Re: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, Docket ID: FDA-2011-N-0920; RIN: 0910-AG36

To Whom It May Concern:

On behalf of Future Harvest—A Chesapeake Alliance for Sustainable Agriculture (Future Harvest CASA), the Institute for Public Representation (IPR) is pleased to submit the following comments on the U.S. Food and Drug Administration’s (FDA) proposed rule, “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,” 78 Fed. Reg. 3646 (hereinafter, the “proposed preventive controls rule”).

Future Harvest CASA is a network of farmers, agricultural professionals, landowners, and consumers living and working in the Chesapeake Bay region. Future Harvest CASA promotes profitable, environmentally sound, and socially responsible food and farming systems that work to sustain communities. IPR is a public interest law firm and a clinical education program at Georgetown University Law Center. Attorneys at IPR assist groups and individuals who are

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3 Id.
unable to obtain effective legal representation on matters, including those that affect the environment.⁵

Many of Future Harvest CASA’s members participate in local food distributions systems, such as community supported agriculture (“CSA”) farm share programs and farmers’ markets, through which they are able to sell fresh, healthy food directly to consumers in their communities. They are concerned that if the preventive controls rule goes forward in its current form, farms engaged in even the slightest amount of packing or holding of another farm’s food as a part of this direct marketing platform may be required to register as facilities, even if the primary purpose of the establishment is to sell food directly to consumers. We seek to mitigate this concern through these comments by asking the agency to (1) clarify the definition of a “retail food establishment,” (2) narrow the definition of a “farm mixed-type facility,” (3) clarify the definition of “cutting,” and (4) change the way facility-size is calculated.

The FDA’s proposed rule goes too far in building a regulatory scheme to ensure food safety,⁶ and fails to provide enough flexibility for small, low-risk facilities. Future Harvest CASA urges the FDA to amend the proposed preventive controls rule based on the comments that follow, which address four main points:

1. The FDA must amend the definition of a “retail food establishment” in 21 C.F.R. § 1.227(b)(11) to clarify that for purposes of determining an establishment’s primary function, sales of food to roadside food stands and farmers’ markets, and sales and distribution through CSA programs count as direct sales to consumers.

2. The FDA should narrow the “farm mixed-type facility” category to make sure that farms engaged in low-risk holding or packing of another farm’s food do not become “farm mixed-type facilities” subject to the rule.

3. The FDA should clarify the definition of “cutting” in the list of activities that are regulated in “off-farm activities” in the proposed rule.

4. The FDA should assess facility size based on sales that flow from “off-farm activities.”

Additionally, we incorporate by reference the public comments submitted to the agency by the National Sustainable Agriculture Coalition (NSAC) and ask the agency to pay particular attention to their comments concerning the withdrawal of qualified exemptions (proposed Subpart E).

⁵ See id.

⁶ According to the summary of the rule in the federal register notice of proposed rulemaking, the preventive controls rule is intended to “build a food safety system for the future that makes modern, science-, and risk-based preventive controls the norm across all sectors of the food system.” Proposed Preventive Controls Rule, supra note 1, at 3646.
1. FDA failed to amend the definition of a “retail food establishment” in 21 CFR § 1.227(b)(11) to clarify that sales to CSAs, roadside food stands, and farmers’ markets count as direct sales to consumers for purposes of defining an establishment’s primary function.

Section 102 of the Food Safety Modernization Act (FSMA) directed the FDA to amend the definition of a “retail food establishment” in section 1.227(b)(11) of title 21, Code of Federal Regulations to clarify that for purposes of determining whether an establishment’s primary purpose is to sell food directly to consumers, sales of food to roadside stands and farmers’ markets, and sales and distribution of food through CSA programs should all count as direct marketing platforms. Under this clarifying language in FSMA, establishments that primarily function to sell food through CSA programs are “retail food establishments.” Retail food establishments are exempt from facility registration requirements, and, thus, are not regulated by the preventive controls rule. However, the FDA failed to make this clarification in the proposed rule. Although section 102 concerns the registration of food facilities, rather than the regulation of those facilities, the preventive controls rule is the correct vehicle for amending the definition of “retail food establishment” because the rule modifies 21 C.F.R. part 1. The agency must amend the definition of a “retail food establishment” in its final rule to avoid violating FSMA. We discuss how the FDA should do this here.

The proposed version of the preventive controls rule violates FSMA because it fails to amend the definition of the term “retail food establishment.” The proposed rule revised part 1 of title 21 of the Code of Federal Regulations, but it did not change the definition of a retail food establishment under section 1.227. The FDA should have revised that section by adding language to clarify that for purposes of assessing whether an establishment’s primary function is to sell directly to consumers, sales to roadside food stands and farmers’ markets, sales and distribution through CSA programs, and sales through any other direct sales platforms identified by the Secretary count as direct sales to consumers. The law makes it clear that some farm mixed-type facilities, as well as some establishments that would otherwise be facilities, could then become “retail food establishments.” Farms that engage in “off-farm activities,” such as packing destined for CSA boxes, would be “retail food establishments,” so long as their primary

7 Food Safety Modernization Act, PL 111-353, 124 STAT. 3885-3973, Jan. 4, 2011 (hereinafter FSMA), at 124 STAT. 3889 (Sec. 102(c)).
8 See 21 U.S.C.A. § 350d(c)(1) (exempting “retail food establishments” from the definition of a facility).
9 The FDA revised other parts of the same regulation (21 C.F.R. § 1.227) in its proposed rule. Proposed Preventive Controls Rule, at 3795.
10 21 C.F.R. § 1.227 is the definitions section for regulations concerning cosmetics, drugs, exports, food labeling, imports labeling, reporting and recordkeeping requirements. The revision to part 1 of title 21, Code of Federal Regulations, can be found in the Proposed Preventive Controls Rule, supra note 1, at 3795. However, the FDA did not revise § 1.227.
11 The definition of “retail food establishment” in the proposed preventive controls rule is identical to the current definition in 21 C.F.R. § 1.227.
function is to sell their produce through one of these newly identified direct sales platforms. Those farm mixed-type facilities would then not be required to register as facilities under FDCA section 415, and would not be subject to the preventive controls rule.

In order to remedy this problem and come into compliance with FSMA, we suggest that the FDA add the following line to the retail food establishment definition in 21 C.F.R. § 1.227: “For purposes of determining the primary function of an establishment, sales of food at roadside stands and farmers markets (where such stand or market is located other than where the food was manufactured or processed), and sales and distribution of food through community supported agriculture programs count as direct sales to consumers.” The FDA could insert this sentence before the last sentence of the definition, which reads, “A ‘retail food establishment’ includes grocery stores, convenience stores, and vending machine locations.” Section 102 of FSMA mandates that “community supported agricultural program” would have the same meaning given the term in section 249.2 of title 7, Code of Federal Regulations, which is “a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer’s crop(s) for that season.” Under this clarification, farms engaging primarily in CSA programs (meaning that over 50% of its sales come from its CSA sales and activities) will be “retail food establishments” and exempt from facility registration requirements, even if they are also farm mixed-type facilities. Even if the law is self-executing, the FDA must change the definition of a “retail food establishment” to avoid confusion for establishments engaged in these types of sales. Furthermore, the law mandated that the FDA clarify how primary function should be determined.

2. The proposed rule unnecessarily regulates a number of entities that should be exempt

The proposed rules seem to require all “farm mixed-type facilities”—i.e. any farms that do any processing or manufacturing, or any packing or holding of other farms’ food—to register as facilities. This reading of the rules, which FDA officials have confirmed through webinars, is quite alarming. When Congress asked the FDA to promulgate regulations with respect to manufacturing, processing, packing and holding activities that occur on-farm, it did not intend for the FDA to bring all farms engaged in any amount of those activities under the umbrella of the rule. Congress was concerned about the potential dangers involved in high-risk processing and manufacturing activities, and in holding and packing of large quantities of food from

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12 Retail food establishments are exempt from facility registration requirements. 21 U.S.C.A § 350d(c)(1).
13 7 C.F.R. § 249.2.
15 Congress called upon the FDA to promulgate regulations with respect to these activities for purposes of section 415 of the Federal Food, Drug, and Cosmetic Act, which concerns registration of facilities. Food Safety Modernization Act, PL 111-353, Jan. 4, 2011 (hereinafter FSMA), at 124 STAT. 3896 (Sec. 103(c)(1)(A));
multiple farms. We recognize that FSMA directed the FDA to regulate some farm mixed-type facilities performing high-risk activities. However, the agency did not have to regulate all farms engaged in any “off-farm activities,” and Congress probably did not intend for them to do so.\textsuperscript{16} We urge the FDA to reevaluate its broad definition of “farm mixed-type facility,” and narrow it so that farms practicing a small amount of low-risk “off-farm activities” are not required to register as facilities. We propose language for a new definition, which would distinguish high-risk holding and packing operations that occur on-farm from low-risk holding and packing of a neighboring farm’s food. This distinction is consistent with the rule’s goal—to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by facilities.\textsuperscript{17} It is also consistent with FSMA’s requirement that the preventive controls rule provide “sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm.”\textsuperscript{18}

\textit{a. The “farm mixed-type facility” category is too broad}

The proposed preventive controls rule will require some farms to register as facilities under section 415 of the Food Drug and Cosmetic Act (“FDCA”) for the very first time. Farms were explicitly excluded from FDCA section 415’s definition of facility when the 2002 Bioterrorism Act added this registration requirement.\textsuperscript{19} Under the changes proposed by the preventive controls rule, farms that engage exclusively in “on-farm activities” (i.e. harvesting, packing their own raw agricultural commodities (RACs), holding their own RACs, and manufacturing or processing their own RACs for consumption on farm) would still not be required to register as facilities, and thus would not be subject to the rule’s requirements.\textsuperscript{20} However, farms that also engage in any “off-farm activities” (i.e. manufacturing or processing any food (including the farm’s own food), or packing or holding another farm’s food), would fall under a new category of entities the proposed rule calls “farm mixed-type facilities.”\textsuperscript{21} These entities would then be required to register as facilities under FDCA section 415, and any “off-farm activities” performed there

\textsuperscript{16} The legislative history of FSMA showed that many senators believed farms would be exempt from the preventive controls rule. See Cong. Rec. S7921, Nov. 17, 2010 (Senator Hatch reassured colleagues that the final bill would not change the existing definition of a facility, meaning that farms would continue to be exempt; Sponsoring Senator Mike Enzi also stated that farmers would remain exempt from registration under the Bioterrorism Act of 2002); see also Cong. Rec. S8225, Nov. 29, 2010 (Senator Chambliss spoke about eliminating the so-called “Tester-Hagan amendment,” which he thought was unnecessary on grounds that the “original bill makes no change in the definition of ‘facility’ under the Bioterrorism Act of 2002, which requires certain facilities to register with FDA, thus farms and restaurants remain exempted in S. 510.”).

\textsuperscript{17} FSMA, supra note 7, at 124 STAT. 3895 (Sec. 103(a)).

\textsuperscript{18} Id. (Sec. 103(n)(3)(A)).

\textsuperscript{19} See id.

\textsuperscript{20} Proposed Preventive Controls Rule, supra note 1, at 3682-83 (Table 4).

\textsuperscript{21} Id. at 3677.
would be subject to the rule’s requirements. A number of these entities would be subject to both the produce safety rule and the preventive controls rule. In many cases, this is unnecessary.

Future Harvest CASA is concerned that the FDA interpreted the mandate in FSMA to promulgate regulations with respect to these activities too broadly. The FDA was not required to regulate all “off-farm activities” that occur on-farm, and there is evidence that Congress did not want the FDA to regulate such a broad new category of entities. For example, FSMA prohibits the Secretary of the FDA from modifying the definition of the term “facility” in FDCA section 415. While the proposed preventive controls rule does not explicitly change that definition, it creates a new, very broad category of entities that would be required to adhere to the same registration standards as facilities. Another compelling reason for why the FDA should narrow the “farm mixed-type facility” category is that there seems to be no purpose in requiring farms with a small amount of low-risk, “off-farm” activity to comply with the entirety of the rule when Congress has already determined that it is unnecessary to regulate very small businesses because the risk of contamination is low. Holding or packing food for a short period of time from a neighboring farm that has already complied with existing regulations deemed appropriate for that commodity is inherently low-risk. In a typical case, a mid-sized family farm may hold a handful of specific items from other farms for sale there, or it may hold and pack items from other farms to take them to a farmer’s market or grocery store. The farms holding or packing food in this scenario are not holding large amounts of different commodities from a large number of farms, where there is high potential for cross-contamination. The commodities are only handled by a small number of people, and they do not undergo any processing. These farms should not be subject to the preventive controls rule.

b. “Double-regulation” of qualified facilities

Another concern we have about the breadth of the FDA’s rule is that for some farm mixed-type facilities, the extra layer of regulation under the preventive controls rule fails to add any new protections. Suppose that a farm mixed-type facility is entitled to a qualified exemption under the preventive controls rule because it is a very small business” (however the FDA

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22 Id.
23 Section 103(c)(1)(A) of FSMA requires the FDA to promulgate regulations with respect to “(i) activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership for purposes of section 415 of the FDCA, as amended by this Act; and (ii) activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership for purposes of section 415.” FSMA, supra note 7, at 3896.
24 See FN 16.
25 FSMA, supra note 7, at 3897 (Sec. 103(c)(1)(B)).
26 If the product is seafood or juice, the neighboring farm would have been required to comply with HAACP; if the commodity is meat or dairy, it would have had to comply with USDA standards and inspections; etc.
ultimately decides to define that term).\textsuperscript{27} That entity would be required to register as a facility under FDCA section 415, and would have to implement the current good manufacturing practice (CGMP) requirements in addition to the produce safety requirements. However, as a qualified facility, it would be exempt from hazard analysis and risk-based preventive controls of subpart C.\textsuperscript{28} In this case, regulation under the preventive controls rule would be completely unnecessary, because the requirements the entity would be subject to would not make the food processed, manufactured, packed or held there any safer than the produce safety requirements already in place. Compliance with the CGMP requirements seems unnecessary for this entity, because the non-produce related provisions of the produce safety requirements (i.e. the standards directed to personnel qualifications and training; the standards directed to health and hygiene; and the standards directed to equipment, buildings, and sanitation) are nearly identical to the CGMP requirements.

It is hard to discern the possible benefit to public health offered by this extra layer of regulation. The benefit to the government, however, is obvious: the registration fee the regulated entity will have to pay under FDCA section 415 will generate money to finance the food safety rules.\textsuperscript{29} As we pointed out in our public comments on the produce safety rule, sustainable family farms will already carry a substantial financial burden due to the agricultural water requirements, and the requirements related to application of biological soil amendments of animal origin.\textsuperscript{30} For any farms that also do any “off-farm activities”\textsuperscript{31} and become “farm mixed-type facilities” under the preventive controls rule, the facility registration fee will be yet another financial burden that could force them to stop their “off-farm activity” (which could be as minimal as holding a neighbor’s fruit in a storage shed before it goes to market), or shut down entirely.

c. Proposal for re-defining “farm mixed-type facility”

The FDA should limit the definition of “farm mixed-type facility” to farms that do a specific type and amount of “off-farm activities,” in order to distinguish low-risk activities that should be exempted from high-risk activities worth regulating. The FDA should redefine “farm mixed-type facilities” as “farms that engage in any processing or manufacturing activities, or farms that engage in packing or holding activities of food not grown, raised, or consumed there

\begin{itemize}
  \item Facilities are eligible for a “qualified exemption” if they are very small businesses, or if they meet the requirements of the so-called “Tester-Hagan” amendment. \textit{See} Proposed Preventive Controls Rule, \textit{supra} note 1, at 3800 (definition of “qualified facility” under proposed § 117.3).
  \item \textit{Id.} at 3805.
  \item \textit{See} Future Harvest CASA’s public comments on the proposed produce safety rule.
  \item “Off-farm activities” include any manufacturing or processing, or any holding or packing of another farm’s food.
\end{itemize}
if: (1) the annual sales from those activities are over 50% of the mixed-type facility’s total annual revenue, (2) the mixed-type facility packs or holds food from a different state, or from beyond a 275-mile radius, or (3) the mixed-type facility packs or holds food from over 10 farms.” These three triggering criteria would distinguish farms that engage in low-risk holding or packing activities as part of a sustainable, farm-to-table distribution system from farm mixed-type facilities that engage in high-risk “off-farm activities” as a significant part of their business. In a farm-to-table distribution system, one “hub farm” might hold and transport a small amount of food from a neighboring farm that, on its own, would not justify an expensive trip to the farmer’s market. Future Harvest CASA’s proposal would ensure that low-risk, collaborative activities that enable mid-sized, diversified farms to distribute and sell their products would be exempt from regulation.

The three criteria for narrowing the definition of a farm mixed-type facility are reasonable. The first limitation, that sales from “off-farm activities” must exceed 50% of the mixed-type facility’s business, would ensure that large-scale operations engaged in packing or holding activities are covered, even if they are local large-scale operations. The second limitation parallels the radius drawn by the THA for farms engaged in direct farm marketing, and distinguishes those farms from farm mixed-type facilities engaged in traditional distribution systems that are merely small in scale. Congress determined that farms and facilities that meet the THA requirements should be exempt from certain requirements under the rule because their unique practices are not high risk. The same logic applies to facilities that only hold or pack food from within a 275-mile radius, and that hold or pack food from under 10 farms. This reasonable carve-out for farms conducting only low-risk “off-farm activities” will allow family farms that participate in local food distribution systems to continue these practices in an economically viable manner.

3. The FDA should clarify the definition of “cutting,” to make sure that the proposed rule does not bring farms standard farming practices under the rule

Future Harvest CASA’s proposal above for narrowing the definition of a “farm mixed-type facility” would only affect holding or packing activities; farm mixed-type facilities engaged in manufacturing or processing would still be required to register as facilities, unless some other exemption applies. However, Future Harvest CASA seeks clarification about how “cutting” is classified in Table 4 of the Federal Register notice of proposed rulemaking, which classifies activities conducted off-farm and on-farm.32 Table 4 lists “cutting/coring/chopping/slicing” as one of the enumerated activities that constitutes on-farm manufacturing or processing. This is problematic because a common practice employed by farmers that grow broccoli and/or

32 Proposed Preventive Controls Rule, supra note 1, at 3682-83.
cauliflower is to give a “second cut” to the stems of the vegetables after they have been picked.\textsuperscript{33} We are concerned that this second cut would be considered manufacturing or processing under the rule, although it is a routine practice used by all farmers who grow broccoli or cauliflower. The FDA should clarify the definition of “cutting” so as to leave no doubt that routine farming activities would not turn farms into farm mixed-type facilities.

4. \textit{The FDA should assess facility size based on sales that flow from “off-farm activities.”}

Our final concern is that the proposed preventive controls rule violates FSMA’s flexibility mandate because it fails to properly assess the size of facilities co-located on farms. Under the proposed rule, the size of a “small food processing facility co-located on a farm” would not be assessed independently of the entire operation. This is due to the fact that the rule evaluates a mixed-type facility’s size based on \textit{all} revenue, including sales from farming activities, \textit{and} processing activities. We seek to remedy this problem by asking the FDA to change the way it evaluates facility size.

We anticipate that the FDA’s response to our above concerns about “double-regulation” above may be that the two sets of regulation (the produce safety rule and the preventive controls rule) are meant to target different parts of the farm mixed-type facility’s operations. We wonder then, why does the preventive controls rule assess facility size based on sales of \textit{all} food, rather than on sales flowing from regulated activities? The FDA has proposed three options for the definition of “very small business” in the preventive controls rule, and each definition assesses size based on sales of \textit{all} food.\textsuperscript{34} If, in theory, the preventive controls requirements only apply to off-farm activities only, the FDA should treat those off-farm activities entirely separately from the farm mixed-type facility’s farming operations. This would require that the regulations also assess the size of a facility based on only those activities. Below, we propose a number of options for how the FDA could define a “very small business,” consistent with the goal of treating off-farm activities separately from on-farm activities.

The FDA did not reach a tentative conclusion on how best to define a “very small business” in the preventive controls rule.\textsuperscript{35} We have a few suggestions for how the FDA can do this, and avoid unnecessary regulation of low-risk off-farm activities. The FDA proposed three possibilities for the definition of a “very small business” in the preventive controls rule — (1) a business that has less than $250,000 in total annual sales of food, adjusted for inflation, (2) a business that has less than $500,000 in total annual sales of food, adjusted for inflation, or (3) a business that has less than $500,000 in total annual sales of food, adjusted for inflation, or (3) a

\textsuperscript{33} The farmer will typically place the broccoli or cauliflower in a simple, non-electric machine that cuts off the rough part of the stem, while it simultaneously places a rubber band around the bottom of the remaining stem.

\textsuperscript{34} Proposed Preventive Controls Rule, \textit{supra} note 1, \textit{at} 3700-02, 3800 (proposed § 117.3).

\textsuperscript{35} Proposed Preventive Controls Rule, \textit{supra} note 1, \textit{at} 3701.
business that has less than $1,000,000 in total annual sales of food, adjusted for inflation. The FDA specifically sought comments on how “a particular dollar amount of sales proposed would be in keeping with Congressional intent - i.e., in light of the provisions in section 418(l) regarding qualified facilities, including the statutory limitations on sales to qualified end-users.”

We believe that of the dollar amount of sales proposed, $1,000,000 is the most consistent with existing definitions of “very small business,” and it is most in line with the results of the Congressionally-mandated food processing sector study conducted by the FDA and USDA. We are aware that if the FDA chooses to define “very small business” using the $1,000,000 sales limit, every facility or farm mixed-type that has a direct marketing exemption will also be a very small business. However, the two exemptions can exist independently because the very small business definition does not subsume the purpose and goal of the direct marketing exemption. Alternatively, the FDA could also adopt our proposal to define a “very small business” based on number of employees. Defining a “very small business” as “a business with 20 or fewer employees” would avoid the redundancy in the qualified exemption part of the rule, and be consistent with the proposed definition of a “small business.” If the FDA prefers to define “very small business” based on sales, we strongly urge the FDA to assess size based on sales that flow from activities regulated by the preventive controls rule only (i.e. sales of food that underwent manufacturing or processing, or that was held or packed at the facility). Nothing in FSMA prevents the FDA from doing so, and this assessment would prevent regulation of “farm mixed-type facilities” that are primarily farms, but that engage in a very small amount of “off-farm” activity. We describe these proposals in more detail below.

a. The FDA should define “very small business” as a business with 20 or fewer employees

While the FDA has not yet reached a tentative conclusion on how to define “very small business,” it has proposed to define “small business” as a “a business employing 500 or fewer employees.” The FDA should also define “very small business” in terms of number of employees to make the two definitions consistent. We suggest that the FDA define “very small business” as “a business employing 20 or fewer employees.” Proportionally, this would make a “very small business” twenty-five times smaller than a small business in terms of number of employees. Defining a “very small business” in this way would significantly differentiate it from a “small business.” Furthermore, the number 20 is consistent with the smallest establishment size

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36 Id. at 3700-02, 3800 (proposed § 117.3).
37 Id. at 3701.
38 The USDA Rural Business Cooperative Service defines a “very small business” as “a business with fewer than 15 employees and less than $1 million in annual receipts.” 7 C.F.R. § 4280.103.
39 Proposed Preventive Controls Rule, supra note 1, at 3800.
that the FDA and the USDA examined in their food processing sector study. The study divided facilities into four different sizes based on how many employees they had: (1) facilities with fewer than 20 employees, (2) facilities with 20 to 99 employees, (3) facilities with 100 to 499 employees, and (4) facilities with 500 or more employees. Finally, other agencies have used similar definitions for “very small business”.

b. If the FDA defines “very small business” based on sales, it should base this evaluation only on sales that flow from activities that are regulated by the preventive controls rule

If the FDA rejects our proposal above, and chooses to use revenue for purposes of defining a “very small business” in the rule, we believe it would be wise for the agency to calculate the monetary limit based on sales flowing from “off-farm activities” only. Logically, it makes sense for a rule that regulates only certain activities within the business to calculate the size of the regulated business based on sales that flow from those regulated activities only. This calculation is crucial in the case of farm mixed-type facilities. It does not make sense that the facility portion of a farm that does a small amount of “off-farm activities” would be subject to all of the rule’s requirements, even if only a small fraction of sales come from the regulated activities. The FDA should therefore define a very small business for purposes of part 117 of the preventive controls rule as “a business that has less than $1,000,000 in annual sales of food flowing from (i) manufacturing or processing activities conducted by the business, or (ii) holding or packing activities conducted by the business if the food was not grown, raised, or consumed there, adjusted for inflation.”

Conclusion

The FDA must revise the preventive controls rule in order to comply with the requirements of FSMA. The proposed rule violates FSMA Section 102(c) because it did not change the definition of a “retail food establishment” to include three newly identified direct marketing platforms. Furthermore, it fails to provide enough flexibility for small businesses, and for food processing facilities co-located on farms. We suggest that the FDA remedy these problems by 1) amending the definition of a “retail food establishment” in 21 C.F.R. section 1.227, 2) narrowing the definition of a “farm mixed-type facility,” 3) clarifying that routine cuts made to vegetable stems on-farm do not make those farms subject to the preventive controls rule, and 4) defining “very small business” as a “business employing 20 or fewer employees,” or, if the FDA wants to define “very small business” in terms of revenue, defining “very small business” as “a business that has less than $1,000,000 in annual sales of food flowing from (i) manufacturing or

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41 Id.
42 See FN 38.
processing activities conducted by the business, or (ii) holding or packing activities conducted by the business if the food was not grown, raised, or consumed there, adjusted for inflation.”

Sincerely,

/s/ Hope Babcock

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To Whom It May Concern:

On behalf of Future Harvest—A Chesapeake Alliance for Sustainable Agriculture (Future Harvest CASA), the Institute for Public Representation (IPR) is pleased to submit the following comments on the U.S. Food and Drug Administration’s (FDA) proposed rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3504 (hereinafter, the “proposed produce safety rule”).

Future Harvest CASA is a network of farmers, agricultural professionals, landowners, and consumers living and working in the Chesapeake Bay region. Future Harvest CASA promotes profitable, environmentally sound, and socially responsible food and farming systems that work to sustain communities. IPR is a public interest law firm and a clinical education program at Georgetown University Law Center. Attorneys at IPR assist groups and individuals who are unable to obtain effective legal representation on matters, including those that affect the environment.

3 Id.
5 See id.
Many of Future Harvest CASA’s members participate in local food distributions systems, such as community supported agriculture (CSA) farm share programs and farmers’ markets, through which they are able to sell fresh, healthy food directly to consumers in their communities. They are concerned that the proposed produce safety rule would not improve produce safety and reduce foodborne illness outbreaks at their farms; rather, it would discourage natural, organic, and sustainable farming practices, and may ultimately drive sustainable family farms out of business. If promulgated in its current form, the proposed rule could potentially reduce access to healthy produce in their communities, and inadvertently encourage the consumption of unhealthy, processed foods instead.

The Food Safety Modernization Act (FSMA)\(^6\) gave the FDA brand new authority to establish science-based minimum standards for the safe production and harvesting of certain agricultural commodities that are consumed raw; namely, intact fruits and vegetables.\(^7\) This is the first-ever opportunity for the FDA to promulgate regulations related to activities that occur on farms. The agency should, therefore, approach this important task cautiously so as to protect the economic viability of all types of farms and avoid promulgating onerous regulations that could permanently put a number of sustainable family farms out of business, while at the same time protecting public health. The FDA can achieve this by following FSMA’s mandate to allow for sufficient flexibility for various types of farms. The following comment identifies a number of problems with the rule, and proposes changes we believe will address these problems, which we encourage the agency to adopt in its final rule.

Future Harvest CASA urges the FDA to amend the proposed produce safety rule based on the comments that follow, which address four main points:

1. The proposed rule will not necessarily enhance the safety of produce grown at sustainable farms, which employ agricultural methods that understand integrated ecosystems.\(^8\) Rather, the proposed rule will disrupt these systems, and force covered farms to adopt less sustainable agricultural practices.
2. Even when the rule provides for a choice between different modes of compliance, it creates incentives to adopt the less sustainable methods.
3. In order to meet FSMA’s requirement that the rule provide for sufficient flexibility for various types of entities and “be appropriate to the scale and diversity of the

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\(^6\) Food Safety Modernization Act, PL 111-353, 124 STAT. 3885-3973, Jan. 4, 2011 (hereinafter FSMA).
\(^7\) Id. at 124 STAT. 3899-3905.
\(^8\) “Sustainable farms are managed as fully-integrated ecosystems, where knowledge of soils, macro and microscopic organisms such as bacteria and fungi, water, crops, weeds, pests, equipment and techniques are used to maximize the long-term health, productivity and economic profitability of the farm.” Jason Bradford and Craig Wichner, *Sustainable Agriculture Whitepaper*, Farmland LP, May 2009, p. 9, available at: http://farmlandlp.com/wp-content/FarmlandLP-SustainableAgWhitepaper.pdf.
production and harvesting of such commodities,” the agency should clarify how it will determine whether an alternative to the rule’s requirements is acceptable.

4. The FDA should assess farm size based on sales of covered produce only.

Additionally, we incorporate by reference the public comments submitted to the agency by the National Sustainable Agriculture Coalition (NSAC) and ask the agency to pay particular attention to their comments concerning the withdrawal of qualified exemptions (proposed Subpart R).

1. The proposed rule does not necessarily improve produce safety on sustainable farms.

The FDA’s proposed produce safety rule addresses specific on-farm activities related to hygiene and produce safety, including hand-washing for employees, maintenance of clean buildings and equipment, application of agricultural water to produce, application of compost and other types of fertilizer to growing areas, and management of wildlife and domesticated animals in and around growing areas. Unfortunately, the standards the proposed rule establishes for each of these activities do not account for the wide range of farming practices employed by farms—especially farms that make up the sustainable farming community. Instead, the agency has acted with an overabundance of caution toward produce safety, and proposed unreasonably high baseline standards that would unnecessarily ban a diverse set of safe farming practices at sustainable farms. The proposed rule’s strict requirements seem aimed at scrubbing farms clean of all possible pathogens. Sterilizing farms, however, will not necessarily advance the goal of ensuring produce safety. In fact, decreasing biodiversity on organic and natural farms will likely result in food that is more susceptible to disease and pathogens from pests, because it will disrupt the ecological balance that sustainable farmers strive to achieve through integrated systems. The proposed requirements are more appropriately geared towards industrial farms that produce a single vegetable in massive quantities, and do not rely on knowledge of integrated ecological systems. The FDA should consider the safety of methods used by sustainable farms that do not involve sterilization, and incorporate these practices into the final rule.

Another reason that sustainable farms engaged in direct farm marketing should not have to comply with the same standards as industrial farms is that they already have strong incentives to ensure that their food is safe. When a consumer buys a bag of spinach from a stand at a farmer’s

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9 FSMA, supra note 5, at 124 STAT. 3900.
10 Proposed Produce Safety Rule, at 3634 (proposed §§ 112.31 – 112.33)
11 Id., at 3638-40 (proposed §§ 112.121 – 112.140).
12 Id., at 3634-36 (proposed §§ 112.41 – 112.50).
13 Id., at 3636-38 (proposed §§ 112.51 – 112.60).
14 Id., at 3638 (proposed §§ 112.81 – 112.83).
15 See Farmland LP Whitepaper, supra note 5, at 15, 20.
16 See Public Comments submitted by the National Sustainable Agriculture Coalition on the Produce Safety Rule.
market, she knows the name and address of the farm that sold her the food (and perhaps the name of the farmer who handled the transaction), and she can trace the product to the physical farm where it was grown. In contrast, the consumer who buys a bag of Dole spinach at a chain grocery store does not know (and will never know) which farm or farms the lettuce inside the bag came from. This is a significant difference between local farms engaged in direct farm marketing sales, and industrial farms that sell through national distributors and put their products on grocery store shelves across the nation. The proposed rules will only serve to layer on complicated, burdensome rules on sustainable farms that already self-regulate, and that may also comply with other programs that assure produce safety, such as the U.S. Department of Agriculture’s (USDA) Good Agricultural Practices (GAP) program.

2. The proposed rule creates incentives for farms to choose unsustainable practices.

The rule’s biological soil amendments of animal origin provisions and agricultural water provisions inadvertently create incentives—particularly, economic incentives—for farmers to adopt less sustainable practices in place of more sustainable alternatives. This is a problem because the adoption of less sustainable practices by farmers nationwide will have a significant effect on the human environment. The FDA failed to do an environmental analysis pursuant to the National Environmental Policy Act (NEPA) in spite of the significant effect the rule will have on the human environment. The FDA should consider the negative environmental effects that could result from the economic incentives created by the rule’s provisions concerning biological soil amendments and agricultural water before promulgating the final rule.

a. The biological soil amendments of animal origin provisions create bad incentives.

In its economic impact analysis, the FDA estimated that farms that currently use untreated, raw manure as fertilizer without waiting the proposed rule’s required nine months before application would switch to the lowest cost alternative in order to meet the requirements of the rule. Based on the FDA’s estimates, the lowest cost alternative for a mixed livestock and produce farm that currently applies raw manure would be to haul its manure for off-site disposal, and purchase commercial compost to use as fertilizer. Using commercial compost is less

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17 *See* Public Comments submitted by the National Sustainable Agriculture Coalition on the Produce Safety Rule.

18 The FDA’s economic impact analysis estimates that it would cost a very small farm an average of $1,583.46 annually to switch to commercial compost. Assuming the FDAs numbers are accurate, the next least expensive option would be for the farm to comply with the 9-month restriction between manure application and harvest, which would cost $2,404 annually. It would cost the farm $3,346 to use synthetic fertilizer and haul its manure. This is by far the least sustainable option, and the estimated cost does not include the externalities associated with these practices. Id. On the high end of the cost spectrum, it would cost the farm $3,974 to make its own compost from the raw manure it has on site, which is the most sustainable alternative. Economic Analysis of the Proposed Produce Safety Rule, at 187-88.

19 *Id.*, at 187.
sustainable than applying manure or composting on-farm because it requires fuel both to get the organic waste to the composting site, and to get the compost to the farm. Additionally, there may be a higher risk of microbial contamination and a greater threat to public health associated with the use of commercial compost than with natural compost made on-farm.\(^{20}\) For example, if a composter receives inputs of dangerous biological material, such as factory farm livestock manure containing high levels of antibiotics, or sewage sludge containing human pathogens, and then fails to treat the compost properly, the application of that compost to harvesting areas would pose a much greater threat to the public health than the application of nutrient-rich manure from grass-fed animals four months prior to harvesting.\(^{21}\)

The FDA did not adequately consider the potential environmental consequences of the biological soil amendments requirements, nor did it consider the possibility that the widespread use of commercial compost may result in more contamination of produce than a sustainable farm’s current practices. Assuming the farm chooses the lowest cost alternative, it will purchase commercial compost, which is less sustainable than either continuing to apply manure using existing practices, or producing its own compost. The latter two alternatives are particularly sustainable because the farm would be able to apply the manure at agronomic rates on-farm, rather than hauling it to a composting facility (if there even is one in the area) or a landfill. This would reduce external environmental costs of hauling manure and purchasing commercial compost, including greenhouse gas emissions associated with transport, and methane emissions associated with storing manure in a landfill.\(^{22}\) The use of commercial compost is not only less sustainable; it is likely more dangerous to public health than waiting four months to apply manure derived from a sustainable or organic farm’s own animals because commercial compost may contain the manure of animals that were fed antibiotics, or even sewage sludge.\(^{23}\)

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\(^{20}\) Biosolids (i.e. sewage sludge) and antibiotic-laden manure from concentrated animal farming operations are accepted at commercial composting facilities. See Composting of Organic Waste, New York State Department of Environmental Conservation, available at http://www.dec.ny.gov/chemical/8798.html; see also EPA, Biosolids Technology Fact Sheet, http://water.epa.gov/scitech/wastetech/upload/2002_10_15_mtb_combioman.pdf; see also 40 C.F.R. § 503 (explaining heating requirements for sewage sludge before it is used in compost); see also Maggie Fry-Manross, “Livestock inputs make importing manure a concern, even for composting,” Rodale Institute, June 8, 2006, available at: http://www.newfarm.org/features/2006/0606/toxicpoop/frymanross.shtml (explaining that “[t]here are operations that will take sludge, CAFO manure and urban green waste and make it into commercial compost”).


\(^{23}\) See FN 17.
b. The agricultural water provisions create bad incentives

We also have concerns about the proposed rule’s agricultural water provisions. To begin on a positive note, Future Harvest CASA would like to express support for the FDA’s proposal to exempt indirect water application methods (such as drip or furrow irrigation) from the rule’s coverage. Drip irrigation is an effective and sustainable water application method that reduces water use by 25-90%, and increases crop yields by 50-100%.\(^{24}\) Water applied through drip irrigation does not contact covered produce, and therefore should not be considered agricultural water. This exemption will be important for sustainable farms, which rely heavily on drip irrigation to water crops.

Our concerns about the agricultural water provisions relate to the different testing requirements the proposed rule sets out for different sources of agricultural water. We are concerned that the proposed rule will provide incentives for farms to draw agricultural water from public or municipal water sources rather than private water sources. Section 112.45(a) of the proposed produce safety rule exempts from its testing requirements water that comes from a Public Water System (as defined in the Safe Drinking Water Act), or from a public water supply that furnishes water that meets the microbial requirements set out in section 112.44(a) of the proposed rules.\(^{25}\) This exception is likely to create a preference for public or municipal water sources because using these sources will allow farms to avoid the expense and time associated with the water testing requirements. If more farms abandon private sources of agricultural water and turn to public water sources, this could unnecessarily strain shared water resources,\(^{26}\) harm aquatic ecosystems,\(^{27}\) and/or lead to new construction of water treatment facilities and water transportation systems.\(^{28}\) Furthermore, the proposed rule’s testing requirements creates a preference for groundwater and water drawn from man-made containments over surface water due to the frequent testing required for untreated surface water where a significant quantity of

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25 Proposed Produce Safety Rule, supra note 5, at 3635.
28 A 2006 EPA survey showed that 52.6% of capital investments made by public and private water supply companies were directed toward system expansion, such as new facilities and transmission systems. U.S. EPA, 2006 Community Water Survey 28–31 (2009), available at http://water.epa.gov/infrastructure/drinkingwater/pws/upload/cwssreportvolumel2006.pdf.
runoff is likely to drain into the source. This could dramatically increase farm dependence on groundwater sources and exacerbate competing demands for these resources. The FDA should reduce the frequency of testing for untreated surface water sources from seven days to once a month. This would create parallel testing requirements with the testing of underground aquifer water that is transferred to a surface water containment, such as an on-farm man-made water reservoir. The every-seven-day testing requirement is so burdensome that farmers are likely to discontinue all use of water drawn from rivers and natural lakes. This would shift farmers’ dependence on that resource to other sources of water, and have significant environmental effects.

Another concern we have with the agricultural water provisions is that they create a preference for the use of antimicrobial pesticides as an appropriate water treatment method. Proposed section 112.45(a)(3) exempts farms that treat their agricultural water from the rule’s water testing requirements, and the only water treatment method that the FDA explicitly approves of in the proposed rule is the application of EPA-approved antimicrobial pesticides. This exemption creates a huge incentive for farms to treat private sources of agricultural water (which they had previously been using without contamination problems) with antimicrobial pesticides to avoid the costs associated with testing agricultural water. This is particularly concerning because in the notice explaining the proposed rule, the FDA acknowledged that “at the present time, no such registration for chemical treatment of irrigation water exists,” but expressed hope that the delayed implementation period for water quality testing would provide industry adequate time to address such issues. Thus, the FDA has actually created a requirement in the rules that encourages not only the use of antimicrobial pesticides; it also provides an incentive for the pesticide industry to create and register new products that could potentially harm the environment.

29 § 112.45(b) requires additional testing at least every seven days during the growing season for untreated surface water form “any source where a significant quantity of runoff is likely to drain into the source,” or at least once every month during the growing season for untreated surface water from “any source where underground aquifer water is transferred to a surface water containment.” Proposed Produce Safety Rule, supra note 5, at 3635.
30 Threats to groundwater supply and quality are growing with the expansion of biofuels, global climate change, hydrofracking, and increased crop irrigation across the eastern states. See Water Conservation in Irrigated Agriculture: Trends and Challenges in the Face of Emerging Demands, supra note 19, at 8-13.
31 See
32 § 112.43(a) directs farms to treat any agricultural that they use if they know or have reason to believe that the water is not safe and of inadequate sanitary quality for its intended use. The FDA explicitly suggests using an EPA-registered antimicrobial pesticide product to treat water, without offering any alternative methods of treatment.
33 Proposed Produce Safety Rule, at 3635.
34 Id. (proposed § 112.43(1)); see id. at 3567 (“treating agricultural water with antimicrobial compounds can be an effective means to eliminate pathogens if done properly, including under conditions that ensure the effectiveness of the active ingredient.”)
35 Id. at 3567.
Additionally, section 112.43 requires the treatment of any agricultural water that a farmer uses, “such as with an EPA-registered antimicrobial pesticide product” if the farmer knows or has reason to believe that the water is not safe and of adequate sanitary quality for its intended use. Given that the FDA has not suggested any acceptable water treatment alternatives, farms that must comply with section 112.43 are likely to treat the water with an antimicrobial pesticide. The FDA has not adequately considered the potential environmental impacts that would result if farms across the country applied antimicrobial pesticides to agricultural water. Chemical treatment of water has residual effects on water quality and human health, and the widespread use of pesticides on a farm’s groundwater and surface water sources will have a detrimental effect on the environment.

Both the biological soil amendments of animal origin and agricultural water provisions of the proposed rule create incentives for farmers to adopt unsustainable practices. The FDA should spend more time thinking about the preferences the rule creates, and do an environmental impact statement under NEPA to consider the consequences of those preferences.

3. The FDA must provide meaningful flexibility for entities that sell directly to consumers.

In certain circumstances, the FDA allows for farms to adopt alternative practices if the farm has “adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement of this part.” Creating allowances for alternative practices is in line with FSMA’s mandate that the proposed rulemaking “provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities.” Future Harvest CASA supports allowing farms to adopt alternative practices and encourages the FDA to clarify the criteria for determining whether the alternative practice would provide the same level of public health protection.

FDA is seeking comment on proposed section 112.12, which allows farms to establish alternatives to certain specified requirements. As proposed, section 112.12 allows farms to

36 Id.
38 See Public Comments submitted by the National Sustainable Agriculture Coalition on the Produce Safety Rule.
39 Id., at 3633 (proposed § 112.12).
40 FSMA, supra note 4, at 124 STAT. 3900.
establish alternatives to four specific requirements in the rule—(1) water testing,\textsuperscript{41} (2) composting,\textsuperscript{42} (3) minimum application intervals for manure and compost agricultural tea,\textsuperscript{43} and (4) minimum application intervals for compost—provided that the alternative meets the requirements of paragraphs (b) and (c). Paragraph (b) requires a farm to have “adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement,”\textsuperscript{44} and paragraph (c) says that this data may be developed by the farm, available in the scientific literature, or available to the farm through a third party.\textsuperscript{45} Farms that chose to use an alternative would be responsible for establishing and maintaining documentation of the scientific data and information relied upon.\textsuperscript{46}

Future Harvest CASA strongly supports the FDA’s proposal to allow farms to adopt alternatives to some of the rule’s requirements. The proposed allowance in section 112.12 is consistent with FSMA’s mandate that the rule provide for sufficient flexibility.\textsuperscript{47} Congress’s emphasis on flexibility is prominent in FSMA; the mandate appears in the law’s section authorizing the produce safety and the preventive controls rules.\textsuperscript{48} FDA Commissioner Hamburg has expressed a commitment to FSMA’s mandate on flexibility for different entities,\textsuperscript{49} and we intend to hold the agency to this commitment. When the FDA opened a docket to obtain information about current practices for the production and packing of fresh produce in 2010, a majority of stakeholders who commented expressed concern about the impact of possible regulations on the livelihoods of those who produce food and their ability to produce food in an economically feasible manner.\textsuperscript{50} Future Harvest CASA asks that the FDA incorporate these widely shared concerns into the final rule by ensuring that the allowances for alternatives to the rule’s requirements are adequately flexible.

\textsuperscript{41} § 112.12(a)(1) allows for alternatives to the requirements in § 112.44(c) for testing water, and taking action based on test results, when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water application method. Proposed Produce Safety Rule, \textit{at} 3633.

\textsuperscript{42} § 112.12(a)(2) allows for alternatives to the composting treatment processes established in § 112.54(c)(1) and (c)(2). \textit{Id.}

\textsuperscript{43} § 112.12(a)(3) allows for alternatives to the minimum application interval established in § 112.56(a)(1)(i) for an untreated biological soil amendment of animal origin that is reasonably likely to contact covered produce after application or for a compost agricultural tea that contains compost agricultural tea additives. \textit{Id.}

\textsuperscript{44} § 112.12(a)(4) allows for alternatives to the minimum application interval established in § 112.56(a)(4)(i) for a biological soil amendment of animal origin treated by a composting process that is reasonably likely to contact covered produce after application. \textit{Id.}

\textsuperscript{45} The data must also support a conclusion that the alternative would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions, including agro-ecological conditions and application interval. \textit{See id.}

\textsuperscript{46} \textit{Id.}

\textsuperscript{47} \textit{Id.}

\textsuperscript{48} FSMA, \textit{supra} note 4, \textit{at} 3900, codified at [ ].

\textsuperscript{49} \textit{Id. at} 3900, 3895.

\textsuperscript{50} Senate Agriculture Appropriations Subcommittee Hearing, April 18, 2013

\textsuperscript{51} Proposed Produce Safety Rule, \textit{supra} note _, \textit{at} 3514.
As currently written, the requirements set out in subpart E on agricultural water, and in subpart F on biological soil amendments of animal origin would be extremely burdensome on diversified, family-run farms. These farms often operate on low profit margins to deliver food directly to members of their communities. They do not have the financial means to completely upend their agricultural water systems or switch to a new source of fertilizer. Even the fees associated with testing their water would be burdensome. In addition to the financial burden, the requirements would force sustainable farms to abandon environmentally friendly farming methods they have developed over generations. These methods successfully rely on the benefits provided by biologically diverse systems. FDA’s proposed allowance for alternatives to four of the rule’s requirements in section 112.12 represents a good step towards a rule that allows for sufficient flexibility. However, Future Harvest CASA is concerned that the rule does not go far enough.

Toward that end, the FDA must clarify what makes an alternative one that “would provide the same level of public health protection” as the requirement set out in the rule. Currently, proposed section 112.12(b) only states that a farm can adopt an alternative if it has “adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part.” Section 112.12(c) provides that a farm can rely on scientific data and information developed on their own, available in the scientific literature, or available to the farm through a third party, but the agency does not specify how it will assess the reliability of those sources. This puts the burden of “proving up” the adequacy of the data relied upon on the farmer. The FDA could, at the very least, explicitly state that certification from a state program, such as the USDA-regulated Good Agricultural Practices (GAP) program, would support a conclusion that the alternative provides the same level of public health protection as the applicable requirement. The agency could also go beyond this minimum assurance by providing examples of other sources that it would accept as reliable. This would lessen the burden on farmers, and provide guidance as to what sources are acceptable.

4. Sales of food should be calculated based on regulated activities only

A pervasive problem with the proposed produce safety rule is that it fails to acknowledge the diversity of farms that will be covered. The rule’s calculation of a farm’s sales, which appears in the definition of a covered farm in section 112.4(a), the definitions of small and very small businesses in section 112.3(b), and the monetary limit for THA-exempt farms in section 112.5(a)(2), seems to disregard the possibility that farms may be selling other “food” in addition to covered produce. Section 112.4 explains that you are a “covered farm” subject to the rule if

52 Id. at 3633.
you are a farm or farm mixed-type facility with an annual monetary value of food sold during the previous three-year period of more than $25,000. “Food” is defined in FDCA section 201(f) as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” In other words, the calculation of sales denotes all food, including meat products, dairy products, processed food products, and all fruits and vegetables (not just raw agricultural commodities covered by the rule).

To use an example, if a small corn farm selling $100,000 worth of corn annually wanted to cultivate a single acre of land to grow blueberries, it would become subject to the rule, even though the amount of covered produce sold annually would amount to only a fraction of the $25,000 limit. We do not believe this is what Congress intended. Although the language of the THA cannot be changed (the exemption for direct farm marketing in FSMA applies to farms if their average annual monetary value of all food sold was less than $500,000), the FDA is free to define the size of covered farms, small businesses (which have three years to comply with the rule after the effective date), and very small businesses (which have four years to comply with the rule after the effective date) based on sales of a farm’s own covered produce only.

The FDA should change the way farm-size is calculated for the purpose of this rule so that farms are encouraged to diversify, rather than be limited to monoculture. We suggest that the FDA change the first line of section 112.4(a) to read, “Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of covered produce sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a “covered farm” subject to this part.” We further suggest that the FDA change the definition of “very small business” in section 112.3(b)(1) to read, “For the purpose of this part, your farm is a very small business if it is subject to this part and, on a rolling basis, the average annual monetary value of covered produce you sold during the previous 3-year period is no more than $250,000.” Likewise, the FDA should change the definition of “small business” in section 112.3(b)(2) to read, “For the purpose of this part, your farm is a small business if it is subject to this part and, on a rolling basis, the average annual monetary value of covered produce you sold during the previous 3-year period is no more than $500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.”

**Conclusion**

The FDA’s produce safety rule will have a significant impact on sustainable farms growing covered produce throughout the country. Future Harvest CASA urges the FDA to consider the proposals made in these comments, and modify the rule to ensure that sustainable farming

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53 Id. at 3632.
remains a viable part of the farming system we depend on for food. If the rule goes forward as proposed, family farms that have spent generations working to build profitable businesses on the foundations of safe, sustainable farming practices may cease to operate. The proposed rule seems to reject a natural approach to farming, instead imposing requirements better suited for industrial monoculture. The FDA has not considered the preferences the rule creates, nor has it considered the environmental impacts that will result from farmers switching practices. We support the FDA’s choice to allow farms to adopt alternative practices to the rule’s requirements; however, we are concerned that the FDA has not provided enough guidance as to which alternatives are acceptable. Finally, farms like the corn farm in the hypothetical above would be discouraged from entering new markets, because the FDA has defined size based on sales of all food, rather than on sales of covered produce. The net effect of the rule could be the demise of numerous diversified family farms practicing sustainable agriculture, and the rise of industrial farms engaged in monoculture. Future Harvest CASA and IPR urge the agency to change the final rule based on our suggestions above so that sustainable farms can continue to feed their communities.

Sincerely,

/s/ Hope Babcock

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