exemptions from the Preventive Controls for Human Food (PCHF) and Preventive Controls for Animal Food (PCAF) rules. Second, FDA finalized its Guidance on current Good Manufacturing Practice (cGMP) requirements for animal food. Third, FDA developed a training program for carriers who are subject to the Sanitary Food Transportation rule. Finally, FDA released a new web page that lists compliance dates for rules that form the foundation of FSMA.

FDA Issues Draft Guidance on "Solely Engaged" Exemptions

FDA has issued Draft Guidance to assist facilities in determining whether they are "solely engaged" in certain activities and therefore exempt from some or all of requirements under the PCHF or PCAF rules. 1/ There are provisions in both the PCHF and PCAF rules that provide exemptions to either the applicable cGMP or Preventive Controls requirements if a facility is "solely engaged" in particular activities. These exemptions are summarized in the following table

Requirements	"Solely Engaged" Exemption
PCHF cGMPs	Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities (RACs) (21 CFR § 117.5(k)(1)(iii))
	Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts) (21 CFR § 117.5(k)(1)(v))
PCHF Preventive Controls	Facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (21 CFR § 117.5(j))
	Facilities solely engaged in the storage of unexposed packaged food (21 CFR § 117.7(a))

1/ "Application of the 'Solely Engaged' Exemptions in Parts 117 and 507: Guidance for Industry," (Oct. 2017), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM580728.pdf.

PCAF cGMPs	Establishments solely engaged in the holding and/or transportation of one or more RACs (21 CFR § 507.5(h)(1))
	Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts) (21 CFR § 507.5(h)(2))
	Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed) (21 CFR § 507.5(h)(3))
PCAF Preventive Controls	Facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (21 CFR § 507.5(g))
	Facilities solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens (21 CFR § 507.10(a))

The draft guidance underscores the principle that "solely engaged" means exactly that—solely engaged. In other words, a facility will only be exempt from a set of requirements if each and every activity the facility performs falls within one or more of the types of activities that are exempt from the requirements. The draft guidance explains:

- If all of the activities performed by a facility are exempt under one or more cGMP exemptions, then the establishment is not subject to the PCHF or PCAF cGMP requirements, as applicable.
- If all of the activities performed by a facility are exempt under one or more Preventive Controls exemptions, then the facility is not subject to the PCHF or PCAF Preventive Controls requirements, as applicable.
- If all of the activities performed by a facility are exempt under a cGMP exemption and a Preventive Controls exemption, then the facility is not subject to either the cGMP or Preventive Controls requirements in the PCHF or PCAF rules, as applicable.
- If any part of a facility is engaged in an activity subject to the cGMP requirements, then the entire facility is subject to cGMPs. If any part of a facility is engaged in an activity subject to the Preventive Controls requirements, then the entire facility is subject to the Preventive Controls requirements.

Accordingly, there are no exceptions that would allow a portion of a facility engaged in exempt activities to be exempt from the requirements, while other parts of a facility that engage in non-exempt activities would be subject to the requirements. Performing any one activity that is outside the scope of the "solely engaged" provision results in the entire facility coming under the rule.

For example, a human food warehouse facility that stores unexposed packaged food and also stores fruits and vegetables in vented cartons (that therefore are exposed to the environment) is not "solely engaged" in storing unexposed packaged food. Therefore, the entire facility is subject to the Preventive Controls requirements.

Comments are requested by April 18, 2018.

FDA Finalizes Animal Food cGMP Guidance

FDA has released "Guidance for Industry #235: Current Good Manufacturing Practice Requirements for Food for Animals," which was published in draft form in August 2016. 2/ The Guidance is

2/ "Guidance for Industry #235: Current Good Manufacturing Practice Requirements for Food for Animals," (Oct. 2017), available at https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforInd

intended for use by facilities that must register as food facilities because they manufacture, process, pack, or hold animal food for consumption in the United States. It contains information to assist these facilities in determining whether they must comply with the cGMP requirements for animal food. For those facilities that are subject to the animal food cGMPs, the guidance provides additional explanation of the cGMPs and recommendations for compliance in areas such as personnel, plant and grounds, sanitation, water supply and plumbing, equipment and utensils, plant operations, and holding and distribution, as well as recommendations for compliance with related requirements such as recordkeeping and training.

Unlike the Draft Guidance, the final Guidance does not address human food byproducts for use as animal food, because FDA has issued separate guidance on this topic. 3/ The final Guidance also includes a self-assessment tool not included in the Draft Guidance, which facilities can use to evaluate their compliance with the cGMPs, as well as additional explanation and examples in response to comments received on the Draft Guidance.

FDA Releases Training Module for Carriers Subject to the Sanitary Food Transportation Rule

FDA has released an online safety training module for carriers that engage in the transportation of food by rail or motor vehicle. 4/ The Sanitary Food Transportation rule requires that carriers covered by the rule train their personnel on potential food safety problems, basic sanitary practices, and carrier responsibilities under the rule. This training requirement applies when the shipper and carrier have agreed in writing that the carrier is at least in part responsible for sanitary conditions during transportation operations.

The module can be completed within an hour, and to successfully complete the training participants must answer a series of multiple-choice questions based on the material presented in the training. Though the rule does not require that carrier personnel complete FDA's training module, carriers can use the training to satisfy the regulation's training requirement. Carriers also could use the module to supplement their own training programs, or they could develop entirely separate training programs.

Carriers subject to the training requirement must establish and maintain records documenting the training of their personnel, and the FDA module will generate a certificate for individuals who successfully complete the course. Companies with a Learning Management System (LMS) also can download the course files and import them into their LMS, which will allow companies to track completion data in their own systems.

FDA Releases Webpage with Key FSMA Compliance Dates

Additionally, FDA has released a new web page on fda.gov listing compliance dates for rules that form the foundation of FSMA: Preventive Controls for Human Food, Preventive Controls for Animal Food, Produce Safety, Foreign Supplier Verification Programs, Sanitary Food Transportation, and Intentional Adulteration. 5/ The webpage lists compliance dates by business size and includes

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ustry/UCM499200.pdf. *See also* "HL Memo - FDA Releases Series of Draft FSMA Guidance Documents," (Sept. 7, 2016).

3/ "Draft Guidance for Industry #239: Human Food By-Products for Use as Animal Food," (Aug. 2016), available at https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf.

4/ The training module is available on FDA's website: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm576097.htm.

5/ Compliance date information is available at: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm540944.htm.

extended compliance dates for certain businesses. There also is a graphic timeline on the page that lists key compliance dates by year.

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We will continue to monitor FDA's implementation of FSMA. Should you have any questions, please do not hesitate to contact us.