

Title: Regulating Our Future- Amendments to the Food Law Code of Practice (England)

CONSULTATION SUMMARY PAGE

Date launched:	05 July 2018	Closing date:	27 September 2018
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<p>Who will this consultation be of most interest to?</p> <p>Local Authorities Food Business Establishments</p>
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<p>What is the subject of this consultation?</p> <p>The Regulating Our Future (ROF) Programme aims to modernise how food businesses in England, Wales and Northern Ireland are regulated to check that our food is safe and what it says it is. The Food Standards Agency (FSA) is planning to review the Food Law Code of Practice (Code) for England to make changes to the process of registration, the application of the food hygiene intervention rating scheme, to recognise national inspection strategies, and to elicit early views from stakeholder on other co-dependent aspects still in development.</p>

<p>What is the purpose of this consultation?</p> <p>The FSA welcomes views on its proposals to amend the Code to operationalise the first phase of ROF related changes. These changes will enable the new digital approach for the process of registration for new business and make changes to the Food Hygiene intervention scheme to enable the targeting of resources to maximise the impact on non-compliant businesses and recognise national inspection strategies, creating better alignment between the Code and Primary Authority. The FSA would also invite views to help inform the future developments of local authority (LA) Performance measures so more meaningful and real-time assessment of a LA's delivery of its obligations are possible.</p>

<p>Responses to this consultation should be sent to:</p>	
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<p>Impact Assessment included?</p>	<p>Yes <input checked="" type="checkbox"/></p>	<p>No <input type="checkbox"/> See Annex A for reason.</p>
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Regulating Our Future- Amendments to the Food Law Code of Practice (England)

DETAIL OF CONSULTATION

1. The Regulating Our Future (ROF) Programme aims to modernise how food businesses in England, Wales and Northern Ireland are regulated to check that our food is safe and what it says it is. We are building a system that is dynamic and flexible and can adapt as the global food economy changes and as technology develops in the future. Our new system will have the sophistication needed to regulate an increasingly diverse food industry and to adapt quickly to changing risks so that it can respond to changing patterns of food production, trade, and consumption when the UK leaves the EU.
2. This consultation focuses on potential changes that will come into effect after April 2019. To ensure that there are no barriers to the implementation of the new system the Food Standards Agency (FSA) is planning to review the Food Law Code of Practice (Code) for England to make changes to the process of registration, the application of the food hygiene intervention rating scheme, to recognise national inspection strategies, and to elicit early views from stakeholders on other co-dependent aspects still in development. A consultation is also being undertaken in Northern Ireland, and the FSA intends to issue a parallel consultation in Wales in the near future, subject to ministerial approval.
3. This is the first of a series of public consultations on the various aspects of the ROF programme. Due to the extended timescales and wide scope of the programme the FSA intends to group changes into manageable phases. This first set of changes to the Code will operationalise some of the principles of ROF programme by improving the registration process and the risk-based targeting of intervention resource by local authorities. The FSA is also seeking views on what new frameworks and performance measures are necessary to ensure that existing local authority regulatory resources are protected in the future.
4. The FSA is undertaking this consultation to seek views on its proposals to amend the Code to operationalise the first phase of ROF by making the following changes to:
 - Reflect that there will be new digital options for the process of registration by new businesses following the introduction of the new FSA web based platform in April 2019.
 - Recognise national inspection strategies (NIS) for food establishments via Primary Authority.

- Make a range of changes to the Food Hygiene risk assessment process for targeting resources to maximise the impact on non-compliant businesses.
 - Consider, when assessing Confidence in management, whether the food business operator proactively registered the new establishment under their control before the business started trading or when food operations commenced;
5. The FSA intendeds to undertake further consultations that will fully quantify the impact of the development of the web based process for registration and setting of data standards. These consultations will be informed by the testing of the system by food businesses and LAs, that will take place in the initial stages of if its development.

Background

6. The Code is the mechanism by which we can operationalise the changes emanating from the ROF programme. The FSA is, therefore, consulting on elements within the ROF programme which represent the first phase of its delivery. This consultation invites views from all stakeholders on specific proposals for change as well as requesting views to inform the development of policy that will support the implementation.
7. Given the ROF programme is being undertaken in a staged approach, this review covers only operational changes to the Code in regards to the assessment of risk and changes necessary to reflect developments in the registration process. It also recognises national inspection strategies for food partnerships, to bring alignment between Primary Authority and the requirements of the Code.
8. It is important to reflect that these proposals should be considered as the early outputs of the programme and will complement and enable the development of proposals such as the predictive risk engine that will be used to determine the regulatory approach for food establishments in the future. The review process, therefore, is a long-term project with further changes planned in 2019 – 2020, with the impact assessments undertaken as part of this consultation only considering the first potential revisions to the establishment intervention rating scheme and registration process.
9. Whilst the FSA is undertaking a consultation exercise now, any changes to the Code that affect how LAs plan and implement official controls will be introduced at the same time as the implementation of the FSA new enhanced registration system and risk engine, to reduce the impact on local authority service planning. The date for the implementation of these changes is dependent on the capacity of the new system handle the adoption of the new approach by LAs, and there are likely to be challenges during this transitional period that will need to be addressed.
10. These changes will improve the regulatory process for the 517,686¹ food establishments registered with LAs in England at 31 March 2017. These include primary producers, manufacturers, processors, packers, importers, distributors, wholesalers, retailers, restaurants and caterers. These establishments are all

¹ <https://www.food.gov.uk/sites/default/files/laemsannualreport201617.pdf>

subject to the requirements of food law that applies in England and originates at European Union level, this includes rules on food hygiene and food standards.

11. Responsibility in England for verifying compliance with food law in these food establishments is delegated to competent authorities. For most of the food businesses in England, the responsibility is mainly delegated to the 352 LAs. In undertaking these responsibilities, LAs as competent authorities must comply with the requirements of Regulation (EC) No. 882/2004² on Official Feed and Food Controls. This Regulation sets out the general risk-based approach and the principles that must be adopted when carrying out Official Controls (checks to ensure compliance with food law).
12. In carrying out their duties, LAs must have regard to the direction given by the FSA in the Code (separate but parallel Codes apply in Wales and Northern Ireland) when discharging their duties. The Codes in England, Wales and Northern Ireland are being reviewed to reflect the developments in approach.

Regulating Our Future

13. The objective of this review of the Code is to begin to embed the principles underpinning the ROF Programme into the process of registration and enable a more accurate assessment of risk that will help target those businesses with higher risk levels and/or are non-compliant. In addition, the aim is to recognise national inspection strategies for food partnerships, to bring alignment between Primary Authority and the requirements of the Code. The five ROF principles are:
 - Businesses are responsible for producing food that is safe and what it says it is, and should be able to demonstrate that they do so. Consumers have a right to information to help them make informed choices about the food they buy – businesses have a responsibility to be transparent and honest in their provision of that information.
 - FSA and regulatory partners' decisions should be tailored, proportionate and based on a clear picture of UK food businesses.
 - The regulator should consider all available sources of information.
 - Businesses doing the right thing for consumers should be recognised; action will be taken against those that do not.
 - Businesses should meet the costs of regulation, which should be no more than they need to be.
14. The changes proposed in this consultation focus on principle 2, that FSA and regulatory partners' decisions should be tailored, proportionate and based on a clear picture of UK food businesses, principle 3, that regulators should consider all available sources of information, principle 4, that businesses doing the right thing for consumers should be recognised; action will be taken against those that do not, and principle 5, that businesses should meet the cost of regulation, which should be no more than they need to be.

² <http://www.food.gov.uk/multimedia/pdfs/8822004ecregulation.pdf>

Business start-up and enhanced registration

15. We will introduce a new digitally-enabled service to make it easier for businesses to register and easier for them to access tailored information and guidance that will enable them to get things right from the start. To do this we are building an online registration service which will give us more information on food businesses at the time they register and will provide real-time access to registration details of all businesses in England, Wales and Northern Ireland.
16. The development phase of the online service was completed in April and testing of a working version with a limited number of LAs and food businesses has commenced. The findings will be used to make improvements ahead of the service going live by March 2019.
17. As part of the re-design of the FSA website, advice for food businesses is being revised to make it easier to follow. The new content will be tested through workshops in the autumn and finalised by December. Following that, specific advice will be categorised against business types and incorporated into the online service providing businesses with tailored advice at the time they register.

Segmentation of food businesses

18. Currently, all new food businesses are inspected when they first start trading, regardless of the food safety risk they present. This 'one size fits all' approach is not sustainable, proportionate or risk-based so we said that we would develop a more sophisticated and data driven method for the segmentation of businesses.
19. The focus to date has been on building a 'risk engine' that uses a set of business rules to generate a 'risk score', which segments businesses into categories. This categorisation will be used to determine the nature, frequency and intensity of official controls for all new business using the online service to register. Our future proposal, which we will be consulting on in due course, is that some businesses - for example, those that provide only low risk food, or those that are of a limited scale and complexity - will no longer receive an initial inspection but rather will only be inspected as and when additional information, or a complaint, indicates that one is necessary.
20. The FSA has also been considering whether there are options for improving the current risk based scheme for setting inspection frequencies at existing businesses. These options have been based upon analysis of local authority historical inspection data and the findings of published research. The aim is to reallocate existing inspection resource from establishments that have demonstrated they are able to maintain high levels of compliance with food safety requirements, to those establishment who require an increased level of intervention from local authorities to ensure that public health is protected.

Primary Authority National Inspection Strategies

21. For businesses (or groups of businesses) in Primary Authority partnerships, where there is sufficient evidence that food safety is well managed across the operations, a primary authority may consider that a lower number of programmed regulatory interventions are warranted. They may, therefore, wish

to develop a national inspection strategy (NIS), which would be contained within an inspection plan.

22. The concept of NIS is not a new one, it was introduced when Primary Authority was first conceived, and at present any primary authority could theoretically develop a food safety NIS and submit this to the Secretary of State for consent.
23. This has not happened to date and the FSA has never issued any National Regulator guidance for primary authorities wishing to use this tool. Furthermore, the current Code does not acknowledge that NIS could exist, or what LAs should do if a primary authority was to issue one.
24. During late 2017 and early 2018 the FSA undertook a 'pathfinder' exercise, working with six Primary Authority partnerships to test whether primary authorities could access and use business's own compliance data to predict local level food hygiene compliance. The aim of the pathfinder was to explore the concept of NIS and identify the work that needs to take place to make NIS possible for food safety partnerships. These pathfinders are nearing completion. The report of an independently conducted evaluation of the findings is expected during the summer of 2018.
25. At present, the FSA understands that a small number of Primary Authority hygiene partnerships in England are actively considering developing NIS, with the view to trialling the concept in England during 2019. The early proposals suggest that the primary authorities will use business data and information, combined with intelligence from the relevant local enforcing authorities, to better inform the frequency of local food hygiene inspections.

Proposals

26. The key proposals within this consultation are as follows. It is important to note these changes only represent part of the overall ROF programme of changes and will support the implementation of other aspects later in the programme
27. The FSA is also inviting initial views from stakeholders to inform the development of associated policy or performance measures, which will also need to be in place to successfully implement these changes.

Key proposals:

The FSA is undertaking this consultation on its proposals to amend the Code to operationalise the first phase of ROF by making the following changes to:

- **Reflect that a new online service for the registration of new food businesses is being developed for implementation at the end of March 2019.**
- **Recognise national inspection strategies for food establishments via Primary Authority, bringing alignment between Primary Authority and the Code.**
- **Introduce definitions for the terms "full compliance" and "sustained compliance" in relation to food businesses.**

- **Make a number of changes to the Food Hygiene risk assessment process for targeting resources to maximise the impact on non-compliant businesses by:**
 - **Recognising the reduced risk presented by food establishment who have demonstrated they can maintain the highest levels of compliance over time;**
 - **Linking the application of the additional score for the vulnerable risk group to the assessment of confidence in management at food businesses.**
 - **Removing the additional score for significant risk and including the significant risk element in the Confidence in management assessment.**
 - **Amending the Method of processing element of the food hygiene intervention scheme to include a situation where an establishment fails to undertake a process, which results in the potential to increase the risk to public health.**
- **Consider, when assessing Confidence in management, whether the food business operator proactively registered the new establishment under their control before the business started trading or when food operations commenced.**
- **The setting of Data Standards for storage and transfer by LAs.**

Proposal 1: Enhanced registration

28. Registration is a legal requirement under Article 6(2) of Regulation (EC) 852/2004, which states that food business operators are to register the establishment(s) under their control with the appropriate competent authority in the manner that the competent authority specifies. This Code review covers the first iteration of work under the Enhanced Registration workstream of the ROF programme which details changes to the process as to how a food business operator (FBO) should register the establishment(s) under their control.
29. This change aims to improve the overall effectiveness, efficiency and consistency of registering food business establishments across England, Wales and Northern Ireland. The information obtained through the newly developed online registration service is fundamental to the success of the other workstreams and the overall ROF Programme as capturing more in-depth data on the businesses activities will allow for a more accurate assessment of risk to be determined using a “risk engine”, enabling an appropriate intervention strategy to be identified.
30. FBOs are required to register at least 28 days before their business starts trading or the food operations commence, however, under the current system for registration, they are only required to provide a limited amount of information about their food establishment to the LA relevant to the location of their food business(s).
31. Registrations are currently submitted to LAs via a variety of routes using different forms developed over time by LAs and in many cases FBOs either start trading before registering and therefore do not receive the appropriate level of support at the earliest

opportunity to aid compliance, and/or register and commence trading prior to a LA inspection taking place.

32. The current registration process works to varying degrees but there is substantial opportunity for improving overall effectiveness, efficiency and consistency. This new service will help alleviate inconsistencies in the overall registration process. It will be easier for FBOs to register as they will be asked pertinent questions relevant to the type of business they are registering and they will obtain the same user experience regardless of their location. LAs will benefit also as there will be reduced manual processing making the overall registration process less labour intensive.
33. Relevant information from the online registration service about the food business operator and their activities will be made available to LAs and the FSA, as the Central Competent Authority (CCA). Gaining an overview of all food businesses establishments will give the FSA a comprehensive understanding of the industry, assist in future policy development, and allow for more effective action to be taken in the event of a food incident or crisis.
34. The information obtained through the new online service will in due course be available for LA officers to view to help inform their intervention strategy, for example, for mobile establishments, the most recent inspection report, which will better inform them of their compliance history and reduce the number of unnecessary inspections.

Q1: The FSA would like to obtain your views on any perceived barriers that could hinder the effective implementation and administration of the online registration service?

Q2: The FSA would like your opinion on whether you consider that enhancing registration through the online service, will have the desired effect of increasing the effectiveness and efficiency of the registration process?

Proposal 2: NIS

35. The FSA recognises that Primary Authority could play a role in achieving the ROF programme outcomes, and is particularly interested in the concept of NIS.
36. Therefore, the FSA has been working with stakeholders to develop a 'Standard' that a Primary Authority partnership would need to meet in order to be able to develop and implement a NIS. It is intended that this Standard will be issued as National Regulator guidance.
37. It should be noted that a NIS for food safety will not completely remove a business or group of businesses from LA proactive interventions. There will always be a need for some local verification that systems are working effectively at a local level, and LAs will be key to this process. Furthermore, reactive interventions fall outside the scope of a NIS so these continue as normal when a NIS is in place.
38. The first version of the FSA 'Standard' for operation of NIS will be published in the summer of 2018. This Standard has been developed in conjunction with stakeholders, and will ensure primary authorities who wish to develop and

implement a NIS are competent and capable to do so. The Standard will also ensure that only the most compliant food businesses are able to access NIS.

39. Alongside the work to develop a Standard for partnerships wishing to develop and implement NIS, the FSA has been working to ensure that there will be the right level of FSA oversight and assurance that the NIS is working effectively, and that food remains safe and what it says it is.
40. A provision has been introduced into the Code which recognises that a primary authority may choose to develop and implement a NIS.
41. In order for a primary authority to implement a NIS, they and their partner business would need to engage with the FSA at an early stage of their development work, and then submit demonstrable evidence that they meet the relevant FSA Standard. This will be assessed by the FSA, who will liaise with The Office of Product Safety and Standards during the statutory consent process.
42. We have previously sought stakeholder views on the draft Standard (made up of a set of criteria and associated guidance), and FSA oversight and assurance proposals which can be viewed here:

<https://www.food.gov.uk/sites/default/files/media/document/PA%20NIS%20Draft%20Guidance%20on%20NIS%20Criteria.pdf>

and

<https://www.food.gov.uk/sites/default/files/media/document/PA%20NIS%20Draft%20Guidance%20on%20NIS%20Criteria.pdf>.

We are currently reviewing the responses that we have received to date.

In this Code consultation, we ask stakeholders:

Q3. What do you see as the benefits of national inspection strategies? Please feel free to answer this question in the context of local authorities, primary authorities, businesses, and/or consumers.

Q4. What challenges do you think that national inspection strategies for food safety partnerships may pose? Please feel free to answer this question in the context of local authorities, primary authorities, businesses, and/or consumers.

Proposal 3: Compliance definition

43. The FSA intends to introduce the following definitions to help categorise compliance levels with establishments, to work alongside the existing definition of broadly compliant. Under the current proposal **Full compliance**, for the purposes of the Code will be defined as an establishment that has been risk rated:

Risk factor
Structure

Score

5 or 0

<i>Hygiene</i>	5 or 0
<i>Confidence in Management</i>	5 or 0

44. The proposal will recognise food businesses that have been assessed to be fully compliant by the LA over a sustained period, by introducing a weighting within the food establishment intervention rating scheme. Food businesses that have been assessed as being fully compliant at the last 2 interventions, and over a minimum period of 3 years, will be considered to have achieved a level of **sustained compliance** that will be recognised in the food establishment intervention rating scheme.

Proposal 4: Changes to the Food Hygiene Risk Assessment

Recognising Sustained Compliance

45. A food business that meets this criterion will be suitable for a reduction to its collective total risk assessment score to recognise its sustained compliance. This reduction could be set at increments of either -5, or -10 or -20. Therefore, food businesses maintaining a level of full compliance at each further intervention will receive an additional reduction to their total risk assessment score. This proposal will over time reduce the focus on those food businesses that have demonstrated sustained levels of compliance and assist LAs to focus regulatory efforts on those establishments who fail to demonstrate compliance with necessary standards (worked examples can be found in tables 3 and 4 below).
46. This proposal is based on evidence, as shown in Table 1 below, that indicates establishments are more likely to demonstrate good levels of compliance during an intervention if they demonstrated these on their previous two interventions. For example, of establishments with a food hygiene rating scheme (FHRS) rating of 5 during the previous two inspections, less than 1% received an FHRS rating of 0-2 following their next inspection.

Q5: The FSA would like stakeholders to consider the proposed description of full compliance and give their opinion as to whether food businesses that achieve this level of compliance should be considered as fully compliant?

Q6: Do you think food businesses should be recognised for sustained compliance if they are assessed to be fully compliant at the last 2 interventions and over a minimum period of 3 years?

Q7: What scale of recognition do you think food businesses should receive to their total risk rating score if they are assessed as fully compliant should it be -5, -10 or -20?

Table 1: shows how the performance on the subsequent intervention varies according to the performance on the two-previous interventions.

<i>FHRS equivalent ratings during the previous two interventions</i>		Number of establishments	% at least Broadly Compliant (FHRS 3-5)
5	5	18,824	99.1%
4	5	3,840	97.3%
3	5	1,382	96.3%
2	5	392	96.2%
0-1	5	410	93.9%
5	4	2,657	95.6%
4	4	5,440	93.9%
3	4	2,737	90.5%
2	4	684	88.3%
0-1	4	893	86.7%
5	3	978	91.6%
4	3	1,859	88.0%
3	3	3,438	84.2%
2	3	792	79.7%
0-1	3	1,101	75.2%
5	2	322	86.3%
4	2	648	79.2%
3	2	842	71.3%
2	2	527	67.0%
0-1	2	396	60.4%
5	0-1	237	83.1%
4	0-1	633	77.1%
3	0-1	1,061	66.3%
2	0-1	452	62.4%
0-1	0-1	1,208	59.1%

47. At the LA update events in January 2018 some LAs expressed concern that if the length of time between interventions is increased, compliance levels would reduce. As indicated in Table 2 below, there seems to be no evidence to indicate that establishments with a two or three-year interval between an intervention, and the next subsequent intervention perform any worse on the subsequent intervention than those with a one-year interval. (It should be noted that there are far fewer establishments with which to look at a three-year gap). Based on this evidence, implementing the sustained compliance amendment will allow LA resource to be redirected to focus on new unrated food businesses and those food businesses that are non-compliant rather than undertaking interventions at fully compliant establishments.

Table 2: Shows the performance on the most recent Intervention (Intervention 3) given the FHRs ratings on each on the two previous Interventions (Intervention 1 and 2) – by the length of time between the most recent Intervention (Intervention 3) and the previous Intervention (Intervention 2).

Comparison between a 1-year gap and a 2-year gap

FHRs equivalent ratings during the previous two inspections (1 and 2)		1 years between inspections 2 and 3				2 years between inspection 2 and 3				Difference (percentage points)		
		Total	On their latest inspection			Total	On their latest inspection			% BC (FHRs 3-5)	% Good/Very Good (FHRs 4-5)	% Very Good (FHRs 5)
			% BC (FHRs 3-5)	% Good/Very Good (FHRs 4-5)	% Very Good (FHRs 5)		% BC (FHRs 3-5)	% Good/Very Good (FHRs 4-5)	% Very Good (FHRs 5)			
5	5	5,539	99%	97%	90%	11,462	99%	97%	90%	0	0	0
4	5	980	98%	96%	84%	2,472	97%	92%	79%	-1	-3	-5
3	5	286	98%	92%	78%	947	96%	91%	76%	-2	-2	-1
0-2	5	151	95%	87%	71%	584	95%	86%	72%	0	-1	+1
5	4	1,356	96%	88%	61%	1,181	95%	86%	57%	-1	-2	-4
4	4	2,558	95%	82%	40%	2,527	93%	81%	42%	-1	-1	+2
3	4	1,097	89%	74%	32%	1,479	92%	74%	32%	+2	0	0
0-2	4	680	88%	74%	34%	819	87%	70%	34%	-2	-3	0
5	3	507	95%	79%	54%	448	88%	66%	39%	-7	-13	-15
4	3	948	89%	60%	28%	867	87%	56%	26%	-1	-4	-2
3	3	1,543	84%	45%	18%	1,745	84%	46%	17%	0	0	-1
0-2	3	861	80%	42%	16%	946	75%	40%	14%	-4	-2	-2
5	0-2	416	88%	72%	46%	141	77%	65%	44%	-10	-8	-2
4	0-2	915	79%	55%	26%	359	77%	54%	26%	-2	-1	0
3	0-2	1,352	69%	38%	15%	531	67%	40%	17%	-2	+2	+2
0-2	0-2	1,959	61%	32%	11%	603	63%	31%	11%	+1	-1	0

Comparison between a 1-year gap and a 3-year gap:

FHR S equivalent ratings during the previous two inspections (1 and 2)		1 years between inspections 2 and 3				3 years between inspections 2 and 3				Difference (percentage points)		
		Total	On their latest inspection			Total	On their latest inspection			% BC (FHR S 3-5)	% Good/ Very Good (FHR S 4-5)	% Very Good (FHR S 5)
			% BC (FHR S 3-5)	% Good/ Very Good (FHR S 4-5)	% Very Good (FHR S 5)		% BC (FHR S 3-5)	% Good/ Very Good (FHR S 4-5)	% Very Good (FHR S 5)			
5	5	5,539	99%	97%	90%	1,823	99%	98%	94%	0	+1	+3
4	5	980	98%	96%	84%	388	97%	94%	84%	-1	-1	0
3	5	286	98%	92%	78%	149	97%	96%	84%	0	+4	+6
0-2	5	151	95%	87%	71%	67	99%	94%	84%	+4	+7	+13
5	4	1,356	96%	88%	61%	120	95%	88%	53%	-1	0	-8
4	4	2,558	95%	82%	40%	355	95%	91%	28%	0	+9	-12
3	4	1,097	89%	74%	32%	161	90%	78%	29%	+1	+5	-3
0-2	4	680	88%	74%	34%	78	87%	74%	37%	-1	+1	+3
Any	3	3,859	86%	53%	25%	303	81%	45%	17%	-4	-8	-8
Any	0-2	4,642	69%	42%	18%	50	54%	30%	12%	-15	-12	-6

Vulnerable Risk Groups

48. In the current Code, an additional score of 22 (which is in addition to the Consumers at Risk score) is applied for establishments involved in the production or service of food intended specifically for consumption by consumers likely to include a vulnerable risk group of more than 20 persons. In this context vulnerable risk groups are those that include people likely to be more susceptible to the effects of poor food hygiene, such as those who are under 5 or over 65, or people who are sick or immuno-compromised. The application of the additional score of 22 has the impact of increasing the risk assessment score for food businesses (thus increasing the intervention frequency) by up to two intervention rating categories.
49. It is proposed to directly link the additional score for the vulnerable risk group of more than 20 persons to the assessment of confidence in management at food businesses. Retaining the current application of the additional score for vulnerable groups recognises that there are certain groups within the population who are more susceptible to developing infection from consuming contaminated food and are likely to suffer more severe symptoms, and therefore, must be afforded an appropriate level of consumer protection.
50. The current application of the additional score increases the intervention frequency for food businesses that produce and/or serve high-risk foods where the ultimate consumers of the product produced include a vulnerable risk group of more than 20 persons. In practice, the additional score is most commonly applied by LAs to food businesses where the identification of these vulnerable groups can be clearly made, such as healthcare settings where food is prepared and supplied directly to a specific vulnerable group, rather than a manufacturer who products are supplied to the whole population, including those who could be considered vulnerable.
51. Food business operators are required under Article 5 of Regulation (EC) No 852/2004 to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Food businesses should therefore have in place appropriate food safety management systems with effective controls to minimise food safety risks and this should include consideration of the intended use of the food. The current additional scoring is applied regardless of whether the food business demonstrates good levels of compliance with food law. Therefore, compliant food businesses in health care settings may receive higher frequency interventions, because of the application of the additional score for the vulnerable risk group, than less compliant food businesses who may also serve a similar number of persons in the vulnerable risk group.
52. To recognise businesses that have food safety management systems in place, it is proposed that the additional score of 22 will not be applied where the food business has been assessed as being fully compliant. Thus, if a food business is assessed as 0 or 5 for the three risk factors listed above, then the additional scoring of 22 would not be applied.
53. This proposal recognises compliant food businesses that have effective management control of hazards by reducing the intervention frequency and the focus of regulatory effort. However, it is proposed that the additional score would still be applied to those food businesses that do not demonstrate full compliance and produce and/or serve high-risk foods where the ultimate

consumers of the product produced include a vulnerable risk group of more than 20 persons.

54. Analysis of the LAEMS data identifies that in health care establishments Confidence in management is higher in these businesses and the level of formal enforcement is low in compliant businesses in those assessed by LAs as being in the vulnerable group category
55. Analysis also shows a marked difference in the levels of formal enforcement actions (of any type) undertaken. Establishments with a vulnerable groups score are 3 times less likely to have action taken against them, compared to the level of enforcement action taken against all food establishments (0.21 % for establishments with a vulnerable groups score, compared to 0.73% of all food establishments).
56. At recent LA update events views were expressed that due to funding cuts, providers are failing to deliver adequate care within health care establishments and in general standards are falling. Maintaining the current frequency of hygiene inspections was, therefore, in some officer's eyes, considered vital. There is currently no evidence to support this from the LAEMS data, however the FSA will continue to monitor the position as evidenced through the 2017/2018 LAEMs returns as a precaution.

Q8: The FSA would invite views on whether you agree with treating fully compliant businesses differently in these circumstances, and the likely positives and negatives of the effects of this proposal?

Q9: The FSA would welcome any documented evidence that would substantiate the view that there has been a significant decline in food safety compliance levels within health care establishments.

Proposal 5: Safeguards

57. It is proposed to put in place safeguards to ensure that the combined effect of proposals 3 and 4 is capped and does not exceed a total reduction of - 40 in the overall intervention rating score of an establishment or reduce an establishment's intervention rating by more than 2 risk categories. This is to ensure that official controls are still undertaken in food businesses in a manner proportionate to the risk. In addition, the FSA proposes that for establishments that are given a score of 22 for vulnerable groups, the risk category reduction arising from proposals 3 and 4 cannot result in an establishment being categorised as less than category D in order to ensure that onsite interventions at the establishment remain the minimum requirement.
58. The following worked examples illustrate the impact of the combined effect of proposal 3 and 4 and the limitations that are imposed.

Example 1

A residential care home rated category C for food hygiene has been assessed to have full compliance at the last 2 interventions and over a minimum period of 3 years. At the next inspection on the 1/05/2019, the vulnerable group score would therefore be removed and a reduction in the total risk element score applied. The example

shows the impact of the different reductions being proposed -5, -10 or -20. At the next inspection on the 1/05/2021 the vulnerable group score is not applied as the care home is assessed to have full compliance and the further reduction in the total risk element score is applied. At the point the cumulative effect gives a total score of 30 or less, the risk category reduction is limited to ensure the establishment remains D rated.

Table 3: Category changes for a residential care home

Inspection Date	1/05/2016	1/11/2017	1/05/2019	1/05/2021
Type of food /handling	30	30	30	30
Method of Processing	0	0	0	0
Consumers at Risk	5	5	5	5
Vulnerable Group	22	22	0 Removed	0 Removed
Hygiene	0	0	5	5
Structure	5	5	5	5
CIM	5	0	5	5
Total	67	62	50	50
Category	C rated	C rated	D rated	D rated
Category (-5)			45 (-5) D rated	40 (-10) D rated
Category (-10)			40 (-10) D rated	30 (-20) Remains D rated as cap applied
Category (-20)			30 (-20) Remains D rated as cap applied	40 (-40) Remains D rated as cap applied

Example 2

A high street restaurant serving steak tartare rated as category C for food hygiene has been assessed to have full compliance at the last 2 interventions and over a minimum period of 3 years. At the next inspection on the 1/05/2019 a reduction in the total risk element score is applied which shows the impact of -5, -10 or -20. At the next inspection on the 1/11/2020 the restaurant is again assessed to have full compliance and therefore a further reduction in the total risk element score is applied.

Table 4: Category changes for a high street restaurant

Inspection date	1/05/2016	1/11/2017	1/05/2019	1/11/2020
Type of food /handling	30	30	30	30

<i>Method of processing</i>	20	20	20	20
<i>Consumers at risk</i>	5	5	5	5
<i>Vulnerable Group</i>	0	0	0	0
<i>Hygiene</i>	0	5	5	0
<i>Structure</i>	0	5	0	0
<i>CIM</i>	0	5	5	0
<i>Total</i>	55	70	65	55
<i>Initial Category</i>	C rated	C rated	C rated	D rated
<i>Category (-5)</i>			60 (-5) C rated	45 (-10) D rated
<i>Category (-10)</i>			55 (-10) C rated	35 (-20) D rated
<i>Category (-20)</i>			45 (-20) D rated	25 (-40) E rated

Proposal 6: Significant Risk

59. The purpose of the Significant risk element of the food establishment intervention scheme is to recognise the seriousness of the repercussions should food businesses fail to adequately address potential risks of contamination by certain micro-organisms which could cause serious food-borne illness.
60. The additional score is to be applied where there is a significant risk:
- of food being contaminated with *Clostridium botulinum* and the micro-organism surviving any processing and multiplying; or
 - of ready-to-eat food being or becoming contaminated with micro-organisms, or their toxins, that are pathogenic to humans, e.g. *E. coli* O157 or other VTEC, *Salmonella* sp.; *Bacillus cereus*.
61. This additional score is currently to be applied on a case-by-case basis and is not intended to be applied generically to whole categories of food business establishments, and must be removed at the next inspection if the significant risk no longer exists.
62. It is proposed to remove the additional score for Significant risk and include the consideration of significant risk in the Confidence in management assessment as it relates to the risk of contamination. The Significant risk score is already linked to the Confidence in management assessment, as its application must be considered against the confidence in management score. If Confidence in management is assessed as 0 or 5, then the food business should not pose a significant risk as there is confidence in the management and control systems and the additional score should not be applied.
63. Food businesses should have in place appropriate food safety management systems with effective controls to minimise food safety risks including all food safety risks associated with their activities, irrespective of the consequences of failing to put effective controls in place. Their management of controls are already assessed as part of Confidence in management. Incorporating the Significant risk element within the Confidence in management assessment allows for better recognition of how these risks are being managed by the

business. In addition, significant risk should be dealt with using appropriate enforcement sanctions following interventions as the risk will not effectively be addressed just by increasing the intervention frequency for the establishment.

64. The 2016/17 LAEMS data shows that there has been significant incorrect application of the additional score for Significant risk, as 24% of the establishments that were given the additional 20 score, were assessed as 0 or 5 for Confidence in management, in direct contradiction with the requirements of the Code. Once these establishments have been excluded, there were 1293 establishments that were allocated this score correctly and of these 929 establishments moved to a different risk category as a result and will be subject to more frequent inspections. This evidence corroborates the feedback obtained at the LA Update events, where LA's highlighted that on occasions the additional score was being used as a management tool to identify certain establishments on their database, rather than it being a current and actual risk consideration.

Q10: Given the issues that exist with the application of this scoring factor, what are your views on retaining this in the food hygiene risk assessment scheme?

Q11: If the additional score is applied for reasons other than a risk factor, what are the perceived benefits and what alternative measures could be used to capture this instead?

Proposal 7: Method of Processing

65. The purpose of the Method of processing element of the food hygiene intervention scheme is to recognise those establishments that undertake a specific method of processing (including those that extend the shelf life of the product) that has the potential to increase the risk to public health beyond that of standard cooking or storage methods. Officers are required to consider if the process itself creates an increased risk or the intention is to increase the shelf life of the product by applying it. It is proposed to change the descriptor to also include the situation where an establishment intentionally does not implement a process which results in an increase risk to public health, an example being raw cows' drinking milk (RCDM) where heat treatment does not take place.

Q12: The FSA believes that officers will already be interpreting the risk assessment approach to apply this risk factor to businesses that do not apply a control process and this revision of the descriptor will not result in any substantial change in inspection frequencies for business. The FSA would welcome any evidence to the contrary.

Proposal 8: Considerations for Confidence in Management assessment

66. Registration is a legal requirement under Article 6(2) of Regulation (EC) 852/2004 which states that food business operators are to register the establishment(s) under their control with the appropriate Competent Authority in the manner that the competent authority specifies. The Code sets out the process for the registration of a food business and requires the FBO to inform the local authority at least 28 days before the business starts trading or the food operations commence. Obtaining relevant support and guidance at this early

stage is recognised as being beneficial to businesses as it helps them get it right from the start and to sustained compliance with food law requirements in the future.

67. We understand that a proportion of food businesses do not proactively register before they start trading, or commence their operations. Whilst we do not have quantitative figures to substantiate the amount, we have carried out some qualitative research to try to understand the different pathways a food business becomes known to the competent authority and out the 112 local authorities surveyed, approximately 10% of new food businesses were identified when already trading. Whilst only based on a small sample size, 10% of the current 634,580 food businesses in England, Wales and Northern Ireland would equate to approximately 63,458 food businesses that could potentially be operating without first being registered.
68. FBOs must either register the establishment(s) under their control or have them approved by the appropriate competent authority depending on the activity they wish to carry out. 99.2% of all food businesses do not require approval which means they can commence trading without any form of assessment to ensure they are suitable to do so.
69. The aim of registration is to inform the competent authority that a new business is planning to open, in order that they can then determine and plan an appropriate level of intervention. This can include various activities to support the food business to achieve compliance with food law, such as the provision of targeted education and advice either face to face or via other methods of communication.
70. The current food establishment intervention scheme fails to recognise when a business has not registered before commencing to trade and gives credit in the same manner as one who did register in line with the legal requirement.
71. FBOs that register in the correct manner demonstrate they are aware of their legal requirements to comply with food law and it is proposed that recognition should be made to those who have proactively registered through the intervention score for Confidence in management.
72. The main aims for considering the introduction of a score for FBOs who had not proactively registered are:
 - To achieve a more consistent approach to how competent authorities deal with food businesses that do not proactively register.
 - To increase the number of food businesses that proactively register their business before the business starts trading or the food operations commence.
 - To drive an increase in compliance levels through increased FHRS scores for new businesses and sustained compliance going forward.
73. At present we are not able to quantify the number of businesses that do not proactively register or the impact this has on their overall compliance with food law, however, there is an ongoing FSA research project to gather data on new food business establishments registering with a selection of Competent Authorities across England, Wales and Northern Ireland.
74. Early results indicate a clear correlation between those FBOs who had registered pro-actively and received support and guidance at the point of start-

up with a higher Food Hygiene Rating Scheme (FHRS) rating at first inspection. In addition, it demonstrates that for FBOs in Wales and Northern Ireland, where it is mandatory to display FHRS ratings, the level of proactive registration is much higher. This indicates FHRS as a driver for proactive registration as it is deemed a commercial benefit to the business.

75. The FSA presented proposals on the concept of applying a weighting under the Confidence in management score for businesses that hadn't registered at a series of local authority events held in December 2017 and January 2018. Various views on whether competent authorities should factor this in were received, however, it was generally considered that introducing this change alone would not make a significant difference to the number of food business operators that pro-actively register.

76. Whilst it is recognised as only one of many options for tackling the issue of non-registration, it is proposed that the fact that a food business has not registered before the business starts trading or the food operations commence should be reflected in the Confidence in management intervention rating score. There are several options as to how this could be achieved that we would like your views on:

- Include new descriptors in the Code under **part 3 - Confidence in management/control procedures**
'include for new food businesses – whether the food business operator proactively registered the establishment under their control before the business started trading or the food operation commenced.'

This would place the onus on the LA to determine an appropriate score to give for failing to proactively register.

- To apply a minimum score of 5 for Confidence in management if a business has not proactively registered. This could have a negative impact on the FHRS rating for the establishment, particularly if other minor interventions are identified;
- To apply a minimum score of 10 for Confidence in management if a food business has not proactively registered, which would have an even greater an impact on their FHRS rating.

Q13: The FSA would welcome any documentary evidence to support the use of a minimum score for the non-registration of a food business

Q14: The FSA would welcome your views as to whether you think the use of a minimum score for non-registration would have enough impact, and if so which score you consider most appropriate.

77. The following worked examples illustrate the impact of applying a specific score for Confidence in management (CIM) for non- proactive registration, on the overall food hygiene rating.

Example 1

If non-proactive registration was not taken into consideration and therefore a score of 0 awarded for CIM, the food hygiene rating would be a 4. Applying a score of 5 or of 10 have the same effect as the outcome would be a 3 rating.

HYGIENE	10	10	10
Structure	10	10	10
CIM	0	5	10
Total Intervention rating scores	20	25	30
Additional Scoring factor	No individual score greater than 10	No individual score greater than 10	No individual score greater than 10
Food Hygiene rating	4	3	3
Descriptor	Good	Generally satisfactory	Generally satisfactory

Example 2

If non-proactive registration was not taken into consideration and therefore a score of 0 for CIM awarded, the food hygiene rating would be a 5. In this example applying a score of 5 or 10 would have a different outcome. If a maximum CIM score of 5 is applied the rating would remain a 5, however if a standard CIM score of 10 is applied the rating is a 4.

HYGIENE	5	5	5
STRUCTURE	5	5	5
CIM	0	5	10
Total intervention rating scores	10	15	20
Additional Scoring factor	No individual score greater than 5	No individual score greater than 5	No individual score greater than 10
Food Hygiene rating	5	5	4
Descriptor	Very Good	Very Good	Good

Example 3

If non-proactive registration was not taken into consideration and therefore a score of 0 for CIM awarded, the food hygiene rating would be a 4. In this example applying a score of 5 or 10 would again have a different outcome. If a maximum CIM score of 5 is applied the rating remains a 4, however if a standard CIM score of 10 is applied the rating is a 3.

HYGIENE	5	5	5
STRUCTURE	10	10	10
CIM	0	5	10
Total Intervention rating scores	15	20	25
Additional Scoring factor	No individual score greater than 5	No individual score greater than 10	No individual score greater than 10
Food Hygiene rating	4	4	3
Descriptor	Good	Good	Generally Satisfactory

Q15: If the additional score is applied to the CIM score for non-registration, what are the perceived benefits and what alternative measures could be used to increase pro-active registration and to improve initial FHS ratings?

Alternative options

78. We recognise that there are many options that could potentially be adopted to either incentivise registration or act as a deterrent. Motivations could include for example the use of financial incentives through reduced business rates or support linked to the registration process and sanctions could take the form of fixed penalty notices (FPNs) or fines.
79. To encourage FBOs to register we plan to carry out a campaign to raise awareness of the need to register and will work with stakeholders to help us educate potential FBOs at the earliest opportunity.
80. LA events carried out in the summer of 2017 and recent LA update events identified support for a Permit to Trade (PTT) or licensing system for all food businesses as a way of improving regulatory controls for food businesses. Whilst this is not included in the initial phase of this work it is something which is being considered longer term as part of the evaluation process. Research will provide the evidence base to establish if there is a case to introduce a PTT/licensing system in the future as a public health protection measure.
81. The introduction of FPNs for failure to comply with the requirement to register is also not within scope of this workstream but is being reviewed as part of a wider piece of work on sustainable funding
82. implementing these proposals, we should be able to determine through the quantitative research whether this has had the desired impact or if further measures are required.

Proposal 9: Data Storage and Transfer

83. The availability of and access to Data, Data Standards and their exploitation are critical to implementing the developing Target Operating Model (TOM) for ROF. Not only is data a critical resource for the FSA in its current operations, more effective use of data will help enable more efficient, effective government and

public services that are responsive to businesses and citizen's needs. Data is a foundation for the FSA, its operations and outcomes as a competent authority and regulator.

84. We are therefore proposing the addition of a new requirement in the Code that will specify how an LA must store and transfer the data it holds, and the need to follow the Data Standard specified by the FSA.

Q16: We would welcome your views on any likely barriers to its implementation or any unintended consequences this Data Standard may have for a Local authorities' delivery of its official control programme.

Supplementary proposals

Supplementary proposals for development:

The FSA also wishes to invite views on the following issues to help inform the development of:

- **New performance measures so more meaningful and real-time assessment of a local authority's delivery of its obligations are possible.**

Balanced Scorecards

85. The FSA is beginning to develop a Balanced Scorecard (BSC), a digitally enabled tool which can use Food Hygiene Rating Scheme (FHRS) data, existing LAEMS data and any other relevant internal and external data sources that may become available to provide a more rounded and more up-to date-picture of the performance and effectiveness of local authorities.
86. Data will be presented through a range of visual tools, including interactive mapping, allowing a more detailed analysis of performance data, making it easier to see and understand performance data and trends on a national basis. This will potentially help to inform the development of more targeted policies for individual countries within the UK. The BSC will also make it easier for LAs to benchmark their performance against other similar authorities which should provide a driver for service improvement.
87. We would welcome views and ideas on the following;

Q17: Are there any other publicly available data sets, apart from LAEMS and FHRS, that could be readily accessed and usefully added to the BSC to improve its scope and potential?

Q18: Are there any other measurable indicators of LA performance besides LAEMS and FHRS that could be developed and used to contribute to the assessment of the effectiveness of LAs? These could be direct or indirect indicators and either quantitative and/or qualitative in nature.

Engagement and Consultation Process

88. The FSA presented the proposed amendments to LAs at a series of LA Update events that were held from December 2017 to January 2018, as well as presenting the proposals to industry representatives at the Food Hygiene Expert Panel. The also FSA held meetings with the Segmentation Working Group prior to the consultation being launched, presenting the proposals to LA representatives, and other stakeholder groups including representatives from industry and the professional bodies. The FSA received detailed responses written responses to our proposals from the enforcement community following the update events.

Summary of responses:

Proposal 1: Enhanced registration

89. At the stakeholder engagement events we received positive support to deliver enhanced registration, however, there was disappointment that the work on strengthening, as opposed to enhancing, the registration process was not being prioritised by the FSA. Shortfalls within the existing registration system were clearly identified, it was highlighted how resource intensive it is for LAs to chase up non- registration and that enforcement action is rarely taken against a food business for failure to register. There is therefore strong support for the introduction of Fixed Penalty Notices (FPNs) as an enforcement sanction for FBOs that fail to register their business.
90. There is also strong support amongst LA's for introducing licensing requirements for food businesses and there was general agreement that a funding mechanism would be necessary to resolve resourcing issues. LA's expressed the view that a charge for licensing would provide a ring- fenced income for official food controls, allowing conditions to be attached to ensure compliance at the point of trade and sanctions available to revoke/ suspend the license.

Proposal 2: NIS

91. Responses from stakeholders with regard to the draft national inspection strategy Standard and FSA proposals for oversight are still being collated, reviewed and considered. Initial thoughts are that the views appear to be mixed, with some being very supportive, and others raising some concerns and suggestions for improvement. All views are being taken into consideration and they will be used to inform the FSA's approach to NIS.

Proposal 3: Full compliance and Sustained Compliance

92. In England, Wales and Northern Ireland the proposed new definitions of 'full compliance' and sustained compliance were considered reasonable, but some LA's questioned the true impact/savings of the proposal. LA's stated that they are already using flexibilities in FLCoP for broadly compliant C/D businesses so they may not demonstrate sustained full compliance for years and therefore believed that the impact on inspections was negligible.

Proposal 4: Vulnerable Risk Groups

93. In England and Northern Ireland there was some support for the vulnerable group score being removed in the circumstances described, so long as there were alternative measures in place to recognise the higher impact of serving to vulnerable groups. There was unanimous objection in Wales on the proposal to remove the additional score of 22 for food businesses serving vulnerable groups

Proposal 6: Significant Risk

94. There was the suggestion that the FSA could introduce some of the factors that influence the 'significant risk' score under CIM. In England and Northern Ireland, a consensus could not be reached. There was, however, agreement that this score wasn't used consistently and therefore if it remained, consistency training was required. The Welsh LA's requested data to determine how often the score is applied and the possible impact of removing the score from the scheme. The general agreement was that if removal of the score did not alter the overall risk category, the change would be supported.

Proposal 8: Consideration of the Registration process

95. There were various views on whether Competent Authorities should factor into the confidence in management score (CIM) that a new business had not registered prior to commencing to trade. It was generally considered that this change alone would not make a significant difference to the number of food business operators that pro-actively register, however, it is a legal requirement and we are aware that some Competent Authorities are already taking non-registration into account when rating a business that had not pro-actively registered. At present we are not able to quantify the situation or the impact of such measures, therefore to ensure a consistent and fair approach further consideration is required.

Further consultation

96. The FSA intends to continue to engage with stakeholders throughout the consultation period, with a further meeting of the Segmentation working group to discuss the proposal, as well as series webinars for those local authority staff who were not able to attend the update sessions at the start of the year. The FSA also intends to undertake additional face to face discussions to address specific stakeholder issues where possible.
97. In relation to the work on NIS, the FSA has requested stakeholder views via the 9th edition of ROF newsletter, which can be viewed below. Engagement with the National Food Hygiene Focus Group, and National Food Standards and Labelling Group also took place during early 2018. The work on NIS was also communicated to all LAs across England, Wales and Northern Ireland via the Smarter Communications platform.

<https://www.food.gov.uk/about-us/ninth-regulating-our-future-newsletter>

98. Upon completion of the consultation the FSA will produce and publish a summary of the consultation responses received and its response to the issues raised. While some changes proposed in this consultation have a specific implementation date, the FSA will delay other changes until other supporting

policy developments are in place to protect local authority resourcing and implemented with any other changes like to have significant impact on LA service delivery to minimise disruption.

Responses

99. Responses are required by close 27 September 2018. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Nathan Philipppo
Segmentation Workstream Lead
Regulating our Future

Enclosed

Annex A: Standard Consultation Information

Annex B: Impact Assessment – Implementation of an Enhanced Registration Scheme

Annex C: Impact Assessment – Recognising National Inspection Strategies for food hygiene and food standards (food safety partnerships)

Annex D: Impact Assessment – Risk Assessment of Food Businesses

Annex E: Table of Changes to Food Law Code of Practice (England)

Annex A: Standard Consultation Information

Disclosure of the information you provide

Information provided in response to this consultation may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want information you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Any automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding.

The Food Standards Agency will be what is known as the 'Controller' of the personal data provided to us.

Why we are collecting your personal data and what we do with it

Your personal data is being collected as an essential part of the consultation process, so that we can contact you regarding your response and for statistical purposes. We may also use it to contact you about related matters.

The Data Protection Act 2018 states that, as a government department, the Food Standards Agency may process personal data as necessary for the effective performance of a task carried out in the public interest. i.e. a consultation.

We retain personal information only for as long as necessary to carry out these functions, and in line with our retention policy. This means that this information will be retained for a minimum of 7 years from receipt.

All the personal data we process is located on servers within the European Union. Our cloud based services have been procured through the government framework agreements and these services have been assessed against the national cyber security centre cloud security principles.

No third parties have access to your personal data unless the law allows them to do so. The Food Standards Agency will sometimes share data with other government departments, public bodies, and organisations which perform public functions to assist them in the performance of their statutory duties or when it is in the public interest.

What are your rights?

You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter.

If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner's Office (ICO) at <https://ico.org.uk/>, or telephone 0303 123 1113.

Our Data Protection Officer in the FSA is the Information Management and Security Team Leader who can be contacted at the following email address:
informationmanagement@foodstandards.gsi.gov.uk

Further information

If you require a more accessible format of this document please send details to the named contact for responses to this consultation and your request will be considered.

Annex B

Title: Regulating Our Future; Amendments to the Food Law Code of Practice (England) - Implementation of an enhanced registration system for food businesses IA No: RPC Reference No: Lead department or agency: Other departments or agencies:		Impact Assessment (IA)			
		Date: 26/06/2018			
		Stage: Development/Options			
		Source of intervention: Domestic			
		Type of measure: Other			
		Contact for enquiries: Beverley Kuster			
Summary: Intervention and Options		RPC Opinion: RPC Opinion Status			
Cost of Preferred (or more likely) Option					
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANDCB in 2014 prices)	One-In, Three-Out	Business Impact Target Status	
£m	£m	£m	Not in scope	Qualifying provision	
What is the problem under consideration? Why is government intervention necessary? <p>Change is needed to the process for registering food business establishments to help us regulate an increasingly diverse food industry and to improve the overall effectiveness, efficiency and consistency of the system. Additional information provided at the point of registration will enable an accurate assessment of risk and help to determine appropriate intervention strategies. In addition, information obtained will give the Food Standards Agency (FSA) as Central Competent Authority, comprehensive understanding of the industry which will assist in future policy development and in the management of food safety incidents.</p>					
What are the policy objectives and the intended effects? <p>Enhancing the registration process is fundamental to delivering the overarching Regulating Our Future Programme (ROF). The policy objectives are: 1) The development of an online registration service that will also give the FSA oversight of all food businesses in England, Wales and Northern Ireland. 2) To provide businesses with tailored support and guidance at the point of registration to assist them to comply with food law and drive up standards. 3) To conduct research to inform an evidence base to support future policy direction and development. 4) To raise awareness of the requirement to register and ultimately to increase the number of proactive registrations</p>					
What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base) <p>Option 1: 'Do Nothing', and continue with the current system of registration. Food Business Operators (FBO) would continue to register through multiple entry points and LAs would continue to adopt a variety of methods of processing and reporting to the FSA. This would not realise the policy objective. Option 2: Introduce an online service for the registration of all new food businesses using a two phased approach</p> <ul style="list-style-type: none"> • Phase 1 (pre EU-exit): Introduce an online registration service for those food businesses legally required by law to register • Phase 2 (post EU-exit: Include those food businesses legally required to seek approval <p>The new registration service proposed in option 2 will work in conjunction with LAs existing MIS/databases and would deliver the policy objectives as set out above. This is the preferred option.</p>					
Will the policy be reviewed? It will/will not be reviewed. If applicable, set review date: Month/Year					
Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope?			Micro Yes	Small Yes	Medium Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded:		Non-traded:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible
SELECT SIGNATORY:

..... Date:

Summary: Analysis & Evidence Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

Option 1 represents the 'Do Nothing' approach. The FSA currently holds no evidence to suggest that any of the important variables will change over time in the absence of intervention. Monetary costs are assumed to remain constant and unchanged.

Other key non-monetised costs by 'main affected groups'

Under the 'Do Nothing' approach, there is no evidence to suggest that non-monetary costs are likely to change in the absence of intervention.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

Option 1 also assumes unchanged monetary benefits. The FSA holds no evidence to suggest that any of the significant variables will change over time if it does not intervene.

Other key non-monetised benefits by 'main affected groups'

With the 'Do Nothing' approach, non-monetised benefits are expected to remain unchanged.

Key assumptions/sensitivities/risks N/A	Discount rate (%)	
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BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	

Summary: Analysis & Evidence Policy Option 2

Description: Make amendments to the establishment intervention rating scheme used to set intervention frequencies. FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised costs by 'main affected groups'

The per-business cost to paper and web registration is £1.95 and £1.22 respectively. The annual total cost is £49,496.85 for paper routes and £123,871.48 for web routes, given forecasts for future registration. Local authorities incur a paper and/or web-based per-application resource cost of £6.88 and £3.45 respectively. Processing paper and web applications in future is estimated as costing £174,635.04 and £350,292.30 respectively. £772,000 is the FSA's estimated cost of developing the digital registration service.

Other key non-monetised costs by 'main affected groups'

Although the per-business cost to paper and web registration could be calculated, these estimates could not be used to calculate the total cost to businesses who are currently trading but are yet to register. Similarly, the resource costs incurred by local authorities of having to process applications for businesses currently unregistered cannot be calculated. The FSA does not have this data available and hence, could not quantify these costs.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised benefits by 'main affected groups'

N/A: Benefits to Option 2 (the preferred option) could not be quantified at this stage. Through stakeholder consultation the FSA seeks to collect data to eventually monetise as many benefits as possible.

Other key non-monetised benefits by 'main affected groups'

Consumers are given better choice and face reductions in the incidence of foodborne illnesses. Food businesses have further opportunities for economic savings and an ability to demonstrate stronger compliance. This would reduce the burden of enforcement. Through data sharing, local authorities benefit from better inspection strategies. The FSA will be able to establish traceability and place itself in a better position for the design and implementation of sound food policy.

Key assumptions/sensitivities/risks	Discount rate (%)	-
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In forecasting future levels of business registration and subsequent authority administration, an industry churn rate has been estimated. Throughout calculations, this percentage is assumed to remain constant.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	Benefits: 0	Net: 0	Zero net cost

Evidence Base (for summary sheets)

Background – Regulating Our Future Programme

1. The Food Standards Agency's (FSA) 'Regulating Our Future' (ROF) Programme aims to modernise how food businesses in England, Wales and Northern Ireland are regulated to check that our food is safe and what it says it is. We are building a system that is dynamic and flexible and can adapt as the global food economy changes and as technology develops in the future.
2. We are doing this so that our system has the sophistication needed to regulate an increasingly diverse food industry and to adapt quickly to changing risks and so that it can respond to changing patterns of food production, trade and consumption when the UK leaves the EU.
3. Ensuring regulatory decisions are tailored, proportionate and based on a clear picture of UK food businesses is one of the 2 principles of the ROF Programme that will be realised through his work. The other is to make it easier for food businesses to be transparent and honest in the provision of information.

POLICY OBJECTIVE

4. Enhancing the registration processes will modernise the current approach for new food businesses when they start-up. Introducing new technology will allow the FSA to maximise the value derived from registration information recorded from businesses. The project aims to improve the accessibility and quality of information for new food businesses in a phased approach. Furthermore, this work is the fundamental foundation to delivering the overarching ROF Programme.

Phase one of the 'Enhanced Registration' project can be split into the following four objectives:

- The development of a digital service for the registration of food businesses streamlining and simplifying the process for food business operators and providing the FSA as the Central Competent Authority (CCA) with a unified view of all food businesses in England, Wales and Northern Ireland. In turn, using an enhanced data set captured at the point of registration to help design an appropriate regulatory regime, improve incident handling and better inform future policy direction.
 - Enhance the current registration process to provide businesses with access to relevant information and guidance promptly, in turn assisting them to comply and drive up standards of compliance.
 - The conduct of research to understand the barriers to proactive registration by new food businesses and to help inform an evidence base to inform the case for the introduction of Fixed Penalty Notices (FPN) and/or a Permit to Trade (PTT) /licensing system as a public health protection measure.
 - Deliver awareness raising campaigns to promote the new registration system, helping to encourage and increase proactive registration of food businesses.
5. The ROF programme is being carried out via several workstreams in a phased approach. For work under the Enhanced Registration workstream, this Code review covers the first iteration which includes details of the process change as to how a food business operator (FBO) registers the establishment(s) under their control.
 6. This change aims to improve the overall effectiveness, efficiency and consistency of registering food business establishments across England, Wales and Northern Ireland.

However, this assessment only covers changes in England, separate consultations will be carried out in Wales and Northern Ireland.

7. It is important to recognise that the newly developed online registration service will be the fundamental foundation to the success of the other workstreams and overall ROF Programme. The online service will capture an enhanced set of data from FBOs at the point of registration, which will be used to assess the risk posed by the food business and subsequently identify an appropriate intervention strategy to ensure efficient use of local authority (LA) resource.
8. In addition, utilising the new technology, LAs will be informed of new food businesses at an earlier opportunity enabling them to provide relevant advice and support to help them get it right from the start.
9. We are still in the development phase of this work and therefore do not have the evidence base required to quantify all of the benefits we anticipate will be achieved through implementation of the new online registration service. However, through the development phase, on-going research and the consultation process we will continue to gather the full evidence base required.

The Current system for registering/obtaining approval for a food business – How it operates

10. FBOs must either register the establishment(s) under their control or have them approved by the appropriate competent authority.
 - Under Article 6(2) of Regulation 852/2004, food business operators (FBOs) must register an establishment(s) under their control that carries out any stage of production, processing and distribution of food, with the appropriate competent authority.
 - Regulation 853/2004 requires that food business establishments handling food of animal origin, with some limited exceptions, be approved by the competent authority prior to trading. For those businesses that require approval, demonstrating compliance with relevant requirements of Regulation 853/2004 is required in addition to full compliance with Regulation 852/2004 before approval can be granted. Registration under Article 6(2) of Regulation 852/2004 is not required for establishments that are subject to approval.
11. 634,584 food establishments are recorded as registered with LAs in the UK as at 31 March 2017. That equates to 99.2% of food businesses in England, Wales and Northern Ireland that are only required to register as opposed to 0.08% obtaining approval for their business.
12. For registration, FBOs are only required to provide a limited amount of information about their food establishment to the LA relevant to the location of their food business(s). They are required to register the establishment with the LA at least 28 days before their business starts trading or the food operations commence. Upon receipt of a submission, LAs utilise the information to determine when to carry out an initial inspection. Currently LAs use a variety of registration forms and approaches for the registration process.
13. For a variety of reasons many FBOs either start trading before registering and therefore do not receive the appropriate level of support at the earliest opportunity to aid compliance, and/or register and commence trading prior to a LA inspection taking place.
14. Those food businesses, however, that produce products of animal origin (meat, fish, dairy or eggs) and supply these to other food establishments require approval. To obtain an approval, a

FBO must provide sufficient information both at application and during an on-site inspection to demonstrate compliance with the relevant hygiene legislation. Until this compliance can be checked and verified, the FBO must not commence operation of the food business.

15. Those establishments requiring approval only represent a small proportion of all food businesses as the majority are only required to register. It is our intention to incorporate those food businesses requiring approval into the new online service at a later phase in the programme.

Why enhance the current registration system?

16. We recognise that the current registration process works to a degree but there is substantial room for improving the overall effectiveness, efficiency and consistency of it for a number of reasons:

- LAs have the option to use variations of the model registration form provided by the FSA, creating inconsistencies between LAs and across the three countries. This approach can be confusing and frustrating for FBOs particularly those who have multiple food businesses located in different LA areas and/or countries.
- At present LAs process and acknowledge food business registrations according to their individual internal procedures. This can involve manual intervention to issue letters/emails and the inputting/verification of data which can be labour intensive.
- The current government online registration service (<https://www.gov.uk/food-business-registration>) redirects FBOs to the LA in which their food business is/will be located, therefore what this route offers is very much defined by the LA, again creating inconsistencies in the process. For example, some FBOs are directed to the LAs registration form, others are simply provided with the address of the LA in which their business is located.
- At present, FBOs follow numerous registration pathways with many businesses requiring registration not being identified until an LA officer notes a change in FBO during an intervention or becomes aware of a new food business when they are out on their district. Qualitative research has identified that the main reason why FBOs do not proactively register is a lack of knowledge or understanding of how to register. Simplifying the process and raising awareness of the new online registration service will help to improve consistency and will better inform FBOs of how to fulfil their legal obligations.
- The current model form only gathers basic minimal information about the food business establishment for example: FBO name, address, business type. This is insufficient to establish the level of risk associated with the business.
- Pertinent data obtained from FBOs at the point of registration and following an intervention by the competent authority is held by individual LAs on a variety of management information systems and in differing formats. These systems do not currently communicate with each other or directly with FSA systems.
- Where FBOs own mobile food business establishments, there is the potential for these to operate across numerous LA boundaries. To prevent unnecessary inspections, details of interventions and enforcement action should be passed to the registering authority to take account of this information to determine the intervention rating. Currently the onus is on the inspecting LA to obtain and share the information in a timely manner, failure to do so can result in an inaccurate assessment of risk and

numerous inspections being carried out as and when the mobile establishment moves from one area to another. This is currently a labour intensive process.

17. We are aware that there is appetite for the introduction of alternative approaches to help increase proactive registration and to ensure that FBOs have the relevant support they need for them to commence trading. Examples include the use of fixed penalty notices (FPNs) for authorised officers to serve on those FBOs who do not proactively register and/or the introduction of a Permit to Trade (PTT) licensing system.
18. The use of sanctions, such as FPNs, is being considered within the wider ROF Programme but due to other legislative priorities such provisions will not be introduced pre-EU exit. In addition, the introduction of a PPT/licensing system could take several years to bring forward and we recognise the need to carry out further research to provide a robust evidence base before these changes can be considered and potentially introduced. By enhancing the current registration system, one of our aims is to obtain further evidence to demonstrate that the introduction of FPNs/PTT licensing system in England, Wales and Northern Ireland are necessary measures to protect public health.

JUSTIFICATION FOR ENHANCING THE CURRENT REGISTRATION SYSTEM

19. Streamlining this process will improve the overall effectiveness and efficiency for both LAs and FBOs, whilst also providing the basis for other areas of the ROF Programme to be formed upon.
20. This new system will alleviate inconsistencies in the registration process and make it more streamlined and less labour intensive. FBOs will be asked questions pertinent to the type of business they are registering and be treated the same regardless of the LA area they are registering in.
21. Raising awareness of the need to register will better inform FBOs of the requirement and increase the number of registrations prior to trading. Enhancing the registration process will provide an opportunity to gather more in-depth information about the business at the point of registration; allowing tailored advice and guidance to be provided to the FBO at the earliest opportunity. Furthermore, by capturing more in-depth information on the business activities, this allows for a more accurate assessment of risk to be determined, enabling an appropriate intervention strategy to be identified.
22. Relevant information about the FBO and their activities obtained through the online registration service will be made available to LAs and the FSA as the CCA. Gaining an overview of all food businesses establishments will give the FSA a comprehensive understanding of the industry and will assist in future policy development and in the management of food safety incidents.
23. The information obtained through the new online service will be available for LAs to view. In addition, information regarding interventions and compliance will be made available through a new FSA system entitled the 'unified view' which is currently under development. This will facilitate co-ordination and planning of interventions for mobile traders that operate across LA boundaries.
24. Based on a small sample size, initial findings demonstrate that there will be savings in the time taken by an FBO to complete the new online registration form as opposed to following the current process.

Benefits for LAs:

25. Streamlining the process, helping to reduce the manual burden on LA officers involved in inputting registration information onto their management information system (MIS)/database.
26. Minimising the need for manual verification checks of details entered on the registration form provided to LAs. Basic generic checks will be included in the initial version of the online form, for example, post codes and address details, with further verification of FBOs to be incorporated at a later stage.
27. LAs will be able to view relevant information on food business establishments from across England, Wales and Northern Ireland via a system called the unified view. This will help to make informed decisions regarding the most appropriate interventions to be undertaken and have an insight into overall business compliance.
28. Through the unified view LAs will be able to make links between food businesses, for example, detect frequent changes of FBO, identify multiple businesses owned by the same FBO, which will help build an overall picture of compliance and aid in the management of food safety incidents.
29. The new online service will alert LAs of a new food business registration in their area enabling them to make contact with the FBO at the earliest opportunity to ascertain what support and guidance they might require. Early findings from some quantitative research suggests that those FBOs that received support at an early stage go on to achieve higher initial Food Hygiene Rating Scores (FHRS) than those who didn't.
30. Obtaining additional information about a new business at the point of registration will enable an assessment of the risk associated with that business. Information obtained will be run through a 'risk engine' which uses a set of business rules to generate a 'risk score' and segments businesses into categories. This categorisation will determine the nature, frequency and intensity of official controls for all new business using the online service to register.
31. The new online registration service proposed for implementation in March 2019, preferred option 2, will be compatible with most of the MIS currently utilised by LAs therefore, there will be no requirement for LAs to change to a new provider. LAs will still be able to obtain supplementary data relevant to their local requirements in addition to that requested through the online registration form.
32. There will be a flow of information between the LAs and the FSA, enabling data to be accessed and used effectively and efficiently by both parties.

Benefits for the FSA (CCA):

33. The new online registration service will obtain information that the FSA as the CCA can access to give a unified view of all food businesses across England, Wales and Northern Ireland which is paramount as we prepare to exit the EU.
34. Greater access to information about food businesses and their activities will assist the FSA in the event of a food incident or crisis, making it easier to trace products and identify relevant links which will provide better public protection.
35. Having a unified view of all food businesses will enable the FSA to better inform future policy direction.

Benefits for FBOs

36. Recent research shows a variety of ways a food business registers or becomes known to the LA, our aim is to simplify the process for a FBO to register their business making it a consistent experience regardless of where their business is located.
37. The new online registration service will provide the FBO with confirmation that their food business has been registered with the LA relevant to their business location. In addition, a food business registration number (FBRN) will be issued that is unique to that registration.
38. Introducing a new online registration service that asks questions relevant to their business activities will enable new businesses to receive links to current and tailored information and advice to help them to start-up successfully. By providing FBOs with tailored guidance to help them comply with food regulations prior to trading, this intervention will increase business awareness and may lead to financial savings, i.e. businesses are less likely to spend money unnecessarily to comply.
39. Initial findings following user testing with a small sample size demonstrated savings in the time taken by an FBO to complete the new online registration form as opposed to completing the current government form (<https://www.gov.uk/food-business-registration>). Utilising the current on-line form took on average 11.2 minutes to complete whereas early testing with the new form asking additional questions is averaging between 6-8 minutes. The new online registration service will ask intuitive questions that are appropriate to the type of business being registered dependant on the answers given to questions throughout the process. User testing is on-going as we continue to develop the service which will enable us to quantify the time savings to FBOs.
40. Achieving compliance with food law from the outset will lead to a high FHRs rating for new businesses which in turn provides commercial benefits for a business

Benefits for consumers:

41. It is anticipated that improved access to guidance for FBOs will in turn result in more compliant food businesses with higher FHRs ratings, which is positive for public health protection and consumer choice and confidence.
42. Consumers will be better informed as they will be able to identify if a food business has fulfilled its legal obligation of registering as a food business.

User Research – Main Findings:

43. Under the current system there are some food businesses who do not proactively register before they begin trading or food operations commence. In addition, some FBOs fail to notify relevant authorities of material changes that may affect risks associated with their business. As stated we recognise that it is important to identify new food businesses at the earliest opportunity to be able to ascertain their compliance level and to provide an appropriate level of support to help them get started. Failure to do so can place consumers at risk.
44. The introduction of a new online registration service will help to address some of these issues as it will make it easier for FBOs to register their business and for LAs to process the registration and determine what support they might require. Information obtained at the point of registration will also be used to assess the risk and help to inform an appropriate intervention strategy.

Engagement:

45. At recent engagement events with LAs we advised of our plans to implement a new online service, here is a summary of the comments we received:

46. At the LA ROF update events that were held in December 2017 and January 2018, there was disappointment that the work on strengthening, as opposed to enhancing, the registration process was not being progressed/prioritised by the FSA and shortfalls within the existing registration system were clearly identified:
- It is resource intensive to chase up non- registration, a financial obligation related to registration could prevent this from happening & free up resource.
 - LA's do not generally take enforcement action, i.e. prosecution, against a food business for failure to register, but the offence may be cited if prosecutions are brought for other matters. The view was that courts would not support formal action if a LA were to enact the word of the law on registration.
 - It was felt that a permit or licence may improve business engagement, as calling it 'registration' implies that it is less serious
47. There is strong support amongst LAs for introducing licensing requirements for food businesses and there was general agreement that a funding mechanism would be necessary to resolve resourcing issues. It was felt that a charge for licensing could provide a ring-fenced income for official food controls, allowing conditions to be attached to ensure compliance at the point of starting to trade and that making sanctions available to revoke/suspend a licence would be helpful enforcement tools for LAs.
48. There was also strong support for the introduction of FPNs as an enforcement sanction for FBOs that fail to register their business and for introducing financial penalties for non-compliance, to affect/influence business behaviour. LAs recognised the benefit of introducing an immediate sanction with ring fenced income that could be used to fund official food controls.
49. LAs requested the FSA to consider the following with regards to the proposed system of enhanced registration:
- Research should be undertaken to incentivise registration, as it was felt that the current form is not difficult to complete yet still many FBOs fail to register
 - A digital form would not always be well received due to the lack of access to, or willingness to use IT by the SMEs and therefore an offline version should also be made available.
 - The registration process should be clear and signpost businesses to where they can obtain advice and guidance. If the registration process is not clear businesses will be confused as to who to register with. If registration is with the FSA, businesses will not know who conducts inspections.
 - Ensure that any future registration process is compatible with all the MIS in use, to provide efficient data capability & prevent duplication of efforts
 - There was a general request to ensure that IT providers are kept fully informed of any proposed changes due to the long lead in time for software development.
 - The Integration with other areas of environmental health work, e.g. premises licensing (alcohol and public entertainment)
50. During the summer 2017 update events LAs expressed their concern with introducing a system that provides a central point for registration, for the following reasons:
- It would not enable LAs to include or obtain information at a local level or to link to local services e.g. local Fire Authority. LAs did, however, recognise the benefit that could result, of links being provided to tailored advice that is updated centrally by FSA to improve consistency in the delivery of advice.

- Difficulties with accessing the information due to Data Protection /FOI considerations.

Comments received are being considered throughout the development process.

51. A number of the comments refer to either the use of sanctions, such as FPNs or the introduction of a PPT/licensing system. Whilst these measures are not within the scope of this phase of work these measures will be considered in the longer term within the wider ROF Programme. Research will provide the evidence base to establish if there is a case to introduce a PTT/licensing system in England, Wales and Northern Ireland in the future as a public health protection measure.
52. To help inform the design of a new online registration service and to better understand FBOs requirements the FSA has commissioned independent research, which is being carried out throughout the development process.

IT development

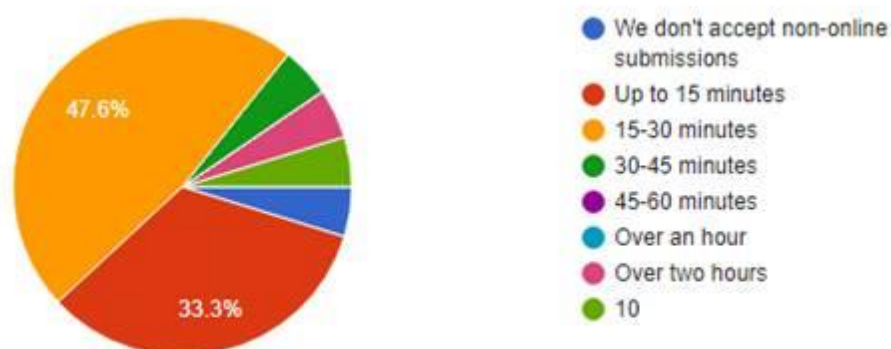
53. The FSA has sought feedback to understand user group perception of the existing registration process and thereby, areas in which the FSA could add the most value. Through a range of research methods that included the conduct of interviews, surveys and enquiries, a sample of over 750 responses were gathered across the FSA, LAs and FBOs.
54. Responses indicate that 75% of the LAs asked either use or accept the business form available online at www.gov.uk. Despite this website being the main route to registration, 60% of LAs are dissatisfied with this process. Quantitative results highlight issues with clarity, as 19% of registrations omit mandatory information (on average), whereas 15% have incorrect information filled in (on average). The current registration process also imposes costs to authorities through a waste of resources. An average of 1 in every 35 inspections of new establishments could not be completed due to the FBO not being open or having ceased trading. Further, an average of 1 in 15 inspections are not undertaken because of the FBO not having started to trade.
55. Research to assess the existing registration process identified and split key user group needs into four categories.
 - Firstly, there is need for better consistency. FBOs expect a requirement to provide the same information and hence, have the same experience across LAs. Authorities seek to fill gaps in mandatory data provided on FBOs by distributing and processing an unambiguous and validated registration form.
 - Secondly, FBOs would like feedback to confirm receipt of their application and after which, to track an audit trail of their registration form and its status.
 - Thirdly, the FSA and LA are the groups that hope to improve data quality. These groups would like the information submitted to authorities to be validated and forwarded to the relevant LA. Data concerning FBOs is to be consistent and held in a similar format across all LAs for the FSA to access.
 - Finally, there is a need for authorities to have a wider overview of food businesses and an ability to share data with one another. For the FSA, up-to-date information concerning the FBO would be available in one place to allow accurate analysis into the performance of both the food operator and LA.
56. Questionnaires were used as part of this work carried out by the FSA within which LAs were asked to provide feedback on their experiences with the existing registration system. The questionnaire sought to better understand details surrounding the processing of applications under different methods of business registration. Non-web and web-based applications are

two routes to registering a business with authorities, thereby making these results the point of focus.

57. To better understand the burden on LAs when processing non-web applications specifically (inclusive of telephone registration, in-person form submissions etc.), the FSA posed the following question:

- *Approximately how long does it take to process a non-online registration form, including the performance of necessary checks and the input of information into the database?*

58. The participating LA is then presented with a list of closed-ended responses. These take the form of duration thresholds that the LA is required to select an answer from. Responses to this question comprises the experience of 21 LAs. Figure 1 provides a pie chart to illustrate results.



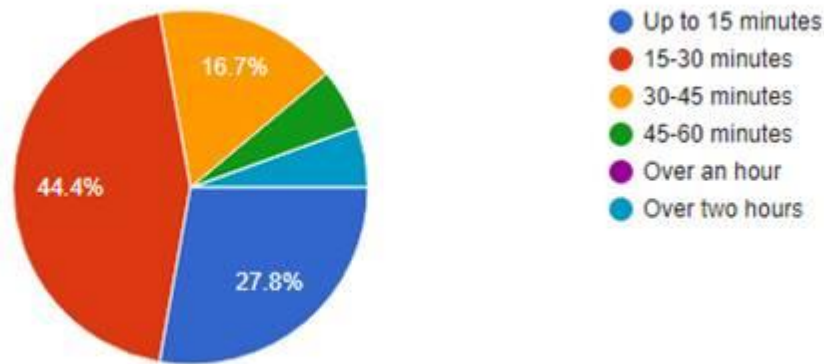
59. 33.3% of respondents believe that it takes up to 15 minutes to process a paper application. For 47.6% of LAs, processing takes between 15-30 minutes. 4.6% (the equivalent of 1 LA) lie in the regions for 30-45 minutes, over 2 hours and 10 hours as the time taken to process an application. Only 1 LA out of those sampled has indicated that they do not accept non-web forms.

60. One reason for the large disparity in results could be due to the fact LAs process registration applications differently. They are to perform different checks and follow different data-input procedures and so, registration applications present a burden to LAs to a varying degree.

61. For web-based applications, the FSA asked the following question:

- *Approximately how long does it take to process a registration form through the www.gov.uk website, including the performance of necessary checks and the input of information into the management information system?*

62. Responses to this question are based on the experience of 18 LAs. Figure 2 provides a pie chart to illustrate results.



63. 27.8% of respondent's state that it takes up to 15 minutes to process a web-based application. The majority of LAs believe this takes between 15-30 minutes, split at 44.4%. For the 30-45-minute threshold, 16.7% of LAs state this to be the case. 5.6% (equivalently, 1 LA) of respondents lie in both the 45-60 and over 2-hour regions.
64. The conclusions from this study indicate that with the large disparity in results, there is scope for bringing processing time down significantly, especially for those at the upper end of duration estimates. There are those business applications that impose high resource costs to LAs, regardless of whether the business opts for non-web or web-based routes.
65. The validity of this study is limited by its relatively small sample size. Although this may not necessarily be representative of all LA experiences across England, Wales and Northern Ireland, these results indicate instances of high resource costs and serve as a useful benchmark to motivate changes to the existing system. These changes are intended to reduce the time taken by LAs to process food business registrations.
66. The FSA has entered the Beta stage of testing the new registration service and is working with LAs to ascertain their experience and see how this compares to the existing process. By distributing the same questionnaires and representing results in a similar fashion, the FSA will be able measure the results accordingly.
67. Beta will also enable the FSA to explore specific points of benefit to be included in the development of the new online service for example, the use of holding areas for FBOs registering too early and automated prompts to check start states to help reduce the number of failed visits.

Quantitative data gathering

68. In addition, a LA data gathering exercise is on-going to provide a significant body of data to progress the final model for the registration and segmentation of food businesses. This exercise aims to provide a quantitative evidence base which will help the FSA establish the performance of the current system; identify the level and type of support provided to new food businesses; analyse the impact of this support on business compliance; evaluate the case for an enhanced registration system and investigate the need for a new food business's pathway to registration as a component of a new risk profiling system.
69. We understand that there are many ways that a new business becomes known to the LA and that the main route is when they voluntarily present themselves to the LA by telephone,

email, via the LA's web site or in person. However, the FSA does not currently have the data to evidence this. In order for the FSA to address the issue of non-registration, it is important to know what these potential routes are.

70. The feedback obtained through LA audits anecdotally suggests that not all food businesses proactively register so again we need to determine the frequency of proactive registration and to identify whether proactive registration levels differ for new food business registrations as opposed to when there is a change of food business operator.
71. We also need to gain a better understanding on the impact of the advice, to determine whether the FBO has been able to understand the advice and implement it successfully to achieve compliance and obtain a good rating under the FHRS.

The following information is being collected by 20 LAs to help inform a robust evidence base:

- Pathway, how was new business identified i.e. voluntarily presents via LA, voluntarily registers via www.gov.uk, via a third party, is discovered trading by the LA, the LA is notified by Other Government Department or via another alternative route;
- Reason for the registration, a new food business operation, a change of food business operator, or a significant change to existing food establishments' operations that requires notification to the LA;
- Establishment ID, Establishment name, address and business type (contact details are not required);
- Date of registration for the food business and date the Food Business Operator (FBO) commenced trading;
- Support given to FBO including the date provided and the way it was given (advice guidance posted or emailed or delivered face to face at a pre-inspection visit) was the advice provided before or after trading/inspection and was the advice charged for by the LA;
- The first intervention and second intervention rating scores, where applicable, for hygiene, structure and confidence in management.

Data is being reported to the FSA monthly for a period of up to 12 months pre-and 12 months post EU exit. The data is to be obtained from a representative sample of both rural and urban authorities located across Northern Ireland, Wales and England.

72. Whilst we only have a small dataset to date, initial findings show that those FBOs who received support at an early opportunity went on to receive a high FHRS score at their first inspection. We will be able to quantify this further as the research progresses.

Qualitative research

73. To complement the quantitative work, we also carried out a social science study on the flow of food business establishments into the regulatory system. The aim of this work was to identify the main pathways that a FBO business becomes known to the LA, why they 'chose' that route and to establish the type of support they received and how helpful they found it.
74. Findings identified that more than three quarters (77%) registered or gained approval voluntarily via their LA whilst 13% via other routes i.e. through 3rd parties leaving approximately 10% that were identified already trading. In relation to the number of food businesses in England, Wales and Northern Ireland this equates to approximately 63,458 that

may not be known to the LA. The quantitative research will help to quantify this figure as it will involve a larger sample size over a longer period of time.

Those FBOs receiving support and advice from the LA are considered to go onto be more compliant than those that did not.

Headline findings from surveyed LAs and FBOs

75. The results of the survey are as follows:

- According to LAs, food businesses most likely to be trading unregistered include takeaways, fixed premises food retailers and stall/market retailers;
- Two thirds of LAs (66%) say they take steps to verify the accuracy of information supplied by FBOs;
- Almost half of LAs (49%) believe that FBOs not proactively registering or seeking approval demonstrate greater instances of non-compliance than those who register voluntarily;
- Thinking back to the time of registration, FBOs would rate their understanding of the registration/approval process at 6 out of 10;
- Just under a quarter (24%) of FBOs believe the registration/approval process could be improved;
- Less than one in 50 LAs believe that all FBOs notify them of significant changes to their business. This is despite 88% of FBOs saying they are aware that this is a legal requirement;
- Just under three quarters of LAs (74%) consider the support they offer to be effective at encouraging FBOs to register or obtain approval;
- 66% of LAs and 58% of FBOs are favourable to the idea of a standardised digital registration system for food businesses;
- 94% of LAs and 25% of FBOs favour the idea of a licensing system (PTT).

76. In combination, the quantitative and qualitative research will provide a robust evidence base and contribute to the longer term aims of the ROF programme.

POLICY OPTIONS

Two options have been identified:

77. **Option 1:** 'Do Nothing', and continue with the current system of registration. FBOs would continue to register through multiple entry points as normal. LAs would continue to adopt a variety of methods to process this information and feed it to the FSA through multiple returns processes and continue to base inspections and ratings on data of similar quality gathered by the current registration system. This would not realise the policy objective.

78. **Option 2:** Introduce an online service for the registration of all new food businesses – two phased approach

- Phase 1: Introduce an online registration service for those food businesses legally required to register (pre-EU exit)
- Phase 2: Include those food businesses legally required to seek approval (post EU-exit)

The new registration service proposed in option 2 will work in conjunction with LAs existing MIS/databases and would deliver the policy objectives as set out above. This is the preferred option.

GROUPS AFFECTED

The following groups are affected:

Consumers

79. A key aspect of registration is to inform the relevant competent authority of business operation to determine the nature of controls applied. Ultimately, the process helps businesses better comply with food hygiene and food standards. By setting themselves up correctly, FBOs place themselves in a better position to protect consumers and reduce their exposure to unacceptable food-related risks.

Food Businesses

80. Food business establishments are the primary focus of the registration process. The number of food businesses who are not currently registered prior to commencing trade in England, Wales and Northern Ireland at any one time has not been quantified but following research using a small sample size it is estimated that there could be in the region of 63,458 such establishments. The enhanced registration proposal would affect both existing businesses who are yet to register as well as all new food businesses in the future.

Local Authorities

81. Local authorities are responsible for official controls in the majority of food businesses, and registration is fundamental to enabling them to discharge their obligations.

The FSA

82. The FSA is the CCA responsible for ensuring that an effective regulatory regime is in place to verify that food businesses meet their obligation to ensure food is safe and what it says it is. In addition to developing the new digital service for registration of food business establishments the FSA will be responsible for providing the operational support the effective operation of the service.

Wider Economy

83. By increasing overall levels of proactive business registration, authorities will be apply suitable controls to FBOs at the appropriate time. Better understanding and compliance with food law prior to trading would help reduce instances of foodborne illness, which would have beneficial impacts on the economy in terms of reduced burden on the National Health Service (NHS), thereby signifying reductions in both health and financial costs to patients. This would include reductions in pain, suffering and death, as well as forgone economic output due to absence from work or a reduction in the workforce.

OPTION APPRAISAL

Option 1: 'Do Nothing', and continue with the current system of registration

Costs and Benefits

84. Option 1 is the baseline against which all other options are appraised. The FSA currently holds no evidence to suggest that any of the important variables in the baseline will change over time in the absence of intervention. With this, the costs and benefits in the baseline across time assume current levels of business registration and compliance, consumer risk and incidences of foodborne illnesses. Similarly, there is no expectation that the intensity of LA or

FSA intervention will change. All costs and benefits in the policy options are measured incrementally against the status quo.

Option 2: Introduce an online service for the registration of all new food businesses – two phased approach

Food Business Costs

Registration of existing businesses

85. Existing food business who have already registered will not be required to re-register their business as part of this process. There are however, those food businesses who have commenced trading, but are yet to register. The introduction of an online registration service and campaign to raise awareness of the requirement to register will help to prompt those FBOs to register, ideally through the online service. As for FBOs who have not commenced trading, an element of familiarisation will be required to ascertain what is required. Paper and online applications will continue to be the two main routes to registration, although online submissions will be encouraged.
86. At this stage, the FSA estimates that registration through the new online service would take an average completion time of between 6-8 minutes and a maximum of 11.2 minutes via paper. User testing is on-going as we continue to develop the model which will enable us to quantify the time savings to FBOs of the new online system and paper form.
87. The time that managers devote to registration can be burdensome. In monetising this burden, the loss in productivity that managers bear can be a point of focus. Calculating this makes use of two variables. The first is the hourly wage earned by the manager, as it is an indicator of productive value. The second is the length of time for which the manager diverts from business activities to register their business onto the new system. The product of the two variables can be used as a proxy for the economic value forgone due to registration.
88. In identifying an accurate figure for the manager's average hourly wage, the 2017 Annual Survey of Hours and Earnings (ASHE) survey is a suitable data source^[1]. Specifically, the median hourly wage for restaurant and catering establishment managers and proprietors is used, and is given in the survey as £10.45. The value for the second variable depends on whether the manager opts for paper- or web-based registration. For the paper application, £10.45 is multiplied by the estimated duration of 11.2 minutes (or 0.186). The per-business cost is £1.95. For web applications, £10.45 is multiplied by the estimated 7-minute duration (or 0.116). The per-business cost to this is £1.22.
89. Data is not available to carry out industry cost calculations as we require an estimation of the total number of businesses that are both unregistered and trading, along with the estimated split for which registration route they are likely to choose. Therefore, only the per-business cost could be calculated.

[1] The 2017 Annual Survey of Hours and Earnings (ASHE) is a detailed and comprehensive survey of earnings information in the United Kingdom. The headline measure of earnings from the ASHE is the median hourly earnings for full-time employees. The median is used because the distribution of earnings is skewed, with more people earning lower wages than higher wages.

Ongoing Registration

90. The new online registration service is expected to capture the majority of new food business registrations in the future. Research carried out by the FSA provides a basis for predicting future levels. It is estimated that 634,584 food businesses are currently in operation across England, Wales and Northern Ireland with a corresponding annual churn rate of 20%. Assuming the churn rate remains constant and unchanged, 126,917 businesses are expected to register per annum.
91. Under the current system, the ratio of paper to online registration is split 60:40. With a new online solution to registration, the FSA aims to significantly increase the proportion of FBOs registering online. Specifically, the ratio for future paper to online business registration is anticipated to be 20:80. Given the churn rate, this ratio provides a corresponding split of 25,383 businesses registering through the paper form and 101,534 businesses registering online every year.
92. The 25,383 businesses expected to register through the paper form in future is multiplied by the per-business productivity loss attributed to this route (£1.95). The productivity loss across these firms is £49,496.85.
93. Similarly, the 101,534 businesses expected to register through the software in future can be multiplied by the per-business productivity loss associated with this journey (£1.22). The productivity loss across these firms is £123,871.48.

Local Authority Costs

One-Off Administration of existing businesses

94. One of the key policy objectives for the FSA is to have oversight of all food businesses operating in the industry and so, following a campaign to raise awareness of the requirement to register, those businesses who are currently unregistered will be prompted to do so. The potential influx of new registrations could present a one-off administration cost to authorities. LAs would need to reallocate their staffing resources to handle the sudden upsurge in registration.
95. Monetising the strain on LA resources involves staff costs as well as the average duration associated with processing an individual application. A variety of staff are involved in processing a business' application. For both paper- and web-based routes, the time breakdown per application is approximated as follows:
- 75% of Administration staff time
 - 24% of Environmental Health Officer (EHO) time
 - 1% of Team Leader time
96. Following this, the median hourly wage for each occupation is identified through the ASHE survey. Local government administrative staff earn a median hourly ASHE wage of £12.24. EHOs earn a median ASHE wage of £18.54. Finally, office managers (used to represent team leaders) earn a median hourly ASHE wage of £14.36. These figures provide the first component in modelling the burden to LAs.
97. The maximum time taken to process a paper-based application is 30 minutes. (47%) Given the time breakdown for each staff along with their respective median hourly ASHE wage, the LA's cost to processing each paper application is £6.88.

98. The maximum time taken to process a web-based application is 15 minutes. Given the time breakdown and median hourly ASHE wages for all staff involved, the LA's cost to processing each online application is £3.45.
99. The costs to processing the two types of registrations are based on conservative duration estimates. User testing is on-going as we continue to develop the new model which will enable us to fully quantify the anticipated time savings to LAs in processing online and paper registration forms. The FSA believes that the new technology will eliminate the need to re-key information. Therefore, the online service is likely to bring down processing time, and hence costs even further.
100. Since the FSA does not know the number of FBOs who are unregistered, it is only possible to estimate the per-application cost to the LA.

Ongoing Administration

101. The forecast for future business registration reflects ongoing administration that LAs would undertake. Based on research carried out by IBM, the 20% churn rate corresponds to 126,917 new entrants who are expected to register every year. The time taken by LAs to process registrations is to be estimated in accordance with the proportion of businesses opting for paper- or web-based routes in future.
102. The ratio for future paper to web registration is predicted as 20:80. With this, 25,383 FBOs are likely to register through paper, relative to 101,534 registering online. Under this prognosis, the per-application cost of £6.88 is multiplied by the 25,383 firms likely to register through the form. The total cost to the LA for this route is £174,635.04. Similarly, the per-application cost of £3.45 is multiplied by the 101,534 firms likely to register online in future. The total cost to the LA for this route is £350,292.30.

FSA Costs

Software Development

103. The net cost of the initial work to develop the new online registration service for implementation in March 2019 will be £772,000. This represents the first iteration of the new service known as the minimal viable product (MVP). Further enhancements will be made in due course.

Benefits

Consumer Benefits

Improved Consumer Choice

104. By streamlining the registration process for food business establishments through the use of technology, consumers and other interested parties would be able to check that a food business had been registered which would provide added confidence that they were aware of their obligations to produce food that is safe to eat.
105. Through improving the flow of information to the consumer, they are placed in a better position to make fully-informed decisions regarding the food that they buy and eat outside of the home.

106. To determine the value of this, the FSA would need to either understand how much the consumer would be willing to pay for better decision-making or observe their behaviour in markets that are similar /related to food health and safety. As the FSA does not have access to this, the value of this benefit could not be estimated.

Foodborne Illnesses

107. The new online service provides FBOs with appropriate guidance and support. Assuming FBOs make use of the guidance they are provided with, they would be able to manage food-related risks more effectively. Therefore, the quality of food supplied to consumers would improve.

108. Sustained improvements in food quality through better risk-management and compliance means consumers are better protected from food risks. Less exposure to this would lead to various long-term health and financial benefits through a reduction in the number of cases of foodborne illnesses and a reduction in associated costs.

109. In monetising the value to a reduction in the number of consumers contracting foodborne illnesses, the FSA would need to examine the relationship between better compliance from FBOs and the number of cases of foodborne illnesses. As this is not held, these benefits could not be quantified.

Food Business Benefits

Economic Savings

110. FBOs are responsible for demonstrating compliance with Food Law, compliance with the relevant regulations provides assurance that FBOs are meeting their duty to protect consumers from foodborne illnesses.

111. Currently FBOs can undertake extensive research on how to comply with their legal requirements, which can be resource intensive. However, by introducing an online service that provides links to tailored support tools, FBOs will be able to access a wealth of appropriate information easily and instantly, before they start trading. This bank of information is available to all FBOs undertaking registration and will provide them with the support they need to get it right from the start and maintain compliance with food law requirements.

112. The time to be saved by FBOs in their search for appropriate information represents an economic saving to the business. Monetising the benefit to this would require data on the time devoted to searching for relevant guidance documents, as well as how this figure adjusts in light of new technology and hence, new guidance. This data is not held by the FSA and so, the benefit could not be quantified.

Burden of Enforcement

113. Option 2 presents an effective way of combining the registration of a food business with the provision of tailored guidance helping businesses to achieve and maintain compliance with relevant Food Law. Raising awareness of the need to register and streamlining the registration process will help to identify the food business at the earliest opportunity, enabling the LA to determine and offer tailored advice and support to businesses. FBOs are expected to capitalise on this new facility and work towards demonstrating higher standards of compliance which they can then sustain.

114. By demonstrating sustained compliance, FBOs may be subject to less controls by LAs over time. This eases the regulatory burden on them, in terms of eliminating the need to devote

resources to various inspections and interventions. This translates to an opportunity to remain productive and add value to their food business.

Local Authority Benefits

Inspections

115. This preferred option is expected to bring several benefits to LAs. It will fundamentally allow for better communication between businesses and authorities by requiring FBOs to submit relevant information about their business through the online service. With LAs being able to access a high-quality and expanded data set, they will gain a better understanding of the nature of the activities to be carried out and their applicable risks. This will help to shape inspection strategies and frequencies to become more risk-based and proportionate to the type of business under consideration.
116. This option will facilitate better communication for LAs across England, Wales and Northern Ireland. Information about new FBOs captured through the new online service and of existing food businesses from the LA management information systems will be made available to LAs through a unified view. This will give additional oversight of information relevant to their enforcement programme and will reduce unnecessary inspections, particularly of mobile traders.
117. The enhanced data that will be captured at the point of registration will enable a more risk based approach to the development of inspection strategies. This has implications for the planning and delivery of official controls and LAs may be able to redirect resource from certain types of business to focus on supporting for new FBOs or target resource at existing establishments that are non-compliant and present the greatest risk to consumers.

FSA Benefits

Traceability

118. Preparation for EU exit is a priority for the FSA. Significant changes to the pattern of food consumption, production and trade will mean that the FSA as a CCA must take measures to ensure we have an overview of the businesses engaged in import and export across England, Wales and Northern Ireland. This will be possible through a comprehensive unified view of food businesses using the information obtained through the online registration service and through other data sources.
119. The introduction of a new online service for the registration of food business establishments will enable the FSA, through the unified view, to have oversight of all food businesses in England, Wales and Northern Ireland. In the event of a possible outbreak in foodborne illness, or other incident the FSA as CCA will be able to identify relevant food businesses that could be receiving or supplying specific products giving us a greater sense of accountability across an international scale.
120. Monetising the benefits of this would involve examining the relationship between foodborne illness and various tools applied by authorities to allow for traceability. This is currently unavailable and hence, this benefit cannot be quantified.

Policy Development

121. A core aspect of this technology would be to make the FSA a better-informed regulator. With access to richer information on all food business establishments, the FSA will be able to better develop policy. Future government policy could be more reflective of FBOs and related agents that operate within it. Furthermore, better policy design increases the likelihood for the government to reach long-term food-related objectives.

WIDER IMPACTS

Small Firms Impact Test

122. The only business costs identified would result from the time reserved to undertake registration of the business. This is a legal requirement for all firms, regardless of size. The FSA does not envision that this would have a significantly disproportionate impact on businesses of a smaller size.

Competition Assessment

123. With better access to documents that enable sustained improvements in compliance, the new system is considered to have a positive impact on the level of competition.

Sustainability

Economic Impact

124. The introduction of a new online service would mean that food businesses give themselves the best opportunity to succeed at onset and should lead to sustained compliance with food hygiene and food safety law. This would lead to better FBO conduct and drive up competition in the market.

Social Impact

125. Social arguments address information barriers and potential health inequalities. Consumers will know if a food business is registered with authorities and hence, this should promote greater trust in those who have registered. With helpful compliance documents available to FBOs, food quality can be improved. This should reduce the consumer's exposure to food-related risks. In time, this would reduce the incidence of foodborne illness and associated costs.

Environmental Impact

126. The FSA considers that the introduction of a new online service for registration capturing all food businesses will have no impact on environmental sustainability issues.

Annex C

Title: Regulating Our Future: Amendments to the Food Law Code of Practice (England) - Recognising national inspection strategies for food hygiene and food standards (food safety partnerships). IA No: RPC Reference No: Lead department or agency: Food Standards Agency Other departments or agencies:	Impact Assessment (IA)
	Date: 05/07/2018
	Stage: Consultation
	Source of intervention: Domestic
	Type of measure: Other
	Contact for enquiries: Kate Harris

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option

Total Net Present Value	Business Net	Net cost to business per year	One-In, Three-Out	Business Impact Target Status
£0m	£0m	£0m	Not applicable	To be determined

What is the problem under consideration? Why is government intervention necessary?

Primary Authority³ currently operates across England and Wales in relation to food safety legislation that is enforced by local authorities.

It offers businesses the opportunity to form a legally recognised partnership with one local authority- the primary authority - which can then provide advice for other local authorities to consider when carrying out inspections or dealing with non-compliance. Primary Authority has a statutory basis, the scheme being introduced around 10 years ago, via the Regulatory Enforcement and Sanctions Act 2008. One of the tools available to a primary authority is an inspection plan – this sets out national priorities for inspection of the business in question, focusing official inspection activity to where it's most needed.

As part of an inspection plan, the primary authority could take the view that it has sufficient evidence that the business is being well managed, and that a lower number or a more tailored style of regulatory interventions are warranted, which would still enable proper regulation of the business and ensure public safety.

The primary authority could consider available information from the business such as:

- Systems for managing compliance
- Data generated from internal compliance checks e.g. through in-house audits
- Data generated by 2nd or 3rd party compliance checks e.g. through external auditing, accreditation checks, test purchases, surveillance and sampling programmes
- Data generated by regulatory checks on the business

If satisfied that the business is compliant and being well managed, a **national inspection strategy** could be put in place by the primary authority. This may control the number of proactive local authority interventions needed.

³ More information on Primary Authority is available at: <https://www.gov.uk/guidance/local-regulation-primary-authority>

At present there are no national inspection strategies for food safety. The Food Standards Agency has been working with stakeholders to consider why this is the case. One of the contributory factors for the lack of uptake in national inspection strategies is that the Food Law Code of Practice (the Code) has not, to date, acknowledged them as a means by which compliant multi-site businesses (or groups of businesses) could be regulated.

The proposed amendments to the Code would address this issue by specifically referencing national inspection strategies thus making them a possibility for food safety partnerships that meet the FSA's robust 'Standard' and oversight mechanisms.

The Standard for national inspection strategies is currently being developed, and is expected to be published during the summer of 2018. For information of the work to develop this Standard please see the 9th edition of the ROF newsletter - <https://www.food.gov.uk/about-us/ninth-regulating-our-future-newsletter>.

What are the policy objectives and the intended effects?

The policy objective is to form better alignment between the provisions of Primary Authority and the Code. By recognising national inspection strategies in the Code, Primary Authority partnerships have the option of considering whether a national inspection strategy, which meets the FSA's Standard, is something that they wish to develop and implement.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do Nothing: Make no changes to the Code so that national inspection strategies remain unrecognised in this document for food safety partnerships. Food partnerships may still choose to develop national inspection strategies, as they are a legitimate tool available to them under Primary Authority. However, there would remain poor alignment between the requirements of the Code and the provisions of the statutory Primary Authority scheme.

Option 2 (Preferred Option): Amend the Code to recognise national inspection strategies for food safety partnerships. Implementing changes to recognise the option for primary authorities to develop a national inspection strategy would provide partnerships with the ability to reduce proactive interventions, and thus some regulatory burden at a local level, if they are confident, and have good evidence, that establishments are compliant and are being well managed. Resources at a local authority level could be re-focused on establishments where there is less evidence of compliance and good management.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: Month/Year

Does implementation go beyond minimum EU requirements?		No		
Are any of these organisations in scope?	MicroY	SmallY	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded:		Non-traded:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible
SELECT SIGNATORY:

Date:

Summary: Analysis & Evidence Policy Option 2

Description: Do Nothing: Make no changes to the Code so that national inspection strategies remain unrecognised in this document for food safety partnerships.

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)			
			Low: Optional	High: Optional	Best Estimate: 0	
COSTS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)		
Low	Optional		Optional	Optional		
High	Optional		Optional	Optional		
Best Estimate	0		0	0		
Description and scale of key monetised costs by 'main affected groups'						
There are no associated monetised costs for this option.						
Other key non-monetised costs by 'main affected groups'						
There are no associated costs for this option.						
BENEFITS (£m)		Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)		
Low	Optional		Optional	Optional		
High	Optional		Optional	Optional		
Best Estimate	0		0	0		
Description and scale of key monetised benefits by 'main affected groups'						
There are no associated monetised benefits for this option.						
Other key non-monetised benefits by 'main affected groups'						
There are no associated benefits for this option.						
Key assumptions/sensitivities/risks (%)				Discount rate	-	

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	Benefits: 0	Net: 0	
			Zero net cost

Summary: Analysis & Evidence Policy Option 2

Description: Amending the Food Law Code of Practice to recognise national inspection strategies for food hygiene and food standards (food safety partnerships)

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised costs by 'main affected groups'

We welcome responses to provide evidence on any monetised costs by affected groups as part of this consultation. We do not expect there to be any cost to business as a result of this as NIS are optional.

Other key non-monetised costs by 'main affected groups'

The provision for a primary authority to establish a national inspection strategy already exists under Primary Authority.

Primary Authority operates on a cost recovery basis, and therefore time spent by a primary authority developing and implementing a national inspection strategy could be cost recovered from the primary authority partner (i.e. business or co-ordinator of businesses).

The actual costs to develop and implement a national inspection strategy will vary significantly as businesses, groups of businesses, and Primary Authority partnerships can vary.

The FSA has been working with 6 primary authorities on a 'pathfinder' project, which is due to report during the summer of 2018. This project will help the FSA start to understand the estimated costs of a partnership meeting the FSA Standard and using business data to predict local level compliance.

During 2018/2019, the FSA will be working with 2 (or more) primary authority partnerships to understand the time and therefore costs involved in developing and implementing national inspection strategies.

We do not foresee local authorities (enforcing authorities) bearing any additional costs by there being national inspection strategies in place. Local authorities may be required to have some engagement with a primary authority who is operating a national inspection strategy, however, this is likely to be less time consuming (and therefore lower in cost), than carrying out a physical inspection.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised benefits by ‘main affected groups’

At present we do not have figures for the monetised benefits. The pathfinder project, expected to report during the summer of 2018, will provide some insight into the number of local interventions that could potentially be reduced if a partnership develops and implements a national inspection strategy.

It is not expected that any business, or group of businesses, will be completely removed from local authority intervention. It is more likely that the percentage of establishments inspected in any one year may reduce, for example from 33% of an estate inspected per year, to 20% or 15% (depending on the business, compliance levels, primary authority confidence etc).

It is not possible to estimate the likely take-up of national inspection strategies for food safety partnerships at present as exploratory work into this area is still underway. We hope that through this consultation, we will gain some insight into partnerships who are interested in developing national inspection strategies and hence we will have a better idea of potential uptake when the consultation concludes.

Other key non-monetised benefits by ‘main affected groups’

A national inspection strategy may lead to a reduction in local authority physical inspections at compliant, well managed businesses. There is however likely to be a need for dialogue between local authorities (enforcing authorities) and primary authorities operating national inspection strategies.

It is envisaged that local authorities would be able to reallocate any saved time resource to less compliant businesses which should deliver additional public health benefits.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5

The costs and benefits to a business of setting up a national inspection strategy will vary considerably. However, it has been assumed that a business will only pursue a national inspection strategy if it will be financially viable to do so. Businesses are under no obligation to set up a national inspection strategy and there are no new burdens being placed upon them if they do not set one up.

The intention of this Code change is to recognise national inspection strategies, thus making them a more viable option for partnerships.

If the Code is not changed to recognise national inspection strategies partnerships may still establish national inspection strategies despite the lack of alignment between the provisions of Primary Authority and the Code.

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	Benefits: 0	Net: 0	
			Zero net cost

Impact Assessment: Primary Authority National Inspection Strategies

EVIDENCE BASE

CURRENT NUMBERS OF PRIMARY AUTHORITIES, INSPECTION PLANS AND NATIONAL INSPECTION STRATEGIES

Currently businesses (or groups of businesses) can have a relationship with a primary authority which may include food hygiene or food standards. These partnerships will fall into environmental health and/or trading standards Primary Authority partnerships.

Unfortunately, it is not currently possible to split out food hygiene and food standards from the wider categories of environmental health and trading standards functions (due to how Primary Authority operates). The data available on the current partnerships and inspection plans are detailed below in **Table 1**.

Table 1: Approximate number of PA and NIS plans (June 2018)

Primary Authority recorded function	Number of partnerships	# of inspection plans	# of inspection plans with food business elements	# of national inspection strategies for food safety partnerships
Environmental Health	613	18	13	0
Trading standards	1040	13	9	0

There are currently no environmental health or trading standards partnerships that operate national inspection strategies for their partnerships.

The only sectors currently using national inspection strategies are for age restricted sales (gambling and alcohol). There are currently (as of June 2018) six Primary Authority partnerships for gambling and one National Inspection Strategy⁴.

There has previously been a NIS for health and safety; it is understood that with HSE's change in direction for local authorities that reduced proactive inspections health and safety national inspection strategy became non-viable.

POLICY IMPACT ANALYSIS

Option 1: Do nothing

Taking no action would have no associated costs or benefits to any parties.

Option 2 (Preferred Option):

Amend the Food Law Code of Practice to recognise national inspection strategies for food standards and food hygiene (food partnerships).

Implementing changes to recognise that businesses (or groups of businesses) can, if they choose, set up a national inspection strategy with their chosen primary authority, would provide alignment between Primary Authority and the Code. If a primary authority partnership judges that a national inspection strategy will deliver benefits in terms of more efficient and risk based

⁴ <http://www.gamblingcommission.gov.uk/for-licensing-authorities/Licensing-authority-toolkit/Premises-assessments/Premises-assessments-toolkit.aspx>

regulation at a local level, they will be able to develop and implement such a strategy, and remain in line with the requirements of the Code.

Costs

The Food Standards Agency is not imposing any regulatory burden on business so there are no associated costs with this proposal. However, to benefit from a national inspection strategy there will be some costs business face in initial setup and ongoing maintenance. This will be met via cost recovery, administered by the primary authority.

To set up a national inspection strategy a business will first have to set-up a partnership with a primary authority (if they do not already have one). The 2011 IA (Impact Assessment of extending the Primary Authority) estimated the net benefit of setting up a partnership with a Primary Authority at around £17,000 (£18,700 2017 prices) per business⁵.

This Impact Assessment is not concerned with the benefits of Primary Authority as it is already possible for businesses to set up partnerships with them on food hygiene and standards and some have already done so. It is not therefore judged proportionate to update the 2011 analysis.

The FSA pathfinder project, working with 6 Primary Authority partnerships, and due to be published during the summer of 2018, is expected to provide better insight into the resource needed to develop and implement national inspection strategies for food safety partnerships. It is expected that any cost incurred by a primary authority will be cost recovered from the partner.

Benefits

The introduction of national inspection strategies is not expected to reduce local authority resource dedicated to food regulation but instead reallocate resource from more compliant to less compliant businesses. The impact of the local authority inspection resource on public health is therefore expected to increase because the inspections will lead to greater improvements at higher risk businesses than being dedicated to lower risk businesses.

RATIONALE FOR FAST TRACK STATUS

The preferred option introduces no burden on business, only a potential benefit for those businesses who choose to utilise national inspection strategies for food safety partnerships. The scale of this benefit is very hard to estimate and so has not been quantified at present. The cost to business of this proposal is therefore £0m, significantly below the £5m annual cost limit before the RPC is required to review the IA.

DISTRIBUTIONAL IMPACTS

While businesses of all sizes can be part of a Primary Authority partnership, a national inspection strategy is likely to be most attractive to large multi-site businesses such as retailers and catering chains who already invest in Primary Authority. For this reason, the preferred option is likely to benefit large business more than small or medium enterprises. SMEs who are in a Primary Authority partnership (including a coordinated partnership) are still eligible to develop and implement national inspection strategies.

⁵ Extending Primary Authority Scheme 2011 IA, page 22, Net Benefits divided by 600 low and 1000 high number of business expected to apply. Appraised over a 15 year period.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/31432/11-987-impact-assessment-extending-primary-authority-scheme.pdf

Annex D

Title: Regulating Our Future: Amendments to the Food Law Code of Practice (England) - Risk Assessment of Food Businesses RPC Reference No: Lead department or agency: Food Standards Agency Other departments or agencies:	Impact Assessment (IA)			
	Date: 05/07/2018			
	Stage: Development/Options			
	Source of intervention: Domestic			
	Type of measure: Other			
Contact for enquiries: Nathan Philippo				
RPC Opinion: Not Applicable				

Summary: Intervention and Options

Cost of Preferred (or more likely) Option

Total Net Present Value	Business Net Present	Net cost to business per year (EANDCB in 2014 prices)	One-In, Three-Out	Business Impact Target Status
£m	£m	£m	Not applicable	To be determined

What is the problem under consideration? Why is government intervention necessary?

Operational changes to the Food Law Code of Practice (The Code) are required to embed Regulating Our Future (ROF) principles into the establishment based approach to risk assessment of food businesses, to ensure enforcement practices are risk based, proportionate and effective. In the UK, local authorities are responsible for monitoring food businesses to check that they comply with the main body of food law. Direction and guidance for local authorities on the approach to take is provided in the statutory Code for each country within the UK. Local authorities must have regard to the requirements set out in the Codes to ensure effective and consistent controls are in place.

What are the policy objectives and the intended effects?

To embed ROF principles into the risk assessment of food businesses, to ensure enforcement practices are risk based, proportionate and effective, to reduce unnecessary burden on businesses. The proposals:

- 1) Clarify and update the descriptors for Method of Processing, Consumers at Risk and Confidence in Management that are used to rate businesses and assign the frequency and nature of interventions
- 2) Introduce the new definitions of full compliance and sustained compliance.
- 3) Provide greater focus on higher risk businesses and those with persistent or serious non-compliances by reducing the frequency of interventions in the lower risk compliant businesses

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing, the Code would not be amended and the current establishment intervention rating scheme system would remain.

Option 2: Make amendments to the establishment intervention rating scheme used to set intervention frequencies.

Option 3: Option 2, with safeguards put in place to ensure that a business intervention frequency cannot be reduced disproportionately.

The preferred option is Option 3 as it would assist to deliver a more risk based and proportionate approach to official control interventions, which also recognises sustained compliance set within safe limits.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 10/2023

Does implementation go beyond minimum EU requirements?	No			
Are any of these organisations in scope?	Micro Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)	Traded:		Non-traded:	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible
SELECT SIGNATORY:

_____ Date
: _____

Summary: Analysis & Evidence Policy Option 3

Description: Do nothing: the code of practice would not be amended and the current system would remain

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised costs by 'main affected groups'
None. This is the baseline which all other options are appraised

Other key non-monetised costs by 'main affected groups'
None. This is the baseline which all other options are appraised

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised benefits by 'main affected groups'
None. This is the baseline which all other options are appraised

Other key non-monetised benefits by 'main affected groups'
None. This is the baseline which all other options are appraised

Key assumptions/sensitivities/risks	Discount rate
Do nothing represents the current policy situation without intervention	

BUSINESS ASSESSMENT (Option 5)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	Benefits: 0	Net: 0	
			Zero net cost

Summary: Analysis & Evidence Policy Option 2

Description: Make amendments to the establishment intervention rating scheme used to set intervention frequencies. FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price)	Year	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate	0		0	0

Description and scale of key monetised costs by ‘main affected groups’

Under this option there would be a familiarisation cost to local authorities in reading and understanding the changes, estimated at £63,660. There would also be a transfer of regulatory burden (the productivity loss to a business of being inspected by the local authority) from more compliant businesses to less compliant businesses. This will be because in some cases local authorities will move resource away from businesses that demonstrate compliance towards businesses that fail to demonstrate compliance. The scale of this transfer will depend on the exact policy implemented but the maximum has been estimated at £824,587.

Other key non-monetised costs by ‘main affected groups’

There are not expected to be any other costs as a result of this option.

BENEFITS (£m)	Total Transition (Constant Price)Years	Average Annual (excl. Transition) (Constant	Total Benefit (Present Value)
Low			
High			
Best Estimate			

Description and scale of key monetised benefits by ‘main affected groups’

The transfer of regulatory burden covered under ‘costs’ (and estimated at a maximum of £824,587) will represent a benefit to those business that show consistent compliance. The value of this benefit will be transferred to less compliant business. Local authorities are expected to reallocate inspection resource to less compliant business so there will be no saving to them from these changes.

Other key non-monetised benefits by ‘main affected groups’

The reallocation of local authority resource to less compliant businesses will deliver enhanced public health benefits. The additional resource dedicated to businesses that represent higher risks to public health is expected to outweigh the reduction in resources dedicated to businesses that represent a lower risk to public health.

Key assumptions/sensitivities/risks

Discount rate (%)

To represent the potential size of the transfer we have assumed that the most costly proposed change will be progressed following consultation. We have also assumed that training and monitoring of the Code changes will be delivered through the existing FSA systems at no additional cost (based on professional advice as such).

BUSINESS ASSESSMENT (Option 6)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	Benefits: 0	Net: 0	

Zero net cost

Summary: Analysis & Evidence Policy Option 3

Description: Option 2, with safeguards put in place to ensure that a business intervention frequency cannot be reduced disproportionately

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised costs by ‘main affected groups’

The familiarisation cost to local authorities in reading and understanding the changes would be the same as option 2, estimated at £63,660. As with option 2 there would be a transfer of regulatory burden from more compliant businesses to less compliant businesses. However, due to the cap limiting how much intervention frequency can be reduced by the maximum size of the estimated transfer is reduced to £718,222.

Other key non-monetised costs by ‘main affected groups’

There are not expected to be any other costs as a result of this option.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised benefits by ‘main affected groups’

The transfer of regulatory burden covered under ‘costs’ (and estimated at a maximum of £718,222) will represent a benefit to those business that show consistent compliance. The value of this benefit will be transferred to less compliant business. Local authorities are expected to reallocate inspection resource to less compliant business so there will be no saving to them from these changes.

Other key non-monetised benefits by ‘main affected groups’

The reallocation of local authority resource to less compliant businesses will deliver enhanced public health benefits. The additional resource dedicated to businesses that represent higher risks to public health is expected to outweigh the reduction in resources dedicated to businesses that represent a lower risk to public health.

Key assumptions/sensitivities/risks

To represent the potential size of the transfer we have assumed that the most costly proposed change will be progressed following consultation. We have also assumed that training and monitoring of the Code changes will be delivered through the existing FSA systems at no additional cost (based on professional advice as such).

Discount rate

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BUSINESS ASSESSMENT (Option 7)

Direct impact on business (Equivalent Annual) £m:	Score for Business Impact Target (qualifying provisions only) £m:
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Evidence Base (for summary sheets)

Problem under consideration

1. The Food Standards Agency (FSA) is responsible for ensuring that an effective regulatory regime is in place to verify that food businesses meet their obligation to ensure food is safe and what it says it is. Local Authorities (LAs) are responsible for most food law enforcement and for verifying food business compliance with food law. Direction and guidance on the approach that LAs should take is included in the statutory Food Law Code of Practice (The Code) for each country which sets out instructions and criteria that LAs must have regard to when discharging their official control duties in relation to food law. The Code requires periodic revision to ensure that it reflects current food law policies and practices so that the official controls undertaken by authorised officers remain effective, consistent and proportionate.
2. The FSA is proposing a number of possible changes to the existing approach to determine the frequency of intervention by LAs at food establishments because it is believed to be outdated and becoming increasingly unsustainable. The FSA is seeking views from interested parties on the scope and impact of the possible measures. The current approach has been in place for more than 30 years and has served consumers well, but has not kept pace with technological change in the food industry, and is not flexible enough to adapt to the changing environment. The existing 'one size fits all' approach to regulating food businesses is ill-suited to the incredibly diverse nature of the industry.

Rationale for intervention

3. It is intended to better recognise those businesses that demonstrate sustained compliance, reducing the regulatory burden on them by ensuring that an intervention is proportionate to their compliant status and the reduced risk to consumers they present. For some businesses, the risk will be so low that they do not merit intervention, for others, inspection could be more frequent than they have experienced to support their move to compliance.

Policy objective

4. The FSA, therefore, intends to revise the hygiene intervention rating scheme in two ways;
 1. updating and clarifying the text used to describe the level of risk;
 2. changing the scores in the intervention rating scheme for certain businesses compliant with food law, which will move them into a lower risk category and thus reduce the intervention frequency. The revision aims to allow LAs to provide a greater focus on businesses with persistent or serious non-compliances by reducing the frequency of interventions in those businesses with good management controls in place. In addition, LA resource can also be then directed towards dealing with the newly opened unrated establishments on a risk priority basis.
5. These changes will improve the regulatory process for the 517,686 food establishments were registered with LAs in England at 31 March 2017. These include primary producers, manufacturers, processors, packers, importers, distributors, wholesalers, retailers, restaurants and caterers. These establishments are all subject to the requirements of food law that applies in England and originates at European Union level, this includes rules on food hygiene and food standards.

6. Responsibility in England for verifying compliance with food law in these food establishments is delegated to competent authorities. For most of the food businesses in England, the responsibility is delegated to the 352 local authorities. In undertaking these responsibilities, LAs as competent authorities must comply with the requirements of Regulation (EC) No. 882/2004⁶ on Official Feed and Food Controls. This Regulation sets out the general risk based approach and the principles that must be adopted when carrying out Official Controls (checks to ensure compliance with food law).
7. In carrying out their duties, LAs must have regard to the direction given by the FSA in the Code (separate but parallel Codes apply in Wales and Northern Ireland) when discharging their duties. These Codes are being reviewed to reflect the developments in approach.
8. The proposed amendments to the food hygiene intervention rating scheme can be summarised as follows:
 - to introduce the terms “full compliance” and “sustained compliance” for food businesses that have been assessed to be compliant by the LA at the last 2 interventions and over a minimum period of 3 years;
 - to link the additional score for the vulnerable risk group to the assessment of confidence in management at food businesses;
 - to remove the additional score for significant risk and include the significant risk element in the confidence in management assessment.
 - to consider, when assessing confidence in management, whether the food business operator proactively registered the new establishment under their control before the business started trading or when food operations commenced;
 - To amend the method of processing element of the food hygiene intervention scheme to include a descriptor to address where an establishment fails to undertake a process, which results in the potential to increase the risk to public health

CONSULTATION

9. The FSA presented the proposed amendments to LAs at a series of LA Update events that were held from December 2017 to January 2018. The FSA held meetings with the ROF Segmentation Working Group prior to the consultation being launched, presenting the proposals to LA representatives, and other stakeholder groups including representatives from industry and the professional bodies. The FSA received detailed responses, from the enforcement community following the update events.

Summary of responses:

Proposed amendment: Full compliance and Sustained Compliance

10. In England, Wales and Northern Ireland the proposed new definitions of ‘full compliance’ and sustained compliance were considered reasonable, but some LAs questioned the true impact/savings of the proposal. LAs stated that they are already using flexibilities in the Code for broadly compliant C/D businesses so they may not demonstrate sustained full compliance to the LA for several years and therefore believed that the impact on interventions was negligible.

⁶ <http://www.food.gov.uk/multimedia/pdfs/8822004eceregulation.pdf>

Q19: The FSA would welcome any documentary evidence that would substantiate the view expressed by some LA that the proposed change will not allow the reallocation of resources.

Proposed amendment: Vulnerable Risk Groups

11. In England and Northern Ireland there was some support for the vulnerable group score being removed in the circumstances described so long as there were alternative measures in place to recognise the higher impact of serving to vulnerable groups. There was unanimous objection from LAs in Wales on the proposal to remove the additional score of 22 for food businesses serving vulnerable groups

Proposed amendment: Significant Risk

12. In England and Northern Ireland, a consensus could not be reached. There was, however, agreement that this score wasn't currently used consistently and therefore if it remained, consistency training would be required. The LAs in Wales requested data to determine how often the score is applied and the possible impact of removing the score from the scheme. The general agreement was that if removal of the score did not alter the overall risk category the change would be supported.

Proposed amendment: Consideration of the Registration process

13. We are taking this opportunity to consult on the principle of factoring the non-registration of a food business into the CIM score as one option for tackling the non-registration of food businesses. There were various views on whether Competent Authorities should factor into the confidence in management score (CIM) that a new business had not registered prior to commencing to trade. It was generally considered that this change alone would not make a significant difference to the number of food business operators that pro-actively register. However, it is a legal requirement and we are aware that some Competent Authorities are already taking non-registration into account when rating a business that had not pro-actively registered. At present we are not able to quantify the situation or the impact of such measures, therefore to ensure a consistent and fair approach further consideration is required.

SECTORS AND GROUPS AFFECTED

Enforcement

Local Authorities

14. To identify the impact of the proposed amendments on LAs we have consulted the ROF Segmentation Working Group and other regional groups that attended the LA ROF Update events. Local authorities will be affected primarily through:
 - Changes to their management information systems
 - Officers will have to familiarise themselves with the amendments to the Code
 - Officers may need to undertake some form of consistency training on its application.

- LAs will benefit from being able to re-allocate resource more efficiently by focusing their resources on non-compliant businesses and new unrated food businesses (see table 1)

15. It is estimated that 1265 authorised officers in England will be affected by these amendments.

Food Standards Agency

16. Food Law enforcement changes over time and it is essential that authorised officers keep up-to-date with these changes. The FSA provides LA officers with opportunities to develop their knowledge through training tools, professional courses and funding for local authority-led work. The FSA works with LAs to further develop their enforcement services and one area in which the FSA is active is a continuing programme of consistency training exercises.

Industry

17. The proposed amendments on sustained compliance will have a positive impact on compliant food businesses, many of whom currently are subject to a number of food hygiene interventions which are not proportionate to the risk they present. This level of intervention would be redressed by the proposed change. The change would apply to a small percentage of food businesses over time as indicated in Table 1 below:

Table 1: Shows the proposed change, estimated in the inspections and FTEs. All calculations use 2016-17 LAEMs data⁷ (without safeguards)

Proposed Change	Est. number of reallocated inspections	% reallocation of inspections	Reallocation in Hrs ⁸	Reallocation in FTEs	% in FTEs reallocated ⁹
Sustained compliance (if FHRs of 5 for at least the last two inspections establishment receives negative 5 adjustment to risk score and for each subsequent inspection with rating of FHRs 5)	6,229	2.4%	21,802	13.8	1.0%
Sustained compliance (if FHRs of 5 for at least the last two inspections establishment receives negative 10 adjustment to risk score and for each subsequent inspection with rating of FHRs 5)	12,947	5.0%	45,314	28.8	2.1%
Sustained compliance (if FHRs of 5 for at least the last two inspections establishment receives negative 20 adjustment to risk score and for each subsequent inspection with rating of FHRs 5)	20,926	8.0%	73,243	46.5	3.3%

⁷ <https://signin.riams.org/connect/revision/kmhfa/Environmental-Health/Annual-report-on-UK-local-authority-food-law-enforcement-1-April-2016-to-31-March-2017>

⁸ Assuming an average inspection takes up 3.5 hrs of an officers time

⁹ Based on the 2016/17 food hygiene allocated FTE professional LA staff figure of 1393.14

Removal of vulnerable groups for FHRS 5	6,212	2.4%	21,743	13.8	1.0%
Risk of contamination removed	672	0.3%	2,350	1.5	0.1%
Sustained compliance (negative 5), Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	12,585	4.8%	44,048	28.0	2.0%
Sustained compliance (negative 10), Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	19,073	7.3%	66,754	42.4	3.0%
Sustained compliance (negative 20), Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	25,736	9.9%	90,077	57.2	4.1%

Table 2: Shows the proposed change, estimated in the inspections and FTEs. All calculations use 2016-17 LAEMs data (with safeguards)

Proposed Change	Est. number of reallocated inspections	% reallocation of inspections	Reallocation in Hrs	Reallocation in FTEs	% in FTEs reallocated
Sustained compliance (if FHRS of 5 for at least the last two inspections establishment receives negative 5 adjustment to risk score and for each subsequent inspection with rating of FHRS 5)	6,124	2.3%	21,433	13.6	1.0%
Sustained compliance (if FHRS of 5 for at least the last two inspections establishment receives negative 10 adjustment to risk score and for each subsequent inspection with rating of FHRS 5)	12,672	4.9%	44,353	28.2	2.0%
Sustained compliance (if FHRS of 5 for at least the last two inspections establishment receives negative 20 adjustment to risk score and for each subsequent inspection with rating of FHRS 5)	19,687	7.5%	68,903	43.7	3.1%

Removal of vulnerable groups for FHRS 5	5,637	2.2%	19,731	12.5	0.9%
Risk of contamination removed	672	0.3%	2,350	1.5	0.1%
Sustained compliance (negative 5), Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	11,033	4.2%	38,616	24.5	1.8%
Sustained compliance (negative 10), Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	16,579	6.4%	58,027	36.8	2.6%
Sustained compliance (negative 20), Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	22,416	8.6%	78,457	49.8	3.6%

Consumers

18. The amendments create an opportunity for a positive impact for consumer protection. Consumers will be assured that officers are able to use their resources more effectively to target non-compliant businesses.
19. The focus on effective, risk-based and proportionate regulation and enforcement provides more frequent inspections of businesses with persistent or serious non-compliances and less frequent inspections of fully compliant businesses. Business compliance with food law is the best way of ensuring safer food and protecting consumers.

OPTION APPRAISAL

COST BENEFIT ANALYSIS

Option 1: Do nothing, the Code would not be amended and the current system would continue

Summary of Costs and Benefits under option 1

20. There are no incremental costs and benefits associated with this option; this is the baseline against which all other options are appraised.

Option 2: Make amendments to the Food Establishment Hygiene Intervention Rating Scheme section in the Food Law Code of Practice.

Costs

Costs to Industry

21. There are no identified costs to industry in relation to the proposed amendments, as food establishments do not need to familiarise themselves with the contents of the Code, as it lays down criteria for LAs. The food businesses that present the highest risk will receive additional regulatory focus from LAs because of the proposed changes and those representing the lowest risk will receive proportionately less regulatory focus.
22. This change represents a transfer of the productivity loss of being inspected by the LA (in the form of employee time spent with the inspector that could be spent elsewhere). The value of this transfer is estimated by multiplying the estimated number of reallocated inspections by an average cost to business per inspection. The average cost to business per inspection is calculated by the average length of an inspection multiplied by the average wage cost of manager in a food business (including overheads). This has been estimated at £32.04 productivity loss to business per inspections. The size of the transfer for each estimated scenario is presented in Table 2.

Table 2: Estimated transfer of productivity loss from low risk businesses to high risk businesses in England under Option 2.

Proposed Change	Est. number of reallocated inspections	Estimated transfer to less compliant businesses
Sustained compliance -5 Based on FHRs of 5 for at least the last two inspections)	6,229	£199,581
Sustained compliance -10 Based on FHRs of 5 for at least the last two inspections)	12,947	£414,817
Sustained compliance -20 Based on FHRs of 5 for at least the last two inspections)	20,926	£670,483
Removal of vulnerable groups below 10 CIM	6,212	£199,043
Risk of contamination removed	671.5	£21,515
Sustained compliance -5 and Removal of vulnerable groups below 10 CIM and Risk of contamination removed	12,585	£403,229
Sustained compliance -10 and Removal of vulnerable groups below 10 CIM and Risk of contamination removed	19,073	£611,086
Sustained compliance -20 and Removal of vulnerable groups below 10 CIM and Risk of contamination removed	25,736	£824,587

Costs to Local Authorities

One - off Familiarisation Costs

23. The proposed amendments will result in a familiarisation cost to LA officers who will need to read and familiarise themselves with the changes. FSA enforcement data shows that as at 31 March 2017, there were 1265 FTE occupied posts engaged in food hygiene law enforcement in England¹⁰.
24. The FSA estimates that an authorised officer will invest approximately two hours reading and familiarising themselves with the descriptors for consumers at risk and confidence in management that are used to rate and assign the frequency and nature of interventions and with the Introduction of the new definitions of full compliance and sustained compliance.
25. The familiarisation cost can be monetised by multiplying the total number of hours needed for officers to familiarise themselves with the changes by the average hourly cost of employing those officers (including overheads). This has been estimated at £48,424¹¹.

¹⁰ <https://signin.riams.org/connect/revision/kmhfa/Environmental-Health/Annual-report-on-UK-local-authority-food-law-enforcement-1-April-2016-to-31-March-2017>

¹¹ ASHE data set (same as above) lists wage for “Inspectors of standards and regulations” at £15.95 (£19.14 including overheads as above). £19.14/hour x 1265 FTEs x 2 hours to familiarise = £48,424.20 total cost to LAs.

Training Costs

26. The FSA has previously provided training to LA officers to support the introduction of changes to the intervention rating scheme on matters of interpretation. These exercises are based around food business inspection scenarios. They can be used as a team exercise or by individuals to work through and give the businesses a food hygiene rating. As the proposals do not relate to any significant change to the interpretation of the rating scheme the FSA does not foresee any additional cost above the familiarisation costs in relation to the change in process. However, the FSA will monitor the application of the rating scheme to determine whether any additional training is required.

Costs to FSA

Monitoring costs

27. The FSA already provides the materials needed by LAs to participate in the consistency monitoring exercises, which are delivered and funded through the FSAs existing resource. While the FSA does not think that additional LA training is required, the results of this monitoring exercise will validate this assumption.

Total Costs

28. The total cost associated with preferred policy Option 3 equates to £48,424 falling only on Local Authorities. There is also a transfer of cost of up to £824,587 from more compliant to less compliant businesses.

Benefits to consumers

29. No monetised benefits to consumers have been identified. However, it is expected that the amendments will have a positive impact on consumers. Consumers will be assured that officers delivering official controls are able to use their resources more effectively to target non-compliant businesses. The focus on effective, risk-based and proportionate regulation and enforcement provides more frequent inspections of businesses with persistent or serious non-compliances and less frequent inspections of fully compliant businesses. We therefore expect the public health benefit per inspection to increase as a result of this change. Business compliance with food law is the best way of ensuring safer food and protecting consumers.

Benefits to industry

Monetised Benefits to industry

30. The benefit to low risk businesses from a reduction in the number of interventions is equal to the cost to higher risk, less compliant businesses of having an increased number of interventions. This is because the resource LAs are putting into interventions is shifting from one group of businesses to the other. This will therefore be a transfer of cost with the overall net cost remaining the same. The estimated size of the transfer in each scenario is listed in Table 3.

Benefits to Local Authorities

Monetised Benefits to Local Authorities

31. The FSA does not foresee any monetised benefits for LAs as there will not be any effect on the total amount of resource expended in the delivery of food official controls carried out at food establishments. However, the changes should allow for reallocation of resource at food business establishments where there is demonstrable evidence of persistent and/or significant non-compliance with food law and on their unrated food establishments, on a risk priority basis bringing better public protection.

Non-monetised Benefits

32. These changes will mean that LA resources will be reallocated away from businesses with a history of full compliance and towards businesses with less compliance. Whilst quantifying the public health benefit of LA inspections of food businesses (due to a reduction in foodborne illness and death, allergic reactions, etc.) is very difficult we can say with confidence that the impact of the reallocated resource will increase. Inspections and enforcement action on businesses which represent a greater risk to public health will have a greater impact than the same action on businesses that present less risk.

Total Benefits

33. There are no monetizable benefits of any of the policy options. The non-monetised benefits will be public health benefits associated with LAs being able to deploy their resources more effectively to target non-compliant businesses.

Justification for Fast Track status

34. The estimated costs of this policy to business are zero (with a transfer between businesses of up to £824,587). If this £824,587 productivity impact was counted as a cost this policy would still fall significantly below the £5m annual de-minimus threshold set by the RPC.

Option 3: To include a score limitation of - 40, so that a business is unable to drop more than 2 risk bands.

Costs

Costs to Industry

35. There are no identified costs to industry in relation to the proposed amendments, as food establishments do not need to familiarise themselves with the contents of the Code, as it lays down criteria for LAs. The food businesses that present the highest risk will receive additional regulatory focus from LAs because of the proposed changes and those presenting the lowest risk will receive proportionately less regulatory focus.
36. This change represents a transfer of the productivity loss of being inspected by the LA (in the form of employee time spent with the authorised officer that could be spent elsewhere). The value of this transfer is estimated by multiplying the estimated number of reallocated inspections by an average cost to business per inspection. The average cost to business per inspection is calculated by the average length of an inspection multiplied by the average wage cost of manager in a food business (including overheads). This has

been estimated at £32.04 productivity loss to business per inspection¹². The size of the transfer for each estimated scenario is presented in Table 3.

Table 3: Estimated transfer of productivity loss from low risk businesses to high risk businesses in England under Option 3.

Proposed Change	Est. number of reallocated inspections	Estimated transfer to less compliant businesses
Sustained compliance -5 Based on FHRS of 5 for at least the last two inspections)	6,124	£196,204
Sustained compliance -10 Based on FHRS of 5 for at least the last two inspections)	12,672	£406,019
Sustained compliance -20 Based on FHRS of 5 for at least the last two inspections)	19,687	£630,762
Removal of vulnerable groups below 10 CIM	5,637	£180,620
Risk of contamination removed	671.5	£21,515
Sustained compliance -5 and Removal of vulnerable groups below 10 CIM and Risk of contamination removed	11,033	£353,504
Sustained compliance -10 and Removal of vulnerable groups below 10 CIM and Risk of contamination removed	16,579	£531,199
Sustained compliance -20 and Removal of vulnerable groups below 10 CIM and Risk of contamination removed	22,416	£718,222

Costs to Local Authorities One - off Familiarisation Costs

37. As option 2.

Training Costs

38. As option 2.

Costs to FSA

Monitoring costs

39. As option 2.

Total Costs

40. The total cost associated with preferred policy Option 3 equates to £48,424 falling only on Local Authorities. There is also a transfer of cost of up to £718,222 from more compliant to less compliant businesses.

Benefits to consumers

41. As option 2.

¹² Assumes an inspection length of 2 hours. Manager wage is based on ASHE 2017 (gross hourly wage for “Managers and proprietors in hospitality and leisure services” at £13.35 (£16.02 including +20% for overheads in line with HMT guidance). 2 hours x £16.02 = £32.04. ASHE dataset is accessible here (Table 14.5a, Row 42, mean hourly wage):

<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashtable14>

Benefits to industry

Monetised Benefits to industry

42. As option 2.

Benefits to Local Authorities

Monetised Benefits to Local Authorities

43. As option 2.

Non-monetised Benefits

44. As option 2.

Total Benefits

45. There are no monetizable benefits of any of the policy options. The non-monetised benefits will be public health benefits associated with LAs being able to deploy their resources more effectively to target non-compliant businesses.

Justification for Fast Track status

46. The estimated costs of this policy to business are zero (with a transfer between businesses of up to £718,222). If this £718,222 productivity impact was counted as a cost this policy would still fall significantly below the £5m annual de-minimus threshold set by the RPC.

OTHER CONSIDERATIONS

Wider Impacts

47. The industry sector most affected by this amendment is restaurants and caterers and establishments within the health care setting, the majority of which are micro or small/medium enterprises. This proposal will result in a proportionally greater benefit for compliant micro or SMEs compared to the wider food industry.

Competition Assessment

48. The proposed amendment should not have any significant positive or negative effect on competition between firms.

Small & micro business assessment

49. The UK food industry sector is comprised of mainly small and micro businesses (generally greater than 90%) and therefore the greatest impact from new feed or food measures introduced in the UK will, in most of cases, be on small and micro businesses. For this reason, the FSA assesses the impact on small and micro businesses as standard when undertaking impact assessments.

50. EU legislation generally applies to food/feed businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken. Due to the high ratio of small and micro feed or food businesses in the UK it is often not feasible to exempt smaller businesses from new food/feed measures as this would fail to achieve the intended effect of reducing risks to consumer health. That said, FSA makes every effort to minimise burdens on small and micro businesses and pays attention to impacts on them. The proposed amendments should not have any disproportionate negative impact on the small and microbusinesses.

Equality impact:

51. This policy has been screened for impact on equalities with specific consideration of all legally protected groups. The policy will introduce changes to operation procedures for local authority food law enforcement officers only. The primary impact of the policy is intended to introduce a benefit to LA resource and enable them to better target their resources to higher risk food businesses, while also recognising the over inspections of some sector types and aiming to reduce the burden of inspection on them. The policy is not believed to present any risks or barriers to equality. Because of this screening, it has been decided that a full equality impact assessment is not required.

Human rights impact:

52. The FSA does not foresee that the proposed change will have a negative impact on the human rights of any person.

Annex E

Code of Practice Review 2018

Table of Changes to Food Law Code of Practice (England)

Section	Reason for Change
1.1.	Slightly amended wording to include FSA issued National Regulator Guidance
2.1.3.1	Slightly amended wording to remove references to Regulatory Division, reference National Inspection Strategies, and update an out of date web link.
2.1.3.2	Replaced reference to Regulatory Division with Office for Product Safety and Standards.
3.2.7.2	Reworded to add clarity when dealing with mobile establishments trading outside registered competent authority area.
3.2.7.4	Wording amended to reference Management Information Systems as a means of providing information to other competent authorities.
3.2.9.3	Amended to reinforce online registration as preferred method.
3.2.9.4	Amended to reflect changes around enhanced registration, including primary use of electronic registration.
3.2.9.6	Section added to reference data storage and transfer of electronic data.
3.2.9.7	Renumbered from 3.2.9.6 and amended to reflect online registration.
3.2.10	Rewording for clarity.
3.2.11	Section added to specifically reference changes to Food Business Operator.
5.1.1	Sentence added to reference national inspection strategies.
5.2	Slightly amended wording to reinforce need to follow FSA recognised national inspection strategies.
5.2.1.1	Sentence added to reference national inspection strategies.
5.2.1.2	Sentence added to reference national inspection strategies.
5.3.1	Sentence added to reference national inspection strategies.
5.6	Sentence added to reference Primary Authority.
5.6.1 Part 1 B	Paragraph added to discount the additional score of 22 if demonstrable effective management controls are in place.
6.1 Part 3 A	Slight amendment to take into account proactive registration.
6.1 Part 3 B & C	Significant additions reflecting proposed changes regarding full and sustained compliance and a minus scoring system for recognising sustained compliance.
Glossary	Added entries for Full Compliance, Sustained Compliance, National Regulator Guidance, National Inspection Strategy, an OPS&S. Removed entry for Regulator Division.

