

## FSA project FS900408: Guidance for Point of Contact Technologies

Task 11.0: Final report outlining the activities undertaken and rationale behind the development of the guidelines

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### Task 11.0: Final report outlining the activities undertaken and rationale behind the development of the guidelines

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## Glossary

- **CONOPS** Concept of operations
- Defra Department for Environment, Food & Rural Affairs
- DNA Deoxyribonucleic acid
- EC-JRC The European Commission's Joint Research Centre
- ELISA Enzyme Linked Immunosorbent Assay
- **ENGL** European Network of GMO Laboratories
- **EU** European Union
- FAN The Food Authenticity Network
- Fera The Food and Environment Research Agency
- FINN Food Industry Intelligence Network
- FSA Food Standards Agency
- FSS Food Standards Scotland
- FT-IR Fourier-transform infrared spectroscopy
- GMO Genetically Modified Organism
- IAEA International Atomic Energy Agency
- IR Infrared
- ISO International Organization for Standardization
- IUPAC International Union of Pure and Applied Chemistry
- JAKIM Jabatan Kemajuan Islam Malaysia
- LIBS Laser-induced breakdown spectroscopy
- LOD Limit of Detection
- LOQ Limit of Quantification
- MHRA Medicines and Healthcare products Regulatory Agency



- **MIR** Mid Infrared spectroscopy
- NFCU National Food Crime Unit
- NGS Next generation sequencing
- NIR Near Infrared spectroscopy
- NMR Nuclear Magnetic Resonance
- **OLs** Official Laboratories
- **PATH-SAFE** Pathogen Surveillance in Agriculture, Food and Environment
- **PASS** Public Analyst Scientific Services
- **PCBs** Polychlorinated biphenyls
- **POD** Probability of detection
- **POC** Point Of Contact
- **POCT** Point-Of-Care Testing
- RSD<sub>r</sub> relative standard deviation generated under repeatability conditions
- RSD<sub>R</sub> relative standard deviation generated under reproducibility conditions
- SFCIU Scottish Food Crime and Incidents Unit
- **UK** United Kingdom
- UKAS United Kingdom Accreditation Service



### **Executive summary**

The last decade has witnessed significant advances in analytical technology, application and scientific best measurement practices for food testing, inclusive of food authenticity, quality and safety analysis. This evolution has also been mirrored in the capabilities and market availability of portable analytical instrumentation which can be deployed at the point of sample testing throughout the food supply chain, often using miniaturised equipment. This area of Point Of Contact (POC) testing is expanding at a rapid rate, and there is a lack of guidance on the application of POC technologies and interpretation of the resultant data in the foods area, providing a significant challenge in the use of results.

This report informs on the current state of the art and availability of POC instrumentation, technologies involved, current applications, commodity testing, gaps and limitations, and end-user requirements, with a specific focus on official controls. This information was collated based on a series of tasks inclusive of further examination of responses to a previous Defra project FA0178 questionnaire, a current literature review, key learnings from synergistic projects and initiatives in the UK and internationally, published guidance on portable analytical instrumentation, engagement with accreditation bodies, stakeholder focus groups and a new questionnaire.

The first phase of the project, which involved the horizon scanning, literature review and stakeholder engagement exercises, revealed that there was no harmonised definition of POC testing in the foods area, although this was generally understood to encompass portable analytical instrumentation which can be deployed at the point of sample testing throughout the food supply chain, often affording the potential to screen samples quickly and cost effectively. The POC area encompassed technologies inclusive of rotational vibrational spectroscopy platforms (Near infrared (NIR), Fourier-transform infrared (FT-IR) and Raman), spectral imaging platforms (multi- and hyperspectral imaging), mass spectrometry, nuclear magnetic resonance (NMR), and biological analyte-based platforms (proteins and nucleic acid-based). In recent years, the areas of NIR, Raman and nucleic acid detection methods have shown increased interest. Topical commodity



and food testing remains consistent with previous years, with areas inclusive of meat and fish speciation, herbs and spices adulteration, and testing for allergens continuing to remain at the forefront of analyses, but also being joined with quality and safety applications. Advantages and benefits of POC testing are generally well understood in terms of providing rapid, real-time results as part of screening approaches. Discussions focussing on the use of POC testing for official controls emphasised the potential of POC devices to provide a useful and cost-effective screening tool. The importance of method validation to provide objective evidence of the fitness for purpose was reiterated.

The second phase of the project was to establish a set of recommendations for developing an infrastructure for guidance for POC testing in the food sector as part of official controls, informed by the results and conclusions associated with the upstream review. A detailed list of guidance and recommendations have been provided, which were further refined following feedback from a cohort of official control representatives, prior to being incorporated into this final report. Key aspects centred on the need to assess end-user requirements (the concept of operations) in addition to applying core method validation principles. Central recommendations also included the need for method validation to be performed on the specific combination of POC technology, instrument, application or commodity as per standard practice, to validate the method performance in the context of field-based setting at the point of application, to establish appropriate reference materials and databases, and to develop a centralised UK-based POC testing and advisory framework for provision of guidance and support as an aid to harmonisation. Future work proposals were made, inclusive of developing a candidate POC test case for method validation to demonstrate cost-saving benefits, as well as a recommendation to further engage with regional official control groups to further assess regional variations and end-user requirements.

"Food you can trust" is a central theme described in the <u>FSA Strategy 2022-2027</u>. This central theme is supported by three pillars which encapsulate the FSA strategy, namely that food is safe, food is what it says it is, and food is healthier and more sustainable. This project advances current knowledge in the area by developing support

mechanisms, focussing on method validation guidance associated with POC technologies, with a firm emphasis on how these can be applied for official controls. This will help inform potential end-users regarding the scope and utility of the POC instrumentation, providing additional confidence in results from this topical and growing sector, supporting its application as a further additional tool for authenticity, quality and safety testing in the food supply chain.

## Introduction

Within the last decade, significant advances have been made in terms of analytical technology, application and scientific best measurement practices in the area of analysis of foods for authenticity, quality and safety. This evolution has also been mirrored in the capabilities and market availability of portable analytical instrumentation which can be deployed at the point of sample testing throughout the food supply chains, often using miniaturised equipment employing technologies such as spectroscopy and immunological techniques (1-5).

Such portable technologies are often regarded as suitable instruments to use as an additional tool to help combat food fraud and are frequently deployed as screening approaches. Whilst the type and modes of actions of technologies that fit under the one umbrella term of such portable or Point Of Contact (POC) instrumentation is vast and ever expanding, all of the instruments generally share common features inclusive of enabling testing of food to take place in real-time and at the point of contact with the sample. However, until recently the application of POC instrumentation has largely been confined to the clinical diagnostic and human forensic areas.

The previous Defra project FA0178 "Assessment of Point of Contact Testing Technologies to Verify Food Authenticity" (6), led by LGC, evaluated the use of POC technologies for food authenticity testing. Main findings from this work included the lack of guidance on the application of POC technologies and interpretation of the resultant data, which provided a significant challenge in the food testing area. A key recommendation was that further guidelines and training/support were needed to promote POC technology uptake, particularly if this was to be used for control purposes as part of the analytical toolkit that Official Laboratories (OLs) can apply.

The current FSA FS900408 project further elaborates on the requirement to develop guidance to promote POC technology uptake, with a focus on use for official controls. One of the main aims of the project was to better understand the potential for POC technology for food testing for official controls and the wider food sector. Phase 01 of the project was involved in horizon scanning and stakeholder engagement, to better inform on the current state of the art and availability of POC instrumentation, technologies involved, current applications, commodity testing, gaps and limitations, and end-user requirements. A series of tasks, inclusive of a deep-dive into pre-existing data sets, an updated literature review, key learnings taken from synergistic projects, international engagement, consultation with the United Kingdom Accreditation Service (UKAS), published guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) and the Pathogen Surveillance in Agriculture, Food and Environment (PATH-SAFE) programme, an online questionnaire, a Focus Group meeting and other forms of key stakeholder engagement, were delivered in order to meet this aim.

Phase 02 of the project was aimed at providing recommendations for developing an infrastructure to support guidance for POC instrumentation in the food sector, as informed through key upstream findings from Phase 01. Key aspects of classical method validation and the concept of operations (end user requirements) were considered in forming these recommendations, which were further qualified through a sensibility check with representatives involved in official controls.

The report described below provides an overview of the work, outlining the activities and findings associated with Phases 01 and 02 on better understanding the application of food testing within the POC sector associated with food testing and focusing on POC use for official controls. Sections include addressing POC definitions and the technologies and instrumentation involved; commodity testing; scope and benefits; limitations; support mechanisms to overcome barriers to uptake; a perspective on the use of POC testing for use in official control purposes, and recommendations on



establishing an infrastructure for guidance for POC testing in the food sector as part of official controls.



### Project Gantt chart

		<b>D</b> : (	Month							
Phase	Task	Brief Description	1	2	3	4	5	6	7	Progress
	Description	Sept	Oct	Nov	Dec	Jan	Feb	Mar		
01		Horizon scanning activities								
	1.1	Deep-dive FA0178 questionnaire								Completed
	1.2	Updated literature review								Completed
	1.3	Learnings from synergistic projects								Completed
	1.4	International engagement								Completed
	2.0	Engagement with UKAS								Completed
	3.0	Stakeholder Focus Group meeting								Completed
	4.0	Questionnaire								Completed
	5.0	MHRA guidance								Completed
	6.0	Alignment with PATH-SAFE								Completed
	7.0	Interim report (Phase 01)								Completed
02		Development of POC guidelines								
	8.0	Validation guidelines								Completed
	10.0	Stakeholder sensibility check								Completed
	11.0	Final report								Completed



## **Delivery against tasks**

#### Phase 01: Horizon scanning and stakeholder engagement

#### Task 1.1: Deep-dive questionnaire

The previous Defra project FA0178 POC questionnaire (6) was formulated to help inform the assessment of the main analytical challenges, research gaps and barriers for uptake of POC technologies. The questionnaire comprised 42 questions and was developed to target individuals involved in the food supply and associated diagnostics sectors. The questionnaire was delivered using the online SurveyMonkey® platform between 20<sup>th</sup> and 31<sup>st</sup> July 2020.

Responses from the full dataset (170 participants) were reanalysed with a focus on current/future potential of POC technologies in the wider food sector, as well as current applications for official controls. Additionally, POC testing for commodities was summarised, alongside evaluating what technologies were being used for POC testing.

The successful application of POC technologies within the UK enforcement sector is critical to their acceptance within the general testing and regulatory communities. The questionnaire identified 8 of 170 respondents who were part of UK enforcement and typically held regulatory functions (6 out of 8 respondents), for example, Port Health Authority, Trading Standards. Further data analysis (Table 1) was performed to capture information relating to these enforcement sector respondents and identified some limited usage of POC technologies within this sector. The questionnaire did not provide additional intelligence regarding official control applications, highlighting the requirement for further investigation through the follow-up questionnaire developed under the current project.

POC-based food authenticity testing methods have been widely developed targeting commodity products, especially high value, as they represent an effective way to screen food products. The POC questionnaire did not provide specific intelligence relating to the usage of POC-based methods for commodity testing. However, a broad range



sample types were highlighted as part of the questionnaire which ranged from alcoholic beverages to oils. Herb and spices and meat/poultry sample types are tested for by over 50% of the respondents which highlights priority samples for consideration as part of the current project.

The FA0178 POC questionnaire highlighted the varied nature of POC testing within the UK food industry and provided an insight into the drivers/barriers to POC uptake. Detailed information regarding the role of POC within the enforcement/OLs communities highlighted the need for a follow-on questionnaire to capture outstanding areas of interest for the current project.

**Table 1.** Table highlighting feedback from enforcement sector respondents (8respondents in total). \* Single reply from maximum of 2 possible respondents

Question	Feedback
Do you use Point-of-Contact (POC)-based	2 out 8 respondents answered this
tests in your business/organisation? e.g.	question with 'Yes'
tests performed using portable or hand-held	
testing devices	
'Do you have any practical experience of	2 out of 6 respondents answered this
POC testing within the foods sector?	question with 'Yes'
What type of POC testing was performed? *	Gravimetric alcohol level testing
Your overall experience of using POC	Useful cheap way of screen testing which
systems*	enable us to stretch our budget further
In your opinion, what are the main drivers	Drivers - Cost saving
and barriers behind the uptake of POC	Barriers - Lack of applicable cost-
systems? *	effective equipment
Perceived benefits and limitations of POC,	Benefits - Saves time and money-result
e.g., time and cost*	obtained in real time
	Limitations - Accuracy and false results
	due to way it has been done



#### Task 1.2: Literature review

An updated literature review was conducted, focusing on 2019 onwards so as not to overlap with the original literature review associated with the previous Defra project FA0178 "Assessment of Point of Contact Testing Technologies to Verify Food Authenticity" (6). The literature review was facilitated through the use of appropriate citation databases (for example, PubMed and ScienceDirect) as well as Google Scholar. Web searches focused on key terms including POC, Point-Of-Care Testing (POCT), portable, miniaturization, hand-held, screening, food authentication, non-targeted, food safety, food analysis, food allergen detection, sensors, and biosensors. Additionally, a search of POC applications for commodities as well as definitions of POC definition were undertaken and around 300 documents (peer-reviewed papers, product literature and websites) were reviewed. This was further augmented through taking key learnings from the recent FSA project FS900293 "Review of methods for the analysis of culinary herbs and spices for authenticity" into account (7).

#### Tasks 1.3 and 1.4: Synergies with other projects and global initiatives

Key learning points in terms of scope, limitations, harmonisation/standardisation and method validation guidance were taken from the following additional projects and global initiatives:

- Defra project FA0194 "Harmonisation and Standardisation in the Field of Next Generation Sequencing" (8)
- Capability building project number 5 on "Next Generation Sequencing and Supportive Technologies to Underpin Food Authenticity and Safety", from the current Government Chemist Programme 2023-2026 (9)
- Discussions with representatives at an international level, inclusive of the International Atomic Energy Agency (IAEA)
- The Food Authenticity Network (FAN)
- UK Food Authenticity Centres of Expertise, as acknowledged by Defra, FSA, Food Standards Scotland (FSS), National Food Crime Unit (NFCU), Scottish



Food Crime and Incidents Unit (SFCIU) as part of a framework for a coordinated to national/international food and feed fraud incidents/investigations

Views, comments, experiences and feedback from the above stakeholders were captured through a series of engagement exercises inclusive of 1:1 meetings, email exchange, site visits, the main Focus Group meeting (Task 3.0) and input into the questionnaire (Task 4.0)

#### Task 2.0: Engagement with UKAS

A meeting was held with a representative from the UKAS regarding the development of a pilot study initiative on ISO 17025 accreditation for non-targeted food authenticity methods, with a focus on screening approaches and databases. Relevant guidance was incorporated into the current project. This opportunity was capitalised upon as a twoway exchange of information to also keep UKAS informed of key findings from the project and ensure synergy in the guidance being developed.

#### Task 3.0: Key stakeholder engagement and focus group meeting

The Focus Group meeting constituted one of the main key stakeholder engagement exercises. The meeting was successfully held on Friday 17<sup>th</sup> November 2023 via MS Teams, including 12 external participants representing UK Competent Authorities (FSA, Defra and FSS), inter-governmental forums, Public Analysts, Trading Standards, Port Health Authorities, Industry, the British Retail Consortium and instrument manufacturers.

The meeting provided an open forum to discuss the core questions of scope and limitations associated with POC testing, inclusive of support mechanisms to overcome the barriers, end-user requirements, food testing applications and reflections on use for control purposes.

#### Task 4.0: Questionnaire

The FSA POC questionnaire built upon the previous Defra FA0178 questionnaire and was formulated to help inform the assessment of the main analytical challenges,



research gaps and barriers for uptake of POC technologies. The questionnaire was developed to target individuals involved in the food supply and associated diagnostics sectors, including enforcement and official controls. This questionnaire consisted of 39 questions and was actively developed and deployed using the online <u>SurveyMonkey</u> platform between 16<sup>th</sup> November and 4<sup>th</sup> December 2023. The questionnaire consisted of a series of multiple choice and free-text box questions focused on recommendations for provision of guidelines for validation and application of POC instrumentation for food testing, with emphasis on UK official controls (see Annex 1). Dissemination routes included the Food Authenticity Network (over 4,300 members) and stakeholder networks inclusive of the Association of Public Analysts, the British Retail Consortium and the Food and Drinks Federation. In total, 124 respondents provided answers to the questionnaire. The anonymised questionnaire responses and associated analytics provided additional insights into the application of POC technologies to food authenticity testing.

The largest group of respondents (59%) were based within the UK and 23% resident in the EU, demonstrating a good level of geographic diversity. No observable trends were seen in the remaining 18% of respondents, which represented diverse geographical regions inclusive of Africa, the Americas, Asia and Oceania. The highest category of responses was received from 'Food Safety Managers', representing 19% of participants, with a smaller grouping of participants identifying as 'Official Controls and Enforcement' (8%). The majority of respondents work within a small/mid-sized organisation (60%) and the top three organisation types comprised 'Manufacturing' (33%), 'Other' (21%) and 'Government' (16%). The 'Other' category contained a diverse range of organisation types that included laboratory equipment manufacturers, consultants, and distributors.

#### Task 5.0: MHRA engagement and guidance

The MHRA has published guidance on the use of POCT devices in relation to healthcare and medicines. This guidance was examined, taking key learning opportunities from the health sector which were directly transferable for POC instrumentation for food testing (10). Overall, the MHRA recommendations also



reinforced the key findings in the food testing sector. In brief, these included the need for classical method validation and assessment of performance characteristics, assessing costs and end-user requirements associated with portable instrumentation, clearly defining the scope of application, and highlighting the requirement to harmonise the application of portable instrumentation and the associated interpretation of results.

#### Task 6.0: Alignment with PATH-SAFE

The <u>PATH-SAFE</u> programme, is a cross-government programme, led by the FSA, engaged in monitoring and tracking food borne pathogens and antimicrobial resistant microbes in the UK. As such, one of its related workstreams is concerned with testing the feasibility of using portable diagnostics as inspection tools, as well as developing appropriate method validations workflows.

A PATH-SAFE programme progress meeting (Innovation in Biosurveillance: Recent progress and new opportunities) was held on the 14<sup>th</sup> November 2023 and attended by a project representative following the kind invitation of the PATH-SAFE Research Programme Manager (FSA Science, Evidence and Research Division). The meeting highlighted potential areas of synergy and facilitated discussions with key programme stakeholders inclusive of Fera and FSA working within the biosurveillance sector, for example, PATH-SAFE Workstream 3 on the use of portable diagnostics. Breakout sessions helped identify barriers to cross sector and government working in biosurveillance with applicability to POC-based food testing, which highlighted barriers including limited data sharing, complex landscape of stakeholders, and the development of solutions such as common training, frameworks or language. The key learnings have been incorporated into the current project.

#### Task 7.0: Interim report

An interim report outlining the horizon scanning activities undertaken and the stakeholder engagement exercises was successfully submitted to the FSA.



# Phase 02 - Development of POC technology guidelines for official controls

#### Task 8.0: Validation guidelines and recommendations

The aim of this task was to provide recommendations for developing an infrastructure for guidance for POC instrumentation in the food sector. Feedback and information collated from Phase 01 "Horizon scanning and Stakeholder Engagement" was used to inform on the direction of travel of Task 8. Recommendations and guidance were developed focussing on the core aspects of method validation, end-user requirements and further feedback from stakeholders involved in official controls. Guidance was provided for developing an infrastructure to support POC deployment and harmonisation in the food sector.

#### Task 10.0: Stakeholder sensibility check

A small but representative cohort of stakeholders involved in official controls were invited to feedback on the main head-line findings associated with the recommendations for the project. In total, ten representatives from eight official control stakeholder organisations, representative of different regions across the UK, participated in this task, providing feedback via an online questionnaire deployed through the SurveyMonkey platform. Feedback was captured and used to further inform on the recommendations as part of the current project.

#### Task 11.0: Final report

The final report outlining the activities undertaken and the rationale behind the development of the guidelines was successfully submitted to the FSA. As informed through the key findings and recommendations associated with the project, a section on suggested further work was also included.



## Key findings

#### Phase 01: Horizon scanning and stakeholder engagement

#### **Definition of POC instrumentation**

It was evident from all Tasks associated with the Phase 01 "Horizon scanning and Stakeholder Engagement" activity, there was no universal definition for the term "Point Of Contact" (POC) technologies/instrumentation for food testing. The nearest equivalent definitions appeared to be POCT in the health sector, defined as medical testing at or near the site of patient care by specially trained healthcare (non-laboratory) professionals (11), (12). If POC testing may be viewed to be analogous to the POCT for medical diagnosis (13), then in the context of food analyses it may encompass tests performed outside of a centralised laboratory facility, including near-site testing and remote testing, where results may typically be available within a relatively quick timeframe.

Whilst there appeared to be no universal definition of POC instrumentation for food testing, what was generally understood was that the area encompassed portable and potentially transportable analytical instrumentation which can be deployed at the point of sample testing throughout the food supply chain, often offering the potential to screen samples quickly and cost effectively. This finding was also supported by the current POC questionnaire which highlighted a complex set of concepts focused on core analytical attributes such as rapid and portable testing. Responses fell into a number of common concept groups inclusive of the importance of testing onsite and on time, testing directly at the point of sampling, use of portable instrumentation, real-time results and rapid testing.

## Identifiable trends in main POC technologies/instrumentation being used for food testing

Previous work from the Defra project FA0178 (6) identified five very general subdivisions which encompassed the plethora of different POC instruments. These



comprised rotational vibrational spectroscopy platforms (Near infrared (NIR), Fouriertransform infrared (FT-IR) and Raman), spectral imaging platforms (multi- and hyperspectral imaging), mass spectrometry, nuclear magnetic resonance (NMR), and biological analyte-based platforms (proteins and nucleic acid-based). These broad subdivisions were further reinforced through the findings of the current FSA FS900408 project.

The literature review revealed that the most common form of POC testing involved vibrational spectroscopy, and in particular NIR spectroscopy. The latter encompasses a broad range of applications (i.e., food authentication, safety and guality assessment) over the widest variety of food commodities in the agri-food sector (for example, milk and dairy products, meat, fish, fruit, vegetables). Whilst NIR appeared to be the most popular category of vibrational spectroscopy available, there was also growing interest in Raman spectroscopy with numerous studies using developmental devices. The updated literature review cited some historical applications of Mid infrared (MIR) spectroscopy for food authentication and adulteration, but there did not appear to be any significant advances in portable MIR technology or recent citations of food-based applications in recent years. The literature cited spectral imaging (multispectral and hyperspectral) as generally being non-destructive in nature, providing spatial distribution information as well as physical attributes and information on chemical components in food samples. More recently, compact hyperspectral imaging cameras have become commercially available and have been implemented for meat authentication (4). The technology is amenable for various agri-tech applications including the detection of fungal contamination in crops and assessing moisture content in situ. Portable multispectral imaging has also been recently evaluated as a screening tool for food safety in food preparation environments (14).

Some important developments over recent years have included the repurposing of a handheld laser-induced breakdown spectroscopy (LIBS) device, the Z-300 LIBS Analyzer (SciAps). This was originally used in the chemical industry but more recently is now showing promise for food-based applications (15).



Protein lateral flow strips are still being used, primarily for the detection of food allergens within food matrices, and salmonella in food (16). Recent evidence suggests that their usage is now even broader and can encompass testing for meat species to help ensure adherence to religious and cultural practices (17).

Portable nucleic acid detection methods are facilitated by DNA barcoding, for example as part of using portable next generation sequencing (NGS) devices) (18, 19), and nucleic acid lateral flow tests (20, 21). These can often involve relatively complex upstream procedures (for example, DNA extraction), but DNA approaches support a wide range of current and topical applications for food testing (for example, meat and fish speciation, testing for herbs and spices adulteration, pathogen detection).

There does not appear to be significant recent advances in the miniaturisation of mass spectrometry-based technology within the last two years. The technology is largely used for chemical analyses (for example, pesticides, insecticides and fungicides) on the surface of fruit and vegetables to ascertain any fraudulent assignment of organic status or to ensure concentrations are below legislative thresholds (22), (23).

NMR spectrometric instruments remain largely laboratory-based due to the need for heavy and expensive magnetics to create the strong magnetic fields. The only significant innovation in the NMR field is the launch of the first battery-powered portable NMR device, WaveGuide Formµla<sup>™</sup>, weighing in at 1.9 kg. However, there is currently no available literature citing food analysis with this device. New techniques under development may support more advances in portable NMR devices over the coming years (24).

From the FSA POC questionnaire, preliminary analysis of stakeholder feedback revealed that approximately 33% of respondents confirmed that they did use POC testing within their organisation, which supports evidence for further growth and uptake in this sector. Whilst POC testing appeared to be most often used upon receipt of a sample at a factory/warehouse, only about 22% of respondents agreed that they used it at source and no respondents utilised POC at the port of entry. The questionnaire showed that currently employed POC technologies appear to be mainly represented by spectroscopic techniques (for example, FT-IR) and immunological approaches (for



example, ELISA) at 39% each. This finding is not unexpected as these techniques are well established and suited to handheld testing, and these results also support the instrument technology breakdown highlighted as part of the above literature review.

#### **Commodity testing**

The updated literature review revealed a range of different commodities being tested for as well as POC applications. Food allergen detection in food matrices was frequently cited, inclusive of testing for the presence of tree nuts, shellfish, egg, gluten, sesame, fish, and milk. Within this space, portable detection was readily achieved using antigen lateral flow test strips (17); (25). Fish speciation was also frequently cited, testing being used to either combat food fraud by the substitution of cheaper and/or inedible species especially in processed food, but to also help ensure food safety (26); (2).

A general search for food authentication revealed POC instrument use for testing of Chinese herbal medicines (27), herbs (28); (29), fish (2), meat (30), and stevia (a sugar substitute) products (31). For geographical origin testing, high value foods inclusive of honey, coffee beans, artisan cheeses, spices, and whiskey were frequently cited for POC testing (15).

Outside the space of food authenticity testing, commodities and products subject to industrial chemical residue testing using POC instruments included fruit, vegetables and cereals (pesticides, insecticides, and fungicide residues) (32), (23). Food safety testing revolved around testing for the presence of mycotoxins (for example, aflatoxins in rice, corn, nuts, chilies and maize) (32), bacteria and other indicators of food spoilage (33), as well as the presence of antibiotics in milk and meat (34).

POC testing for quality control included analysis of crops *in situ* for such characteristics as firmness, pH, moisture, and chemical composition including sugars. This included critical stable crops such as potatoes, yams, and other important root and tuber crops (for example, cassava that are heavily cultivated in the Southern Hemisphere as a main source of carbohydrate and energy for nearly 700 million people) (35).



Feedback from international agencies included the application of POC testing for authenticity/adulteration of herbs and spices. Cited examples included adulteration of oregano with olive leaves, and substitution of saffron with lower grade/different material.

Feedback and discussions at the Focus Group meeting further emphasised the requirement for the area to be intelligence-led rather than instrument/technology-led. POC testing appeared to be most effective when used as part of high-volume repetitive analyses (for example, as part of screening processes), where a single model/method was demonstrated to be cost effective, examples including large grain/rice shipments.

Where possible, combining authenticity and health/safety testing on one product appeared to maximise the use of POC instrumentation, for example when analysing vegetable and mineral oils. Testing of large grain shipments for a range of components and criteria, inclusive of quality, PCBs (polychlorinated biphenyls - industrial products or chemicals found in some pains, glues, plastics, etc.), mycotoxins, aflatoxins, dioxins, pesticides and veterinary drugs were cited. In these instances, many of the analytes were very expensive to test for individually in the laboratory-based environment, and therefore represented an opportunity for POC-based approaches. Handheld refractometers for monitoring sugar content across a range of fresh foods (for example, fruit and vegetables) were shown to be popular in the retail industry.

As a number of POC technologies (for example, spectroscopic-based) are nondestructive, there are opportunities to apply them to sampling expensive commodities such as herbs and spices. Combined feedback from the Focus Group meeting and literature review suggested that POC testing in the topical areas of honey authenticity testing and the detection of allergens in foods represented viable options for the future, with some evidence of current developments in these areas. For example, there have been recent publications citing the use of laser induced breakdown spectroscopy (LIBS) for rapid honey authentication which are laboratory-based (36). Evidence of utility of using a hand-held LIBS *in lieu* of laboratory-based LIBS for the analysis of numerous food groups, claiming comparable or superior accuracy to the laboratory-based counterparts has also been published (15). For example, the classifier accuracy of six distinct varieties of vanilla extract was  $98.30 \pm 0.69\%$  for the handheld device compared with  $94.50 \pm 1.51\%$  for the benchtop LIBS instrument. This particular study by Wu *et al.* (15) exhibited an unusually high level of scientific rigour for the analyses of five distinct food products, with classifier accuracy exceeding 81 % on both platforms. The quality of this study heavily contrasts with the majority of product literature and publications for other vibrational spectroscopy POC devices whereby an example spectrum for the target analyte is commonly the only information provided. The format adopted in the study by Wu *et al.* may perhaps serve as a useful guide for the testing regime for all candidate POC platform technologies. Following the required developmental and full method validation workflows, it may be possible to use a handheld version for any foodstuff that is already amenable to analysis by laboratory-based LIBS.

The FSA POC questionnaire revealed that POC-based food authenticity testing methods have been widely developed to target commodity products. This is particularly prevalent when looking at high value commodities (for example spices), where POC testing may represent a cost-effective way to screen food products. Further insight into what types of commodity (based on the Food and Agriculture Organization of the United Nations criteria) are typically being tested using POC instrumentation highlighted a number of high priority commodities that comprised 'Spices' (66% of question respondents), Eggs (55% of question respondents), 'Meat' (49% of question respondents) and 'Vegetable Oils' (49% of question respondents) which aligns well with the FA0178 project. These priority commodities for POC testing highlight the variety of sample types being characterised using POC-based approaches.

#### Advantages and benefits of POC technologies and instrumentation

Combined intelligence from all of the Tasks comprising Phase 01 identified a range of potential and realised benefits associated with the use of POC testing in the food supply chain. A number of these benefits have been previously described in detail within Defra project FA0178 (6) and will not be detailed in full in this final report for brevity. However, the current FSA project also revealed further details on these or different benefits, which have been elaborated upon below.



Chief amongst these were that the portable nature of POC instrumentation can provide a clear utility for checking/monitoring of different parts and points of interest in the food supply chain. Real-time monitoring may facilitate quick and effective intervention enabling timely quarantine and removal of suspect products from the market. Such testing could also allow stock, samples, or a shipment to be rejected or to stop product distribution, sale and consumption, therefore mitigating safety issues, costly recalls and brand reputational damage.

From a sampling perspective, as POC devices may help support quick and costeffective sampling, this may help support effective sampling of heterogeneous and bulky materials where multiple samples can be analysed at once, reducing sampling error that can be inherent when testing bulk materials. Equally well, the rapidity of sampling may also mean that "sampling hotspots" can be focused on with better ease, for example the targeting of problematic sampling areas such as sample

segregation/sedimentation/layering during transit. POC instrumentation may lend itself well to high volume and repetitive testing in problem areas (for example, grain shipments) linked through to cost-effectiveness. It was also suggested that POC instrumentation being used as an effective screening tool may allow objective prioritisation and reduction of the number of samples sent for expensive laboratory testing, thereby reducing overall testing costs and/or broadening the testing remit.

The utility of POC instrumentation can be extended beyond food authenticity testing and can be used for quality control as well. For example, POC testing can have an application in checking the consistency of a food product along the supply chain and testing that it has not changed, as opposed to testing for specific ingredients.

The cost associated with modern instrumentation continues to be driven down with advances in micro/optical-electronics and the current competitive market environment. Smaller instrument and sample size also often means smaller reagent/consumable volumes, resulting in cost savings and less wastage, having less of a detrimental impact upon sustainability and the environment.

The non-destructive nature of some POC technologies and instrumentation means that they could fill a bespoke niche when sampling for expensive commodities such as herbs



and spices (for example, saffron). The majority of POC instruments are based on vibrational spectroscopy or imaging methods, facilitating non-targeted and multi-analyte approaches. This means that that one such instrument has the potential for multiple uses across different commodities and with a variety of applications.

Feedback provided from representatives from Official Controls based on the original Defra project FA0178 included that the main drivers and benefits were cost and time saving opportunities, highlighting that POC devices had the potential to provide results in real-time.

In terms of the POC technologies themselves, vibrational spectroscopy instruments were generally characterised by ease of use, cost-effectiveness, requirement for minimal sample processing, rapid turnaround time for results, and the ability to be non-destructive in nature. Spectral imaging was also generally non-destructive in nature and could provide spatial distribution information as well as physical attributes and information on chemical components. Antigen lateral flow devices demonstrated ease of use, cost-effectiveness and rapid turnaround time, as well as being disposable in nature.

Nucleic acid lateral flow devices also mirrored the ease of use, cost-effectiveness and are disposable, but still require a multistep process including DNA extraction. DNA barcoding affords a very high level of discrimination between very closely related species, but requires upstream DNA extraction and library preparation by a skilled operator. Mass spectrometry offers high accuracy measurement but is more constrained to chemical analysis and true portability as a handheld device is yet to be fully realised.

Based on the current FSA POC questionnaire, 58% of the total questionnaire respondents confirmed that their organisation conducts food authenticity testing which provides a good level of stakeholder intelligence. In terms of key food authenticity questions, the most common ones appeared to be concerned with 'Does it comply with the label/legal requirement?' (87% of question respondents) and 'Have I got the correct composition?' (67% of respondents). Most authenticity testing was applied 'Upon



receipt' of materials (57% of question respondents) or 'At source' (14% of question respondents).

Analysis of stakeholder feedback captured as part of the current FSA POC questionnaire highlighted a similar set of perceived benefits as previously highlighted by the literature review and Focus Group meeting. This included concepts inclusive of 'Fast turnaround time', 'Cost and time saving' and 'Screening tools', as well as ease of use.

## Barriers to uptake and limitations of POC technologies and instrumentation

A list of barriers to the uptake and perceived limitations associated with POC technologies has previously been described in detail in Defra project FA0178 (6). However, the current FSA project also revealed further details on these as well as different challenges, which have been highlighted below.

The updated literature review frequently cited the accuracy and availability of universal databases/libraries (for example, spectral and sequence) and reference materials to be a limiting factor for effective POC deployment. Universally accessible databases and sharing of information was identified as a current impediment for uptake of POC instruments. Most recently, during late 2023, Wiley and Metrohm launched accessible comprehensive databases for predicted IR spectra (37) and Raman spectra (38), respectively.

Whilst POC devices are characterised by a range of different technologies, the literature review revealed that the deployment of truly portable mass spectrometry instrumentation may be more limited unless the food analysis is linked to industrial chemical detection (39); (23). The more traditional, but in some cases transportable, benchtop mass spectrometry instruments are required to undertake more complex analyses such as speciation and authentication (40).

Whilst vibrational spectroscopy "point-and-shoot" handheld devices offer ease of use, it is often difficult to compare the platform robustness between different devices given the limited spectral wavelength range that the miniaturised platforms offer. There may only



be a partial overlap or no overlap in the operating wavelength range given that devices tend to be tailored for dedicated applications (in terms of the target analyte(s) and test matrix). Due to economic constraints, end-users are often reluctant to purchase multiple devices to facilitate a broader range of applications or analyte testing (41), a finding further reinforced in the Focus Group meetings.

Engagement with international expert groups highlighted the need for credible POC instrumentation. Discussions emphasised the occurrence and possibility of some handheld devices, now available in the public domain, which had undergone costly publicity campaigns but appeared lacking in credible method validation data. Discussions highlighted the need for open access and curated databases, a common theme seen throughout all areas of feedback. Miniaturisation of a piece of equipment may also mean reduced scope or specifications, and method validation of the instrument in a field setting is key. Furthermore, observations regarding POC instrumentation pointed to some results being commodity specific, and transferability was also cited as a potential issue.

The Focus Group meeting reinforced a number of challenges previously identified in the current project. The inherent costs of using POC devices, not just associated with the initial purchase of the instrument, but also for maintenance costs (38), was highlighted. Analytical capabilities of POC devices was a concern, which would benefit from further characterisation through method validation. Error rates of some POC devices were also raised. For more routine applications, it was suggested that POC devices should be simpler to use. Additionally, it was remarked that the scope of the POC application should be better defined to make it clear what commodities, matrices and analytes an instrument was suitable for. As with any analytical approach, the need for appropriate reference materials and access to curated databases was also emphasised. Defining the scope and application of POC testing was also emphasised in published MHRA guidance (10).

Further discussions at the Focus Group highlighted the main use of POC devices for screening purposes, with a potential limitation that samples need to be further verified by confirmatory testing in a laboratory environment, for example for official control



purposes. Coupled with this, it was commented that the error rate associated with POC approaches needed to be fit for purpose (for example, false negative rate), such that genuinely positive samples were not excluded from being analysed in the laboratory environment.

The complexity of sample preparation and sample representativeness were considered barriers, albeit acknowledging that this is not confined just to POC instrumentation. In particular, small sample size could be a concern, particularly so if the original consignment or lot/batch from which this was derived was not considered homogenous.

In terms of multiple use, the application of POC instrumentation to a wide range of matrices and commodities was considered important, particularly when trade variations may make specific previous/historical tests obsolete. It was mentioned that, from a retailer perspective, the ideal situation is to have one POC instrument that has broad analyte and sample applicability (for example, hand-held refractometers to check Brix (sugar content) of some fresh produce) in order to keep costs down.

Whilst it was acknowledged that the field of POC testing for food analysis is in its formative stages, a potential barrier for future uptake, which was emphasised in the Defra FA0178 project (6) but further reinforced by feedback from the POC questionnaire and focus group meeting, could be the lack of quantitative testing capability (for example, for compliance against a threshold level for labelling). It was also remarked upon that the quality of some POC devices could be further improved, citing better design, user interface and removal of software bugs. Additionally, should part of successful application of a POC instrument be kit based, then the consumables/reagents associated with that kit should have a suitable shelf-life. Finally, it was commented that costs associated with both acquisition and maintenance of ISO 17025 for a particular POC test, should this be a requirement, may be inhibitive to uptake.

Re-examination of the original Defra FA0178 (6) questionnaire in terms of relevant responses from those involved in official controls revealed that one of the main limitations was the lack of applicable cost-effective equipment. Accuracy and false (positive/negative) results by some POC instrumentation was also emphasised.



Subsequent stakeholder engagement through the FSA POC questionnaire augmented findings derived from the literature review and Defra POC questionnaire. Preliminary analysis of the current questionnaire highlighted the main perceived limitations of POC-based systems in the food industry which included 'Price/cost', 'Accuracy' and 'Qualitative'. These findings support that the main limitations and barriers have not changed between the current and original POC questionnaire which relates to a 3-year time period.

## Support mechanisms to overcome barriers/limitations of POC technologies

The literature review revealed that different POC device manufacturers implement a plethora of multivariate analyses. It may therefore be helpful to provide end-users with guidelines to understand the purpose of each chemometric approach. This will help support the consumer to make an informed decision when choosing a particular device to use.

In general, more validation studies, especially taking into account real field-based testing constraints, need to be performed. With most cross-platform evaluations, the sample treatment and analysis tend to be executed in the laboratory and there needs to be a holistic view of the feasibility to perform all necessary sample pretreatment steps in a field-based setting in addition to assessing the portability of the analytical step.

For some vibrational spectroscopy POC devices, integration with mobile phones has recently been achieved (42), (43) but there is still scope for more widespread adoption of this approach.

Collating results from the literature review also suggested that universally accessible and curated spectral databases of reference materials would be beneficial. This will help steer end-users to choose the most appropriate limited spectral range handheld device based on the spectral profile of the target analyte.

Key take home messages on POC limitations as highlighted through the Defra project FA0194 "Harmonisation and Standardisation in the Field of Next Generation



Sequencing" (8) and related Government Chemist Programme 2023-2026 projects (9), include the variability in POC instrumentation and results, emphasising the need for appropriate harmonisation and standardisation activities. These projects have also emphasised the importance of establishing performance characteristics and associated minimum performance criteria to demonstrate fitness for purpose. Establishment of guidance on critical steps in the development and application processes, as well as developing a central UK-based POC testing framework, were seen as beneficial. The need for harmonisation in the application of portable instrumentation and associated interpretation of results was also highlighted as applied to the medical field by the MHRA (10).

Engagement with international expert groups echoed a number of the support mechanisms previously mentioned. Method validation remains key in providing objective evidence of the fitness for purpose of a POC instrument. One potential approach is to first validate the method on a bench-top instrument, then show the transferability/robustness of the methods on the hand-held device. Key validation aspects included transferability and applicability (scope) of the method. It was also noted that it would be useful to capitalise upon key learning opportunities in other sectors, for example the successful use of POC instrumentation at Border Controls for the detection of drugs and explosives. The requirement for method validation was also highlighted by the MHRA in relation to published guidance on portable devices in the medical field (10).

It was further reinforced that the area needs to be intelligence led in terms of the food authenticity issue/analytical question dictating what the challenge is, prior to recommending a suitable POC approach. The area of POC testing is very broad, and the commodity, coupled with the analytical question, will help dictate what technology and instrument to apply. The concept of intelligence led recommendations, referred to earlier, was also a central concept discussed at the Focus Group meeting, which emphasised the importance of stating what the analytical question and requirement was. Such intelligence led issues would then help determine the appropriate technology, instrument and application. Development and utility need to be



intelligence/requirement led, such that a technology/instrument is developed to fit a particular food testing need, as opposed to technology led where a food testing need is being used to fit a particular technology/instrument. This should be further augmented through trade/flow led evidence, where goods that are regularly tested for and imported may be best positioned to directly benefit from POC instrumentation.

This intelligence could include the sample type and volume which is being routinely tested for, which can influence the choice of technology and correct application. Such intelligence led recommendations could be used to concentrate on areas where traditional laboratory-based testing is very expensive, hence demonstrating a niche where POC screening devices would be useful. It was seen as beneficial if such intelligence could be steered and provided by reputable and expert bodies inclusive of the NFCU, SFCIU, FSA, FIIN, FAN, Port Health Authority (accounting for the largest amount of imports into the country) and local authority level, etc.

To help promote uptake, it was suggested that it would be beneficial to develop and demonstrate an objective and successful business case using an example POC instrument and application. This could be inclusive of stating what the estimated cost savings were and across what timeframe.

Emphasis from the majority of all stakeholders cited the primary use of the POC instrumentation as screening devices. Discussions at the Focus Group supported the need to develop a central facility (for example, Centre of Expertise) to provide independent advice, selection criteria, and assessment of cost-effectiveness of POC instrumentation, as well as maintain and share relevant databases. Such a central facility could help by maintaining an appropriate reference/database, facilitating objective comparability of results and linking these to a common reference.

The Focus Group meeting also highlighted that costs and funding were a barrier/limitation to uptake of POC instruments. It would therefore be useful to look for opportunities where the areas of authenticity and safety could potentially be combined in the same test for example, formaldehyde as a preservative, vegetable oils, mineral oils, Sudan dye, etc., Finally, provision of guidance on non-targeted and multi-analyte instrumentation would be a benefit.

Analysis of stakeholder feedback captured as part of the current FSA POC questionnaire highlighted a variety of potential support mechanisms to help underpin the usage and uptake of POC-based systems. These included a role for government, regulatory/accreditation organisations or a Centre of Expertise. Such a central facility could help in the provision of financial support, validated methods, organise interlaboratory studies and training/guidance, as well as a general support framework inclusive of appropriate reference libraries/training sets. Additional support mechanisms involve understanding how to improve the interpretation of results, the dependency of POC instrumentation on databases/reference materials and confidence of end-users in POC generated results. Respondents highlighted areas such as 'database curation', 'agreed minimum performance standards' and 'industrywide acceptance thresholds' to support the interpretation of results.

#### Use of POC technologies for official control purposes

A deep-dive into the previous Defra FA0178 (6) questionnaire responses associated with official controls indicated that POC testing had the potential to provide a useful and cost-effective screening test to enable better use of limited budgets. Analysis of the current FSA POC questionnaire identified a set of respondents that stated that they work in official controls (19 out of 72 respondents for this section) and this cohort reported some limited experience (majority response) in the use of POC-based testing for official control purposes. This finding indicated that POC technologies are more widely available/evaluated within the official control community than may have been originally anticipated. Respondents who work within official controls highlighted core areas such as 'Budgets', 'Training, validation and guidance' and 'validation and accreditation' to support the use of POC instrumentation within this sector.

Based on the updated literature review, no uses of POC testing in the framework of UK official controls were cited. On the international side, it was noted that an antigen lateral flow test for pork (specifically porcine heat resistant muscular glycoprotein) was of interest to Jabatan Kemajuan Islam Malaysia (JAKIM) (a regulatory body in the Malaysian government in charge of halal certification of meat to confirm the absence of adulteration with pork) (17), and handheld multispectral fluorescence imaging systems

for the detection of microbial and viral surface contamination may be of interest to food safety inspectors (14). Both of these applications however would benefit from further method validation.

In terms of engagement with international agencies involved in food testing, feedback emphasised that work was still mainly focused on research and development, as opposed to being applied for official control purposes. However, responses also indicated the successful deployment of handheld screening devices at Border Controls for detection of explosives and drugs, which could be a key learning opportunity.

The Focus Group meeting provided a forum for engagement and exchange of ideas and experiences on the utility of POC instrumentation for food testing, with a particular focus on official controls. Whilst there was general recognition by participants that POC technologies should only be used for screening purposes, the scope and utility of the POC application should be addressed through method validation. General feedback acknowledged that "POC technology/instrumentation" was a very broad area, which would potentially benefit from being further sub-divided such that guidance on a more technology/instruments further supported the need to develop a centrally held facility (for example, Centre of Expertise) which would maintain and share updated and curated databases to ensure comparability of results from POC testing. Such a facility could also have a role in provision of independent advice, selection criteria, and assessment of cost-effectiveness of POC instrumentation.

Some participants also felt that minimising exposure to having to take a formal sample for costly and time-consuming laboratory-based analyses could be seen as very beneficial. This could be a role that POC screening approaches may help contribute towards if results are known with confidence. Additionally, there was acknowledgement that, budgetary constraints aside, POC instrumentation would facilitate excellent monitoring and hence control of the food supply chain, due to its portable and rapid nature.

The importance of having correct training and relevant skill sets to operate POC instrumentation was emphasised, in order to make a more informed judgement on the



result. Suggestions were made regarding whether this could be further augmented by using appropriately trained staff from OLs at the site of testing. It was commented that uptake of POC devices would benefit from making the instrumentation and interpretation of results simpler. It was stressed that the instrumentation needs to be easy to use to afford better deployment, ideally in the form of simple and quick one-shot "dip stick" methods. Affordable POC instrumentation may facilitate triaging and allow focus on more urgent areas. An example of £30 per sample test cost was quoted for a POC test to be effective for official controls.

Given budgetary constraints, it was discussed whether it was feasible to have a joint partnership between OLs and industry. This would combine intelligence led aspects with bigger probable budgets and critical mass of food testing, potentially facilitating greater scope and support, where industry may be in favourable position to test products coming into the country and at manufacturing sites.

An additional suggestion was to focus efforts on cross-training of staff associated with Designated Points of Entry into the UK, inclusive of Ports and Borders. The rationale behind this was to help ensure consistency in terms of application of POC technologies and their interpretation, as well as addressing the root cause of the problem for food imports coupled with associated appropriate intelligence gathering.

As with any analytical capability building and maintenance exercise, sources of funding would have to be tapped into to help acquire and maintain any accreditation in the POC area, as well as being needed to help support purchase of the instrumentation and cover running costs.

With respect to a workable operating model for controls using POC instruments, it was recommended that further views be sought with representative cross sections of different regional groups in the UK. Separate local authorities may operate independently and slightly differently, depending upon the available resources inclusive of bespoke Food Standards and Environmental Health officers. Such an engagement activity is also likely to take into account any regional variations in uptake/deployment of bespoke POC instruments (for example, ports compared to large urban conurbations).

# Phase 02 - Development of POC technology guidelines for official controls

Results and conclusions from Phase 01 of the study were used to inform and establish a set of recommendations for developing an infrastructure for guidance for POC testing in the food sector as part of official controls. Feedback from Task 10 on the stakeholder sensibility check of the recommendations with a cohort of official control representatives was used to further refine the resulting guidance and recommendations.

## Scope of the guidance

Feedback from all tasks associated with the Phase 01 horizon scanning and stakeholder engagement exercise (inclusive of the literature review, questionnaires, engagement with national/international bodies and the stakeholder Focus Group meeting), concluded that there was no universally accepted definition associated with POC testing for food analysis.

The plethora of technologies/instrumentation which facilitate POC testing are very diverse and ever-expanding, in line with advances in miniaturisation and portability of analytical equipment. This is further impacted by the variability in food testing applications (authenticity, quality, safety) and the range of commodities where the testing is applied. It is this very diversity which creates a barrier and precludes universal adoption of a single set of guidance, method validation requirements and recommendations for POC testing.

The method validation guidance described below relates to the provision of general guidance which should have universal applicability irrespective of technology, instrument, application or commodity. However, it is recommended that method validation guidance be further examined and developed for individual technologies, instruments, or applications and commodity testing combinations, as per standard practice.



## **Recommendations from Phase 01**

Feedback received from Phase 01 supports the generation of guidance which is bespoke to the specific combination of POC technology, instrument, application and commodity testing. In broad terms, POC technologies can be split into five general subdivisions, which may form an initial basis for generation of specific guidance. These sub-divisions are:

- Rotational vibrational spectroscopy platforms (NIR, FT-IR and Raman)
- Spectral imaging platforms (multi- and hyperspectral imaging)
- Mass spectrometry
- NMR
- Biological analyte-based platforms (proteins and nucleic acid-based)

To help promote uptake of POC testing, feedback from Phase 01 also recommended focusing on instruments which can facilitate multiplicity of testing – those approaches which offer multiple authenticity, safety, quality and commodity testing applications with just the one instrument. One such candidate area for a case study and consideration for further development may be the NIR technology area, as this was identified as one of most common technologies used with a broad range of authenticity, quality, and safety testing applications. This should be coupled with consideration for topical commodity testing, of which feedback from Phase 01 suggested priorities commodities included meat and fish speciation, testing for adulteration in herbs and spices, and detection of allergens in food samples.

Results from Phase 01 also strongly indicated a requirement for the area of POC testing in foods to be intelligence/trade/flow led, rather than instrument/technology led. This concept focusses on provision of evidence from such things as border controls, trading standards, imports and exports, and other ways of monitoring market trends in foods. This will help ensure an informed decision on what testing should be conducted is made, as opposed to the area being led by attempting to find an application for commodity testing which will fit a particular POC instrument.



Feedback from Phase 01 indicated that more generalised advantages of POC testing were well understood, but evidence was also presented from the current project recommending POC application in the following areas:

- Portability and real-time monitoring lending itself well to repetitive testing situations, such as grain or rice shipments/containers;
- The non-destructive nature of some POC approaches may have clear utility for screening high value commodities such as spices (for example, saffron);
- Real-time monitoring may facilitate quick and effective intervention enabling timely quarantine and removal of suspect products from the market. Such testing could also allow stock, samples, or a shipment to be rejected or to stop product distribution, sale and consumption, therefore potentially mitigating safety concerns, costly recalls and brand reputational damage;
- Utility for "sampling hotspots" in a shipment/container due to the portable and real-time nature of POC instruments, allowing problematic areas to be focused on (for example, layering or sedimentation of sample during transit, suspected heterogenous areas, other positional differences, etc.).

Additionally, feedback from Phase 01 also indicated that the miniaturisation of analytical equipment may also result in more restricted scope and specifications of an instrument. It is therefore recommended that POC instrumentation be mainly focused on in terms of utilisation as screening approaches compared to their bench-top based laboratory counterparts.

## **Method validation**

Method validation can be defined as 'Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled' (44). All stakeholders from Phase 01 agreed that method validation (and the generation of method validation data) is a fundamental aspect in providing confidence associated with a result. It appeared that validation data was not always available for each technology/instrument/application/commodity combination, and where it was available, there may be deficits in which performance characteristics were being



assessed. It is a recommendation from this project that any method associated with POC testing be subject to full method validation, in line with standard practices associated with validating a method from any type of instrument.

The process of method validation and method validation principles are contained in a number of key texts. These include the ISO 9000 series on Quality Management Systems, the ISO 16140 series on method validation (in a microbial background), ISO 17468 on technical rules for validation, ISO 17025 for accreditation of methods, a number of EC-JRC ENGL guidance documents illustrating well established and characterised method validation in a foods (GMO) setting, IUPAC recommendations, and Eurachem guides on analytical methods and use of terminology ((45); (46); (47); (48); (49); (50); (51); (52); (53); (54); (55)).

Jointly, a number of these key texts introduce and state the importance of method validation (development and characterisation of a method) and method verification (application of a validated method in a new laboratory), as well as the need for single-laboratory validation and inter-laboratory collaborative trials to provide evidence of the fitness for purpose of a method.

A number of common performance characteristics are jointly referred to in the above key publications, whose assessment is a requirement as part of the method validation process. Full details on the performance characteristics (as well as how to assess these) can be found in the key texts above, but a shortened list is provided here:

**Trueness** (often expressed a bias), which can be defined as "The closeness of agreement between the average value obtained from a large set of test results and an accepted reference value" (44); (49)

**Precision** can be defined as "The closeness of agreement between independent test results obtained under stipulated conditions" (44). Different measures of precision can be made, ranging from repeatability and intermediate precision through to reproducibility.

**Repeatability** can be defined as "measurement precision under a set of in-house repeatability conditions in a specific laboratory. In-house repeatability conditions



include the same measurement procedure, same technicians, same measuring system, same operating conditions, same location and replicate measurements on the same or similar objects over a short period of time in a particular laboratory" (44). It is often expressed as the relative standard deviation calculated from results generated under repeatability conditions (RSD<sub>r</sub>).

**Reproducibility** can be defined as "measurement precision under a set of inhouse reproducibility conditions in a specific laboratory. In-house reproducibility conditions include different technicians, different operating conditions and replicate measurements on the same or similar objects over a longer period of time in a particular laboratory" (46). It is often expressed as the relative standard deviation calculated from results generated under reproducibility conditions (RSD<sub>R</sub>).

**Selectivity** can be defined as "Property of a method to respond exclusively to the characteristic or analyte of interest" (49) and "the extent to which the method can be used to determine particular analytes in mixtures or matrices without interferences from other components of similar behaviour" (56).

**Sensitivity** (biological) is often characterised by the Limit of Detection (LOD) and the Limit of Quantification (LOQ) for molecular biology methods. The LOD can be defined as "The lowest amount or concentration of analyte in a sample, which can be reliably detected, but not necessarily quantified" (49). The LOD will be based on Type I error rate (the probability  $\alpha$  of making a type I error (false positive rate)) and type II error rate (the probability  $\beta$  of making a type II error (false negative rate)) (49). The LOQ can be defined as "The lowest amount or concentration of analyte in a sample that can be reliably quantified with an acceptable level of trueness and precision" (49).

**Robustness** (ruggedness) can be defined as a measure of the method's capacity to remain unaffected by small, but deliberate variations in method parameters. Ruggedness provides an indication of the method's reliability during normal usage" (57).



As part of method validation it is also important to understand and evaluate the **measurement uncertainty** associated with a method. A full description of measurement uncertainty estimation is beyond the remit of the current project, but uncertainty can be defined as "an interval associated with a measurement result which expresses the range of values that can reasonably be attributed to the quantity being measured" (52).

In some cases, it may also be important to characterise additional performance characteristics as part of the method validation process. These will be dependent upon the exact technology/instrument/application/commodity combination. Examples include:

**Applicability**, which can be defined as "The description of analytes, sample materials (matrices) and concentrations to which the module can be applied." (49).

**Practicability**, which can be defined as "The ease of operations, the feasibility and efficiency of implementation, the associated unitary costs (for example cost/sample) of the module." (49).

**Dynamic/working range**, which can be defined as "The range of concentrations over which the module performs in a linear manner with an acceptable level of trueness and precision" (49) and the "interval over which the method provides results with an acceptable uncertainty. The lower end of the working range is bounded by the LOQ" (52).

**Probability of detection (POD)** can be defined as "The probability of a positive analytical outcome for a qualitative method for a given matrix at a given concentration. It is estimated by the expected proportion of positive results for the given matrix at the given analyte concentration" (46), (49).

The literature review also revealed a trend in that in a number of cross-platform evaluations, the sample treatment and analysis tend to be executed in the laboratory as opposed to in the field at the point of test. It is therefore a recommendation that there needs to be a holistic view of the feasibility to perform all necessary sample



pretreatment steps in a field-based setting in addition to assessing the portability of the analytical step.

Alongside evaluation of the performance characteristics as part of method validation, feedback received from stakeholders representing official controls also indicated a preference to evaluate the scope, error rates, quality and user interface of POC instruments. This was following feedback received relating to some experiences regarding software errors, poor workmanship and poor user interfaces associated with some specific POC devices. Equally well, the same cohort also advised that it would be useful to establish guidance on critical steps and minimum performance criteria associated with the application of POC instruments for food testing. The concept of clearly defining the scope and evaluating end-user requirements was also further reinforced through published guidance for portable devices in the medical sector (10).

Although it is universally applicable across all analytical techniques, it was further highlighted in this project that the efficacy of analytical results associated with POC instrumentation is also very much dependent upon access to a universally agreed reference material or materials. Such reference materials allow results to be effectively compared amongst each other relative to a common reference standard.

## **Concept of operations**

The concept of operations (CONOPS) revolves around further elucidation of end-user requirements to make a more informed decision on the applicability of POC testing for specific situations. This further reinforces the perception that one set of guidance notes does not suit every scenario, and that other factors which cannot be evaluated as part of traditional method validation in a laboratory environment play an equally important factor. Assessment of end-user requirements was also a central theme in the published MHRA guidance (10).

Defra project FA0178 discussed many factors which can comprise the concept of operations (6), but a key list of these factors is also presented here for completeness:

- Expense instrument cost, maintenance and servicing, test costs
- Availability of instrument/training/expertise



- Ease of use of the instrument
- Size, weight and portability
- Time to result
- Quantitative capability
- Food types
- Complexity of sample preparation, sample size and representativeness
- Results format and interpretation

Feedback from official control stakeholders further elaborated upon the CONOPS factor of costs associated with POC devices. This cited not only the upfront costs associated with purchasing the initial instrument, but also costs for reagents and consumables, maintenance and calibration/servicing costs, as well as costs associated with acquiring and then maintaining any appropriate accreditation. Costs may also be incurred for training relevant staff on the operation of the POC instrument and how to interpret data.

Feedback from this cohort also cited the requirement for the POC instrument to be easy to use to help afford better uptake and deployment, providing the example of a quick and simple "dip stick" type of approach. It was commented that affordable and accessible POC instrumentation may help facilitate triaging of samples, potentially allowing refocusing of the limited resources on to more urgent sampling and analytical areas.

## Additional feedback from official control stakeholders

Feedback from official control stakeholders also supported overall findings from the rest of the stakeholder engagement exercise of Phase 01 of the current project, in that it is proposed that a centralised UK-based POC testing and advisory framework would be beneficial. This is in the face of an often-bewildering array of different options available for POC instrumentation and in an effort to harmonise the area. It was suggested that such a framework could provide advice on validated methods as well as training and other guidance. The framework could be responsible for providing independent advice on POC instruments and tests, as well as helping assess the cost-effectiveness of POC instrumentation. It was further proposed that the framework could play a key role in



maintaining appropriate reference materials and curated databases, helping ensure comparability of results within the POC testing community. It was further suggested that the framework could also be a conduit for providing financial support in the POC testing area, although how this latter mechanism would function in practice would require further discussion.



Project recommendations	Percentage of
	respondents who either
	'Agree' or 'Strongly
	Agree' with the
	recommendation
The exact combination of POC	90%
technology/instrument/application/commodity often	
precludes universal adoption of a single set of	
guidance, method validation requirements and	
recommendations.	
Validation guidance should be provided on the exact	100%
combination of POC	
technology/instrument/application/commodity.	
Method validation should not be confined to the	100%
laboratory-based environment, but should also take	
into account the field-based setting at the point of	
application.	
Appropriate reference materials and databases should	100%
be developed, maintained and made available to	
enable the proper comparison of results relative to a	
common reference.	
As well as the classical method validation parameters	100%
described above, evaluation of the end-user	
requirements (e.g., instrument costs, running costs,	
accreditation costs, availability, ease of use, training,	
time to result, etc.,) should also be considered.	

**Table 2**. Stakeholder assessment of core project recommendations



Project recommendations	Percentage of respondents who either 'Agree' or 'Strongly Agree' with the recommendation
A case example, based on some of the more promising	90%
POC instrument and commodity combination, should	
be used as a candidate for method validation as an	
illustrative example, clearly demonstrating the utility as	
well as cost-saving potential of the application.	
It would be useful to have a centralised UK-based POC	100%
testing and advisory framework. This could provide a	
harmonised approach to validating methods, training,	
independent advice, assessment of cost effectiveness	
of POC methods, and maintenance and curation of	
open access databases and reference materials to	
ensure comparability of results between laboratories.	
Further engagement with regional groups in the UK	100%
associated with official controls should be sought, in	
order to canvass additional views and regional	
variations for POC requirements.	

A representative cohort of stakeholders involved in official controls (ten representatives from eight official control stakeholder organisations) provided feedback on the main head-line findings associated with the recommendations for the project to help confirm their relevancy and appropriateness for official controls. Stakeholder sentiment feedback clearly showed that the presented core project recommendations (Table 2) were found to be overwhelmingly supported by the questionnaire respondents, with at least 90 % either agreeing or strongly agreeing with the recommendations which demonstrated the appropriate level of relevancy. General feedback arising from this

questionnaire highlighted a variety of concerns within the community that ranged from legislative changes required to permit the use of POC for official controls, streamlining guidance to support standardisation and ensuring that testing employed by enforcement officers should be simple and robust. These recommendations and feedback were incorporated into the final report.

Finally, feedback from official control stakeholders also highlighted the need to seek further engagement with regional groups in the UK associated with official controls, in order to canvass additional views and regional variations for POC requirements. This was based on acknowledging that different local authorities may exhibit different priorities and requirements for sampling and analysis, based on their years of experience and expertise of operating within that field. It was thus important to capture all views within the official control stakeholder community which may exhibit some regional variations.

# **Key recommendations**

The following key recommendations are made as part of this project:

- The plethora of options for POC testing in the food sector is so diverse that this
  often precludes universal adoption of a single set of guidance, method validation
  requirements and recommendations. It is therefore recommended that validation
  guidance should be provided on the specific POC technology, instrument,
  application, and commodity combination. Furthermore, method validation should
  not be confined to the laboratory-based environment, but should also take into
  account the field-based setting at the point of application.
- Appropriate reference materials and open access databases should be developed, maintained and made available to enable the proper comparison of results relative to a common reference.
- As well as more traditional method validation approaches, evaluation of the enduser requirements (for example, instrument costs, running costs, accreditation costs, availability, ease of use, training, time to result, etc.) should also be considered.



- A case example, based on some of the more promising POC instrument and commodity combination, should be used as a candidate for method validation as an illustrative example, clearly demonstrating the utility as well as cost-saving potential of the application.
- It is recommended that a centralised UK-based POC testing and advisory framework be established. This could provide a harmonised approach to validating methods, training, independent advice, assessment of cost effectiveness of POC methods, and maintenance and curation of open access databases and reference materials to ensure comparability of results between laboratories.
- Finally, further engagement with regional groups in the UK associated with official controls should be sought, in order to canvass additional views and regional variations for POC requirements.

# **Further work**

## Method validation: case example

The exact combination of POC technology/instrument/application/commodity precludes universal adoption of a single set of guidance, method validation requirements and recommendations. Validation guidance should therefore be provided on the specific POC technology, instrument, application and commodity combination.

POC instruments which facilitate the following should be prioritised:

- Multi-analyte testing (applications on the one instrument for multiple food authenticity, quality and safety tests);
- Application in repetitive testing situations;
- Non-destructive applications for high value commodities;
- Sampling of problematic/heterogenous sample shipments;



- Real-time monitoring for removal of suspect products destined for the market, enabling the production, distribution, sale or consumption of the product to be stopped;
- Quick, easy and cost-effective to use;
- Utilisation primarily as screening approaches due to potentially more limited specifications/scope following miniaturisation of equipment.

As suggested at the POC Focus Group meeting, it is recommended to develop an objective and successful business case using an example POC instrument coupled with a topical application, clearly demonstrating estimated cost savings across a defined period of time. A case example, based on the most promising POC instrument/commodity combination, should be used as a candidate for method validation as an illustrative example. Evidence suggests that NIR-based instrumentation coupled with testing for meat, fish, herbs and spices or allergens, could be a suitable combination.

As part of the method validation, the following performance characteristics should be evaluated and clearly stated: scope of the method; trueness (bias); precision (both repeatability and reproducibility estimates); selectivity; sensitivity (LOD and LOQ); robustness (ruggedness); error rates; as well as an associated measurement uncertainty estimate. Due consideration should be given to the use of method validation and verification, as well as single-laboratory (intra-laboratory) validation and (interlaboratory) collaborative trials, to provide appropriate estimates of the afore mentioned performance characteristics and objective evidence of the fitness for purpose of that method for the end-user.

As well as the traditional method validation parameters described above, evaluation of factors which contribute to end-user requirements should also be considered. Examples would include POC method expense (instrument cost, maintenance and servicing, test costs, reagent and consumable costs, accreditation costs (acquisition and maintenance)); availability of instrument, training, or expertise; ease of use of the instrument (quality, workmanship, software errors, user interface); size, weight and

portability; time to result; quantitative capability; food types; complexity of sample preparation, sample size and representativeness; results format and interpretation.

# Further assessment of regional differences in official control stakeholder requirements

Further pro-active engagement with regional groups in the UK associated with official controls should be sought, in order to evaluate additional views and potential regional variations for POC requirements. This will help make a more informed decision on representative needs and requirements for POC instrumentation for official controls.

# Conclusion

Whilst there appears to be no universal definition of POC testing for food analysis, this is generally understood to include portable analytical instrumentation which can be deployed at the point of sample testing throughout the food supply chain, frequently offering the potential to screen samples quickly and cost effectively. The plethora of technologies and instrumentation which qualify as POC devices is very wide and ever expanding, as advances continue to be made in miniaturisation and portability of analytical equipment.

Phase 01 of this project, encompassing the "Horizon scanning and Stakeholder Engagement" activities, revealed interesting trends in the uptake and use of POC technologies and instruments for food testing. In recent years, the areas of NIR, Raman and nucleic acid detection methods have shown increased interest. Topical commodity and food testing remains consistent with previous years, with areas inclusive of meat and fish speciation, herbs and spices adulteration analysis, and testing for allergens continuing to remain at the forefront of analyses, but also being joined with quality and safety applications.

Advantages and benefits of POC testing are generally well understood in terms of providing rapid, real-time results as part of effective screening approaches. This project also helped identify the role that POC testing may play for effective monitoring of the



food supply chain, facilitating timely intervention to stop product distribution, sale or consumption where necessary. The non-destructive and non-targeted nature of some POC instruments may also help facilitate greater uptake. Limitations and barriers to uptake of these technologies were also examined, acknowledging that a number of these are universal across any analytical sector, be this laboratory-based or POCbased. Examples included access to appropriate reference materials and curated/harmonised centrally held databases for ease of comparison. Support mechanisms included development of such reference materials and databases, the requirement for the area to be intelligence/trade flow led as opposed to instrument led, augmented by further training and method validation.

Discussions focussing on the use of POC testing for official controls emphasised the potential of POC devices to provide a useful and cost-effective screening test. The importance of method validation to provide objective evidence of the fitness for purpose was reiterated. Whilst the benefits of POC testing for intervention in the food supply chain were stressed, it was also acknowledged that POC testing was a very broad area, and validation and guidance may have to be technology and instrument specific. The importance of training was emphasised, as well as the requirement for cost-effective simple testing solutions in order that POC testing can be more readily used for official controls. Usage should be intelligence led, and the ideal POC instrument would be effective across a range of commodities and matrices, to further increase uptake. It was recommended that further engagement be sought with regional groups in the UK associated with official controls, in order to canvass additional views and regional variations for POC requirements. Additionally, the establishment of a central facility (for example, Centre of Expertise) to provide independent advice and share updated curated databases to ensure comparability of results from POC testing, was discussed as a clear benefit.

Information from Phase 01 "Horizon scanning and Stakeholder Engagement" was used to inform on the direction of travel of Phase 02 "Development of POC Technology Guidelines for Official Controls". Phase 02 focused on provision of recommendations for developing an infrastructure for guidance for POC instrumentation in the food sector.



Recommendations focused on the central aspects of the need to assess end-user requirements (the CONOPS), alongside classic method validation parameters. Key recommendations and findings included method validation to be performed on the specific combination of POC technology/instrument/application/ commodity as per standard practice, to validate the method performance in the context of field-based setting at the point of application, to develop appropriate reference materials and databases, to evaluate end-user requirements, and to develop a centralised UK-based POC testing and advisory framework for provision of advice and support as an aid to harmonisation.

Whilst the advantages of POC testing for food analysis are relatively well understood, further harmonisation is required in this area to enable the full potential of analysis using POC instruments to be realised and results interpreted with confidence. Following extensive stakeholder engagement and feedback exercises, this report has provided a set of guidelines and recommendations to help enable the development of an infrastructure to support such harmonisation. The study culminates in two additional recommendations for future work to further promote utility of POC applications for food testing, these being to validate a specific POC application coupled with a topical commodity testing application as a case example to demonstrate the advantages and cost saving opportunities, as well as further engagement with different regional official control stakeholder groups, to better capture any regional differences and end-user requirements.

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# Annexes

# Annex 1 – SurveyMonkey questionnaire text

### Questionnaire: Point of Contact Testing within the Foods Sector

#### Introduction

The last decade has witnessed significant advances in analytical technologies with the capabilities to support food integrity and authenticity testing within the rapidly evolving food industry. Devices that allow diagnostic tests to be performed at or near the point of need, often termed Point-of-contact (POC), represent a growing area within the food sector with the potential to provide real-time monitoring of input materials and production process. POC devices can range from handheld spectroscopic devices such as Raman and FT-IR instruments to desktop portable systems inclusive of compact mass spectrometry, NMR and next generation sequencing (NGS) systems.

The National Measurement Laboratory at LGC are leading on an FSA funded project investigating the utility and potential of POC technologies in the food sector and have devised this questionnaire to support the evidence building phase of the project. The questionnaire is targeted at individuals involved in the food supply and allied sectors, including primary production, supply, manufacturing, and enforcement/regulations. Your participation in this questionnaire will directly help inform the direction of the project and contribute to guidance within the sector.

Please do not provide any information that could be used to identify you. Thank you for participating in our questionnaire which should only take around 15 minutes to complete.

#### About you

1. Country/area of residence



- Africa
- Americas
- Asia
- Europe
- Oceania
- United Kingdom of Great Britain and Northern
- Ireland
- 2. Which of the following best describes you occupation? (please select which applies)
  - Academic
  - Accreditation
  - Analyst
  - Authority, e.g., Trading Standards
  - Food safety manager
  - Laboratory manager
  - Management
  - Official controls and enforcement
  - Research scientist
  - Sales/marketing
  - Student
  - Supply chain assurance
  - Quality manager
  - Other (please specify)

3. Approximate number of employees in your organisation? (please select which applies)

- Less than 10
- Between 11 and 50
- Between 51 and 250
- More than 250



- 4. Which food related sector(s) do you work in? (please select all that apply)
  - Academia
  - Consultancy/training
  - Distribution
  - Equipment/instrumentation
  - Farming/primary production
  - Manufacturing
  - Primary processing
  - Research
  - Regulatory
  - Retail
  - Testing
  - Other (please specify)
- 5. Which of the following best describes your organisation? (please tick all that apply)
  - Accreditation body
  - Enforcement
  - Farming/primary production
  - Government
  - Manufacturing
  - Official controls
  - Private testing laboratory
  - Regulatory body
  - University/Research Institute
  - Other (please specify)

#### About food authenticity testing in your organisation

6. Does your organisation conduct food authenticity testing? e.g., performed inhouse or

commissioned testing (please select which applies)



- Yes
- No

7. What are your key food authenticity questions? (please select \* all that apply)

- Does it comply with the label/legal requirement?
- Have I got what I ordered?
- Have I got the correct grade/quality?
- Have I got the correct quantity?
- Have I got the correct functionality? e.g.,
- nutritional content.
- Have I got the correct composition?
- Is it the correct country of origin?
- Not sure
- Other (please specify)
- 8. What food component are you typically targeting as part of your testing system?

9. When does your organisation typically employ authenticity testing? (please select which applies)

- At source
- At the port of entry
- Upon receipt
- Not sure
- Other (please specify)

10. Which types of test sample are most frequently encountered?

#### Your thoughts regarding POC testing

- 11. What do you understand by the concept of 'Point-of-Contact' testing?
- 12. In your opinion, what are the key current and future applications for POC-based

testing within the foods industry?



13. What do you see POC systems being primarily used within the foods sector? (please select all that apply)

- Confirmatory tools
- Monitoring processes
- Presumptive testing
- Real-time testing
- Screening tools
- Quantitative testing
- Qualitative testing
- Not sure
- Other (please specify)

14. What are the main analytical points were POC instrumentation is being used for food authenticity testing? (please select all which apply)

- At source
- At the port of entry
- In transit/distribution
- Upon receipt to factory/warehouse
- Post-production
- Not sure
- Other (please specify)

15. What core technologies do you feel currently fit under the POC umbrella term and likely to play an important role in the future? (please select all that apply)

- Chromatographic, e.g. HPLC
- Chemical, e.g. colorimetric
- Gravimetric, e.g. mass
- Immunological, e.g. ELISA
- Imaging
- Nucleic acid testing, including PCR and Sequencing



- Mass spectrometry
- Microbiology
- Microscopy
- Spectroscopic, including NIR and Raman
- Not sure
- Other (please specify)

16. Which of the following commodity types (defined by FAO criteria) are POC instruments currently being applied to and what level of priority would you rate this application? (please rate the testing priority level using the scale 'Low', 'Medium' and 'High')

- Alcoholic beverages
- Animal fats
- Cereals (excluding
- beer)
- Eggs
- Fish and sea food
- Fruit (excluding
- wine)
- Meat (slaughtered)
- Milk (excl. butter)
- Miscellaneous, e.g.,
- infant food
- Oil crops
- Pulses
- Spices
- Starchy roots
- Stimulants, e.g.,
- coffee & tea
- Sugar crops



- Sweeteners
- Tree nuts
- Vegetable oils
- Vegetables
- Other (please specify)

## **POC support**

17. In your opinion, what are the main benefits of POC-based systems in the foods industry?

18. In your opinion, what are the main limitations of POC-based systems in the foods industry?

19. What needs to be done in order to overcome some of these limitations/barriers and help promote the uptake of POC instrumentation?

20. What type of support from Government and regulatory/accreditation organisations could help the application of POC testing?

21. What is required to support the validation of POC technology for specific food authenticity applications?

22. What aspects associated with application of POC technologies, and the interpretation of results would benefit more from further refinement, harmonisation and guidelines?

23. What dependency do POC instrumentation have on databases and reference materials?

24. What confidence do end-users see in results from POC instrumentation, and is there a need for further confirmatory analysis?

25. Please rank the following POC device support attributes in order of priority (please select all that apply and the associated testing priority level using the scale 'Low', 'Medium' and 'High')



- Availability of reference materials
- Comprehensive training and user community
- Freely available reference databases/libraries
- Strong regulatory framework
- Further comments

#### **Official controls**

26. Do you work in official controls

- Yes
- No

27. What is your experience of using POC-based testing for official control purposes?

- None
- Limited
- Extensive

28. What is required to support the use of POC instrumentation for official control

purposes?

29. Any further comments?

## About POC testing in your business/organisation

\* 30. Do you use Point-of-Contact (POC)-based tests in your business/organisation?, e.g. tests performed using portable or hand-held testing devices (please select which applies)

- Yes
- No

31. Where in your business/organisation do you use POC-based testing? (please select all that apply)



- At source
- At the port of entry
- In transit/distribution
- Upon receipt to factory/warehouse
- Post-production
- Not sure

32. What type of POC technologies are currently employed to perform testing? (please select all that apply)

- Chromatographic, e.g. HPLC
- Chemical, e.g. colorimetric
- Gravimetric, e.g. mass
- Immunological, e.g. ELISA
- Imaging
- Nucleic acid testing, including PCR and sequencing
- Mass spectrometry
- Microbiology
- Microscopy
- Spectroscopic, including NIR and Raman
- Not sure
- Other (please specify)

33. What type of POC testing was performed and please indicate whether the method was accredited?

34. How do you utilise POC testing in your analytical workflow? e.g., screening only or in combination with a confirmatory test

## Your practical experience with POC testing

35. Do you have any practical experience of POC testing within the foods sector? (please select which applies)



- Yes
- No
- 36. What type of POC testing was performed?
- 37. Which types/models of POC instruments/systems have you used?
- 38. Your overall experience of using POC systems

### Additional feedback

The questionnaire organisers would welcome any additional feedback on areas such as POC testing, including for use in Official Controls or general food authenticity testing.

39. Any additional feedback?

Please click on 'Done' in order to submit or 'Prev' to edit your responses.

We would like to thank you for participating in this questionnaire. Please feel free to contact the LGC project team at foods.support@lgcgroup.com if you wish to discuss the role of POC technologies further or have any related queries.

