

FSS REGULATORY STRATEGY

1 Purpose of the paper

1.1 This paper is for **Discussion**.

1.2 The purpose of this paper is to ask the Board to consider further our proposed future regulatory strategy, which is a key part of the approach to how we deliver the FSS strategy to 2021.

1.3 The Board is asked to:

- **Consider** the revisions proposed to our draft regulatory strategy following public consultation and consumer and stakeholder engagement, attached at Annex A.
- **Agree** that the elements of effective and sustainable regulatory oversight, and principles of official control delivery, should be streamlined and incorporated into the regulatory strategy, as shown at paragraph 2.6.
- **Agree** a sixth better regulation principle should be added, as shown at paragraph 3.2.
- **Consider** if the language in the compliance spectrum at paragraph 5.14 remains appropriate following stakeholder comments.
- **Agree** the final regulatory strategy should be published after the general election on 8 June 2017.
- **Note** early stakeholder and consumer views on core programme areas at Annex B.

2 Background

2.1 Development of a regulatory strategy is a key activity supporting delivery of Outcome 4 – *responsible food businesses flourish* – in the FSS strategy ‘*Shaping Scotland’s Food Future: Our Strategy to 2021*’. It will set out our vision and future direction for how we will fulfil our role as a national regulator in Scotland.

2.2 The draft regulatory strategy agreed by the Board in March 2016¹, along with the subsequent papers the Board considered in June and August 2016 on the principles of official control delivery and key elements of an effective and sustainable system of regulatory oversight^{2,3}, established our proposed

¹http://www.foodstandards.gov.scot/sites/default/files/Board%20meeting%20-%202016%20March%2016%20-%20Developing%20Regulatory%20Strategy%20160308_0.pdf

²<http://www.foodstandards.gov.scot/sites/default/files/Board%20meeting%20-2016%20June%2015%20-%20Key%20principles%20on%20future%20delivery%20of%20Official%20controls%20-%20Sandy%20McDougall.pdf>

³<http://www.foodstandards.gov.scot/sites/default/files/Effective%20and%20Sustainable%20Official%20Controls%20-%20FSS160808.pdf>

strategic approach as a basis for further dialogue and consultation with stakeholders.

- 2.3 Since then, there has been an extensive programme of engagement with industry stakeholders, the Scottish enforcement community, other regulators, and consumers to seek their views on FSS's proposed regulatory approach, culminating in a 12 week public consultation exercise which closed on 18 April 2017. This engagement also provided an opportunity to gauge early stakeholder views on certain aspects of the regulatory system for food and feed that may need to be reviewed or changed in the future, to inform further FSS policy development within the supporting regulatory strategy programme.
- 2.4 The outcome of this consultation work and proposed amendments to the draft regulatory strategy are detailed below.

3 Discussion

- 3.1 The Board can be advised that there is widespread support for the aims and objectives of our regulatory strategy, as these have been broadly endorsed by all Scottish stakeholders with whom we met and who responded to the formal consultation exercise. Notably, food and drink industry representative bodies and Scottish local authorities have welcomed the flexible regulatory approach represented in the strategy, and FSS's clear commitment to meeting our better regulation obligations under the Regulatory Reform (Scotland) Act 2014 and associated Scottish Regulators' Strategic Code of Practice.
- 3.2 Stakeholders strongly supported the outcome-based approach that has been adopted in the strategy. Only minor comments were received on the proposed five regulatory outcomes, with a suggestion that it is made clearer that food and feed businesses are included. Consumers also clearly understood the terms 'responsible' and 'irresponsible' businesses. Similarly, stakeholders were generally supportive of the proposed elements and principles of regulatory oversight and official control delivery previously agreed by the Board, and the executive considers these should now be merged into the regulatory strategy to describe further how we plan to shape the direction for the future.
- 3.3 *It is proposed that these are streamlined and incorporated into the regulatory strategy, as shown at paragraph 2.6.*
- 3.4 It should be noted that a number of respondents from the Scottish food law enforcement community were opposed to one of the proposed principles of official control delivery – *that responsible, compliant food businesses may be recognised through alternative mechanisms of regulatory assurance, approved and verified by FSS*. This is reflective of wider concerns within the enforcement community around potential regulatory approaches to private assurance in the official control system for food and feed, where there is a perceived risk that such approaches could dilute robust regulatory oversight of food safety if given greater prominence. Similar concerns emerged during the consumer insight work, where the concept of rewarding businesses that excelled in legal compliance through alternative regulatory mechanisms did not sit comfortably with consumers. It is clear that consumers have a high degree of trust and

confidence in the current regulatory system, although it is recognised that at this early stage there isn't sufficient information available that shows how such an approach would work with third party accreditation being integrated within a regulatory framework of controls. Unsurprisingly, enforcement and consumer reservations were not shared by industry stakeholders, who broadly endorsed the concept of third party certification schemes being utilised in a regulatory context where there is convergence with legislative standards, particularly to support 'due diligence' requirements.⁴

- 3.5 A number of respondents proposed the addition of a sixth better regulation principle – that regulation be *proportionate, consistent, accountable, transparent, targeted and timely*. The view was expressed that such a 'timely' principle is already espoused by SEPA and certain Scottish local authorities, reflecting the need for regulatory intervention and enforcement action to be considered and undertaken at the earliest practicable opportunity to minimise any risks to public health and prevent any contributing behaviour from becoming chronic, persistent or established. Timely regulatory intervention is also important to minimise potential impacts on business as a result of delayed or lengthy enforcement action.
- 3.6 *The executive supports this proposal, and would recommend to the Board that it should be included, as shown at paragraph 3.2.*
- 3.7 Both the concept of a national compliance spectrum for food and feed and the regulatory decision making framework, set out at paragraphs 5.13 and 5.14 of the regulatory strategy, were well received and broadly supported. Some concerns were expressed that the language of the compliance spectrum, notably the terms 'criminal' and 'chancer', could be viewed negatively by the food and drink industry. Some consumers were also confused by these terms, leaving many feeling less confident in the regulatory system, although the underlying concepts were understood and supported and it was recognised the compliance spectrum is not intended to be public facing.
- 3.8 A number of local authority respondents suggested the compliance spectrum should be more closely aligned with the 'ladder' food business risk rating scheme, currently being piloted by FSS and several local authorities, to support an effective and consistent approach to food law enforcement in Scotland. If adopted, the new risk rating scheme will apply to the vast majority of Scottish food businesses, and the 'compliance matrix' underpinning it, while reflecting the overall compliance spectrum approach, uses more neutral language for official risk rating purposes. For example, the term 'serious non-compliance' is used to reflect wilful or sustained non-compliance, and 'full and continuing compliance' is used where a business is rated as fully compliant or where there is evidence of going beyond legislative requirements.

⁴ The Board may wish to note the recent Codex discussion paper on regulatory approaches to third party certification in food safety, prepared by Canada and the UK, available at: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/ru/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-733-23%252FWD%252Ffc23_08e.pdf

- 3.9 In considering this suggestion it should be emphasised that a key objective of the compliance spectrum approach in the Scottish Regulators' Strategic Code of Practice is to encourage regulators to fully understand the attitudes and behaviours underlying why a business is compliant or otherwise, as well as the compliance outcome, and to target interventions accordingly. As such, we would not recommend adoption of this change as it risks undermining this important strategic objective. However, we would welcome the Board's views, which we will also share with Scottish Government colleagues currently leading a review of the Code.
- 3.10 *The executive considers the language of the compliance spectrum at paragraph 5.14 remains appropriate for strategic food and feed enforcement purposes, but would welcome the Board's views.*

4 Regulatory strategy implementation

- 4.1 Once the Board is content to agree the final regulatory strategy our focus will shift towards strategy implementation and delivery, and the work that is needed to build a food and feed regulatory system for Scotland that is effective, efficient and sustainable for the future.
- 4.2 The Board were advised in March 2016, as part of their consideration of the initial draft regulatory strategy, that the executive has established a Programme Board to provide overall strategic direction and governance of the supporting regulatory strategy programme, including coordination with other FSS strategies and programmes.
- 4.3 The regulatory strategy programme has been established as an initial three year programme of work, to align with the three year FSS Corporate Plan from April 2016 – March 2019, and considerable progress has been made to embed appropriate programme management and progress reporting structures. The programme has absorbed a number of existing projects that are already well developed, given the contribution they will make to the achievement of the five regulatory outcomes contained in the regulatory strategy. This includes, for example, significant projects to develop a new 'ladder' food business risk rating scheme (noted above), development of a Scottish National Database (SND) for enforcement monitoring purposes, and work to implement a regional model for the delivery of animal feed official controls. These are key elements of the 'future delivery' workstream, supporting delivery of regulatory outcome 4 – *food and feed official control systems are sustainable, responsive and robust*. Performance metrics are being developed within each of these projects, with an emphasis on assessing how they contribute to delivery of the FSS regulatory strategy.
- 4.4 The Board will wish to note that a number of core areas within the regulatory strategy programme remain at an early policy development stage. This includes those related to reviewing existing food business registration requirements and the merits of prior approval for all food businesses, alternative mechanisms for obtaining assurance about the performance of food businesses and future assurance models, and charging for official controls. During the consultation

on the draft regulatory strategy FSS took the opportunity to seek initial stakeholder and consumer views on these core areas, and this feedback will be used to inform more detailed policy option appraisal, impact analysis, and further stakeholder consultation which will need to be undertaken in due course.

4.5 The Board is invited to note this early feedback summarised in Annex B.

5 Identification of risks and issues

- 5.1 Delivering on our regulatory strategy will be a major programme of work for FSS, which we will be taking forward post-election.
- 5.2 The nature of the food and drink industry across the UK market will require close collaboration with the FSA as they develop their Regulating our Future (RoF) programme in the rest of the UK. There are likely to be synergies, linkages and dependencies across both programmes, and importantly, we need to ensure any areas of possible divergence are clearly understood.
- 5.3 Similarly, in looking to the future, it will be important to seek and build the necessary political, stakeholder and consumer support to drive the change that will be needed, statutory or otherwise, to implement better, more cost-effective regulatory delivery models. Partnership working between FSS and local authorities will remain a central feature of our overall approach.
- 5.4 Internally within FSS, appropriate resourcing and prioritisation of regulatory strategy workstreams and projects will be critical to successful programme delivery. The Programme Board's role is scrutinising and challenging issues of programme governance and resourcing, and the executive will bring any relevant matters to the attention of the Board and/or Audit and Risk Committee as required.

6 Conclusion

- 6.1 Finalising the over-arching regulatory strategy will be a key milestone for FSS, and we very much welcome the constructive comments that have been received from stakeholders to help us refine our proposed regulatory approach. The executive looks forward to working with a wide range of organisations and partners as we move towards strategy implementation, to shape the future food and feed regulatory landscape in Scotland for the benefit of consumers and to help responsible businesses flourish.

6.2 The Board is asked to:

- **Consider** the revisions proposed to our draft regulatory strategy following public consultation and consumer and stakeholder engagement, attached at Annex A.
- **Agree** that the elements of effective and sustainable regulatory oversight, and principles of official control delivery, should be streamlined and incorporated into the regulatory strategy, as shown at paragraph 2.6.
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ANNEX A

Revision 3 of the FSS regulatory strategy is attached separately.

ANNEX B

The Board are invited to note the following summary of early stakeholder and consumer views on core areas of the regulatory strategy programme:

Registration & prior approval of food businesses

1. Most stakeholders acknowledged the need and rationale for food business registration, but questioned the benefits of the current system. Local authorities in particular felt it provided minimal value given the low proportion of new businesses that proactively register within 28 days of trade commencing, the lack of effective sanction for not registering, and resultant absence of any deterrent value.
2. It is clear that local authorities are strongly supportive of strengthening the existing registration system through some form of prior approval or pre-trading authorisation for all food businesses, such as licensing or enhanced registration, that would require minimum standards to be met before a businesses can start trading. Industry respondents also acknowledged the potential benefits of prior approval of all food businesses, as it was felt this would provide a mechanism for assessing business needs and providing support before trading commences. The potential for coordinating any future scheme with existing Business Gateway and other local services was noted.
3. The likely impacts of introducing such a prior approval scheme on start-up businesses and local authorities was recognised, and a number of respondents stressed the need to carry out detailed cost/benefit assessment of any future policy proposals across different businesses sectors and sizes.

Supporting responsible food businesses

4. A common theme to emerge from discussions with industry stakeholders was a request for clear and simple guidance on regulatory requirements, particularly to support smaller businesses, and the need for consistent regulatory interpretation by enforcement authorities. Industry feedback suggests that many food businesses value the relationship they have with their local Environmental Health and/or Trading Standards officer, which is often relied upon as a key source of business advice and support.
5. Industry stakeholders also welcomed FSS's commitment to proactively work with food businesses and associated support organisations. This was reinforced during the consumer insight work, with consumers showing strong support for an open, helpful and collaborative approach between food businesses and regulators, but with a clear expectation that FSS will retain an authoritative role and ensure appropriate regulatory intervention and sanction occur where required.
6. During the consultation exercise stakeholders also provided views on priority areas for developing supporting technical guidance and compliance tools for the food and drink industry. Several respondents suggested the need for additional

web based tools and further applications to assist businesses, particularly those involved in high risk manufacturing.

Dealing with poor performance

7. There is widespread recognition amongst all stakeholders of the potential for serious non-compliance with food and feed law to cause reputational damage to the Scottish food and drink industry, and that appropriate punitive fines and sanction should be enforced. A general view was expressed that sanctions need to be reasonable and proportionate, and that businesses have fair and accessible routes to challenge or appeal regulatory decisions.
8. A number of local authorities noted the difficulties involved in reporting cases of non-compliance to the Procurator Fiscal (PF), and the intensive resources this entails which removes officers from front line inspections. Local authorities endorsed the need for a dedicated specialist PF to consider food law cases, and the introduction of sentencing guidelines in Scotland for food law offences, similar to those that have been introduced in England and Wales for food safety and health and safety breaches.
9. Local authorities were also strongly supportive of the introduction of new administrative sanctions, notably Fixed Penalty and Compliance Notices, using primary powers available in The Food (Scotland) Act 2015, as well as mandatory display of Food Hygiene Information Scheme (FHIS) certificates. A number of additional enforcement tools were proposed, such as a 'Stop Notice' linked to operating without prior approval, and the extension of Remedial Action Notices (RANs) to food standards matters.
10. Stakeholders also recognised the role of reputational sanction as a useful deterrent through effective publicising of food safety infringements, where cases were proved beyond doubt.

Regulatory assurance & future delivery

11. Industry stakeholders broadly welcomed the concept of third party certification and assurance schemes being utilised in the food regulatory system. It was felt this would support due diligence requirements, increase the value of scheme membership, minimise duplication of effort between public and private bodies, and support risk based targeting of official inspections in line with the compliance spectrum approach. The need for robust scheme standards (e.g. relevant ISO and/or UKAS accreditation) and governance systems, including appropriate recognition, management and audit processes that are consistently implemented, were recognised as important factors if third party schemes are to be a useful tool for regulators. The potential for independent data generated by these schemes to be shared with regulatory authorities was also highlighted, although the need to maintain trust and a constructive relationship between industry and regulators was stressed, and some concerns were expressed around the purpose of greater data sharing of this nature. Support was also expressed for implementing Primary Authority arrangements in Scotland, and the need for reciprocal recognition with the scheme already in place in England and Wales (note this is a Scottish Government lead policy area).

12. Detailed views have been provided by local authorities on the issue of private assurance, which will require further consideration. As noted above, it is clear the Scottish enforcement community have significant concerns in this area, where there is a perceived risk that greater integration of third party schemes within the regulatory system could dilute a robust regulatory approach to food safety. The strongly stated and consistent position that has been expressed by local authorities is that consumer protection and regulatory assurance should be maintained through appropriately funded and resourced official controls delivered at a local government level. Whilst acknowledging the role and value of third party certification schemes, it was strongly felt that these should be seen as complimentary, and not a substitution for official controls.
13. Specific issues were raised around potential conflict of interest given the commercial focus of private assurance schemes, auditor competence, audit quality and the degree to which membership of an assurance scheme gives any greater level of public health protection, dealing with non-conformity, and the possible need for third party bodies to be designated as delegated control bodies under EU legislation if utilised as part of the official control regime. A specific suggestion was also made to explore the possibility for FSS and local authorities to provide public certification/accreditation services to the food and drink industry, as part of our regulatory oversight and verification role, clearly separated from existing enforcement functions.
14. While the resource and financial pressures on local food law enforcement services across Scotland is acknowledged, the general sense amongst local authorities is that there is significant public confidence in the current regulatory regime for delivery of official controls through local public services. This view has been borne out to some extent through consumer research, with consumers indicating a high degree of trust and confidence in the food regulatory system, which is generally taken for granted. The concept of rewarding food businesses for compliance, or going beyond compliance, did not generally sit well with consumers, and any suggestion of greater industry 'self-regulation' or less frequent inspections on an 'earned recognition' basis was generally received with a degree of discomfort. Nonetheless, consumers emphasised the need for FSS to maintain its central oversight role in assuring the overall regulatory system.

Funding

15. Industry stakeholders expressed general opposition to any significant increase in regulatory costs to the Scottish food and drink sector, or disruptive changes to charging structures, given the current challenging business environment and wider economic impacts that can be expected. One major industry association, representing over 18,000 smaller businesses, noted it was difficult to comment further on the principle that the food and drink industry should contribute to the cost of maintaining an effective and sustainable regulatory system for food and feed without a more detailed understanding of the financial model that would underpin it. The need for proportionality was emphasised in the context of financial pressures on both businesses and public services, and it was clear industry stakeholders felt that compliant food businesses should not be subject to

any, or at least minimal, additional cost increases over and above existing contributions through business rates and general taxation. This reflected their overall support for the 'polluter pays' and 'fee for intervention' approach to cost recovery, aligning with the principle in the FSS regulatory strategy that non-compliance should cost more than compliance.

16. Local authorities and Scottish enforcement bodies were broadly supportive of the principle of charging businesses for food and feed official controls, with certain exceptions, and the main theme to emerge was around the need to consider any difference in approach between charging for routine and non-routine regulatory interventions. While strongly supportive of the need to charge businesses for additional official controls to deal with non-compliance over and above normal scheduled inspection work, as provided for in EU official controls legislation, reservations were expressed around charging businesses for routine official controls. It was suggested a detailed feasibility study should be undertaken in this area. The key issues raised were around economic burdens on legitimate businesses, the basis for charge calculations, existing industry contributions through business rates and taxation, and a perceived risk that direct funding could compromise regulator impartiality. Again, there was strong support for the principle that any charges should be focused on the least compliant businesses. Local authorities also expressed widespread support for applying a fee to any food business prior approval mechanism if this was to be considered in the future.