

The FDA New Era of Smarter Food Safety Low- or No-Cost Tech-Enabled Traceability Challenge

Frequently Asked Questions

Why is the FDA using a challenge to address this issue?

The FDA views open innovation as a promising avenue for advancing solutions that can aid in our response to foodborne contamination events.

Traceability lends itself to this type of challenge, in which the distributed intelligence of the global scientific and innovation communities in the food industry can be the basis of open dialogue about both the problems and ways of solving them. Industry has existing experience with traceability systems being implemented in other countries and the challenge format allows for more rapid innovation to further advance tech-enabled solutions that will assist the food industry in implementing traceability systems.

Further, open innovation is especially important given the challenge's goals to identify low-cost or no-cost solutions that may be adopted quickly. This challenge is leading the way toward advances in scalable and cost-effective traceability hardware, software, or data analytics platforms that can be used across the food supply chain to assist operations in implementing traceability systems.

Has FDA hosted any challenges before?

The challenge administrator is precisionFDA, which provides a secure, cloud-based, high-performance computing platform that engages a community of over 5,000 users across the world to research, collaborate, and define standards for evaluating omics tests, analytical and bioinformatics pipelines, and regulatory science exploration.

precisionFDA (precision.fda.gov) has run 28 different challenges and received 600 submissions. It serves as a catalyst for knowledge generation by convening community challenges and app-a-thons that galvanize dialogue and scientific discovery around multi-omics technologies.

It has several awards – notably the Bio-IT World Best Practices Award in 2016 and the FedHealthIT Innovation Award in 2019 – and their challenges have been cited in 27 scientific articles (manuscripts) and 11 scientific press releases.

What traceability needs should tech-enabled solutions submitted for this challenge seek to address?

When considering solutions to submit to the challenge, entrants should consider the specific traceability challenges that are unique to specific segments of the human and animal food supply chain – including primary producers (such as entities involved in farming and fishing); importers; manufacturers/processors; distributors (such as wholesalers, distribution centers,

and repackers); and retailers and foodservice (such as retail food establishments and restaurants).

What is the benefit to those who enter the food traceability challenge?

The visibility gained from this challenge will be significant. We will post the winners and links to their YouTube.com videos on precision.fda.gov. Additionally, the winners will have the opportunity to present live during a webinar that will occur at the completion of the challenge. Finally, a list of featured participants (and links to their submission videos) may also be made available on precision.fda.gov at the completion of the challenge.

What does FDA get out of this?

Identifying Existing Solutions. The FDA is shining a light on both existing solutions and new ideas. Given the size of the food industry, there are many traceability solutions that may be unfamiliar to the majority of interested groups – including the FDA. This will give the FDA visibility into the many solutions already in use and the traceability challenges they are already seeking to solve.

Understanding hurdles, sparking ideas. We all need to better understand the hurdles faced by different segments of the food supply chain when it comes to traceability. Discussion of these challenges and identification of potential scalable, cost-effective solutions to help address these issues should spark additional ideas and dialogue, generating new solutions even after the challenge concludes.

And what does the food industry get out of this?

Entities throughout the human and animal food supply chain are looking for scalable, cost-effective, tech-enabled traceability solutions, but may not be aware of solutions that currently exist or new ideas that are on the horizon. We have received multiple requests for assistance in identifying tech-enabled traceability solutions that address specific traceability challenges faced by the human and animal food industry. This challenge may provide a vehicle for industry to find those solutions.

Is the challenge related to the Proposed Food Traceability Rule that FDA published in September 2020?

No. The challenge is not related to, nor are we seeking solutions that pertain to, the [Proposed Food Traceability Rule](#), which is mandated by the FDA Food Safety Modernization Act (FSMA) to require additional recordkeeping for certain foods.

This challenge is focused on encouraging development of innovative approaches for scalable, cost-effective food traceability solutions to advance widespread implementation of tech-enabled traceability systems throughout the supply chain.

The FSMA Proposed Rule on Food Traceability proposes to establish additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the [Food Traceability List](#). The proposed rule also contains certain provisions that, if finalized, would allow for various exemptions and modified requirements.

[More FAQs with additional information on submission criteria are available to challenge registrants on the launch website.](#)