TENNESSEE DEPARTMENT OF AGRICULTURE

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COMMISSIONER

REGULATORY SERVICES
FOOD & DAIRY

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Tennessee Department of Agriculture's response to the call for opinions on the Standard 3, Risk Based Frequency Issue:

The Tennessee Department of Agriculture (TDA) is currently still in the process of implementing the MFRPS program but the regulatory goal of reducing the risk of foodborne illness for the public has long been in place. TDA strongly believes that applying the framework provided by the MFRPS to our existing regulatory program will provide an efficient way to reduce variation when applying food safety regulations to manufacturing firms, and subsequently the risk foodborne illness for the public. However, using a strict, line-by-line, one-size-fits-all approach in applying the standards to all state programs appears to be inherently restrictive when considering the range of possible scenarios that could be encountered in regulating food manufacturing firms. TDA alone regulates 29 different categories of food manufacturers and warehouses, ranging from bakeries to custom slaughter plants, which may operate within a corporate owned grocery store or a home kitchen. While TDA fully intends to implement the requirements of the MFRPS as written, it seems prudent to allow FDA auditors some freedom to accept a justifiable deviation from an individual requirement within a MFRPS standard, as long as this exception will improve (and not impede) the State's ability to achieve the goal of a high-quality, risk-based food safety program.

As the benefits of a uniform application of the MFRPS program to state programs has already been documented within the standards themselves, a standard application process to obtain approval to deviate from the standard requirements should be agreed upon. Experts, deemed to be qualified by the FDA, should be used to determine if a state program needs an exception to the standard requirements and if the proposed alternative will be able to achieve the goal(s) of that standard. The term "experts" is interpreted here to mean individuals who are well versed in MFRPS, their interpretation, and implementation in a variety of settings. To reduce the element of subjectivity where possible, it is recommended applications would be evaluated by more than one qualified person, similar to a scientific peer-review process. For example, a list of qualified individuals could be maintained through AFDO or the Manufactured Foods Regulatory Program Alliance (MFRPA), and applications for an exception would be forwarded to 3 or 5 experts from that list identified to be familiar with the state and/or standard in question for review and response. A MFRPA committee designated to reviewing requests on a regular basis for an exception to a standard's requirements might also satisfy this need. A time frame for application review should be strictly enforced by the FDA (a three month turnaround is suggested), so that the State's ability to react and implement the final decision for their regulatory program is not hindered. As part of the application process, references and reasoning within the justification provided by the applicant as well as the response for the proposed exception should be well documented and available (at least by request) to other states.

The variability discussed above, as well as the MFRPS stated purpose of fostering a program that strives for continuous improvement and innovation, demands a periodic re-evaluation of the program including any approved variance granted. The auditing requirements listed as part of MFRPS Standards 4 and 9 appear to offer logical opportunities and time frames to evaluate the continued need for the exception. If the need for the exception is still present, the State could provide documentation

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that the original scenario under which the exception was granted is still in effect. Some documentation that the goals of the MFRPS standard are being met while the deviation from a specific requirement is being implemented would also be appropriate. If there is no longer a need for the exception, documentation should be provided that the original requirement is now being met or a plan to do so is being implemented, as described in the MFRPS reporting requirements.

In conclusion, TDA believes in the benefits afforded by implementing a uniform framework such as that required for participation in the MFRPS program for food safety programs across the US. However, given the dynamic challenges presented in regulating food manufacturers and the scenario presented by FDA with this announcement, an option to grant approval for a well justified exception seems warranted. The process to apply for an exception should be clearly defined and should impose requirements in accordance with the ideals of the MFRPS program.

TDA appreciated the opportunity to provide input on this issue, please contact us if you have any questions about our response.

Sincerely,

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