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1.0 FOR COMMENT

- 1.1 This document sets out the broad thinking so far around the assurance (oversight) framework that will be necessary to underpin the final Primary Authority National Inspection Strategy (PA NIS) system (for food) once this has been determined and put in place as part of the Regulating our Future (ROF) model. The scope of this paper is limited to the second tier of assurance, indicated in figure 1.

Figure 1: PA NIS Assurance Pyramid



- 1.2 We are taking an open policy making approach. Consequently, this paper has been drafted in close liaison with a number of primary authorities, informed by LA engagement events run by the FSA in Summer 2017 and therefore is not an exclusive top-down proposition. It is now at the stage where it is appropriate to seek the views of wider stakeholders.
- 1.3 This paper recognises that primary authorities carry out a valuable role in supporting businesses to achieve compliance and that they are well-placed to contribute to the broad

umbrella of PA NIS assurance. It also recognises the responsibility the FSA has, as central competent authority, to play its part in providing 2nd tier independent assurance.

- 1.4 This work is being carried out in parallel with the FSA PA NIS pathfinder study.
- 1.5 **Please read the paper; we would then very much appreciate your views on the following:**
 1. **The proposed mechanism for the Receipt and Assessment of PA NIS Proposals and any additional or alternative support structures or mechanisms you believe are appropriate.**
 2. **What specific competencies, if any, you think FSA officials should have to assess NIS proposals from PAs.**
 3. **The proposal that option 2 (appendix 1) is the most appropriate and broadly cost-effective assurance model for further development**
 - a. **If not, why not and what would you propose instead? Why is your proposal more appropriate and cost-effective?**
 - b. **If so, is there anything additional or limiting that you feel is essential and why?**
 - c. **Please comment on the provisional performance indicators. Please suggest any additional or alternative indicators you feel would constitute reliable, valid and effective indicators of PA performance in implementing a NIS.**
 4. **The principle that “all PAs operating NIS must be able to provide sufficient assurance, based on valid and verifiable evidence, that all regulatory compliance data they use is reliable, representative, complete (where necessary) and available to the PA in a timely manner, regardless of its source.”**
 5. **How the FSA might best evaluate PA compliance with the principle in 4 above.**
 6. **The principle that a PA which fails to meet the requirements of the FSA PA NIS Standard (what will become part of the National Regulator Guidance) may be asked to take action to address the situation or, where appropriate, revert to the intervention frequency requirements detailed in the food and feed law codes of practice.**
 7. **Please outline your thoughts on the likely cost impact on PAs of the assurance model, justifying your response with FTE figures where necessary. NOTE: your estimation should only reflect costs OVER AND ABOVE those that would be incurred under the existing PA NIS system.**
 8. **We are considering the need for a ‘whistleblowing’ mechanism by which food businesses, LAs or PAs can report any concerns to the FSA in confidence. We would welcome your thoughts on this and any suggestions for a preferred mechanism.**
 9. **At the beginning of your response, please identify whether you are a PA, LA or other.**

- 1.6 PLEASE NOTE: The choice of assurance options is not necessarily limited to the three options set down in this paper. We are interested in any alternative or additional assurance mechanisms you may feel are more appropriate.**

2.0 INTRODUCTION

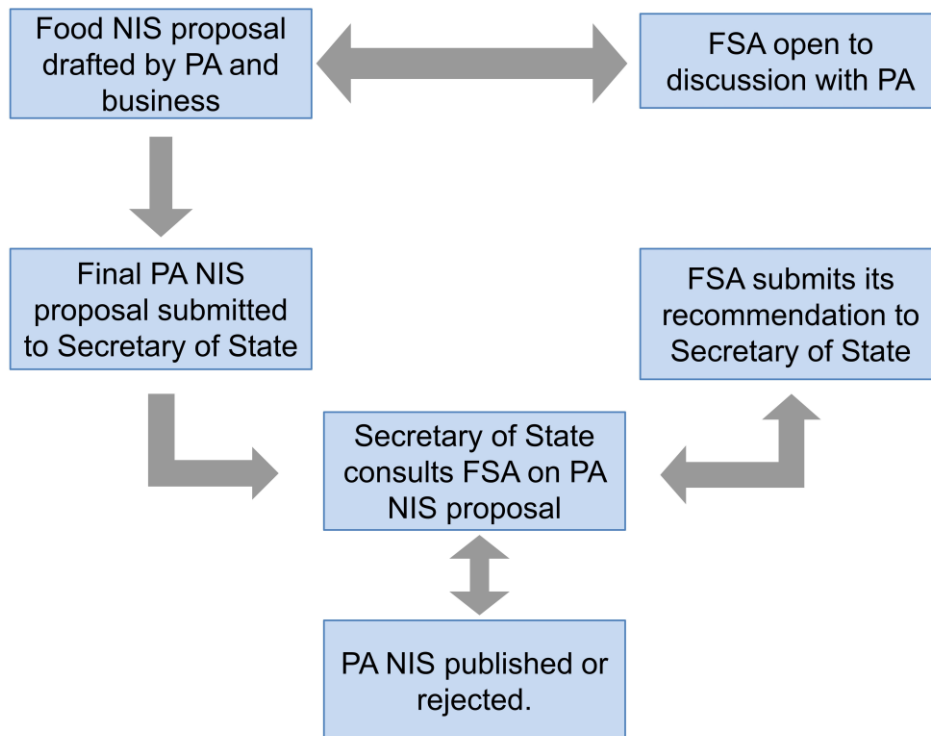
- 2.1 ROF is exploring whether and how NIS for food could contribute to the delivery model for food regulation [<https://www.food.gov.uk/sites/default/files/nis-feasibility-study.pdf>, <https://www.gov.uk/government/publications/primary-authority-overview>].
- 2.2 To compliment this we are developing mechanisms for the receipt and evaluation of PA NIS proposals from BEIS and draft proposals directly from PAs.
- 2.3 A PA is responsible for managing and monitoring adherence to the terms of an individual NIS by the business or group of businesses and we are developing assurance mechanisms to independently monitor and evaluate the reliability and validity of PA NIS and to maintain the confidence of the public and food businesses in PA NIS.

3.0 DISCUSSION

Process for the Receipt and Assessment of PA NIS Proposals – Current Thinking

- 3.1 If a PA wishes to propose an NIS, the FSA would encourage PAs to discuss their proposals with us at an early stage. Based on early PA stakeholder feedback, this is a suggestion which is supported.
- 3.2 Where the FSA in its role as a relevant national regulator is formally consulted on a proposed NIS by the Secretary of State and we reach the view that NIS complies with the FSA PA NIS Standard (national regulator guidance, once published) and PA Statutory Guidance, then a recommendation to approve the NIS is made to BEIS.
- 3.3 Similarly, it is proposed that where a formally submitted NIS proposal does not meet the FSA PA NIS Standard, the FSA will make a recommendation to BEIS to reject the NIS proposal in its current form. The FSA will give feedback to the PA and will be open to discussion to explore the viability of an amended NIS proposal from the PA.
- 3.4 A summary of the procedure 3.1 to 3.3 might be as illustrated in figure 2 below.

Figure 2. Representation of Relative Roles



- 3.5 We may put in place a new PA NIS proposal assessment form to be used by FSA staff, based on the FSA PA NIS Standard and the PA Statutory Guidance. A new form with specific prompts based on the FSA PA NIS Standard and PA Statutory Guidance could improve the efficiency of the NIS proposal process for PAs and support a consistent approach to the evaluation of such proposals. This work would be set in the future once the FSA PA NIS Standard is finalised and subject to further consultation with BEIS. We welcome your views on this proposal.
- 3.6 BEIS have indicated that they are amenable to an extension to the current 10 day period within which an NIS proposal must be determined, on a case-by-case basis.
- 3.7 Our thinking on the receipt and assessment of PA NIS proposals is intended to reflect an efficient, supportive and consistent approach in our role as a PA national regulator, and within the bounds of our role as central competent authority (CCA) for food and feed safety and standards. However, suggestions to improve this model or for alternative NIS proposal assessment models are welcome.
- 3.8 The competencies of FSA staff evaluating NIS proposals would include familiarity with primary authority legislation, guidance and operation and food hygiene and standards policy and delivery (as they do now). Early work on the draft PA NIS criteria and stakeholder views have suggested additional competencies that may be necessary and which we will consider. Further views on the nature of any additional competencies you feel would be necessary are welcome.

Process for the Ongoing Assurance of PA NIS – Current Thinking

- 3.9 PAs taking part in the FSA PA NIS pathfinder project stakeholders have indicated their clear support for a robust system of assurance operated by the FSA to underpin the credibility and integrity of NIS. However, they have also indicated that such a system should have a minimal impact on PA resource, if the option to operate an NIS is to remain attractive to PAs and food businesses.
- 3.10 During the LA engagement events run by the FSA in Summer 2017, delegates indicated their support for quality assurance and interventions to ensure NIS are robust and operating as intended. They also indicated that they would like to see some or all of the following of assurance & performance management mechanisms in a PA NIS assurance system:
- Panel review/peer review of PA performance (panel review was not defined)
 - Formal FSA audits including competency checks
 - Sufficient FSA competency to assess and audit PAs
- 3.11 Many of these mechanisms align with EC assurance requirements and good practice (i.e. systematic, evidence-based, independent assurance) and existing assurance mechanisms used within the FSA.
- 3.12 Following feedback from PA stakeholders and the LA events we have generated three options for the proposed PA NIS ongoing assurance process:
- Option 1 is a system of audit, an independent intervention mechanism and reporting structures;
 - Option 2 is a combination of performance monitoring and management/support supported by an independent audit function, intervention mechanism and reporting structures.
 - Option 3 is an option to put in place no assurance system.
- 3.13 Option 1 offers a ‘slimmed down’ assurance model, which incorporates no ongoing performance monitoring and support, simply periodic audit and escalation where necessary. As such it is a weaker assurance option than option 2. It does however offer the benefit of having minimal impact on PA resource.
- 3.14 Option 2 provides a more informative and proactive assurance model as it includes elements of ongoing performance monitoring and management/support as well as periodic audit and escalation where necessary. You may recognise it as a broad parallel with the existing FSA LA assurance regime.
- 3.15 All three options are detailed in appendix 1, together with some ideas for PA performance monitoring criteria. Please read and consider these.
- 3.16 **PLEASE NOTE: The choice of assurance options is not necessarily limited to the three options set down here. We are particularly keen to consider any alternative assurance models you may feel are more appropriate.**
- 3.17 Assurance options 1 and 2 would be subject to the same minimum audit criteria:

- PA Statutory Guidance
- FSA PA NIS Standard
- Relevant EU and UK statutory instruments
- Food Law Code of Practice and other relevant centrally issued guidance

3.18 Whichever option is chosen, the FSA will develop an intervention/escalation procedure to be implemented when a PA does not meet the requirements of the FSA PA NIS Standard. An appropriate procedure will be risk-based, proportionate and graduated in its approach and include realistic timescales for PAs to restore standards where non-conformities are found. Such a procedure would include a direction for LAs to revert to the intervention frequencies detailed in the food and feed law codes of practice, for the business (either individual units or as a whole) in question. However, it is anticipated that such action would not be the first resort in the absence of an imminent risk to health.

4.0 WHISTLEBLOWING

4.1 Initial stakeholder comments have been supportive of the FSA providing a 'whistleblowing' facility to allow food businesses, LAs and PAs to confidentially report any concerns regarding a food or feed PA NIS to the FSA in confidence. The FSA already operates a Whistleblowing scheme, which could be expanded in scope to include PA NIS concerns. We welcome any additional comments.

Assurance Option 1

ASSURANCE MECHANISM	DESCRIPTION	FREQUENCY	RELATIVE BENEFIT	RELATIVE DIS-BENEFIT
On-site audits of PAs	The FSA carries periodic audits of all PAs operating NIS	Welcome comments on appropriate frequency but will be risk-based. At present, audit every 3-5 years proposed for planning purposes.	A robust assurance measure - provides in-depth qualitative and quantitative information on PA NIS performance against scheme requirements (audit criteria).	Additional resource impact on PA during and around audit.
FSA Interventions	Risk-based, proportionate and graduated escalation interventions in the event of audit recommendations not being adequately implemented.	As required – impossible to quantify. May range from a single telephone call to the PA to an on-site half-day visit of a day or two. Escalations are rare under the current FSA LA audit regime.	Essential to complete the continuous improvement process and ensure regulatory compliance.	Additional resource impact on PAs.

<p>FSA internal & external reporting</p>	<p>High-level reporting of PA NIS performance against FSA national regulator guidance, based entirely on audit data.</p>	<p>Internal: part of ongoing quarterly assurance reporting protocol.</p> <p>External: one public summary report at the end of each three-year audit programme.</p>	<p>Essential to provide independent scrutiny and public transparency.</p> <p>NOTE: this would not be a report on PA performance against BEIS guidance.</p>	<p>N/a – required.</p>
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Assurance Option 2

ASSURANCE MECHANISM	DESCRIPTION	FREQUENCY	RELATIVE BENEFIT	RELATIVE DIS-BENEFIT
performance monitoring	Establish and operate a system of limited Primary Authority NIS performance returns to the FSA (manual spreadsheet returns initially)*	Quarterly (aligns with FSA internal reporting frequency)	Enables early identification of potential risks to NIS integrity, impact on PA resources, negative trends. Facilitates proactive response by the FSA to support PA / investigate further.	Additional resource impact on PAs in reporting, but anticipated to be minimal*
Performance analysis	FSA staff carry out quarterly analysis and where necessary flag issues for follow up by intervention.	Quarterly	Enables early and targeted FSA support / intervention should potential risks to NIS integrity be identified.	Additional resource impact on PAs (responding to any FSA performance queries raised following analysis)
On-site audits of PAs	The FSA carries periodic audits of all PAs operating NIS	Welcome comments on appropriate frequency but will be risk-	A robust assurance measure - provides in-depth qualitative and	Additional resource impact on PA during and around audit.

		based. At present, audit every 3-5 years proposed for planning purposes.	quantitative information on PA NiS performance against scheme requirements (audit criteria).	
FSA Interventions	Interventions would be risk-based – that is, proportionate to the degree of non-conformance with NIS criteria and national regulator guidance and any risk to health. They would likely range from informal follow up activities prompted by performance analysis, to the pursuit of compliance with audit recommendations (as under the current LA audit system) and restoration of normal Code of	(1) As required – impossible to quantify other than case by case. May range from a single telephone call to the PA to referral for an on-site audit. (2) Escalations are rare under the current FSA LA audit regime.	Essential to complete the continuous improvement process and ensure regulatory compliance.	Additional resource impact on PAs

	Practice intervention frequencies (only anticipated in the event of a serious or ongoing failure of the PA to meet the required standard.)			
FSA internal & external reporting	High-level reporting of PA NIS performance against FSA national regulator guidance.	Internal: Quarterly. External: Annual public performance report and one public summary report at the end of each three year audit programme.	Essential to provide independent scrutiny and public transparency. NOTE: this would not be a report on PA performance against BEIS guidance.	N/a – required.

* Option 2: Performance Monitoring - Provisional Indicators for Comment

It is proposed that PA performance indicators are further developed and tested. It is provisionally proposed that manual returns include the following performance data in Excel format (blank spreadsheet to be provided to PA by FSA):

- **FTE occupied PA posts** – *quick to estimate*
- **Date of most recent PA NIS evaluation** – *quick to report*
- Potential to measure **overdue official control interventions** nationally (a proxy trend indicator to tell PA/FSA if LAs as a whole are neglecting the business more and more over time) for the business by combining FHRS and LAEMS data analyses – *more research required*
- **FHRS profile** (number of business units rated under each FHRS rating 0-5). – *existing PA check, quick to produce from FHRS website*
- **%age Broad Compliance** (sweeps up units exempt/excluded from FHRS) – *should be quick to produce from PA business data – PA comments welcome*
- **%age FHRS ratings 4 and above** - *existing PA check, quick to produce from FHRS website*
- **Ratio of enforcement actions/total number of business units** for the business (stratified into notices, prosecutions and simple cautions) – *is this consistently available from business data to PA?*
- **Ratio of significant non-compliances/total number of business units** reported by the business to its PA – *just a concept; needs exploration with PA stakeholders to define 'significant non-compliance' and determine potential as a risk indicator*
- **No. of food alerts for action** implicating the business
- **No. of incidents** implicating the business

As PA NIS outcomes are difficult to measure directly, these indicators represent a proxy measure in the form of output indicators which are known to indicate potential risks to service delivery or the sale of safe food and feed.

Assurance Option 3

ASSURANCE MECHANISM	DESCRIPTION	FREQUENCY	RELATIVE BENEFIT	RELATIVE DIS-BENEFIT
None	<p>This is the null option.</p> <p>No performance monitoring & analysis.</p> <p>No audits of compliance with FSA national regulator guidance</p> <p>No proactive FSA interventions.</p> <p>No internal or external FSA reporting of PA assurance activity in relation to the standard set out by the FSA national regulator guidance.</p>	None.	No additional performance monitoring or assurance costs to the FSA or PAs.	<p>Absence of assurance that PA NIS are being operated to the standard sufficient to safeguard food safety and the credibility of the partnerships and businesses concerned, FSA and BEIS.</p> <p>CCA Assurance desirable to demonstrate independent oversight to public and safeguard credibility of NIS and FSA. Supported by PA stakeholders and BEIS.</p>