



Lewis, Glenda R

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PM

to Becky, me, Mary, Glenda

Becky and Dave,

Thank you for your time today to discuss CFP Issue 2020-II-015 that asks for a written notification for food allergens in unpackaged food in retail food establishments. I wanted to follow up with a note summarizing our discussion. Becky Vought, Dave McSwane, Mary Cartagena, and I met today by call.

As a reminder, FDA initiated this call because we wanted to be transparent with the CFP on the concerns FDA has about the potential for unintentional cross contact in a retail food establishment that is not fully addressed by adding a written notification requirement in the Food Code. Further, we have concerns about the new code section would be implemented to address unintentional cross contact when providing written food allergen notifications and we have concerns with how the new section can best be enforced by regulators. I mentioned this concern at the 2022 Spring CFP Board meeting and the call today was scheduled to follow up to the FDA thinking at that time, which was to not include the CFP recommended language in the 2022 Food Code.

I explained that in the interim of the CFP Board meeting and the call today with CFP leadership, FDA has been in internal discussion on this, taking into consideration the strong CFP response to go ahead and include the language into the Food Code. We are also taking into consideration that the industry offered to work with FDA on long term measures to ensure consistent industry implementation and regulatory enforcement. FDA subsequently has arrived, at this time, on the option to include the CFP recommended language and add language into Annex 3, Public Health Reasons. FDA envisions a multi-stage approach may be needed to fully address all aspects of this recommendation to inform food allergic consumers and address the FDA concerns. We also want to engage with industry and regulatory to leverage for addressing implementation and enforcement pathways. The CFP Allergen Committee work is also a factor to be included/considered.

Current thinking has FDA thinking to submit an FDA Issue to the 2023 CFP meeting in January 2023 for addressing cross contact in the Code and Annex.

Additionally, internal FDA discussions continue, and we will need to have clearance from our attorneys to ensure the CFP recommended change does not create any legal conflicts with existing labeling laws. We work to keep the Food Code consistent with federal laws and these efforts internally are to meet that intent.

Any final action by FDA is pending our attorney input, but our intent at this time is to include the language. Our attorney's opinion will outweigh that if doing so will contradict the CFR or the Act, or if adding it will create problems for adoption of it in the SLTT jurisdictions.

Lastly, the CFP Board is having a virtual meeting in July and its Fall Board meeting in October and FDA will give an update at both meetings. In our discussion today, we agreed to give an update to the CFP Allergen Committee where CFP Leadership (Becky, Dave, and Todd) along with Mary and I join an upcoming CFP Allergen Committee meeting. **CFP leads will** invite the Allergen Committee Chairs to join the Board meeting in July for the discussion when FDA updates the Board.

Glenda

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