Food Standards Agency

Phase 2: Review of the UK's official food and feed laboratories

EY Executive Summary report: 29 March 2019

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This Executive Summary report does not include the substantive sections as presented in our Final report.

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Executive Summary



Executive Summary – Background



Background

The Food Standards Agency (FSA) has responsibility at central Government level for the main body of food and feed safety law in England, Wales and Northern Ireland. The FSA is the Central Competent Authority (CCA) for enforcement. Food Standards Scotland (FSS) undertakes a similar role in Scotland.

In accordance with legislation, part of the CCAs' remit includes responsibility for ensuring the United Kingdom (UK) has sufficient laboratory capacity and capability to deliver official controls to ensure the safety and standards of food and animal feed stuffs.

Over the years, there has been a decrease in the overall number of Official Laboratories (OLs) which can undertake food and feed enforcement, as the work has been contracted out of Local Authority (LA) owned laboratories to others in the OL network.

This has necessitated the FSA and Government Departments to consider whether they will have access to sufficient laboratory services after European Union (EU) Exit in order to undertake their legislative Competent Authority (CA) responsibilities. This, along with wider issues in laboratory capacity and capability both pre- and post- EU Exit, led to the FSA Board to endorse a formal review of the UK official laboratory system.

OLs are defined in Regulation (EU) 2017/625 (EU Reg 625) and include official feed and food laboratories that undertake official control work for CCAs. In the UK, some of the OLs are designated as Official Control Laboratories (OCLs). OCLs are designated by the FSA/FSS in primary legislation and include both public and private sector Public Analysts (PAs)*, Agricultural Analyst (AA)* laboratories and government laboratories including those for microbiological services with Food Examiners (FE)*.

The public-sector laboratories include those owned by LAs and Government Departments across the UK. Laboratories that undertake work for the CCAs and their agencies or Directorates, such as the Health and Safety Executive (HSE) and the Veterinary Medicines Directorate (VMD), are also designated OLs. This network of laboratories undertakes work for the FSA, FSS, Department for Environment, Food and Rural Affairs (Defra), Department of Health and Social Care (DHSC), Public Health agencies in England, Wales and Northern Ireland, Scottish Government, LAs and Trading Standards across the UK.



* See glossary on page 26 for further detail

Executive Summary – Background



Background

EU Reference Laboratories (EURLs) are tasked with ensuring high-quality and uniform testing throughout the EU and their tasks, duties and requirements are defined in Regulation (EU) 882/2004 (superseded by EU Reg 625). Furthermore, the EURLs support the European Commission (EC) with risk management and risk assessment. EURLs support National Reference Laboratories (NRLs) by providing analytical methods and diagnostic techniques, training NRL staff, providing the EC with scientific and technical expertise relating to laboratory analysis and collaborate with laboratories in non-EU countries. EURLs are funded annually through the EU.

NRLs support the OCL/OL network in providing specialist expertise and training. They are tasked with coordinating and organising the activities of the official laboratories and disseminating results appropriately.

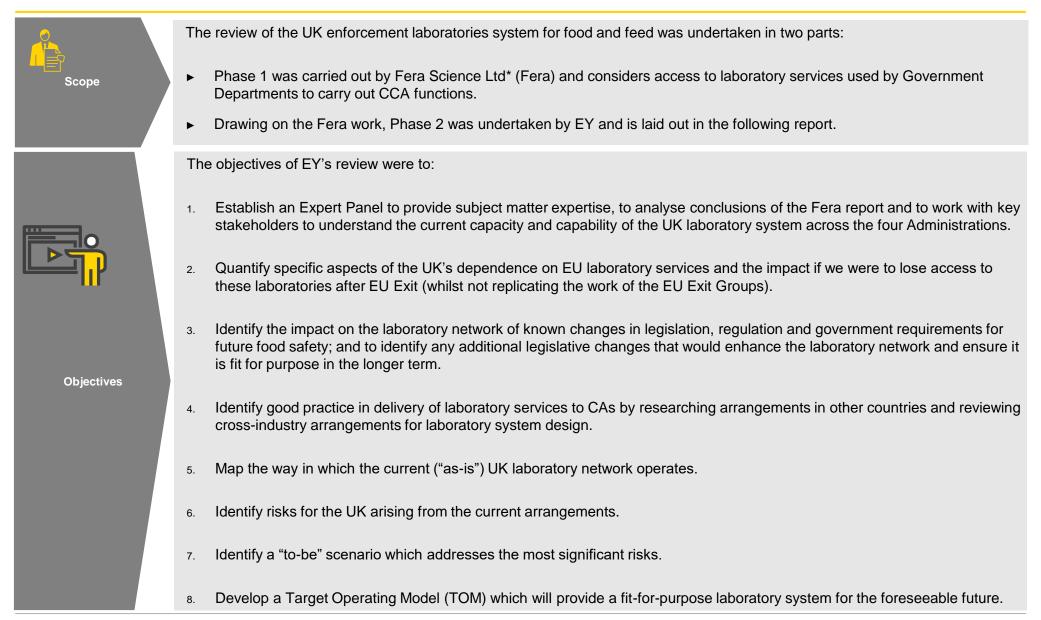
OCLs carry out the analysis of samples taken during official controls. To be considered as an OCL, laboratories must be compliant with and accredited for the standard ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories". In addition, labs should also be accredited for the appropriate methods of analysis to be used in the analyses they intend to undertake.

Arrangements for commissioning laboratory testing services to support official control, enforcement and surveillance activities for food and feed differ in the four UK countries, encompassing a range of funding models with variable reliance on financial support and contract work from LAs and Central Government, in addition to commercial income.

The exceptions to these arrangements are the surveillance programmes for residues of veterinary medicines and pesticides, where Defra is the CCA. These programmes already comply with specific structured and detailed legislative requirements, and are organised centrally by the VMD and the HSE, covering the whole of the UK. The cost of the veterinary medicines programme is covered by the agriculture industry and the pesticides programme is funded jointly by the agriculture industry and Government.



Executive Summary – Scope and Objectives



* See glossary on page 26 for further detail

Executive Summary – Assumptions and Limitations

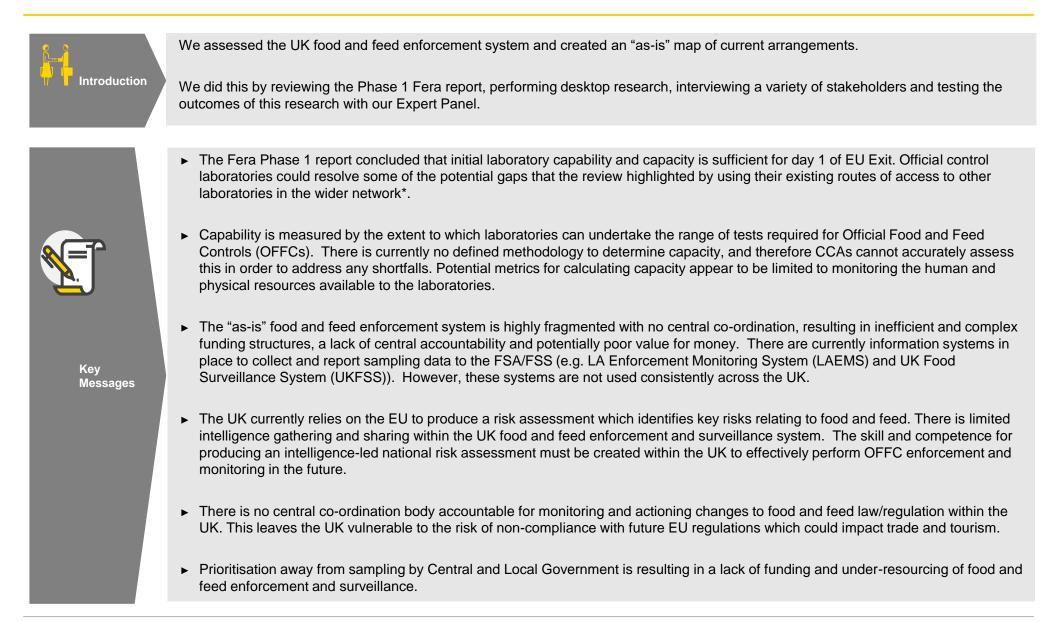


Assumptions and Limitations

- The Phase 2 review built on the information collected by Fera. Working drafts were made available to us from 14 December 2018 and the final report was provided to EY on 07 March 2019. EY did not perform any procedures to confirm the accuracy of the information in the Phase 1 report.
- To supplement the Fera report, EY and the FSA/FSS carried out a further survey of laboratory arrangements. All research and informationgathering was concluded on or before 15 February 2019 and therefore responses received later were not considered in this report.
- The extent of fragmentation of the UK food and feed network was greater than initially thought and EY engaged with a wide variety of stakeholders to obtain a holistic view, facilitated by the FSA/FSS. The extent of stakeholder engagement was limited to those identified during the course of the review and their availability for interview.
- There are a number of working groups set up by Defra, the FSA, Department for International Trade, other Government Departments and agencies to address potential risks surrounding EU Exit and we have not duplicated their activities.
- The UK has made a commitment (as part of the EU Withdrawal Act) to adopt and comply with EU food and feed regulations, after necessary UK considerations and changes. EU Reg 625 is being drafted into UK legislation. The specifics of this exercise are beyond the scope of this review and are being considered by a separate working group.
- There is a lack of clarity around whether some current "partnering"/sub-contracting arrangements related to laboratory services will be acceptable under EU Reg 625 and clarification is being sought by the FSA separately to our review.
- Research into global and cross-industry testing arrangements were limited to publicly-available information, which itself was limited by stakeholders' concerns relating to commercial confidentiality.
- ► The proposed options for the TOM were based on the information made available to us during the course of the review.
- No separate deliverable was produced by the Expert Panel, whose role was to use their knowledge and experience to challenge and test our findings and conclusions.
- ▶ Further assumptions and limitations are noted per section in the Final report.



Executive Summary – Current situation



Executive Summary – Risk Assessment

Introduction

We carried out a risk assessment on the "as-is" situation to identify mitigating actions which could reduce risks to an acceptable level. These actions informed our "to-be" options and the building blocks for a new TOM.

We identified the following high risks in the current UK food and feed enforcement system. In no particular order, these risks are:

High Risks	Mitigation
Insufficient risk assessment undertaken in the UK, as UK depends upon risk assessment currently created by the EU	Implement a UK intelligence-led risk assessment and risk management function possibly within a central body accountable for food and feed oversight/enforcement.
Fragmented system with no co-ordination and accountability resulting in potentially ineffective use of resources	Establish a central Accountable Body to coordinate, create and manage risk assessment.
Lack of centralisation, standardisation and sharing of existing resources	Create a Commissioning Body to direct samples and improve food and feed safety enforcement, streamline testing and gain efficiencies.
Fragmentation of the system results in financial and labour inefficiencies	Develop more co-ordinated and efficient system for commissioning of testing.
Inability to plan for required capacity and capability	Establish a nationally recognised method to measure capacity and capability. Implement a national risk assessment which accounts for the available capacity and capability, identifying where additional resources/services are required and enabling sufficient contingency to address unplanned incidents.
Negative impact to "UK brand" based on perceived weaknesses in the UK food and feed enforcement system	Implement a coordinated UK framework where parties are accountable for their involvement in the system. Establish a clear 'line of sight' between policy creation and delivery to inform the narrative and give confidence in the system. This narrative should include a consistent message of how the UK ensures food and feed are safe.
Limited use of private laboratories due to potential conflicts of interest	Co-ordinate activity, via a central Commissioning Body, to ensure that nationally there is a minimum of two suppliers with capacity and capability to carry out each test to address any surge in requirements.
Budget fragmentation and a lack of central accountability results in no clear picture of overall spend on OFFC and potentially lost efficiencies in the system	Simplify the food and feed safety enforcement system and streamline funding, assuming current resources are sufficient.
Actual or perceived increase in the number of food safety incidents impacting consumers, tourism and trade	Central Accountable Body to hold CAs to account for implementing required surveillance and sample testing in accordance with a national risk assessment. Accountable body to have the responsibility for immediately responding to threats both in terms of minimising risks and in handling the media, based on the narrative created.
Limited priority of sampling is given by Central and Local Government resulting in a lack of funding allocation and under-resourcing of food and feed enforcement and surveillance	Strong leadership at national level to promote the importance of food and feed safety and necessity for adequate measures to be taken at a local level. Create new ways of funding testing that are not reliant on public money and so give added resilience to the UK framework in case of funding cuts or constraints.
Insufficient succession planning around Official Control Scientists (i.e. PA, FE, AA)	Assign appointment responsibility to the Central Accountable Body, who can then also undertake succession planning.
Samples are compromised in the collection process	Implement effective and consistent training, and introduce a new requirement for specific Continuous Professional Development (CPD) for Authorised Sampling Officers (ASOs).
Inability to access specialised information and databases (e.g. Genome Sequencing Database) limiting number of laboratories which can comment on specific test findings	Use the Commissioning Body to direct tests to the laboratories which hold the relevant databases. Investigate whether databases can be located centrally and perhaps accessed under licence. Increase levels of information-sharing and intelligence gathering where possible.
Lack of demand resulting in demise of specialist skills/knowledge/ methodology/equipment	Central Commissioning Body to co-ordinate and direct testing to appropriate to ensure specialist resources are maintained.



Executive Summary – "To-Be" Model



The risks arising from the current system mean the UK cannot continue with the system as is. We used our risk assessment, research, including global and cross-industry good practice, to identify a set of potential changes and proposed a new operating model. To underpin this, we developed a set of design principles. We tested these with the Expert Panel to ensure they were fit for purpose. We then created a set of options for the "to-be" model and summarised the advantages and disadvantages of each one. This resulted in a TOM comprising a specific combination of the options to take forward, which is summarised on the following pages.



Global and cross industry insights

- The Netherlands went through a centralisation process and efficiencies were secured by reducing the number of laboratories from 24 to six. A further reduction from six to one did not provide additional value.
- Germany has a well funded laboratory system with high sampling and detection rates. However, this does not directly equate to a "better" system as Germany is currently ranked third in terms of the Rapid Alert System for Food and Feed (RASFF), compared to the UK's second place.
- The Republic of Ireland (ROI) has a similar structure to the UK laboratory network and has continued to designate PAs. However, it interprets "suitably qualified" differently to the UK and the ROI PA qualification no longer includes the Mastership in Chemical Analysis (MChemA). This creates an opportunity for the UK to revisit the requirements of the PA qualification, while retaining the same level of quality.
- All other countries reviewed appear to use a centrally coordinated national plan/risk assessment, which results in more directed and informed sampling. The UK could use this approach to improve OFFC enforcement and surveillance.
- The UK food and feed enforcement system could benefit from applying a model similar to the National Intelligence Model employed by the Police Forensic System. This would align LA food sampling with a centrally coordinated national sampling plan, taking into account information provided by the LAs as well as national risks. This model is already used by FSA/FSS in other areas e.g. FSA uses this model for feed testing in England and FSA/FSS use this system to address food fraud.
- The water industry has a supplier-funded and driven system where the onus for water safety lies with the water suppliers. The introduction of a business-funded levy could increase funding for UK OFFC enforcement and surveillance.



Executive Summary – Design Principles

Introduction	 Any future TOM must deliver FSA's and FSS' purpose of ensuring the food and feed in the UK is safe. It must: be based on current requirements be sufficiently flexible to accommodate future changes minimise the risks resulting from shortfalls in the current operating model. Our proposed TOM is based on the following design principles:
Food and Feed Safety Enforcement	
Strategic	Delivering long term priorities for the whole sector, aligned from the top down
Efficient	Resources used in the most effective manner to maximise investment and minimise competition
Accountable	Each party in the system clearly accountable for their actions, with strong leadership
Simplified	Straightforward, transparent system with minimal fragmentation
Sustainable	Long term protection of UK consumers, tourists and trade
Informed	Activities and decisions underpinned by shared information and processes
Co ordinated	All Administrations working together, with processes standardised as much as possible



Executive Summary – "To-Be" Model



Building blocks

We identified six key areas where improvements could be made to address the risks in the current system and in each area (or building block) we identified a number of options (see page 13). We then selected the most practical option from each building block to form our TOM (see page 14).

The six building blocks are:

Strategy and Accountability

Options for providing an oversight structure which is responsible for determining the national strategy and holds stakeholders accountable for the actions they are delegated to perform.

Funding

Options for generating additional income for the purpose of carrying out the UK's OFFC.

Organisation of Laboratories

Options for structuring the laboratory network to enable efficient use of resources and effective delivery of testing.

• Public Analysts' Appointment

Options for locating PAs within the system to ensure continuity of service.

• Public Analysts' Qualification

Options for revising the PA qualification requirements.

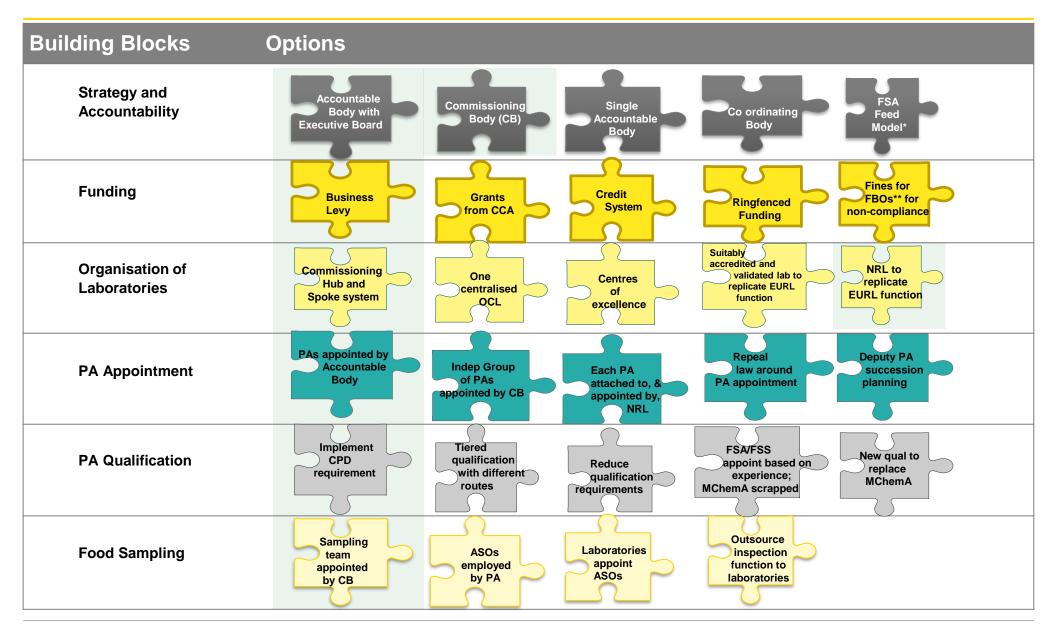
• Food Sampling

Options for improving the organisation and reporting structures of ASOs.

Considering the current political climate and various factors, these options can be implemented in isolation or in tandem.

In addition to this, we suggested a number of options for the co-ordination of LAs' sampling strategies.

Executive Summary – Building Block Options



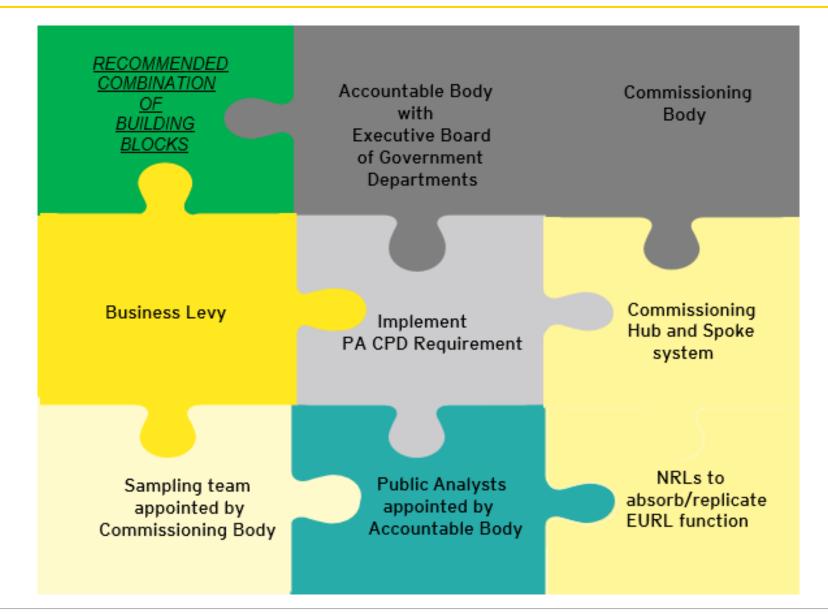
* See glossary on page 26 for further detail

** See list of abbreviations on pages 22-24

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Executive Summary – Combining the Building Blocks





Executive Summary – Recommended Building Blocks



Strategy and Accountability:

Accountable Body with an Executive Board, which includes representatives from all CCAs (from all Administrations) and potentially from industry. The Accountable Body would be responsible for defining strategy, risk assessment and management, national sampling strategy and priorities. It would hold all other parties to account for delivering their part of the food and feed enforcement process.

All CCAs to use a single Commissioning Body to execute and coordinate intelligence gathering by CAs, to be fed back to Accountable Body to inform the risk assessment and national priorities. The Commissioning Body will also review sampling plans provided by LAs etc to ensure sampling is efficient throughout the UK. This Commissioning Body could also undertake a "hub" role, directing samples to specific laboratories according to need (see below).

Funding:

A business funded levy, calculated on one of a range of possible metrics e.g. advertising, VAT, revenue, etc.

For example: if a levy of 0.01% of revenue were imposed on all food/feed businesses that pay VAT (with a tax free threshold of £100k per business), a conservative estimate is that this would raise around £9.3m of additional funding for food and feed testing.

Organisation of Laboratories:

Commissioning Hub plus "spoke" laboratory system – the hub would direct samples to specific OCLs/OLs in order to build economies of scale. Samples would be directed for testing based on a variety of factors such as time/distance travelled, laboratory capacity/capability, access to relevant database to interpret findings, etc. ASOs transport these samples directly from FBO to lab performing the testing.

Co-ordinating requests nationally would ensure no laboratory incurs high costs for tests which are only required in very small numbers.

No change to number or location of laboratories or to current arrangements for highly specialised testing. However, the Hub could maintain a database to ensure there are at least two potential suppliers (OCLs / private / outside of the UK) with the ability to undertake every OFFC test required.

NRLs to retain their current function and additionally to absorb/replicate functions of the EURLs (see page 5 for information on NRL and EURL functions).

Public Analysts' Appointment:

All PAs would be appointed by the new Accountable/Commissioning Body.

Public Analysts' Qualification:

All PAs would be required to demonstrate specific CPD (in addition to MChemA or equivalent qualification) to demonstrate currency of knowledge.

Food Sampling:

Sampling team appointed by Commissioning Body, which ensures training standards are met and maintained. The team operates on a Regional basis, working alongside and under the instruction of LAs.



Executive Summary – Recommended TOM



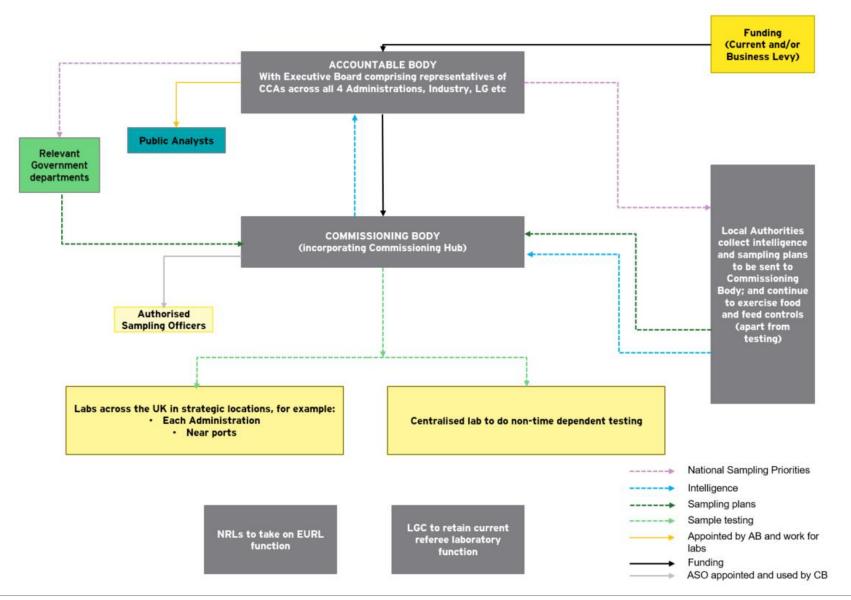
Linking the building blocks to the Recommended TOM The Building Blocks in the earlier pages have been organized into one TOM, illustrated on the following page.

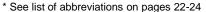
For ease of reference, we have highlighted the components of the TOM in the same colours as the building block pieces in pages 13 and 14.

Detailed explanations of the building block options, including pros and cons, can be found in the body of the report.



Executive Summary – Recommended TOM







Executive Summary – Conclusion

8 2	We have recommended a TOM, which is a combination of options, incorporates all design principles and includes the following:
	One central Accountable Body coordinating the creation and delivery of an intelligence-led national risk assessment – potentially FSA/FSS-led. This central accountable body will have an Executive Board which brings together representation from all Government Departments and bodies which undertake testing to provide rigorous oversight, accountability and cost-effective delivery.
Recommended TOM Summary	 Central Commissioning Body with responsibility for delivering the strategy set by the Accountable Body, informing the local delivery of food and feed enforcement and monitoring to ensure food and feed are safe for public needs.
	 Co-ordinated planning and delivery of sample testing to nominated OCLs increasing the efficiency of the system, reducing costs, and enabling an effective response in times of surge or threat.
	 Effective feedback of testing and other enforcement procedures to drive improvement in the national strategy and in the intelligence-led risk assessment.
	For the CCAs to achieve their objectives in the delivery of food and feed safety, the TOM must:
Conclusion	 Prioritise public safety and ensure consumer/public protection
	 Actively manage and centrally co-ordinate food and feed enforcement and surveillance
	 Create and enforce a clear narrative and national risk assessment
	Maintain public and stakeholder confidence
	 Require and encourage intelligence sharing
	 Encourage and support fair trade, overseas investment and local tourism.



Executive Summary – Next Steps

Short-Term

• FSA/FSS to confirm their roles in decision-making and change management.

• Establish communication with all UK groups working on related EU Exit issues to inform the process of decision-making and change management.

• Develop a narrative to address questions from trade and media around how the UK ensures food and feed is safe.

• Continue efforts to clarify partnering/sub-contracting under EU Reg 625.

• Confirm operational areas where change can make the greatest impact and socialize the key TOM components, focusing on "quick wins".

Medium-Term

• Build the TOM which enables delivery of the UK's objectives for food and feed enforcement and surveillance.

• Create a plan for implementation of the desired TOM, including transitional arrangements.

• Assess the capacity and capability of the UK food and feed enforcement system and plan for at least two laboratories to have capacity and capability to fulfil each OFFC testing requirement.

• Develop the skills and expertise to create a UK-wide risk assessment and identify key sources of information to underpin its delivery.

- Allocate responsibility for monitoring changes to EU/other regulations and ensuring an appropriate UK response to maintain trade relationships.
- Review the application of "suitably qualified" insofar as it relates to the PA qualification requirements.

Long-Term

- Ensure the narrative is consistently delivered, maintained and revised at reasonable intervals.
- Establish systems to ensure consistent and responsive implementation of the TOM across all stakeholders as needs change.
- Establish succession planning for all skills/expertise to maintain the desired TOM, including systems to retain sufficient organisational memory to respond appropriately to required change.
- Develop and maintain intelligencegathering systems.
- Continue timely system updates to respond to changes in EU and other countries' critical regulations which affect food and feed to protect consumers and maintain and increase levels of trade and tourism.











Appendix A - Abbreviations

Abbreviation	Description
AA	Agricultural Analyst
ASO	Authorised Sampling Officer
BEIS	Department for Business, Energy and Industrial Strategy
CA	Competent Authority
СВ	Commissioning Body
CCA	Central Competent Authority
CPD	Continuous Professional Development
CRD	Chemicals Residue Division
DAERA	Department of Agriculture, Environment and Rural Affairs in Northern Ireland
Defra	Department for Environment, Food and Rural Affairs
DHSC	Department of Health and Social Care
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
EU Reg 625	Regulation (EU) 2017/625
EURL	European Union Reference Laboratory
FBO	Food Business Operator
FE	Food Examiner
Fera	Fera Science Ltd
Fol	Freedom of Information
FSA	Food Standards Agency



Appendix A - Abbreviations

Abbreviation	Description
FSS	Food Standards Scotland
HMRC	HM Revenue and Customs
НМТ	HM Treasury
HSE	Health and Safety Executive
IMSOC	Integrated Management System for Official Controls
IPAFFS	Imports of Products, Animals, Food and Feed System
LA	Local Authority
LAEMS	Local Authority Enforcement Monitoring System
LG	Local Government
LGC	Laboratory of the Government Chemist
LIMS	Laboratory Information Management System
MChemA	Mastership in Chemical Analysis
MHCLG	Ministry of Housing, Communities and Local Government
NRL	National Reference Laboratory
NVWA	Netherlands Food and Consumer Product Safety Authority
OCL	Official Control Laboratory
OFFC	Official Food and Feed Controls
OL	Official Laboratory
OPSS	Office for Product Safety and Standards



Appendix A - Abbreviations

Abbreviation	Description
РА	Public Analyst
PHA	Port Health Authority
PHE	Public Health England
РНО	Port Health Officer
RASFF	Rapid Alert System for Food and Feed
ROI	Republic of Ireland
RSC	Royal Society of Chemistry
SME	Small and Medium sized Enterprises
ТОМ	Target Operating Model
TRACES	Trade Control and Expert System
UK	United Kingdom
UKAS	United Kingdom Accreditation Service
UKFSS	United Kingdom Food Surveillance System
VMD	Veterinary Medicines Directorate
WGS	Whole Genome Sequencing
WUR	Wageningen University and Research







Appendix B - Glossary

Term	Description
Agricultural Analyst	An Agricultural Analyst is a food scientist qualified under the UK Feed (Sampling and Analysis and Specified Undesirable Substances) Regulations 2010 and appointed by a UK Food Authority under section 67 of the UK Agricultural Act 1970. An AA undertakes analysis of feed and fertilizer samples.
Fera	Fera Science Ltd is a joint venture between Defra and Capita and a national and international centre of excellence for interdisciplinary investigation and problem solving across plant and bee health, crop protection, sustainable agriculture, food and feed quality and chemical safety in the environment.
FSA Feed Model	 'New Feed Delivery Model' is a multi-faceted solution to improve the effectiveness of official feed controls, delivered in partnership with key stakeholders, ensuring timely, appropriate, proportionate and consistent delivery of controls to secure compliance with feed law. This model includes: National Trading Standards Feed Delivery Programme Inland Feed Inspection Programme Local and national co-ordinated sampling programmes Regional Point of Entry Import Controls Activity Programme Feed Delivery Programme Improvement Projects.
Food Examiner	A Food Examiner is a food scientist qualified under the UK Food Safety (Sampling & Qualifications) Regulations 2013 and instructed by the UK Food Authority under section 27 of the Food Safety Act 1990 to undertake microbiological examination of food samples.
Public Analyst	A Public Analyst is a food scientist qualified under the UK Food Safety (Sampling & Qualifications) Regulations 2013 and appointed by a UK Food Authority under section 27 of the Food Safety Act 1990 to undertake chemical analysis of food samples



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