PATH-SAFE: Onsite Diagnostics

Alongside the development of laboratory-based approaches and methodologies, undertaken within a separate theme, this PATH-SAFE theme has specifically considered the application of onsite diagnostics (OSD) for the rapid detection of foodborne pathogens (FBP), outside of a conventional laboratory setting.

Overview

The advancement of rapid and accurate onsite diagnostic methods provides a real opportunity in relation to detection and control of foodborne pathogens.

The first phase of this work undertaken in 22/23 and 23/24 focused on the identification of promising technologies that could be piloted for on-site testing of foodborne pathogens, including piloting selected technologies.

A comprehensive literature review was undertaken to identify technologies under development for on-site testing. This included both technologies proven or presumed to be applicable in detecting targets relevant to food safety, as well as those developed for other sectors. These technologies were assessed through a customised technology readiness level (TRL) framework with each technology assigned a TRL in combination with each in-scope pathogen or matrix.

To understand the testing requirements in real world scenarios, both "strategic" and "operational" stakeholders were mapped and engaged in focus groups and interviews. This provided a broad perspective on on-site testing and supported identification of sectors or processes that are well-suited or not suited for portable detection technologies.

Results from the literature review and end-user study led to the shortlisting of technologies based on relative maturity and suitability for on-site use, mapped against potential applications within the food sector for deployment of the technologies. This decision matrix allowed an evaluation of each of the shortlisted technologies in the context of specific end-user needs, and a final selection was made based on the outcome.

Two technologies were selected, validated in the laboratory and various performance criteria such as specificity, sensitivity, repeatability, and reproducibility were evaluated. The finalised methods were tested in the hands of end-users, with end-user training initially provided in a controlled environment and subsequently the end users conducted the tests themselves onsite and provided feedback.

A separate, but related piece of work was undertaken by UKHSA and 20/30 Labs to explore the possibility of repurposing of rapid, Covid-19 in-field wastewater diagnostic technology for the detection of foodborne pathogens. This work demonstrated that rapid detection of seven foodborne pathogens in wastewater is feasible using rapid Loop-mediated isothermal amplification (LAMP) based technologies.

This work has demonstrated the potential utility of using onsite diagnostics as inspection tools in the FBD arena, whilst also identifying that there are no "ready-made" solutions on the market that meets the specific needs of end-users but found that there are a wide variety of emerging technologies. It has therefore become apparent that guidance for the 'real world' deployment of onsite diagnostics, is essential. The focus of the 24/25 continuation work is to develop such a set

of guidelines, in particular for the use of onsite diagnostics for official controls in the food sector. End user insights and perspectives will be sought, and a case study will be developed to illustrate application of the guidelines. Needs from the policy, legislative and accreditation body perspectives will also be considered (Fera).

Delivery partners

Delivery partners for this work:

- Fera Science
- University of Lincoln

Status

A survey to collect feedback from a range of end users and key stakeholders (including those involved in the development of on-site diagnostic technologies, their deployment and also their accreditation) about what the recommendations should contain was conducted over September and October. Results are being analysed and written up at present.

Considerations are also being made towards selection of a case study for the final part of the project. The case study will be conducted between January – March 2025 and may take a modelling approach, looking at how the recommendations may be feasibly applied in several different settings.

Key successes

Key successes for this work include:

- horizon scanning identified more than 65 potential onsite diagnostic technologies, which were subsequently assessed using a Technology Readiness Level (TRL) framework developed as part of PATH-SAFE
- two onsite diagnostic technologies successfully piloted by end users in onsite locations and key scenarios
- significant end-user engagement through the completion of an end-user study to understand community needs and to help in identifying sectors or processes that are well-studied, or not, for portable detection technologies

Outputs

All projects were presented at the PATH-SAFE Biosurveillance Conference on 28 and 29 February 2024 in London.?[Recordings, slides and posters are available on the?conference webpage](.).?