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NSMA
National Seasoning Manufacturers Association

November 22, 2013

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

RE: Docket No. FDA-2011-N-0920
Current Good Manufacturing Practice and Risk-Based Preventive Controls for Human Food

Submitted via eRulemaking Portal: http://www.regulations.gov

To Whom It May Concern:

The National Seasoning Manufacturers Association (NSMA) appreciates the opportunity to submit comments on the proposed rule, "Current Good Manufacturing Practice and Risk-Based Preventive Controls for Human Food" published in the Federal Register on January 16, 2013.

NSMA is a trade association representing the U.S. seasoning industry. Founded in 1973, our membership manufactures more than 98% of seasonings consumed in the United States. The NSMA is composed of member companies that produce food ingredients including but not limited to seasonings, spices, flavorings, additives, and other vegetable ingredients and derivatives. Accordingly, our membership will be greatly impacted by the rules proposed under the Food Safety Modernization Act (FSMA) that relate to the implementation of the Hazard Analysis and Preventive Controls, along with the revisions to the Current Good Manufacturing Practice regulations.

General Comments on Proposed Rule

NSMA and its members are fully committed to food safety. As spices and seasonings are an integral component of many food flavoring systems, we understand the importance of preventing contamination throughout the U.S. food supply chain. NSMA acknowledges that the burden of ensuring the safety and wholesomeness of seasonings must be borne by the domestic processor. We favor the approach taken in the proposed legislation, to focus on prevention rather than remediation. We commend the FDA for taking the necessary steps to modernize the U.S. food safety system.

In the sections that follow, we present the seasoning's industry's perspective on the specific provisions of the proposed rule. Additionally, we offer these general comments on the proposed regulation.

1. Preventive controls policy should be based on the best and latest science available from recognized scientific institutions. An effective food safety system must respond quickly to evolving food safety hazards and advances in science. We urge the agency to consider flexibility that allows facilities to respond to new information and hazards utilizing validation and verification mechanisms rather than prescribed microbial control processes.

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2. Each product and manufacturing product is unique. As such, facilities need sufficient latitude to design food safety systems that fit their unique products, processes, and environments. We recommend the agency ensure the proposed rules are flexible enough to allow individual facilities to adapt their food safety programs to their own unique circumstances.
3. FDA did not propose codified language on environmental testing, product testing, or supplier verification. If the agency intends to adopt provisions on these, we request agency establish a mechanism for public comment on the specific codified language, such as through a tentative or interim final rule that is not effective until after the agency receives and considers public comment. Allowing for public comment ensures alignment with the Administrative Procedures Act.

Definition of Very Small Business (78 FR 3658)

In the proposed rule, the FDA seeks comments on the three options presented for the definition of a very small business. NSMA supports the use of Option 3 to define a very small business as one that is less than $1,000,000 in total annual sales of food, adjusted for inflation. Based on our experience within the food industry, and specifically spice and seasoning industry, businesses with less than $1,000,000 total annual sales represent a micro-business. We agree with FDA's assessment that the total percentage of food produced by these facilities represents a small portion of the food produced within the United States.

Revised Current Good Manufacturing Practice (Proposed § 117 Subpart B)

NSMA supports the proposed revisions to Current Good Manufacturing Practice (CGMP), and we agree with the approach to strengthen existing provisions with the additional requirements to protect against cross-contact. The comments that follow are primarily aimed at fine-tuning the proposed regulations.

4. The proposed regulation includes many revisions to the CGMP regulations to clarify that protection against contamination also requires protection against cross-contact of food to address allergens (78 FR 3718). We agree with the agency's proposed use of the term "cross-contact" as distinct from "cross contamination", as this terminology accurately reflects the unintentional incorporation of food allergens. NSMA suggests that FDA refine the term to provide greater clarity, such as "allergen cross-contact" or "cross-contact with allergens".

   Additionally, we ask the agency to clarify that the proposed regulations do not impose a zero-tolerance policy for allergens, recognized that such a policy is not achievable in allergen management. As there are no established thresholds for allergens and current allergen detection methods have limited detection levels, there is no practical means for food manufacturers to prove the absence of allergens, and should not be held to such a standard. We encourage the FDA to continue its efforts to establish tolerances for allergens.
5. FDA seeks comment on the training requirement for supervisors and workers in the proposed rule (78 FR 3729). We support the inclusion of a training requirement for supervisors and workers, and suggest that language for the training requirement allow for flexibility for the establishment to determine the scope and frequency of education and training appropriate for its staff. This position is consistent with the concept

that control measures in the food safety plan should be tailored to the specific facility and operations. Likewise, this approval aligns with the Global Food Safety Initiative (GFSI) guidance, which is based on the recommendations of the Codex Alimentarius Commission. We do not recommend that FDA impose specific requirements for frequency, scope, or records. An overly prescriptive approach will create an unnecessary financial burden with no food safety improvement.

6. The proposed regulations includes many provisions requiring the "the protection of packaging from cross-contamination or cross-contact." NSMA suggests that the FDA clarify the term "packaging" to mean only food-contact packaging, and does not include secondary packaging that is not food-contact (shipping cases, labels, shrink wrap, etc.). Alternatively, FDA may use the term "primary packaging", which is a commonly used term in the food industry to refer to packaging that comes in direct contact with the food product.

Hazard Analysis (Proposed § 117.130 at 78 FR 3732-3738)

In Proposed 117.130(c), the regulation requires "evaluation of whether a hazard is reasonably likely to occur, including an assessment of the severity of the illness or injury if the hazard were to occur." The proposed regulation uses HACCP terminology, "reasonably likely to occur", and we are concerned about the potential for such language to be a gateway to all hazards being treated as critical control points. If all control points are treated as CCPs, then the control measures and attention to the most critical points in the process will be diluted. We agree that both severity and probability are critical to the successful evaluation of potential hazards and their significance. This methodology is consistent with international standards. For example, Codex HACCP guidelines specify that the hazard analysis should evaluate "the likely occurrence of hazard and severity of their adverse health effects". We request that FDA reconsider the language to ensure that it aligns with the FSMA statutory language and international standards.

Radiological Hazards (Proposed § 117.130 at 78 FR 3806)

NSMA requests that FDA consider that radiological hazards do not need to be examined as a separate hazard category. We contend that radiological hazards can be addressed as a chemical hazard on the basis of the following rationale:

1. FSMA requires FDA to develop regulations consistent with existing domestic and international standards. NACMCF HACCP guidelines, CODEX HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry do not address radiological hazards as a separate hazard category.
2. A radionuclide is by definition an unstable form of a chemical element that radioactively decays, resulting in the emission of nuclear radiation. Therefore, consideration of radiological risks as a subset of chemical hazards is not incompatible with the FSMA statute requiring analysis of radiological hazards.
3. FDA concluded that radiological contamination of food occurs very infrequently:
   - "Radiological contamination of foods is a rare event" (78 FR 3667).
   - "… the Hazard Identification section of this document does not include radiological hazards because they are too rare in food to be considered associated with any food category other than

water" (*Qualitative Risk Assessment Risk of Activity / Food Combinations for Activities Conducted in a Facility Co-Located on a Farm).*

- "The presence of radiological hazards in foods is a rare event and consumer exposure to harmful levels of radionuclide hazards is very low (United Nations Scientific Committee on the Effects of Atomic Radiation, 2008). Use of water that contains a radionuclide to manufacture a food is not reasonably likely when using water from a domestic municipal source subject to regulation by EPA (40 CFR 141.66; see 65 FR 76708, Federal Register of December 7, 2000). When events (such as accidents or natural disasters) occur that could result in radiological contamination of water sources, there is generally much publicity that would alert a farm mixed-type facility to a potential risk in using a potentially contaminated water source, and we expect that government agencies, including FDA, would be likely to take specific actions based on the circumstances to prevent consumer exposure" (*Qualitative Risk Assessment Risk of Activity / Food Combinations for Activities Conducted in a Facility Co-Located on a Farm)..*

4. In the Preliminary Regulatory Impact Analysis, FDA presumes that the rule would not impose additional costs on large food companies. We disagree with this assumption, and expect that all food companies would incur expenses from revising existing food safety plans. Radiological hazards as a separate hazard category would require the re-development of ingredient and process assessments and hazard analyses. Modification of these documents would require a significant dedication of resources, and create an undue burden on the industry for no food safety improvement.

Furthermore, we request that FDA provide clarification on radiological hazards in the form of guidance to accompany the final rule. Specifically, we request the guidance address the following concerns and questions:

1. What sources of radiological hazards should a facility consider beyond the two types cited by FDA in the proposed rule, i.e. incorporating water containing radionuclides into food, and accidental contamination as the result of an accidental release from a nuclear facility?
2. What constitutes "reasonably likely to occur" in the case of accidental contamination? Would proximity to a nuclear facility be used to assess this type of radiological hazard as RLTO? If so, then we request FDA provide guidance on the proximity to a nuclear facility that poses as RLTO.

Verification (Proposed § 117.150 at 78 FR 3752-3756)

NSMA agrees with the FDA regarding the need for verification procedures to ensure that preventive controls are effective and consistently implemented. We support the approach in the proposed regulation with the following specific comments on the proposed time frames for verification activities and approach to validation and verification of preventive controls:

1. FDA proposed a time frame of six weeks for initial validation of preventive controls. We recommend that the time frame should be 90 days, consistent with the time frame set forth by the FSIS guidance on validation.

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2. FDA proposes that validation is not required for food allergen controls, sanitation controls, or recall plan on the basis that validation of these controls is not essential, practical, or relevant. We agree with the FDA's approach, and support the argument that validation of certain controls is unnecessary.

3. The proposed regulation includes a provision for review of monitoring and corrective action records within one week after the records are created. NSMA agrees with the FDA that review of records is a critical verification tool for facilities to identify any potential problems with the implementation of food safety controls. However, we do not agree that a one week time frame is appropriate for all facilities or processes. In many circumstances, a shorter or longer time frame may be appropriate. For instance, records for a critical time / temperature process controls may be more appropriately reviewed daily. In other circumstances, a time frame of longer than one week may be practical and effective. We recommend that FDA reconsider this aspect of the provision, and provide a more flexible phrasing such as "within a reasonable time frame", consistent with the proposed language for the review of calibration records.

Qualified Individual (Proposed § 117.3 at 78 FR 3699 and Proposed § 117.155 at 78 FR 3761)

The term "qualified individual" is included in many provisions of the proposed rule, and is defined within rules as "a person who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA or is otherwise qualified through job experience to develop and apply a food safety system." We request FDA develop guidance on how an individual would be qualified through job experience. Specifically, how will the FDA consider an individual's length of experience, job functions and responsibilities, and education when evaluating an individual's status as qualified? Furthermore, how will FDA expect this job experience to be documented in records for proof of qualification?

Additional Potential Provisions Not Being Proposed

The agency discusses several potential preventive control and verification measures within the proposed rule, and requests comment on these additional measures that are not being proposed.

NSMA members (i.e. seasoning manufacturers) typically produce a multitude of products. Examples include a single spice or spice blend; spice blends combined with ingredients (e.g. flour, starch, sugar, salt) that are used in relatively small amounts for flavoring; dry mixes for marinades, injects, soup bases, dressings, sauces, gravies. These products may be distributed to retail outlets, foodservice operators, or go to other processors. Due to the almost limitless types of ingredients used by seasoning manufacturers, food safety plans include controlling the risk associated with multiple ingredient categories. Much of this work is done at the supplier level.

Salmonella spp. poses the greatest concern to seasoning manufacturers given that the dry blending process affords no viable method to significantly minimize microbiological hazards. To ensure safety at consumption, the seasoning manufacturer must be aware of the product's intended use, i.e. the ready-to-eat (RTE) or for further processing. Ingredients intended for further processing are often incorporated into blends where either the processor or consumer will apply a validated kill step. Only RTE ingredients will be used in products destined for RTE

applications and the seasoning manufacturer may need to implement additional "RTE" GMPs to ensure that they do not contaminate RTE products post blending.

Please note that NSMA agrees with the agency's definition of ready-to-eat food and contends that the above considerations are consistent with that definition. It is with the above considerations that we offer our comments on product testing, environmental monitoring, and supplier approval and verification.

Product Testing (78 FR 3763)

Finished product testing is limited in terms of usefulness. Due to the statistical limitations of testing programs, it cannot be considered a preventive control. NSMA believes that product testing must be determined on a risk-based approach and cost-benefit analysis. Pathogen testing, particularly *salmonella* testing, of blends produced by seasoning manufacturers adds cost with no benefit. Ensuring that all ingredients are already RTE and minimizing the likelihood of post processing contamination are better indicators of safety than pathogen testing of RTE products. It is a fact that untreated agricultural commodities are likely to be contaminated, and even low levels of pathogens may be not be detected by the most rigorous microbiological sampling program. A negative pathogen test result may be mistakenly interpreted to suggest the blend is pathogen free. It must also be recognized that where untreated raw agricultural commodities are ingredients, a positive pathogen will eventually result. This does not result in a health risk when the product is intended for further processing. The kill step will be applied later in the food chain prior to consumption. A negative test result does not guarantee that a product is pathogen free, and therefore NSMA recommends that we do not rely on finished product testing as a control measure for food safety. Exceptional cases where product testing might be required should be identified by an individual facilities' food safety assessment.

Environmental Testing (78 FR 3764)

NSMA agrees that environmental monitoring is a useful means of monitoring and verifying the effectiveness of preventive controls within a facility. We conclude that a responsible manufacturer will perform a risk assessment and establish a scientifically-based program for the prevention and monitoring of environmental pathogens. In fact, within a dry blending and seasoning manufacturing operation where no lethality can be applied, it can be used as verification of post processing food safety system.

We do not support the inclusion of specific requirements for environmental testing in the regulation due to the variety of food products and processes covered by the proposed rule. The hazard analysis should drive the need and specifics of an environmental monitoring plan within the facility since each facility is unique in terms of products, processes, and environment. Specific requirements dictating the frequency or target organism could potentially lead to unnecessary testing or discourage manufacturers from more aggressive environmental sampling. For instance, many facilities apply the zone concept to their environmental monitoring program. Routine testing of food contact surfaces (zone 1) is not part of the typical environmental monitoring program. Best practices indicate the zone 1 testing is useful only in limited circumstances such as corrective action or investigative activities. Therefore, allowing flexibility for a facility to build a scientifically-valid program that is appropriate to the facility's unique processes and hazards will result in the best food safety outcome.

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Supplier Approval and Verification (78 FR 3765)

Supplier approval and verification programs are widely used in the industry to ensure raw materials and ingredients are procured from only those suppliers that can meet company specifications for food safety and quality. We support the inclusion of supplier controls in the proposed rule. Again, we suggest FDA consider a flexible approach and direct manufacturers to develop a risk-based supplier verification program that takes into account the inherent risks of the ingredient and the performance history of the supplier.

We support the inclusion of second and third-party audits in a supplier verification program when the approach is flexible and the frequency of onsite audits is driven by risk assessment. Likewise, we feel it is important that FDA not have access to supplier audit reports as this would compromise the confidentially established between the company and its supplier. Rather, FDA should focus on accessing records that demonstrate the manufacturer is conducting the supplier verification activities as established in their risk-based supplier verification plan.

Complaints (78 FR 3767)

FDA requests comments on the potential provision for facility review of complaints as a component of verification activities for preventive controls. NSMA concurs with the agency that consumer complaints can play an important role in evaluating the effectiveness of a food safety plan. However, we disagree that complaint review should be a required verification activity as such a requirement is outside the agency's statutory authority under FSMA. Furthermore, the majority of complaints are often related to quality issues, not food safety, and such a requirement would create a financial burden with little to no food safety gain for many manufacturers.

Facility Profile (78 FR 3768)

The agency suggests that it would be beneficial if the agency had access to a facility's food safety plan in advance of an inspection. FDA proposes an electronic form approach for a facility to submit specific data elements to create a "facility profile". NSMA is opposed to the concept of facility profiles as this requirement is outside FDA's statutory authority under FSMA. Furthermore, reviewing hazards, controls, and other elements of the food safety controls without actual observation of the facility operations may lead to inaccurate assessment of the facility's food safety system and risks.

Records (Proposed § 117 Subpart F)

NSMA understands value in proper recordkeeping as part of an effective food safety system. However, we are opposed to several provisions within the proposed rule as it pertains to records:

1. Proposed § 117.305 requires that electronic records are kept in accordance with part 11. Such a requirement would create a need to redesign existing recordkeeping systems for many facilities. This would result in an excessive financial burden on the industry with no food safety improvement. We urge the agency to consider a simplified requirement for electronic records to assure the authenticity of such records and exempt Part 117 records from compliance with Part 11.

2. Proposed § 117.320 requires that all Part 117 records be made available to the FDA upon request. The agency seeks comments on whether it is appropriate to include the provision requiring the electronic submission of records to the FDA when requested. NSMA strongly disagrees with the concept of remote access to facility records. First, such a provision is outside the statutory authority of the FDA under FSMA. Second, review of records onsite during a regulatory inspection provides the FDA representative the full context of information that is shown on the records. To review the records without context may lead to inaccurate assumptions and premature conclusions about a facility's food safety system. Lastly, many seasoning manufacturers receive supplier and customer records under the protection of confidentially agreements. As such, manufacturers cannot legally disclose those records to a third party without written release from the owner of the proprietary information.

3. Proposed § 117.325 establishes that Part 117 records would be subject to public disclosure under Part 20 and the Freedom of Information Act (FOIA). NSMA requests that FDA give Part 117 records the same level of protection afforded to HACCP records under § 123.9(d) and 120.12(f).

   NSMA is deeply concerned about the volume of records that would be subject to disclosure and commercial sensitivity of many of these records. The records subject to the public disclosure requirement would include the food safety plan, monitoring records, corrective action records, verification records, and training records. Product testing, environmental monitoring, and supplier verification records could potentially be subject to this requirement if the final rule incorporates additional verification requirements. Food defense records could also be potentially subject if a facility chooses to integrate food defense measures into their food safety plan for consolidation purposes. The potential for trade secrets, confidential information, or food defense strategies to be inadvertently released without proper redaction is significantly increased when the volume of records subject to disclosure is considered.

   Alternatively, following the precedent established for HACCP records under the juice and seafood HACCP regulations, sensitive information contained within preventive control records could be adequately protected. NSMA requests that Part 117 records not be subject to public disclosure unless they have been previously disclosed to the public, they relate to a product or ingredient that has been abandoned and no longer represents a trade secret or confidential information, or disclosure could not reasonably be expected to cause a competitive hardship.

Preliminary Regulatory Impact Analysis

NSMA believes that the Preliminary Regulatory Impact Analysis (PRIA) greatly underestimates the expected costs from the proposed rule. We do not agree with FDA's conclusion that the rule as currently proposed will be cost-neutral to large facilities. Without substantial changes to the proposed, as noted above, even facilities with established food safety plans will need to adjust their plans to be in compliance with the rule. Largely, this would entail adjustments to the hazard analysis and recordkeeping systems. Additionally, we question the time estimates provided in the PRIA for specific tasks under the proposed rule. For instance, the PRIA estimates that 24 to 48 total labor hours would be required for a first hazard analysis, and subsequent hazard analysis would require 12 to 24 total labor hours. We believe this greatly underestimates the time required for hazard analyses when fully accounting for the multi-disciplinary approach where teams of individuals from different areas of expertise participate in the analysis process. Likewise, the scientific research required for analysis takes a significant amount of time. We request that the

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agency reassess the estimates provided in the PRIA, and make the changes necessary to ensure the impact of the proposed rule minimizes the financial burden to companies while ensuring food safety improvement within the food supply chain.

The NSMA organization appreciates the opportunity to provide these comments for consideration. Our members are committed to ensuring the safety of seasoning products. If we can assist the agency with additional information or industry perspective, please do not hesitate to contact us.

Respectfully,

Richard Alsmeyer, Ph.D.
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