



**DRAFT**

# **REGULATORY STRATEGY**



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### 1 OUR VISION

- 1.1 We will create a food and drink environment in Scotland that benefits, protects and is trusted by consumers and contribute to the wider Scottish Government aim of increasing sustainable economic growth, helping to make Scotland the most attractive place for doing business in Europe.
- 1.2 Consumer protection is at the heart of everything we do through effective risk assessment, risk management and risk communication, and we are committed to working closely with local and national enforcement authorities to shape the future food regulatory landscape in Scotland for the benefit of both consumers and responsible food businesses.
- 1.3 This draft strategy document supports the process of shaping that future, enabling delivery of key priorities in the FSS Strategy to 2021.

### 2 A REGULATORY FRAMEWORK

#### Scope

- 2.1 The Food (Scotland Act) 2015 established Food Standards Scotland (FSS) as the public food body for Scotland with a clear statutory responsibility to protect consumers from food safety risks, to improve dietary health, and to protect consumers other interests in relation to food. We are part of the Scottish administration, independent from Scottish Ministers and directly accountable to the Scottish Parliament.
- 2.2 The scope of this strategy covers the full range of FSS regulatory functions: developing national food and feed policy; promoting Scottish interests in discussions on technical UK, EU and international food safety and standards; regulatory implementation and decision making; operational delivery and enforcement; and assessing the performance of food and feed enforcement authorities in Scotland.
- 2.3 It also provides a framework within which we expect food and feed enforcement authorities to carry out their regulatory functions on behalf of Scottish Ministers.

#### Regulatory outcomes

- 2.4 Following the outcome-based approach in Scotland's National Performance Framework, the specific regulatory outcomes set out here expand on Outcome 4 in the FSS Strategy – *responsible food businesses flourish* – to give clear purpose and

direction to what we want to achieve as a national regulator, with a primary focus on achieving real and lasting benefits for consumers and responsible food businesses.<sup>1</sup>

2.5 Five regulatory outcomes are proposed against which the success of our regulatory strategy can be evaluated:

1. *Consumers are protected*
2. *Responsible food businesses flourish*
3. *Irresponsible food businesses are dealt with effectively*
4. *Food and feed official control systems are sustainable, responsive and robust*
5. *FSS is a trusted, empowered and effective regulator*

### ***Regulatory approaches***

2.6 In working to achieve these outcomes, our actions will be governed by the principles established in the FSS Strategy, all of which impact on our role as a regulator. These will guide our regulatory approaches to enable effective delivery of our strategic priorities, ensuring we meet our wider obligations as a Scottish national regulator and reflect the broader policy environment in which we operate. Our commitment to the Scottish Government's approach to better regulation, as set out in the Scottish Regulator's Strategic Code of Practice, will be a central theme, as will our role in supporting wider food and drink policy in Scotland.

2.7 The key elements of our regulatory approach are:

- *Risk and evidence based decision making*
- *Targeted interventions*
- *Understanding those we regulate*
- *Enabling business compliance and growth*
- *Clear communication*
- *Working with other regulators*

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<sup>1</sup><http://www.gov.scot/Topics/Government/public-bodies/topics-public%20bodies>

2.8 We will seek to integrate these elements across all of our policy and regulatory functions.

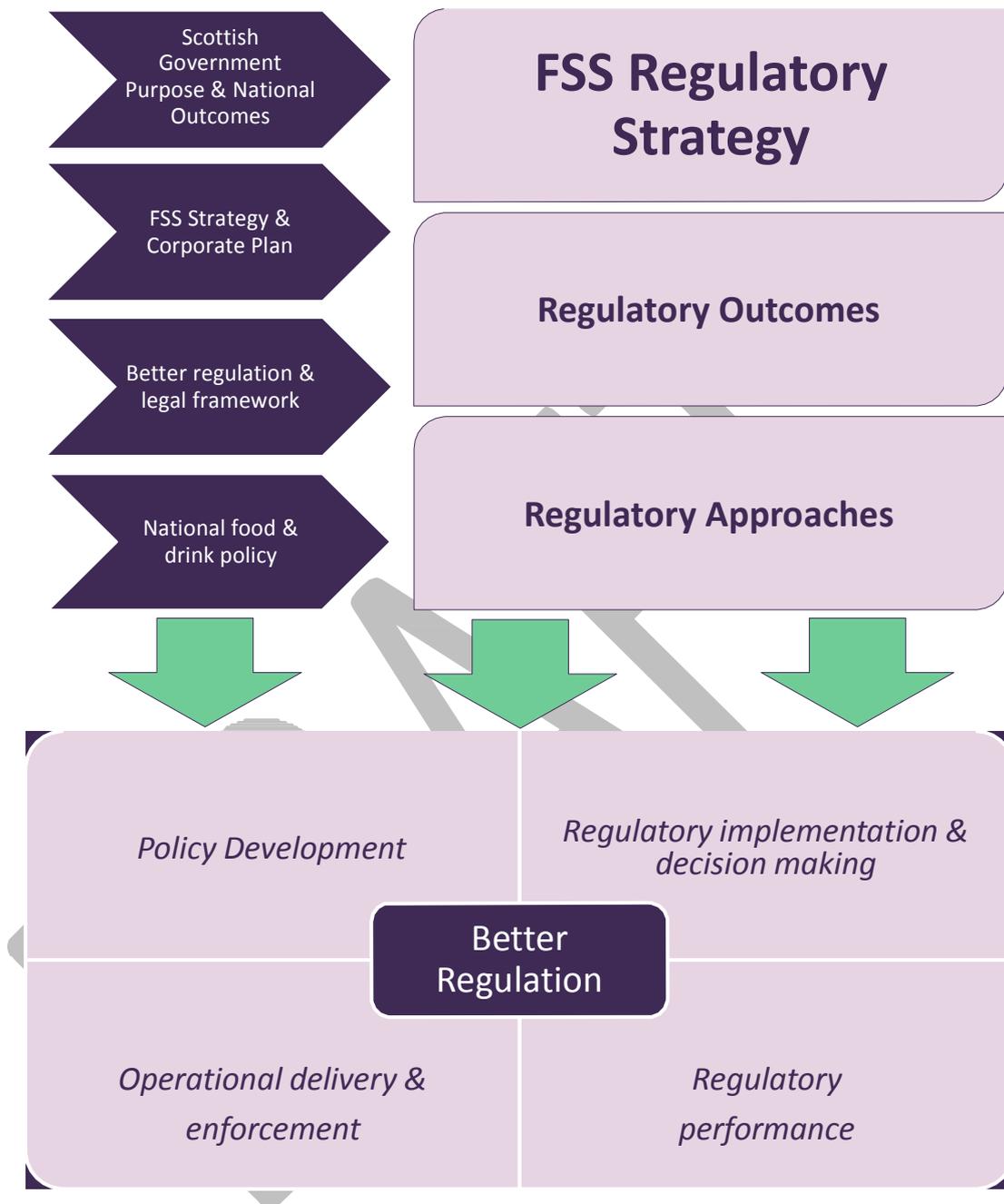


Figure 1. FSS regulatory framework

***How we will achieve this***

2.9 In fulfilling our role as a national regulator FSS will act in a way that is transparent to consumers, business, enforcement authorities and other stakeholders so they understand why we act, and react, in the way that we do.

2.10 We will adopt the following ways of working to secure the desired regulatory outcomes:

- a. *We will promote a mature, open relationship between regulators and those who are regulated – establishing trust is vital.* In striving to be a trusted and effective regulator FSS will aim to work in partnership with industry to achieve common objectives, with an attitude of openness and shared interest.
- b. *We will share and promote best practice with the food and drink industry in Scotland.* It is important that food and feed businesses are clear about their responsibilities, and we will promote best practice through guidance, advice and other means to support and enable business compliance.
- c. *We will seek to influence developing UK, EU, and international food safety and standards policy at the earliest possible stage to reflect Scottish perspectives and champion risk-based, proportionate food and feed law.* This will require effective and sustained working relationships at all levels, including with the UK and Scottish representations to the EU and through our input into Codex Alimentarius discussions.
- d. *We will be open to a broad range of approaches and interventions to regulating the Scottish food and feed industry within the existing legal framework.* This means adapting our regulatory approaches and interventions where appropriate and making use of the flexibilities available to regulators and business in existing food and feed law.
- e. *We will support different ways of gaining compliance assurance where it is appropriate and feasible to do so, including through third parties.* The vast majority of food and feed businesses value and strive for compliance – indeed many choose to go beyond compliance in pursuit of higher levels of corporate and social responsibility.
- f. *We will consider the need for government regulation to achieve public health outcomes where voluntary industry approaches have failed to deliver.* FSS has a clear mandate to protect consumers from food safety risks and improve the extent to which they have diets conducive to good health. Where evidence shows that voluntary approaches to achieving these public health outcomes are not working we will be open to considering alternatives, including recommending to Scottish Ministers the need for statutory regulation.
- g. *We will work with others to seek to change unnecessary and disproportionate regulation, minimising burdens on business where appropriate.* In applying the five principles of better regulation we will seek to ensure the costs of compliance are no more than they need to be, and any new regulation is proportionate and risk based.
- h. *We will be transparent and consistent in our regulatory decision making process and the mechanisms by which we target enforcement interventions to drive up business*

*compliance*. This will be essential in building trust amongst consumers and the business community, improving consumer protection, and maintaining the reputation of Scottish businesses in the global marketplace.

- i. *Official controls to verify business compliance should be delivered in ways that are proportionate and cost effective, with businesses contributing to these costs*. We will review our approach to charging for official controls within the context of proposals to revise the EU framework legislation in Regulation (EC) No 882/2004.
- j. *FSS will work with enforcement authorities and other regulators to share services and information where it is feasible and appropriate to do so*. Collaborative regulatory delivery across Scotland's public services is an important element of the Scottish Government's approach to better regulation. This includes agreeing secure mechanisms for sharing information on compliance and risk in areas of common interest or activity – following the principle of collect once, use often – within the constraints of the Data Protection Act 1998.
- k. *FSS will seek to improve existing data and information sharing arrangements with the food and feed industry*. FSS will explore, with businesses, ways in which commercial information on food testing and sampling can be shared and utilised more effectively, including consideration of a food testing disclosure policy and the potential use of 'safe spaces' and third party facilitation. This should benefit both industry and regulators, and support development of a FSS food surveillance strategy.

### **3 MEETING OUR WIDER GOVERNMENT OBLIGATIONS**

#### ***Better regulation***

- 3.1 We fully support the Scottish Government's approach to better regulation which aims to reduce unnecessary regulatory burdens on business, helping to support the Government's wider Purpose – to focus Government and public services on creating a more successful country, with opportunities for all of Scotland to flourish, through increasing sustainable economic growth.
- 3.2 As part of our statutory duty under the Regulatory Reform (Scotland ) Act 2014 to contribute to sustainable economic growth FSS will aim to eliminate obsolete and inefficient regulation, tackle inconsistencies in regulatory systems and enhance Scotland's competitiveness by:
  - Championing the five principles of better regulation – that regulation be ***proportionate, consistent, accountable, transparent and targeted***.
  - Carefully assessing the impact of any new regulations.
  - Working closely with enforcement authorities, other regulators and the independent business-led Regulatory Review Group.

- 3.3 During consultation on any proposed new regulations, FSS will carry out targeted face to face visits with those affected in Scotland, paying particular attention to the potential impacts on SMEs, to support development of robust Business and Regulatory Impact Assessments (BRIAs) in line with Scottish Government policy.
- 3.4 In developing and implementing new regulation, we will have ‘due regard’ to the approaches set out in the Scottish Regulators’ Strategic Code of Practice<sup>2</sup>, acting in accordance with the Code to support delivery of our primary statutory objectives in the Food (Scotland) Act 2015 and elsewhere in food law, including our legal obligation to operate in a way that is proportionate, transparent and accountable.
- 3.5 FSS will continue to fully participate in national regulatory forums designed to allow Scottish regulators to share ideas and best practice, and to discuss joint approaches to regulatory delivery. FSS will collaborate, share services and resources where appropriate, and co-produce guidance with food and feed enforcement authorities. We will seek new and innovative ways of working to maximise efficiency, and share and reduce costs and minimise burdens on both regulators and those they regulate.

#### ***Statement of compliance***

- 3.6 Regulatory bodies subject to the Scottish Regulators’ Code are required to use existing governance arrangements to publish an annual statement on compliance with the Code. FSS will include this in our Statement on Performance Functions, published in accordance with the requirements of Section 5 of the Food (Scotland) Act 2015, and corresponding annual report.<sup>3</sup>

#### ***External scrutiny***

- 3.7 External scrutiny of public services comprises a range of independent activities – regulation, audit, inspection and complaints handling – directed at public service providers to help provide assurance about the quality of service and their continued improvement.<sup>4</sup> This includes the services provided by enforcement authorities to deliver official food and feed controls for the benefit of consumers and business.
- 3.8 In FSS’s work to audit and assess the performance of local authorities and other food and feed enforcement bodies we will apply the Scottish Government’s five principles of external scrutiny – *public focus, independence, proportionality, transparency, accountability* – to ensure our external scrutiny activity is targeted where needed, and

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<sup>2</sup> <http://www.gov.scot/Topics/Business-Industry/support/better-regulation/BetterRegulationBillConsultation/CodeofPractice/StrategicCodeofPractice>

<sup>3</sup> <http://www.foodstandards.gov.scot/sites/default/files/Code%20of%20Governance%20-%20Statement%20on%20Performance%20of%20Functions.pdf>

<sup>4</sup> <http://www.gov.scot/Topics/Government/PublicServiceReform/IndependentReviewofReg>

applied proportionately, and that the costs of scrutiny are balanced with the benefits to service users and other stakeholders.

- 3.9 In doing so we will adopt a user focused approach, and cooperate with other scrutiny bodies where appropriate, ensuring we meet our statutory duties under the Public Services Reform (Scotland) Act 2010.<sup>5</sup>

#### **4 PROTECTING CONSUMERS AND SUPPORTING RESPONSIBLE BUSINESSES**

- 4.1 We have an incredibly rich and diverse food and drink industry in Scotland, which is a major contributor to the Scottish economy – valued at £10.5 billion in 2012, with ambitions to grow the industry to £16.5 billion by 2017.<sup>67</sup>
- 4.2 The Scottish Government’s national food and drink policy provides the overarching national framework for growing this key industry sector, and achieving their wider aspiration for Scotland to become a good food nation. In our primary consumer protection role FSS has an important part to play in contributing to sustainable economic growth within the sector by adopting a proportionate and targeted regulatory approach.<sup>8</sup> The vast majority of Scottish food businesses are compliant with food and feed law, and we will seek to work with industry to safeguard and enhance the international reputation of the Scottish food and drink industry, promoting a culture which values regulatory compliance, so that food and drink sold in Scotland is safe, authentic and contributes to healthy diets.
- 4.3 FSS fundamentally believes that compliance is both good for consumers and good for business. The protection of public health is compatible with business and economic growth. Therefore those who are committed to compliance will be supported, but irresponsible food businesses who put consumers at risk, flout the law, or jeopardise Scotland’s reputation, will be dealt with robustly through the application of effective and dissuasive sanctions.

#### **5 SHAPING THE FUTURE**

- 5.1 The outcomes and approaches we have set out establish a framework for what we want to achieve, and how we will act, as Scotland’s national food regulator. It also provides a starting point to begin thinking about how we want to shape the regulatory food and feed landscape to meet the needs and challenges of a modern and forward looking Scotland.
- 5.2 Whatever the nature of Scotland’s future relationship with the European Union, the existing body of EU food law and how it evolves will continue to be an important international standard in shaping our trade relationships and in securing export

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<sup>5</sup> Sections 112 – 114, <http://www.legislation.gov.uk/asp/2010/8/contents>

<sup>6</sup> <http://www.gov.scot/Resource/0038/00389160.pdf>

<sup>7</sup> <http://www.foodanddrink.scot/about-us.aspx>

<sup>8</sup> <http://www.gov.scot/Topics/Business-Industry/Food-Industry/national-strategy>

markets. Therefore a crucial role for FSS is to engage fully on those EU food and feed matters affecting Scotland, both now and in the future, to influence outcomes that support our strategic direction.

- 5.3 In protecting consumers, FSS will need to be flexible in our approach, able to respond rapidly to changing circumstances within the national and global food and feed supply chain, with the capacity to target our responses effectively and swiftly to emerging risks, food incidents, and food crime. This will require a strategic approach to regulatory intervention, and coordination with a range of other regulatory authorities, including the Food Standards Agency and other national food agencies.
- 5.4 We also need to support responsible food businesses by enabling compliance and promoting best practice, and work closely with our delivery partners to address the increasing pressures faced by food and feed law enforcement services in Scotland. In meeting these challenges, FSS is confident that by working together we can create a sustainable future delivery landscape that protects consumers, is cost-effective for taxpayers and business, and which ensures we meet our legal obligations.

#### ***Approaches to industry regulation***

- 5.5 The basic purpose of regulation is behaviour change, to achieve a specific outcome or policy objective. In relation to food, it is about ensuring businesses to do the right thing for consumers so that food is safe, authentic and contributes to healthy diets. Although most food and feed law is currently established at EU level, FSS will be open to a range of regulatory approaches within the existing legal framework to achieve our policy objectives.
- 5.6 This may include:
- *Responsible industry self-regulation*
  - *Third party regulation*
  - *Voluntary or co-regulation*
  - *Statutory 'command and control' regulation*
  - *Charging for official control delivery, ensuring non-compliance costs more than compliance*
  - *Reputational recognition and sanction that stops short of regulatory action*
- 5.7 The approaches we consider will depend on a number of factors, including food business compliance levels. Where businesses demonstrate sustained compliance we will, where possible, support different ways of third party assurance and a greater role for earned recognition to reduce inspection burdens. In areas where evidence suggests the food regulatory system needs to be strengthened, FSS will be open to recommending statutory interventions to Scottish Ministers where appropriate to ensure consumers remain protected.
- 5.8 We recognise concerns in some sections of the Scottish food and drink industry about the use of voluntary regulation and schemes, mainly around maintaining a level

playing field, consistency of standards, and a lack of sanctions for non-participation. Therefore, in considering the use of voluntary versus statutory approaches to regulation FSS will seek the views of industry and other stakeholders to inform policy development, ensuring the impact of any proposed voluntary approach is fully assessed in the context of the five principles of better regulation.

- 5.9 Regardless of the approach taken, consumer protection will remain paramount. It will be vitally important to retain the trust and confidence of consumers, and this will be our primary focus in striving to be a trusted and effective regulator. FSS will always seek to align business incentives with consumer interests, helping to shape business preferences in a way that achieves the right outcomes for consumers in Scotland.

### ***Policy and regulatory decision making***

- 5.10 FSS understands the need for consistency and proportionality in the development, application and interpretation of national and international regulatory standards, while recognising there may be tensions in seeking to achieve both. Therefore, we believe it is important that our approach to regulatory decision making is founded on a transparent set of principles and the use of objective evidence.
- 5.11 In developing any national policy for Scotland, FSS is committed to evidence based policymaking to meet the needs and challenges we face, ensuring policy decisions are supported by robust science and evidence. We will also consider all potential impacts, applying the principles of better regulation, and fully involve consumers and stakeholders in the policy process.
- 5.12 In terms of EU law, in many areas there is explicit flexibility in how it can be implemented or applied, or implicit scope for interpretation of the rules and requirements to fit local circumstances. In addition, for the most part, Scottish Ministers are free to determine and apply the necessary enforcement mechanisms they see fit to deliver EU policy objectives.
- 5.13 In making decisions on these policy and regulatory matters FSS proposes to adopt the following principles:
- i. In circumstances where legal requirements are explicitly and specifically set at an EU level, and are directly applicable in Member States, Scottish Ministers and FSS have clear legal obligations to ensure the consistent application of this law while we remain a member of the European Union. It will therefore be important to influence emerging EU law, during all its development stages, to seek to ensure it meets better regulation principles whilst protecting public health.*
  - ii. If existing EU law is considered to be disproportionate and not in the interest of consumers and business, FSS will apply influence at all levels to seek change when we believe change is needed.*
  - iii. FSS's priority will always be public health protection and consumers interests. Where the EU law provides for flexibility in application or interpretation, FSS will*

seek to make maximum use of permitted flexibilities available to regulators and business, in line with the 5 principles of better regulation, so long as the adoption of the flexibility won't adversely affect public health outcomes or consumers interests.

- iv. With respect to any specific stand-alone national policy it develops in Scotland for the benefit of consumers, FSS is committed to fully considering the principles of better regulation during development and fully involving consumer and stakeholder interests in the development process itself.

**National compliance spectrum**

5.14 To guide regulatory action and intervention and the effective targeting of food and feed law enforcement across Scotland, FSS proposes the adoption of a national food and feed compliance spectrum, using the model successfully adopted by SEPA which is highlighted as an example of good practice in the Scottish Regulators' Code. This is intended to assist FSS and enforcement authorities to tailor enforcement, intervention and engagement strategies in accordance with food business compliance levels, helping to embed a strategic approach to the delivery of official controls across Scotland – regardless of who is delivering them.

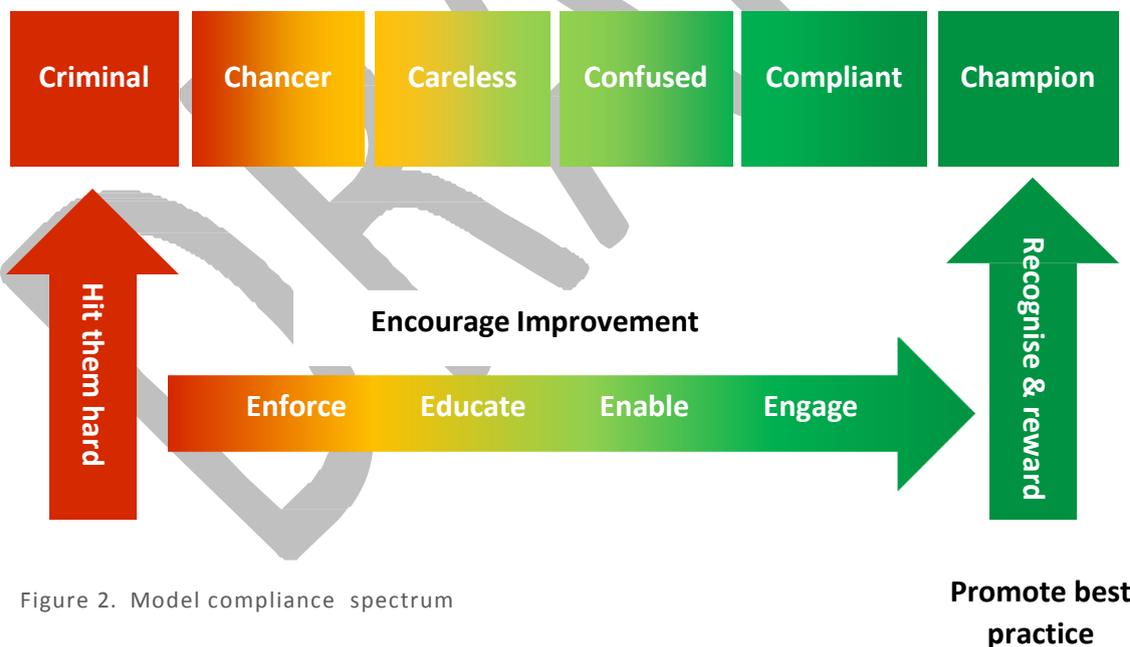


Figure 2. Model compliance spectrum

5.15 As a communication tool, having a clear national compliance spectrum that is consistent with the model adopted by other regulators will also help food businesses themselves to understand how they are performing, and what to expect from FSS and other enforcement authorities in the way we act. Our clear message is that we will support, incentivise and reward sustained compliance, and deal effectively with non-compliance.

- 5.16 The national compliance spectrum will also support alignment of national and local enforcement policies, by encouraging a consistent set of enforcement standards and risk rating approaches through integration with existing codes of practice and enforcement guidelines, e.g. the Food and Feed Law Codes of Practice and associated Practice Guidance, and the Scottish Manual for Official Controls.
- 5.17 This is expected to be further strengthened by Scottish Government proposals to implement Primary Authority arrangements relating to the devolved regulatory responsibilities of local authorities in Scotland, including food and feed.<sup>9</sup> This will allow a business, operating in two or more local authorities, to form a partnership with one local authority in order to receive assured advice and support in relation to a range of regulations, helping to ensure local regulation is consistent and delivers efficiencies for both business and regulators. FSS will continue to work closely with the Scottish Government as the scheme is developed and implemented in Scotland.

### ***Business support***

- 5.18 FSS and enforcement authorities have an important role in providing accessible channels for food businesses in Scotland to obtain advice on the regulatory requirements that affect them. FSS will seek to provide this directly through web based and other digital platforms, and we will continue to work with the Scottish Government and Scottish Enterprise to integrate food and feed guidance with existing business gateway and advice services.
- 5.19 In developing tailored advice, codes of practice, and supporting guidance we will seek to co-produce this with business and stakeholders, to ensure it is proportionate, fit for purpose, and promotes best practice. We will also work with the Food Standards Agency to jointly endorse UK-wide Industry Guides, and support development of specific Scottish guidance and National Standards.
- 5.20 In doing so, we will seek to define and describe what compliance looks like in practical ways, so that businesses are clear on what they need to do to achieve compliance.

### ***Penalties and sanctions***

- 5.21 In combating food crime, and dealing with serious non-compliance, it is essential that sanctions and penalties are effective and sufficiently punitive. There are a range of penalties available to the Scottish Courts for food offences, enabling the level of sanction to be escalated commensurate with the seriousness of the offence.
- 5.22 The new powers in The Food (Scotland) Act 2015 will also enable enforcement authorities in Scotland to use new administrative sanctions, such as fixed penalty notices, to deal with less serious offences, helping to reduce the burden on the

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<sup>9</sup> <http://www.gov.scot/Topics/Business-Industry/support/better-regulation/BetterRegulationBillConsultation/PrimaryAuthorityConsultation>

Scottish Court System. As part of the work to implement these new administrative sanctions FSS will consider the need for appropriate appeal mechanisms and guidance to support their consistent application. We will also undertake a broader review of the full range of penalties and sanctions in Scottish food and feed law to ensure they are effective, dissuasive, and aligned with our strategic priorities. This will include engagement with the new Scottish Sentencing Council on the need for specific sentencing guidelines for offences under food law.

### ***Future delivery***

- 5.23 In the longer term, we know the sustainability of local food and feed enforcement services will be a key challenge for Scotland, along with rest of the UK. Therefore we will work with enforcement authorities to consider what is needed for delivery to be sustainable in the future, learning from the approaches and successes of other countries, both in Europe and internationally, including the potential role for third party assurance as part of a comprehensive system of official controls. We will also review existing mechanisms for food business registration and approval where we believe this will benefit consumers and delivery of our strategic objectives.
- 5.24 Sustainable funding mechanisms will also need to be considered in the context of the revised EU food and feed official controls framework, which establishes the mandatory charging regime. The principle that non-compliance should cost is well established, and FSS will work in partnership with industry to explore how charging businesses fees for food and feed inspection services may further improve compliance levels in Scotland.

## **6 REGULATORY PERFORMANCE**

- 6.1 In applying the Scottish Government principles of external scrutiny in FSS's work to audit the performance of local authorities and other food and feed enforcement bodies, we will cooperate and coordinate our activity with designated scrutiny bodies in Scotland as required to improve the efficiency and effectiveness of our scrutiny functions. We will also seek to coordinate our activity with other regulatory bodies, where appropriate, including HMRC, SEPA, HSE, and the UK Border Force.
- 6.2 We will develop clear direction and default procedures, so that enforcement authorities are clear about the steps that FSS will take if the performance of official control delivery does not meet the required standard.
- 6.3 FSS regulatory performance will be audited by Scottish Government Internal Audit, Food Standards Agency Internal Audit, DG Health and Food Safety of the European Commission, and with regard to matters of regulatory finance, Audit Scotland. The FSS Board has also established an Audit and Risk Committee as a committee of the Board to support them in their responsibilities for issues of risk, control and governance and associated assurance.

## 7 REGULATORY STRATEGY GOVERNANCE

- 7.1 FSS has established a formal Programme Board to oversee development of its regulatory strategy, providing overall strategic direction and governance assurance. Both the Scottish Government and the Food Standards Agency are represented on the Programme Board.
- 7.2 Our regulatory strategy will be underpinned by a programme of activities, currently under development, to support delivery of our regulatory outcomes with clear performance indicators. FSS will align our delivery approach with the broader Scottish approach to Government and public sector reform, with a clear vision for change and continuous improvement.<sup>10</sup>
- 7.3 This strategy document is intended to be the starting point, and we look forward to engaging in dialogue and further consultation with our key stakeholders, as we work together to create a food and drink environment in Scotland that protects, benefits and is trusted by consumers.

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<sup>10</sup><http://www.gov.scot/Publications/2015/04/9736/9>

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