Summary: Intervention & Options

Department/Agency:	Title:	
Food Standards Agency	Impact Assessment for The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009	
Stage: Final	Version: 2	Date: 3 December 2009

Related Publications: Commission Regulation (EC) No. 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council of as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements.

Available to view download at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:314:0036:0042:EN:PDF

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What is the problem under consideration? Why is government intervention necessary?

Commission Regulation (EC) No. 1170/2009 will amend the Food Supplements Directive 2002/46/EC, to permit the use of a further 67 vitamin and mineral sources in food supplements following favourable safety assessments from the European Food Safety Authority (EFSA). These sources are currently permitted for use in the UK under a legislative provision which expires on 31 December 2009 and Government intervention is necessary to legally permit their continued use. Currently, national regulations are necessary to give domestic effect to amendments to the Directive of this kind. Government intervention is necessary to ensure that any such changes to the Directive in the future are processed swiftly into national law. Commission Regulation (EC) No. 1170/2009 will also amend Regulation (EC) No. 1925/2006 to permit the use of a further 10 vitamin and mineral sources for addition to foods. Government intervention is necessary to give domestic legal effect to the Regulation, as amended.

What are the policy objectives and the intended effects?

The policy objectives are to (a) amend national legislation relating to permit the continued use of 67 vitamin and mineral sources in food supplements, (b) give automatic effect, in national law, to any future changes to Directive 2002/46/EC which specifically relate to vitamins, minerals and their sources permitted for use in food supplements, and (c) provide for the enforcement of Regulation (EC) No. 1925/2006, as amended by Commission Regulation (EC) No. 1170/2009.

What policy options have been considered? Please justify any preferred option. [max 430 characters]

Option 1: Do nothing. **Option 2**: National regulations to implement amendments to the Directive, in so doing giving automatic effect, in national law, to future amendments to the Directive of this kind. The preferred option is **Option 2**. If national regulations are not enacted, this would have the effect of prohibiting, from 1 January 2010, the use of 67 vitamin and mineral sources in food supplements which would otherwise be permitted for such use and expose the UK to possible infraction proceedings by the European Commission. It would also mean that national enforcement powers in relation to Regulation (EC) No. 1925/2006 would not extend to that Regulation as amended.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

A review of the costs and benefits will be carried out during January 2015.

Ministerial/CEO Sign-off For final proposal/implementation stage Impact Assessments:

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) the benefits justify the costs.

Signed by the responsible Minister/~~Chief Executive~~*:

..... Date: 8/12/09

* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

Summary: Analysis & Evidence

Policy Option: 1	Description: National Legislation to Implement amendments to the EC Food Supplements Directive 2002/46/EC to be effected by Commission Regulation (EC) No. 1170/2009

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition)	**Yrs**	For England: One-off familiarisation costs of £3,000 - £19,000 (rounded) but true cost more likely to be near £3,000. Includes local authority costs.
£3,000 – 19,000	1	
Average Annual Cost (excluding one-off)		
£ Not known		**Total Cost** (PV) **£3,000 – 19,000**

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups' see non-monetisted benefits below
One-off	**Yrs**	See non monetised benefits below
£		
Average Annual Benefit (excluding one-off)		
£ Not known		**Total Benefit** (PV) **£**

Other **key non-monetised benefits** by 'main affected groups' Giving automatic effect, in national law, to any future amendments to the Food Supplements Directive 2002/46/EC in respect of vitamins, minerals and their sources permitted for use will save the public purse by avoiding the need to produce implementing Statutory Instruments and may afford industry a commercial advantage.

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	**Net Benefit Range** (NPV)	**NET BENEFIT** (NPV Best estimate)
		£ -3k to -19k	**£ -3k**

What is the geographic coverage of the policy/option?				England	
On what date will the policy be implemented?				1 January 2010	
Which organisation(s) will enforce the policy?				LAs & PHAs	
What is the total annual cost of enforcement for these organisations?				£	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£	
What is the value of changes in greenhouse gas emissions?				£	
Will the proposal have a significant impact on competition?				Not Known	
Annual cost (£-£) per organisation (excluding one-off)	Micro **0**	Small **0**	Medium **0**	Large **0**	
Are any of these organisations exempt?	No	No	No	No	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ Decrease of £ **Net Impact** £

Key: **Annual costs and benefits:** **(Net) Present**

Evidence Base (for summary sheets)

Reason for Intervention

Commission Regulation (EC) No. 1170/2009 of the European Parliament and of Council of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council of as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements (OJ No. L314, 1.12.2009, p.36) ('Regulation 1170/2009') will further amend Directive 2002/46/EC of the European Parliament and of the Council on the approximation of laws of the Member States ('the Food Supplements Directive') to permit the use of an additional 67 vitamin and mineral sources in food supplements following favourable safety assessments from the European Food Safety Authority (EFSA). These vitamin and mineral sources are currently permitted for use in the UK under a legislative provision which expires on 31 December 2009 and Government intervention is necessary to legally permit their continued use. Currently, national regulations are necessary to give domestic legal effect to amendments to the Directive of this kind. Government intervention is necessary to ensure that any such changes to the Directive in the future are processed swiftly into national law.

Regulation 1170/2009 will also amend Regulation (EC) No. 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ('Regulation 1925/2006') to permit the use of a further 10 vitamin and mineral sources for addition to foods. Government intervention is necessary to give domestic legal effect to the Regulation, as amended by Regulation 1170/2009.

Intended effect

The intended effect of the Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009 is to:

- Amend the Food Supplements Regulations to permit the continued use of 67 vitamin and mineral sources in food supplements and, to give automatic effect, in national law, to any future changes to the Food Supplements Directive which relate to the vitamins, minerals and their sources permitted for use in food supplements.

- Give domestic legal effect to Regulation 1925/2006, as amended by Regulation 1170/2009.

- Update references in the national food supplements regulations to legislation which has been amended since the regulations were enacted.

Background

1. Food Supplements

Introduction

The Food Supplements Directive is implemented, in England, by the Food Supplements (England) Regulations 2003 (SI 2003/1387) ('the Food Supplements Regulations').

Use of Vitamins and Minerals in Food Supplements

Lists of vitamins and minerals (e.g. Vitamin C, Magnesium etc.) and the specific sources of these (e.g. Calcium L-ascorbate, Magnesium lactate etc) permitted for use in food supplements

are respectively set out at Annexes I and II to the Directive. These lists are replicated in Schedules 1 and 2 to the Food Supplements Regulations respectively.

Derogation

Article 4(6) of the Food Supplements Directive affords a derogation for the use of sources of vitamin and minerals which are not listed in Annex II to the Directive. The derogation, which is implemented by Regulation 5(3) of the Food Supplements Regulations, and expires on 31 December 2009, is conditional upon:

- The vitamin or mineral source having been used in the manufacture of food supplements on sale in the European Community on 12 July 2002;
- A dossier supporting the use of the vitamin or mineral source having been submitted for assessment by the European Food Safety Authority (EFSA) by 12 July 2005;
- The absence of an unfavourable opinion from EFSA as to the safety of the vitamin or mineral source for use in food supplements.

In the UK, all vitamin and mineral sources for which dossiers were submitted in accordance with the terms of the derogation were permitted for use in food supplements.

Commission Regulation (EC) No. 1170/2009

Regulation 1170/2009 will add 67 vitamin and mineral sources which have received favourable opinions from EFSA to the list in Annex II to the Food Supplements Directive and add 2 minerals to Annex I to the Directive.

Annexes I and II to Regulation 1170/2009 will respectively replace Annexes I and II to the Directive:

- **Annex I** to the Regulation consolidates the vitamins and minerals currently permitted for use in food supplements, with 2 additional minerals – Boron and Silicon - arising from favourable opinions from EFSA on sources of these minerals. Boron and Silicon will appear in Annex I to the Directive for the first time.
- **Annex II** to the Regulation consolidates the vitamin and mineral sources currently permitted for use in food supplements with an additional 67 which have received favourable opinions from EFSA as to their bioavailability and safety for use in food supplements. Sources of Boron and Silicon will appear in Annex II to the Directive for the first time.

The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009

The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009 will come into force on 1 January 2010 after the derogation expires. They will implement the amendments effected to the Food Supplements Directive by Regulation 1170/2009, principally by:

- Amending Regulation 5(1)(a) and (b) of the Food Supplements Regulations to refer directly to Annexes I and II to the Food Supplements Directive, rather than to Schedules 1 and 2 to the national Regulations.
- Removing Schedules 1 and 2 to the Food Supplements Regulations.

- Removing Regulation 5(3) of the Food Supplements Regulations which makes references to the derogation afforded by Article 4(6) of the Food Supplements Directive which expires on 31 December 2009.

Any future amendments to the lists of vitamins, minerals and their sources permitted for use in food supplements in Annexes I and II to the Food Supplements Directive will have automatic effect in national law. This will mean that industry will be able to place food supplements containing newly approved sources of vitamins and minerals on the market as soon as the relevant amendments to the Food Supplements Directive come into force, which may offer commercial advantages. Stakeholders will be kept informed during the development of any relevant European Union (EU) amending legislation and will have the opportunity to make comments.

Any amendments to the Food Supplements Directive other than to the Annexes as applied by regulation 5 (i.e. relating solely to the vitamins and minerals and their sources permitted for use in food supplements) will not have automatic effect in national law. This will include any future amendments to set maximum and minimum levels for vitamins and minerals in daily doses of food supplements under Article 5 of the Directive. National legislation will still be required to implement amendments to the Directive of this kind, along with full, formal, public consultation.

2. Foods to Which Vitamins and Minerals are Added ('Fortified Foods')

The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 give domestic legal effect to Regulation 1925/2006.

The Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009 will provide for the enforcement of the amendments Regulation 1170/2009 will effect to Regulation 1925/2006, by updating the definition of "the EC Regulation" in Regulation 2 of the Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007.

Options

Option 1: Do nothing.

Option 2: National regulations to implement amendments to the Food Supplements Directive, in so doing giving automatic effect, in national law, to future amendments future amendments to the Food Supplements Directive with regard to vitamins, minerals and their sources permitted for use in food supplements.

The preferred option is **Option 2**. If national regulations are not enacted, this would have the effect of prohibiting, from 1 January 2010, the use of 67 vitamin and mineral sources in food supplements which would otherwise be permitted for such use and expose the UK to possible infraction proceedings by the European Commission. Not giving automatic effect to amendments to the Directive as regards the vitamins, mineral and their sources permitted for use in food supplements would mean that newly approved sources would not be available for use by industry until national implementing legislation comes into force causing delays and disadvantaging industry. If national regulations are not enacted, national enforcement powers in relation to Regulation 1925/2006 would not extend to that Regulation, as amended.

Costs and benefits of options

Option 1

If national regulations are not enacted, this would have the effect of prohibiting, from 1 January 2010, the use of 67 vitamin and mineral sources in food supplements which would otherwise be permitted for such use. Costs to the food supplements industry would arise from the loss to the market, from 1 January 2010, of products containing these sources. Businesses would also have to remove relevant exisiting products from sale from 1 January 2010. It would also expose the UK to possible infraction proceedings by the European Commission. If exisiting products had to be removed from sale from 1 January 2010 there would also be a reduction in consumer choice.

Option 2

Benefits to Food Businesses:

- Continued, uninterrupted, use in food supplements of 67 vitamin and mineral sources currently permitted for use under the derogation after its expiry on 31 December 2009.

- Certainty as to the vitamin and minerals and their sources permitted for use in food supplements.

- Certainty should improve compliance and reduce the need for enforcement interventions.

- Vitamin and minerals and their sources permitted for use in food supplements will, for the first time, be harmonised across the EU, facilitating free trade in vitamin and mineral food supplements.

- Giving automatic effect, in national law, to any future changes to the Food Supplements Directive which specifically relate to vitamins, minerals and their sources permitted for use in food supplements will enable industry to place food supplements containing newly approved sources of vitamins and minerals on the market as soon as the relevant amendments to the Food Supplements Directive come into force, which may offer commercial advantages.

The majority of those who submitted substantive comments to the public consultation (see the section entitled 'Consultation' below for full details) supported permitting the use of the 67 additional vitamin and mineral sources in food supplements.

Costs to Food Businesses

It is expected that there may be one-off costs involved in being aware of, and becoming familiar with, the amendments to the national regulations. We expect that most of the businesses affected will be in the food manufacturing sector, with minimal impacts to food supplement retailers. Accordingly, we have used SIC code 10.89[a] to estimate the number of businesses affected and believe this will be an overestimate as it includes manufacturers of other food products, including food supplements[b].

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a http://www.statistics.gov.uk/methods_quality/sic/downloads/SIC2007explanatorynotes.pdf

b 10.89 Manufacture of other food products n.e.c. This class includes:
- manufacture of soups and broths
- manufacture of artificial honey and caramel
- manufacture of perishable prepared foods, such as: sandwiches; fresh (uncooked) pizza
- manufacture of food supplements and other food products n.e.c.

It is estimated by the Agency that it would take one manager 15 minutes to read the Schedule. To estimate the cost to business, the average hourly pay rate for managers in storage, retailing and distribution of £11.90[a], is up-rated by 30% to account for overheads to £15.47 or £3.09 per 15 minutes. Multiplying out by the estimated number of businesses affected, (likely to overestimate) amounts to £2,700 for the UK (rounded).

Manufacture of other food products n.e.c.	SIC Code 10.89	Total Costs	
England	740	£	2,287
Scotland	65	£	201
Wales	50	£	155
Northern Ireland	20	£	62
UK	875	£	2,704

There may be some retailers who also need to be aware and become familiar with the amendments to national regulations. Accordingly, we have used SIC Code 47.29[b] to estimate the number of retailers affected[c] but acknowledge that this is an overestimate. Therefore the true cost will be nearer to £2,700 than £21,700 (£19,034 + £2,704). Figures rounded.

Other retail sale of food in specialised stores	SIC Code 47.29	Total Costs	
England	5,235	£	16,176
Scotland	440	£	1,360
Wales	325	£	1,004
Northern Ireland	160	£	494
UK	6,160	£	19,034

Benefits to Enforcement Authorities

- Certainty as to the vitamin and minerals and their sources permitted for use in food supplements, facilitating official controls.

- Certainty should improve compliance and reduce the need for interventions by enforcement authorities in connection with the use of vitamin and mineral sources in food supplements.

- Harmonisation of vitamin and minerals and their sources permitted for use in food supplements will facilitate official controls.

Costs to food / feed authorities

We expect that there will be one-off costs involved in being aware of, and becoming familiar with, the amendments to the national regulations. It is estimated by the Agency that it would take one local authority officer in each of the 469 local authorities in the UK 15 minutes to be aware of, and become familiar with, the amendments to the national regulations including fortified foods. With an average hourly pay rate for trading standards officers**d** of approximately £15.58 which, in-line with the standard cost model is then up-rated by 30% to account for overheads to £20.25 and £4.05 per 15 minutes. This would be equivalent to a one-off

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a Used as no other appropriate category could be found: Annual Survey of Hours & Earnings 2009 http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313

b SIC Code 47.29 Other retail sale of food in specialised stores
This class includes:
- retail sale of dairy products and eggs
- retail sale of other food products n.e.c.

c Using wage rate of £3.09 as per previous calculation

d ASHE 2009 ibid. Inspectors of factories, utilities and trading standards

familiarisation cost of approximately £1,000 for the UK (rounded) assuming that one officer can then disseminate this information to colleagues.

LA familiarisation costs	Local Authorities with Food Standards Responsibility	Total Cost
England	151	£ 612
Scotland	32	£ 130
Wales	22	£ 89
Northern Ireland	26	£ 105
UK total	231	£ 936

Total monetised costs to local authorities and business would amount to £4,000 to £23,000 for the UK as a whole (rounded to nearest thousand). However, as outlined above, we believe the true familiarisation costs will be closer to £4,000.

Benefits to consumers:

- Continued availability in food supplements of 67 vitamin and mineral sources currently permitted for use under the derogation after its expiry on 31 December 2009.

- Harmonisation of vitamin and minerals and their sources permitted for use in food supplements may generate commercial competition which may yield benefits to consumers in terms of reduced costs and product innovation.

Administrative Burden Costs

Option 1 may lead to business reformulating, re-labelling and re-packaging products to achieve compliance to enable them to be marketed and there would be a significant additional administrative burden.

There would be no additional administrative burdens to business from Option 2.

Consultation

Informal Consultation

The Food Standards Agency undertook a series of informal consultations with stakeholders during 2009. On 2 April 2009, a letter was sent to stakeholders and enforcement authorities reminding them of the ending of the derogation period, providing a comprehensive overview of the situation and inviting comments on the vitamin and mineral sources which were included in a very early draft of the Commission Regulation.

On 17 February, 16 June and 6 July 2009 short, informal, consultations were undertaken with stakeholders by e-mail on drafts of what became Regulation 1170/2009 prior to their consideration at meetings of the EU Standing Committee on the Food Chain and Animal Health (SCoFCAH). The draft of the Regulation which achieved a qualified majority vote in SCoFCAH on 15 July 2009 was circulated to stakeholders and enforcement authorities on 28 July 2009.

Formal Consultation

A public consultation on the draft statutory instrument was carried out between 28 September and 9 November 2009. The consultation package was sent to known stakeholders, including

enforcement authorities, by e-mail and in hard copy to stakeholders without e-mail addresses. It was also published on the Food Standards Agency's website at:

http://www.food.gov.uk/consultations/consulteng/2009/supvitmin

A total of 11 responses to the consultation were received, all from food supplements stakeholders. The majority of those who submitted substantive comments supported permitting the use of the 67 additional vitamin and mineral sources in food supplements. Two stakeholders supported permitting the use of the additional vitamin and mineral sources, but were concerned about the effect of the proposal to give automatic effect, in national law, to amendments to Food Supplements Directive in this regard may have on Parliamentary scrutiny. One respondent gave qualified support to permitting the use of the additional vitamin and mineral sources in food supplements but queried the procedures for their assessment by the European competent authorities, the omission of certain substances and the addition of a particular mineral source. One respondent made a suggestion about the provision of guidance in respect of a particular vitamin source. Two respondents had no comments.

A summary of responses to the consultation which reflects the further necessary amendments to the Food Supplements Regulations identified by the Food Standards Agency during the consultation, as detailed immediately below, will be published on the Food Standards Agency's website at:

http://www.food.gov.uk/consultations/consulteng/2009/?completed=Yes

Further Necessary Amendments Identified During the Consultation

During the public consultation, the Food Standards Agency identified further amendments to the food supplements regulations as being necessary in order to update references to other legislation which has been amended since the regulations were enacted, specifically:

(i) The reference, in Regulation 3(2), to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as regards the definition of 'medicinal products', to which there have been further amendments;

(ii) The reference, in Regulation 6(3)(e), to the Annex to Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions which was revised by Commission Directive 2008/100/EC amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions. This amendment will complete the implementation of Commission Directive 2008/100/EC in England (see below).

Regulation 6(3)(e) of the Food Supplements Regulations implements Article 8(3) of the Food Supplements Directive which requires that the amounts of vitamins and minerals in recommended daily doses of food supplements are expressed on product labelling as a percentage of any recommended daily allowance (RDA) set out in the Annex to Council Directive 90/496/EEC. Commission Directive 2008/100/EC, which came into force in November 2008, amended Council Directive 90/496/EEC and, amongst other things, made amendments to the RDAs for certain vitamins and minerals.

All relevant food, including food supplements, must comply with Council Directive 90/496/EEC, as amended, by 31 October 2012. The implementation, in England, of Commission Directive 2008/100/EC and its impact on stakeholders, was the subject of a public consultation conducted by the Food Standards Agency from 6 March until 29 May 2009. All stakeholders,

including food supplements stakeholders, were consulted. The consultation documents, a summary of consultation responses and the final Impact Assessment can respectively be found on the Food Standards Agency website at:

http://www.food.gov.uk/consultations/consulteng/2009/draftfoodlabelnutdecengregs

http://www.food.gov.uk/multimedia/pdfs/consultationresponse/respondraftfoodlabelnutdecen.pdf

http://www.food.gov.uk/multimedia/pdfs/iafoodlabellingregs09.pdf

Enforcement

Responsibilities for enforcement, sanctions and monitoring are the same as those set out in the original regulations and will continue to be carried out by the relevant enforcement authorities using existing enforcement powers.

Simplification

The harmonisation, across the EU, of vitamins, minerals and their sources permitted for use in food supplements simplifies the legislative position in this area and should benefit business.

The preferred option should simplify and shorten the process for implementing future changes to the lists of vitamins, minerals and their sources permitted for use in food supplements.

Implementation and Review

Regulation 1170/2009 will come into force on 21 December 2009 and the Food Supplements (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) Regulations 2009 will come into force on 1 January 2010.

A review of the costs and benefits will be carried out during January 2015.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	Yes	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	No	No
Rural Proofing	No	No

Annexes

Competition Assessment

We do not expect any competition issues arising from this policy.

Small Firms Impact Test

We do not expect any specific issues arising for small firms as a result of this policy.

Sustainable development

Option 1 would have a significant negative economic and environmental impact resulting from the requirement to remove and destroy existing products from the market from 1 January 2010. Businesses would have to develop new products and packaging to replace those lost to the market

Option 2 would allow the continued use of existing product and packaging and there would be no significant economic and environmental impact.

Option 2 is therefore more sustainable.

Race equality issues

We do not expect any specific race equality issues arising as a result of this policy.

Gender equality issues

We do not expect any specific gender equality issues arising as a result of this policy.

Disability equality issues

We do not expect any specific disability equality issues arising as a result of this policy.