

REGULATING OUR FUTURE – ASSURANCE FRAMEWORK FOR PRIMARY AUTHORITY NATIONAL INSPECTION STRATEGIES AND NEXT STEPS ON REGULATED PRIVATE ASSURANCE

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SUMMARY

1. This paper provides an update on progress made to explore Primary Authority national inspection strategies (NIS) and to develop FSA NIS Standards as part of the Regulating Our Future (ROF) Programme and describes the impact for the FSA of introducing new assurance frameworks into the delivery model and the opportunity this presents to align activities. It also provides an update on the next steps to be undertaken within the programme in respect of regulated private assurance.
2. The Board is asked to:
 - **consider and agree** the proposal to set a NIS standard for primary authorities: the NIS Primary Authorities' Standard;
 - **consider and agree** the outline process and governance for recognising a NIS: the NIS Recognition Standard;
 - **consider and agree** the outline framework for providing assurance on operation of individual NIS: the NIS Assurance Standard;
 - **consider and comment** on the impact of introducing a new assurance framework for the FSA structure; ABD
 - **consider and comment** on the next steps for developing regulated private assurance

INTRODUCTION

3. Primary Authority¹ currently operates across England and Wales in relation to food safety legislation that is enforced by local authorities (LAs). It is administered by the Department of Business, Energy and Industrial Strategy (BEIS) on behalf of the Secretary of State.
4. Primary Authority has a statutory basis, the scheme being introduced around 10 years ago, via the Regulatory Enforcement and Sanctions Act 2008. It offers

¹ More information on Primary Authority is available at: <https://www.gov.uk/guidance/local-regulation-primary-authority>

businesses the opportunity to form a legally recognised partnership with one LA - the primary authority - which can then provide advice for other LAs to consider when carrying out inspections or dealing with non-compliance.

5. A primary authority can develop an inspection plan, underpinned by an evidence based rationale, to set out national priorities for inspection of the business in question, focusing routine official control activity by LAs to where it is most needed.
6. As part of an inspection plan, the primary authority could take the view that it has sufficient evidence that the business has robust compliance measures in place, is managing food safety, and therefore the business should be subject to a more focused style of regulatory interventions.
7. An inspection plan can go a stage further and the primary authority could propose a NIS that controls the number and frequency of proactive LA interventions. The primary authority then submits this proposal to BEIS for consent by the Secretary of State. The FSA is consulted as part of this consent process.
8. At present there are no NIS for food safety and, through ROF, we have been working with stakeholders to consider why this is the case. In early 2017 we brought together eight primary authority partnerships to explore how NIS might work in practice².
9. One of the contributory factors for the lack of uptake in NIS is that the Food Law Code of Practice (the Code) has not, to date, formally acknowledged them as a means by which multi-site businesses (or groups of businesses) could be regulated.
10. The current consultation on proposed changes to the Food Law Code of Practice in England³ introduced specific reference to NIS thus making them a possibility for food safety partnerships that meet the FSA's robust standards. The consultation includes provision to enable the frequency of checks at individual outlets to be set as part of a FSA recognised NIS and to formalise the requirement for LAs to follow FSA recognised NIS. We plan to replicate this in Wales.
11. The Regulatory Enforcement and Sanctions Act 2008 and guidance recognises differing degrees of devolution across the nations of the UK. Therefore,

² <https://www.food.gov.uk/about-us/sixth-edition-of-regulating-our-future-newsletter#primary-authority-national-inspection-strategy-feasibility-study>

³ <https://www.food.gov.uk/news-alerts/consultations/regulating-our-future-amendments-to-the-food-law-code-of-practice-england>

regulatory functions, including food safety, that have been devolved to the government in Northern Ireland are outside the scope of Primary Authority. However, District Councils in Northern Ireland have committed to giving effect to the general principles of Primary Authority in relation to regulatory functions that are not within scope of the scheme in Northern Ireland and we're exploring how the principles of the NIS approach could be used in Northern Ireland.

12. Our work with stakeholders has led us to the position that NISs are suited to multi-site businesses (or groups of businesses) demonstrating high levels of compliance. Assurance that the business is meeting its responsibilities will be assessed centrally by its primary authority (working to the FSA Standard), feedback from LAs will be used to check that the NIS is working and the FSA will have oversight (through FSA Standards) that the approach is reliable and robust. This means responsible businesses could face a lower burden from regulation, and LA resource can be better targeted to the businesses that present the greatest (residual) risk to public health and helping new businesses get it right from the start.
13. We worked with six primary authority partnerships on a project to test the concept of NIS; to explore PAs accessing and using business compliance data, and to find out what needs to be done to make food related NIS a success. This work has led us towards establishing a framework, including three FSA Standards, for NIS to operate in the 'Assurance' part of the Target Operating Model.
14. The project involved primary authorities accessing business information about outlets that had been inspected by an LA officer. Without viewing the most recent LA inspection report/ outcome, the primary authorities used business information to complete a compliance assessment in which they would predict a Food Hygiene Rating Scheme (FHRS) rating for the outlet and determine whether they felt it needed to be inspected or not. The project has been independently evaluated and will be published on food.gov
15. In the majority of cases (80%), primary authorities' predicted ratings matched with the actual food hygiene rating given following the LA inspection, indicating that using business data to predict local level compliance provides reasonable levels of accuracy. In 15% of cases, primary authorities' predicted food hygiene ratings were lower than the LA inspection ratings, leaving 5% where the PA rating was higher.
16. An investigation into 30 variations between predicted and actual food hygiene ratings (by comparing compliance assessment information with corresponding

LA inspection reports/records) was undertaken to identify potential reasons for the variations. Reasons for variations included:

- The two approaches to monitoring compliance (physical inspection vs. compliance assessment) capture two different moments in time. This was by far the most common cause of variation between predicted and actual ratings as the rating is a snapshot of standards at a point in time.
 - Variation also occurred in cases where primary authorities had been provided with information showing there had been a compliance issue at the outlet being assessed but had not been given any accompanying evidence showing that these issues had been addressed by the business.
 - In a few cases, LA inspection records or reports and business data revealed similar issues, however, the LA officer and primary authority officer completing the compliance assessment had different views about the risk that these issues posed to food safety.
17. The evaluation found that although most businesses, primary authorities and LAs interviewed considered NIS to be broadly feasible, they often raised concerns and added caveats to this view. These usually involved some stipulations about the type of businesses that should be involved and the need for sufficient oversight. These concerns will be addressed through the FSA's NIS Standards.

FSA SETTING THE STANDARDS

18. In June last year we published our paper on 'Why food regulation needs to change and how we are going to do it'⁴. It outlines the key changes that will be made to the regulatory regime including the way that the FSA will set standards to allow businesses to prove the ways in which they comply with the rules and regulations that protect the public.
19. As outlined above we have been working on three FSA NIS Standards; once available we will be publishing them, as drafts, on food.gov and we will be issuing national regulator guidance on them. These draft standards have been developed in conjunction with those taking part in the project (primary authorities and businesses) and colleagues at BEIS. We have sought contribution, views and comments including via the ROF Expert Advisory Groups and Consumer Panel, ROF newsletter⁵, food.gov, LAs and professional groups.

⁴ https://www.food.gov.uk/sites/default/files/media/document/rof-paper-july2017_0.pdf

⁵ <https://www.food.gov.uk/about-us/ninth-regulating-our-future-newsletter>

20. NIS, operating in accordance with the FSA NIS Standards will be one form of Regulated Private Assurance (RPA) within the assurance hierarchy triangle. The standards form a framework to ensure NIS are robust and operate with the right level of oversight.



THE STANDARDS

NIS Primary Authorities' Standard

21. Primary authority partnerships will have to meet this before we will recognise their NIS. It will include requirements for the primary authority to provide evidence of their capacity, resilience and competence; that they have reviewed and verified the business' management controls and systems in relation to food safety; that they have arrangements in place to access and review the business' systems that demonstrate compliance with food law and, that the business has suitable processes to identify and rectify non-compliances in a timely way.

NIS Recognition Standard

22. This standard will apply to the FSA. It will outline how we will assess NIS proposals and the governance we will put in place to provide for a consistent and transparent approach.
23. If a primary authority wishes to establish a NIS, we will encourage them to discuss their proposals with us at an early stage, before formal submission of the proposal to BEIS who would then consult FSA for their view.
24. NIS proposals will be evaluated and assessed against the NIS Primary Authorities' Standard and technical guidance relevant to the NIS by an FSA team. The team will make recommendation for decision by Head of Division as to whether FSA should recognise the NIS.
25. The FSA will advise the primary authority and BEIS of the outcome of the decision, providing our reasons in cases where the NIS has not been recognised.

26. When the FSA recognises a NIS, we will instruct local authorities to follow it and put in place arrangements to monitor this.

NIS Assurance Standard

27. When a NIS is operating there will be a need for FSA assurance that it is working as intended, public health is protected and to instil confidence and trust in consumers, regulators and business.
28. Our proposal, developed in conjunction with stakeholders, is for a transparent risk-based system operated by the FSA and incorporating the following:
- quarterly / annual performance reporting (by the primary authority to the FSA), monitoring and analysis;
 - periodic, transparent focused audits of all primary authorities operating NIS (risk-based frequency);
 - follow-up with the primary authority, including consideration of root cause analysis and risk assessment when things go wrong at the business;
 - a clear, proportionate and transparent intervention policy to be applied consistently and robustly where there is evidence that the NIS Primary Authorities' Standard is not being met; and
 - ultimately, where necessary, the suspension or removal of FSA recognition for the NIS and the return of individual outlets to controls at the frequency laid down in the Code.

Testing

29. A small number of primary authority partnerships in England are actively considering developing NIS where the primary authority will use business data and information to inform the frequency of local food hygiene inspections. This will give us an opportunity, dependent on the partnership's timescales (but likely from late 2018 and during 2019) to refine the FSA Standards in light of the evaluation of the aforementioned project and to test how they work in practice – for the primary authority partnership, for local authorities and for the FSA in 'assuring the assurers' - followed by further refinement of the NIS Standards where necessary.

30. We recognise that decreasing the frequency of food hygiene controls at individual outlets has consequences for FHRs and this is something that the evaluation of the project also identified. In conjunction with LAs, businesses and consumers, we are exploring how NIS may inform FHRs and the need for revised arrangements for FHRs safeguard mechanisms as the current ones will not be fully appropriate for businesses within NIS. In tandem we will also be considering the need for safeguards (appeals and right to reply to FSA decisions) plus mechanisms for stakeholders to raise concerns and escalation of concerns about the operation of NIS.

Resources

31. The FSA will need the capability and capacity (suitably competent staff) to assess and recognise NIS proposals and to provide assurance that established NIS are operating in accordance with the NIS Primary Authorities' Standard. Demand and resource to operate the assessment, recognition and assurance of NIS is difficult to estimate as there are currently no NIS operating.
32. Given we are about to move to phased go live to test and further develop the detail, the FSA will meet the cost of its own resource in recognising and assuring NIS. As NIS become established we will more clearly understand the resource requirements; resourcing could then be re-visited in the wider context of sustainable funding.

IMPACT FOR FSA STRUCTURE

33. The changes that we are making to the regulatory regime, particularly with regard to those in the first tier of regulatory assurance delivery, where we are introducing different forms of RPA such as NIS, will have an impact on the structure and resourcing of the FSA. The current design of the second tier for FSA oversight of delivery is based on a first tier that is predominantly focused on official controls delivered by the FSA and LAs and it is not well equipped to support the formalised and increased intake of RPA into the model.
34. In addition, there are different arrangements in place across the organisation for setting standards and providing oversight where assurance activities are undertaken by the FSA and local authorities. There is therefore an opportunity for the FSA to exploit the potential synergy between the various FSA official control delivery oversight roles that currently exist and to improve the overall arrangements for governance of delivery.
35. In our role as Central Competent Authority and an excellent, accountable, modern regulator, it will be critical that we have effective arrangements in place

for operation and oversight of assurance in the first tier to enable us to set robust FSA Standards for Regulated Private Assurance and official controls, verify that these are being adhered to, intervene where they are not, and demonstrate this to others. It will therefore be necessary to review the design of the FSA and put in place an appropriate structure to enable all the activities associated with the second tier of oversight, including those detailed in paragraph 27 above, to be delivered in a consistent and effective manner. An exercise has been undertaken to establish the capabilities that we will require to deliver these functions competently and work to review the organisational design is underway.

NEXT STEPS FOR REGULATED PRIVATE ASSURANCE

36. We are also exploring other forms of regulated private assurance and how they may be used to inform the nature, frequency and intensity of official controls. This includes work to deliver against ROF and the Cutting Plant and Cold Store Review objectives. We are exploring how information on business' compliance with the BRC Global Standard for Food could be used to inform official control activity. To inform our thinking we will be commencing a feasibility study in September focusing on cutting plants subject to official controls by the FSA that are certified against BRC Global Standard for Food.
37. We are also working with other European central competent authorities and the GFSI (Global Food Safety Initiative) ⁶. GFSI benchmarks assurance scheme standards to determine equivalence between private assurance schemes, whilst leaving flexibility and choice in the marketplace. Our work with GFSI includes a comparative analysis of the GFSI benchmark requirements and EU food safety legislation. This will add to our thinking on what information from businesses might be of most use to inform that nature of official controls.

CONCLUSIONS

38. The Board is asked to:
 - consider and agree the proposal to set a NIS standard for primary authorities: the NIS PA Standard;
 - consider and agree the outline process and governance for recognising a NIS: the NIS Recognition Standard;
 - consider and agree the outline framework for providing assurance on operation of individual NIS: the NIS Assurance Standard;

⁶ GFSI is an industry driven global collaboration with the vision of 'safe food for consumers, everywhere'.
<https://www.mygfsi.com/>

- consider and comment on the impact of introducing a new assurance framework for the FSA structure; and
- consider and comment on the next steps for developing regulated private assurance.