

From: Klaman, Theresa <Theresa.Klaman@fda.hhs.gov>
Sent: Friday, April 3, 2020 4:26 PM
To: Johnsen, Ellen E [FS HN] <johnsene@iastate.edu>
Subject: RE: NCR FSMA virtual conference

Ellen,

I may have created a little confusion during the virtual conference and maple syrup.

I would like to share the following with the entire group.

Saps (e.g., agave, birch, maple, palm) do not fit the definition of “produce” and therefore are not subject to the Produce Safety Rule. Algae (e.g., seaweed) is not produce and therefore also not subject to the Produce Safety Rule (Draft Compliance & Implementation Guidance, Page 11). Therefore should not be included in the inventory.

The requirements for hazard analysis and risk-based preventive controls do not apply to on-farm manufacturing/processing of food by a small or very small business if the manufacturing/processing activities are limited to the specific low-risk manufacturing/processing activity/food combinations (21 CFR 117.5(h)(3)). Syrup production is considered a low risk manufacturing/processing activity. You may find the attached Guidance for Industry useful when working with stakeholders. The relevant section is highlighted.

Thank you in advance for your assistance.

Sincerely,

Theresa C Klaman

Consumer Safety Officer

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