Comment on FSMA Proposed Rules, Section 105: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Washtenaw Food Policy Council

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Washtenaw County, with just under 350,000 residents, just over 160,000 acres of farmland, and approximately 1300 farms, is located in southeastern Michigan. The Washtenaw County Food Policy Council (WFPC) is a board appointed by the Washtenaw County Board of Commissioners to represent an alliance of local food system stakeholders. The mission of the WFPC is to increase and preserve access to safe, local, and healthy food for all County residents.

The WFPC supports a viable, economical, and sustainable local food system through multiple strategies, including:

- Strengthening the connections between food, health, natural resource protection, economic development, and the agricultural community;
- Researching, analyzing and reporting on information about the local food system;
- Advocating for and advising on food system and food policy implementation;
- Promoting and providing education on food system issues.

In early May of 2013, the Farmers' Policy Action Team (PAT) of the WFPC undertook to examine the Proposed Rules, ascertain their likely impacts upon Washtenaw County's farmers and food system, and collect farmers' reactions and feedback. We submit our findings in the hope of aiding FDA's rulemaking process. We wish to promote an expectation that standards originating from different levels of government be as uniform as possible, and be appropriately tailored to the demands, practices, and further development of local agriculture.

The remainder of this document is divided into three parts.

Part I concerns the Preliminary Regulatory Impact Assessment (PRIA). We discuss our concerns about disproportionately high costs of compliance for very small farms, and offer our expectations of what effect the Proposed Rules might have upon the development of our local food system. We examine the methodology by which FDA has calculated the expected benefits of the Proposed Rules. We offer for FDA's consideration two alternative cost-benefit frameworks that would justify less extensive or different regulation than that which has been proposed.

Part II contains our general comments regarding sections of the Proposed Rules that form the framework of the rule. We support FDA's integrated approach and FDA's delineation of very small and

small businesses at $250,000 and $500,000, respectively. We are concerned that ambiguities in the definition of farms and the inability to reinstate a qualified exemption once withdrawn may unduly burden farmers who were never negligent in their practices.

Part III goes through selected sections of the Proposed Rules which detail specific requirements. We compare the Proposed Rules' requirements to existing MSFRA and GAP standards, and we give our comment on perceived discrepancies between the standards. We have attempted to cover each subpart of the Proposed Rules in some detail, and we voice our support for those provisions which are not controversial among County farmers.

As a benchmark for the Proposed Rules' likely impact upon small farmers in southeastern Michigan, we have chosen to compare the FSMA Proposed Rules for Produce Safety to the Michigan Safe Food Risk Assessment (MSFRA). MSFRA is an assessment program implemented by the Michigan Department of Agriculture and Rural Development (MDARD). The program is targeted at small farms, for whom the costs of GAP audits are prohibitive. On one hand, completing the MSFRA provides a voluntary, confidential and fee-free stepping stone to GAP. On the other hand, MSFRA also provides a fee-free food safety assessment option to those who do not choose to proceed to GAP. The MSFRA standards were developed in close consultation with MSU Extension to be sensitive to the needs and capabilities of Michigan's small farmers.

In most areas, we have found that the standards put forth by MSFRA and FSMA broadly agree. These areas tend not to be contentious to local farmers. However, we have also found significant discrepancies between the MSFRA standards and the proposed FSMA standards in those related to the use of animal wastes as soil amendments (subpart F) and those related to wild animals (subpart I) . These areas are also those in which the negative reactions against the Proposed Rules expressed by local farmers have been common and strong. We therefore suggest that these sections of the Proposed Rules be revised.

We appreciate the extensive work that FDA has already done to put forth these Proposed Rules, and the triple extension of comment period that enabled our response effort to be organized. We thank you in advance for the time it will take to read this feedback. We hope that our comment will eventually prove useful in the formulation of the final rules.

Respectfully submitted,

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[ATTEST: Lawrence Kestenbaum, Washtenaw County Clerk] (upon endorsement of the full Council)

Part I: Comments on the Preliminary Regulatory Impact Assessment

Costs of Compliance Disproportionately Impact Small, Diversified Farms

Over the past ten years, growth in Washtenaw County's local food sector, especially the produce sector, has been driven by new, small farmers who specialize in selling locally at higher price premiums. **We are concerned that the regulatory burden of the proposed rules may negatively impact the growth potential of Washtenaw County's local food system by hurting the viability and competitiveness of very small and diversified farms.**

The expected annual cost for non-exempt very small farms to comply with the Proposed Rules is $4,697, and the expected annual cost for exempt farms is $295. For comparison, the mean annual net cash income of Washtenaw County farm operations reported in the 2007 Census of Agriculture was $9,095. Washtenaw County farmers thus need to be exempt to reasonably bear the costs of compliance with the Proposed Rules. While new produce farmers are likely to be exempt, these costs could disproportionately impact well-established grain, dairy, and meat farmers seeking to diversify into produce, who might find it harder to qualify for exemption. (Please also see our related comment in Part II on subpart A.)

Several farmers have also voiced concerns that distributors, institutional buyers, and/or insurers might begin to demand FSMA-compliance from producers, irrespective of farm size or exemption status. It is probable that FSMA requirements would become institutionalized as *de facto* requirements enforced upon the industry, and their compliance costs would be incurred on many small and very small farms despite those farms being exempt under law. Such developments may make it more difficult for small farmers to access institutional markets, which often act as “anchor customers”, providing a stable source of business and justifying investments in the upscaling of farm operations.

Compliance costs absorbed into the expenses of farm operations obviously hurt farmer viability, but farmers also have the option of passing compliance costs on to consumers. We nevertheless expect that passing on costs to consumers would also impede the development of our local food system. Because Washtenaw County land values are relatively high, even established farms here tend to be smaller. We therefore expect that the proportional impact of the proposed regulation upon County farmers would be larger than average.

If the local food system passes on proportionally more costs than non-local food as a result of the Proposed Rules, then we expect the price premium for local food over non-local food to increase. A higher price premium would make it more difficult for local food to compete in mainstream retail channels, and may shrink the potential for new small farmers to exploit their current market channels. As we would be opposed to such developments, **we urge FDA to attempt to further minimize the financial impact of the final rules upon very small farms.**

Potential Weaknesses in the Model and Framework Used to Evaluate Benefits

The currently proposed cost-benefit framework assigns the responsibility for the safety of all FDA-regulated produce in the entire food system to produce farmers:

> We estimate the potential change in the probability of fresh produce contamination as a function of the relative likelihood of contamination from each specific pathway and the potential efficacy of the proposed preventive controls in reducing the risk of fresh produce contamination within a specific pathway of contamination. **This change in the**

> **probability of contamination is then applied to the current baseline of foodborne illnesses attributable to FDA-regulated produce.** Based on current scientific literature, expert elicitation, census data, research, and outbreak investigations, we think that we can estimate potential range of measurable effectiveness of the proposed produce regulation on the current burden of illness as a whole. Additionally, these data are stratified to examine the effect amongst specific commodities, or contamination pathways. (PRIA, p. 70, emphasis ours)

We disagree with this framework. Many processes, *e.g.*, grading, sorting, processing, packaging, transport, and distribution, occur after the food leaves the farm, and introduce microbial food safety risk. These risks are mentioned in the PRIA, but are not accounted for in its valuation of the Proposed Rules' benefits. We would prefer a produce safety framework that explicitly recognizes on-farm food safety as the food system's first line of defense, but not the only such line. Under such a framework, regulations of on-farm practices would be supplemented with efforts to improve surveillance of the food system, especially of imports, and reduce the severity of outbreaks once discovered.

The theoretical model used in the PRIA to estimate the likely benefits of regulation models produce contamination events, and assumes

> "that a reduced probability of contamination will result in a corresponding reduction in the expected number of illnesses. [...] Specifically, [FDA assumes] a 40% variation in the relationship; varying 20% above or below the 1-to-1 relationship here." (PRIA, p. 79)

We agree that the primary effect of successful regulation of farmers' agricultural practices will be to reduce the incidence of produce contamination. For the purposes of our further argument we assume that reductions in contamination through the various pathways investigated in the PRIA would be roughly proportional to reductions in outbreak incidence.

Nevertheless, the number of illnesses suffered by the public is not proportional to outbreak incidence. The number of illnesses suffered is the integral of outbreak severity over all outbreak incidents, and outbreak severity varies widely. When framed in terms of outbreak incidence and severity, FDA's assumption that illnesses respond proportionally to abatement of contamination is defensible to the extent that outbreaks are uniform in severity.

The outbreak data given in table 16 of the PRIA provide strong evidence against the uniformity of outbreaks. Over the period 2003-2008, ~40% of reported food poisoning cases and related hospitalizations originated from only two outbreaks, and the least severe ~65% of outbreaks only account for about ~20% of all reported cases and related hospitalizations. Figure 1 at the end of this Part I presents a graph based upon this same data, showing the actual worst-case relationship between abatement of contamination and harm reduction on the basis of cases reported.

On the basis of the above evidence, **we caution that FDA's assumption that illnesses decline in proportion to the incidence of contamination may lead to an overestimation of the Proposed Rules' likely benefits.**

Because FDA has not discriminated between outbreak incidence and severity, the costs of the Proposed Rules have been balanced against benefits determined on the basis of the *mean rate of produce-borne illness over the entire population of outbreaks*. **We note that the mean outbreak severity is driven by a very small number of outstandingly severe outbreaks, and the PRIA has not linked the outstanding severity of these outbreaks to any particular farming practices for which rules are currently being proposed.** In fact, both of these outbreaks were caused by imported produce. Is FDA prepared to evenly and effectively enforce any proposed rules upon foreign farms, and upon large domestic distributors who aggregate produce from many foreign farms?

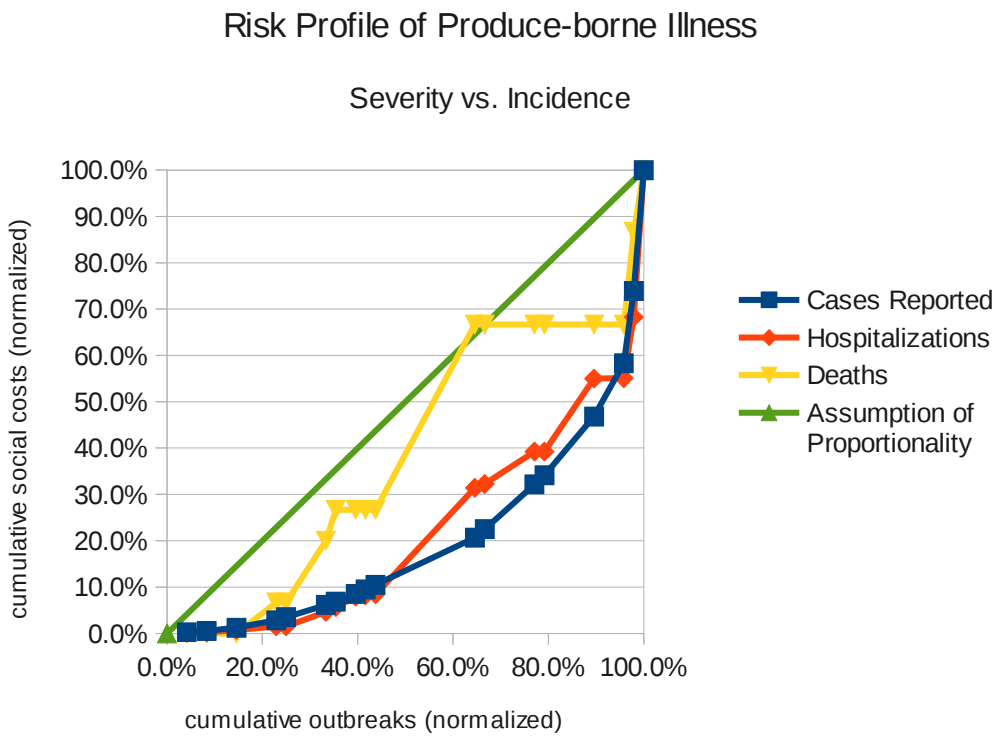
While we agree that farmers' practices can contribute to reducing the incidence of outbreaks, we believe that outbreak severity is not under farmer control, but instead more a function of downstream factors, such as market channel and product quality control. **As the PRIA does not extensively discuss the potential factors controlling outbreak severity, we would like to propose two alternative frameworks that would take it into account.**

1) FDA could attempt to take outbreak severity into account in its model using the dataset that was used to produce the PRIA. Specifically, the procedure detailed in PRIA pp. 71-73 could be modified by weighting each of the outbreaks in the 2003-2008 period by their observed severity. Where the current model gives a likelihood of contamination through each pathway, this alternative would instead give a direct measure of preventable illnesses statistically associated with each pathway of contamination.

In our view, this alternative model would begin to resolve the weaknesses that we have identified in the current PRIA model, and we expect that FDA would further refine this suggestion. Choosing this method would effectively replace FDA's assumption that illnesses respond proportionally to contamination with the alternative assumption that more severe outbreaks in the future will arise from contamination by the same pathways as more severe outbreaks in the past. We advise that FDA investigate the degree to which this alternative assumption might be justified. If the alternative assumption is justified, then this modified model would more correctly assign the burden of regulation to the different avenues of contamination that have already been considered. We expect that under this framework, requirements in certain areas of the Proposed Rules would be strengthened, and others weakened, or even dropped entirely.

2) If the first framework given above proves to be unworkable, FDA could also treat outbreak severity as a black box, and choose to hold farmers responsible only for *rates of illness associated with outbreaks of median severity* (or at minimum, some other *percentile* measure of severity.) This alternative makes only the assumption that future outbreaks will show a similar distribution of severity as the outbreaks in the 2003-2008 dataset. Under this framework, the benefits that would be attributed to the Proposed Rules would decline by at least ~50%, so a less extensive set of rules than those that have been proposed would be finalized.

Figure 1 (contains color): Response of illness to abated contamination could show significant deviation from proportionality assumed in the PRIA's benefits analysis. CDC outbreak data reprinted in the PRIA, Table 16.



Part II: Comments on the General Framework of the Proposed Rules

The Subparts of the Proposed Rules dealt with in Part II are Subparts A, B, P, Q, and R.

Subpart A (Definitions)

112.1
We support FDA's presently proposed integrated approach over a commodity-specific approach. The promulgation of different standards for different covered crops would not be as compatible with the management of highly diversified, small farms.

112.3
FDA has requested comment on the proposed delineations of small businesses (Gross Agricultural Revenue (GAR) < $500,000) and very small businesses (GAR < $250,000). We support the proposed definition of very small businesses as those grossing less than $250,000 annually (of covered produce,) as nearly all Washtenaw County farmers would benefit from the additional 2 years to comply.

112.5
We request that the exact entity to which a qualified exemption *sensu* 112.5 applies be clarified. **Current language makes ambiguous whether, in the case of a transfer of facility ownership, a qualified exemption (or the withdrawal of such an exemption) follows the farm, or the owner, or neither.** On one hand, 112.4 (b) states, "You are not a covered farm [...] if we have not withdrawn your exemption[...]," suggesting that the exemption follows the owner. On the other hand, 112.203 only requires that the name, address and location of the farm be specified in an order to revoke an exemption, not the owner.

> Hypothetically, suppose that farmer A owns and operates farm X. During that time, their qualified exemption was withdrawn, and farmer A sells their entire ownership stake in all of farm X's facilities to neighboring farmer B, whose exemption for their farm Y has not yet been withdrawn, and who now takes charge of operating both facilities. What is the status of the amalgamated farm's exemption?

Please reference our comments on subparts P, Q, R for additional, related comment.

We suggest that only covered produce should count against the exemption thresholds, and for the purposes of computing whether more than half of the food sold was to qualified end-users. These distinctions are important because they would preserve the option for farms to diversify their production. Farms whose main business is not in covered produce should have the option of diversifying into the production of a small volume of produce for direct farm marketing without bearing the burden of regulation intended for large-volume produce growers. Small produce farmers may also find it advantageous to add commodity crops to their production.

> For example, under currently proposed rules as written, a meat producer grossing $475,000 in a year who adds only $30,000 worth of covered produce to their product line would nevertheless be ineligible for a qualified exemption from Section 105, because their establishment's GAR would be greater than $500,000. A soybean farm grossing $100,000 who sold their crop to an exporter and added $30,000 of CSA distribution directly to households would also be ineligible, because more than half of food sold by value was not to qualified end-users, even though all the produce was. Adopting our suggested revision would fix both of these cases, making the farms eligible for exemption.

Subpart B (General Requirements)

112.11

FDA has requested general comment on the approach of 112.11. We agree with the approach of this proposed rule, though we further suggest that 112.11 might better acknowledge the various interests that farmers must balance over the course of running their businesses in addition to food safety.

We support the promulgation of a general standard of due care to be followed at any covered farm. Proposed 112.11 would establish the duty borne by operators of covered farms to their eventual consumers. In the event that proposed subparts with specific requirements are not adopted in the final rules, 112.11 would still cover all applicable activities. It would also provide a framework for justifying inevitable future changes to the rules, to keep pace with technological changes in agriculture and in microbial surveillance.

However, we are concerned that proposed 112.11, as written, does not explicitly allow for farmers to consider any other interests pertinent to the maintenance of a healthy farming system. **We suggest that 112.11 be revised to explicitly recognize potential interests that would be encountered over the course of farm management that may countervail the interest of food safety**, such as the practice of integrated pest management (IPM) or the conservation of endangered species.

> For instance, FDA has already had to issue guidance on this matter regarding proposed subpart I, in stating that the provisions of 112.11 are not intended to require the exclusion of wild animals from the farm, or other interventions disruptive to the agroecosystem. (Please also see our comment on subpart I for a more detailed discussion of this topic.) Clearly, FDA acknowledges that certain environmental interests countervail those of food safety, yet no provision is currently made for this in the codified text.

Subparts P, Q, R (Variances, Compliance, Enforcement, and Withdrawal of Qualified Exemptions)

We are greatly concerned that in the event an order is issued to withdraw a farm's qualified exemption *sensu* 112.5, there is no procedure for that qualified exemption to be reinstated, besides an appeal that must be filed within 10 calendar days of the date of the order. **Farms that have had their exemptions withdrawn at any point in the past,** having undertaken and documented appropriate corrective action and monitored the efficacy of the new practice, **should be able to petition the Secretary to have their qualified exemptions reinstated.**

We suggest that the language for such a procedure could follow the language found elsewhere in FSMA, in section 102(b)(3), which provides for the registrant of a food facility *sensu* Section 415 (21 U.S.C. 350d) whose registration was suspended to submit a corrective action plan and the vacating of the suspension order following the plan's successful implementation. Such a procedure is necessary in general, and especially necessary in the context of potential changes in farms' management.

> Consider (again) the hypothetical that a farmer A, having had their qualified exemption revoked, decides to sell the farm, and farmer B buys the farm from farmer A. If as suggested by 112.203, the exemption/revocation follows the farm as a facility, then farmer B (through no fault of their own) also inherits the revoked exemption. Without a procedure for farmers like farmer B to apply for the regulatory blank slate they deserve, a class of 'blighted' farms with revoked exemptions will be created over time. The foreseeable adverse consequences of such policy for rural development are self-evident. New and socially disadvantaged farmers will be disproportionately adversely impacted. They will find it more difficult to access 'unblighted' farms and agricultural land, and will suffer market disadvantage from having to bear a greater regulatory burden.

Part III: Comments on Selected Specific Requirements detailed within the Proposed Rules

The Subparts of the Proposed Rules dealt with in Part III are Subparts C, D, E, F, I, K, L, M, N, and O, but not in that order. Instead of proceeding through the relevant sections alphabetically, we have instead chosen to organize them by their recordkeeping requirements. We first briefly discuss subpart O on recordkeeping itself, then visit those sections for which recordkeeping would be required, and conclude with those sections for which recordkeeping would not be required.

Throughout this section, we make comparative reference to the standards of the MSFRA and GAP. **We generally accept MSFRA as the standard encouraged by MDARD for all covered farms to follow.** The MSFRA is a stepping stone to GAP, so GAP is always at least as stringent as the MSFRA. Also, both MSFRA and GAP are voluntary programs, whereas the standards put forth in these Subparts shall be required by law of all covered farms not exempt. Hence, in this part **we wish to direct more careful scrutiny towards those few instances where the Proposed Rules, intended to represent science-based minimum standards, are more stringent than standards recognized as voluntary by the industry**. A summary table of the FSMA, the MSFRA, and the GAP standards relevant to each of the discussed subparts can be found in the Appendix.

Subpart O (Recordkeeping Standards)

As the standards proposed in this section are less stringent than those encouraged under MSFRA, **we have no objection against subpart O of the Proposed Rules.**

Subparts for which FDA proposes to require records under FSMA:

Subpart C (Personnel Food Safety Training)

As the standards proposed in this section are less stringent than those encouraged under MSFRA, **we have no objection against subpart C of the Proposed Rules**. At least one farmer has voiced support for the Proposed Rules' standard that (only) one operator must receive formal food safety training, adding that the Proposed Rules better allow for the use of family labor under formally trained supervision than even the MSFRA standard, which requires that all employees be trained formally.

Subpart E (Agricultural Water Testing)

Interviews with local farmers have not elicited strong reactions either in support of or against the rules proposed in this subpart. However, we would encourage review of MDARD's submitted comments, which we anticipate to extensively discuss the proposed Agricultural Water standards.

Subpart F (Application of manure and other soil amendments of animal origin)

The proposed standards on manure are one area where the requirements of the FSMA Proposed Rules are far more stringent than both those of MSFRA and those of GAP. In examining the record in the *Federal Register*, the scientific support for the Proposed Rules appears to be general, at best. One farmer pointed out to us that the Proposed Rules do not differentiate clearly between the products of a vermicomposting process and manure. Another farmer voiced the opinion that the Proposed Rules would impose undue burdens upon the design and operation of coupled aquaculture-aquaponics systems. As all of the studies cited in the *Federal Register* are concerned with manure and manure management, we thus question whether the wording “biological soil amendment of animal origin” is

too broad. We inquire whether the proposed rules should be restricted to apply only to manure of mammalian or avian origin, and not to other biological soil amendments of animal origin not investigated.

Many local farmers have voiced that a 9-month minimum application interval would be a *de facto* prohibition on using raw manure to fertilize any covered produce. The scientific literature cited by FDA in the *Register* does not reference studies conducted on northern U.S. soils with an extended annual freezing period or analogs thereof. **In the course of our attempt to evaluate whether the Proposed Rules represent suitable science-based minimum standards, we conducted our own literature review upon the subject of pathogen survival in manure-amended soils.**

Our review of the scientific literature does not strongly support the raw manure provisions detailed in subpart F of the Proposed Rules. The results of our review are tabulated at the end of this Part III. Most of the studies document pathogen survival times of no more than the MSFRA/GAP recommendation of 120 days, and even the studies that do not observe extirpation by that time demonstrate substantial log-cfu reduction by then.

Thus, in light of our own review of the scientific literature, we disagree with FDA's conclusion that the raw manure minimum application interval should be 9 months long, as currently proposed. We believe that the scientific basis upon which FDA has made its conclusion is not strong enough to justify overturning existing best practices and safety standards. **We therefore recommend that the requirements of this subpart F be revised to align with current MSFRA/GAP recommendations, and to be consistent with the requirements of the National Organic Program (NOP) as required by the text of FSMA.** The NOP rules require a 120-day interval for belowground crops, a 90-day interval for aboveground crops, and no interval (0 days) for properly composted manure.

More generally, we question whether it is appropriate to define minimum application intervals on a national level irrespective of local growing conditions. We suggest instead that more finely tailored rules than those that were Proposed could be developed and implemented in closer consultation and cooperation with State Departments of Agriculture.

Subpart L (Equipment Sanitization)

As the standards proposed are substantially equivalent to those encouraged under MSFRA, **we support subpart L of the Proposed Rules as written.**

Subpart M (Sprouts)

The proprietor of Washtenaw County's sole sprout-producing business has indicated to us that while the requirements that would be laid down by subpart M are extremely stringent, his facility is already in compliance with most of them. His facility is fully enclosed, and he already conducts microbial testing on spent culture water for *E. coli* and *Salmonella*. However, this proprietor was unfamiliar with the new proposed requirements to test the growing environment for *Listeria* sp./*L. monocytogenes*. In general, the proprietor wishes us to support regulation that would bring other sprout-growing businesses up to the standard that his business already follows. Thus, **we support subpart M of the Proposed Rules as written.**

FDA has sought comment on measures that would not unduly burden the suppliers of seeds used for sprouting. The proprietor suggests that irradiation of seeds used for sprouting be required of seed suppliers. His own supplier is located abroad, and the irradiation used is documented by U.S. Customs.

Subparts for which FDA is not proposing to require records under FSMA:

Subpart D (Personnel Health and Hygiene)

As the standards proposed are substantially equivalent to those encouraged under MSFRA, **we support subpart D of the Proposed Rules as written.**

Subparts I and K (Wild and Domesticated Animals; Identification and non-Harvest of Produce Contaminated with Animal Excreta)

In general, **we cannot support the spirit of the rules proposed in this subpart,** which seeks to use the boundaries of a farm and the notion of intrusion to delineate a zone whose microbial cleanliness is the farmer's responsibility. The fact remains that most production space is exposed to the wild environment, over which farmers do not have control. In addition, some wild animals provide important ecosystem services to farms, and many wild animals (e.g., pollinator and earthworm diversity) are used as indicators for the health of an agroecosystem. By framing the issue entirely in terms of intrusion, the Proposed Rules fail to acknowledge these realities. **Farmers, especially small farmers, need the regulatory flexibility to balance the provisioning of ecosystem services with the biological hazards posed by the presence of the wild animals that provide them.** We believe that acknowledging these realities would cause a more flexible and practical framework to emerge.

Subpart I would require farmers to monitor covered produce for the intrusion of wild animals. In the event that the monitoring effort documents substantial intrusion, subpart K would only require that affected covered produce be evaluated for its suitability for harvest. This requirement is less stringent than the GAP standard that measures be implemented to exclude such animals from the farm. **We support the framework of the requirements set forth in the Proposed Rules at 112.83(2)(b) and 112.112 over the requirements set forth in GAP, as the former offer small farmers more operational flexibility.**

Despite this, monitoring for animal intrusion is a standard that many farmers feel is untenable, as was noted in the *Federal Register*, but not extensively addressed therein. Notably, MSFRA standards do not require monitoring for animal intrusion, even though GAP does, suggesting that MDARD does not expect small farmers to monitor for animal intrusion. Even one GAP-certified farmer voiced that animal monitoring for birds was an unrealistic standard in any open-air farm.

We agree that some degree of monitoring is a minimum step necessary to inform any farm management decision regarding wild animals. However, we are concerned that the Proposed Rules may entertain a fiction of management that does not exist in practice. The three relevant clauses are quoted below:

> **112.11** [You must take] measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated [...] on account of such hazards.
> **112.83(2)(b)** If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, you must monitor those areas that are used for a covered activity for evidence of animal intrusion.
> **112.112** You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta.

The consistency of these three clauses presupposes the hypothesis that reasonable monitoring efforts against intrusion (112.83(2)(b)), followed by reasonable efforts to control any damage from intrusion (112.112), suffice to provide reasonable assurance that produce has not been adulterated (112.11).

However, based upon our experiences and interviews, most farmers acknowledge that for every intrusion detected, several will have occurred. It is reasonable to assume that if intrusion is observed, covered produce has been silently contaminated, and the traces of such contamination may be subsequently erased by exposure to the environment. Most farmers thus reasonably believe that no reasonable effort to monitor wild animal intrusion could provide reasonable assurance that covered produce is not contaminated or adulterated. Only an unreasonably extensive monitoring effort, or prophylactic measures to exclude such animals, could provide reasonable assurance to that effect.

It is for this reason that the farmers we have interviewed commonly consider requirements to monitor animal intrusion 'untenable'. They fear that the prevention clause of 112.11 and subclause 112.83(2)(b) may combine to set forth an unintentionally stringent requirement. The general requirement of 112.11 to provide reasonable assurance against adulteration is commonly construed to turn the requirement to monitor the intrusion of wild animals into the farm into a *de facto* requirement to exclude such animals from the farm, despite the guidance that FDA has already issued on the matter that 112.11 is not intended to set forth such a requirement.

Thus, we suggest that the proposed regulation pertaining to wild animals detailed in this subpart I be generally revised to address the aforementioned concerns. **We reiterate our support for proposed 112.83(2)(b) and 112.112.** We recognize that by requiring monitoring for intrusion and the identification and non-harvest of affected produce, FDA is proposing regulation that agrees with the choices a reasonable farmer would make. Indeed, no farmer we have interviewed has expressed objection to the requirements of subpart I that was not fundamentally related to the extent and efficacy of monitoring that might be required to avoid implementing exclusion measures. Identification and non-harvest of visibly contaminated produce are already part of standard practice.

In addition, we submit some suggested refinements for FDA's consideration. We suggest that FDA codify in subpart I that measures to exclude wild animals would not be required. We further suggest that the clause in section 112.112 that requires the identification and non-harvest of produce contaminated by animal excreta be revised to specify “mammalian or avian excreta” so as to avoid the suggestion that farmers should exclude insects or sterilize soil. This latter revision would also begin to serve the function of providing a list of “animals of concern”, the value of which FDA has already recognized.

Subpart K (Miscellaneous Standards for Growing, Packing, Holding, Harvesting)

As the other standards proposed in this subpart are substantially equivalent to those encouraged under MSFRA, **we support the remainder of subpart K of the Proposed Rules as written.**

Subpart N (Analytical Methods)

No comment.

Table: Literature Review on Pathogen Survival in Manure-Amended Soils	
Citation	**Findings**
Himathongkham et al. 1999	Storage of manure for 105 days at 4℃ sufficient to achieve 5-fold log reduction in *E. coli* O157:H7
Jiang et al. 2002	*E. coli* O157:H7 in contaminated soil samples held at 5℃ was not detected after 77 days
Avery et al. 2004	Survival of *E. coli* O157:H7 applied to surface and subsurface investigated in UK soils. Decimal reduction times of ~10 d observed in the 6 weeks following subsurface application.
Islam et al. 2004a	*Salmonella* persisted for 161 and up to 231 days in soils amended with contaminated composts on which lettuce and parsley, respectively, were grown, and was detected for up to 63 days and 231 days on lettuce and parsley, respectively.
Islam et al. 2004b	*E. coli* O157:H7 persisted for 154 to 217 days in soils amended with contaminated composts and was detected on lettuce and parsley for up to 77 and 177 days, respectively, after seedlings were planted.
Franz et al. 2005	Faster decline of *E. coli* O157:H7 populations was observed in organic than in conventional soils
Islam et al. 2005	After incorporation of contaminated manure and irrigation with contaminated water, *E. coli* O157:H7 was reduced to 2.0-2.5 log cfu/g by 120 days, though extirpation could take up to 200 days.
Holley et al. 2006	Survival of *Salmonella* investigated over 180 days in Manitoba soils at temperature sequences representing summer-to-winter and winter-to-summer transitions. Decimal reduction times of no greater than 30 days observed for all but one treatment. 30-day application interval advised.
Mukherjee et al. 2006	First report of a confirmed pathogenic strain of *E. coli* O157:H7 present in environmental manure, not a laboratory strain. In a Minnesota soil, the pathogenic count declined to a undetectable level in all the plots monitored within 92 days after application of untreated manure.
You et al. 2006	Investigated the survival characteristics of *Salmonella* serovar Newport in manure and manure-amended soils. Decimal reduction times between 14 and 32 days observed.
Franz et al. 2008	*E. coli* O157:H7 declined to undetectable levels in 54 to 105 days in a study of 36 soils in the Netherlands
Semenov et al. 2009	*E. coli* O157:H7 survival in manure was shorter than survival in slurry. No such difference was observed for *Salmonella.*
Garcia et al. 2010	Survival of *Salmonella* in soil samples was investigated at 5, 15, and 25℃. Survival was longest at 5 ℃. This effect was mediated by protozoan predation.
Semonov et al. 2011	Survival of *E. coli* O157:H7 much longer in anaerobic conditions than in aerobic conditions.
Oliveira et al. 2012	*E. coli* O157:H7 survived up to 9 weeks in soil in Spain, with better survival in fall than in spring

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Appendix: Comparison of selected FSMA, MSFRA, and GAP standards

The most stringent of the three standards in each category is **bolded**.

Subpart	FSMA	MSFRA	GAP
C: Personnel Food Safety Training	• Training documents trainees, content, date of training. • All personnel must receive food safety training. • At least one person responsible for farm food safety must have undergone training equivalent to standard FDA food safety curriculum.	• Training documents trainees, content, date of training. • **Formal training required for all personnel.**	• Training documents trainees, content, date of training. • **Formal training required for all personnel.**
D: Health/Hygiene	• Adequate and readily accessible toilets/lavatories. • Sick workers not allowed contact with produce.	• Toilets/lavatories in compliance **with OSHA regulations.** • Sick workers not allowed contact with produce.	• Toilets/lavatories in compliance **with OSHA regulations.** • Sick workers not allowed contact with produce.
E: Agricultural Water	• Water testing **required quarterly** during the growing season. • Standards more stringent for irrigation and other direct-contact applications than for other uses.	• Water testing required annually for well water or thrice annually for surface water. • Standards different for irrigation and for fertigation/chemigation.	• Water testing required annually for well water or thrice annually for surface water. • Standards different for irrigation and for fertigation/chemigation.
F: Soil Amendments of Animal Origin	• Raw manure to be applied **no later than 9 months** before any contact with covered produce. • Results of composting process must be **verified and recorded.**	• Raw manure to be applied no later than 2 weeks before planting, 120 days before harvest. • Any composting process must be documented.	• Raw manure to be applied no later than 2 weeks before planting, 120 days before harvest. • Results of composting process must be **verified and recorded.**
I: Domesticated and Wild Animals	• Monitoring for wild animal intrusion required. • In the event of intrusion, potentially affected produce must be evaluated to determine suitability for harvest.	• None	• Monitoring for wild animal intrusion documented. • In the event of intrusion, **measures to exclude animals documented.**
K: Miscellaneous	• Re-sanitization of reused packaging required. • General requirements to avoid contamination during harvest.	• Re-sanitization of reused packaging **documented.** • Specific requirements to avoid contamination during harvest.	• Re-sanitization of reused packaging **documented.** • Specific requirements to avoid contamination during harvest.
L: Equipment Sanitization	• Sanitization schedule for all harvesting, packing, and holding equipment documented.	• Sanitization schedule for harvesting and holding containers documented. • Proper storage of packing materials required. • Sanitization schedule for all food contact surfaces documented.	• Sanitization schedule for harvesting and holding containers documented. • Proper storage of packing materials required. • Sanitization schedule for all food contact surfaces documented.
M: Sprouts	• **Facility must be fully enclosed.** • **Testing of spent culture water for *E. coli* and *Salmonella* documented.** • **Environmental testing for *Listeria* sp./*L. monocytogenes* documented.**	• None specified.	• unknown, not reviewed here.
O: Recordkeeping	• Written food safety plan not required.	• Written food safety plan expected.	• Written food safety plan **required.**