



February 12, 2021

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
(Submitted electronically: www.regulations.gov)

Re: Docket No. FDA-2014-N-0053 for Requirements for Additional Traceability Records for Certain Foods

To Whom It May Concern:

The American Cheese Society (ACS) appreciates the opportunity to participate in the U.S. Food and Drug Administration's (FDA) comment period for the proposed food traceability rule. ACS is an international non-profit trade association with 2100 members, with our top 3 membership categories being cheesemakers (41%), retailers (22%), and distributors (12%). The cheese industry has a commitment to traceability - from feed to final product - and supports efforts to enhance transparency through the supply chain. We would like to take this opportunity to share our perspective and concerns with the proposed rule.

Define Soft Cheese

We thank the FDA for developing the memorandum that provides clarified language regarding cheese on the Food Traceability List. We understand the cheese that is included on this list is defined as all cheese - pasteurized or not- that has greater than 39% moisture content.

We would like to request the FDA provide further information on how soft cheese is defined. The Standards of Identity define the composition for soft ripened cheese, semi-soft, and hard cheese, but not for soft, unripened cheese. We want to minimize industry confusion about what products are included in this rule. Further information on the definition of this category by FDA for the purpose of this rule is essential.

Harmonize with Preventive Controls for Human Foods Facility Exemptions

We appreciate FDA's efforts for flexibility, and that FDA has included exemptions to this proposed rule. We believe in scale appropriate regulation, and we feel it will minimize confusion if the exemptions from the Traceability Rule are harmonized with those from the Preventive Controls rule. We request that the exemptions follow the "qualified facility" definitions as promulgated in the Preventive Control Rule.

Fund and Support Training

The Food Traceability rule introduces a new vocabulary that will take time for the industry to learn and apply. We request the FDA provide the steps they plan to take on how they will support educating affected groups on the lexicon of this rule. In addition, a timetable of how implementation will be supported with appropriate training and resources to ensure compliance.

Clarify Digital Recordkeeping

Our membership consists of many small businesses for whom the implementation of this rule has the potential to have a major economic impact. Ensuring that the access to technology and



tools, as well as the training necessary to use them is not cost prohibited is of utmost importance. There are cheesemakers among our membership that are Plain Sect (e.g., Amish), and do not use electronic recordkeeping or any other electrical devices for their business. Therefore, we ask FDA to include alternate means of acceptable recordkeeping for these processors. We would like to see additional flexibility on the requirement to have digital records within 48 hours. Our members are entrepreneurs: we encourage the FDA to consider the potential economic hurdles new businesses might face, and encourage the FDA to consider technologies and systems that are appropriate for different scale businesses.

Publish Data Privacy Rules and Responsibilities

Additionally, the FDA should address what systems they will be using to receive, store and access the digital records. Further, transparency and clarity on the interoperability of technology systems between the FDA and small businesses must be addressed. FDA should release as much information as possible on how it plans to secure data and mitigate company privacy concerns.

The American Cheese Society looks forward to further clarification from the FDA on these issues.

In summary:

- Define Soft Cheese
- Harmonize with Preventive Controls for Human Foods Facility Exemptions
- Fund and Support Training
- Clarify Digital Recordkeeping
- Allow Non-Digital Alternatives
- Publish Data Privacy Rules and Responsibilities

Thank you,

The American Cheese Society Board of Directors

ABOUT ACS

The American Cheese Society (ACS) is the leading organization supporting the understanding, appreciation, and promotion of artisan, farmstead, and specialty cheeses produced in the Americas. Over 2,400 members strong, ACS provides advocacy, education, business development, and networking opportunities for cheesemakers, retailers, enthusiasts, and the extended industry. ACS strives to continually raise the quality and availability of cheese in the Americas. Since its founding in 1983, ACS proudly hosts North America's foremost annual educational conference and world-renowned cheese judging and competition. For more information, visit www.cheesesociety.org