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Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

Docket Nos. FDA-2011-N-0920
RIN 0910-AG36

Sent via electronic submissions on the Federal eRulemaking Portal: www.regulations.gov

Re: Comments on FDA Proposed Rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 79 Federal Register 58523 (September 29, 2014)

To Whom It May Concern,

These comments on the Food and Drug Administration's (FDA) Proposed Rule for the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Rule or PCR) are submitted on behalf of the Harvard Law School Food Law and Policy Clinic (FLPC).

The FLPC was established in 2010 in order to link Harvard Law students with opportunities to provide pro bono legal assistance to individuals and communities on various food law and policy issues. FLPC aims to increase access to healthy foods, prevent diet-related diseases such as obesity and type 2 diabetes, and assist small and sustainable farmers and producers in participating in local food markets. Our concern that the proposed rules would disproportionately impact the types of operations we seek to serve prompted us to submit recommendations during the first comment period and to again submit comments to the repropoed rules. Our work on this topic is closely connected to the work of the National Sustainable Agriculture Coalition (NSAC), and therefore, we continue to support the comments submitted by NSAC and their member organizations.

We applaud FDA for incorporating into this amended proposed rule many of the recommendations that we made during the first comment period. These revisions support small-

and midsized farmers and facilities, who are crucial to the U.S. food system: they increase the diversity of our food system; provide essential sources of fresh fruits and vegetables for a variety of markets; and serve as economic drivers, often playing an integral role in rural (and increasingly urban and suburban) economies. In particular, we urge FDA to finalize the procedure for reinstatement of an exemption applicable to a qualified facility and the provision allowing FDA to take intermediary steps before issuing an order to withdraw the exemption applicable to a qualified facility.

We believe further revisions could more adequately take into account the realities of these small- and midsized food production operations. In particular, we encourage FDA to require that specific information about the reason for concern be included in both the mandatory notice of intent to withdraw a qualified exemption and the order to withdraw a qualified exemption. We have included comments and recommended modified language based on our comments.

Congress stated in the legislative history of the Food Safety Modernization Act (FSMA) that one goal of FSMA is to create standard practices for food manufacturing and processing facilities that will improve the safety of the nation's food supply in a way that accommodates the diversity of food manufacturing and processing operations. The FLPC recognizes the magnitude and complexity of the task delegated to FDA and commends FDA for its efforts to write regulations that take into consideration the various sizes and types of food production operations across the country. There are, however, a few places where the proposed rule can still be strengthened to better accommodate the realities of small- and mid-sized food production operations, particularly around the qualified exemption provisions.

Thank you for your consideration of the FLPC's comments and recommendations on this proposed rule.

Sincerely,



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These comments were also made possible by the research, writing, and editing of Alexandra Jordan, Harvard Law student in the Harvard Food Law and Policy Clinic.

Acknowledgements

These comments were written in consultation with Sophia Kruszewski, of the National Sustainable Agriculture Coalition.

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I. Comments on the Withdrawal of an Exemption Applicable to a Qualified Facility in Subpart E

1. Definitions and Evidentiary Standards

Establish an evidentiary standard for withdrawal of a qualified exemption and add definitions of “directly linked,” “necessary,” “associated,” and “material to the safety of the food.”

In response to the first round of Preventive Controls Rule comments, FDA notes that it does not consider it necessary to define terms such as “directly linked,” “necessary,” “associated,” or “material to the safety of food.” We urge FDA to reconsider our earlier comments that explain the importance of adding an evidentiary standard in § 117.251(a)(2) and defining these terms in § 117.3.

First, we encourage FDA to include a “credible and substantial evidence” standard that provides an explicit threshold that FDA must meet to trigger procedures for withdrawal of an exemption. The current language allows FDA to withdraw the exemption based on conditions or conduct “associated” with a qualified facility.¹ Given the gravity of costs and stigma that a facility may face if its exemption is withdrawn, a much clearer threshold should be conveyed so that withdrawal orders are based on evidence rather than allegations. Including a “credible and substantial evidence” standard would ensure that FDA uses its resources in the most efficient way by only pursuing exemption withdrawal proceedings in the most deserving cases.

Second, we suggest that FDA clarify how outbreaks may be “directly linked” to a qualified facility. FDA may withdraw a qualified facility’s exemption if an active investigation of a foodborne illness outbreak is “directly linked” to the qualified facility.² Because of the significant implications for the facility if its exemption is withdrawn, it is important to have a specific definition of “directly linked.” In the event of a foodborne illness outbreak, there is undoubtedly significant pressure on FDA to determine the source of the foodborne illness and prevent it from increasing. Defining “directly linked” will help FDA to determine when it can withdraw a qualified facility’s exemption by ensuring actual proof of a link between outbreaks and facilities exists and that the link is not overly attenuated.

Third, FDA should define “necessary” as “when absolutely required.” FDA may withdraw an exemption when it is “necessary” to protect public health.³ Due to the significant financial

¹ Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. 58434, 58569 (Sub. E § 117.251(a)(2)) (proposed Sept. 29, 2014), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2014-09-29/pdf/2014-22447.pdf>.

² 79 Fed. Reg. at 58569 (Sub. E § 117.251(a)(1)).

³ 79 Fed. Reg. at 58569 (Sub. E § 117.251(a)(2)).

burden that a facility owner or operator could face if his or her exemption is withdrawn, the exemption should only be withdrawn when FDA is certain that it is absolutely required to protect public health.

Fourth, FDA should provide a concrete definition of “associated.” FDA may withdraw the exemption based on conditions or conduct “associated” with a qualified facility.⁴ Without further clarification, even a very attenuated connection between conditions and facilities will suffice for FDA to withdraw an exemption.

Finally, FDA should clarify the meaning of “material to the safety of the food.”⁵ Without defining this phrase, it is possible that every conceivable risk to safety is “material” under the current rule. We encourage FDA to add language indicating that, for conduct or conditions to be material to food safety, there must be a reasonable probability that the conduct or conditions will contribute to an outbreak of foodborne illness.

Recommendation: FDA should introduce a “credible and substantial evidence standard” and define the terms “directly linked,” “necessary,” “associated,” and “material to the safety of the food.”

Suggested Language:

§ 117.251 Circumstances that may lead FDA to withdraw the exemption applicable to a qualified facility.

(a) FDA may withdraw the exemption applicable to a qualified facility under § 117.5(a):

(2) If FDA determines based on credible and substantial evidence that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility; conditions or conduct are material to the safety of food when there is a reasonable probability that they will contribute to an outbreak of foodborne illness.

§ 117.3 Definitions

Associated means that which is directly and closely connected, as established by credible and substantial evidence, to a farm, farm mixed-type facility, or facility.

Directly linked means that which in a direct manner, as established by credible and substantial evidence, is immediately connected to activities on a farm, farm mixed-type facility, or facility that are under the control of the owner, operator, or agent in charge of the farm, farm mixed-type facility, or facility.

⁴ 79 Fed. Reg. at 58569 (Sub. E § 117.251(a)(2)).

⁵ 79 Fed. Reg. at 58569 (Sub. E § 117.251(a)(2)).

Necessary means that which is absolutely required, as established by credible and substantial evidence, to protect public health.

Material to the safety of food means traits, aspects, or characteristics of conduct actually taking place, or conditions specifically in existence on a farm or in a facility, that are directly relevant to ensuring the safety of food; that can be clearly measured; and that are identified through direct examination of the activities, conduct, and conditions of an individual farm or facility.

2. Notice of Intent to Withdraw and Possible Intermediary Steps

Finalize the revised language that allows FDA to take intermediary steps before issuance of an order to withdraw an exemption.

The revised language of § 117.251(b)(1) in the Preventive Controls Rule allows FDA to take intermediary steps before issuing an order to withdraw an exemption. We support the inclusion of this provision and the use of these intermediary steps, which include a “warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction.”⁶ Using intermediary steps, rather than automatically resorting to withdrawal of an exemption, opens a dialogue between FDA and farm owners and allows them to work together to protect food safety. We encourage FDA to maintain these revisions allowing FDA to take intermediary steps prior to issuance of an order in the final rule.

Finalize revised language that requires notice to the facility owner prior to issuance of an order to withdraw an exemption.

We applaud FDA for adding § 117.251(b)(2) to require FDA to notify the owner, operator or agent in charge of the qualified facility before issuing an order to withdraw an exemption. The mandatory notice of intent to withdraw gives the qualified facility a chance to rectify the circumstances before an order to withdraw an exemption is issued, allowing the facility to avoid potentially burdensome appeals costs and FDA to avoid expending resources on easily-remedied situations. FDA must also “provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing” and “consider the actions taken by the facility.”⁷ We encourage FDA to maintain these revisions requiring notice prior to issuance of an order in the final rule.

Require the mandatory notice of intent to withdraw a qualified exemption under § 117.251(b)(2) to include (a) specific information about the reason for the notice of intent to withdraw and (b) how the facility can remedy the issue.

⁶ 79 Fed. Reg. at 58569 (Sub. E § 117.251(b)(1)).

⁷ 79 Fed. Reg. at 58569 (Sub. E § 117.251(b)(2)).

As mentioned above, under newly added § 117.251(b)(2), FDA must issue a notice of intent to withdraw a qualified exemption. We encourage FDA to include specific information about the reason for the notice within the notice of intent to withdraw a qualified exemption. Facility owners will be better able to address concerns and respond promptly if they understand the evidence that prompted FDA to issue the notice. In addition, FDA should include information about how the facility owner can remedy the situation in the notice of intent to withdraw. Because the owner has such a short window to respond to the notice (10 days), the notice should provide information that will allow the owners to properly address the allegations and respond to FDA with a clear plan to remedy the issue. Such information might include referrals to sources of technical assistance.

Recommendation: FDA should add language to proposed § 117.251 that requires the mandatory notice of intent to withdraw a qualified exemption to include specific information about the reason for the notice and information about how the facility can remedy the issue.

Suggested Language:

§ 117.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.

(b) Before FDA issues an order to withdraw an exemption applicable to a qualified facility, FDA:

(2) Must notify the owner, operator, or agent in charge of the facility, in writing, of circumstances that may lead FDA to withdraw the exemption, including facts specific to the situation and information about how the facility can remedy the situation, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 10 calendar days of the date of receipt of the notification, to FDA's notification;

3. Approval and Issuance of the Order to Withdraw a Qualified Exemption

Finalize the requirement that an order must be approved before it is issued.

The revised rules require that an FDA District Director, or an FDA official senior to such Director, approve the order to withdraw an exemption before it is issued.⁸ This ensures that FDA is accountable and has a clear administrative procedure for issuing orders. We urge FDA to adopt the provision requiring approval before issuance of an order to withdraw an exemption in the final rule.

Deliver the order to withdraw an exemption in a way that provides confirmation of receipt.

⁸ 79 Fed. Reg. at 58570 (Sub. E § 117.254(a)).

An additional provision in § 117.254 should require that the order to withdraw an exemption applicable to a qualified facility is delivered in a manner by which delivery and receipt can be confirmed. Unless the order is delivered in a way that allows for confirmation, it will be difficult to determine the day from which to toll the 120 day window for compliance and the 10 calendar day window for appeals under § 117.257(d). Requiring delivery that confirms the order is received, such as through certified mail with a confirmation of delivery, would ensure the facility received the order and create a record of the date of receipt. This is important to standardize the process for every facility owner, and to ensure that the facility owner receives the order before the time limit for appeal has passed.

Recommendation: In the final Preventive Controls Rule, FDA should add language to § 117.254 requiring that the exemption withdrawal order is delivered in a manner by which delivery and receipt can be confirmed.

Suggested Language:

§ 117.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility in a manner by which delivery and receipt of the order can be confirmed.

4. Contents of the Order to Withdraw a Qualified Exemption

Finalize revised language that explicitly states that a facility owner has two options after receiving the order to withdraw an exemption: comply with Subpart C of the Preventive Controls Rule or appeal the order.

We commend FDA for adding language to § 117.257 that clarifies a facility owner's two options after receiving the order to withdraw an exemption: comply with Subpart C of the Preventive Controls Rule or appeal the order.⁹ Explicitly stating these two options helps owners of facilities to better understand their next steps. We support FDA including this revised language in the final rule.

Require the order to withdraw an exemption applicable to a qualified facility to include (a) specific information about the reason for withdrawal; (b) information about the compliance requirements; and (c) information about the opportunity to request an informal hearing.

Again, we applaud FDA for revising the Preventive Controls Rule so that the order to withdraw an exemption contains a statement that a facility owner may either comply with Subpart C of the Preventive Controls Rule or appeal the order. However, facility owners may not be able to

⁹ 79 Fed. Reg. at 58570 (Sub. E § 117.257(d)).

comply if they do not understand the specific reasons for the order to withdraw the exemption. Currently, FDA must only provide the facility with a “brief, general statement of the reasons for the order.”¹⁰ FDA should require inclusion of more specific information about the reason for withdrawal, namely the evidence on which the order is based. Specific information will also ensure that each withdrawal determination is individualized to a particular facility and that FDA’s decision to withdraw the exemption is not arbitrary or capricious.

The order should also contain detailed information about compliance requirements. This information should explain the requirements in layperson’s terms and might include referrals to sources of technical assistance. Additionally, the short window to appeal necessitates that facility owners understand their procedural rights immediately upon receipt of the order. The withdrawal order should notify the facility owner that he or she has a right to an informal hearing under § 117.207 and that the informal hearing request must be submitted with the appeal within 10 calendar days of the date of receipt of the order.¹¹

Recommendation: FDA should add language to § 117.257 that requires the order to include the evidence on which the order is based and information about compliance requirements. FDA should also add language requiring that the order notify the facility owner that he or she has the option to request an informal hearing as part of the appeals process.

Suggested Language:

§ 117.257 Contents of an order to withdraw an exemption applicable to a qualified facility.

(c) A brief, general statement of the reasons for the order, including information relevant to:

(1) Whether the order is based on § 117.251(a) or 117.251(b); ~~An active investigation of a foodborne illness outbreak that is directly linked to the facility; or~~

(2) The evidence on which the order is based; ~~Conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed or held at such facility;~~

(3)(i) If the order is based on § 117.251(a), the order shall identify evidence linking the active investigation of a foodborne illness outbreak to the facility; or

(ii) If the order is based on § 117.251(b), the order shall:

(A) Include measurable evidence that has been collected using generally accepted scientific standards indicating the presence of pathogens of public health significance within the facility that pose an imminent threat to public health;

(B) Identify conduct or conditions within the facility that are material to the safety of food; and

(C) Include a statement explaining how altering the conduct or conditions would prevent or mitigate a foodborne illness outbreak.

¹⁰ 79 Fed. Reg. at 58570 (Sub. E § 117.257(c)).

¹¹ 79 Fed. Reg. at 58570 (Sub. E § 117.267(a)(2)).

...

(f) A statement that the facility may request an informal hearing as part of the appeals process within 10 calendar days of receipt of the order and any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 117.270;

5. Timeframe for Compliance with the Preventive Controls Rule

Finalize the 120-day compliance time frame for qualified facilities whose exemption has been withdrawn.

Under the revised rule, all facilities whose exemptions have been withdrawn must come into compliance with Subpart C of the Preventive Controls Rule within “120 calendar dates of receipt of the order.”¹² We commend FDA for increasing the compliance timeline to 120 days, as well as tolling the compliance timeline from the date the order is received rather than the date it is issued. We agree with FDA’s remarks that the 60-day timeframe in the 2013 proposed Preventive Controls Rule withdrawal provisions was insufficient for a facility to comply with Subpart C of the Preventive Controls Rule, and we encourage FDA to adopt the 120-day timeframe in the final rule.

6. Appealing the Order to Withdraw an Exemption Applicable to a Qualified Facility

Finalize revised language that requires the order to withdraw the exemption to include notice that appeals must be submitted within 10 calendar days of the receipt of the order.

In the revised rules, FDA requires notification to the facility that the appeal must be submitted within 10 calendar days of the receipt of the order.¹³ These changes are very helpful in giving facilities the opportunity to come into compliance and understanding the timeline for appeals. We urge FDA to include this revised language in the final rule.

Finalize revised language that tolls the ten-day timeline for appeal from the date the order was received by the facility.

Revised language in the Preventive Controls Rule tolls the 10-day timeline for appeal from the date the order was received by the facility, rather than the date the order was issued by FDA.¹⁴ Since mailing times can vary depending on the location of the facility or unforeseen circumstances, this change standardizes the number of days a facility will have to appeal the

¹² 79 Fed. Reg. at 58570 (Sub. E § 117.260(a)(1)).

¹³ 79 Fed. Reg. at 58570 (Sub. E § 117.257(d)).

¹⁴ 79 Fed. Reg. at 58570 (Sub. E § 117.257 and § 117.264).

order and alleviates the possibility that the deadline for appeals will pass before the facility receives the order. We encourage FDA to include this revision in the final rule.

7. Reinstatement of a Withdrawn Qualified Exemption

Finalize the procedure for reinstatement of a withdrawn exemption.

The inclusion of § 117.287 to establish and explain the procedure for reinstating a qualified exemption was a very important addition that should be included in the final rule. This provision allows a facility to regain its exemption after eliminating the problem that led to the withdrawal, thereby easing the regulatory burden for small and very small businesses. Without the opportunity for reinstatement of the exemption, facility owners would permanently lose their exemption and face going out of business due to the significant costs that they would incur. This would jeopardize the robust number and diversity of facilities that make up this country's food economy.

Additionally, there may be some scenarios in which a facility's exemption is withdrawn under § 117.257(c)(1) and then the active investigation later determines that the foodborne illness outbreak is not linked to the facility.¹⁵ This provision ensures that the facility can regain its exemption and is not permanently punished for a foodborne illness outbreak to which it was not actually linked. And if an exemption is withdrawn based on "conditions or conduct associated with the qualified facility that are material to the safety of the food," then providing an avenue for reinstatement of the exemption incentivizes the facility to continuously improve its food safety practices.¹⁶ Consequently, we encourage FDA to include this procedure for reinstatement of a qualified exemption in the final rule.

Clarify that an FDA District Director will reinstate an exemption applicable to a qualified facility under § 117.287(a) "within 10 days."

As mentioned above, an exemption applicable to a qualified facility may be reinstated if (1) an FDA District Director reinstates it on his own initiative after determining that the facility has resolved problems with the conditions and conduct that are material to the safety of the food, (2) a facility owner asks FDA to reinstate the exemption, or (3) a qualified exemption was withdrawn under § 117.251(a)(1) and FDA later determines that the outbreak is not linked to that facility.¹⁷ The first pathway appears very discretionary, as there is no designated timeline for an FDA District Director to reinstate the exemption after making that determination. We encourage FDA to add "within 10 days" to this provision so that FDA has a timeline within which it must reinstate a facility's exemption after the problems leading to the withdrawal have been resolved.

¹⁵ 79 Fed. Reg. at 58570 (Sub. E § 117.287(c)).

¹⁶ 79 Fed. Reg. at 58569 (Sub. E § 117.251(a)(2)).

¹⁷ 79 Fed. Reg. at 58570 (Sub. E § 117.287).

Recommendation: FDA should add language to § 117.287(a) clarifying that the FDA District Director shall reinstate a qualified exemption “within 10 days” if the Director determines that the facility has adequately resolved problems.

Suggested Language:

§ 117.287 Reinstatement of an exemption that was withdrawn.

(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)) determines that the facility has adequately resolved problems with the conduct and conditions that are material to the safety of the food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance of CFSAN) shall, on his own initiative or request of a facility, reinstate the qualified exemption within 10 days.

Provide the opportunity for an informal hearing during the reinstatement of a qualified exemption process.

We also encourage FDA to provide the opportunity for an informal hearing during the reinstatement process. Currently, a facility owner must submit a written request to ask FDA to reinstate an exemption and does not have an opportunity for an informal hearing.¹⁸ An informal hearing would allow the facility owner to present evidence showing that the conditions triggering the withdrawal of the exemption have been resolved, explain this evidence, and engage in a dialogue with the FDA representative overseeing the informal hearing in a way that a written request does not allow. It would also create a record for appeal if FDA denies reinstatement of the exemption.

Recommendation: FDA should provide facility owners the opportunity for an informal hearing during the reinstatement process.

Suggested Language:

§ 117.287 Reinstatement of an exemption that was withdrawn.

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

- (1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

¹⁸ 79 Fed. Reg. at 58570 (Sub. E § 117.287(b)).

(2) Present data and information to demonstrate that you have adequately resolved the problems with the conditions or conduct that are material to the safety of the food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak.

(c) FDA shall provide the owner, operator, or agent in charge of the facility an opportunity for an informal hearing, upon request of said owner, operator, or agent, to be held not later than 10 business days after the request, on the reasons the facility's exemption should be reinstated.