NATIONAL SUSTAINABLE AGRICULTURE COALITION

December 4, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: A New Era of Smarter Food Safety; Public Meeting, Request for Comments; Docket No. FDA-2019-N-4187

The National Sustainable Agriculture Coalition (NSAC) is an alliance of grassroots organizations[i] from across the country that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities. NSAC member groups work directly with small and mid-sized family farmers, sustainable and organic farmers, and food processors to improve their food safety knowledge and practices. NSAC members have engaged in the Food Safety Modernization Act (FSMA) process at the legislative, rulemaking, and implementation stages, and we are thankful for our continued partnership with the Food and Drug Administration (FDA) throughout this process to ensure the implementation of FSMA is successful and supportive of sustainable agriculture and food systems.

NSAC is excited about the opportunity to continue working with FDA to ensure a New Era of Smarter Food Safety is both cognizant and supportive of sustainable agriculture and food systems. We strongly believe farmer voices must be represented throughout the discussions and development of the 2020 New Era of Smarter Food Safety Blueprint. One of NSAC's key principles on food safety is that "all farms, farmers, and farm staff, from the owners to the most transient farm helpers, have a role in producing safe food." We encourage FDA to include these stakeholders in the development of not only the New Era of Smarter Food Safety Blueprint, but also the continuous FSMA implementation and rulemaking processes.

NSAC is excited about the opportunity to play a key role in the New Era of Smarter Food Safety. We thank FDA for this opportunity to comment, and look forward to providing additional input, future education resources, and further opportunities for dialogue between FDA and farmers and food businesses within our network.

Sincerely,

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[i] Agriculture and Land-Based Training Association Salinas, CA; Alternative Energy Resources Organization Helena, MT; CCOF Santa Cruz, CA; California FarmLink Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture) Hereford, TX; Catholic Rural Life St Paul, MN; Center for Rural Affairs Lyons, NE; Clagett Farm/Chesapeake Bay Foundation Upper Marlboro, MD; Community Alliance with Family Farmers Davis, CA; Community Involved in Sustaining Agriculture South Deerfield, MA; Dakota Rural Action Brookings, SD; Delta Land and Community, Inc. Almyra, AR; Ecological Farming Association Soquel, CA; Farmer-Veteran Coalition Davis, CA; Florida Organic Growers Gainesville, FL; FoodCorps, OR; GrassWorks New Holstein, WI; Hmong National Development, Inc. St Paul, MN and Washington, DC; Illinois Stewardship Alliance Springfield, IL; Institute for Agriculture and Trade Policy Minneapolis, MN; Interfaith Sustainable Food Collaborative Sebastopol, CA; Iowa Natural Heritage Foundation Des Moines, IA; Izaak Walton League of America St. Paul, MN/Gaithersburg, MD; Kansas Rural Center Topeka, KS; The Kerr Center for Sustainable Agriculture Poteau, OK; Land Stewardship Project Minneapolis, MN; MAFO St Cloud, MN; Michael Fields Agricultural Institute East Troy, WI; Michigan Food & Farming Systems – MIFFS East Lansing, MI; Michigan Organic Food and Farm Alliance Lansing, MI; Midwest Organic and Sustainable Education Service Spring Valley, WI; Montana Organic Association Eureka, MT; The National Center for Appropriate Technology Butte, MT; National Center for Frontier Communities Silver City, NM; National Hmong American Farmers Fresno, CA; Nebraska Sustainable Agriculture Society Ceresco, NE; Northeast Organic Dairy Producers Alliance Deerfield, MA; Northern Plains Sustainable Agriculture Society LaMoure, ND; Northwest Center for Alternatives to Pesticides Eugene, OR; Ohio Ecological Food & Farm Association Columbus, OH; Oregon Tilth Corvallis, OR; Organic Farming Research Foundation Santa Cruz, CA; Organic Seed Alliance Port Townsend, WA; Rural Advancement Foundation International – USA Pittsboro, NC; Union of Concerned Scientists Food and Environment Program Cambridge, MA; Virginia Association for Biological Farming Lexington, VA; Wild Farm Alliance Watsonville, CA; Women, Food, and Agriculture Network Ames, IA.

RECOMMENDATIONS

A. NEW AND EVOLVING DIGITAL TECHNOLOGIES WILL PLAY A PIVOTAL ROLE IN TRACING THE ORIGIN OF A CONTAMINATED FOOD TO ITS SOURCE IN MINUTES, OR EVEN SECONDS, INSTEAD OF DAYS OR WEEKS

1. What are the most significant actions FDA could undertake to enable industry to enhance traceability across the entire global food supply chain?

NSAC recommends two significant actions to enable enhanced traceability across the food supply chain: 1) a focus on education and training efforts around traceability that are scale appropriate; and 2) support and encourage clear, transparent product labels. We understand there are also other efforts FDA could undertake to enhance traceability across the supply chain, but believe these two efforts are practical steps for improving traceability for food businesses of all sizes and models. We welcome further discussion with FDA around additional steps that can be taken to improve traceability efforts.

Within NSAC, we encourage all farms to have a strong traceability system in place to reduce both food safety and financial risks. Our members have provided trainings, resources, and technical assistance to farmers around creating or improving their traceability system.[1] NSAC is also currently working on an Alternate Curricula to the Produce Safety Rule that will include topics such as traceability, labeling, and recall readiness, and we are thankful for FDA's continued support for this necessary work.

We strongly encourage FDA to provide additional support to ensure an abundance of educational resources are available on traceability, labeling, and recall readiness. There is a need for more training and education that focus on the varying approaches to traceability, depending on the farm or food business type, size, and resources. Hands-on technical assistance from relevant experts in the field will also be necessary for all of the different approaches to traceability that food businesses might consider. FDA should work with relevant organizations and industry stakeholders to develop additional resources and training efforts to ensure traceability works for everyone across the entire food supply chain.

NSAC also recommends that FDA continue to work with relevant industry stakeholders to determine what voluntary approaches to labeling can improve traceability throughout the supply chain. FDA should consider how transparent product labels provide necessary information for tracing a product through each step of the supply chain. A product is easily traceable when it includes the farm, wholesale facility, and/ or processing facility's name and contact information, for each location throughout the supply chain for the life of that product.

[1] *See, e.g.*, Gap Certification: Traceability, Carolina Farm Stewardship Association, https://www.youtube.com/watch?v=mWzcHeEoohs&feature=youtu.be; Food Safety Plan Templates, Community Alliance with Family Farmers, https://www.caff.org/food-safety/food-safety-plan-templates/

We applaud FDA's past support for geographic-based labeling efforts that will improve traceability across long supply chains. For example, the new region-based labeling approach for romaine,[2] led by major distributors and produce industry groups, is an important step toward providing both the public and FDA, as well as the Center for Disease Control and Prevention (CDC), with timely and specific information about the location of a foodborne illness outbreak.

FDA should explore what product labeling improvements will ensure that in the event of an outbreak, a product can be clearly identified by all stakeholders, including consumers. NSAC's food safety policy states that there should be absolute transparency around all food products, including production processes. We also believe that this information should be widely accessible to the general public, regardless of what a consumer can afford to pay for the information. We encourage FDA to work with a diverse group of stakeholders, including consumers, to ensure labels are both transparent and informative.

As stated in FDA's request for comments, "the New Era of Food Safety is about more than technology," and we encourage FDA to focus on all methods (e.g. paper records, software, etc.) which can foster a better culture of food safety and reduce risks across the supply chain. The ability to react to a foodborne illness in a timely manner is crucial. NSAC members will continue to work with farms of all sizes to ensure their traceability systems are able to quickly react. We hope FDA acknowledges the successes of certain traceability systems, including paper recordkeeping, transparent informative product labels, and recall readiness plans, as they consider the role technology might play in the future of product traceability.

4. Are there mechanisms FDA could employ to incentivize adoption of real-time, end-to-end food traceability throughout the food sector?

FDA must adopt an approach that recognizes real-time, end-to-end food traceability differs based on size and other factors unique to certain sectors of the food industry. If there are traceability mechanisms FDA decides to encourage, affordability and access should not be barriers for certain sectors of the food industry or smaller businesses.

We agree with the industry stakeholders who mentioned at the October 21, 2019 Public Meeting on the New Era of Smarter Food Safety that financial incentives are one way to ensure affordability is not a barrier for farmers. While financial incentives might help farmers adopt new real-time end-to-end traceability, the amount of financial assistance must be enough to provide a significant return on investment.

There are also other barriers beyond affordability that cannot be addressed by financial resources alone. New technology may not be adoptable for farmers who lack access to internet or cell phone service. We will expand upon the additional barriers in the question below.

We recognize that FDA is encouraging voluntary efforts to adopt this new technology. We also acknowledge FDA may be asked to require certain traceability mechanisms that is beyond their legal authority. NSAC strongly urges that FDA continue to remain within their legal authority to enhance

[2] Questions & Answers on Voluntary Romaine Growing Region Labeling, Produce Marketing Association, https://www.pma.com/content/articles/2018/11/qa-romaine.

traceability, and appreciates FDA's voluntary approach.[3] FDA must ensure that agency action taken around digital technology and traceability remain within FDA's legal authority.

Congress included a number of exceptions in FSMA to ensure traceability efforts are realistic for farm operations.[4] For example, FSMA allows labeling that preserves the identity of the farm to satisfy traceability requirements.[5] NSAC supports this realistic approach because direct-marketed products whose identity is preserved from farm to the end consumer are fully traceable.

NSAC also encourages FDA to ensure their upcoming rulemaking on Additional Recordkeeping Requirements for High Risk Foods considers multiple factors when deciding what products are "high risk" foods. FDA should determine a product's risk based on multiple variables, including the method and manner of production, handling, processing, distribution, delivery and preparation. In accordance with our food safety policy, we believe "the life cycle of a food product and how it is treated throughout all stages from production to consumption, is the prime driver of the level of risk that product may carry forward to the end consumer."

Overall, we encourage FDA to take an approach that is realistic and affordable for all types of food businesses, including farms and the small retailers and wholesalers that purchase products directly from farmers. We are pleased to see the FDA's Food for Thought Ideas on How to Bring a New Era of Smarter Food Safety included multiple recommendations for stakeholder input. FDA should move forward with these ideas and ensure that stakeholders are able to provide input around both what might improve their traceability system and the future proposed rule on Additional Recordkeeping Requirements for High Risk Foods.

5. What are the challenges to creating a more digital, traceable global food supply, and how might FDA approach this in a manner that creates shared value for all participants?

There are a number of barriers farms of varying sizes will face if a more digital, technology-based traceability system is required by either FDA or third party buyers. FDA must consider how disproportionate costs will reduce market options and create barriers to entry for producers of all sizes. Farms already depend on slim margins, and some operations cannot afford third party buyer requests for more technology-based systems.

For a number of small farm operations, there is not a return on investment when retailers require expensive traceability technology. Also, different buyers require different systems, which is impossible for small and medium sized farms to afford, let alone spend the time to understand and implement the technology. Costs can include not only the software system or subscription, but also the cost to maintain equipment and internet subscriptions. A return on investment is dependent on scale, and efforts to enhance traceability must as well.

The types of systems in place may also not be applicable for farms selling in local and regional markets and directly to consumers. The digital systems that already exist were developed for

[3] *See* 21 U.S.C. § 2223(d)-(i).
[4] 21 U.S.C. § 2223(d)-(i).
[5] 21 U.S.C. § 2223(d)(6)(b).

national and international companies. Farmers selling locally do not have the same reach and have different needs, so it is impractical to require that they adopt the same scale of traceability.

FDA must also recognize that even if a farm can afford the technology, they may not be able to use it. For farms in rural areas, there is oftentimes a lack of access to broadband or telecommunications capability.[6] The technology would also have to be adapted by farmers of varying backgrounds, and must include options in multiple languages in order to be widely adopted by farmers.

There are also a number of concerns around how the information will be used, and if the information in a digital traceability system would be shared widely. Farmers would need an assurance from both the companies and FDA that their privacy would not be breached if they were to adopt this technology.

There must continue to be alternate options for farms that cannot afford or access this technology. FDA should support efforts that include a traceability system that includes paper records, a recall readiness plan, transparent labeling, and traceability exercises that are scale appropriate. These types of traceability systems can continue to be effectively implemented by farms of sizes.

NSAC urges FDA to recognize the disproportionate costs to farms and food businesses that already rely on slim margins. We appreciate FDA's continued support for family farms with different supply chains and food safety risks. We look forward to working with FDA in the future to ensure foodborne illness outbreaks provide consumers with details about an outbreak's location and its path through the complex food system via multiple methods, including non-digital options.

B. TO FULLY REALIZE A PREVENTIVE CONTROLS SYSTEM THAT RAPIDLY INCORPORATES NEW KNOWLEDGE, WE MUST ALSO ASK IF WE CAN WE MAKE PROCESSES AND COMMUNICATIONS MORE EFFECTIVE, EFFICIENT, AND IN SOME CASES, SIMPLER

1. What are the most significant actions FDA could undertake to promote and support the use of smarter tools for prevention?

NSAC welcomes further discussion around this topic with FDA. We believe there are a number of significant actions FDA could take to promote the use of smarter tools for all types of farm operations. The two action items we encourage FDA to explore immediately include 1) financial support to farmers to adopt new food safety practices, and 2) stakeholder roundtables to determine what additional actions will support smarter food safety practices. NSAC also recommends FDA explore other actions such as additional research on several topics, including smarter food safety practices, relevant risks, and affordable risk management tools.

FDA should make new resources available to financially support small and medium sized farms and food businesses with food safety upgrades in partnership with the U.S. Department of Agriculture (USDA). According to an USDA Economic Research Service report, very small and small farms face significantly higher compliance costs – 6.04 to 6.77 percent of annual sales, as compared to 0.92

[6] *See* 2018 Broadband Deployment Report, Federal Communications Commission, https://www.fcc.gov/reports-research/reports/broadband-progress-reports/2018-broadband-deployment-report.

percent for large farms.[7] Smaller farms will be at a competitive disadvantage because of the disproportionate burden of compliance costs. This assistance could help offset the cost of on-farm food safety infrastructure upgrades and relevant food safety audit costs. NSAC encourages FDA to work with USDA to create new and support already existing programs that would help family farmers manage the costs associated with complying with the FSMA Produce Safety Rule and adopting new food safety practices.

We encourage FDA to consider stakeholder roundtables to further explore this topic, and other topics related to the New Era of Smarter Food Safety. The roundtables should include a diverse representation of stakeholders throughout the food industry.

We also recommend farmer specific roundtables around two topics in FDA's Food for Thought Ideas on How to Bring a New Era of Smarter Food Safety under the "Develop Innovative Approaches to Inspection and Compliance" section: 1) the voluntary program where farms could submit audits by certified third parties and have fewer Produce Safety Rule or Preventive Controls Rules inspections as a result of a successful third party audit; and 2) the use of real-time monitoring for pathogens on farms.

We support FDA's interest in providing a transparent process that will inform all regulated farms about the role third party food safety audits play in Produce Safety Rule and Preventive Controls Rules inspections. We recommend FDA also consider the impact this might have on small farms that are not able to afford annual third party food safety audits. If FDA takes this approach, we encourage the accreditation of multiple third-party food safety audits that meet the applicable standards.

FDA must also hear from stakeholders on the impact of real-time monitoring on farms. Any real-time monitoring must be science-based and ensure monitoring accurately detects foodborne pathogens. The financial impact of any real-time monitoring for small or medium size farms must also be taken into consideration. As FDA considers real-time remote monitoring for conditions on farms, it must narrow the scope to be risk-based and scale appropriate.

NSAC is excited to provide additional input from our membership base in the future on these topics, and welcomes the opportunity to partner with FDA on further opportunities for stakeholder input.

3. What further steps can be taken to advance the safety of domestic and foreign commodities that have been the subject of frequent contamination incidents?

We believe there are several research efforts FDA should support that could provide additional information on the risks associated with that commodity and best practices to reduce those risks. Overall, we encourage FDA to invest in research that provides a broader range of validated methods of risk mitigation. FDA should also support additional guidance and technical assistance from both within FDA and from outside third-party experts.

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[7] John Bovay et al., Estimated Costs for Fruit and Vegetable Producers to Comply with the Food Safety Modernization Act's Produce Rule, USDA Economic Research Service, https://www.ers.usda.gov/webdocs/publications/89749/eib-195.pdf?v=43319.

We recommend FDA focus additional research efforts around investigating risks throughout the supply chain, including all supply chain lengths and whether or not risk increases based on supply chain length. FDA should partner with USDA's National Institute of Food and Agriculture on these research efforts. Throughout the supply chain, at every stage risks are introduced that far exceed those from most farm-related activities. Risk-reduction at the farm cannot reduce the risks that are further along in the supply chain.

FDA must research the consequences of concentration and global distribution in order to fully understand and integrate into risk assessments improved food safety practices for commodities with frequent contamination incidents. For example, food is often processed in concentrated facilities, sometimes several days, weeks, or months prior to when it reaches the end-consumer. Food is then shipped from this facility to locations across the globe. The risks associated with lengthy supply chains have not been sufficiently explored.

NSAC policy on food safety calls for "an open, ongoing, and transparent scientific effort to understand risks and alternative interventions." Based on this principle, we encourage FDA to support research around the following topics:

- Vegetative buffering and biological diversity's potential for increasing beneficial microbial populations to act against pathogenic microbes;

- A research focus on emitters of contamination (e.g., confined animal feeding operations) and future regulations that could ensure locations that harbor and spread harmful pathogens also meet the required testing levels for food safety (e.g. 10 generic *E. coli* or less per 100mL);

- Differences between the different types of biological soil amendments of animal origin and any risk-based differences, specifically with worm castings;

- Research that can provide risk-based recommendations on how much produce must be discarded based on: 1) the type of animal (geese vs. deer vs. grazing animals) that has contaminated the produce; and 2) the type of animal contamination – i.e., fecal contamination vs. saliva; and

- Science and risk-based options for ensuring water contaminated with foodborne pathogens does not contact produce that is typically consumed raw that is based on the actual risk of that water source spreading foodborne illness pathogens to produce. It should also focus on the varying risks depending on the different type of produce the water comes into contact with.[8]

[8] In NSAC's comments to the original and proposed rule for the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, we provided extensive suggestions on Subpart E and hope FDA continues to take these comments into consideration as they revise the water requirements. Ariane Lotti, Assistant Policy Director, National Sustainable Agriculture Coalition, Comment Letter on Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Nov. 15, 2013), https://www.regulations.gov/document?D=FDA-2011-N-0921-1339; Sophia Kruszewski, Policy Specialist, National Sustainable Agriculture Coalition, Comment Letter on Supplemental Proposed Rule for Standards for the Growing,

C. Evolving Business Models Present Food Safety Challenges as Well as Novel Considerations Around Regulatory Framework and Oversight at the Federal, State, Territorial, and Local Level

1. What are the most significant actions FDA could undertake to help ensure the safety of foods delivered under a variety of new business models, such as e-commerce?

NSAC is supportive of additional opportunities for stakeholder input around this topic that was mentioned in FDA's Food for Thought Ideas on How to Bring a New Era of Smarter Food Safety. Several farms are now utilizing similar business models to expand their direct-to-consumer market. We are pleased FDA is looking to start a dialogue with this sector of the industry.

However, we are concerned that the costs of certain regulations and technologies will stifle small business growth and entrepreneurship. NSAC encourages FDA to ensure all regulations are scale appropriate and include any necessary exemptions for small businesses that would ensure entrepreneurship is not stifled and new businesses are still able to enter this market.

D. We Want To Do More To Use and Leverage Proven Organizational Culture and Behavioral Science Principles and Techniques To Enhance Organizational and Employee Compliance With Desired Food Safety Practices and Behaviors

1. What are the most significant actions FDA could undertake to foster and support the development of food safety cultures globally?

NSAC appreciates FDA's interest in developing "education, trainings, and tools to foster and advance industry best practices." We recommend FDA increase financial resources for trainings that are taught by diverse audiences and include culturally appropriate or operation specific information. We also encourage FDA support for additional food safety trainings offered in languages other than English.

In instilling better food safety culture, matching constituents with culturally relevant trainers is essential for ensuring trainings are taught in an appropriate and equitable manner. We also hear frequently about the need for more trainings in Hmong and Spanish, and recommend FDA support these additional trainings.

There is also a need for food safety trainings specific to the type of operation. There is an increased interest among urban farmers who want to pursue relevant food safety trainings, but there are few trainings offered that are specific to urban agriculture's unique risks and realistic practices that can mitigate those risks. Recently, NSAC members have also been asked about trainings specific to hydroponic and aquaponic operations, as existing trainings are oftentimes not applicable to these operations.

Harvesting, Packing, and Holding of Produce for Human Consumption (Dec. 15, 2014), https://www.regulations.gov/document?D=FDA-2011-N-0921-1339.

NSAC also believes improving food safety culture should include everyone and appreciates FDA's efforts to reach all stakeholders, including consumers. We recognize that consumer education and creating a culture of food safety not just across regulated industry, but the entire public, will be key.

We believe each unique business and person working with food understands their role in ensuring a safe food supply for their consumers. NSAC encourages FDA to provide continued support for a diverse set of food safety trainings and technical assistance to increase the culture of food safety from farm to fork.

3. What are the obstacles to creating food safety cultures throughout the supply chain?

One obstacle we frequently observe is the lack of scale and culturally appropriate food safety regulations, trainings, and other educational resources. NSAC encourages FDA to engage a broad base of producers to discuss what types of educational efforts will develop practical food safety systems.

4. Are there changes that FDA can and should take in how it approaches food safety to place further emphasis on prevention?

FDA must continue to increase both their own and third-party research efforts to determine new methods and approaches that reduce food safety risks throughout the supply chain. FDA's regulations must be science-based. We recommend FDA host a future listening session or roundtable with relevant stakeholders to discuss current research gaps. NSAC would be happy to partner with FDA on such an effort.

In closing, we thank FDA for this opportunity to comment, and look forward to providing additional input, future education resources, and further opportunities for dialogue between FDA and farmers and food businesses within our network.