

Primary Authority National Inspection Strategy Draft Criteria and Guidance
Draft for comment by external stakeholders, version 1
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Introduction

The Department for Business, Energy and Industrial Strategy (BEIS) Primary Authority Statutory Guidance document¹ details what is expected of a primary authority when developing a national inspection strategy. The document sets out what must be included in the rationale document that is submitted to the Secretary of State for consent.

The Statutory Guidance states that when developing a national inspection strategy, primary authorities must take account of any relevant national regulators' published strategies, guidance, priority topics or risk assessment methodologies, and obligations set by relevant national regulators.

As the national regulator for food, the Food Standards Agency (FSA) has specified a set of criteria that needs to be in place for a primary authority to operate a national inspection strategy for food hygiene and/or food standards. Primary authorities will need to satisfy the FSA that they meet each of the criteria relevant to their partnership before they implement a national inspection strategy for food.

We advise that primary authorities seeking to develop a national inspection strategy for food engage with the FSA at the earliest opportunity to discuss their proposal and how they intend to demonstrate meeting the relevant criteria.

This document sets out the FSA's criteria, and provides primary authorities with guidance as to how they may demonstrate meeting them. There is more than one way of demonstrating meeting each criterion and the examples provided are not exhaustive.

This document will develop into the FSA Standard for primary authorities wishing to establish and operate a national inspection strategy.

¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/648597/primary-authority-statutory-guidance-2017.pdf

Number	Criteria	Essential to demonstrate	Advice for food hygiene and standards partnerships
1.	The national inspection strategy is appropriate for the business (or group of businesses)	<ul style="list-style-type: none"> • The business (or group of businesses) is subject to regular proactive interventions by local authorities. The type and number of establishments, a description of the typical the Food Law Code of Practice intervention rating categories, and the number of proactive interventions received during the previous 12-month period, must be provided to the FSA. The number of reactive food related referrals made to the primary authority in the previous 12 months must also be provided to the FSA. • The business has sustained levels of food law compliance across its establishments regulated by local authorities. This is detailed further in criterion 6. • The business has its own internal or second/third party checks on compliance in place. This is covered further in criterion 9. 	<ul style="list-style-type: none"> • An overview of the partnership should be provided to the FSA, including details of how long the partnership has been established, a summary of partnership work activities, and method and frequency of communications. This will show that the business is actively engaged with their primary authority. • National inspection strategies are most likely to be appropriate for businesses who receive regular proactive interventions such as inspections, sampling visits, or test purchasing. • They are will only be appropriate for businesses that can demonstrate sustained levels of legal compliance across their establishments, with their own checks and balances in place. • As reactive interventions fall outside the scope of an inspection plan, if a business's interaction with local authority regulators is largely reactive (e.g. investigation of complaints), then a national inspection strategy is not likely to be appropriate. • Businesses which require approval under (EC) 853/2004, and businesses which require export certification, will not be suitable for a national inspection strategy, as risk based local authority

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			<p>proactive interaction is still likely to be necessary.</p> <ul style="list-style-type: none"> • Whilst coordinated partnerships are not excluded from national inspection strategies, it is likely that direct partnerships are more appropriate. • It is likely that some level of local authority proactive interaction will be required to contribute to verification that the national inspection strategy is working as intended.
2.	Primary authority demonstrates its competency and capability in relation to the partner business (or group of businesses)	<ul style="list-style-type: none"> • Officers involved in the partnership must as a minimum meet the baseline qualification requirements, and demonstrate all relevant competencies, as detailed in Chapter 4 of the Food Law Code of Practice². There must be evidence that the officers have had their competency assessed annually by a Lead Food Officer or manager. • Officers involved in the partnership must have demonstrable experience and knowledge of the business type they are regulating, including all processes involved in the food business's operations. They could demonstrate this via their experiences gained working in food regulation, and/or in the food industry. Their experience should be documented and submitted to the FSA. 	<ul style="list-style-type: none"> • The Regulators Development Needs Analysis tool (RDNA), or some other equivalent means of competency assessment, may be useful in demonstrating the competencies of primary authority officers who are responsible for implementing a national inspection strategy. • It is likely that the officers involved in the partnership will have food related auditing experience, and/or hold relevant qualification, e.g. ISO9001, or ISO22000. • It is likely that the officers will have attended BEIS Primary Authority training, or received primary authority briefings/training in house.

² https://www.food.gov.uk/sites/default/files/food_law_code_of_practice_2017.pdf

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		<ul style="list-style-type: none"> • Officers must have a demonstrable understanding of the Primary Authority scheme. This may be demonstrated via documenting their experience, and/or by attending training offered by BEIS, or another provider (e.g. in-house training). This must be submitted to the FSA. • Where a primary authority is reviewing and analysing business compliance data, for example, sampling and audit data, the officers must be competent in this field. This must be demonstrated by submitting qualifications and/or by detailing their experience to the FSA. • In addition to the primary authority officer demonstrating their competency, the local authority providing the primary authority services must also ensure that they can demonstrate they are competent, capable and their service has resilience. • The authority should be making use of the relevant BEIS tools to periodically review the primary authority services that they are providing. These include the partnership review tool, the service review tool, or they may be using an alternative means of ensuring that they are reviewing their service to ensure it is meets the requirements of the BEIS Statutory Guidance. Details of how they review the 	<ul style="list-style-type: none"> • The FSA will consider the nature, complexity and scale of the business, the compliance history, and the scope of the partnership in considering the appropriateness of resource allocated to the partnership. • Resilience of the primary authority service and capacity within the team will also be considered. • The FSA may refer to the findings of any recent audit of the local authority, and/or any local authority intervention data returns, when considering the capability to implement and manage a national inspection strategy.

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		<p>partnership and service must be provided to the FSA.</p> <ul style="list-style-type: none"> • The primary authority must provide evidence that the partnership is appropriately resourced and has adequate business continuity plans in place to maintain the partnership and oversight of a national inspection strategy in the event of officer absence. The scope of the partnership must be detailed to the FSA, as well as the FTE officers working on it, or the average number of hours spent per week/month. The primary authority will be asked to confirm how this resource will be reviewed and maintained for the duration that the partnership operates a national inspection strategy. • The primary authority must have the resource to evaluate the national inspection strategy periodically, as required by the Statutory Guidance. 	
3.	Business has food safety 'pre-requisites' in place	<ul style="list-style-type: none"> • The primary authority must satisfy itself, and have evidence that, the business has the basic food safety pre-requisites arrangements in place and that these are maintained. Details of the business's pre-requisites and how the primary authority has assessed them must be provided to the 	<ul style="list-style-type: none"> • The FSA's myHACCP³ web tool provides some detail on what pre-requisites are. The following is taken from this online resource: • There are some controls for food safety that are common in that they are required in most food businesses.

³ <https://myhaccp.food.gov.uk/help/guidance/preparatory-stage-a-prerequisite-food-hygiene-requirements>

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		<p>FSA. Primary Authority Advice on the pre-requisite programme must be provided.</p>	<p>They need to be in place well before HACCP based controls specific to [your/a] business are implemented - they are prerequisites to HACCP;</p> <ul style="list-style-type: none"> • There are hazards that can occur at numerous steps in the process (not specific to one particular process step) or have the potential to occur across the establishment. These are often controlled by prerequisite food hygiene requirements that are 'generic' (e.g. pest control, training, good hygiene practice); • The control of these hazards is a pre-requirement to HACCP, the control mechanisms have thus been termed 'prerequisite requirements'. The prerequisite requirements are vital to ensure that the base environmental and operating conditions are appropriate and suitable for the production of safe food; • If prerequisite food hygiene requirements are effectively implemented and managed they underpin the HACCP system.

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4.	Primary authority to have issued Primary Authority Advice on the food safety management system for food hygiene, and/or the management controls/systems in relation to food standards (as appropriate)	<ul style="list-style-type: none"> • In terms of hygiene partnerships, the primary authority must have reviewed, and issued Primary Authority Advice to the business, on the food safety management system as it applies to business outlets that are regulated by local authorities. A copy of the Primary Authority Advice must be made available to the FSA. • The primary authority must be satisfied and have issued Primary Authority Advice to confirm that the business is carrying out effective monitoring of critical controls, keeping satisfactory records, and is taking appropriate corrective action when things go wrong. • In terms of food standards partnerships, the primary authority must have reviewed, and issued Primary Authority Advice to the business, on relevant aspects of how food standards are managed at the business. A copy of the Primary Authority Advice must be made available to the FSA. 	<ul style="list-style-type: none"> • Issuing Primary Authority Advice on the food safety management system is likely to include the business's pre-requisite programme (see criterion 3), the HACCP plans (if appropriate), the food safety controls in place at critical control points, and how these controls are monitored. • For food standards partnerships, examples of where Primary Authority Advice to the business may be relevant include nutrition/health claims, compliance with compositional requirements, allergens, labelling, and management of use by dates etc.
5.	Primary authority to have verified implementation	<ul style="list-style-type: none"> • The primary authority must have evidence that the management systems are being implemented as documented. The way in which partnerships demonstrate this will 	<ul style="list-style-type: none"> • Examples of how implementation of the food safety management system could be verified by a primary authority include:

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	of the food safety management system for food hygiene, and/or the management controls/systems in relation to food standards (as appropriate)	vary, and the examples in the adjacent column should be considered by partnerships. Relevant evidence will be submitted to the FSA.	<ul style="list-style-type: none"> • Reviewing local authority feedback from interventions such as inspections, test purchasing, sampling, food hygiene rating data, referrals, including complaints and reactive work etc.; • Reviewing inspection plan feedback; • Compliance data provided by the business, such as first, second or third-party audit data, sampling data etc.; • The primary authority carrying out their own checks at business sites within and outside their own local authority area, and other verification activities as appropriate.
6.	Primary authority to have reviewed and verified compliance history	<ul style="list-style-type: none"> • The primary authority must have evidence that the business is compliant with food law across its estate. The way in which partnerships demonstrate this to the FSA will vary, and the examples in the adjacent column should be considered by partnerships. 	<ul style="list-style-type: none"> • Examples of how the primary authority could demonstrate they have reviewed and verified compliance history include: • Considering the relevant food related referrals made to them by local authorities over a 24 months period; • Considering relevant enforcement action proposed or taken against the business over a period of 24 months; • The business's food hygiene rating data for the previous 24 months (for hygiene partnerships). The primary

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			<p>authority will need to be assured that the business's sites are all broadly compliant (FHRS of 3 or above), and over 95% of sites are rated as a 4 or a 5;</p> <ul style="list-style-type: none"> • Their own findings, having carried out inspections of sites and sampling (if appropriate); • Feedback from local authorities using the partnership's inspection plan (if appropriate); • Considering any food safety incidents or product withdrawals and recalls. • It is likely that primary authorities that are ready for a national inspection strategy will have had an inspection plan in place for 12 months, and will have data from this that demonstrates high levels of regulatory compliance in the business.
7.	Primary authority has robust process for issuing Primary	<ul style="list-style-type: none"> • The primary authority must be fully compliant with the requirements of the Primary Authority Statutory Guidance. • The primary authority must have auditable processes in place to consider and issue Primary Authority Advice, for example a process or procedure that is followed, and 	<ul style="list-style-type: none"> • Robust processes are likely to include: • An internal peer review of an officer's work when they are reviewing matters with the view to issuing Primary Authority Advice;

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	Authority Advice in place	documents to support this. Details of these processes/procedures must be made available to the FSA.	<ul style="list-style-type: none"> • Primary Authority Advice should be signed off by an appropriate officer on behalf of the primary authority, for example a service manager.
8.	Primary authority accesses and reviews food safety compliance across the business operations which are subject to local authority control	<ul style="list-style-type: none"> • The primary authority must have arrangements in place to access and review the business systems which demonstrate compliance with food law. The details of these arrangements must be provided to the FSA. • The arrangements must detail how the primary authority accesses and reviews the business's compliance with their own food safety management systems. 	<ul style="list-style-type: none"> • Arrangements to access and review compliance are likely to include: • The primary authority having direct access to business compliance data, such as audit and sampling data or regular and timely reporting of the business's own compliance data to the primary authority; • Evidence of regular contact with business to jointly review compliance data; • Arrangements for the reporting of serious incidents that pose an imminent risk of food not being safe and/or what it says it is, so that they are promptly brought to the primary authority's attention; • Feedback from relevant regulators, for example, local authorities, being fully accessible to the primary authority.

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9.	Business's own audit 'maps' to legislative requirements	<ul style="list-style-type: none"> • The details of the business's own audit arrangements must be provided to the FSA, including the scope, content, and whether audits are first, second or third party. • The primary authority must have established that the business's own checks include an assessment of all relevant legal requirements that a regulator would reasonably be expected to check on a proactive intervention. Details of this mapping exercise must be provided to the FSA. • The business's own checks must be carried out at a frequency that is no less than they would experience from local authority interventions. The frequency of the business's own checks must be provided to the FSA. • The primary authority must have deemed the qualification and competency specification of those responsible for carrying out audits as being appropriate. These must be provided to the FSA. There must be evidence that those carrying out the business's own checks are suitably qualified and competent, with the ability to identify food hazards relevant to the business type and operations. 	<ul style="list-style-type: none"> • The business's own checks do not need to be included in any one 'audit', but the sum of their own checks must be equivalent to (or greater than) a local authority planned regulatory intervention i.e. the totality of the business's own checks needs to be considered by the primary authority.

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		<ul style="list-style-type: none"> The primary authority must have issued Primary Authority Advice on the business's own auditing arrangements. 	
10.	Evidence that non-compliances are dealt with	<ul style="list-style-type: none"> The primary authority will need to provide assurance that the business has processes in place to identify non-compliances in a timely way and rectify them within an appropriate time frame and in an appropriate manner to ensure food is safe and what it says it is. How the business has demonstrated this to the primary authority will need to be shared with the FSA. 	<ul style="list-style-type: none"> Businesses will identify things that are going wrong – what is important is that they find them, protect public health, put things right in an effective and timely way, and act to prevent a recurrence. The primary authority may wish to consider the timeliness and appropriateness of: <ul style="list-style-type: none"> How the business identifies compliance issues; Corrective actions taken because of business's own audit findings or surveillance data; Follow up from local authority interventions that identified non-compliances with the law or business's own standards; Measures in place to review and respond to results of samples taken from the business, either by the primary authority or enforcing authorities;

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			<ul style="list-style-type: none"> • Planned preventative maintenance of equipment and structures; • Responding to emergency situations such as loss of hot water or pest issues to protect public health; • Follow up when the primary authority has brought an issue to the business's attention; • Follow up from customer complaints; • Follow up from product withdrawals and recalls.
11.	Evidence of peer review, risk-based internal monitoring, and/or benchmarking	<ul style="list-style-type: none"> • The primary authority must demonstrate that they are taking appropriate measures to review the work of the primary authority officers who are active in the partnership. The details of supervision and management of officers must be provided to the FSA. • The primary authority must demonstrate that they have a means of ensuring their decisions are consistent with those of other regulators and partnerships. Examples of how a primary authority might do this are detailed in the adjacent column. Details of how the primary authority does this must be provided to the FSA. 	<ul style="list-style-type: none"> • This could include internal peer review of: • Primary Authority Advice prior to issuing (see criteria 7); • How a partnership and/or officer is performing its duties, such as handling referrals, assessing inspection plan feedback etc. • It could also include engagement with groups designed to facilitate benchmarking between peers, including the BEIS expert panels, FSA facilitated groups, or other relevant groups;

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			<ul style="list-style-type: none"> • Use of online platforms such as the Knowledge Hub to benchmark and achieve consistency; • Audits/peer review of the primary authority service and processes by colleagues from another Council department, or an external organisation, such as another local authority.