GT GreenbergTraurig

# Alert | Health Care & FDA Practice

December 2021

## FDA Issues Final Rule on Laboratory Accreditation for Analyses of Foods

On Dec. 3, 2021, the U.S. Food and Drug Administration issued its final rule on Laboratory Accreditation for Analyses of Foods (LAAF). The rule was mandated by the Food Safety Modernization Act of 2011, and its roots go back to FDA efforts in the 1990s and 2000s to establish uniform standards for import-related food testing and to strengthen FDA's oversight over such testing.

The LAAF rule establishes a regulatory framework, to be implemented by the FDA over the course of the next year or so, for accreditation of laboratories to conduct certain types of food testing. FDA will recognize accreditation bodies, which in turn will accredit laboratories to the standards established by the rule. After FDA determines that a sufficient number of laboratories are accredited under the rule, certain types of testing will have to be conducted using only these laboratories (which the rule refers to as "LAAF-accredited laboratories").

The LAAF-accreditation requirements of the rule include ISO 17025 accreditation and ILAC-MRA signatory status, as well as significant additional requirements specific to the rule. The analysis, sampling, and test reports for the food testing conducted under the rule also will need to meet certain requirements specified by the rule. Notably, both in-house and third-party laboratories are eligible for LAAF-accreditation.

The LAAF rule may significantly impact laboratories that test food offered for import to the United States but detained by FDA as potentially violative. When the rule is fully implemented, laboratories will need to

be LAAF-accredited to conduct this food import detention testing. Other testing to support removal from an FDA import alert also would need to be conducted in accordance with the rule by LAAF-accredited laboratories.

The rule affects other types of businesses as well, to varying degrees. Under the rule, importers of food detained by FDA will need to ensure the laboratory they hire to conduct the import detention testing is LAAF-accredited. Producers of shell eggs, sprouts, and bottled water also will need to use LAAF-accredited laboratories to conduct certain types of follow-up testing specified by the rule. The rule also allows FDA to require, through an administrative order process, companies to use LAAF-accredited laboratories to conduct food testing (including environmental testing) to address a suspected or identified safety problem. The rule also requires food testing to be conducted by an LAAF-accredited laboratory when (a) part of a corrective action plan submitted after an FDA order suspending the registration of a food facility or (b) as part of evidence submitted for an appeal of an FDA administrative food detention order.

FDA intends to announce in early 2022 that accreditation bodies may apply for FDA recognition under the LAAF rule. Once FDA has recognized a sufficient number of accreditation bodies, it will announce that laboratories may apply to the recognized accreditation bodies for LAAF-accreditation. When FDA determines there is sufficient LAAF-accredited laboratory capacity for at least one category of food testing covered by the rule, it will publish a document in the Federal Register giving six months' notice that importers and/or producers of shell eggs, sprouts, and bottled water will be required to use an LAAF-accredited laboratory to conduct certain types of food testing as described by the rule.

## Authors

This GT Alert was prepared by:


- Nancy E. Taylor | +1 202.331.3133 | taylorn@gtlaw.com
- Tyler M. Scandalios | +1 202.530.8573 | scandaliost@gtlaw.com