

Title: Regulating Our Future – Amendments to the Food Law Code of Practice (Wales)

CONSULTATION SUMMARY PAGE

Date launched:	31 AUGUST 2018	Closing date:	23 NOVEMBER 2018
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Who will this consultation be of most interest to?
Consumers
Local Authorities
Food Business Operators

What is the subject of this consultation?
 The Food Standards Agency’s (FSA) Regulating Our Future (ROF) programme aims to modernise how food businesses in Wales, England and Northern Ireland are regulated to check that our food is safe and what it says it is. The FSA is planning to update the Food Law Code of Practice (Code) for Wales to make changes to the process of registration, the application of the food hygiene intervention rating scheme to ensure interventions are appropriately targeted to maximise the impact on non-compliant food businesses and recognise national inspection strategies (NIS). The consultation also intends to seek early stakeholder views on other co-dependent aspects of the ROF programme which are still in development.

What is the purpose of this consultation?
 The FSA welcomes views on its proposals to amend the Code to provide for the operation of the first phase of ROF related changes. The changes will enable the new digital approach for the process of registration for new businesses, make changes to the food hygiene intervention rating scheme to enable the targeting of resources to maximise the impact on non-compliant food businesses and to recognise NIS, creating better alignment between the Code and Primary Authority (PA). The FSA would also invite views to help inform future developments for local authority (LA) performance measures so more meaningful and real-time assessment of LA delivery of food law enforcement services is possible.

Responses to this consultation should be sent to:

<p>Daniel Morelli Local Authority Partnership Manager Local Authority Partnership Team</p> <p>FOOD STANDARDS AGENCY Tel: 029 2067 8902</p>	<p>11th Floor Southgate House Wood Street Cardiff CF10 1EW Email: lasupportwales@food.gov.uk</p>
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Impact Assessment included?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/> See Annex A for reason.
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Regulating Our Future - Amendments to the Food Law Code of Practice (Wales)

DETAIL OF CONSULTATION

1. The Food Standards Agency's (FSA) Regulating Our Future (ROF) programme aims to modernise how food businesses in Wales, England and Northern Ireland are regulated to check food is safe and what it says it is. The FSA is building a system that is dynamic, flexible and can adapt as the global food economy changes and as technology develops in the future. The 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 variations in patterns of food production, trade, and consumption when the UK leaves the European Union (EU).
2. This consultation focuses on proposed changes that will come into effect after March 2019. To ensure that there are no barriers to the implementation of the new system, the FSA is planning to update the Food Law Code of Practice (Code) for Wales to make changes to the process of registration, the application of the food hygiene intervention rating scheme to ensure interventions are appropriately targeted to maximise the impact on non-compliant food businesses and recognise national inspection strategies (NIS). The consultation also intends to seek early stakeholder views on other co-dependent aspects of the ROF programme which are still in development.

Consultations are also underway in England and Northern Ireland.

3. This is the first of a series of public consultations on the various aspects of the ROF programme. Given the wide scope of the programme and the anticipated timeframe for implementation, the FSA intends to group changes into manageable phases. This first set of changes which provide for the operation of some of the principles of the ROF programme, include improving the registration process and the risk-based targeting of intervention resource by local authorities (LAs). The FSA is seeking views on what new frameworks and performance measures are necessary to ensure that existing LA food law enforcement resources are sustained in the future.
4. The FSA is seeking views on the proposed changes to:
 - Reflect that there will be enhanced digital options for the process of registration by new food businesses following the introduction of the FSA web-based platform in March 2019.
 - Recognise NIS for food businesses via Primary Authority (PA).
 - Make several changes to the food hygiene risk assessment process for targeting resources to maximise the impact on non-compliant food businesses.
 - Consider, when assessing Confidence in Management (CiM), whether the food business operator (FBO) proactively registered the new establishment under their control, before the business started trading or food operations commenced.

5. The FSA intends to carry out further consultations that will 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 in the initial stages of its development.

Background

6. The Code is the mechanism by which the FSA may provide for the operation of changes identified through the ROF programme. This consultation represents the first phase of its delivery. Responses from stakeholders are invited on the specific proposals for change, as well as views to inform the development of policy that will support the implementation.
7. It is important to recognise these proposals are the first stages to implement the programme and should enable the development of further proposals, such as a predictive risk engine that will be used to determine the approach to regulating food establishments in the future. The review process is a long-term project with further changes planned in 2019/20. The impact assessments accompanying this consultation only consider the first phase, which relate to revisions to the food hygiene intervention rating scheme and registration process.
8. Whilst the FSA is undertaking a consultation exercise now, any changes to the Code that affect how LAs plan and implement their food law enforcement responsibilities, will be introduced at the same time, as the implementation of the enhanced registration system and risk engine. This approach is being taken to reduce the impact on LA service planning and delivery. The date for the implementation of these changes will rely on the adoption of the system by LAs and there are likely to be challenges during the transitional period which will need to be addressed.
9. These proposed changes should improve the regulatory process for all food establishments registered with LAs in Wales, which is reported to be 34,655¹ at 31 March 2017. These food businesses include retailers, restaurants, caterers, manufacturers, processors, packers, importers, distributors and wholesalers. These establishments are all subject to the requirements of food law that applies in Wales and originates at EU level, including rules on food hygiene and food standards.
10. Responsibility for verifying compliance with food law in these food establishments is delegated to the 22 LAs in Wales. 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 principles that must be adopted when carrying out official controls (checks to verify compliance with food law).
11. When discharging their duties, LAs must have regard to the direction given by the FSA in the Code. The Codes in Wales, England and Northern Ireland are being reviewed and updated to reflect the developments in approach.

¹ https://signin.riams.org/files/display_inline/45859/laemsannualreport201617-22012018.pdf

² <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:165:0001:0141:EN:PDF>

Regulating Our Future

12. The objective of this update to the Code is to start to introduce the principles underpinning the ROF programme. The five ROF principles are:
 1. 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.
 2. FSA and regulatory partners' decisions should be tailored, proportionate and based on a clear picture of UK food businesses.
 3. The regulator should consider all available sources of information.
 4. Businesses doing the right thing for consumers should be recognised; action will be taken against those that do not.
 5. Businesses should meet the costs of regulation, which should be no more than they need to be.

The changes proposed in this consultation focus on principles 2, 3, 4 and 5.

Business start-up and enhanced registration

13. The FSA proposes to introduce a new digitally-enabled service to make it easier for food businesses to register and access tailored information and guidance, which will enable them to get things right from the start. To do this the FSA are building an online registration service that will provide more information on food businesses at the time they register and real-time access to registration details.
14. 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 across Wales, England and Northern Ireland is underway. The findings will be used to make improvements ahead of the service going live by March 2019.
15. As part of the re-design of the FSA website, advice for food businesses is being revised to make it easier to understand. The updated content will be tested through workshops in the autumn and finalised by December 2018. 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

16. 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 the FSA is developing a more sophisticated and data driven method for the segmentation of new businesses.
17. 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 food law enforcement activities for all new businesses using the online service to register. The future proposal, which will be consulted on in due course, is that some businesses will no longer receive an initial food hygiene inspection. For example, businesses that supply only low risk food, or those that are of a limited scale and complexity, will only be inspected as and when additional information, or a complaint, indicates that one is necessary.

18. The FSA has also been considering whether there are options for improving the current food hygiene intervention rating scheme for determining inspection or intervention frequencies at existing businesses. These options have been based upon analysis of historical LA inspection data and the findings of published research. The aim is to reallocate existing intervention resources from food establishments that have demonstrated they are able to maintain high-levels of compliance with food safety requirements, to those who require an increase in LA intervention to ensure public health is protected.

Primary Authority National Inspection Strategies

19. Food businesses (or groups of businesses) with a Primary Authority Partnership (PAP) that have demonstrated food safety is well managed across the operations, may be considered suitable for a lower number of programmed interventions by the PA. The PAP may wish to develop a NIS, which would be contained within an inspection plan.
20. The concept of NIS is not a new one, it was introduced when PA was first conceived, and at present any PA could theoretically develop a food safety NIS.
21. This has not happened to date and the FSA has never issued any national regulator guidance for PAs wishing to use this tool. Furthermore, the current Code does not acknowledge that NIS could exist, or what LAs should do if a PA was to issue one.
22. During late 2017 and early 2018, the FSA undertook a 'pathfinder' exercise, working with six PAPs to test whether PAs could access and use businesses' own compliance data to predict food hygiene compliance at a local level. 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 PAPs covering food safety. These pathfinders are nearing completion. The report of an independently conducted evaluation of the findings is expected during the summer of 2018.
23. At present, the FSA understands that a small number of PAPs covering food safety in England are actively considering developing NIS with the view to trialling the concept in England during 2019. The early proposals suggest that the PAs will use business data and information, combined with intelligence from relevant local enforcing authorities, to better inform the frequency of local food hygiene inspections. It should be noted that where a business regulated in both England and Wales, in relation to England only and devolved matters, chooses to partner with only one LA, whether in England or Wales, a NIS would not have statutory effect in the other nation. Only a LA in Wales should be nominated in respect of devolved matters.

Proposals

24. The key proposals are set-out below. 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
25. The FSA is inviting views from stakeholders to inform the development of associated policy and LA performance measures, which need to be in place to effectively implement these changes.

Key proposals:

The FSA is undertaking this consultation on its proposals to amend the Code to provide for the operation of 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 NIS for food businesses via PA, bringing better alignment between PA and the Code.**
- **Introduce definitions for the terms “full compliance” and “sustained compliance” in relation to food businesses.**
- **Make 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 high-levels of compliance over time;**
 - **Linking the application of the additional score for the vulnerable risk group to the assessment of CiM at food businesses.**
 - **Removing the additional score for significant risk and including the significant risk element in the CiM assessment.**
 - **Amending the Method of Processing element of the food hygiene intervention rating scheme to have regard to circumstances where an establishment fails to undertake a process, which results in the potential to increase risk to public health.**
- **Consider, when assessing CiM, whether the food business operator proactively registered the establishment under their control before the business started trading or when food operations commenced.**
- **The setting of data standards for storage and transfer of data by LAs.**

Proposal 1: Enhanced Registration

26. Registration is a legal requirement under Article 6(2) of Regulation (EC) No 852/2004, which states that FBOs are to register the establishment(s) under their control, with the appropriate competent authority, in the manner that the competent authority specifies. This Code update covers the first iteration of work under the Enhanced Registration workstream of the ROF programme, which details changes to the process of how a FBO should register the establishment(s) under their control.
27. This change aims to improve the overall effectiveness, efficiency and consistency of the registration process across Wales, England and Northern Ireland. The information obtained through the newly developed online registration service will be key to the success of the overall ROF programme in capturing more in-depth data on the businesses activities. The new system should allow for a more accurate assessment of risk to be determined using a “risk engine”, to enable an appropriate intervention strategy to be identified.
28. 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, FBOs are only required to provide a limited amount of information about their food establishment to the LA.
29. Registrations are currently submitted on a variety of forms to LAs using a number of routes. Feedback suggests that in some instances FBOs either start trading before registering or register and commence trading in advance of receiving an inspection. These businesses may not have received the appropriate level of support at the earliest opportunity to aid compliance.
30. Whilst the current registration process works, there is substantial opportunity for improving its overall effectiveness, efficiency and consistency. The new service will help alleviate inconsistencies in the overall registration process. It will be easier for FBOs to register, as they will be asked questions relevant to the type of business they are registering and they will obtain the same user experience regardless of their location. LAs will also benefit through reduced manual processing, making the overall registration process less labour intensive.
31. Information from the online registration service about the FBO and their activities will be made available to LAs and the FSA. Obtaining details of all food establishments will provide the FSA with an overview of the food industry, which may assist in future policy development, and allow for more effective action to be taken in the event of a food incident.
32. The information obtained through the new online service will also be available for LAs to view in order to help inform their intervention strategies. For example, for mobile establishments, access to the most recent inspection report will better inform LAs of the business’ compliance history and aim to reduce the number of unnecessary inspections/interventions.

Stakeholder responses are invited on the following:

- 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 enhancing registration through the new online service will have the desired effect of increasing the effectiveness and efficiency of the registration process.

Proposal 2: NIS

33. The FSA recognises that PAs could play a role in achieving ROF programme outcomes, and is particularly interested in the concept of NIS.
34. The FSA has been working with stakeholders to develop a 'Standard' that a PAP would need to meet to be able to develop and implement a NIS. It is intended that this Standard will be issued as national regulator guidance.
35. It should be noted that a NIS for food 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 would continue as normal even where a NIS is in place.
36. 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 PAs 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.
37. Alongside the work to develop a Standard for PAPs wishing to develop and implement NIS, the FSA has been working to ensure there will be the right level of FSA oversight and assurance the NIS is working effectively.
38. A provision has been introduced into the Code which recognises that a PA may choose to develop and implement a NIS.
39. Where a PA is considering implementing a NIS, they and their partner business would need to engage with the FSA at an early stage of their development and be able to submit robust evidence that they meet the FSA Standard. This will be assessed by the FSA, who will liaise with the Office of Product Safety and Standards (OPSS) during the statutory consent process.
40. Stakeholder views have been sought 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

The FSA is currently reviewing the responses that have been submitted.

Stakeholder responses are invited on the following questions:

- Q3. What do you see as the benefits of national inspection strategies (NISs)? Please feel free to answer this question in the context of local authorities, Primary Authorities (PAs), businesses, and/or consumers.
- Q4. What challenges do you think national inspection strategies (NISs) for food safety partnerships may pose? Please feel free to answer this question in the context of local authorities, Primary Authorities (PAs), businesses, and/or consumers.

Proposal 3: Introduction of Compliance Definitions

- 41. The FSA intends to introduce definitions for “full compliance” and “sustained compliance” to help categorise compliance levels at establishments, that complement the existing definition of broadly compliant.
- 42. **Full compliance**, for the purposes of the Code will be defined as an establishment that has been risk rated:

Risk factor	Score
<i>Structure</i>	5 or 0
<i>Hygiene</i>	5 or 0
<i>Confidence in Management</i>	5 or 0

- 43. **Sustained compliance** will recognise food establishments that have been assessed to be fully compliant by the LA over a defined period, by introducing a weighting within the food hygiene intervention rating scheme. Food establishments that have been assessed as being fully compliant at the last two 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 hygiene intervention rating scheme.

Proposal 4: Changes to the Food Hygiene Intervention Rating Scheme

Recognising Sustained Compliance

- 44. A food establishment meeting this criterion will be suitable for a reduction to the total risk assessment score. 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 incremental reduction to their total risk assessment score. This proposal will over time reduce the regulatory focus on those food establishments that have demonstrated sustained levels of compliance and will assist LAs to better target their resources on those non-compliant establishments. (worked examples can be found in tables 3 and 4 below).

45. This proposal is based on evidence, as shown in Table 1 below, that indicates establishments are more likely to be compliant where they demonstrated good levels of compliance on their previous two interventions. For example, less than 1% of establishments that had achieved a Food Hygiene Rating Scheme (FHRS) rating of 5 during the previous two inspections received a FHRS rating of 0-2 at their next inspection.

Stakeholder responses are invited on the following questions:

- Q5: What are your views on the proposed definition of full compliance and whether food establishments that achieve this should be considered as fully compliant?
- Q6: Do you think food establishments should be recognised for sustained compliance if they are assessed to be fully compliant at the last two interventions and over a minimum period of 3 years?
- Q7: What scale of reduction to their total food hygiene intervention rating scheme score do you think food establishments should receive to recognise full compliance (e.g. -5, -10 or -20)?

<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%

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

46. At the LA engagement events held in January 2018, some LAs expressed concern that if the length of time between interventions is increased, then compliance levels may 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 interventions 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 proposal will allow LA resource to be redirected at unrated food establishments and those food businesses that are non-compliant.

Table 2: Shows the performance at the most recent Intervention (Intervention 3) given the FHRS ratings for each of 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:

FHRS 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 (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%	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

47. In the current Code, an additional score of 22 (which is in addition to the Consumers at Risk score) is applied to establishments involved in the production or service of high-risk food intended specifically for consumption by Vulnerable Risk Groups of more than 20 people. In this context, Vulnerable Risk Groups are those people likely to be more susceptible to the effects of poor food hygiene, e.g. people under 5, over 65, or are sick or immuno-compromised. The application of the additional score of 22 has the impact of increasing the food hygiene intervention rating scheme score for food establishments (thus increasing the intervention frequency) by up to two intervention rating categories.
48. It is proposed to directly link the additional score for the Vulnerable Risk Group to the assessment of CiM at food establishments. Retaining the current application of the Vulnerable Risk Groups score recognises certain groups within the population are more susceptible to developing infection from consuming contaminated food. These people are likely to suffer more severe symptoms, and must be afforded an appropriate level of consumer protection.
49. In practice, the Vulnerable Risk Groups score is most commonly applied by LAs to food establishments where this identification can be clearly made, such as hospital settings, rather than a manufacturer whose products are supplied to the whole population, including those who could be considered vulnerable.
50. FBOs 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 Hazard Analysis and Critical Control Point (HACCP) principles. Food businesses should have in place effective food safety management systems to minimise food safety risks and this should include consideration of the intended use of the food. The current Vulnerable Risk Groups score is applied regardless of whether the food business demonstrates good levels of compliance with food law. Therefore, compliant food businesses serving Vulnerable Risk Groups may receive a higher frequency of interventions compared to other less compliant food establishments.
51. To recognise businesses that have effective food safety management systems in place, it is proposed that the Vulnerable Risk Groups score will not be applied where the food establishment is assessed as fully compliant. For example, if a food business is assessed as 0 or 5 for the three compliance scores, the additional scoring of 22 would not be applied.
52. This proposal recognises compliant food establishments that have effective food safety management systems by reducing the intervention frequency. However, it is proposed that the Vulnerable Risk Groups score would still be applied to food establishments serving high-risk foods to vulnerable consumers that do not demonstrate full compliance.
53. Analysis of the LAEMS data identifies that CiM scores are higher in health care establishments where a Vulnerable Risk Groups score has been applied and that the level of formal enforcement is low.
54. Analysis also shows a marked difference in the levels of formal enforcement actions (of any type) undertaken. Establishments with a Vulnerable Risk Groups

score are three 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 Risk Groups score, compared to 0.73% of all food establishments).

55. At recent LA engagement 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. Therefore, maintaining the current frequency of hygiene interventions was considered necessary by some officers. There is currently no evidence to support this from the LAEMS data, but the FSA will continue to monitor the position using 2017/2018 LAEMS returns.

Stakeholder responses are invited on the following questions:

Q8: Do you agree with treating fully compliant businesses differently in these circumstances, and the likely positives and negatives of the impacts of this proposal?

Q9: Do you have any documented evidence that would substantiate the view that there has been a significant decline in food safety compliance levels within food establishments where a Vulnerable Risk Groups score has been applied?

Proposal 5: Safeguards

56. It is proposed to put in place safeguards to ensure the combined effect of proposals 3 and 4 is capped and does not exceed a total reduction of -40 in the overall food hygiene intervention rating scheme score or reduce an intervention rating by more than two risk categories. This is to ensure that official controls are still undertaken at food establishments in a manner proportionate to the risk. In addition, the FSA proposes that for establishments that are given a score of 22 for Vulnerable Risk Groups, the risk category reduction arising from proposals 3 and 4 cannot result in an establishment being categorised as less than category D. This will ensure that intervention visits to establishment remain the minimum requirement.
57. 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 two interventions and over a minimum period of 3 years. At the next inspection on the 01/05/2019, the Vulnerable Risk Groups score would 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 01/05/2021, the Vulnerable Risk Groups score is not applied as the care home is assessed to have full compliance and the further reduction in the total risk 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	01/05/2016	01/11/2017	01/05/2019	01/05/2021
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	0	0
Structure	5	5	5	5
CIM	5	0	0	0
Total	67	62	40	40
Category	C rated	C rated	D rated	D rated
Category (-5)			35 (-5) D rated	30 (-10) Remains D rated as cap applied
Category (-10)			30 (-10) Remains D rated as cap applied	20 (-20) Remains D rated as cap applied
Category (-20)			20 (-20) Remains D rated as cap applied	0 (-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 two interventions and over a minimum period of 3 years. At the next inspection on the 01/05/2019 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 01/11/2020, the restaurant is again assessed to have full compliance and 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
Method of processing	20	20	20	20
Consumers at risk	5	5	5	5
Vulnerable Group	0	0	0	0
Hygiene	0	5	5	0
Structure	0	5	0	0
CIM	0	5	5	0
Total	55	70	65	55
Initial Category	C rated	C rated	C rated	C rated
Category (-5)			60 (-5) C rated	45 (-10) C rated
Category (-10)			55 (-10) C rated	35 (-20) D rated
Category (-20)			45 (-20) C rated	15 (-40) Remains D rated as cap applied

Proposal 6: Significant Risk

58. The Significant Risk score in the food hygiene intervention rating scheme is to recognise the potential of serious foodborne illness where a food business fails to address specific risks of contamination.
59. This Significant Risk score should be applied in circumstances:
- 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*.
60. This should be applied on a case-by-case basis. It is not intended to be applied generically to whole categories of food businesses and must be removed if, at the next inspection, the significant risk no longer exists.
61. This proposal suggests removal of the Significant Risk score and for consideration of significant risk to be included in the CiM assessment, as it relates to the risk of contamination. The Significant Risk score is already intrinsically linked to the CiM assessment. If CiM is assessed as 0 or 5, the food establishment should not pose a significant risk as there is confidence in the management of food safety and the score would not be applied.
62. Food businesses should have appropriate food safety management systems in place to minimise food safety risks irrespective of the consequences of failing to implement effective controls. Their management of controls are already assessed as part of CiM. Incorporating the significant risk element within the CiM assessment allows for better recognition of how these risks are being managed by the business. Significant risk should be dealt with using appropriate enforcement sanctions following interventions as the risk will not be addressed through increasing the intervention frequency.

The Wales 2016/17 LAEMS data shows 109 establishments had the Significant Risk score applied. Twenty of those food establishments (15%) had been assessed as 0 or 5 for CiM, in direct contradiction to the requirements of the Code. This means 89 food establishments in Wales were allocated the score appropriately. In respect of the 20 incorrectly allocated Significant Risk scores, if the score was removed this would result in 18 food establishments changing risk category. This evidence corroborates the feedback obtained at the LA engagement events, where LAs highlighted that on occasions the Significant Risk score was being used to identify certain establishments on their database, rather than it being a current and actual risk consideration.

Stakeholder responses are invited on the following questions:

Q10: Given the issues that exist with the application of the Significant Risk score, what are your views on retaining this in the food hygiene intervention rating scheme?

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

Proposal 7: Method of Processing

63. The Method of Processing element of the food hygiene intervention rating scheme is intended to recognise those establishments that undertake a specific method of processing. These include processes or activities intending to extend the shelf life of a product, which has the potential to increase the risk to public health beyond that of standard cooking or storage methods e.g. vacuum packing. Officers are required to consider if the activity or process itself creates an increased risk. It is proposed to amend the descriptor to include circumstances where a food establishment's operations intentionally do not include a process that would increase the risk to public health, e.g. raw cows' drinking milk (RCDM) where pasteurisation/heat treatment does not take place.

Stakeholder responses are invited on the following questions:

Q12: The FSA believes the proposed amendment to the Method of Processing descriptor will not result in any substantial change in inspection frequencies for food establishments. Do you have evidence to the contrary?

Proposal 8: Considerations for Confidence in Management Assessment

64. Registration is a legal requirement under Article 6(2) of Regulation (EC) No 852/2004, which states FBOs are to register the establishment(s) under their control, with the appropriate competent authority in the manner they specify. The Code sets-out the process for the registration of a food business and requires the FBO to inform the LA 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 beneficial to businesses, as it helps them get it right from the start and to sustain compliance with food law.
65. The FSA is aware that a proportion of FBOs do not proactively register before they start trading or commence their operations. Whilst the FSA cannot currently quantify this, qualitative research has been undertaken to understand the different pathways a food business becomes known to the local authority.
66. In a survey of 112 local authorities, approximately 10% of new food businesses were identified when they were already trading. Whilst based on a small sample size, 10% of the current 634,580 food businesses in Wales, England and Northern Ireland would equate to approximately 63,458 food businesses that could potentially be operating without first being registered.
67. The majority of food businesses (99.2%) require registration, with a small proportion that need to be approved before they can commence trading. Those requiring registration may commence trading without any form of assessment to ensure they comply with food law.
68. The aim of registration is to inform the LA that a new business is planning to open. The LA can then plan to undertake appropriate interventions. This can include various activities to support the food business to achieve compliance, such as the provision of targeted education and advice through various methods.

69. The current food hygiene intervention rating scheme does not have regard to whether food businesses have proactively registered.
70. FBOs that register in the correct manner demonstrate compliance with the legal requirement and it is proposed these are recognised in the intervention score applied for CiM.
71. The main aims for considering the introduction of an increased score for FBOs who had not proactively registered are:
- To achieve a more consistent approach to how LAs deal with food businesses that do not proactively register.
 - To increase the number of FBOs that proactively register before the business starts trading or the food operations commence.
 - To drive an increase in compliance through FHRs ratings being impacted, where a new business has not proactively registered and to sustain compliance.
72. There is ongoing FSA research to gather data on new food establishments registering with a selection of LAs across Wales, England and Northern Ireland. 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 these businesses receiving a higher FHRs rating at the first inspection.
73. The FSA presented proposals at a series of LA engagement events held in December 2017 and January 2018, on the concept of applying a weighting under the CiM score for businesses that had not proactively registered. Views on whether LAs 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 FBOs that pro-actively register.
74. Whilst there are other options for addressing the issue of non-registration, it is proposed this should be reflected in the CiM score. The FSA would welcome your views on the options to achieve this as set-out below:
- Include new descriptors in the Code under **part 3 - CiM/control procedures**
 ‘include for new food businesses – whether the FBO proactively registered the establishment under their control before the business started trading or the food operation commenced.’

 This would fall to the LA to determine an appropriate score to apply for failing to proactively register.
 - To apply a minimum score of 5 for CiM where a business has not proactively registered. This may have a negative impact on the FHRs rating for the establishment, particularly if other non-compliances are identified;
 - To apply a minimum score of 10 for CiM where a food business has not proactively registered, which would have a greater impact on their FHRs rating.

Stakeholder responses are invited on the following questions:

Q13: Do you have any documentary evidence to support the use of a minimum score for the non-registration of a food business?

Q14: Do you think the use of a minimum score for non-registration would have enough impact, and if so which score do you consider most appropriate?

The following worked examples illustrate the impact of applying a specific score for CiM for non-proactive registration on the overall food hygiene rating.

Example 1

If the requirement to proactively register is not taken into consideration and a score of 0 awarded for CIM, the food hygiene rating would be a 4. Applying a score of 5 or 10 would have the same effect as the outcome would be a rating of 3.

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 the requirement to proactively register is not taken into consideration and 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 maximum CIM score of 10 is applied the rating would be 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 the requirement to proactively register is not taken into consideration and 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 an increased CIM score is applied for non-registration, what are the benefits?

Q16: Are there any alternative measures that could be used to improve (i) proactive registration, and (ii) to improve initial FHRs ratings?

Alternative options

75. The FSA recognises there are many options that could potentially be adopted to either incentivise pro-active registration or act as a deterrent for failure to register. Motivations could include the use of financial incentives through reduced business rates or support packages offered as part of the registration process. Sanctions could also be applied in the form of fixed penalty notices (FPNs).
76. To encourage FBOs to register, the FSA intends to carry out a campaign to raise awareness of the requirement to register and will work with stakeholders to help educate potential FBOs at the earliest opportunity.
77. LA engagement events carried out in 2017 and 2018 identified support for a Permit to Trade (PTT) or licensing system for all food businesses. This was widely considered to be an effective way of improving regulatory controls for food businesses. Whilst this is not included in the initial phase of the work, this will be further explored during 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 protection measure.
78. The introduction of FPNs for failure to comply with the requirement to register is also not within scope of this workstream, but will be considered within the wider piece of work on sustainable funding.

Proposal 9: Data Storage and Transfer

79. The availability of and access to data, data standards and their exploitation are critical to implementing the developing Target Operating Model (TOM) for ROF. The use of data is critical for the FSA in its role as a regulator. Better use of data will support the efficient and effective operation of government and public services, responsive to businesses and citizen's needs.
80. The FSA proposal is to include a new requirement in the Code that will specify how LAs must store and transfer data and the need to follow a specified data standard.

Stakeholder responses are invited on the following question:

Q17: Do you envisage any barriers to the implementation or any unintended consequences of a data standard on LA delivery of official controls?

Supplementary proposals

Supplementary proposals for development:

The FSA also wishes to invite views to help inform the development of the following new performance measures to allow more meaningful and real-time assessment of LA delivery of its obligations.

Balanced Scorecard

81. The FSA is developing a Balanced Scorecard (BSC). This is a digitally enabled tool that will use FHRS data and LAEMS data to provide a more rounded and up-to date information on the performance and effectiveness of LA delivery. The BSC may also consider other relevant internal and external data sources available in the future.
82. Data will be presented through a range of visual tools, including interactive mapping. This will allow a detailed analysis of data, making it easier to view and understand LA performance and trends on a national basis. This will potentially help to inform the development of more targeted policies for Wales, England and Northern Ireland. The BSC will also make it easier for LAs to benchmark their performance against other similar authorities. This should provide a driver for service improvement.

Stakeholder responses are invited on the following questions:

Q17: Do you know of any publicly available data sets, other than LAEMS and FHRs, which could be added to the BSC to improve its scope?

Q18: Are there any other measurable indicators of LA performance, other than LAEMS and FHRs which could be developed and used to monitor the effectiveness of LA delivery? These could be direct or indirect indicators and quantitative or qualitative measures.

Engagement and Consultation Process

83. The FSA presented these proposed changes at a series of LA engagement events, as well as presenting the proposals to industry representatives at the Food Hygiene Expert Panel. In Wales, there were three workshops, one in north Wales, one in mid-Wales and one in south Wales on 11 and 18 January and 1 February 2018. These were attended by approximately 50 LA representatives. The FSA also held meetings with the Segmentation Working Group prior to the consultation being launched at which the proposals were presented to LA representatives, and other stakeholders, including industry and professional body representatives. The FSA received detailed responses to the proposals from LAs.

Summary of responses:

Proposal 1: Enhanced Registration

84. At the stakeholder engagement events there was general 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 FBO for failure to register. There was strong support for the introduction of FPNs as an enforcement sanction for FBOs that fail to pro-actively register their business.
85. There was also strong support amongst LAs for introducing licensing requirements for food businesses and general agreement that a funding mechanism is necessary to resolve resourcing issues. LAs expressed the view that a charge for licensing would provide an income for official food controls that could be ring-fenced. Licensing would also enable conditions to be attached to ensure compliance at the point of trade and sanctions could be applied e.g. revocation/suspension of the licence.

Proposal 2: NIS

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

Proposal 3: Full compliance and Sustained Compliance

87. In Wales, England 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 available to them in the Code for broadly compliant category C and for category D rated establishments so these may not demonstrate sustained compliance for years. It was considered that the impact on inspections was negligible.

Proposal 4: Vulnerable Risk Groups

88. In England and Northern Ireland there was some support for the Vulnerable Risk Groups 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

89. 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. However, there was agreement that this score was not used consistently and if it remained, consistency training was needed. 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.

Proposal 8: Consideration of the Registration Process

90. There were various views on whether LAs should take account of whether a new food business had proactively registered in the CiM score. It was generally considered that this change alone would not make a significant difference to the number of FBOs that pro-actively register. It is a legal requirement and the FSA is aware that some LAs are already taking non-registration into account when rating a business.

Further Consultation

91. The FSA intends to continue to engage with stakeholders throughout the consultation period, including additional face to face discussions to address specific stakeholder issues where possible. In Wales the FSA will be meeting with representatives of the Directors of Public Protection in Wales (DPPW) in September and will be presenting its proposals to the Welsh Government's working group set-up to provide assurance to Welsh Ministers that Wales' needs are taken account of within the FSA's ROF programme.
92. In relation to the work on NIS, the FSA has requested stakeholder views initially via the 9th edition of the 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 LAs across Wales, England and Northern Ireland using the RIAMS/Smarter Communications platform.

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

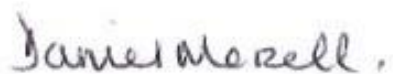
93. On completion of the consultation, the FSA will produce and publish a summary of consultation feedback and its response to the comments raised. While some changes proposed in this consultation have a specific implementation date, the FSA will delay other changes until supporting policy is in place to ensure minimal impact on LA service delivery.

Responses

94. Responses are required by close on **23 November 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 faithfully,



Daniel Morelli
Local Authority Partnership Manager

Enclosed

Annex A: Standard Consultation Information

Annex B: Enhanced Registration Impact Assessment

Annex C: National Inspection Strategy Impact Assessment

Annex D: Risk Assessment Changes Impact Assessment

Annex E: Code Table of Changes

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@food.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.

Atodiad B

Title: Regulating Our Future – Amendments to the Food Law Code of Practice (Wales) – Implementation of an Enhanced Registration System for Food Businesses IA No: Lead department or agency: Other departments or agencies:				Impact Assessment (IA)			
				Date: 30/08/2018			
				Stage: Development/Options			
				Source of intervention: Domestic			
				Type of measure: Other			
Contact for enquiries: Daniel Morelli				RPC Opinion: RPC Opinion Status			
Summary: Intervention and Options							
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? Change is proposed to the process of food business registration to assist the Food Standards Agency (FSA) in identifying an increasingly diverse food industry and to improve the overall effectiveness, efficiency and consistency of food business registration. Additional information provided at the point of registration will allow for an assessment to be undertaken to determine an appropriate risk-based approach to intervention strategies for new businesses. In addition, information obtained will provide the FSA as Central Competent Authority (CCA), with a comprehensive understanding of the food industry. This should help inform future policy development and in the management of food safety incidents.							
What are the policy objectives and the intended effects? Enhancing the registration process is a key element in the operational delivery of the FSA's Regulating Our Future (ROF) programme. The policy objectives are: <ol style="list-style-type: none"> 1) The development of an online registration service that will provide the FSA with oversight of all food businesses in Wales, England and Northern Ireland. 2) To provide food businesses with tailored support and guidance at the point of registration to assist them in complying with food law and improve 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 with the intention of increasing the number of food business that proactively register 							
What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base) Option 1: 'Do Nothing', and continue with the current system of registration. Food Business Operators (FBOs) would continue to register through different methods. Local authorities (LAs) would continue to adopt a range of approaches to processing and reporting information 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: <ul style="list-style-type: none"> • Phase 1 (pre EU-exit): Introduce an online registration service for those food businesses required by law to register • Phase 2 (post EU-exit): Incorporate into the system those food businesses legally required to seek approval. The new registration service proposed in option 2 will work in conjunction with LAs' existing Management Information Systems (MIS)/databases and would deliver the policy objectives set-out. This is the preferred option.							
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	Large Yes		
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded:		Non-traded:		

Annex B

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 'Do Nothing'. The FSA currently has no evidence to suggest 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'

'Do Nothing'. 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 'Do Nothing'. It is assumed that the monetary benefits will remain unchanged. The FSA has 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'

'Do Nothing'. The non-monetary 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 cost to each business (per-business cost) for paper and web-based registration is £1.95 and £1.22, respectively. The total annual cost to the UK is £49,496.85 for paper registration submissions and £123,871.48 for web-based methods, according to forecasts for future registration. LAs incur a paper and/or web-based per-application resource cost of £6.88 and £3.45, respectively. Processing paper and web-based applications in future is estimated to cost £174,635.04 and £350,292.30, respectively. The FSA's estimated cost of developing the digital registration service is £772,000.

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

Although the per-business cost for paper and web-based registration could be calculated, these estimates cannot be used to calculate the total cost to businesses that are currently trading, but have not registered. Similarly, the resource costs incurred by LAs of having to process applications for those food businesses that are currently not registered cannot be calculated. The FSA does not have data available and, hence, cannot 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: Option 2 (the preferred option) the benefits cannot be quantified at this stage. Through stakeholder consultation, the FSA seeks to collect data to assist in monetise as many benefits as possible.

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

It is envisaged that consumers will have better access to information about food businesses and that there will be reductions in the incidence of foodborne illnesses. Food businesses have further opportunities for economic savings and the 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

-

In forecasting the future levels of food business registration and ensuing LA administration, an industry churn rate has been estimated. According to 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 Wales, England and Northern Ireland are regulated to check that our food is safe and what it says it is. The FSA is 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. The FSA is doing this so that the system has the sophistication needed to regulate an increasingly diverse food industry, to adapt quickly to changing risks and to respond to changing patterns of food production, trade and consumption when the United Kingdom (UK) leaves the European Union (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 this 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 supplied by 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 key element in the operational delivery of the FSA's ROF programme.

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

- The development of an improved digital service for the registration of food businesses, streamlining and simplifying the process for the user (FBOs), reducing administrative burdens for LAs and providing the FSA as Central Competent Authority (CCA) with a unified view of all food businesses in Wales, England and Northern Ireland. Using an enhanced data set captured at the point of registration should help design an appropriate regulatory regime, improve incident handling and better inform future policy direction.
 - To provide businesses with access to relevant information and guidance promptly, increasing the opportunity for them to ensure compliance with food law and improve standards of compliance.
 - To carry out research to understand the barriers to new businesses proactively registering and to help develop 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 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 developed via several workstreams, with the intention of introducing changes in a phased approach. This update to the Food Law Code of Practice (the Code), includes input from the Enhanced Registration workstream, and introduces a process change for FBOs for registering the food establishment(s) under their control.

6. The changes aim to improve the overall effectiveness, efficiency and consistency of food business registration across Wales, England and Northern Ireland. However, this assessment only covers changes in Wales, separate consultations are underway in England and Northern Ireland.
7. It is important to recognise the proposed online registration service will be fundamental 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. This will allow for an assessment to be undertaken to determine an appropriate risk-based approach to intervention strategies for new businesses and ensure the efficient use of LA resources.
8. The proposal to use a digital solution will also ensure LAs are informed of new food businesses at the earliest opportunity. This will enable LAs to provide relevant advice and support to assist businesses in achieving compliance from the start.
9. As this work is still in its development phase, the FSA does not have the evidence base required to quantify all the benefits it anticipates will be achieved through implementation of the new online registration service. Work will continue to gather the full evidence base required through on-going research and the consultation process.

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 apply for approval with the appropriate competent authority (CA).
 - Under Article 6(2) of Regulation (EC) No 852/2004, FBOs must register an establishment(s) under their control that carries out any stage of production, processing and distribution of food, with the appropriate CA.
 - Regulation (EC) No 853/2004 requires that food establishments handling certain foods of animal origin, with some exceptions, be approved by the CA prior to trading. In respect of businesses that require approval, it is necessary that they demonstrate compliance with relevant requirements of Regulation (EC) No 853/2004, in addition to compliance with Regulation (EC) No 852/2004 before approval can be granted. Registration under Article 6(2) of Regulation (EC) No 852/2004 is not required for establishments that are subject to approval.
11. In the UK, 634,584 food establishments are recorded as registered with LAs as at 31 March 2017. That equates to 99.2% of food businesses in Wales, England and Northern Ireland being required to register whilst 0.8% are approved. In Wales, there were over 35,000 food businesses registered with LAs at 31 March 2017.
12. FBOs are only required to provide a limited amount of information when registering with the LA. Registration is required at least 28 days before the business starts trading or the food operations commence. Upon receipt of a registration, LAs use the information to determine when to carry out an initial inspection. Currently, LAs use a number of different registration forms and approaches for the registration process.
13. For a variety of reasons, many FBOs either start trading before registering and/or register but commence trading prior to a LA inspection taking place. This means FBOs may not receive the appropriate level of support at the earliest opportunity to aid compliance.
14. Food businesses that produce certain products of animal origin (meat, fish, dairy or eggs) and supply these to other food establishments, may require approval. To obtain approval, a FBO must provide more detailed information on the approval application form, and during an

on-site inspection, to demonstrate compliance with the relevant hygiene legislation. Until compliance has been checked and verified, the FBO is not allowed to commence operation of the food business.

15. Establishments requiring approval only represent a small proportion of all food businesses, as the majority are only required to register. The FSA intends to incorporate food businesses requiring approval into the new online service at a later phase in the programme.

Why Enhance the Current Registration System?

16. Whilst the current registration process works, the FSA recognises that there are opportunities for improving its overall effectiveness, efficiency and consistency. The reasons for this include:

- LAs currently have the option to adapt and issue variations of the model registration form provided by the FSA. This can create inconsistencies between LAs and across Wales, England and Northern Ireland. This approach can be confusing and frustrating for FBOs, particularly those who have multiple food establishments located in different LA areas and/or countries.
- LAs process and acknowledge food business registrations according to their individual internal procedures. This can involve administrative activities to issue letters/emails and the inputting/verification of data on MIS, 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 establishment is/will be located. The route for registration is defined by the LA, creating inconsistencies in the process. For example, some FBOs are directed to the LA's registration form, others are simply provided with the address of the LA in which their business is located.
- FBOs follow numerous registration pathways, and many businesses requiring registration are not being identified until an LA receives information to that effect either from its own officers or from consumers. Qualitative research has identified that the main reason FBOs do not proactively register is a lack of knowledge or understanding about how to register. Simplifying the process and taking the opportunity to raise awareness of the new online registration service will help to improve consistency and better inform FBOs of how to fulfil their legal obligations.
- The current model form only gathers basic information about the food business establishment, for example: the FBO's name, address, and business type. This is insufficient to assess the level of risk associated with the business.
- Pertinent information obtained from FBOs at the point of registration and following an intervention by the CA 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 with FSA systems.
- In respect of FBOs that own mobile food establishments, there is the potential for these to operate across numerous LA boundaries. To prevent unnecessary regulatory activity, details of interventions and enforcement activity should be referred to the registering authority to take account when determining an 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 interventions being carried out as and when the mobile establishment moves between LA areas. This can be a labour-intensive process.

17. The FSA is aware that there is an appetite for the introduction of alternative approaches to secure an increase in proactive registration and to ensure that FBOs have the relevant support they need before they commence trading. Examples include the use of FPNs for 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 PTT/licensing system could take several years to bring forward, as there is a need to carry out further research to provide a robust evidence base before these changes can be considered and potentially introduced. Through enhancing the current registration system, the FSA aims is to obtain evidence to demonstrate that the introduction of FPNs/PTT licensing system in Wales, England and Northern Ireland are necessary measures to protect public health.

Justification for Enhancing the Current Registration System

19. Introducing an online registration service will streamline the process, improving the overall effectiveness and efficiency for LAs and FBOs, whilst also providing the foundation for introducing other ROF programme deliverables.
20. This new service should alleviate inconsistencies in the registration process and make it less labour intensive. For example, FBOs in different LA areas will be asked the same questions that are pertinent to the type of business they are registering.
21. Opportunities to raise awareness of the need to register will better inform FBOs of the legal requirement and potentially increase the number of businesses that register 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. This will allow for tailored advice and guidance to be provided to the FBO at the earliest opportunity. Furthermore, through capturing more in-depth information on 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, a new FSA system currently under development, called “the unified view”, will mean information regarding interventions and compliance will be made available to support the co-ordination of activity e.g. for mobile traders that operate across LA boundaries.
24. The system should also ensure the reduction in time taken by a FBO to register their business as opposed to following the current process. Initial findings of a study using a small sample size suggests that there will savings realised from the new system.

Benefits for Local Authorities

25. Introducing an online service will streamline the process, helping to reduce the burden for LA officers involved in manually inputting registration information onto MIS/databases. For example, there will be no need for manual verification checks of post codes and addresses,

as these will be incorporated into the initial version of the online form. At a later date, this will be expanded to include further verification of FBOs.

26. LAs will be able to view relevant information about food establishments from across Wales, England and Northern Ireland via the unified view. This will help to make informed decisions regarding the most appropriate interventions to undertake and provide a better understanding of overall business compliance. The unified view will allow LAs to make links between food businesses, such as being able to detect frequent changes of FBO, or identifying multiple businesses owned by the same FBO. This will help build an overall picture of compliance and assist in the management of food safety incidents.
27. The new online service will alert LAs of a new food business registering in their area enabling them to contact the FBO at the earliest opportunity to ascertain what support and guidance they might require. Early findings from some quantitative research suggests those FBOs that received support at an early stage go on to achieve higher initial food hygiene ratings than those who did not.
28. 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 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 businesses using the online service to register.
29. The new service 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.
30. There will be an improved flow of information between the LAs and the FSA, enabling data to be accessed and used effectively and efficiently.

Benefits for the Food Standards Agency

31. The new online registration service will gather information that will enable the FSA, as the CCA, to have a unified overview of all food businesses across Wales, England and Northern Ireland, which is paramount as the UK prepares to exit the EU.
32. 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.
33. Having a unified view of all food businesses will enable the FSA to better inform future policy direction.

Benefits for Food Business Operators

34. Recent research shows there are a variety of ways a food business registers or becomes known to the LA. The new service aims to simplify the registration process for a FBO, making it a consistent experience regardless of where their business is located.
35. 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.
36. Introducing a new online registration service that asks questions relevant to the business activities will enable new businesses to receive links to current and tailored information and advice that will help them to start-up successfully. The provision of tailored guidance to help

FBOs comply with food law prior to trading will improve business awareness and may lead to financial savings, i.e. businesses are less likely to spend money unnecessarily to comply.

37. Initial findings following a small user testing study have shown savings in the time taken by a FBO to complete the new online registration form as opposed to completing the current government form (<https://www.gov.uk/food-business-registration>). Completion of the current on-line form took on average 11.2 minutes, whereas early testing of the new form which asks additional questions is averaging between 6-8 minutes. The new online registration service will ask questions that are appropriate to the type of business being registered that are dependent on the answers given to questions throughout the process. Further user testing, to quantify time savings to FBOs, is on-going as the FSA continues to develop the service.
38. Achieving compliance with food law from the outset should lead to a high food hygiene rating for new businesses, which in turn provides commercial benefits for a business.

Benefits for Consumers

39. It is anticipated that improved access to guidance for FBOs will in turn result in more compliant food businesses with higher food hygiene ratings, which is positive for public health protection and consumer choice and confidence.
40. Consumers will have greater confidence as they will be able to identify if a food business has fulfilled its legal obligation to register.

User Research – Main Findings

41. Some food businesses 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.
42. The introduction of a new online registration service will help to identify new food businesses at the outset, make it easier for FBOs to register their business, assess the risk and inform an appropriate intervention strategy based on the information obtained. It will also direct LAs support to the food businesses that need it.

Engagement

43. The plans to implement a new online service were shared with LAs during several engagement events. At the LA ROF engagement events held in December 2017 and January 2018, there was disappointment that the work to introduce PTT, as opposed to an enhanced registration process, was not being progressed/prioritised by the FSA. Shortfalls in the existing registration system were clearly identified and included:
 - It is resource intensive to chase up non-registration. A financial obligation related to registration could prevent this from happening and free up resource.
 - LAs 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 whereas to enforce the word of the law in respect of registration.
 - A permit or licence may improve business engagement i.e. the word 'registration' implies a less formal process.
44. There was strong support amongst LAs for introducing licensing requirements for food businesses, although there was general agreement that a funding mechanism would be

necessary to resolve resourcing issues. It was suggested 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 start-up. A licence could also introduce additional sanctions to deal with non-compliance e.g. revocation/suspension.

45. 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 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.
46. LAs requested that the FSA considered the following with regards to the proposed system of enhanced registration:
 - Research should be undertaken to explore incentives for registration, as currently many FBOs fail to register despite the current form not being difficult to complete.
 - A digital form would not always be well received due to the lack of access to, or willingness to use IT by the small and medium sized enterprises (SMEs). 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. For example, if the registration process sits with the FSA, businesses may not know who conducts inspections.
 - Ensure that any future registration process is compatible with all the MIS in use, to provide efficient data capability and prevent duplication of effort.
 - 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).
47. LAs have also expressed concern about 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. However, LAs recognised the benefit that could result from links being provided to tailored advice that is updated centrally by the FSA to improve consistency in the provision of advice.
 - Difficulties with accessing the information due to Data Protection/FOI considerations.

The FSA will consider these comments and views throughout the development process.

48. Whilst the use of sanctions, such as FPNs, or the introduction of a PTT/licensing system 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 an evidence base to establish if there is a case to introduce a PTT/licensing system in Wales, England and Northern Ireland as a public protection measure.
49. 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

50. The FSA has requested information to better understand user perception of the existing registration process to identify areas in which the most value could be added. A sample of

over 750 responses from the FSA, LAs and FBOs have been collected using a range of research methods that included interviews, surveys and enquiries.

51. Responses indicate that 75% of the LAs asked either use or accept the online business form available 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 on average 19% of registrations omit mandatory information, whereas on average 15% have incorrect information provided. The current registration process also imposes costs to LAs due to unnecessary use of resources. For example, an average of 1 in 35 inspections of new establishments could not be completed because the FBO had not opened or had ceased trading. Further, an average of 1 in 15 inspections are not undertaken because of the FBO does not begin trading.
52. Research to assess the existing registration process identified, and separated key user group needs into, four categories.
 - Better consistency is needed. FBOs expect to have the same registration experience regardless of their LA, providing the same information at all times. On the other hand, LAs need to fill current gaps in mandatory data, which can be achieved through providing a unified, unambiguous and validated registration form.
 - FBOs would like confirmation of receipt of the application and be able to track the registration and its status.
 - The FSA and LAs would like to improve data quality. These groups would like the information submitted to LAs to be validated and forwarded to the relevant LA. Data concerning FBOs should be consistent in content and format across all LAs and accessible to the FSA.
 - LAs need to be able to share data with one another, enabling a wider overview of food businesses. For the FSA, up-to-date information concerning the FBO would be available in one place to allow accurate analysis into the performance of the FBO and the LA.
53. The FSA used questionnaires as part of this work and 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 the non-web and web-based methods of business registration.
54. To better understand the burden on LAs when processing non-web applications (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?*
55. The participating LA is then presented with a list of closed-ended responses. These take the form of duration thresholds from which the LA is required to select an answer. Responses to this question comprise the experience of 21 LAs. Figure 1 provides a pie chart to illustrate results.

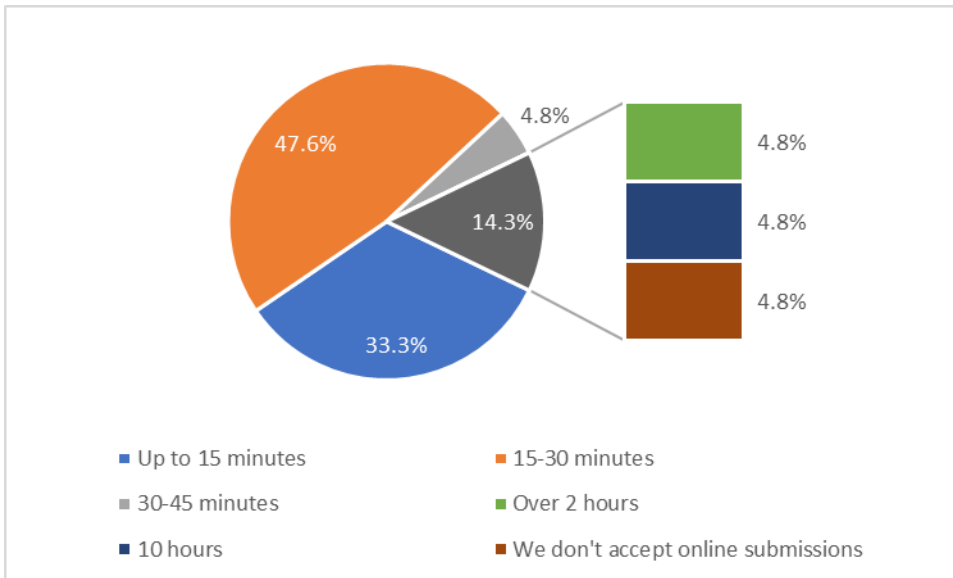


Figure 1. Responses of 21 LAs (shown as a percentage) to the question “Approximately how long does it take to process a non-online registration form, including the performance of necessary checks and the input of information into the database?”.

56. In total, 33.3% of respondents believe that it takes up to 15 minutes to process a paper registration form, with 47.6% of LAs indicating that processing takes between 15-30 minutes. There was one LA, equating to 4.6%, which indicated that processing can take 30-45 minutes, another LA indicating over 2 hours and a further LA indicating 10 hours. One LA out of those surveyed indicated they do not accept non-web forms.
57. The disparity in results are attributed to the different processes applied by LAs for registering food businesses. These include carrying out different checks and following different data-input procedures. The conclusion is that registration present a burden to LAs albeit to varying degrees.
58. 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?*
59. Responses to this question are based on the experience of 18 LAs. Figure 2 provides a pie chart to illustrate results.

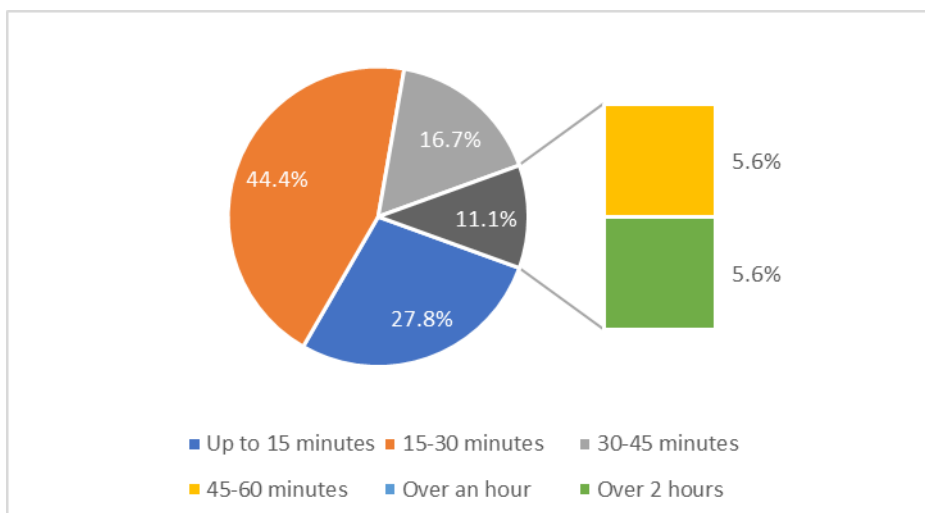


Figure 2. Responses of 18 LAs (shown as a percentage) to the question “*Approximately how long does it take to process a registration form through the www.gov.uk website, including the performance of necessary checks and the input of information into the management information system?*”.

60. A total of 27.8% of respondents stated that it takes up to 15 minutes to process a web-based application. The majority of LAs (44.4%) indicated it takes between 15-30 minutes. There were 16.7% of LAs that indicated it takes between 30-45 minutes. Finally, 5.6% (equivalent to 1 LA) indicated it takes 45-60 minutes and another LA indicated over 2-hours.
61. The conclusions from this study showed that, with the disparity in results, there is scope for bringing processing time down significantly, especially for those at the upper end of duration estimates. It was also clear there are business applications that impose high resource costs to LAs, regardless of whether the business opts for non-web or web-based routes for registration.
62. 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 Wales, England and Northern Ireland, these results indicate instances of high resource costs and serve as a useful benchmark to introduce changes to the existing system. The proposed changes are intended to reduce the time taken by LAs to process food business registrations.
63. The FSA has entered the Beta stage of testing the new registration service and is working with LAs to get their views and see how it compares to the existing process. Through administering the same questionnaires and representing results in a similar fashion, the FSA will be able to measure the results accordingly.
64. The Beta stage 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 dates to help reduce the number of failed visits.

Quantitative Data Gathering

65. An LA data gathering exercise to provide a significant body of information to progress the final model for the registration and segmentation of food businesses is on-going. 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 pathway to registration as a component of a new risk profiling system.
66. The FSA acknowledges that there are many ways a new business becomes known to the LA and that the main route is when they voluntarily present themselves by telephone, email, via the LA’s website or in person. For the FSA to address the issue of non-registration, it is important to know any other potential routes.
67. The feedback obtained through LA audits anecdotally suggests that not all food businesses proactively register. Therefore, the FSA needs to determine the frequency of proactive registration.
68. The FSA also needs to gain a better understanding on the impact of the advice, to determine whether the FBO has been able to understand and implement it successfully to achieve compliance and obtain a good rating under the FHRS.

The following information is being collected by 20 urban and rural LAs located across Wales, England and Northern Ireland to help inform a robust evidence base:

- How the new business was identified (pathway) i.e. voluntarily presented via LA, voluntarily registered via [www.gov.uk/third party](http://www.gov.uk/third_party), discovered trading by the LA, the LA was notified by other Government Departments or via another alternative route;
- Reason for the registration i.e. a new food business operation, a change of food business operator, or a significant change to existing food establishment's operations that requires notification to the LA;
- Establishment's ID, establishment's name, address and business type (contact details are not required);
- Date of registration for the food business and date the FBO commenced trading;
- Support given to the 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). If the advice was provided before or after trading/inspection, and if the LA charged for the advice;
- 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. Whilst the FSA only has a small dataset to date, initial findings show that those FBOs who received support at an early opportunity received a high FHRS rating at their first inspection. The FSA will be able to quantify this further as the research progresses.

Qualitative Research

69. To complement the quantitative research, the FSA also carried out a social science study on the flow of food business establishments into the regulatory system. The aim of this was to identify the main pathways through which a new business becomes known to the LA, why that route was 'chosen', to establish the type of support they received and how helpful they found it.
70. Findings showed more than three quarters (77%) registered or gained approval voluntarily via their LA, whilst 13% became known via other routes i.e. through third parties, leaving approximately 10% that were identified already trading. In relation to the number of food businesses in Wales, England and Northern Ireland, this equates to approximately 63,458 that may not be known to the LA when they start up. The quantitative research will help to better quantify the 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 on to be more compliant than those that did not.

Headline Findings from Surveyed LAs and FBOs

71. The results of the survey are as follows:
- According to LAs, food businesses most likely to be trading unregistered include takeaways, fixed establishment 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 on average 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).
72. 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:

73. **Option 1:** 'Do Nothing', and continue with the current system of registration. FBOs would continue to register through different methods. LAs would continue to adopt a range of approaches to processing and reporting information to the FSA. This would not realise the policy objective.
74. **Option 2:** Introduce an online service for the registration of all new food businesses using a two-phased approach:
- Phase 1 (pre EU-exit): Introduce an online registration service for those food businesses required by law to register
 - Phase 2 (post EU-exit): Incorporate into the system those food businesses legally required to seek approval.

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

Groups Affected

The following groups are affected:

Consumers

75. A key aspect of registration is to inform the relevant CA of business operation to determine the nature of regulatory intervention applied. Ultimately, the process helps businesses better comply with food law by setting themselves up correctly, FBOs place themselves in a better position to protect and reduce consumer exposure to unacceptable food-related risks.

Food Businesses

76. 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 Wales, England and Northern Ireland at any one time has not been quantified. Following research

using a small sample size, it is estimated that there could be approximately 63,458 establishments across the UK. The enhanced registration proposal would affect existing businesses which are yet to register as well as all new food businesses in the future.

Local Authorities

77. LAs are responsible for food law enforcement, including official controls in the majority of food businesses, and registration is fundamental to enabling them to discharge their obligations.

The FSA

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

Wider Economy

79. Through increasing overall levels of proactive business registration, LAs will be able to apply suitable, timely controls at food establishments. Better understanding and compliance with food law by FBOs prior to trading may help reduce instances of foodborne illness. This could have beneficial impacts on the economy in terms of reduced burden on the National Health Service (NHS), thereby signifying reductions in health costs and financial costs to potential sufferers of food related illnesses. 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

80. 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. Therefore, the costs and benefits in the baseline across time assume current levels of business registration, 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

81. Existing food businesses who have already registered will not be required to re-register their business as part of this process. Those FBOs who have commenced trading, but are yet to register will need to register their business. The introduction of an online registration service and campaign to raise awareness of the requirement to register will help to prompt 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 methods for registration, although online submissions will be encouraged.
82. 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 using paper. User testing is on-going as the model continued to develop, which will enable the time savings to FBOs in using the new online system and paper form to be quantified.
83. 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.
84. In identifying an accurate figure for the manager's average hourly wage, the 2017 Annual Survey of Hours and Earnings (ASHE) is a suitable data source³. Specifically, the median hourly wage for restaurant and catering establishment managers and proprietors is reported at £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 of this is £1.22.
85. Data is not available to carry out industry cost calculations as an estimation of the total number of businesses that are unregistered and trading, along with the estimated split for which registration method they are likely to choose is needed. Therefore, the per-business cost can only be calculated.

Ongoing Registration

86. 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 Wales, England 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.

³ 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.

87. 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.
88. 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 total productivity loss across these businesses is £49,496.85.
89. Similarly, the 101,534 businesses expected to register through the new online service in future can be multiplied by the per-business productivity loss associated with this method (£1.22). The productivity loss across these firms is £123,871.48.

Local Authority Costs

One-Off Administration of existing businesses

90. One of the key policy objectives for the FSA is to have a strategic overview of all food businesses operating in Wales, England and Northern Ireland. The FSA anticipates, following a campaign to raise awareness of the requirement to register, there will be an increase in the number of registrations by those businesses which are unregistered. This increase could present a one-off administration cost to LAs needing to reallocate staff resources.
91. Monetising the strain on LA resources involves staff costs as well as the average duration associated with processing an individual registration. A variety of staff are involved in processing a business' registration. For both paper and web-based methods, 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.
92. 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.
93. The typical time taken to process a paper-based registration is 30 minutes. Given the time breakdown for each staff along with their respective median hourly ASHE wage, the LA's cost for processing each paper application is £6.88.
94. The typical 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 for processing each online application is £3.45.
95. The costs for processing the two types of registrations are based on conservative duration estimates. User testing, which will enable us to quantify the anticipated time savings, is on-going as the new service continues to develop. The FSA believes that use of the new technology will eliminate the need to re-enter information bringing down costs further by reducing processing time.

96. 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

97. 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 food businesses 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 methods in future.
98. 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. According to this estimate, the per-registration cost of £6.88 is multiplied by the 25,383 food businesses likely to register using the form. The total cost to LAs for this method is £174,635.04. Similarly, the per-registration cost of £3.45 is multiplied by the 101,534 food businesses expected to register online in future. The total cost to the LA for this method is £350,292.30.

FSA Costs

Software Development

99. 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

100. Streamlining the registration process for food businesses, through the use of technology and making certain information publicly available, will enable consumers, and other interested parties, to check the status of a food business. This will provide for greater consumer confidence in the businesses compliance with food law requirements.
101. Through improving the availability of information, consumers will be better informed to make decisions regarding the food that they buy and eat outside of the home.
102. The FSA has been unable to estimate the value of this benefit, as it does not have access to information about how much the consumer would be willing to pay for improved access to information to aid decision-making, and is unable to observe behaviour in markets that are similar/related to food safety.

Foodborne Illnesses

103. The new online service is intended to provide FBOs with appropriate guidance and support. Assuming FBOs make use of the guidance which they are provided, there is potential for food-related risks to be managed and controlled more effectively. This reduces the risk to consumers and could potentially improve the quality of food.

104. Sustained improvements in food quality through better risk-management and compliance means consumers are better protected from food risks. Less exposure to this could 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.
105. In monetising the value of a reduction in the number of consumers contracting foodborne illnesses, the FSA would need to examine the relationship between better food business compliance and the number of cases of foodborne illnesses. As this information is not held, these benefits cannot be quantified.

Food Business Benefits

Economic Savings

106. FBO compliance with food law requirements provides assurance that FBOs are meeting their duty to protect consumers from foodborne illnesses. Researching how they can comply can take time and resource and may lead to FBOs not always obtaining the right information for their business.
107. Introducing an online service that provides links to tailored support tools will provide FBOs with a wealth of appropriate information easily and instantly before they start trading. A similar level of information will be available to all FBOs completing an online registration.
108. The time saved by FBOs in their search for appropriate information represents an economic saving to the business. Monetising the benefit of this requires 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 the benefit cannot be quantified.

Burden of Enforcement

109. Option 2 presents an effective way of combining the registration of a food business with the provision of tailored guidance to help businesses 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.
110. Food businesses able to demonstrate compliance when they start-up are more likely to sustained standards and may be subject to less controls by LAs over time. This may ease the regulatory burden with a reduction in the time allocated to various inspections and interventions. This translates to an opportunity to remain productive and add value to their food business.

Local Authority Benefits

Inspections

111. This preferred option is expected to bring several benefits to LAs. It will fundamentally allow for better communication with businesses by requiring FBOs to submit relevant information using 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 shape inspection strategies and for interventions to become more risk-based and proportionate to the type of business under consideration.

112. This option will facilitate better communication for LAs across Wales, England and Northern Ireland. Information about new FBOs captured through the new online service and of existing food businesses from the LA MIS will be shared across LAs. This will provide additional information relevant to a LA's enforcement programme and may reduce unnecessary inspections, particularly of mobile traders.
113. 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. LAs may be able to redirect resource from certain types of business to focus on support for new FBOs or target resource at existing establishments that are non-compliant and present the greatest risk to consumers.

FSA Benefits

Traceability

114. 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, must take measures to ensure it has an overview of the businesses engaged in import and export across Wales, England 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 other data sources.
115. In the event of a possible outbreak of foodborne illness or other food related incident, the FSA, will be able to identify relevant food businesses that could be receiving or supplying specific products giving it a greater sense of accountability across an international scale.
116. Monetising this benefit would involve examining the relationship between foodborne illness and various tools applied by LAs to allow for traceability. As this information is currently unavailable, this benefit cannot be quantified.

Policy Development

117. A key objective of this proposal is to make the FSA a better-informed regulator. With access to richer information for all food establishments, the FSA will be able to better develop policy. Future government policy could be more reflective of the nature and profile of FBOs and related agents. Furthermore, better policy design increases the likelihood for the government to reach long-term food-related objectives.

Wider Impacts

Small Firms Impact Test

118. Business costs identified relate to the time taken registering the business. This is a legal requirement for all businesses, regardless of size. The FSA does not consider this would have a significantly disproportionate impact on businesses of a smaller size.

Competition Assessment

119. 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.

Economic Impact

120. The introduction of a new online service with the signposting of relevant advice and guidance at the outset would mean that food businesses have the opportunity to succeed. This should lead to compliance with food law requirements. This should lead to better FBO behaviour and drive up competition in the market.

Social Impact

121. Social arguments address information barriers and potential health inequalities. Consumers will know if a food business is registered with a LA and, hence, this should promote greater trust in those who have registered. With helpful compliance documents available to FBOs, food safety and 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

122. 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 (Wales) - Recognising national inspection strategies (NIS) for food hygiene and food standards (food partnerships). IA No: Lead department or agency: Food Standards Agency Other departments or agencies:	Impact Assessment (IA)
	Date: 30/08/2018
	Stage: Consultation
	Source of intervention: Domestic
	Type of measure: Other
	Contact for enquiries: Daniel Morelli
Summary: Intervention and Options	RPC Opinion: Not Applicable

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
£0m	£0m	£0m	Not applicable	To be determined	

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

Primary Authority (PA)⁴ currently operates across England and Wales in relation to food safety legislation that is enforced by local authorities. In England and Wales, a PA can provide services in relation to all the regulatory areas in scope that it has responsibility for:

- a PA in England or Wales can advise on reserved regulatory areas (including fire safety, health and safety, metrology, product safety)
- a PA in England can advise on 'England only' regulatory areas (including food, agriculture, animal health, environment, housing and public health)
- a PA in Wales can advise on devolved Welsh regulatory areas (including food, agriculture, animal health, environment, housing and public health).

Businesses trading in England and Wales that are regulated in relation to devolved matters and wish to benefit from PA in both nations will need to partner with a PA in England and a PA in Wales. It should be noted that only a local authority in Wales should be nominated in respect of relevant functions that relate to devolved Welsh matters. These primary authorities will be able to work closely together to provide an efficient service.

PA offers businesses the opportunity to form a legally recognised partnership with one local authority- the 'PA', which can then provide advice for other local authorities to consider when carrying out inspections or dealing with non-compliance. PA has a statutory basis, the scheme was introduced around 10 years ago, via the Regulatory Enforcement and Sanctions Act 2008. One of the statutory tools a PA may use is an Inspection Plan to guide local authority checks on business compliance, where the PA sees that this would be beneficial in improving the coordination and efficiency of such checks. Inspection Plans can set-out national priorities for inspection of the business in question, focusing activity on areas where it's most needed.

As part of an Inspection Plan, the PA 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 intervention is warranted, which would still enable proper regulation of the business and ensure public safety.

The PA 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

⁴ More information on Primary Authority is available at: <https://www.gov.uk/guidance/local-regulation-primary-authority>

Annex C

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 and with the agreement of the business, a **national inspection strategy** (NIS) could be put in place by the PA. This may reduce the number or intensity of proactive local authority interventions needed.

At present there are no NIS for food safety. The Food Standards Agency (FSA) has been working with relevant stakeholders to consider why this is the case. One of the contributory factors for the lack of uptake is that the Food Law Code of Practice (the Code) has not, to date, acknowledged them as an approach 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 and including information on NIS thus making them a possibility for food partnerships that meet the FSA's robust 'Standard' and oversight mechanisms.

The FSA's Standard for NIS is currently being developed, and is expected to be published during the summer of 2018. Information on the work underway to develop this Standard is provided in the 9th edition of the ROF newsletter, available at: <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 PA and the Code, recognising NIS in the Code. Primary Authority Partnerships (PAPs) have the option of considering whether NIS, 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 NIS remain unrecognised for food partnerships. Food partnerships may still choose to develop national inspection strategies, as they are a legitimate tool available to them under PA. However, there would remain poor alignment between the requirements of the Code and the provisions of the statutory PA scheme.

Option 2 (Preferred Option): Amend the Code to recognise NIS for food partnerships. Implementing changes to recognise the option for primary authorities to develop a national inspection strategy would provide partnerships with the ability to reduce the frequency and intensity of proactive interventions. This will assist in removing some regulatory burden at a local level, if where the PA is confident, and has good evidence, that establishments are compliant and are being well managed. Resources at a local authority level could be re-directed at establishments where there is less evidence of compliance and poor 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?	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 2

Description: Do Nothing: Make no changes to the Code so that NIS remain unrecognised in this document for food 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

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 (%)	-
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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 NIS for food hygiene and food standards (food 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

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 FSA welcomes responses to provide evidence on any monetised costs by affected groups as part of this consultation. It is not envisaged there will be cost to business as a result of this option as NIS are optional.

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

The provision for a PA to establish a NIS already exists under PA legislation.

PA operates on a cost recovery basis, and therefore cost incurred by a PA developing and implementing a national inspection strategy could be recovered from the PA 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 PAP can vary.

The FSA has been working with six 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) PAP to understand the time and costs involved in developing and implementing NIS.

We do not foresee local authorities (enforcing authorities) bearing any additional costs due to the implementation of national inspection strategies. Local authorities may be required to have some engagement with a PA who is operating a national inspection strategy, but 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, PA confidence etc).

It is not possible to estimate the likely take-up of NIS for food partnerships at present as exploratory work into this area is still underway. It is hoped that through this consultation, the FSA will gain some insight into partnerships who are interested in developing NIS and will obtain 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. It is likely there will be a need for dialogue between local authorities (enforcing authorities) and primary authorities operating NIS.

It is envisaged that local authorities would be able to re-allocate any saved time resource to less compliant businesses, which could 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 should be no new burdens placed on them if they do not set one up.

The intention of this Code change is to recognise NIS, thus making a more viable option for partnerships.

If the Code is not changed to recognise NIS, partnerships may still establish NIS despite the lack of alignment between the provisions of PA 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	

Impact Assessment: Primary Authority National Inspection Strategies

EVIDENCE BASE

CURRENT NUMBERS OF PRIMARY AUTHORITIES, INSPECTION PLANS AND NATIONAL INSPECTION STRATEGIES IN WALES AND ENGLAND.

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

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 PA 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 (August 2018)

Primary Authority recorded function		Number of partnerships (Wales and England)	Number of partnerships (Wales)	# of inspection plans	# of inspection plans with food business elements	# of national inspection strategies for food partnerships
Environmental Health		660	39	20 (None for Wales)	13	0
Trading standards		1103	37	15 (None for Wales)	9	0

There are currently no environmental health or trading standards partnerships that operate NIS for their partnerships.

The only sectors currently using NIS are for age restricted sales (gambling and alcohol). There are currently (as of June 2018) six PAPs for gambling and one National Inspection Strategy⁵.

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 PA, would provide alignment between PA and the Code. If a PAP judges that a national inspection strategy will deliver benefits in terms of more efficient and risk based 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.

⁵ <http://www.gamblingcommission.gov.uk/for-licensing-authorities/Licensing-authority-toolkit/Premises-assessments/Premises-assessments-toolkit.aspx>

Costs

The FSA is not imposing any regulatory burden on businesses so there are no associated costs with this proposal. However, to benefit from a national inspection strategy there will be some costs faced by businesses in the initial setup and ongoing maintenance. These will be administered by the PA and met on a cost recovery basis.

To set-up a national inspection strategy a business will first have to set-up a partnership with a PA (if they do not already have one). The 2011 Impact Assessment (IA) of extending the PA estimated the net benefit of setting up a partnership with a PA at around £17,000 (£18,700 2017 prices) per business⁶.

This IA is not concerned with the benefits of PA as it is already possible for businesses to set-up partnerships with them on food hygiene and standards and some have already done so. Therefore, it is not considered proportionate to update the 2011 analysis.

The FSA pathfinder project, working with 6 PAPs, and due to be published during the summer of 2018, is expected to provide better insight into the resource needed to develop and implement NIS for food partnerships. It is expected that any cost incurred by a PA will be cost recovered from the partner.

Benefits

The introduction of NIS is not intended to reduce local authority resource dedicated to food regulation, but could instead enable the reallocation of that resource from more compliant to less compliant businesses. The impact of the transfer of local authority inspection resource towards high-risk businesses may therefore improve public health outcomes.

DISTRIBUTIONAL IMPACTS

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

⁶ 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 (Wales) - 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: Daniel Morelli				

Summary: Intervention and Options

RPC Opinion: Not Applicable

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 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) for Wales are required to implement the Food Standard Agency's (FSA's) Regulating Our Future (ROF) principles into the establishment based approach to risk assessment of food businesses. These changes are aimed at ensuring 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 food law. Direction and guidance for local authorities (LAs) on the approach to take is provided in the Code for each country in the UK. LAs must have regard to the requirements set-out in the Code to ensure effective and consistent delivery of food law enforcement services.

What are the policy objectives and the intended effects?

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

- 1) Amend and clarify descriptors for Method of Processing, Consumers at Risk and Confidence in Management (CIM) that are used to rate businesses and assign frequency and nature of interventions.
- 2) Introduce new definitions for full compliance and sustained compliance.
- 3) Provide for targeting of high-risk and non-compliant businesses by reducing the frequency of intervention. in low risk and 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 food hygiene intervention rating scheme system would remain.

Option 2: Make amendments to the food hygiene intervention rating scheme used to determine the nature and frequency of interventions.

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

The preferred option is Option 3 as it would allow for delivery of 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 against which all other options are appraised.

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

None. This is the baseline against 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 against which all other options are appraised.

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

None. This is the baseline against which all other options are appraised.

Key assumptions/sensitivities/risks

Discount rate (%)

None. This is the baseline against which all other options are appraised.

BUSINESS ASSESSMENT

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) 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'

Under this option there would be a familiarisation cost to LAs in reading and understanding the changes, estimated at £6,240. There would also be a transfer of regulatory burden (the productivity loss to a business of being inspected by the LA from more compliant businesses to less compliant businesses). This will be because in some cases LAs will divert resources from businesses that demonstrate compliance to businesses that do not demonstrate acceptable levels of compliance. The scale of this transfer will depend on the exact policy implemented but the maximum has been estimated at £56,317.

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 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'

The transfer of regulatory burden covered under 'costs' (and estimated at a maximum of £56,317) will represent a benefit to those businesses that demonstrate sustained compliance. The value of this benefit will be transferred to less compliant businesses. LAs are expected to reallocate inspection/intervention resource to less compliant businesses so there should be no saving arising from these changes.

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

The reallocation of LA resources to less compliant businesses will deliver enhanced public health benefits. The additional resources 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, it has been assumed that the proposed change which incurs the highest costs will be progressed following consultation. It has also been assumed that training and monitoring of the Food Law Code of Practice (the Code) changes will be delivered through the existing FSA systems at no additional cost.

BUSINESS ASSESSMENT

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

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) (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 familiarisation cost to LAs in reading and understanding the changes would be the same as option 2, estimated at £6,240. As with option 2, there would be a transfer of regulatory burden from more compliant businesses to less compliant businesses. However, due to the safeguards (capping) to limit how much an intervention frequency being reduced, the maximum size of the estimated transfer is reduced to £48,749.

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 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’

The transfer of regulatory burden covered under ‘costs’ (and estimated at a maximum of £48,749) will represent a benefit to those businesses that show sustained compliance. The value of this benefit will be transferred to less compliant businesses. LAs are expected to reallocate inspection resource to less compliant business so there should be no savings arising from these changes.

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

The reallocation of LA resources to less compliant businesses will deliver enhanced public health benefits. The additional resources 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 proposed change which incurs the highest costs will be progressed following consultation. It has also been assumed that training and monitoring of the Food Law Code of Practice (the Code) changes will be delivered through existing FSA systems at no additional cost.		

BUSINESS ASSESSMENT

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)

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 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 determining the frequency of LA interventions at food establishments because the current system is considered to be outdated and will become 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 or the incredibly diverse nature of the industry.

Rationale for Intervention

3. It is intended to better recognise those businesses that demonstrate sustained compliance by ensuring that an intervention is proportionate to their level of compliance (compliance status) and the reduced risk to consumers that they pose, resulting in reducing the regulatory burden on them. For some businesses, the risk may be so low that they do not warrant intervention, for others, inspection could be more frequent than they have experienced to support their move to compliance.

Policy Objective

4. The FSA intends to revise the hygiene intervention rating scheme in two ways;
 - a. updating and clarifying the text used to describe the level of risk;
 - b. changing the scores in the intervention rating scheme for certain food businesses found to be compliant with food law. This will move them into a lower risk category, resulting in a reduce intervention frequency. The aim is to allow LAs to provide a greater focus on less compliant businesses, in particular those where persistent or serious non-compliances are identified, by reducing the frequency of interventions at those businesses with good food safety controls in place. In addition, LA resources can be directed towards dealing with new food businesses on a risk priority basis.
5. These changes will improve the regulatory process for the 34,655 food establishments registered with LAs in Wales 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 Wales and originates at European Union (EU) level.
6. Responsibility for verifying compliance with food law in these food establishments is delegated to the 22 LAs in Wales. In undertaking these responsibilities, LAs, as food authorities, must comply with the requirements of Regulation (EC) No 882/2004⁷ on Official Controls Performed to Ensure the Verification of Compliance with Feed and Food Law, Animal Health and Animal Welfare Rules. This Regulation sets out the general risk based approach and the principles

⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0882-20180701&qid=1535104547851&from=EN>

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 England and Northern Ireland) when discharging their duties. These Codes are being updated 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 two interventions and over a minimum period of 3 years;
 - to link the additional score for the Vulnerable Risk Groups to the assessment of Confidence in Management (CIM) at food businesses;
 - to remove the additional score for significant risk and include the significant risk element in the CIM assessment.
 - to consider, when assessing CIM, whether the food business operator (FBO) 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 engagement events that were held from December 2017 to January 2018 across Wales, England and Northern Ireland. In Wales, the FSA hosted three workshops, one in north Wales, one in mid-Wales and one in south Wales on 11 and 18 January and 1 February 2018. These were attended by approximately 50 LA representatives. The FSA also held meetings with the ROF Segmentation Working Group prior to this consultation being launched, which included LA representatives, and other stakeholder groups comprising industry representatives and professional bodies. In Wales, the FSA will ask the Working Group (WG), established at the request of the then Minister for Social Services and Public Health (Rebecca Evans), to consider the proposals at its next meeting as part of the consultation process. The WG is chaired by the Welsh Government and was set-up to provide an assurance to Welsh Ministers that Wales’ needs are taken account of within the FSA’s ROF programme of reform. The FSA received detailed responses, from the enforcement community following the engagement events.

Summary of responses:

Proposed Amendment: Full Compliance and Sustained Compliance

10. In Wales, England 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. Some LAs stated that they are already using flexibilities in the Code for broadly compliant category C and for category D rated establishments so they may not demonstrate sustained, full compliance to the LA for several years. Therefore, it is believed that the impact on interventions will be negligible.

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

Proposed Amendment: Vulnerable Risk Groups

11. There was objection from LAs in Wales on the proposal to remove the additional score of 22 for food businesses serving vulnerable groups. 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.

Proposed Amendment: Significant Risk

12. LAs in Wales requested data to determine how often the score is applied and the possible impact of removing the score from the scheme. This data has been included into the Code consultation document. The general agreement was that if removal of the score did not alter the overall risk category the change would be supported. 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.

Proposed Amendment: Consideration of the Registration Process

13. There were various views on whether LAs should take into account that a new business had not registered prior to trading when determining the (CIM) score. It was generally considered that this change alone would not make a significant difference to the number of FBOs that pro-actively register. However, it is a legal requirement and the FSA is aware that some LAs are already taking non-registration into account when rating a business that had not pro-actively registered. The FSA is not currently able to quantify the impact of this change. Therefore, to ensure a consistent and fair approach, further consideration is required and the FSA is taking this opportunity to consult on the principle of considering a business' failure to proactively register into the CIM score as one option for address this issue.

SECTORS AND GROUPS AFFECTED

Enforcement

Local Authorities

14. To identify the impact of the proposed amendments on LAs, the FSA has consulted the ROF Segmentation Working Group and other regional groups that attended the LA ROF engagement events. LAs will be affected primarily through:
 - Changes to their management information systems (MIS).
 - Officers will have to familiarise themselves with the amendments to the Code.
 - Officers may need to undertake some form of consistency training on the application of these changes.
 - The ability to re-allocate resource more efficiently by focusing resources on non-compliant businesses and new food establishments (see Table 1).
15. It is estimated that 163 authorised officers in Wales will require training to effectively implement the changes.

Food Standards Agency

16. There are changes in food law enforcement over time and it is necessary for authorised officers keep up-to-date. The FSA provides LA officers with opportunities to develop their knowledge through training tools, professional courses and funding for LA work. The FSA works with LAs to further develop their enforcement services and one area the FSA is particularly active is in providing ongoing programme of consistency training.

Food Business

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:

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, the establishment receives negative 5 adjustment to risk score and for each subsequent inspection with rating of FHRS 5)	434	2.5%	1,520	1.0	0.6%
Sustained compliance (if FHRS of 5 for at least the last two inspections, the establishment receives negative 10 adjustment to risk score and for each subsequent inspection with rating of FHRS 5)	906	5.2%	3,170	2.0	1.2%
Sustained compliance (if FHRS of 5 for at least the last two inspections, the establishment receives negative 20 adjustment to risk score and for each subsequent inspection with rating of FHRS 5)	1,420	8.2%	4,969	3.2	1.9%
Removal of vulnerable groups for FHRS 5	431	2.5%	1,507	1.0	0.6%
Risk of contamination removed	52	0.3%	182	0.12	0.07%
Sustained compliance (negative 5). Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	880	5.1%	3,081	2.0	1.2%
Sustained compliance (negative 10). Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	1,340	7.7%	4,690	3.0	1.8%
Sustained compliance (negative 20). Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	1,758	10.1%	6,152	3.9	2.4%

Table 1: Shows the proposed change, estimated in the inspections and Full Time Equivalents (FTEs). All calculations use 2016-17 LAEMs data¹⁰ (without safeguards).

⁸ Assuming an average inspection takes up 3.5 hrs of an officer's time

⁹ Based on the 2016/17 food hygiene allocated Full Time Equivalent (FTE) professional LA staff figure of 163

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, the establishment receives negative 5 adjustment to risk score and for each subsequent inspection with rating of FHRS 5)	425	2.4%	1,489	0.9	0.6%
Sustained compliance (if FHRS of 5 for at least the last two inspections, the establishment receives negative 10 adjustment to risk score and for each subsequent inspection with rating of FHRS 5)	883	5.1%	3,090	2.0	1.2%
Sustained compliance (if FHRS of 5 for at least the last two inspections, the establishment receives negative 20 adjustment to risk score and for each subsequent inspection with rating of FHRS 5)	1,329	7.7%	4,650	3.0	1.8%
Removal of vulnerable groups for FHRS 5	386	2.2%	1,350	0.9	0.5%
Risk of contamination removed	52	0.3%	182	0.12	0.07%
Sustained compliance (negative 5). Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	776	4.5%	2,717	1.7	1.1%
Sustained compliance (negative 10). Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	1,165	6.7%	4,079	2.6	1.6%
Sustained compliance (negative 20). Removal of vulnerable groups for FHRS 5 and Risk of contamination removed	1,522	8.8%	5,325	3.4	2.1%

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

Consumers

18. The amendments create an opportunity for a positive impact for public protection. Consumers will be assured that officers are able to use their resources more effectively to target non-compliant businesses.

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>

19. The focus on effective, risk-based, and proportionate regulation and enforcement provides more frequent inspections/interventions at establishment where persistent or serious non-compliances are identified, and less frequent inspections should be applied to fully compliant businesses. Business compliance with food law will ensure safer food and consumer protection.

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 a 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.

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)	434	£13,916
Sustained compliance -10 based on FHRS of 5 for at least the last two inspections)	906	£29,022
Sustained compliance -20 based on FHRS of 5 for at least the last two inspections)	1,420	£45,490
Removal of vulnerable groups below 10 CIM	431	£13,793
Risk of contamination removed	52	£1,666
Sustained compliance -5 and removal of vulnerable groups below 10 CIM and risk of contamination removed	880	£28,208
Sustained compliance -10 and removal of vulnerable groups below 10 CIM and risk of contamination removed	1,340	£42,937
Sustained compliance -20 and removal of vulnerable groups below 10 CIM and risk of contamination removed	1,758	£56,317

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

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. Local Authority Enforcement Monitoring System (LAEMS) data shows that as at 31 March 2017, there were 163 FTE occupied posts engaged in food hygiene enforcement in Wales¹¹.
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 CIM 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 £6,240¹².

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 FSA's existing resources. 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 policy Option 2 equates to £6,420 for LAs. There is also a transfer of cost of up to £56,317 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. Therefore, it is expected that the public health benefit per inspection will increase as a result of this change. Business compliance with food law will ensure safer food and consumer protection.

¹¹ <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>

¹² 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 163 FTEs x 2 hours to familiarise = £6,420 total cost to LAs.

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. Therefore, there will 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 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 unrated food establishments, on a risk priority basis improving 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 difficult, the FSA 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 at businesses that present a lower risk.

Total Benefits

33. There are no monetisable 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.

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

34. 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.
35. 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 inspection¹³. The size of the transfer for each estimated scenario is presented in Table 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)	425	£13,629
Sustained compliance -10 based on FHRS of 5 for at least the last two inspections)	883	£28,286
Sustained compliance -20 based on FHRS of 5 for at least the last two inspections)	1,329	£42,567
Removal of vulnerable groups below 10 CIM	386	£12,356
Risk of contamination removed	52	£1,666
Sustained compliance -5 and removal of vulnerable groups below 10 CIM and risk of contamination removed	776	£24,873
Sustained compliance -10 and removal of vulnerable groups below 10 CIM and risk of contamination removed	1,165	£37,377
Sustained compliance -20 and removal of vulnerable groups below 10 CIM and risk of contamination removed	1,522	£48,748

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

Costs to Local Authorities

One - off Familiarisation Costs

36. As option 2.

Training Costs

37. As option 2.

Costs to FSA

Monitoring costs

38. As option 2.

Total Costs

39. The total cost associated with preferred policy Option 3 equates to £6,240 falling only to LAs. There is also a transfer of cost of up to £48,749 from more compliant to less compliant businesses.

Benefits to consumers

40. As option 2.

Benefits to industry

Monetised Benefits to industry

41. As option 2.

¹³ 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/occupation4digit/soc2010ashtable14>

Benefits to Local Authorities

Monetised Benefits to Local Authorities

42. As option 2.

Non-monetised Benefits

43. As option 2.

Total Benefits

44. There are no monetisable 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.

OTHER CONSIDERATIONS

Wider Impacts

45. The industry sector most affected by this amendment in Wales are restaurants and caterers. These are in the main micro or small/medium enterprises (SMEs). This proposal will result in a proportionally greater benefit for compliant micro or SMEs compared to the wider food industry.

Competition Assessment

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

Small & Micro Business Assessment

47. The United Kingdom (UK) food industry sector is comprised of mainly small and micro businesses (generally greater than 90%) and therefore the greatest impact from new changes will, in most 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.

48. European Union (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 food businesses in the UK, it is often not feasible to exempt smaller businesses from new food measures, as this would fail to achieve the intended effect of reducing risks to public 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:

49. This policy has been screened for impact on equalities with specific consideration of all legally protected groups. The policy will introduce changes to operational procedures for LA food law enforcement officers only. The primary impact of the policy is intended to introduce an initial benefit to LA resource enabling them to target their resources to higher risk food businesses to better protect consumers. Compliant businesses could also benefit from a reduced frequency of inspection. The policy is not believed to present any risks or barriers to equality. It has been decided that a full equality impact assessment is not required.

Human rights impact:

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

Annex E

Changes applied into CoP (Wales)	
Chapter 1 - Introduction	Reference to National Regulator Guidance included.
2.1.2	Reference to parts 1 and 2 of the Regulatory Enforcement and Sanctions Act 2008, and the Office for Product Safety and Standards included. Reference to the FSA recognised national inspection strategies (NIS) included.
2.1.3	Re-wording of the fifth paragraph. Deletion of first sentence of the sixth paragraph relating to Home Authority Principle.
3.2.7.2	Re-wording of the type of appropriate interventions and the need to inform the registering food authority of findings and enforcement actions taken.
3.2.7.4	Title amended.
3.2.9.3	Full re-wording of information on 'channels of registration' and 'action to take on receipt of registration'. Proposal to include weblink to online registration system.
3.2.9.4, 3.2.9.6 & 3.2.9.7	Full re-wording of information on 'Action on Receipt of Completed Registration', paragraph added on 'Data Storage Transfer' and full re-wording of information on 'Acknowledgement of Registration', including approach to handling and retaining paper registration.
3.2.10	Additional explanation of the types of business changes that require notification to the relevant FA. Deletion of second paragraph on actions to taken on receipt of a notification of changes.
3.2.11	Additional paragraph on notifications about changes to FBO or cease trading.
3.3.3	Weblink to Approval of Establishments Guidance updated.
3.3.8	Weblink to Approval of Establishments Guidance updated.

5.1.1	Additional paragraphs on the requirement for Food Authorities to review their Written Service Plans, to accommodate the work of FSA national inspection strategies (NIS) and how the FSA will communicate the relevant work.
5.2	Last paragraph re-worded to include references to inspection plans to direct official controls and NIS.
5.2.3.1	Auto numbering of footnotes from 23 onwards to correct numerical error.
5.2.7.1	Sentence included on how frequency of interventions at food businesses that are part of a national inspection strategy, and how PA and FSA will communicate with the Food Authority.
5.2.14	Full re-wording of the first paragraph on 'Enforcement at Points of Entry and Inland' and deletion of subsequent two paragraphs.
5.2.17.4.1.1 to 5.2.17.4.1.7	These bullet points are detailed explanations directly related to point 5.2.17.4.1. These were previously bullet points 5.2.17.4.2 to 5.2.17.4.8 but have been replaced as subheadings of 5.2.17.4.1.
5.2.17.4. (formerly 5.2.17.4.9)	Changes in former points 5.2.17.4.2 to 5.2.17.4.8 have altered this numeration.
5.2.17.4.2.1 to 5.2.17.4.2.5 5.2.17.4.10 to 5.2.17.4.14	These bullet points are detailed explanations directly related to former point 5.2.17.4.2 (formerly 5.2.17.4.9). These are now sub-entries for 5.2.17.4.2, in previous versions showing as sections 5.2.17.4.10 to .5.2.17.4.14.
Annex 1	New descriptions added: <ul style="list-style-type: none"> ○ Full Compliance. ○ National Inspection Strategy ○ National Regulator Guidance ○ Office for Product Safety and Standards (OPS&S) ○ Sustained Compliance
A5.1, Part 1, B	Establishments that intentionally do not implement a process included in the description. Lack of a process included in the description for score 20.
A5.1, Part 1,	Second paragraph added specifying when the additional score of 22 must not be applied.

C, PLUS	
A5.1, Part 3	Point restructured, with a sub-division in sections A, B and C. Section on 'significant risk' score deleted.
A5.1, Part 3, A	This point was previously A5.1 Part 3 only. Sixth paragraph (need for officers to reflect the level of reassurance provided by checks undertaken on the food safety management directly at an individual establishment via an independent 3 rd party) removed. Seventh paragraph includes comment that bullet points on factors that will influence the inspector's judgement are not the sole ones to be considered. Bullet point added for new businesses. Removal of comment for the requirement for businesses to retain records flexibly to avoid burdens to small businesses. Line for "and may have external audit processes in place" removed from score 0 when referring to effective self-checks.
A5.1, Part 3, B	Point added (Recognising Compliance). The point covers the need for officers to consider previous assessments and what Full Compliance and Sustained Compliance mean.
A5.1, Part 3, C	Point added (Recognising Sustained Compliance). The point covers additional scoring systems for businesses with positive records for 2 or more inspections in the last 3 years. Illustrative table added on how the scoring would work.