

EFFECTIVE AND SUSTAINABLE OFFICIAL CONTROLS

1 Purpose

1.1 This paper is for discussion and agreement.

1.2 This paper sets out the need for an effective and sustainable regulatory oversight system for food and feed safety and standards for Scotland. The strategic relevance of this is that such a system will continue to support delivery of our strategic priorities to protect consumers, maintain consumer confidence in food and feed controls in Scotland and support responsible, compliant businesses and hence their contribution of the food industry to the Scottish economy.

1.3 The current system of Official Controls (OCs) that are carried out by ourselves and by local authorities (LAs) underpin our regulatory oversight activities. Whilst it is clearly the legal responsibility of food and feed businesses to produce safe food and feed, OCs, which verify that FBOs are meeting their responsibilities, help to protect consumers from risks associated with food and feed. Further, FSS considers that OCs are an essential component in securing the reputation of Scotland's food and drink industry both nationally and internationally. As defined in EU food law, official control means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules.

1.4 It is important to remember that it is the Food Business Operator's (FBO) responsibility to produce safe food. The vast majority take their responsibilities seriously and the role of OCs should be to verify that they have done so. We consider that system currently in place in Scotland is generally effective, but nonetheless that there is scope to improve it for the benefit of consumers and businesses, and to consider what is necessary to ensure that the system is sustainable for the future.

1.5 The Board is asked to:

- **Agree** that an effective and sustainable system of regulatory oversight system for Scotland aligns with FSS's strategic direction;
- **Note** that OCs are currently largely drawn from EU food and feed law, so the outcome of the EU referendum and Scotland's future relationship with the EU is highly relevant to our future direction;
- **Note** that there are challenges facing the current system, including resource pressures that may impact on OC delivery;
- **Comment** on the six elements proposed at Section 6.2 for an effective and sustainable system for Scotland;
- **Agree** that FSS should engage in dialogue with consumers and stakeholders.

2 Link to FSS Strategic Outcomes

2.1 This high level paper is relevant to all six of FSS's Strategic Outcomes.

3 Background

Previous System Failures and A Model for the Future

3.1 We need to go back as far as 1997 to understand the modern era of food and feed regulation in the UK and the creation of the Food Standards Agency (FSA) in the wake of the BSE crisis. Before the 1997 general election Professor Philip James was commissioned to set out a blueprint for a Food Standards Agency. A fundamental principle in Professor James's proposal was to avoid the potential for conflicts of interest within what was then the Ministry of Agriculture, Farming and Food (MAFF), arising from its dual responsibility for protecting public health in relation to food and feed and for sponsoring the agriculture and food industries. Further, as well as setting out a plan to re-establish public confidence in the national mechanisms for handling problems concerning food, he recommended that this Agency should be responsible for food law enforcement including co-ordinating, monitoring, setting standards for and auditing of LA food law enforcement activities. Professor James made recommendations to secure the sustainability of activities that we now know as OCs.

3.2 The FSA was established by statute in the Food Standards Act 1999 and came in to being in April 2000 as a UK-wide non-Ministerial Department working in the context of food and feed being devolved matters. One of the key aims was the establishment of the FSA as a single body to address the previous fragmentation and lack of co-ordination between the various government bodies involved in food safety and also address complaints, generally from businesses, of uneven enforcement of food law.

3.3 Between 2002 and 2006 the FSA role in co-ordination of food law delivery across the UK was heavily influenced by fundamental changes in food and feed law at EU level. This included the introduction of a package of new directly applicable legislative measures designed to consolidate the pre-existing food safety and hygiene legislation, to ensure transparency, consistency and effectiveness of the legal requirements across the whole of the EU. These measures were principally introduced to address concerns of duplication, complexity and under implementation of the various EU Directives which applied prior to this consolidation. A key aim was to provide member states with confidence in the standards being applied in all member states by specifying in law a high level of consumer protection and establishing a level playing field to underpin the free trade elements of the single market.

3.4 The main elements of this new EU package of measures with respect to arrangements for the organisation and delivery of official controls, is provided for in EC Regulation 882/2004. This Regulation requires member states to ensure the adequacy of its OC systems to deliver the requirements of the directly applicable EU law and to establish a National Control Plan (NCP), outlining the means by which assurance on this would be provided to the Commission. It also established the

requirement for an annual report on the application of the NCP to be provided to the Commission.

3.5 In July 2011 Professor Jim Scudamore was asked by Scottish Ministers to chair an Expert Panel to conduct a study to assess the feasibility of establishing a stand-alone Scottish Food Standards organisation including a Scottish meat inspection delivery body.

3.6 When considering sustainable economic growth, Professor Scudamore noted that the Scottish food and drink industry is a key sector which offers Scotland particular opportunities for growth due to existing comparative advantages and through the potential to capitalise on Scotland's unique natural assets. The food and drink industry strategy at the time provided strong direction for longer-term expansion of the sector, aiming to grow the industry turnover from £10 billion to £12.5 billion by 2017. Professor Scudamore commented that "In achieving this it is essential that food standards and safety are maintained."

3.7 In February 2013 Professor Scudamore, again commissioned by the Scottish Government, chaired an Expert Advisory Group to carry out a review of the lessons to be learned from the horsemeat incident. The horsemeat incident affected consumer confidence in the food industry and raised wider concerns for consumers about the adequacy of OCs over a complex supply chain. He noted that the Scottish Government wished to create a world-leading food surveillance system and the report of the Expert Group recommended that FSS should consider how to improve the use and collation of information across food standards and food safety to ensure Scotland has a world recognised surveillance system in place. He also identified that there was an urgent need to identify the scientific capacity and capability that FSS and LAs would require to deliver OCs in the future.

4 Possible Consequences of Ineffective Regulatory Oversight

4.1 For compliant businesses, OCs should verify that they have met their responsibilities to produce safe food. An ineffective system of regulatory oversight would impact on both consumers and businesses. An ineffective system of regulatory oversight could lead to reduced consumer protection with the potential for adverse public health consequences. This could also result in a loss of confidence in the Scottish food sector as a result of food related incidents. Ineffective oversight that could not verify business compliance and consumer protection would have implications for businesses in terms of accessing markets, including export markets.

4.2 Businesses benefit from effective regulatory oversight, regardless of where they market their products. Consumer confidence that controls are effective is universally important and other regulators must have confidence in our systems in order that trade is permitted and facilitated. An effective and risk based system of regulatory oversight in Scotland with clear accountability will be required to support businesses wherever they are seeking to grow their markets, and will be essential for any negotiations on equivalence as part of trade negotiations and arrangements. Any indication that controls in Scotland are weak and ineffective would increase the risk of additional barriers to trade for Scotland.

5 The Current OC Delivery Landscape in Scotland

5.1 The current landscape for the delivery of food and feed OCs in Scotland involves a combination of activities delivered by LAs and FSS. LAs are legally designated as the competent authorities for approximately 650 establishments that they approve in line with food law, and for around another 60,000 other food businesses which are registered with them. FSS is responsible for the delivery of OCs in approximately 100 meat establishments that are approved by FSS. As currently required by food law, FSS has full time presence in 30 abattoirs, part time presence in game handling establishments (GHE) and risk-based presence in 60 cutting plants. FSS is also responsible for running the Scottish shellfish monitoring programme, which ensures that OCs are delivered in that sector either by FSS or LAs, depending on the activity in question. The Board has agreed that FSS should develop a centralised model for OCs in the feed sector from April 2017, and we are currently working toward this.

5.2 OCs can take a number of different forms and include routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples. Guidance on the coordination and structure of OCs is provided to LAs in Scotland through the statutory Food Law Code of Practice, which aims to ensure an effective, consistent and proportionate approach to the delivery of OCs across Scotland in order to protect food safety and the wider interests of consumers. A similar Code is applicable to feed.

5.3 In FSS approved meat establishments, the Manual for Official Controls (MOC) provides details of the tasks, responsibilities and duties of Food Standards Scotland (FSS) staff and veterinary contractors.

5.4 The Multi-Annual National Control Plan (MANCP) is a requirement of Regulation (EC) No 882/2004 on official controls. It is a European requirement that all member states have a national control plan, and the plan provides the basis of assessments of the performance of the UK's national control systems by the European Commission's inspection services. The purpose of the plan is to ensure that effective control systems are in place for monitoring and enforcing feed and food law, animal health and animal welfare rules, and plant health law. It details the roles and responsibilities of the different authorities and organisations across the UK involved in monitoring compliance with, and enforcement of, feed and food law, animal health and welfare rules and plant health requirements. The MANCP provides an overview of how authorities and other bodies work together to safeguard public, animal and plant health, to protect consumers and to promote animal welfare. It also describes, across the UK, how we enforce food and feed law and how we monitor and verify that relevant requirements are met, and that systems of OCs and other appropriate surveillance and monitoring activities, covering all stages of production, processing and distribution of feed and food, are maintained. Progress on implementation of the MANCP is monitored on an ongoing basis and annual reports are prepared and submitted to the European Commission.

6 An Effective and Sustainable Regulatory Oversight System for Scotland

6.1 As outlined in Section 5, there is currently a well-established system and infrastructure for OCs in Scotland, and generally it is considered to be effective in protecting consumers and allowing businesses to operate. It is our view however, that there is scope to improve the current system to address some current and potential future vulnerabilities, including ensuring that in addition to having an effective system, that it is economically sustainable in terms of the resources available to support its delivery. The points outlined below are, we believe, examples of where the current system and how it is resourced present us with challenges for the future:

- The current system does not differentiate sufficiently between businesses in terms of their approach to compliance. There is scope to align incentives to support greater compliance, for the benefit of consumers and businesses.
- Whilst the current system includes risk-based interventions, there is scope to improve how FSS and LAs direct and target resources that more effectively tackle poorly performing businesses, and to have the right tools and deterrents to ensure that businesses become compliant, or are no longer able to operate. This includes having effective and meaningful sanctions.
- There is currently no consensus on how effective regulatory oversight should be funded. At present, some sectors of the industry pay all or a significant proportion of the cost of controls whilst others do not. This 'unlevel playing field' means that there are differences in how businesses see their role in contributing to the costs of a system that provides them with benefits, including consumer assurance and market access.
- The current system may not be sufficiently responsive to industry innovation and often doesn't track the pace of change in industry.
- Regulatory controls aren't always focussed on the issues that matter for food safety and consumer protection, such as the current meat inspection framework that has been slow to modernise and focus on current and future hazards.
- There are inefficiencies due to duplication of effort between industry and government that could be reduced with better information sharing. For example public resources used for sampling, while industry also carries out its own sampling. Building a culture of mutual trust to enable data and information to be shared as part of an assurance framework could provide significant benefits and efficiencies.
- For commercial reasons, many businesses are involved in other types of assurance, for example, through third parties. These have costs for businesses, and may duplicate requirements for regulatory oversight. A system that was more readily able to recognise and take assurance from other activities such as appropriate third party accreditation could deliver benefits.

- Rightly, there are ambitions for economic growth, but if these do not address an increased demand for regulatory oversight, then there can be a disconnect between the demand for and supply of regulatory activities. In a landscape of reducing public sector resources, this could have risks for consumer protection, or be a barrier to growth. For example, it is thought that at best, LA resources for OC activities have remained static for the last three years, while the number of businesses within scope for OCs has grown by 4.2% over the same period.
- The diversity the food and drink sector means it can be difficult to focus resources in ways that are flexible and responsive to need.

6.2 So we consider that there is scope to improve the current system, and to start this dialogue, propose that an effective and sustainable system of regulatory oversight for Scotland would include the following six elements:

- Consumers have trust in the regulatory oversight of businesses;
- The standards applied to food and feed production are internationally recognised;
- Business have confidence in regulatory oversight, are confident that good compliance is recognised, and that non-compliance is addressed effectively;
- Ensuring compliance is achieved through risk-based, proportionate and effective enforcement where necessary;
- There is confidence in systems for monitoring, reporting and evaluating performance of both businesses and the regulator;
- Controls are effective and sustainable, protect consumers and support the reputation of Scotland and Scottish businesses.

Consumers have trust in the regulatory oversight of Food Businesses

6.2.1 The primary mechanism for achieving this level of trust is through putting consumers first. This is the value at the heart of FSS's vision: *to create a food and drink environment in Scotland that benefits, protects and is trusted by consumers*. In setting out our core principles we have stated that public health and consumer protection are central to our work. In fulfilling our regulatory obligations, both consumers and businesses will understand that our decisions are made with the clear intention of protecting consumers. Consumers will recognise that regulatory oversight supports compliant businesses while being effective at dealing with non-compliant ones. Consumers will understand that compliance is good for both consumers and business, with protection of public health being compatible with business and economic growth. A regulatory system therefore needs to provide consumers with sufficient information to receive such assurance and to enable them to make the best decisions for their circumstances.

The standards applied to food and feed production are internationally recognised

6.3.1 Currently, the vast majority of the standards and requirements are defined through EU food and feed law, with and supporting domestic food and feed regulations that apply in Scotland. There are also standards through World Trade

Organisation and the Codex Alimentarius. The importance of standards is not just that they protect consumers and enable trade - their importance also lies in scope for comparison and the ability to set benchmarks by which Governments and regulators can make decisions.

6.3.2 Whilst it is too early to predict or understand the impact of the EU referendum outcome in relation to food and feed law, it is possible that some stakeholders may lobby Governments to reduce what they perceive to be disproportionate EU regulation. While the possibility of such changes should not be ruled out at this stage, the clear risk is that any changes not in accordance with international requirements could impact on businesses' ability to export, and potentially on the wider reputation of the sector, if the reductions in regulation were seen to go too far in reducing standards. This means it is important that the consequences of any proposed future changes must be clearly understood by assessing the potential impacts on both consumer protection and acceptability, on trade, and ensuring a level playing field. Whilst many businesses focus on the domestic market, their activities can impact in the international arena. Serious non-compliance and incidents in the domestic market could impact adversely on the reputation of Scottish food exports and the reputation of the Scottish industry abroad.

Business have confidence in regulatory oversight, are confident that good compliance is recognised and that non-compliance is addressed effectively

6.4.1 We have committed in our draft Regulatory Strategy to embed the five principles of better regulation¹ in our policy development and regulatory delivery. Food Standards Scotland is an 'in-scope' regulator under the Regulatory Reform (Scotland) Act 2014 and this provides a statutory obligation to contribute to economic growth, so long as this doesn't conflict with our overall purpose of protecting public health and general consumer protection with respect to food and feed. Our draft Regulatory Strategy also states that we will recognise those businesses who are demonstrating and committing to best practice. An effective and efficient regulatory oversight system that is sustainable for the future will play an important part in underpinning these aspirations.

6.4.2 To guide regulatory action and intervention and the effective targeting of food and feed law enforcement across Scotland, we are currently consulting on the proposal 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 our delivery partners to tailor enforcement, intervention and engagement 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.

6.4.3 There are many FBOs who clearly take their responsibilities seriously. An effective and sustainable system should recognise that in its approach. This would mean making use of accreditation schemes where schemes align with regulatory compliance, and are underpinned by evidence demonstrating that they are effective. We also consider that there should be scope for the reduction of regulatory burdens if

¹ Proportionate, Consistent, Accountable, Transparent and Targeted.

businesses achieve sustained compliance. This type of approach could have cost advantages for compliant businesses.

Ensuring compliance is achieved through risk-based, proportionate and effective enforcement where necessary

6.5.1 Where businesses demonstrate a disregard for compliance then they should not benefit from reduced regulatory oversight. In fact, the opposite should happen and regulatory intervention should increase until the business improves, or if it fails to meet the requirements for compliance, closes. Our draft Regulatory Strategy commits to supporting this aspiration by targeting enforcement interventions against those businesses that might put consumers at undue risk or damage the Scottish industry's reputation through reckless or fraudulent activity. In some businesses, the FBO does not appear to consistently take their responsibilities seriously and OCs should aim to either move them into compliance, or deal with them effectively if they cannot or will not comply. A key expectation of compliant businesses is that non-compliant businesses are tackled effectively, otherwise they have an unfair advantage and may be seen as benefitting from non-compliance.

There is confidence in systems for monitoring, reporting and evaluating performance of both businesses and the regulator

6.6.1 Confidence in the regulatory system has to be supported by evidence that the system is working effectively and is able to demonstrate overall levels of compliance as well as ensuring that action is taken to address non-compliance. It also requires effective sampling and surveillance systems as part of the assurance process. This does not mean the regulator must do this directly, but the regulator must have access to, and be assured about, the relevant information.

6.6.2 Performance management frameworks should be in place to demonstrate the effectiveness of controls, that avoids conflating the number of controls delivered as a measure of effectiveness. More outcome focussed performance measures will need to be developed as we formulate and implement new or different processes. For the use of third party assurance, for example, it means having a system in place that provides assurance around the application of the standards by scheme members as well as effective mechanisms for dealing with non-compliance.

Controls are effective and sustainable, protect consumers and support the reputation of Scotland and Scottish businesses

6.7.1 A successful food and drink economy marries two essential elements: the first is a confident and compliant business sector that produces safe, quality products that are attractive to consumers and that they can trust; the second element is complimentary regulatory oversight that is affordable and provides assurance on the product safety and other aspects of regulatory compliance.

6.7.2 The first element is key, regardless of the market for the products, and the second element is essential for any country that wants to export its products to other markets, e.g. third countries that will not permit imports if they are not assured that the regulatory oversight in the exporting country is effective. So a country's reputation is judged not just by the safety and quality of the products, but also by the oversight

and compliance with requirements set out either in legislation or in internationally recognised standards such as through Codex. It is likely that there are some businesses that perceive regulation to be nothing more than a burden, but many others recognise and value the benefits of regulation and regulatory oversight. There will always be variability in how businesses and sectors perceive regulation, and regulators will always be challenged to ensure that regulation and regulatory oversight do not 'gold plate'. So whilst not gold plating, our system must be able to demonstrate that it protects consumers, supports and benefits responsible and compliant food businesses and applies proportionate enforcement if and when necessary.

6.7.3 As well as being effective, our systems must also be financially sustainable. We know sectors of the food industry are subject to a wide variation in the type and cost of OCs that in Scotland, depending on the nature of the business, are currently delivered by LAs or by FSS. We also know that the Scottish Government and the food and drink industry, rightly, have ambitions for further growth and, if successful, and all other things remaining equal, the costs to FSS and LAs of increased requirement for regulatory oversight due to sector expansion are expected to increase.

6.7.4 It is not in question that OCs have to be funded. There are likely to be many different types of possible funding models, but at its most simplistic, OCs may be funded either wholly by public funding, wholly by industry or a combination of public and industry funding. In some countries, industry pays full cost of OCs whilst in others, OCs are funded publicly. In Scotland (and the rest of the UK) the majority of OCs, with some exceptions, notably meat OCs where costs are shared between industry and Government, are not currently charged to the industry. While we can, working with industry, continue to improve the efficiency with how OCs are delivered and potentially reduce costs further, an increasing demand for OCs as the sector grows without parallel means of meeting the extra resource requirement raises similar risks as an ineffective system – that over-stretched resources may result in regulatory oversight being ineffective.

6.7.5 Future sustainability of the current framework of OCs is increasingly under pressure primarily through reductions in public sector funding. The Board has already agreed actions to mitigate the risks to consumer protection and to Scotland's reputation from the failure by some LAs to carry out OCs on animal feed. There is a broader risk to consumers and businesses if other strategic priorities of FSS and/or LAs are impacted in order to support regulatory oversight through delivering OCs.

6.7.6 Inevitably, questions of cost and affordability are inextricably linked to the type of regulatory system we want to have in place. This is not an argument for increasing costs – a clear principle needs to be that the costs should only be what they need to be to deliver the system. But it is not sustainable to assume that expansion of the food and drink sectors can happen with no additional costs to regulators. From an FSS perspective we are clear that working with industry, there are changes we can make to current systems of oversight to improve our efficiency and be more targeted in our approach, but a sustainable system is not cost-free.

6.7.7 Ultimately, therefore before determining what the funding approaches might be, there needs to be discussion and agreement within Scotland on the system of

regulatory oversight that we want and that is compliant with legal obligations. In general, responsible businesses recognise and value the benefits of proportionate, effective and efficient regulation and regulatory oversight. What we therefore need to determine with stakeholders is the right approach for Scotland, and how we sustain that for the future.

7 Risks

7.1 A number of risks of not having an effective and sustainable system of regulatory oversight for Scotland are outlined in this paper – consumers may lose confidence in the food supply chain, with consequential impacts on business. The benefits of a system are not understood or valued by all those operating in the sector. Failure to have such a system could prevent businesses from accessing existing and new markets. There are risks related to not adequately resourcing or funding a system – this could lead to it becoming ineffective or unsustainable, which could in turn have negative impacts on consumers and businesses. Lack of clarity about roles and responsibilities for different resourcing and funding models risks clouding the separation between businesses and regulators. Supporting a system of regulatory oversight at the expense of other strategic priorities could reduce the ability of FSS to deliver other outcomes for consumers.

8 Conclusions/Recommendations

8.1 The Board is asked to:

- **Agree** that an effective and sustainable system of regulatory oversight system for Scotland aligns with FSS's strategic direction;
- **Note** that OCs are currently largely drawn from EU food and feed law, so the outcome of the EU referendum and Scotland's future relationship with the EU is highly relevant to our future direction;
- **Note** that there are challenges facing the current system, including resource pressures that may impact on OC delivery;
- **Comment** on the six elements proposed at Section 6.2 for such a system;
- **Agree** that FSS should engage in dialogue with consumers and stakeholders.

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