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FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

THE OFFICIAL FEED AND FOOD CONTROLS (SCOTLAND) AMENDMENT REGULATIONS 2011

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FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

1.1. The Official Feed and Food Controls (Scotland) Amendment Regulations 2011

2. Purpose and intended effect

• Objectives

- 2.1. Increase public health protection by removing the right of food business operators (FBOs) that are not compliant with food law to continue to operate until the appeal is heard.
- 2.2. Ensure that appropriate legal measures, in line with EU food law, are put in place.

• Background

- 2.3. The draft Scottish Statutory Instrument (SSI) which is the subject of this Business & Regulatory Impact Assessment (BRIA) will amend the Official Feed and Food Controls (Scotland) Regulations 2009 (SSI 2009/446), which provide for the execution and enforcement in Scotland of Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules.
- 2.4. The draft SSI will specifically remove regulation 12(5) (and regulation 12(6) and 12(7) dependent provisions) and thereby remove the FBO's right to continue to operate pending the determination of the appeal. An explanation of the provisions of the 2011 Regulations was outlined in the consultation letter and the draft SSI is at Annex B of the consultation package.
- 2.5. The Regulations apply to Scotland only. England, Wales and Northern Ireland are making separate but parallel legislation.

Regulation (EC) 882/2004 on official controls

- 2.6. Regulation (EC) 882/2004¹ sets out requirements for the authorities in EU Member States that have responsibility for monitoring and verifying compliance with, and enforcement of, feed and food law (and animal health and animal welfare rules), i.e. the 'competent authorities' responsible for organising and undertaking 'official controls'.
- 2.7. A risk assessment for Regulation (EC) 882/2004 as a whole concluded that the new arrangements would contribute towards a reduction in food-borne disease, a reduction in contamination incidents and to increased consumer protection, and to a reduction in the costs associated with these. It would also lead, in turn, to increased consumer confidence in food produced within the Community and in imported food. With regard to the provisions on imports of non-POAO, by filling a gap in the current EU harmonised legislation, it was considered that these would help to improve public health protection by ensuring better targeting of controls and more effective management of risks.
- 2.8. Regulation (EC) 853/2004² of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin specifies hygiene rules for businesses that produce products of animal origin who must either be registered or, where appropriate, approved by the competent authority before they can sell food. The Food Standards Agency (FSA) is the competent authority under Regulation 853/2004 for the approval of slaughterhouses, cutting plants and game handling establishments where official controls are carried out by official veterinarians. Food authorities are the competent authorities for

¹ Official Journal L191, 28.5.2004, 1-52

² Official Journal L139, 30.4.2004, 55–205

the approval of those establishments where official controls are not the responsibility of official veterinarians.

- 2.9. Regulation (EC) 882/2004 requires the competent authorities (the FSA/food authority) to visit an establishment on receipt of an application for approval. The FSA/food authority grants full approval if the establishment complies with the relevant requirements of food law in relation to infrastructure, equipment and operational requirements. A conditional approval is granted if the establishment meets all the infrastructure and equipment requirements. Conditional approval can be given for a maximum period of six months, where it is evident from a further visit that clear progress has been made but the establishment does not meet all of the relevant requirements. After that six-month period, either full approval or a refusal must be given.
- 2.10. The standard 6 month time limit which allows a FBO to operate under conditional approval is set out in Article 31 of Regulation 882/2004. However the EU Food Hygiene legislation recognises the particular circumstances for certain businesses in the fishery products sector and, in the case of factory and freezer vessels, article 3.2 of Regulation 854/2004 permits the maximum period for conditional approval to be extended, if necessary, up to a maximum of 12 months. In addition, Annex III of Regulation 854/2004 allows official controls in these establishments to be carried out by the competent authority of another Member State or permitted third country.
- 2.11. Regulation 12(1) of the Official Feed and Food Controls (Scotland) Regulations 2009, which provide for the execution and enforcement of Regulation (EC) 882/2004 in Scotland, states that if the FBO approval to operate is refused or withdrawn, the FBO can appeal against that decision to a Sheriff Court. Regulation 12 (5) allows the FBO to continue to operate pending the determination of the appeal. Similar rules apply in England, Wales and Northern Ireland.
- 2.12. The right to continue to operate pending the outcome of the appeal was previously set out in domestic legislation, which transposed the former sectoral Hygiene Directives that prescribed the structural and hygiene requirements for premises which had to be licensed to produce red, white and wild game meat.
- 2.13. When the new EU food hygiene legislation and the Food Hygiene (Scotland) Regulations 2006 came into force on 11 January 2006, the right to continue operating pending the hearing of an appeal against refusal or withdrawal of an approval was retained.
- 2.14. The right of the FBO, who does not comply with food law, to continue operating pending the outcome of the appeal is inconsistent with EU legislation and is undesirable in terms of maximising public health protection.
- 2.15. As part of an exercise to assess all establishments that were licensed to operate on 31 December 2005 for approval, a total of 61 plants in Great Britain (the majority of them located in England) have been refused approval and have exercised their right of appeal since January 2006. Not all of these cases were heard in Court, as in some cases the appeal was withdrawn or the establishment ceased operating. Generally, hearings have been delayed because it took a long time for dates to be allocated in the Courts.
- 2.16. As at 4 January 2011, the position for GB is as follows: during 2009-2010 ten appeals were dealt with and none has been resolved quickly (Table 1a). Case 6 has been ongoing since May 2009 and remains unresolved. Case 3 has been ongoing from November to August 2009, when the appeal was withdrawn. Businesses that were given approval did not have their approvals re-instated by the magistrates' court. They were granted approval (or conditional approval) subsequent to their withdrawal of the appeal and then making requisite improvements to ensure compliance with the law. Tables 1b and 1c help to put

the extent of appeals into context; however, now that all the plants that were operating on 31 December 2005 have been assessed for approval the number of new plants that are likely to appeal against a decision not to grant approval is likely to be much lower than the number that appealed, for example, during 2009-2010.

2.17. In Northern Ireland, three establishments have been refused approval since 2006. All three appealed, two withdrew their appeal and have since received full approval. One premise still has their appeal pending since February 2010.

Appellant	Dates: Refusal-Resolution	Duration	Status*
1	29.7.2009-3.2.2010	6 months	Appeal withdrawn-No New Approval given
2	25.9.2009-12.2.2010	4 months	Appeal withdrawn-New Conditional Approval given
3	3.11.2009-7.6.2010	8 months	Appeal withdrawn-Approval Revoked
4	27.5.2009-31.12.2009	7 months	Appeal withdrawn-No New Approval Given
5	25.6.2009-9.10.2009	31/2 months	Approval reinstated
6	19.5.2009-present	11 months	Trial date and judicial review outstanding
7	8.2.2010-present	2 months	Trial date outstanding
8	8.2.2010-6.4.2010	2 months	Appeal withdrawn-No New Approval Given
9	19.6.2009-12.2.2010	7 ¹ ⁄ ₂ months	Appeal withdrawn-New Conditional Approval Given
10	4.12.2009-10.2.2010	2 months	Appeal withdrawn-New Conditional Approval given

Table 1a - The Appeals Duration Process 2009-2010

* Withdrawal of an appeal by an appellant FBO operates as an acceptance of the FSA's original refusal decision. Therefore the approval subsequently issued is a new approval.

<u>Table 1b - Extent of UK appeals against FSA's refusal of approval decision (01/01/2006 to 30/11/2010) – No. of FBOs Affected.</u>

Appeals and Refusals Resolution	No. of FBOs affected
FBOs refused approval	67
FBOs that appealed to a court	49
FBOs that subsequently withdrew (abandoned) their appeal in order to gain new approval	38
FBOs maintaining their appeal in order to gain court decision	11
Cases determined in court in FSA's favour (i.e. the cases were dismissed)	8
Appeals upheld by courts	N/A
Appeals pending	3

<u>Table 1c - Extent of UK appeals against FSA's refusal of approval decision (1 January 2006 to 30 November 2010) – Percentage of FBOs Affected.</u>

Appeals and Refusals Resolution	% of FBOs affected
Percentage of FBOs refused approval	5% ³
Percentage of FBOs refused approval that appealed to a court	73%
Percentage of FBOs that subsequently withdrew (abandoned) their appeal in order to gain new approval	78%
Percentage of FBOs maintaining their appeal in order to gain court decision	22%
Percentage of cases determined in court in FSA's favour (i.e. the cases were dismissed)	73% ⁴
Appeals upheld by courts	N/A
Appeals pending	27% ⁵

³ As a % of UK FSA approved establishments

⁴ As a % of FBOs maintaining appeal (8/11 = 0.727)

⁵ As a % of FBOs maintaining appeal (3/11 = 0.272)

Rationale for Government Intervention

- 2.18. Consumers and food manufacturers need to be confident that any food product of animal origin they buy is safe, but they cannot assess this fully from its appearance when it is offered for sale. Government intervention through effective hygiene controls in the production of food is necessary to address this information asymmetry.
- 2.19. Government intervention is necessary to remove the right of FBO, not compliant with food law, to continue operating pending the resolution of an appeal against refusal or withdrawal of an establishment's approval, and bring national rules in line with EU food law.
- 2.20. The principal purpose of amending the Official Feed and Food Controls (Scotland) Regulations 2009 is to increase consumer protection against risks associated with products of animal origin. This will be achieved by removing the right of FBO, not compliant with food law, to continue operating pending the outcome of an appeal.
- 2.21. In addition, since Regulation (EC) 882/2004 on official controls performed to ensure compliance with feed and food law, does not specifically provide a right for FBOs to continue operating pending the outcome of an appeal, the new SSI will bring domestic legislation into alignment with European legislation.
- 2.22. This is in accordance with the Scottish Government's national performance framework to contribute to living longer, healthier lives in Scotland.

3. Consultation

- 3.1. Stakeholders were informed of the proposed change in policy at the Current and Future Meat Controls (CFMC) Working Group in June 2010. The minutes are available on the FSA's website at http://www.food.gov.uk/multimedia/pdfs/committee/cfmcmins100625.pdf
- 3.2. Stakeholders (including representatives from meat industry) were informed about the proposed change in policy at the Chief Executive's Industry Stakeholder Forum in June 2010.
- 3.3. The proposed change in policy was discussed at the July 2010 FSA open Board meeting. The discussion paper and the minutes are available at the links below: http://www.food.gov.uk/multimedia/pdfs/board/fsa100704.pdf http://www.food.gov.uk/multimedia/pdfs/board/boardmins072010.pdf
- 3.4. A full 12-week written public consultation on the draft SSI which is the subject of this BRIA (and a partial version of this BRIA) was undertaken between 20 September and 10 December 2010. Respondents' views were taken into account in finalising the costs and benefits. The estimate for Official Veterinarian's salary has been revised by using median hourly wage of 'Veterinarians' (£17.36) plus 30% overheads. A few respondents commented that half of the cases that had been resolved in Table 1 resulted in approval being given; leading to the assumption that those businesses were essentially compliant and therefore the FSA should not have refused approval in the first place.
- 3.5. This is incorrect and text has been included to provide an explanation of the outcome of appeals against FSA refusal of approval decisions. In particular, it should be noted that the withdrawal of an appeal by a FBO confirms the correctness of the FSA's decision to refuse approval. As indicated in Table 1, businesses that were subsequently given approval did not have their approval re-instated by the magistrate's court but following assessment by the FSA of a new request for approval, following completion of the necessary improvements.

4. Options

Option 1: Do nothing – maintain current 'right to operate' rules.

This is the baseline with which other options are compared.

Option 2: Introduce the Official Feed and Food Controls (Scotland) Amendment Regulations 2011 to revoke regulation 12(5) to (7) and thereby remove the FBO's right to continue to operate pending the determination of the appeal.

• Sectors and groups affected

Competent authorities

- 4.1. The Regulations are concerned with the role of the enforcement (competent) authorities responsible for organising and undertaking official feed and food controls. Refusal, or withdrawal of approval, is a last resort that is only applied where, despite a lengthy process of enforcement actions by the official veterinarian (OV) or Environmental Health Officer working with the FBO, serious deficiencies remain.
- 4.2. The current appeal process can be lengthy, during which time the FBO can continue to operate. During this time FSA Operations may have take day to day enforcement action to address deficiencies in compliance pending appeal. This is unsatisfactory, in particular, if the right to carry on operating is out of step with EU law.

Food businesses

4.3. The Regulations would remove the right of FBO s, not compliant with food law, to continue operating pending the resolution of an appeal against refusal or withdrawal of an establishment's approval, in order to adequately address the associated public health risk.

Consumers

4.4. The Regulations will contribute towards the overall expected benefits of the application of Regulation (EC) 882/2004, i.e. a reduction in food-borne disease, a reduction in contamination incidents and increased consumer protection.

Costs

Costs to industry

Familiarisation Costs

4.5. There will be a reading and familiarisation cost to food business establishments for reading the draft Regulations. It is estimated that it will take 10 minutes per business to read and familiarise themselves with the Official Feed and Food Controls (Scotland) Amendment Regulations 2011 and disseminate this through the business. Based on current estimation there are 640 food businesses operating in Scotland that would be directly affected by the proposed Regulations. Table 2 displays the number of businesses affected in the UK broken down by country.

Country	FSA Approved Premises	LA Approved Premises	Total Premises
England	1015	4496	5511
Wales	88	248	336
Scotland	158	482	640
Northern Ireland	55	167	222
UK	1316	5393	6709

Table 2- Number	of	businesses	affected

Note: the number of LA approved premises may include some duplication with the number of FSA approved plants. Also the number of premises under LA control tends to fluctuate (from month to month), as new businesses are established and others close. This introduces some variability in the familiarisation cost estimates for industry.

4.6. To quantify the one off familiarisation cost to industry we first calculate the familiarisation cost per business. The familiarisation cost per business is calculated by multiplying the hourly wage rate of a business manager of £16.94⁶ by the ten minutes taken to understand the regulation, resulting in a familiarisation cost per business of £2.82⁷. To quantify the overall one off familiarisation cost to industry we multiply the familiarisation cost per firm by the number of businesses affected by the regulation. This results in a one off familiarisation cost in Scotland to businesses of £1807. Table 3 displays the familiarisation cost to industry broken down by country.

Country	Familiarisation cost (£)
England	15558
Wales	949
Scotland	1807
Northern Ireland	627
UK	18941

Table 3 - Familiarisation cost to industry

Note: Figures may not sum due to rounding

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

Equivalent Annual Costs (EAC)

4.7. In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula . Under Standard HMT Green book guidance a discount rate of 3.5% is used. Total one-off costs to industry in Scotland have been estimated as £1807. This yields an EAC for industry in Scotland of approximately £217 over 10 years and for the UK as a whole approximately £2277 over 10 years.

⁶ Wage rate obtained from The Annual Survey of Household Earnings (2010)

⁽http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Managers In Farming, Horticulture, Forestry And Fishing' is used (£13.03 plus 30% overheads)

 $^{^{7}}$ 10 minutes * £16.94 = £2.82

Table 4 – EAC to Industry

Country	EAC (£)
England	1871
Wales	114
Scotland	217
Northern Ireland	75
UK	2277

Non-monetised Costs

4.8. Closure of food business establishments would also entail a cost relevant to the FBO. This cost is unquantifiable as it depends on the size and type of business, volume of and profit from production, and timing of appeal. However, such costs could be justified since non-compliant FBOs should not be operating.

Costs to Enforcement Authorities

Competent Authority (Local Authorities)

4.9. There will be a familiarisation cost for all Local Authorities (LAs) staff involved in delivering official controls in approved establishments. It is estimated that it will take an Environmental Health Officer (EHO) 10 minutes to read and familiarise themselves with the Official Feed and Food Controls (Scotland) Regulations 2011. The familiarisation cost per LA is calculated by multiplying the reading time, 10 minutes, by the wage rate applied to an Environmental Health Officer of £20.45⁸, which equates to a familiarisation cost per LA of £3.41⁹. To quantify the overall familiarisation cost to enforcement authorities we multiply the familiarisation cost per LA by the number of LAs in Scotland. There are 434 LAs in the UK with responsibility for the enforcement of food hygiene legislation, who will need to familiarise themselves with this guidance. There are 32 LAs in Scotland which gives a one off familiarisation cost to LA's in Scotland of £109. Table 5 displays the familiarisation cost and the number of LAs broken down by country.

Country	Number of LAs	Familiarisation cost (£)
England	354	1206
Wales	22	75
Scotland	32	109
Northern Ireland	26	89
UK	434	1479

Table 5 - Number of Local Authorities and familiarisation cost per country

Note: Totals may not sum due to rounding

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

⁸ Wage rate obtained from The Annual Survey of Household Earnings (2010)

⁽http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Environmental Health Officers' is used (£15.73 plus 30% overheads)

⁹ 10 minutes * £20.45 = £3.41

Equivalent Annual Costs (EAC)

4.10. As with one off costs to industry the one off cost for Local Authorities requires equivalently annualising in line with Green Book guidance. The total one-off cost to Local Authorities in Scotland has been estimated as £109. This yields an EAC for LAs in Scotland of approximately £13, over 10 years and for the UK as a whole approximately £178 over 10 years.

Country	EAC (£)	
England	145	
Wales	9	
Scotland	13	
Northern Ireland	11	
UK	178	

Table 6 – EAC to Local Authorities

Competent Authority (FSA)

4.11. We estimate that each Official Veterinarian (OV) will invest 10 minutes in reading and familiarising themselves with the Regulations and disseminating to key staff in the organisation. To quantify the familiarisation cost to the FSA we need to calculate the familiarisation cost per OV reading amendments to the Official Feed and Food Controls (Scotland) Regulations 2011. An hourly wage rate of £22.57¹⁰ has been applied to an OV, and when multiplied by the reading time equates to a familiarisation cost per OV of £3.76¹¹. To quantify the familiarisation cost for the FSA in Scotland we multiply the familiarisation cost of £196 for the FSA in Scotland, 52, which equates to a one-off familiarisation cost of £196 for the FSA in Scotland. Table 7 displays the familiarisation cost for the FSA broken down by country.

Table 7 - Com	petent Authority	familiarisation cost

Country	Number of OVs	Familiarisation cost
England	271	1019
Wales	35	132
Scotland	52	196
Northern Ireland	30	113
UK	388	1459

Note: Totals may not sum due to rounding

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

Equivalent Annual Costs (EAC)

4.12. One-off costs to the FSA must also be expressed as equivalent annual costs (EAC). Total one-off familiarisation cost to the FSA in Scotland has been estimated as £196. This yields an EAC to the FSA in Scotland of approximately £24 over 10 years.

¹⁰ Wage rate obtained from The Annual Survey of Household Earnings (2010)

⁽http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Veterinarians' is used (£17.36 plus 30% overheads)

¹¹ 10 minutes * £22.57 = £3.76

Table 8 – EAC to the FSA

Country	EAC (£)
England	123
Wales	16
Scotland	24
Northern Ireland	14
UK	175

Non-Monetised Costs

Legal Costs

4.13. Amending the Official Feed and Food Controls (Scotland) Regulations 2009 to remove the FBO 's right to continue operating pending an appeal means that a FBO would face a loss of income as they would be required to cease operations immediately. If the appeal is upheld, then it is possible that businesses, through legal action, may seek redress, which would be both difficult to estimate and quantify.

Benefits

Benefits to Consumers

4.14. Option 2 would deliver public health benefits as it will minimise the potential health risk to consumers posed by FBOs with poor hygiene practices. Health Protection Scotland (HPS) reported 7186 cases of food poisoning in 2007 and the estimated cost of food-borne diseases for the UK is £1.66 billion. Although the benefits of this option are unquantifiable any option which contributes towards a reduction in the cost of foodborne disease is likely to have a significant economic benefit.

Benefits to Enforcers

4.15. Enforcement authorities will make savings derived from not having to carry out official controls in establishments, pending the determination of the appeal, as they would no longer be allowed to operate under appeal. However, uncertainty concerning the number of plants likely to be refused approval in future means we are unable to accurately estimate and quantify the potential cost savings associated with the preferred policy option.

Benefits to Industry

4.16. Industry is likely to benefit from increased consumer confidence in food safety.

5. Scottish Firms Impact Test

5.1. Businesses had the opportunity to put forward their views throughout the consultation which was sent to 150 businesses, organisations and local authorities in Scotland. Six responses were received and substantive comments shall be posted on FSA's website at <u>www.food.gov.uk</u>. As part of the BRIA engagement process, face-to face meetings were arranged with 10 businesses ranging from small to large slaughterhouses, cutting plants and including the red meat, poultry and game handling sectors.

Competition Assessment

5.2. The proposals do not contain a strong competition element, as they apply equally to all FBOs and bring domestic legislation in line with European legislation to protect public food safety.

Test run of business forms

5.3. No new or additional forms will be introduced

6. Legal Aid Test

6.1. Amending the Official Feed and Food Controls (Scotland) Regulations 2009 to remove the FBO 's right to continue operating pending an appeal means that a FBO would face a loss of income as they would be required to cease operations immediately. If the appeal is upheld, then it is possible that businesses, through legal action, may seek redress, which would be both difficult to estimate and quantify.

7. Enforcement, sanctions and monitoring

• Enforcement

7.1. This amendment removes a regulation and does not change the current enforcement regime.

Sanctions

7.2. No changes are being proposed to the criminal sanctions or civil penalties contained in the existing legislation.

Monitoring

7.3. The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including enforcement authorities, as part of the ongoing policy process. FSA mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

8. Implementation and delivery plan

- 8.1. This amendment is required to bring domestic legislation into line with European legislation, specifically Regulation (EC) 882/2005 on official controls to ensure compliance with food & food law
- 8.2. The amendment should come into force on 1 April 2011. All relevant documentation shall be posted on the FSA's food.gov.uk website; stakeholders shall be informed by an Interested Parties letter and the SSI shall be posted on the legislation.gov.uk website.

9. Post-implementation review

- 9.1. The FSA anticipates reviewing this policy as part of a proposed EU review in 2013 which aims to ensure the effective implementation of relevant Community law; ensure that the UK enforces feed and food law & monitors and verifies that relevant requirements are met; and that systems of official controls and other appropriate surveillance and monitoring activities, covering all stages of production, processing and distribution of feed and food are maintained.
- 9.2. As part of this review the UK will examine its system of official controls for monitoring and verifying compliance with feed and food law, to ensure that in delivering these controls, account has been taken of the UK Government's regulatory reform agenda and the Better Regulation Commission Principles of Good Regulation. We will aim to continue to ensure a proportionate risk-based approach that protects public health and consumer interests, without imposing unnecessary burdens on the authorities responsible for undertaking these controls or those that are subject to them.
- 9.3. FSA will re-evaluate the estimated costs and benefits by undertaking discussions with industry, trade organisations and enforcement bodies to establish cost/savings and increased level of consumers' protection.

Declaration and publication

I have read the impact assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs I am satisfied that business impact has been assessed with the support of businesses in Scotland.

S. Malario-

10/02/11

Minister's signature

Minister's title

MINISTER FOR PUBLIC HEATTH & SPORT

Date

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Environmental Impact

1. The FSA's remit is to protect the interests of consumers in relation to food safety, both now and in the future. In doing so, the FSA takes sustainable development into account in all of its activities and policy decisions.

Race/Gender/Disability issues

2. The FSA believes that the proposal will have no impact on race, gender or disability equality issues. Charities and voluntary organisations are also unlikely to be affected by these proposals.