FSA SAMPLING STRATEGY: OUR FUTURE APPROACH TO SAMPLING

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1. Introduction

1.1 The Board is asked to:

- Provide strategic direction on our proposed future approach to sampling and in particular:
  - Our rationale for sampling and;
  - The guiding principles that will underpin design and delivery of future sampling exercises;
- Review and endorse our plans for implementation of sampling approaches within the wider approach to surveillance.

2. Background

2.1 Sampling (and the analysis of those samples) for chemical and microbiological risks, underpins the work of the FSA and others, such as Local Authorities (LAs), in maintaining the safety and authenticity of the food supply chain. It supports the FSA's statutory obligations as a regulator, provides vital evidence and data, and is an integral part of its wider surveillance efforts. Ultimately it is an essential component required to protect consumers.

2.2 Yet while essential, it is not infallible or without challenges. Sampling and analysis can be costly and place a resource burden on those delivering it. It can also create false reassurance; poorly designed and delivered sampling programmes will deliver unreliable or even meaningless data. These factors are compounded by the diversity of drivers behind the need for sampling and the fragmented nature of the sampling stakeholder landscape.

2.3 The challenges of delivering an effective sampling programme are clearly demonstrated by reviewing the performance of the FSA's National Coordinated Sampling Programme (NCSP), which ended in 2016-17. Ultimately this programme was complex and provided poor value for money; costing £2.2M at its peak in 2013-14, yet often failing to deliver the desired benefits. Further issues were linked to the UK Food Surveillance System (UKFSS), a national database for the central storage of analytical results from feed and food samples, taken by enforcement authorities (e.g. local and port health authorities, DAERA in NI) as part of their official controls. Patchy uptake of the UKFSS (e.g. with only 50% of English LAs using it) and data quality issues, meant that access to meaningful data through this system was variable. Ultimately these issues combined to prompt the cessation of the NCSP but in turn allowed investment to be focused on building a new surveillance approach,

designed to deal with EU Exit. This has put the FSA in a better overall position and one upon which we can build a re-designed sampling strategy.

2.4 While the NCSP was flawed, its absence has (in part) contributed to a decline in sampling activity by LAs. The FSA sees sampling as playing an essential role in maintaining food standards and we now need to decide what national strategic approach is required.

2.5 The strategy presented here is designed to address this challenge, demonstrating how the FSA, working with LAs and other competent authorities, can deliver an effective sampling programme, that not only links to the wider surveillance activities of the Agency and others in the UK and internationally but which delivers excellent outcomes and value for taxpayers.

3. Sampling as Part of Surveillance

3.1 Sampling must be seen as a core component of our wider surveillance programme; as a valuable source of data, to sit alongside other types of self-generated data collection and those datasets obtained from external sources.

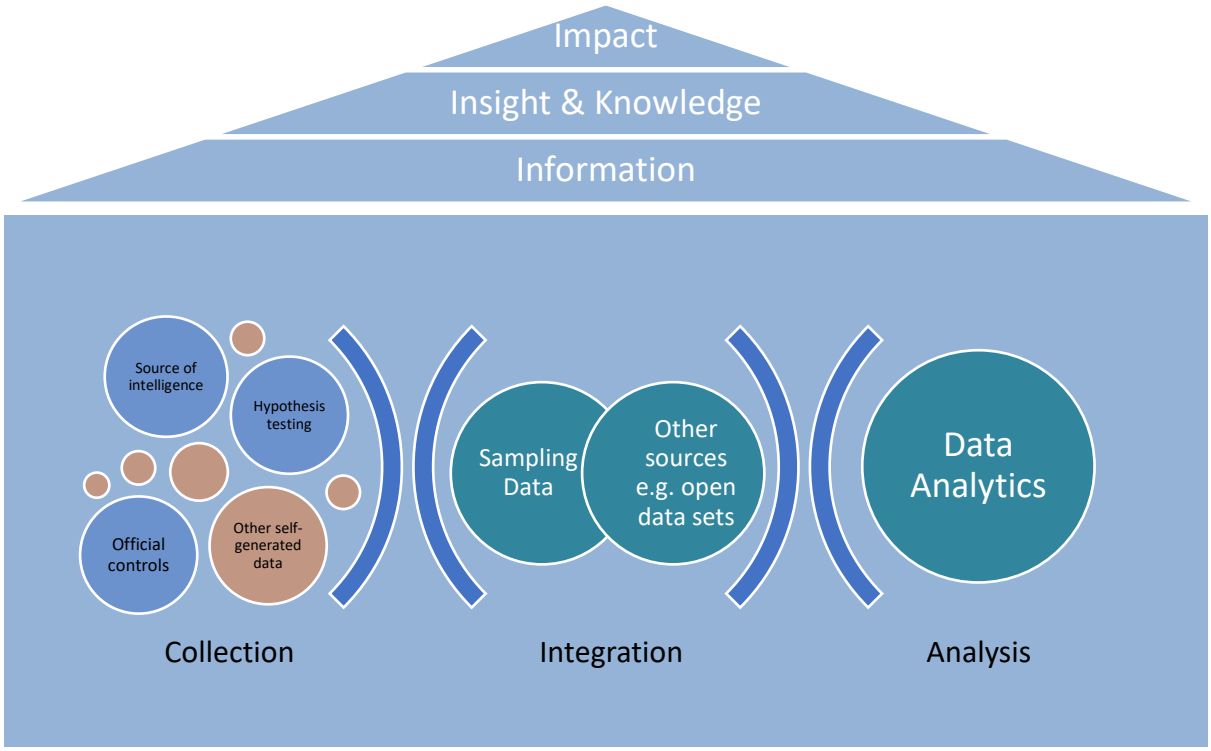
3.2 In this context, sampling sits within a three-stage surveillance data system (Fig. 1); as a means of collecting data (Stage 1) which can then be integrated with other data (Stage 2), before being analysed (Stage 3). In this way data can be used to generate meaningful 'information', which in turn creates 'insight & knowledge', which we use to make decisions and sometimes take-action ('impact'). This follows the data pyramid model, as highlighted in the recent FSA Chief Scientific Advisor's report on data standards[1].

4. Sampling Stakeholder Mapping

4.1 Given the diversity of food sampling purposes both within the FSA and across the UK, it is important to map out the key stakeholders - both internal and external – required to deliver and support an effective sampling strategy. An outline summary of this mapping is included in Annex 1. This will be further developed as the sampling strategy becomes implemented and embedded (see Implementation, Phase 1, section 31).

[1] https://www.food.gov.uk/sites/default/files/media/document/chief-scientific-advisers-report-on-data-standards.pdf

Figure 1: How sampling fits within the data pyramid model



5. The FSA's Sampling Strategy

Overview

5.1 Building on work started in 2018, the FSA has been developing its sampling strategy; clarifying the rationale for conducting sampling and presenting its overarching approach to how it will be delivered. The strategy will work as both internal guidance for those across the FSA who are commissioning sampling but can also be used by external partners, competent authorities and stakeholders; providing clarification of the FSA's role and obligations in this area.

5.2 The strategy has been specifically designed to link to other ongoing initiatives and activities, for example the review of Official Control Laboratories and our strategic surveillance work.

5.3 Overall the strategy is designed as a high-level, holistic framework, setting-out and guiding our approach to sampling and how we can use this to influence others engaged in sampling. It is intended to steer direction when developing new sampling activities but not to act as a comprehensive 'instruction manual' for delivering them.

Our rationale for sampling

5.4 Following on from the reference to sampling made in the December 2018 Board paper on surveillance[2], it is clear that 'sampling' means different things to different people and serves different purposes. Therefore, there is a need to provide clarity and a rationale for the different types of sampling that the FSA and competent authorities conduct or support. We are using three categories of sampling activity:

i. Sampling as a source of intelligence data

5.5 Results from analysis of samples collected by others – including local authorities and industry (for example through the Food Industry Intelligence Network) – are a crucial input to our surveillance capability. Although results of small, ad hoc, local or intelligence-led sampling programmes conducted by others, may be of limited value individually, we are developing tools and using algorithms which allow us to integrate multiple data sets.

5.6 To get maximum value we need to be able to identify, access, interrogate and integrate data from sampling programmes conducted by others. We would not expect to pay for access to data but may enter into agreements with others to govern our access to and use of data. We continue to encourage all actors in the food system to publish their data as Open Data[3] but recognise this is a long-term ambition or may be limited because of the sensitivity of the data involved.

5.7 Our position as central competent authority for food and feed gives legitimacy to our role in setting and promulgating standards for data and metadata (which will help integration of different data sets) and endorsing fit-for-purpose analytical methods (to support confidence in the quality of the data we use).

ii. Sampling as a means of testing hypotheses

5.8 Our strategic surveillance capability may generate hypotheses, for example about the potential for contamination or adulteration of the UK food supply, that we need to test. Where there is no existing authoritative data that would allow us to do this, new sampling and analysis may provide a means of testing the hypothesis.

5.9 In designing and implementing sampling to test hypotheses, you need to balance statistical power, risk appetite and cost. An important part of the process of setting an appropriate sampling frame is deciding on the power needed. Put simply, the greater the certainty of detecting a low-frequency event you require, the more samples you need to take and the more expensive the sampling and analysis will be. Decisions should account for power and opportunity cost, among other factors.

[2] https://www.food.gov.uk/sites/default/files/media/document/fsa-18-12-07-annual-surveillance-report-final_1.pdf

[3] DEFINITION: Open data is data that can be freely used, re-used and redistributed by anyone - subject only, at most, to the requirement to attribute and share alike.

5.10 In this area, we would expect to pay for data collection, although would look for opportunities for cost sharing with others, provided this did not compromise our ability to test our hypothesis. We will commission the collection and analysis of samples as for any other piece of evidence gathering; balancing speed, cost and quality. As the commissioning body, we would expect to set the sampling frame, clearly identifying the point(s) in the food supply chain at which samples are taken, to specify acceptable method(s) of analysis, and to specify standards for data collection and transmission. For example, the data collected would be assumed to be published as Open Data.

5.11 The aim of this sampling will be to support, or discount, hypotheses generated by our surveillance capability and in this way to inform the development of national enforcement priorities.

5.12 As our data-driven surveillance approach develops, and its use expands, this area of sampling is likely to become increasingly important to validate and quality assure the outputs of our enhanced modelling and data analytics capability.

iii. Sampling for the purpose of official controls

5.13 Sampling as an official control fulfils a diverse range of functions and is a key element for an effective integrated official control programme. Sampling activities range from being a tool for ensuring verification of compliance with feed and food law in individual food establishments (that are undertaken on a risk basis decided locally), to the classification and monitoring sampling of shellfish production areas, where legislation stipulates a specific programme of sampling and where the coordination and cost of this statutory duty is shared between the FSA as the CCA and LAs as the CAs.

5.14 Sampling of this type is undertaken by the relevant competent authority (which may be local authorities, DAERA or the FSA) and those samples are analysed by an official control laboratory and may be used as the basis for enforcement action (as determined in the Food Law Code of Practice).

5.15 While this contrasts with sampling described in the previous phase of hypothesis testing, the two phases are linked. By performing sampling that allows us to test and confirm a hypothesis that relates to a risk to food or feed safety or authenticity, we can incorporate these issues into the national enforcement priorities, which we set jointly with local authorities, allowing for the development of a co-ordinated programme for official sampling and testing.

5.16 Where official control sampling is undertaken, we will need to work closely with the relevant authorities and official control laboratories taking and analysing the samples, to agree and implement an appropriate sampling frame, agree acceptable methods of analysis, and set out arrangements for recording, collating and transmitting the resultant analytical data to appropriate data standards. Where the sampling is undertaken by local authorities, the decision

as to any enforcement action rests with the local authority in line with their individual enforcement policies.

The guiding principles of the sampling strategy

5.17 While the purpose and context of sampling will vary, there are consistent, generic and coherent overarching guiding principles that underpin the design and delivery of sampling schemes (Fig. 2). These nine guiding principles for sampling should be:

1) Sampling programmes should be evidence-based ensuring that they are directed based upon risk and/or intelligence.
2) Sampling programmes should be based on sound statistics to ensure that any data generated is meaningful, robust and defendable. Using statistically-driven sampling approaches ensures that the number of samples taken is appropriate to address the purpose for which it was designed and offers value for money.
3) Sampling programmes should be outcome driven, ensuring that the purpose of any sampling is clearly determined as part of the programme design process.
4) Sampling programmes should be designed and conducted openly and transparently. Accepting commercial in confidence, GDPR and other legal considerations, the aim should be that all sampling data, with the associated sampling and analysis methods regime, is published.
5) Where possible, sampling activities should be co-ordinated to maximise efficiency and effectiveness. In addition to internal co-ordination, cross-government partnership will also be essential, with an initial focus on working with:
    a. Food Standards Scotland: as the FSA's strategy covers England, Wales and Northern Ireland, UK co-ordination can only be achieved through strong co-operation with FSS. They too are developing a sampling strategy[4] and both agencies are actively engaging to ensure synergy and alignment.
    b. Defra: as the policy lead on food labelling and non-food safety standards, Defra is also developing a strategic approach to sampling. As with the FSS, the opportunities to avoid overlaps and seek synergies exist and as a result we are actively engaging with Defra too.
6) To ensure mutual recognition, sampling and testing should align to international standards (e.g. Codex, ISO), both in terms of high-level principles (e.g. CCMAS CAC/GL 50-2004 General Guidelines on Sampling) but also specific sampling standards (where applicable).
7) When sampling activities are being designed, due consideration should be given to the physical sample and its associated meta-data, including how it is collected, stored, retained and archived. The potential for using samples for multiple purposes should be considered accepting that there may be benefits of 'collect once, test for many' in terms of efficiency

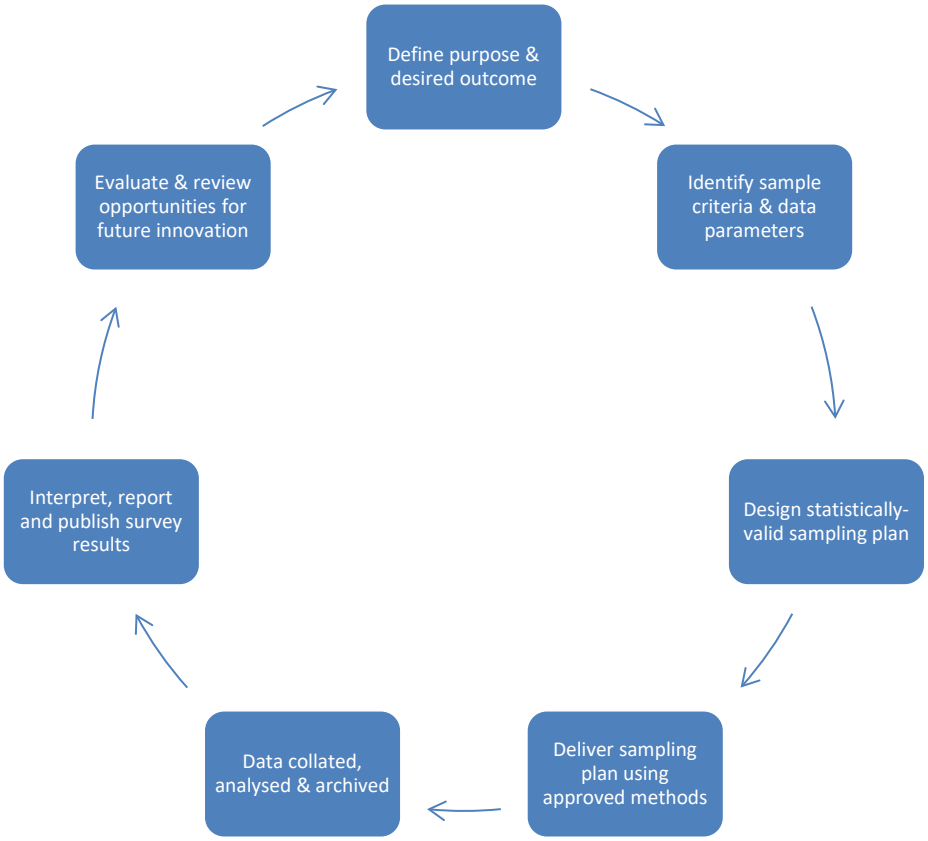
[4] 'A sustainable strategy for food sampling in Scotland'

(noting that this will only be possible with certain types of sampling e.g. not enforcement samples).

8) As part of the ongoing development of sampling approaches, insights from horizon-scanning and technology foresight should be used to identify and drive innovation in our approach to improve efficacy and efficiency. Examples might be the use of new digital technology, such as AI.

9) Sampling programmes should be subject to regular review and evaluation to ensure that they are delivering both the required outcomes and value.

Figure 2: How the guiding principles impact on the design and delivery of sampling activities



6. Implementation

6.1 Subject to the Board's recommendations, the sampling strategy will be finalised, and implementation started within Q2 of this financial year (target date: September 2019).

6.2 Given the size and complexity of strategy, the implementation project has been designed in two phases:

- **Phase 1** will focus on finalising the strategy, based upon the Board's discussion and decisions, and establishing governance approaches. This phase will be focused on the first three quarters of 2019.
- **Phase 2** will focus on fully implementing the strategy, including the development of new tools and embedding the strategy across the FSA. This phase will be focused across 2020.

Phase 1 implementation

6.3 To ensure effective governance and cross-agency engagement, an FSA-sampling working group will be established (either as a stand-alone group or as part of a wider surveillance programme board). Working to EMT-agreed Terms of Reference, this group will bring together the appropriate FSA team to ensure effective cross-Directorate support and leadership and provide linkage through to other initiatives/activities across the FSA e.g. those involved in the operational delivery of strategic surveillance.

6.4 As part of the implementation a detailed sampling roadmap will be developed. This will show the timeline and key milestones for the future development and implementation of the sampling strategy, covering 19-20 and 20-21. It will also include critical review points: key amongst these being a progress review paper to be presented to the Board (target date: June 2020).

6.5 To ensure effective implementation and engagement across the FSA, with other FSA initiatives (e.g. Strategic Surveillance) and external (e.g. OGDs) food sampling activities, the sampling mapping exercise (present here in outline; Annex 1) will be finalised with appropriate granularity to ensure the all required connections are visible, ensuring full alignment can be achieved (target date: September 2019).

6.6 In order to develop effective partnerships with others from across government (in particular FSS and Defra), a new cross-governmental sampling steering group will be established. This group will provide a conduit for co-ordination of sampling activities, agreeing common standards and information exchange. This aligns to principle 5 above (target date: December 2019).

6.7 To provide guidance to those developing sampling activities, a set of sampling guidelines will be developed, based around the guiding principles (especially principles 1-4, 6 & 7) and using the framework identified in Fig. 2 (target date: December 2019).

Phase 2 implementation

6.8 As prioritised under the guiding principles (principle 9), we will need to assess the outputs and evaluate the impact of our sampling activities. To achieve this, a new sampling evaluation process/system for will be developed.

6.9 As the strategy is implemented, key consideration will need to be given to sample data management (principles 4 & 7), to ensure data is freely accessible, standardised and of the appropriate quality (e.g. with suitable meta-data). This will need to include discussions regarding the future of UKFSS and should this system be upgraded or replaced, or whether alternative arrangements can be identified.

6.10 The implementation of the sampling strategy will be aligned with the Official Control Laboratories review, which is reporting in 2019. The OCL review has also considered the role of sampling in terms of national testing capability and within the strategy, the potential role for public analysts and National Reference Laboratories (NRLs) in co-ordination, advice provision and method development should be explored. This work aligns to principles 5, 6 & 7.

6.11 To support implementation of principle 8, an innovation programme will be established. Working with the outputs from the FSA's Science Council Working Group 3 report on Horizon Scanning[5] and other sources, this will identify new technologies with the potential for driving innovation in sampling (e.g. new digital tools or portable diagnostics). This co-ordinated R&D programme will utilise the FSA's Strategic Evidence Fund (SEF), as well as being informed by in-flight projects e.g. the '21st century Abattoir' and 'Internet of Food Things'.

7. Conclusions

7.1 The development of an effective sampling strategy is essential to ensure the FSA can deliver its purpose and value for money. This paper lays out the rationale for sampling, the strategic sampling framework the FSA intends to use in the future and the approach it is taking to develop and implement that strategy. To achieve this, the Board is asked to:

- Provide strategic direction on our proposed future approach to sampling and in particular:
  - Our rationale for sampling and;
  - The guiding principles that will underpin design and delivery of future sampling exercises;
- Review and endorse our plans for implementation of sampling approaches within the wider approach to surveillance.

[5] paper to be presented at June 2019 Board

Annex 1: Sampling mapping exercise

- To understand the diversity of sampling activities conducted across the food supply chain by the FSA, other competent authorities/government departments, a mapping exercise was conducted. This involved collating data from multiple teams within the FSA to understand the types and volumes of sampling, and where these aligned to the work of others.
- The data collected from this will be used as the starting point for a detailed mapping (Phase 1 implementation; see this paper Page 8, Section 33), which will identify critical linkages and key dependencies. This will steer our future engagement and provide the basis for identifying which stakeholders and partners are essential to create a joined-up approach to sampling.
- In this annex we provide a high-level overview of the sampling landscape, highlighting:
    - Sampling responsibilities across government
    - Sampling activity mapped across the FSA
    - Sampling by category and description

This Annex consists of three tables/figures:

- Table 1: Division of responsibility for official controls based upon The United Kingdom Multi-Annual National Control Plan (UK MANCP 2013-2019)
- Figure 1: Summary of sampling activity across the FSA by directorate, unit/division, based upon three sampling categories (as identified in this paper; section entitled Our rationale for sampling, page 3)
- Table 2: Overview of sampling carried out by category with summary description

Table 1: Division of responsibility for official controls based upon The United Kingdom Multi-Annual National Control Plan (UK MANCP 2013-2019) [6]

FSA & FSS[a]	Food Law	General - traceability, hygiene, rapid alert system (RASFF[b])	Import controls (public health aspects)	Labelling – all general labelling, food safety aspects (incl. allergens); nutritional & health claim (Scotland, Wales & Northern Ireland)	Composition and standards (Scotland, Wales & Northern Ireland) except for organic products	Biological safety, e.g. transmittable spongiform encephalopathies (TSEs), salmonella	Chemical safety, e.g. additives, contaminants, food contact materials	Biotechnology, genetically modified food
	Feed Law	General – traceability, rapid alert system (RASFF[b])	Import controls (public health aspects)	Labelling	Composition and standards	Biological safety, e.g. feed hygiene	Chemical safety (prohibited & undesirable substances)	Biotechnology, genetically modified feed
Defra[c] (& its agencies), SG AFRC[d], WG NR[e] & DAERA[f]	Food Law		Import controls, (animal health aspects for products of animal origin)	Beef labelling, protected food name, general labelling where does not relate to safety or nutrition	Composition and standards except for food for particular nutritional uses (England); organic products (all UK)		Pesticides residues of veterinary products	
	Feed Law	Animal by-products			Feed ban	Medicated feed	Chemical safety	Specified feed additives
DH[g], HSE[h] (CRD[i])	Food Law			Labelling nutrition and nutritional health claims (England)	Composition and standards for foods for particular nutritional uses		Residues of pesticides	
FBOs[k]	Food Law	Food business operators ensuring foods and feeds satisfy the requirements of food and feed laws at all stages of production, processing and distribution, from farm to fork						
	Feed Law							

[a] Food Standards Scotland (FSS)
[b] Rapid Alert System for Food and Feed (RASFF)
[c] Department for Environment, Food and Rural Affairs (Defra)
[d] Scottish Government Agriculture, Food and Rural Communities Directorate (SG AFRC)
[e] Welsh Government Natural Resources (WG NR)
[f] Department of Agriculture, Environment and Rural Affairs in Northern Ireland (DAERA)
[g] Department of Health (DH)
[h] Health and Safety Executive (HSE)
[i] Chemicals Regulation Directorate (CRD)
[k] Food Business Operators (FBOs)

[6] https://www.food.gov.uk/sites/default/files/media/document/uk-multi-national-control-plan-2013-2019-updated-2018-2.pdf

Figure 1: Summary of sampling activity across the FSA by directorate, unit/division, based upon three sampling categories (as identified in this paper; section entitled *Our rationale for sampling*, page 3)

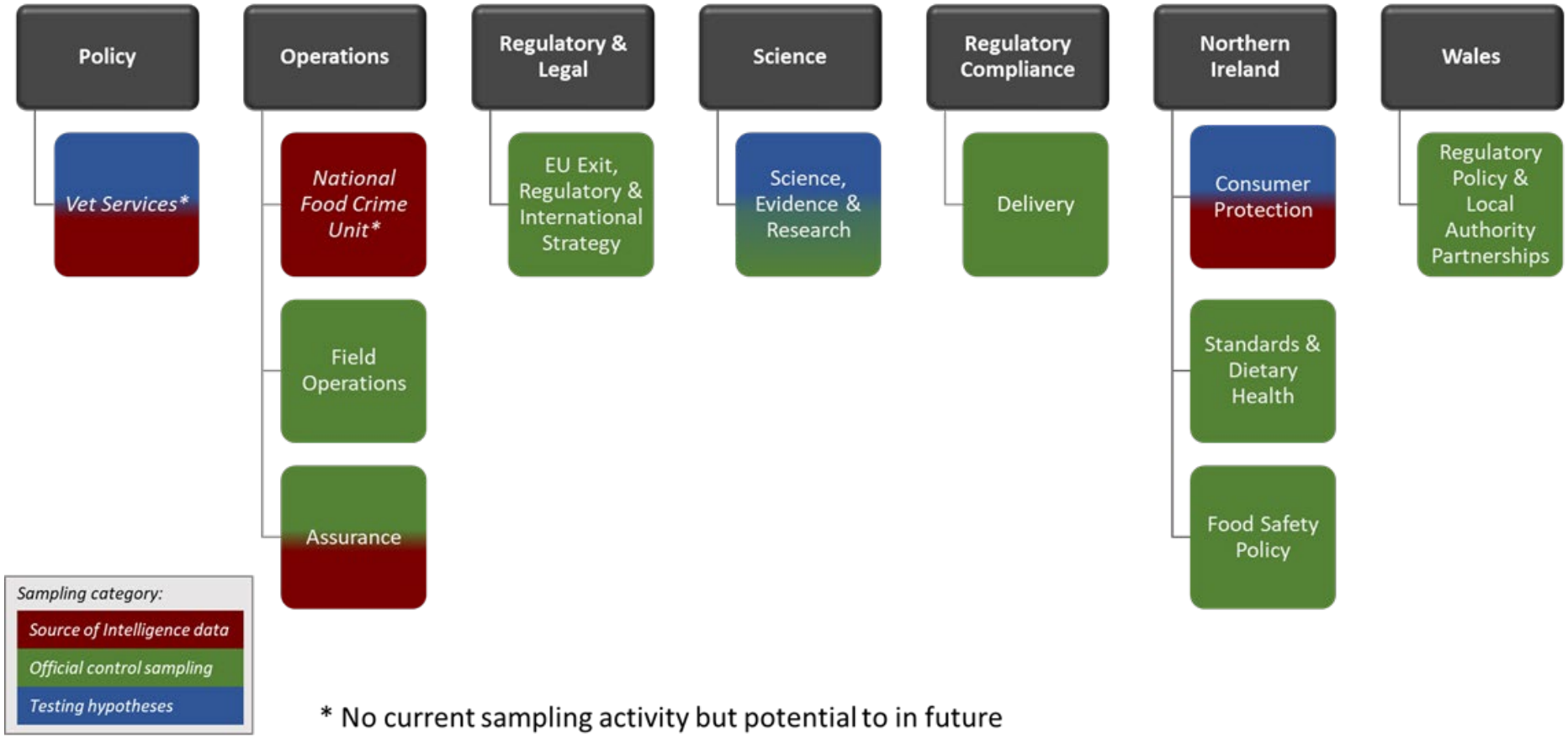


Table 2: Overview of sampling carried out by category with summary description

Category	Description	Responsible party	Key External Partners	Number of samples	Frequency
Official control sampling	• Fulfilling the legal requirements set out in the regulations • Official control monitoring programmes • Testing, monitoring and providing advice to food business operators	• FSA • Local Authorities	• Local Authorities • Public sector organisations (including laboratory & science agencies, other government departments, national trading standards) • Private sector organisations (mostly testing laboratories) • Public analysts, official control laboratories, & national reference laboratories • Food business operators	• Decided by individual authorities (from zero to thousands per annum) • Decided by FSA (range from ~20 to ~500,000)	• Ongoing routine sampling • Ad-hoc/one-off • Monthly/weekly • Annual programme
Source of Intelligence data	• Investigation samples • Follow-up samples • Compliance samples	• FSA	• Local Authorities • Other Government Departments	• Decided by FSA teams/units (from 10s to 1,000s)	• Ad-hoc/one-off • Annual programme
Testing hypotheses	• Evidence generation & data collection	• FSA	• Public and private sector R&D providers	• Project specific (from 10s to 1,000s)	• Ad-hoc/one-off • Annual programme