Title: The Bread and Flour Regulations 1998 **IA No:** DEFRA1444 **Lead department or agency:** Defra **Other departments or agencies:** Dept of Health	**Impact Assessment (IA)** **Date:** 07/12/2012 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Michelle McQuillan 0207 238 4352

Summary: Intervention and Options

RPC Opinion: N/A

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
-£0.06m-£24.44m	-£0.05m-£0.03m	£0.004m-£0.005m	Yes	OUT

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

The Bread and Flour Regulations (BFR) 1998 require all wheat flour other than wholemeal to be fortified with four nutrients, namely calcium, iron, thiamin and niacin to replace what is lost in the milling process. Such requirements date back to early post war times and food rationing and were aimed at improving public health. As part of the Government's Red Tape Challenge (RTC) initiative to reduce the regulatory burden on industry all food rules were subject to review in 2011. Whilst most food legislation stems from the EU, rules on bread and flour are purely national. The RTC exercise concluded that Government should hold a public consultation on the continuing need for mandatory fortification of bread and flour in England and consider deregulation in this area.

What are the policy objectives and the intended effects?

The objectives are to remove or reduce the burden of regulation where it is no longer needed. It is possible that the rules contained in the BFR introduced in the post war period are no longer necessary today. Any policy decision on the removal of mandatory fortifcation will take into account an assessment of the health impacts , the impact on industry and the interests of consumers. The intended effect is to repeal or reduce the regulatory burden of the BFR where practicably possible but without compromising public health.

What policy Options have been considered, including any alternatives to regulation? Please justify preferred Option (further details in Evidence Base)

Baseline- Do nothing. Continue to require mandatory fortification of flour with calcium, iron, niacin and thiamin. Existing regulatory requirements in England to remain in line with the rest of the UK.

Option 1- Partial fortification – removing the obligation to fortify with thiamin and niacin but continue flour fortification with calcium and iron.

Option 2- No mandatory fortification. Repeal existing BFR in England ending the compulsory fortification of flour for all 4 vitamins and minerals. It would then be up to manufacturers to decide whether to fortify. Voluntary fortification would be desirable but it would be a decision for industry.

Option 3a- Fortification of bread flour only.

Option 3b- Fortification but provide for production and use of unfortified flour in products where flour constitutes less than [10 %][1] of the total product.

No preferred Option has been chosen as the purpose of the consultation is to help inform Minister's final decisions.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date: 5 years on**						
Does implementation go beyond minimum EU requirements?			Yes (No EU rules exist)			
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes	
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** 0		**Non-traded:** 0	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading Options.

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

[1] A figure of 10% has been suggested but the appropriate level is part of the consultation process.

Summary: Analysis & Evidence

Policy Option 1

Description: Partial fortification – removing the obligation to fortify with thiamin and niacin but continue flour fortification with calcium and iron.

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 3.40

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	0.04		0	**0.04**

Description and scale of key monetised costs by 'main affected groups'

Industry: One-off familiarisation costs £31,974 (PV) (EAC[2] £3,715);

Government: One-off familiarisation costs £7,798 (PV) (EAC £906);

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

Industry: One-off redundant stock of premix suppliers; Other impacts on premix suppliers - unemployment and further impacts on local economy (recurring).

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	0		0.4	**3.44**

Description and scale of key monetised benefits by 'main affected groups'

Industry: Recurring reduction in regulatory burden - savings for millers and manufacturers are passed down the food chain and assumed to be captured as a lower priced to consumers (see below).

Consumers: Recurring lower prices for consumers equivalent to £3,443,075 (PV) (average annual benefit £400,000)

Other key non-monetised benefits by 'main affected groups'

Industry: A more proportionate enforcement procedure for businesses.

Government: Simpler enforcement procedures for enforcement officers.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

Assumes that no voluntary fortification will take place.
Assumes competitive markets; all input cost savings from millers is passed through the food chain all the way to the consumer via the manufacturers. However, the final distributional outcome will depend on the competitiveness of the market.
Assumes that labelling costs are captured in the Food Information for Consumers Regulation IA.
Familiarisation assumptions are fully explained in Annex 3.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	YES	OUT

[2] EAC = Equivalent Annual Cost

Summary: Analysis & Evidence

Policy Option 2

Description: No mandatory fortification. Repeal existing BFR in England ending the compulsory fortification of flour for all 4 vitamins and minerals.

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 24.44

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	0.04		0	**0.04**

Description and scale of key monetised costs by 'main affected groups'

Industry: As Option 1; One-off familiarisation costs £31,974 (PV) (EAC £3,715);

Government: As Option 1; One-off familiarisation costs £7,798 (PV) (EAC £906);

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

Industry: One-off redundant stock of premix suppliers; Other impacts on premix suppliers - unemployment and further impacts on local economy (recurring). These costs are expected to be more of an impact than Option 1.

Consumers: Negative health effects – reduced calcium and iron intakes leading to higher risks of osteoporosis and iron deficiency anaemia respectively. No expected impacts on niacin and thiamin levels.

Government: Recurring social care costs and NHS costs

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		2.84	**24.48**

Description and scale of key monetised benefits by 'main affected groups'

Industry: Recurring reduction in regulatory burden - savings for millers and manufacturers are passed down the food chain and assumed to be captured as a lower priced to consumers (see below).

Consumers: Recurring lower prices for consumers equivalent to £24,445,830 (PV) (average annual benefit £2,840,000).

Government: Recurring reduced enforcement for local authorities of £33,563 PV (average annual benefit £3,899)

Other key non-monetised benefits by 'main affected groups'

Industry: Increased trade for millers of non-fortified flour – Unfortified flour can be produced lawfully in the UK and allows millers to compete directly with unfortified flour producers from abroad.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

Assumes that no voluntary fortification will take place.
Assumes competitive markets; all input cost savings from millers is passed through the food chain all the way to the consumer via the manufacturers. However, the final distributional outcome will depend on the competitiveness of the market.
Assumes that labelling costs are captured in the Food Information for Consumers Regulation IA.
Familiarisation assumptions are fully explained in Annex 3.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net: 0**	YES	OUT

Summary: Analysis & Evidence

Policy Option 3a

Description: Fortification of bread flour only.

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 9.49

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	0.04		0.00	**0.04**

Description and scale of key monetised costs by 'main affected groups'

Industry: As Option 1; One-off familiarisation costs £31,974 (PV) (EAC £3,715);

Government: As Option 1; One-off familiarisation costs £7,798 (PV) (EAC £906);

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

Industry: One-off redundant stock of premix suppliers; Other impacts on premix suppliers - unemployment and further impacts on local economy (recurring). These costs are expected to be smaller than Option 2; capital investment costs related to fortifying bread flour only (likely to be significant).

Consumers: Negative health effects – reduced calcium and iron intakes leading to higher risks of osteoporosis and iron deficiency anaemia. This is likely to be less than Option 2 because it is bread flour only that is being fortified, not all flour.

Government: Increased health costs to the NHS and increased social care. This is likely to be less than Option 2 because it is bread flour only that is being fortified, not all flour.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		1.11	**9.53**

Description and scale of key monetised benefits by 'main affected groups'

Industry: Recurring reduction in regulatory burden - savings for millers and manufacturers are passed down the food chain and assumed to be captured as a lower priced to consumers (see below);

Consumers: Recurring lower prices for consumers equivalent to £9,533,874 (PV) (average annual benefit £1,107,600).

Other key non-monetised benefits by 'main affected groups'

Industry: A more proportionate enforcement procedure for businesses; Increased trade for millers of non-fortified flour – Unfortified flour can be produced lawfully in the UK for non bread use and allows millers to compete directly with unfortified flour producers from abroad.

Government: Simpler enforcement procedures for enforcement officers.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

Assumes that no voluntary fortification will take place.

Assumes competitive markets; all input cost savings from millers is passed through the food chain all the way to the consumer via the manufacturers. However, the final distributional outcome will depend on the competitiveness of the market.

Assumes that labelling costs are captured in the Food Information for Consumers Regulation IA.

Familiarisation assumptions are fully explained in Annex 3.

BUSINESS ASSESSMENT (Option 3a)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	YES	OUT

Summary: Analysis & Evidence — Policy Option 3b

Description: Fortification but provide for production and use of unfortified flour in products where flour constitutes less than 10% of the total product.

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -0.06

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	0.06		0	**0.06**

Description and scale of key monetised costs by 'main affected groups'

Industry: One-off familiarisation costs £47,932 (PV) (EAC £5,568) – larger than all other Options;

Government: One-off familiarisation costs £7,798 (PV) (EAC £906).

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

Industry: One-off change in flour suppliers for those using flour as a minor ingredient. This will involving searching and negotiating with new foreign suppliers.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

There are no monetised benefits currently available for this Option.

More information is required on savings from new enforcement procedures, which we are seeking through consultation. Other than enforcement benefits, we do not anticipate any further benefits because we assume market conditions will be unaffected.

Other key non-monetised benefits by 'main affected groups'

Industry: A more proportionate enforcement procedure for businesses.

Government: Simpler enforcement procedures for enforcement officers.

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

Assumes flour suppliers continue with existing fortification practices due to potential capital investment costs needed to meet the relatively small demand for unfortified flour (3-5%).
Assumes that no voluntary fortification will take place.
Assumes that labelling costs are captured in the Food Information for Consumers Regulation IA.
Familiarisation assumptions are fully explained in Annex 3.

BUSINESS ASSESSMENT (Option 3b)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	YES	OUT

Evidence Base (for summary sheets)

References

- Bread and Flour Regulations 1998 SI 1998/141 http://www.legislation.gov.uk/uksi/1998/141/contents/made
- Guidance note to the Regulations - July 2008
- SACN Risk Assessment: UK Bread and Flour Regulations position statement 15 June 2012 www.sacn.gov.uk
- NABIM UK Flour Milling Industry 2012 report www.nabim.org.uk
- Federation of Bakers Factsheet No 3 www.bakersfederation.org.uk

Policy Landscape

One of the current Government priorities is to reduce unnecessary burdens on business and remove burdensome or outdated regulations where they are no longer needed. As part of the Red Tape Challenge Exercise covering the Hospitality theme a review of all existing rules covering food labelling and compositional standards was carried out. One of the conclusions of this exercise was to review the continued need for national rules on bread and flour. This consultation seeks the views of stakeholders on whether the BFR and its requirement to fortify flour should be retained and looks at possible Options for change.

Current UK regulations

The Bread and Flour Regulations (BFR) 1998 lay down compositional and labelling rules for bread and flour. The Regulations were introduced post war to improve the nutritional status of the population during food rationing. The existing rules apply to Great Britain and have been jointly made by Defra and Health Ministers as well as the Secretary of States for Scotland and Wales. Separate but equivalent rules apply in Northern Ireland.

Many of the original requirements which were contained in the Regulations such as those relating to additives and the use of flour treatments agents have been removed over the years and either no longer applies or is now controlled via other horizontal rules such as those on additives. These regulations now serve only to require the fortification of flour and lay down specifications for these fortificants as well as setting rules on the use of the terms wholemeal and wheat germ. This IA is primarily therefore considering the need for continued mandatory flour fortification requirements. If fortification is deemed no longer necessary then this would provide a basis for deregulation and repeal the Regulations. Provision for the terms wholemeal and wheat germ is seen as a minor component of the Regulations and would likely have little effect if removed.

Any changes to the existing rules are proposed for England only, since food is now a devolved matter.

The Regulations legally require all white and brown flour produced in Great Britain to be fortified with four specific vitamins and minerals, namely calcium, iron, thiamine and niacin, at specified levels. Calcium is added for fortification purposes while the remaining three nutrients are added to restore the levels to that which is lost during the flour milling process. See Table 1 for details of the full requirements.

Table 1: Required nutrients and levels added to wheat flour (except wholemeal flour)

Nutrient	Amount per 100g flour	Form
Calcium**	235-390mg	Calcium carbonate
Iron	≥1.65mg	Any or a combination of: - ferrous sulphate - green ferric ammonium citrate - ferric ammonium citrate - dried ferrous sulphate - iron powder
And Thiamin	≥0.24mg	Thiamine hydrochloride
Niacin	≥1.60mg	Nicotinic acid or nicotinamide

** except self-raising flour which contains ≥ 0.2% Ca

There are certain exceptions to the rules. Calcium is not required to be added to self-raising flour when it has a calcium content of not less than 0.2%, or to wholemeal or malt flour. In addition iron, thiamin and niacin are not required to be added to wholemeal flour but these should be naturally present in the

quantities prescribed. This is because during the milling process of wholemeal flour the bran and germ which is added will already contain these nutrients.

Wholemeal and wheat germ

The Regulations also contain requirements on the use of the words “wholemeal” and “wheat germ”. These terms may only be used on the labelling or advertising of bread if the bread meets the following criteria:

Wholemeal - all the flour used as an ingredient in the preparation of the bread must be wholemeal. The term “wholemeal” is not defined in law; however it is generally accepted that wholemeal flour is the entire wheat grain, which contains the bran and the germ.

Wheat germ – the bread must have an added processed wheat germ content of at least 10% calculated on the dry matter of the bread.

Other descriptions of bread, such as “white”, “brown”, “stone-ground” are not specifically prescribed by law. However, the use of such descriptions will be subject to the rules of the Food Labelling Regulations 1996 – “where there is no name prescribed by law for a food, the name used must be sufficiently precise to inform the purchaser of the true nature of the food and must not mislead”.

The compositional requirements apply to flour made from wheat only. The Regulations also define bread (for the purposes of those regulations only).

Devolved Authorities

Both food and health are devolved matters therefore Scotland, Wales and Northern Ireland are currently considering their policy positions on this issue and have not yet taken a view. Views of the devolved authorities will also be subject to consideration in deciding the chosen Option. The current BFR 1998 apply across England, Wales and Scotland while separate but analogous regulations apply in Northern Ireland. Legally it is entirely possible for England to decide to repeal its rules on bread and flour in isolation while the other devolved countries retain their existing rules. However logistically this may be more problematical because of the nature of the bread and flour industry in the UK. The bulk of flour milling operations in the UK are located in England, 3 are located in Scotland, 2 in Northern Ireland, and one in Wales. Those in Scotland and Wales produce around 100k tonnes of flour per year out of an annual total of 4.1 million tonnes, meaning by far most of the UK flour produced is in England It is also notable that around 40 to 50% of all flour sold across Northern Ireland and Southern Ireland is produced in Great Britain.[3]

The main flour milling companies such as Allied, Rank Hovis, ADM and Carrs own several flour mills in England but also across Scotland, Wales and Northern Ireland. It would be challenging for companies to have to work to different fortification policies across their UK sites and it is unlikely they will be enthusiastic towards changes which affect England only. In addition, the majority of mills are located in England but product distribution of flour and flour containing products is diverse across the UK. Any change to the regulatory climate in England is likely to affect Scotland, Wales and Northern Ireland.

Due to the nature of the distribution of mills a change in policy on fortification in England is therefore likely to have direct impacts on Scotland, Wales and Northern Ireland even if they choose not to change their existing policy on fortification. There is also potential for increased burdens on industry if fortified flour still needs to be produced in order to retain existing exports to these countries including to the Republic of Ireland. Industry may be hampered by differences in the rules across the UK and could see this as increasing rather than decreasing regulatory burdens particularly for those companies with several mills spread across the four devolved countries of the UK.

Fortification in the rest of the world

The rest of Europe except Republic of Ireland (who have similar rules to ours) does not have any mandatory fortification requirements for flour and, indeed, some member states such as Denmark have a general anti-fortification food policy. Worldwide, however, there are many countries which have mandatory requirements for flour fortification particularly across Africa and North and South America.

[3] Private communication from NABIM to Defra

The USA and Canada require mandatory fortification of flour in much the same manner as the UK and notably also, for example, require folic acid fortification.

Current industry practices

All white and brown wheat flour produced in the UK is currently fortified at the milling stage as this is the most straightforward approach. The industry is generally content with the current mandatory provisions in the regulations which have existed for over 50 years. These provisions also provide a level playing field for industry by ensuring all flour is manufactured to the same nutrient criteria.

Although separate to this exercise, certain sectors of industry have expressed concerns about forthcoming changes to existing labelling rules which will mean that, from 2014, flour users will have to label the added fortificants in the ingredients list. At present they are exempt under the Food Labelling Regulations 1996 from labelling these fortificants. However, this represents an under implementation of EU rules and the new Food Information Regulation agreed in 2011 will in future require any bread, flour or any flour containing product to be labelled with these added nutrients. In particular those using flour in small quantities as a minor ingredient, are concerned about the effect of these future labelling requirements. Industry have highlighted that consumers may be unaware of the current fortification requirements and may therefore think this is something new when the nutrients are labelled or may be misled and think they are getting more nutrients than they actually are. Countries that are not in favour of fortification may choose not to buy our products when the fortificants are identified on the label. Some have suggested a solution might be to allow for the production, sale and use of non-fortified wheat flour when used as a minor ingredient in a compound foodstuff. For example flour is used in the preparation of smarties and its contribution will be insignificant in terms of nutrient intake, but in the future these mandatory vitamins and minerals, as components of the flour, will need to be listed on the ingredients list. This Option is being considered as part of this consultation (Option 3) and could assist the trade in this respect without compromising intakes of these vitamins and minerals.

Rationale for intervention

Under the Government's Red Tape Challenge exercise all food labelling, food standards and compositional rules were put under the spotlight with the aim of removing redundant regulation or simplifying rules in the case of others. A commitment was given to hold a formal public consultation on the continuing need for mandatory fortification of flour in England required by the BFR with a view to scrapping these national rules if no longer needed.

The legislative requirement to fortify flour was introduced post war in order to restore the iron, thiamin and niacin that are lost in the milling process to the levels present in unrefined flour. The addition of calcium was introduced in the 1940s as a means of providing more calcium in the diet at a time when dairy products (a good source of calcium) were limited. The current consultation is looking at whether, 60 years on, fortification is still necessary for the nutritional health of the UK population and, if not, whether industry would benefit from deregulatory moves in this area.

Many of the original requirements which were contained in the Regulations such as those relating to additives and flour treatment agents have now been removed and are contained in separate horizontal rules controlling the use of additives. The primary purpose of the BFR is therefore almost entirely in relation to the fortification requirements and the reason these rules still exist.

Industry has raised concerns about the cost implications of relabelling all flour containing products with the four nutrients. If the Regulations were revoked then the labelling problem would be alleviated to some extent for those who then choose not to fortify at all.

Policy objective

The objective is to reduce the regulatory burden on industry by considering whether national rules on bread and flour could be revoked without compromising public health. To help ensure this is met, an assessment of the Options including the effects on industry and the health implications of removing or amending the current fortification requirements in England has been made. As fortification of flour is a matter of heath policy the Department of Health has been involved in considering the impacts on health

of a change in flour fortification policy. They have asked their Scientific Advisory Committee on Nutrition (SACN) to assess the risks to the health of the population of removing the current fortification requirements for white and brown flour. This can be found at Annex 4. These assessments have enabled us to identify the health costs and benefits identified in this IA. We are now consulting to seek further evidence and opinion on the various Options.

Baseline and Options

Baseline– DO NOTHING - FULL FORTIFICATION

Do nothing. Continue to require mandatory fortification of flour in England with calcium, iron, niacin and thiamin. The regulatory requirements will remain in line with the rest of the UK.

Option 1– PARTIAL FORTIFICATION

Removal of the obligation to fortify flour with thiamin and niacin but continue to require mandatory fortification of flour with calcium and iron. This will require reformulation of the premix if industry chooses not to add the two nutrients which are no longer mandatory. Continues some measure of protection against insufficiency of calcium and iron. Labelling of iron and calcium would be required but these costs would be covered by the Food Information Regulation (FIR) impacts.

Option 2– NO FORTIFICATION

Removal of mandatory fortification requirements for all four nutrients through repeal of the existing BFR in England. This will end the compulsory fortification of flour in England only. It would then be up to manufacturers to decide whether to fortify voluntarily. This will reduce the burden on manufacturers as they will have no product specific compositional regulations to comply with. However, there will be a risk on insufficiency particularly for calcium and iron in some population groups. It will also be harder to monitor the population's intake of these nutrients because there will be no control over the amounts added.

Option 3

3a: Continue with fortification requirements but for bread flour only.

3b: Continue with existing mandatory fortification of flour but provide for production and use of unfortified flour in products where flour constitutes less than 10% of total ingredients.

Voluntary fortification

At present, fortification with the four nutrients is mandatory but, if this requirement was removed, industry would be free to choose whether to continue voluntarily to fortify. However, any voluntary fortification would then need to adhere to European rules on the addition of vitamin and minerals to food and any associated claims would need to comply with nutrition and health claim rules.

Because fortification of flour is a mandatory requirement laid down in our national law, the UK has been able to take advantage of derogation from the current requirements of Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (fortified food regulations). The Fortified Food Regulations permits vitamins and minerals to be added but only at significant levels (15% of the RDA), as defined in the Nutrition Labelling Directive 90/496/EU (amended by Directive 2008/100/EC). If the mandatory provision is removed then the Fortified Food Regulations will apply and, based on existing flour fortification levels, only calcium and thiamin would meet the requirement to be added at a level above 15% of the RDA. If millers/flour processors wished to continue fortifying flour if a full deregulatory approach was adopted, then reformulation would be required i.e. the current fortification levels for iron and niacin are insufficient to meet 15% of the RDA. Table 2 shows the additional amount of fortificants required to meet the 15% level for flour.

The Fortified Food Regulations apply only to the primary food that is fortified i.e. the flour itself. Any product made using fortified flour (bread, cake, sauces etc.) falls outside of the scope of the regulations. If businesses wanted to make any voluntary claims about a nutrient they would need to comply with the Nutrition and Health Claims Regulations (EC) 1924/2006. For example, 'contains a source of iron' would need to contain, as a rule, 15% of the RDA.

Table 2: Regulatory fortification requirements

Fortificant	*Fortification requirements (mg/100g flour) Bread & Four Regulations 1998*	*Recommended Daily Allowance (RDA) (mg per day) Directive 2008/100/EC*	*Flour fortification as a proportion of the RDA (per 100g flour)*	*Flour fortification as a proportion of the RDA (per 100g bread assuming bread 60% flour)*
Calcium carbonate	≥235 ≤390 (94-156mg calcium)*	800	12-20%	7-12%
Iron	≥1.65	14	12%	7%
Thiamin hydrochloride	≥0.24 (0.21mg thiamin**	1.1	19%	11%
Niacin	≥1.6	16	10%	6%

*Calcium carbonate ($CaCO_3$) is 40% elemental calcium (atomic mass calcium = 40.078)

** Pure thiamin is 89% of the hydrochloride salt. Molecular weight of thiamin is 300.8. Molecular weight of thiamin hydrochloride is 337.3

Generally, relying on a voluntary fortification approach may not work as past experience on voluntary fortification with other B vitamins such as folic acid has been unsuccessful. It may also bring other issues to the fore such as those relating to the potential to exceed safe levels, potential technical issues around fortifying the bread rather than the flour and achieving a consistent dosage.

Markets affected

Vitamin and premix suppliers[4]

The four nutrients required are added to the flour stream by way of a premix. This premix is supplied either as a complete blend of all 4 nutrients together or a blend of three of the nutrients (iron, thiamin and niacin) with calcium being added separately as Creta Praeperata (Calcium Carbonate). LFI (UK) Ltd are the main suppliers of the 3 vitamin mix known as Vitamix / Mastermix and also supply the vitamin pre-blend to Omaya who supply the complete blend called 'CretaPlus'. This is favoured by some millers but flexibility of addition is traded for convenience which appeals to some millers and not to others. The cost of adding the nutrients individually would be significantly more than adding as part of a three vitamin mix. See Table 3.

LFI estimates that the direct cost to the miller of meeting the current legal minimum levels required in the BFR fortification is low and works out at around 30p per tonne of flour for the iron niacin and thiamin plus an additional 41p per tonne of flour for fortification with calcium.

LFI is the main company supplying the vitamin premixes used in British flour mills and has been making food powder blends for the milling and baking industries since 1989. They employ a total of 25 people and in 2011 sold more than 320 tonnes of vitamin blends to UK millers with a value approaching 5% of their £7.5 million turnover. The loss of this trade if the legal requirements were removed, and millers chose not to fortify, would be detrimental to this small business and could result in loss of staff and possible redundancy for at least two semi skilled staff.

The cost of the four nutrients is estimated below:

Thiamin (added as thiamine hydrochloride) is made by a small number of manufacturers, mainly in China. There is currently a shortage of this material and prices that had fallen over a number of years to

[4] Prices quoted in this sub section refer to current prices provided by premix manufacturer, LFI (UK) Ltd to Defra. Current prices are relatively similar to 2011 prices.

around £10 per kg are now well over £20 per kg. The cost to millers of adding thiamin alone has been estimated to be approximately 22p/tonne

Niacin (added as nicotinamide) is made by a few manufacturers worldwide and is mainly sourced from India and China. Prices are around £7 per kg. The cost to millers of adding Niacin alone has been estimated to be approximately 23p/tonne.

Iron (added as reduced Iron) is normally sourced from the USA and meeting the specific requirements of the BFR is known to be quite challenging. Prices are around £2.60 per kg. Most millers organise their mill flows such that the mix containing reduced iron is added after control magnets, but before final redress sifters.

Iron can also be added as ferric ammonium citrate in cases where millers cannot organise their mill flows to add the mix after the magnets. These millers require a vitamin product made using the citrate which is significantly dearer as the citrate delivers less iron than reduced iron and costs around twice as much. The cost to millers of adding Iron alone has been estimated to be approximately 20p/tonne.

The price of calcium (added as creta praeperata (calcium carbonate)) is currently around £115 per tonne. This price is cheaper than flour, so there is a tendency to work at the upper levels of addition required by the regulations (235 - 390 mg per 100g of flour). Calcium is often added separately by millers with an estimated cost of approximately 41p/tonne.

Table 3: Cost to miller of adding mandatory fortificants required by the BFR

Nutrient	£ Cost (per tonne of flour)
Thiamin	0.22p
Niacin	0.23p
Iron	0.20p
Calcium	0.41p
Vitamin Premix (Thiamin + Niacin + Iron)	0.30p

* Note that the costs are not additive as adding nutrients individually will still require use of an excipient such as Gypsum (Calcium Sulphate) and testing plus packaging.

Flour millers

The National Association of British and Irish Millers (NABIM) represent the interests of the major flour millers in the UK (and Republic of Ireland). The flour milling industry has an annual turnover of around £1billion. NABIM's 2012 report states that there are 32 milling companies operating 56 mills in the UK producing just over 4 million tonnes of flour for food use[5]. The reports estimates that in 2001/12 UK wheat accounts for around 83% of usage by flour millers with the remaining 17% imported for its different qualities needed to produce stronger flours. The two largest companies account for some 40% of UK flour production. The UK is fairly self sufficient in flour, a vast improvement on the situation some years ago, with a small positive trade balance. Imports of flour account for approximately 1-2% of UK flour sales (60,000 tonnes) whilst about 3-4% of production is exported (175,000 tonnes). Both import and export volumes tend to fluctuate along with currency appreciation or depreciation. The main export

[5] NABIM UK Flour Milling Industry 2012 Report

destination for UK millers is the Republic of Ireland (about 75,000 tonnes per year), whilst France (about 30,000 tonnes per year) is the single largest supplier of flour imports.

In 2011, 5.1 million tonnes of UK wheat was milled; producing just under 4.8 million tonnes (Mt) of flour (some goes to starch production). White bread making flour accounts for half of the flour produced in the UK (52%) with wholemeal and brown flours (7 and 2% respectively) making much lower contributions. Flour sold prepacked to the consumer accounts for around 2.7% of production while other uses such as biscuit flour accounts for 12.6% and flour for use in cakes 2.7%. Flour is also destined for further uses in food ingredients which accounts for 3.7% of production.

Bread manufacturers [6]

The UK Bakery market is worth £3.4 billion and is one of the largest markets in the food industry. Total volume is just under 4 billion units; this equates to nearly 12 million loaves per day.

Whilst the value of the UK retail bread category is in slight decline it is still worth around £2bn. This sector is driven predominantly by the larger (plant) baking companies' which produce around 80% of bread sold in the UK. In-store bakeries (ISBs) within supermarkets produce about 17% and high street retail (craft) master bakers produce the rest.

The 3 main manufacturers (Warburton's, Allied Bakeries and Premier Foods,) account for almost three quarters of the plant bread market by value. Due to the short shelf life, the majority of the bread sold in the UK is produced here. Bread is bought by 99% of British households, and the equivalent of nearly 12 million loaves are sold each day. Approximately 75% of the bread eaten is white and sandwiches are thought to account for 50% of overall bread consumption. Average bread purchases are the equivalent of 43 loaves per person per year. According to the government's National Diet and Nutrition Survey, estimated mean bread consumption is 87 grammes per day for adults aged 19 to 64 years (higher for men (101g) than for women (73g)). This equates to approximately 2½ slices of medium sliced bread.

The Bakery Snacks market is the second largest Bakery category with a value of around £640m. It includes traditional Bakery products such as hot cross buns, crumpets and muffins through to more contemporary products such as panettone. The Rolls and Baps category is the third largest Bakery sector and is worth approximately £514m. In store baked rolls account for 50% of the market and plant wrapped rolls 50%.

Manufacturing sector

Flour is used as an ingredient in many foods such as batters, biscuits, cakes, pies and a range of coatings. It is also used as a minor ingredient in a wide range of foods. It is difficult to estimate how much flour is used by non bread manufacturers but figures from NABIM's 2012 annual report suggest around 12.6% is used in biscuits, 2.7% in cakes and 3.7% as an ingredient in other foods.

For the purposes of this IA, the term "manufacturers" refers to all manufacturers that use flour to produce food products.

Consumers

Consumers will be directly affected by any changes in the regulatory requirements. Consumers will be affected by lower prices, which are assumed to be passed through the food chain. Some groups of the population may be adversely affected by the removal of certain fortificants (see discussion on health impacts above). The extent of these effects will depend on the Option. Increased information from new labelling requirements is also beneficial for consumers. These benefits are specifically covered under the Food Information Regulation Impact Assessment.

We would welcome feedback on any other sectors affected.

Other relevant issues

Relabelling issues

[6] Federation of Bakers, Factsheet No.3, UK Bakery Market (Rev Sept 2010)

The industry is content with current mandatory fortification requirements but is concerned with forthcoming labelling changes which will mean they will have to label the fortificants. At present they have derogation under the Food Labelling Regulations 1996 from labelling these fortificants. This will be seen as an under implementation of EU rules and the newly adopted Food Information Regulation 1169/2011 will require all ingredients to be labelled including those nutrients added to flour.

A change in Government policy on flour fortification may also result in additional labelling changes. If flour is not fortified then industry will only have to label any voluntary additions. If flour is partially fortified those mandatory fortificants will need to be labelled. However any re-labelling costs could be mitigated if changes in flour fortification requirements are aligned with the changes being brought in as a result of the Food Information Regulation (1169/2011). This will enable industry to address all labelling changes at the same time. The new labelling rules are due to come into force in the UK by the end of December 2014 and efforts would be made to coincide any changes to the BFR with this date.

Enforcement

Enforcement of the Regulations is currently carried out by trading standards officers in local authorities and by environmental health officers in London boroughs. The Regulations are generally enforced at the milling stage where the nutrients are added.

Health impacts

Fortification of Flour - Health Assessment

Calcium is the most abundant mineral in the human body and is important for a range of functions in the body including muscle contraction, nerve functions and for the activity of several enzymes. It is a key component of bones and teeth. Deficiency of calcium is linked to rickets, osteomalacia and osteoporosis.

Iron is a component of haemoglobin and is essential for transportation of oxygen throughout the body. Iron is also a component of a number of enzymes involved in a range of the body's metabolic processes. Progressive iron deficiency can lead to iron deficiency anaemia. Low intakes of iron may also be associated with tiredness/lethargy and reproductive health issues for women.

Niacin is an important factor in the utilisation of food energy and deficiency is rare in the UK.

Thiamin is necessary for the release of energy from carbohydrate; deficiency is rare in the UK but some groups have increased needs. Thiamin deficiency in developed countries is associated with alcoholism where low intake can result in alcoholic neuropathy. Further information on the function of these nutrients in the body together with food sources, current intake and effects of deficiency are shown in the SACN report at Annex 4.

Modelling

The most recent data from the National Diet and Nutrition Survey (NDNS[7]) Rolling Programme was used to model the impact of removing the mandatory fortificants from flour on intakes of those nutrients, in adults, older adults and children (see SACN risk assessment at Annex 4). The NDNS dataset was interrogated to provide a distribution of estimated flour consumption by age/sex, based on estimates of the percentage of flour in each NDNS food group. These estimates of flour consumption were used to model the impact of removing mandatory fortification of wheat flour on mean intakes of each fortificant nutrient and on the distribution of intakes in relation to Dietary Reference Values (DRVs).

Assessment of the impact of possible changes to existing fortification practices

Calcium

Low calcium intakes are already seen in a substantial proportion of older children and young women and this is of particular concern. Removal of added calcium from flour would increase the proportion of these groups below the Lower Reference Nutrient Intake (LRNI)[8] (from 15% to 21% for girls; from 8% to 12%

[7] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsStatistics/DH_128166

[8] The LRNI represents a daily level of intake for a nutrient, which, if consumed on a regular daily basis would almost certainly be inadequate for most individuals. The LRNI is not a definitive diagnostic threshold for inadequate nutrient intakes, but because consistent intakes below it re associated with functional and symptomatic nutrient deficiency disorders the LRNI represents a threshold for risk assessment and management of possible nutrient deficiency at a population level.

for boys; and from 6% to 9% for women aged 19 to 64 years). There would also be a general downward shift in population intakes of calcium except for the youngest age group (1½ - 3 years). The increase in the proportion with intakes below the LRNI implies increased risk of deficiency which has been associated with poor bone health. Bone accretion in childhood and adolescence is affected by total calcium intake and determines adult bone mass which is a significant predictor of fracture risk late in life. Currently almost half of all women and one in six men experience osteoporotic fracture in their lifetime.

Iron

A high proportion of girls and women already have low iron intakes and there is evidence of iron deficiency anaemia and low iron stores in a proportion of adult women and older girls in the UK. Removal of iron from wheat flour would increase the proportions below the LRNI from 44% to 50% for girls and from 22% to 25% for women aged 19 to 64 years. Removing iron currently added to wheat flour could result in increased levels of iron deficiency. The impact of low iron intakes on the risk of iron deficiency is unclear as to some extent the body is able to adapt to variation in iron intake. In addition, there is limited evidence of a beneficial effect on iron status from the addition of iron to wheat flour at a population level.

Niacin and Thiamin

Modelling of NDNS data suggests that the impact of removal of added thiamin and niacin from wheat flour may be small.

Socioeconomic and regional health impacts

There has been a long term decline in bread consumption but it remains an important source of the fortificant nutrients, particularly calcium. Survey data shows that the impact of removing mandatory fortification of flour could be greater in low socioeconomic groups as they tend to have lower intakes of these and other nutrients compared with the general population and bread makes a larger contribution to their nutrient intake. There may be regional differences in impact as there are differences in bread consumption by UK country and by regions of England. Regional differences may reflect socio-economic variations.

Effects of the Options under discussion

We would welcome your views on each of the Options discussed below. Some general questions on the effects on stakeholders are outlined in the box below and additionally we have also included some specific questions related to each of the Options under discussion and would welcome any information or comments on these also.

General Questions relating to the Options outlined

Q1 (*millers, vitamin manufacturers and manufacturers using flour*) Will there be any one-off costs for your business or those that you represent as a result of any of the Options discussed? If so, how much? Will there be costs from changing labelling or new labels and if so, could you please quantify them? (Excluding FIR related changes)

Q2: (*millers, vitamin manufacturers and manufacturers using flour*) Will the Options discussed result in ongoing costs or benefits to your business or the businesses you represent? If so, could you please quantify them?

Q3: (*millers, vitamin manufacturers and manufacturers using flour*) Are there any other effects of the Options discussed for your business or those that you represent? If so, could you please quantify them?

Q4: (*enforcement authorities*) What costs or benefits will you incur as a result of the Options discussed in the Impact Assessment? Please quantify these costs or benefits if you can.

Q5: (*consumers and consumer groups*) Will there be any benefits or disadvantages to you or the people you represent as a result of the Options discussed? Please provide details.

Q6: (*small businesses and their representative organisations*) To what extent will you or the businesses you represent be affected by the Options discussed? Please provide details of benefits and costs if you can.

Q7: (*minority ethnic businesses and their representative organisations*) To what extent will you or the businesses you represent be affected by the Options discussed? Please provide details of benefits and costs if you can.

Q8: (*health professionals*) Is there a need for the current fortification requirements? Views are sought on the removal or partial removal of existing requirements on the population or certain groups. (See SACN assessment at Annex 4)

Costs and Benefits

Assessment of One in One Out (OIOO)

Applying the OIOO methodology to the policy issue means that these Regulations **are subject to OIOO**.

It can be classified as **'OUT'** as the cost to both Government and industry are anticipated to be outweighed by the savings and benefits. At this stage, additional information is required to accurately assess the monetised costs and benefits and this will be sought as part of the consultation. The business assessment figures on the summary pages are shown as zero at this time, until the additional information has been gathered in

Option 2 is most likely to be classed as an OUT. Currently, there may be minor costs to industry. Option 2 also meets the Government's deregulatory commitments under RTC and would count towards the overall policy of reducing regulation. Option 1 and 3a and b are not fully deregulatory.

It should be noted that in Options 1, 2 and 3a, competitive markets have been assumed such that the cost to premix suppliers in lost trade is exactly offset by the benefit to the millers and bread manufacturers. This is then passed on to the consumer. However, the final distributional outcome will depend on the competitiveness of the market.

Options

Baseline: DO NOTHING - FULL FORTIFICATION

Description

This is the business as usual Option: retaining the existing mandatory rules on bread and flour. Millers will continue to be required to add the four nutrients at the current specified levels. Vitamin and premix providers will still continue to supply the necessary products and therefore not affected. This Option will ensure that the proportions of the population with low intakes (particularly for calcium and iron in older children and young adults) does not increase and that the risk of exacerbation of current public health burden associated with osteoporosis and anaemia is minimised as a result of reduced levels of calcium and iron respectively in flour. This is not a deregulatory measure and will not reduce any burdens on industry. However flour millers have not voiced any concerns at the current fortification requirements. Any concerns relate to the future labelling requirements of the four nutrients once the new rules on food labelling come into force at the end of 2014. This is outside the scope of this impact assessment.

This would not be a deregulatory measure

Costs and Benefits of maintaining policy baseline

Industry

Costs – There are no incremental costs associated with this Option. This is the baseline to which all other Options are compared. Labelling costs have been captured in the Food Information for Consumers Regulation Impact Assessment. Fortifying flour is not onerous on industry but there will be additional labelling costs when the new Food Information Regulations come into force at the end of 2014 as the current exemption not to label the mandatory nutrients will cease. However, this is not a factor in this consultation as labelling will be required whether nutrient addition is voluntary or mandatory. Industry may choose to add higher levels of the nutrients once they have to label them in order to make additional claims and use this as a marketing tool.

Benefits – There are no incremental benefits associated with this Option. This is the baseline against which all other Options are appraised. In terms of benefits this maintains the status quo so intakes of the four nutrients would be retained. Industry has not expressed any difficulty in complying with the current regulations. Although not a deregulatory measure, the current regime has been in place for over 60 years and it is not overly burdensome for industry. Flour millers are currently geared up to fortify flour easily so continuing with the requirement is not likely to have any significant implications on industry.

Government and Local Authorities (LAs)

Costs- There should be no additional costs to English Local Authorities (LAs), or to Government. LAs will be required to continue to enforce the requirements of the BFR but this is at nominal cost as flour is routinely fortified at the milling stage.

Benefits - There should be no additional benefits to English Local Authorities (LAs), or to Government. English Local Authorities currently enforce the regulations and the rules provide a legal base to ensure fortification takes place.

Consumers

Costs - There would be no additional costs to consumers as the status quo is retained. Following introduction of new labelling rules at the end of 2014 consumers will benefit from additional labelling of flour and flour containing products where the four mandatory nutrients will need to be included on the label. This benefit is covered under the FIR impact assessment.

Benefits - There would be no additional benefits to consumers as the status quo is retained; the nutritional status of the population for all four nutrients continues to be protected. There are currently no concerns about high intakes for any of the four nutrients which are currently required.

Option 1 – PARTIAL FORTIFICATION

Description

This would require fortification of flour with calcium and iron only to protect against risk of insufficiency in at risk groups. The SACN modelling exercise found that the removal of added calcium from wheat flour would adversely affect intakes for young people aged 11-18 years and women aged 19-64 years. Removing added iron from wheat flour would have the greatest impact for girls and women of reproductive age, who have higher iron requirements. SACN noted that there is less evidence for public health benefit to maintain fortification of wheat flour with niacin and thiamin.

While this Option does provide some deregulatory measures it will still retain some regulatory burden for industry. It may also have a detrimental effect on certain sectors such as the premix suppliers. It may also result in some relabelling costs for any foods which provide voluntary nutritional information although some of this may be absorbed into relabelling plans as a result of FIR. Overall the effect on industry is likely to be minimal as regulations are still in force.

This Option is not fully deregulatory but it is reducing some of the burden on industry as regulations will still be required to ensure iron and calcium are added.

Costs and Benefits of Option 1

Industry

Costs

Familiarisation costs (one-off) – *This is a monetised cost.*

There may be some one-off familiarisation costs to industry as they need to become familiar with the relaxation of the rules for niacin and thiamin. Time will be spent acquiring, reading and understanding the legislation, seeking external advice where necessary. It is estimated that it would take a compliance officer no more than one hour to read and become familiar with the regulations and disseminate the key information to staff.

Familiarisation costs are measured in terms of time costs and are therefore quantified by multiplying the time it takes for an official to read and familiarise him/herself with the Regulation by their wage rate. The relevant average hourly rate[9] is uprated by 30% to take account of non-wage labour costs and overheads non-wage labour costs and overheads, in line with standard cost model methodology[10].

The main assumptions for consultation are outlined below. Annex 3 provides the full assumptions used and provides a business breakdown of all affected industry parties. For millers, 1 hour of one production manager's time has been assumed to capture reading the guidance and understanding the implications to their particular business. For medium and large manufacturers, 1 hour of one baker's time per business has been assumed. For micro and small manufacturers, 2 hours has been assumed. The additional hour is given to micro and small businesses to allow for extra time to interpret the regulation. Given these assumptions, the total one off familiarisation costs for industry in England are estimated at around £31,974.

In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (EACs) by dividing the one-off cost by an annuity factor[11]. The total one-off familiarisation cost to businesses in England translates to an equivalent annual cost of £3,715 over a ten year period.

Table 4: Total familiarisation costs to business by Equivalent Annual Cost and by Country

	Number of Food Business Operators	Total Familiarisation Cost	Equivalised Annual Cost
England	**1,581**	**£31,974**	**£3,715**
Wales	126	£2,532	£294
Scotland	163	£3,284	£382
NI	122	£2,457	£285
UK	1,992	£40,247	£4,676

Q9. Stakeholders are invited to comment on whether the assumptions outlined in Annex 3 are reasonable for Option 1.

Redundant stock of vitamin premix suppliers (one off) – *This cost is currently non-monetised*

[9] Wage rates are obtained from ASHE 2011

[10] http://www.berr.gov.uk/files/file44503.pdf

[11] The annuity factor is essentially the sum of the discount factors across the time period over which the policy is appraised. The equivalent annual cost formula is as follows:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^{j} \left(\frac{1}{1+r_i} \right)$$

There may also be a cost to premix suppliers concerning redundant stock that cannot be sold. This might be offset with enough advanced warning of the changes.

Q10. Would there be any costs associated with the using up of redundant stocks of premix or fortified flour. If so please supply details?

Unemployment and impact on local economy (recurring) – *These costs are currently non-monetised.*

This Option could have a significant negative effect on the trade sales of premix suppliers supplying niacin and thiamin. This monetised cost is assumed to be passed through the supply chain to the consumer in terms of lower prices and is explained in the distribution effects section of this Option.

However, the loss in trade could see a reduction in the scale of operations of the premix suppliers and may lead to a contraction in employment size and negative multiplier effects on the local economy. These costs have yet to be monetised. Suppliers of niacin and thiamin (operating outside of the UK) would also be affected as these would no longer be needed.

Q11. Premix suppliers are invited to supply details on the impact of partial fortification on their scale of operations and employment size.

Benefits

Reduction in regulatory burden (recurring) – *This is a monetised benefit.*

Millers and manufacturers using flour in their products will benefit from some reduction in regulatory burden in requiring mandatory addition of only two nutrients, calcium and iron, compared to the current four. This would free up industry to choose whether they wanted to fortify flour with niacin and thiamin and make use of additional marketing claims if they wanted. It has been assumed that industry will not voluntarily fortify.

This benefit is assumed to be passed through the supply chain to the consumer in terms of lower prices. For this IA, we have presented this benefit has in the consumer section.

Q12. Stakeholders are invited to comment on whether the assumption of not continuing to fortify voluntarily is reasonable under this Option.

A more proportionate enforcement procedure for businesses - *This is currently a non-monetised benefit.*

There would be a benefit to industry in terms of moving from the current criminal sanctions regime to a new regime providing for enforcement by way of compliance notice, followed up by a criminal offence in those cases where a compliance notice is not complied with. It is anticipated that the gains will originate from reduced costs and the time saved to businesses in resolving the issues more quickly. This will materialise in the fact the vast majority of contraventions will be resolved through the issuing of compliance notices.

Information provided in the food standards enforcement actions report for 2010/11 shows that there were 69 food standards prosecutions concluded in England[12]. Although it is not possible to give precise figures, the likelihood is that prosecutions resulting from the contravention of the BFR are extremely low or possibly none at all. We would expect the number of cases referred to criminal courts to be reduced. Therefore, this benefit is likely to be small given the number of cases associated with bread and flour are anticipated to be small.

Q13. Stakeholders are invited to comment on the scale of costs saved from this new enforcement procedure.

[12] http://www.food.gov.uk/multimedia/pdfs/board/fsa111108.pdf

Consumers

Costs - There will be no additional costs to consumers. There should be no adverse health impacts as currently niacin and thiamin intakes are adequate across the UK population. The SACN report (see Annex 4, page 4) acknowledges that mean intakes of thiamin and niacin equivalents remain above the RNI for each age/sex group. In addition, the proportion with intakes below the LRNI remains around 0-1% for niacin equivalents and 0-3% for thiamin with no more than 1% below the LRNI for niacin, and no more than 4% below the LRNI for thiamin in any group.

Alternative sources of thiamin can be found from meat but, as meat is considerably more expensive than bread, this would incur costs to consumers who chose this route to maintain their thiamin intakes. Flour would continue to be fortified with calcium and iron, the two nutrients identified as carrying a risk of public health impact.

Benefits

Lower prices for consumers (recurring) – *This is a monetised benefit.*

Assuming that all cost savings for millers and manufacturers are passed down the food chain to the consumer, there will be a benefit to the consumer. The monetised benefit refers to the difference in the premix unit price that premix manufacturers were charging for all for fortificants compared to the premix unit price charged for just calcium and iron. This can be calculated by the difference of £0.71 (four fortificants) and £0.61 (two fortificants), that is £0.10 per tonne and production of 4 million tonnes of flour for food consumption every year (See Table 3, p.12), equivalent to £400,000 per year.

However, for each individual, the monetised benefit is small. As an illustrative example, the cost saving of £400,000 per year, of which this flour produces approximately 4,380,000,000 a year, translates to a saving of £0.01 for the average consumer that consumes 3 loaves of bread per week (see Table 5 below.)

Table 5: Illustrative example of cost savings to consumers

Annual cost savings to consumers	Number of loaves eaten per year	Annual savings of a typical person's bread consumption
£400,000	**4,380,000,000**	**£0.01**

Government and Local Authorities

Costs

Familiarisation costs (one-off) – *This is a monetised cost.*

Although fairly small, local authorities will also need to become familiar with the updated Regulations. It is estimated that it would take one Trading Standards officer **1 hour** to read the guidance. Once again, wage rates have been uprated by 30% to take account of non-wage labour costs and overheads non-wage labour costs and overheads, in accordance with the standard cost model.

Based on the number of enforcement authorities with responsibility for food this is thought to be a cost of around £8,000, as outlined in Table 6, translating into an equivalent annual cost of £906 over a ten year period. This cost may be slightly reduced if training is made available both on the provisions of the FIR but also the new approach to enforcement in England through the use of compliance notices as a front line method of enforcement. Under all Options opportunities to provide this support can be explored and will result in a training cost for central and local Government. All workings are provided in Annex 3.

Table 6: Familiarisation costs for trading standards officers, by Equivalent Annual Cost to Enforcement by Country[13]

	Number of Local Authorities	Total Familiarisation Cost	Equivalised Annual Cost
England	**433**	**£7,798**	**£906**
Wales	22	£396	£46
Scotland	32	£576	£67
Northern Ireland	26	£468	£54
UK	513	£9,239	£1,073

Q14. Enforcement officers are invited to comment on whether the familiarisation assumptions outlined in Annex 3 are reasonable.

Simpler enforcement procedures for enforcement officers – *This benefit is currently non-monetised.* There is a potential benefit to Government in terms of moving from the current criminal sanctions regime to the new civil sanctions regime. It is anticipated that the gains will originate from reduced court costs as the number of hearings will be reduced as issues will be resolved through issuing Compliance Notices, and the time saved to enforcement officers in resolving the issues more quickly instead of preparing for a court case. However, this benefit is likely to be relatively small given the number of cases associated with food labelling dealt with by enforcers are anticipated to be small.

Q15. In what way would a Compliance Notice approach benefit enforcement officers in general? Can you quantify any savings that may be realised?

Q16. What other additional costs might there be associated with partial fortification?

Q17. We would welcome any additional data on potential health costs which should be considered.

Q18. We would welcome any additional views on this partial fortification Option and any advantages or disadvantages associated with this Option.

Summary of monetised costs and benefits of Option 1

Table 7 provides a summary of the monetised costs and benefits for policy Option 1. The net present value is £3.40 million over 10 years. However, the business net present value is around -£32,000. This reflects large benefits incurred by consumers but also the lack of information in terms of monetised costs and benefits.

[13] Source for local authority numbers
(1) England – 433 – http://www.communities.gov.uk/newsroom/factsandfigures/local/facts/localgovernment/?id=1682861
(2) Scotland – 32 – http://www.direct.gov.uk/en/dl1/directories/devolvedadministrations/dg_4003604
(3) Wales – 22 – http://wales.gov.uk/topics/localgovernment/localauthorities/?lang=en
(4) Northern Ireland – 26 – http://www.doeni.gov.uk/index/local_government/council_structure.htm

Table 7: Summary of monetised costs and benefits - Option 1

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total cost/benefit	Annual Cost or Benefits/EA	PV
COSTS													
Industry													
Familiarisation (transition)	£31,974	£0	£0	£0	£0	£0	£0	£0	£0	£0	£31,974	£3,715	£31,974
Total Industry Costs	**£31,974**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£31,974**	**£3,715**	**£31,974**
Government													
Familiarisation (transition)	£7,798	£0	£0	£0	£0	£0	£0	£0	£0	£0	£7,798	£906	£7,798
Total Government Costs	**£7,798**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£7,798**	**£906**	**£7,798**
TOTAL COSTS	**£39,772**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£39,772**	**£4,621**	**£39,772**
BENEFITS													
Consumers													
Lower prices for bread and products containing flour	£400,000	£400,000	£400,000	£400,000	£400,000	£400,000	£400,000	£400,000	£400,000	£400,000	£4,000,000	£400,000	£3,443,075
Total Consumer Benefits	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£4,000,000**	**£400,000**	**£3,443,075**
TOTAL BENEFITS	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£4,000,000**	**£400,000**	**£3,443,075**
NET BENEFIT													
Total Net (Benefit)	**£360,228**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£400,000**	**£3,960,228**	**£395,379**	**£3,403,303**
Total Net Business (Benefit)	-£31,974	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£31,974	-£3,715	-£31,974

Risks

Voluntary fortification

We assume that industry will not fortify. However, this is a commercial decision for industry but we recognise that there may be additional cost and/or benefit in choosing to voluntarily fortify. As such, we have outlined below, the main costs and benefits that may be incurred. These costs and benefits are not included in the impact assessment.

Additional time for familiarisation - It is possible that more enforcement might actually be necessary if industry chooses to fortify voluntarily as the Fortified Food Regulations would need to be enforced. Therefore, enforcers and firms may need to re-familiarise themselves with Fortified Foods Regulations and what industry are allowed to do.

Reformulation cost – Industry may choose voluntarily to fortify flour but a disincentive to this may be that fortification would need to take place in larger amounts than at present in order to comply with the Fortified Food Regulations in meeting the 15% of the RDA requirement and the provision of nutrition labelling (see page 10).This will incur a one-off reformulation cost for the premix supplier as well as increased costs for the manufacturers.

Greater choice – If industry were to fortify, consumers who wish to buy bread made from unfortified flour will have a greater choice. Unfortified bread may generally be expected to be more readily available for those wishing to avoid added nutrients, for example some people need to avoid iron or calcium for certain medical reasons. This is currently a non-monetised benefit.

More information for consumers – In addition, if industry were to fortify, new labelling requirements will mean any nutrients added will need to be clearly identified in the ingredients list and accompanied with the required nutritional labelling information. Wholemeal will continue to contain a natural level of 3 of the nutrients (iron, thiamin and niacin) and consumers could thus choose wholemeal if they wanted to maintain their intakes of these nutrients from bread.

Distributional effects

This Option is likely to incur distributional effects along the food chain. Competitive markets have been assumed; all input cost savings from millers is passed through the food chain all the way to the consumer via the manufacturers. However, the final distributional outcome will depend on the competitiveness of the market. The distributional effects are outlined below.

Premix suppliers who currently produce the fortificant premix are likely to lose trade from no longer having to supply niacin and thiamin in the premix to millers. As outlined in the benefits to the consumer, existing evidence from industry suggests that premix suppliers are likely to lose £4 million over a 10 year period, an annual cost of £0.4 million per annum.

Millers and manufacturers will benefit from the some cost savings of not adding niacin and thiamin to flour. This gain for millers is linked to the loss of trade incurred by premix suppliers as it is a direct transfer. Therefore, millers in the UK are likely to benefit by £0.4million each year or £4 million over a 10 year period. There may be some cost savings to bakers and manufacturers using flour as an ingredient if millers pass the cost savings resulting from a cheaper premix purchase price.

Consumers are likely to benefit from some cost savings of purchasing end products if these savings are passed along the chain. Again, as it is linked to the cost to premix suppliers and, in turn, the benefit to millers and manufacturers, it is assumed that consumers in the UK are likely to benefit by £0.4million each year or £4 million over a 10 year period (as outlined in the consumer benefits section above.) This is the saving to consumers is the same saving as that of millers and manufacturers, not in addition.

Option 2 - NO FORTIFICATION

Description

This Option would remove specific rules on bread and flour in England. It would be up to industry to decide whether to fortify flour voluntarily or not. Assessment of this Option is based on industry not continuing to fortify because any voluntary action would need to comply with the Fortified Food Regulations. If voluntary fortification was chosen by industry the nutrients would need to meet the 15% RDA requirement meaning that larger amounts of two of the nutrients (iron and niacin) would be required (see Table 2).

This is a deregulatory measure and would further reduce the burden of regulation on industry. However, it would also remove the current level playing field with other parts of the UK and millers may find it more problematical to have different demands from their customers. Opening up the requirements could therefore put extra burdens on the millers. There would be public health impacts relating to insufficiency particularly for calcium and iron in some population groups? It may also be harder to monitor the population's intake of these nutrients because there will be no control over the amounts added.

It is feasible that repeal of the rules could be enacted within the new Food Information Regulations in England thereby avoiding the need for a separate SI for revocation.

This would be a deregulatory measure.

Costs and Benefits of Option 2

Industry

Costs

Familiarisation costs (one-off) – *This is a monetised cost.*

Same as Option 1. Although the repeal of the BFR will mean that there is no regulation, industry will need to familiarise themselves with the consequences of the repeal.

Q19. Stakeholders are invited to comment on whether the assumptions outlined in Annex 3 are reasonable for Option 2.

Redundant stock of vitamin premix suppliers (one off) – *This cost is currently non-monetised*.

As in Option 1, there may also be a cost to premix suppliers concerning redundant stock that cannot be sold. However, we anticipate that these costs are likely to be larger than Option 1 although this might be offset with enough advanced warning of the changes.

Q20. Would there be any costs associated with the using up of redundant stocks of premix or fortified flour. If so please supply details?

Unemployment and impact on local economy (recurring) – *These costs are currently non-monetised.*

As Option 1; this Option could have a significant negative effect on the trade sales of premix suppliers supplying niacin and thiamin. This monetised cost is assumed to be passed through the supply chain to the consumer in terms of lower prices and is explained in the distribution effects section of this Option.

However, the loss in trade could currents scale of operations of the premix suppliers may lead to a contraction in employment size and negative multiplier effects on the local economy. It is anticipated that these costs will be larger than in Option 1. Suppliers of niacin and thiamin (operating outside of the UK) would also be affected as these would no longer be needed.

Q21. Premix suppliers are invited to supply details on the impact of no mandatory fortification on their scale of operations and employment size.

Benefits

Reduction in regulatory burden (recurring) – *This is a monetised benefit.*

As in Option 1; millers and manufacturers using flour in their products will benefit from reduction in regulatory burden in not having to fortify any of the four fortificants compared to the current practise of all four. This would free up industry to choose whether they wanted to fortify flour with niacin, thiamin, calcium and iron in order to make use of additional marketing claims if they wanted. As in Option 1, it has been assumed that industry will not voluntarily fortify. This monetised benefit, which is larger than in Option 1, is also assumed to be passed through the supply chain to the consumer in terms of lower prices and is explained in the distribution effects section of this Option.

Q22. Stakeholders are invited to comment on whether the assumption of not continuing to fortify voluntarily is reasonable under this Option.

Q23. If voluntary fortification is a reasonable assumption, please provide any available evidence to estimate the cost savings from not having to reformulate the premix.

Increased trade for millers in non fortified flour – *This is currently a non-monetised benefit.*

Non fortified flour used in ingredient use can be produced lawfully in the UK and allows millers to compete directly with unfortified flour producers from the EU and abroad. This could have competitive benefits for millers allowing access to potentially new markets. For manufacturers of products containing flour as an ingredient, there could also be competitive advantages here as flour will not contain any added nutrients.

Q24. Stakeholders are invited to provide any information data that may help to estimate the potential trade opportunities.

Q25. What additional costs might result if a range of fortified and unfortified flours were required? Would there be any reduction in productivity?

Q26. Would there be any significant affect on the market or in trade?

Consumers

Costs

Negative health effects – *This cost is currently non-monetised.*

White and brown wheat flours are important sources of calcium, iron, niacin and thiamin in the UK diet. The recent SACN risk assessment (See Annex 4) suggests that if the fortification requirements of the BFR were no longer required then more people would be likely to fail to meet the nutritional recommendations particularly for iron and calcium. Older children, young adults and low income groups would be particularly adversely affected by reduction in calcium and to a lesser extent iron content of flour. Although it is not possible monetise the end outcomes on consumers, it is possible to provide the scale of the direct impact on diets, which are outlined below.

1. **Reduced calcium intake –** If industry no longer fortify flour then this Option may result in the number of older girls with intakes below the Lower Reference Nutrient Intake (LRNI) for calcium increasing from 15% to 21% with similar increases for older boys (8% below the LRNI increasing to 12%) and women (increase from 6% below the LRNI to 9%). There is evidence that habitual calcium intakes below the LRNI are not compatible with future good bone health.
2. **Reduced iron intake –** For iron, a high proportion of girls and women have low intakes and removal from flour is likely to result in an increase in the proportions below the LRNI (44% to 50% for girls and 22% to 25% for women) with potential adverse effects on anaemia. Iron deficiency anaemia has been reported to increase tiredness and lethargy and has been associated with negative pregnancy outcomes. However, the health cost to consumers of anaemia is likely to be relatively small.

Since wheat flour represents a uniformly consumed ingredient across ethnic groups, removal of fortification requirements may result in impacts for all ethnic groups. This may increase an already significant public health burden.

Bread consumption is also in decline but it still remains an important source of iron. Low income groups who tend to consume more bread may be more affected. Regional differences, possibly linked to socioeconomic factors, in bread and flour consumption may result in certain areas being more adversely affected by removal of mandatory fortification. White bread purchases in England are highest in the West Midlands and lowest in London with a difference of 162g/week for white bread and 170g/week for total bread. The overall result could be a decline in iron intakes for certain population groups.

At the same time, there are other sources of iron in the diet and iron is also routinely added to other foods, particularly breakfast cereals, on a voluntary basis. There is also debate about the availability of iron from fortified foods and the ability of the body to increase absorption of iron when iron status is low.

Q27. Other views on the health impacts of non fortification are welcomed.

Benefits

Lower prices for consumers (recurring) – *This is a monetised benefit.*

As in Option 1; Assuming that all cost savings for millers and manufacturers are passed down the food chain to the consumer, there will be a benefit to the consumer. The monetised benefit refers to the difference in the premix unit price that premix manufacturers were charging for all for fortificants compared to the absence of any premix and therefore a premix unit price of 0. This can be calculated by the difference of £0.71 (four fortificants) and £0.00 (no fortificants), that is £0.71 per tonne and production of 4 million tonnes of flour for food consumption every year (See Table 3, p.12), equivalent to £2.84 million per year or £28.4 million over 10 years.

However, for each individual, the monetised benefit is small. As an illustrative example, the cost saving of £2.84 million per year, of which this flour produces approximately 4,380,000,000 a year, translates to a saving of £0.10 for the average consumer that consumes 3 loaves of bread per week (see Table 8 below.)

Table 8: Illustrative example of cost savings to consumers

Annual cost savings to consumers	Number of loaves eaten per year	Annual savings of a typical person's bread consumption
£2,840,000	4,380,000,000	£0.10

Government and local authorities

Costs

Familiarisation costs (one-off) – *This is a monetised cost.*

Same as Option 1.

Q28. Stakeholders are invited to comment on whether the assumptions outlined in Annex 3 are reasonable for Option 2.

Social care costs and NHS costs (recurring) – *These costs are currently non-monetised.*

Although evidence suggests that calcium and iron deficiencies contribute to osteoporosis and anaemia respectively, no studies have been able to quantify the correlation between the diseases and intake levels. Therefore, despite that fact that the conditions are costly to the NHS, particularly osteoporotic fractures, we are not able to estimate a figure for additional total health costs that would arise from ending flour fortification. However, it is possible to provide an illustrative example to provide the magnitude of the health impacts.

1. Osteoporosis

    a. Social care costs - As stated earlier, many sufferers of osteoporosis who develop a fracture require support in their everyday lives because of restricted mobility. As this is generally provided by local authorities, a higher rate of osteoporosis may impose additional costs on them. The social care costs associated with hip fractures have been estimated to be £3,879 on average over two years and those of spine and forearm fractures have been put at £225[2].

    b. NHS Costs – A higher incidence of osteoporosis would have cost implications for the NHS mainly resulting from treating bone fractures. The cost to the NHS of treating hip fracture is approximately £12,000[14] which includes the cost of operation, hospitalisation and referral to intermediate care. Spine and forearm fractures are less expensive to treat - roughly £3,500 and £1,000 respectively. The NHS may incur additional costs from drug treatments for osteoporosis. The cost of these drugs is on average £2000 per person for a 5 year course of treatment[2].

Assuming that no mandatory fortification were to lead to an increase in the hip, spine and forearm fractures by **2%** per annum, this could lead to:

- An increase in social care costs of £3.06 million per year
- An increase in NHS costs[15] £22.39 million per year

Q29. Stakeholders are invited to comment on whether the illustrative health cost assumptions are reasonable for Option 2. If not, please provide evidence.

2. Anaemia

Given that the effects of iron deficient anaemia are so varied, it is difficult to estimate the cost that a higher incidence of the disease would generate for affected groups including consumers and the NHS. While no analysis has been done to our knowledge of the quality of life effects of being anaemic, the symptoms of anaemia such as tiredness, lethargy and shortness of breath are generally fairly mild and are easily treated with iron supplements. The health and social care costs to local authorities and the NHS of anaemia is therefore relatively small.

Benefits

Reduced enforcement for local authorities (recurring) – *This is a monetised benefit.*

There would be one less set of food regulations for LAs to enforce. Trading standards officers will no longer have to enforce the laws regarding mandatory fortification so there may be a small reduction in their time spent on bread and flour enforcement. This will be an annual saving over the 10 year period when compared to the baseline.

However, time spent by LAs enforcing the BFR across the existing 56 mills is anticipated to be small as flour is fortified at the mill in most cases. It may also be possible to repeal the BFR in England through the new FIR rather than through a separate revocation SI.

[14] Fracture prevention and service: an economic evaluation DH 2009
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_110098

[15] An aggregate of all costs for operation, hospitalisation and referral to intermediate care and drug treatment

Table 9 presents the time saving benefits. It is anticipated that this reduced enforcement equates to **30 minutes** of one Trading Standards officer's time. In accordance with the standard cost model, wage rates outlined in Annex 3 have been uprated by 30% to take account of non-wage labour costs and overheads non-wage labour costs and overheads.

Based on the number of enforcement authorities with responsibility for food this is thought to be a benefit of around £3,900, translating into an equivalent annual cost of £453 over a ten year period.

Table 9: Time saving benefits from reduced enforcement from Bread and Flour cases, by Equivalised Annual Benefit and by Country

	Number of Local Authorities	Total Enforcement Savings	Annual Enforcement Savings
England	**433**	**£38,992**	**£3,899**
Wales	22	£1,981	£198
Scotland	32	£2,882	£288
Northern Ireland	26	£2,341	£234
UK	513	£46,196	£4,620

Q30. Stakeholders are invited to comment on whether the time saving assumptions above are reasonable for Option 2.

Summary of monetised costs and benefits of Option 2

Table 10 provides a summary of the monetised costs and benefits for policy Option 2. The net present value is £24.44 million over 10 years.
However, the business net present value is around -£32,000. This reflects large benefits incurred by consumers but also the lack of information in terms of monetised costs and benefits.

Table 10: Summary of monetised costs and benefits - Option 2

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total cost/benefit	Annual Cost or Benefits/EA	PV
COSTS													
Industry													
Familiarisation (transition)	£31,974	£0	£0	£0	£0	£0	£0	£0	£0	£0	£31,974	£3,715	£31,974
Total Industry Costs	**£31,974**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£31,974**	**£3,715**	**£31,974**
Government													
Familiarisation (transition)	£7,798	£0	£0	£0	£0	£0	£0	£0	£0	£0	£7,798	£906	£7,798
Total Government Costs	**£7,798**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£7,798**	**£906**	**£7,798**
TOTAL COSTS	**£39,772**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£39,772**	**£4,621**	**£39,772**
BENEFITS													
Government													
Adminstrative burden savings	£3,899	£3,899	£3,899	£3,899	£3,899	£3,899	£3,899	£3,899	£3,899	£3,899	£38,992	£3,899	£33,563
Total Government Benefits	**£3,899**	**£3,899**	**£3,899**	**£3,899**	**£3,899**	**£3,899**	**£3,899**	**£3,899**	**£3,899**	**£3,899**	**£38,992**	**£3,899**	**£33,563**
Consumers													
Lower prices for bread and products containing flour	£2,840,000	£2,840,000	£2,840,000	£2,840,000	£2,840,000	£2,840,000	£2,840,000	£2,840,000	£2,840,000	£2,840,000	£28,400,000	£2,840,000	£24,445,830
Total Consumer Benefits	**£2,840,000**	**£2,840,000**	**£2,840,000**	**£2,840,000**	**£2,840,000**	**£2,840,000**	**£2,840,000**	**£2,840,000**	**£2,840,000**	**£2,840,000**	**£28,400,000**	**£2,840,000**	**£24,445,830**
TOTAL BENEFITS	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£28,438,992**	**£2,843,899**	**£24,479,392**
NET BENEFIT													
Total Net (Benefit)	**£2,804,127**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£2,843,899**	**£28,399,220**	**£2,839,279**	**£24,439,621**
Total Net Business (Benefit)	-£31,974	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£31,974	-£3,715	-£31,974

Risks

Socioeconomic and regional health impacts

The impact of removing the mandatory addition of nutrients to flour could be greater in low income groups, particularly for calcium and iron. This is because low income groups tend to have lower intakes of these nutrients compared with the general population and tend to consume more bread (particularly white bread). (See SACN report Annex 4) For example for white bread the lowest income quintile purchased170g/week more than the highest quintile, approximately equivalent to an additional small slice of bread per day (24g). Removing the addition of nutrients to white bread alone would reduce the iron and calcium content of the diet for the lowest income quintile by 0.14mg iron and 28mg calcium per day (2% of the EAR for iron and 5% for calcium).

In term of regional effects white bread consumption (NDNS data from 2000/01) for men was found to be higher in Northern England and Central and South West England and Wales than in Scotland and London and the South East. However no differences were found for women and no clear pattern for other age groups. There was also no clear pattern of regional differences in consumption of other flour-containing products.

It should be noted that any apparent regional differences may be partly due to socioeconomic factors.

Voluntary fortification

In the same way as Option 1, we assume that industry will not fortify. However, this is a commercial decision for industry but we recognise that there may be additional cost and/or benefit in choosing to voluntarily fortify. As such, we have outlined below, the main costs and benefits that may be incurred. These economic costs and benefits are not included in this impact assessment.

Additional time for familiarisation - It is possible that more enforcement might actually be necessary if industry chooses to fortify voluntarily as the Fortified Food regulations would need to be enforced. Therefore, firms and enforcers may need to re-familiarise themselves with Fortified Foods Regulations and what industry are allowed to do.

Reformulation cost – Industry may choose voluntarily to fortify flour but a disincentive to this may be that fortification would need to take place in larger amounts than at present in order to comply with the Fortified Food Regulations in meeting the 15% of the RDA requirement and the provision of nutrition labelling (see page 10).This will incur a one-off reformulation cost for the premix supplier as well as increased costs for the manufacturers.

Greater choice – If industry were to fortify, consumers who wish to buy bread made from unfortified flour will have a greater choice. Unfortified bread may generally be expected to be more readily available for those wishing to avoid added nutrients, for example some people need to avoid iron or calcium for certain medical reasons. This is currently a non-monetised benefit.

More information for consumers – In addition, if industry were to fortify, new labelling requirements will mean any nutrients added will need to be clearly identified in the ingredients list and accompanied with the required nutritional labelling information. Wholemeal will continue to contain a natural level of 3 of the nutrients (iron, thiamin and niacin) and consumers could thus choose wholemeal if they wanted to maintain their intakes of these nutrients from bread.

Distributional effects

This Option is likely to incur distributional effects along the food chain. Competitive markets have been assumed; all input cost savings from millers is passed through the food chain all the way to the consumer via the manufacturers. However, the final distributional outcome will depend on the competitiveness of the market. The distributional effects are outlined below.

Premix suppliers who currently produce the fortificant premix will lose trade from no longer having to supply the premix to millers. As outlined in the benefits to the consumer, existing evidence from industry suggests that premix suppliers are likely to lose £28.4 million over a 10 year period, an annual cost of £2.84 million per annum.

Millers and manufacturers will benefit from the some cost savings of completely removing of fortification requirements to flour. This gain for millers is linked to the loss of trade incurred by premix suppliers as it is a direct transfer. Therefore, millers in the UK are likely to benefit by £2.84 each year or £28.4 million over a 10 year period. There may be some cost savings to bakers and manufacturers using flour as an ingredient if millers pass the cost savings resulting from a cheaper premix purchase price.

Consumers are likely to benefit from some cost savings of purchasing end products if these savings are passed along the chain. Again, as it is linked to the cost to premix suppliers and, in turn, the benefit to millers and manufacturers, it is assumed that consumers in the UK are likely to benefit by £2.84million each year or £28.4 million over a 10 year period (as outlined in the consumer benefits section above.) This is the saving to consumers is the same saving as that of millers and manufacturers, not in addition.

Q30. We would welcome any further evidence which should be considered which demonstrates the cost implications of the removal of fortification on health and/or the economy'.

Q31. Are there any other costs or benefits of the removal of flour fortification that have not been considered?

Option 3

Some further possible options have been considered which may reduce the regulatory burden for industry but still continue to protect the health of the UK population health. These have not been considered in depth but if stakeholder views suggest they would be a viable Option then further work on costs and benefits could be carried out.

Option 3a- Fortification of bread flour only

Description

This Option would require fortification of bread flour only with the four nutrients. The UK bakery market is worth £3.4 billion according to data from the Federation of Bakers and bread accounts for 61% of value sales. Bread is consumed by 99% of the population so this Option retains fortification for bread as the main source of fortified flour in the diet.

There is no legislative definition of bread flour so this would have to be considered. It could be defined based on its protein content (higher protein content flours tend to be used for bread making than for cake and biscuit making). Alternatively, legislation could simply focus on defining the use to which the flour is put, i.e. any flour which is to be used for making bread, or certain types of bread, is "bread-making flour" for the purposes of legislation.

This could be seen as an attractive Option as it focuses fortification on bread which is the most commonly consumed source of flour and allows other users of flour to use unfortified flour if desired. This enables a degree of protection for intakes of all four nutrients although there will be an increase in the numbers with intakes below the LRNI which may impact upon public health, particularly bone health and iron deficiency anaemia. For the flour miller this may complicate matters as they will have to produce fortified and unfortified flour.

This would not be a fully deregulatory measure as regulations will still be required.

Industry

Costs

Familiarisation costs (one-off) – *This is a monetised cost.*

Same as Option 1 and 2.

Q32. Stakeholders are invited to comment on whether the assumptions outlined in Annex 3 are reasonable for Option 3a.

Redundant stock (one off) – *This cost is currently non-monetised.*

As in Options 1 and 2, there may also be a cost to premix suppliers concerning redundant stock that cannot be sold. This might be offset with enough advanced warning of the changes. We assume that these costs are likely to be smaller than Option 2.

Q33. Would there be any costs associated with the using up of redundant stocks of premix or fortified flour. If so please supply details?

Unemployment and impact on local economy (recurring) – *These costs are currently non-monetised.*

As in Options 1 and 2; this Option could have a negative effect on the trade sales of premix suppliers supplying the fortificants for non bread flour. This monetised cost is assumed to be passed through the supply chain to the consumer in terms of lower prices and is explained in the distribution effects section of this Option.

However, the loss in trade could see a reduction in the scale of operations of the premix suppliers and may lead to a contraction in employment size and negative multiplier effects on the local economy. It is

anticipated that these costs will be smaller than in Option 2. Suppliers of fortificants (operating outside of the UK) to the premix suppliers would also be affected as these would no longer be needed.

Q34. Premix suppliers are invited to supply details on the impact on their scale of operations and employment size of just supplying premix for bread flour purposes.

Capital investment costs – *This is currently a non-monetised cost*.

Fortification of bread making flour only would probably require capital investment in mills for new fortification equipment. Previous costs when assessing folic acid fortification estimated this at approximately £20k per site[16]. However, the addition of new equipment may be impossible for certain sites due to layout of the mills and space constraints. In addition, there would be significant operational complexities and managerial challenges in distinguishing between flours of different protein content.

Fortifying bread flour only could add significant costs to millers as they would be producing unfortified flour for non bread use alongside fortified flour for bread use. The milling industry is likely to argue that bread-making flour cannot be separated easily from other flours in mills although, as already indicated, it might be possible to achieve separation of flours according to protein content. There is however no strict protein threshold for different products.

One other alternative Option could be to fortify at the bread making stage. However, fortification of bread in the bakery is technically more demanding than the fortification of flour in the flourmill; for example it is harder to achieve accurate fortification levels in the bakery compared to the flour mill because of the large number of recipes used to make bread. In terms of administrative burdens, the fewer the number of smaller firms affected, the lower the cost to industry. Therefore the Option of fortifying bread is likely to have a much greater cost compared with fortification at the mill as there are many more bakeries than mills.

Q35. Millers are invited to supply details on estimates regarding new fortification equipment needed for bread making flour.

Benefits

Reduction in regulatory burden (recurring) – *This is a monetised benefit.*

As in Options 1 and 2; Millers and manufacturers using flour in their products will benefit from reduction in regulatory burden in only having to fortify bread flour with the four fortificants compared to the current practice of having to fortify flour more generally. This would free up industry to choose whether they wanted to fortify non bread flour with calcium, iron, niacin and thiamin in order to make use of additional marketing claims if they wanted.

As in Options 1 and 2, it has been assumed that industry will not voluntarily fortify. This monetised benefit is also assumed to be passed through the supply chain to the consumer in terms of lower prices and is explained in the distribution effects section of this Option.

A more proportionate enforcement procedure for businesses – *This is currently a non-monetised benefit.*
Same as Option 1.

Increased trade for millers in non fortified flour – *This is currently a non-monetised benefit.*

Same as Option 2.

Consumers

Costs

Negative health impacts – *This is currently a non-monetised cost*.

[16] FSA Board Paper; FSA 07/06/04 Agenda Item 3.1, 14 June 2007- Improving folate intakes of women of reproductive age and preventing neural tube defects: practical issues; Para 24

Consumption of bread is widespread throughout the population and this Option therefore focuses attention on bread as the main dietary source of fortified flour. Modelling suggests that intakes of calcium, iron, niacin and thiamin from flour could fall by up to 40% under this Option (see Annex 4). Therefore, the health impacts to consumers would be less than a no fortification Option but there may be detrimental effects for some consumers.

Benefits

Lower prices for consumers (recurring) – *This is a monetised benefit.*

Assuming that all cost savings for millers and manufacturers are passed down the food chain to the consumer, there will be a benefit to the consumer. The monetised benefit refers to the difference in the premix unit price that premix manufacturers were charging for all for fortificants of £0.71 per tonne for all 4 million tonnes of flour used for food consumption production every year, compared to only fortifying 61% of total flour used for bread flour, that is 2.44 million tonnes. This is equivalent to a cost saving to consumers of £1.1 million per year or £11.08 million over 10 years.

However, for each individual, the monetised benefit is small. As an illustrative example, the cost saving of £11.08 million per year, of which this flour produces approximately 4,380,000,000 a year, translates to a saving of £0.04 for the average consumer that consumes 3 loaves of bread per week (see Table 11 below.)

Table 11: Illustrative example of cost savings to consumers

Annual cost savings to consumers	Number of loaves eaten per year	Annual savings of a typical person's bread consumption
£1,107,600	**4,380,000,000**	**£0.04**

Government and local authorities

Costs

Familiarisation costs (one-off) – *This is a monetised cost.*

Same as Options 1 and 2.

Q36. Enforcement officers are invited to comment on whether the familiarisation assumptions outlined in Annex 3 are reasonable.

Social care and NHS Costs – *This is a monetised cost.*

As explained above, modelling suggests that intakes of calcium, iron, niacin and thiamin from flour could fall by up to 40% under this Option. This may lead, therefore, to the adverse health impacts described in the no fortification Option (Option 2), namely higher incidence of osteoporosis and iron deficient anaemia. However, given that we are unsure of the correlation between the incidence of the public health impact and the level of intake of the relevant nutrient we cannot estimate the possible additional total health costs that may occur. However, it is possible to provide an illustrative example to provide the magnitude of the health impacts.

1. Osteoporosis
    c. Social care costs - As stated earlier, many sufferers of osteoporosis who develop a fracture require support in their everyday lives because of restricted mobility. As this is generally provided by local authorities, a higher rate of osteoporosis may impose additional costs on them. The social care costs associated with hip fractures have been

estimated to be £3,879 on average over two years and those of spine and forearm fractures have been put at £225[2].

d. NHS Costs – A higher incidence of osteoporosis would have cost implications for the NHS mainly resulting from treating bone fractures. The cost to the NHS of treating hip fracture is approximately £12,000[17] which includes the cost of operation, hospitalisation and referral to intermediate care. Spine and forearm fractures are less expensive to treat - roughly £3,500 and £1,000 respectively. The NHS may incur additional costs from drug treatments for osteoporosis. The cost of these drugs is on average £2000 per person for a 5 year course of treatment[2].

Assuming that no mandatory fortification were to lead to an increase in the hip, spine and forearm fractures by **0.5%** per annum, this could lead to:

- An increase in social care costs of £0.68 million per year
- An increase in NHS costs[18] £5.6 million per year

Q29. Stakeholders are invited to comment on whether the illustrative health cost assumptions are reasonable for Option 2. If not, please provide evidence.

2. Anaemia

Given that the effects of iron deficient anaemia are so varied, it is difficult to estimate the cost that a higher incidence of the disease would generate for affected groups including consumers and the NHS. While no analysis has been done to our knowledge of the quality of life effects of being anaemic, the symptoms of anaemia such as tiredness, lethargy and shortness of breath are generally fairly mild and are easily treated with iron supplements. Similar to Option 2, the health and social care costs to local authorities and the NHS of anaemia is therefore relatively small.

Benefits

Simpler enforcement procedures for enforcement officers – *This benefit is currently non-monetised.*

Same as Option 1.

Q37. In what way would a Compliance Notice approach benefit enforcement officers in general? Can you quantify any savings that may be realised?

Q38. Is this a viable Option and what challenges would millers face?

Q39. What additional costs would be associated with production of fortified and unfortified flour?

Summary of monetised costs and benefits of Option 3a

Table 12 provides a summary of the monetised costs and benefits for policy 3a. The net present value is £9.49 million over 10 years. However, the business net present value is around -£32,000. This reflects large benefits incurred by consumers but also the lack of information in terms of monetised costs and benefits.

[17] Fracture prevention and service: an economic evaluation DH 2009
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_110098
[18] An aggregate of all costs for operation, hospitalisation and referral to intermediate care and drug treatment

Table 12: Summary of monetised costs and benefits - Option 3a

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total cost/benefit	Annual Cost or Benefits/EA	PV
COSTS													
Industry													
Familiarisation (transition)	£31,974	£0	£0	£0	£0	£0	£0	£0	£0	£0	£31,974	£3,715	£31,974
Total Industry Costs	**£31,974**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£31,974**	**£3,715**	**£31,974**
Government													
Familiarisation (transition)	£7,798	£0	£0	£0	£0	£0	£0	£0	£0	£0	£7,798	£906	£7,798
Total Government Costs	**£7,798**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£7,798**	**£906**	**£7,798**
TOTAL COSTS	**£39,772**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£39,772**	**£4,621**	**£39,772**
BENEFITS													
Consumers													
Lower prices for bread and products containing flour	£1,107,600	£1,107,600	£1,107,600	£1,107,600	£1,107,600	£1,107,600	£1,107,600	£1,107,600	£1,107,600	£1,107,600	£11,076,000	£1,107,600	£9,533,874
Total Consumer Benefits	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£11,076,000**	**£1,107,600**	**£9,533,874**
TOTAL BENEFITS	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£11,076,000**	**£1,107,600**	**£9,533,874**
NET BENEFIT													
Total Net (Benefit)	**£1,067,828**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£1,107,600**	**£11,036,228**	**£1,102,979**	**£9,494,102**
Total Net Business (Benefit)	-£31,974	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£31,974	-£3,715	-£31,974

Distributional effects

This Option is likely to incur distributional effects along the food chain. Competitive markets have been assumed; all input cost savings from millers is passed through the food chain all the way to the consumer via the manufacturers. However, the final distributional outcome will depend on the competitiveness of the market. The distributional effects are outlined below.

Premix suppliers who currently produce the fortificants premix are likely to lose trade from no longer having to supply any of the four fortificants for non-bread products. As outlined in the benefits to the consumer, existing evidence from industry suggests that premix suppliers are likely to lose £11.08 million over a 10 year period, an annual cost of £1.11 million per annum.

Millers and manufacturers will benefit from the some cost savings of fortifying bread flour only. This gain for millers is linked to the loss of trade incurred by premix suppliers as it is a direct transfer. Therefore, millers in the UK are likely to benefit £11.08 million over a 10 year period, an annual benefit of £1.11 million per annum. There may be some cost savings to bakers and manufacturers using flour as an ingredient if millers pass the cost savings resulting from a cheaper premix purchase price.

Consumers are likely to benefit from some cost savings of purchasing end products if these savings are passed along the chain. Again, as it is linked to the cost to premix suppliers and, in turn, the benefit to millers and manufacturers, it is assumed that consumers in the UK are likely to benefit by £1.1 million each year or £11.08 million over a 10 year period (as outlined in the consumer benefits section above.) This is the saving to consumers is the same saving as that of millers and manufacturers, not in addition.

Option 3b– Exemption for flour destined for minor ingredient use

Description

This Option would retain the existing rules on fortification of flour but also provide for the use of unfortified flour in products where flour is not the primary ingredient and comprises less than 10% of the product. This would have the advantage of retaining fortification requirements and protecting intakes of the four nutrients although it is not possible accurately to model the impact of this Option. A threshold level would need to be agreed, with informal views suggesting a level of 10% might be appropriate. Foods where flour is present as a minor ingredient make only a small contribution to intakes and it is likely therefore that any health benefits currently gained from fortification would remain.

This would not be a deregulatory measure as regulations will still be required.

Industry

Costs

Familiarisation costs (one-off) – *This is a monetised cost.*
Under this Option, industry will need to familiarise themselves with the consequences of allowing unfortified flour to be milled and used as a minor ingredient. Users of flour will be more significantly affected as the onus on fortification would then fall to the product manufacturers to ensure they were using the correct flour within the threshold levels and may result in added burdens on the manufacturing industry. An **additional one hour** compared to all other previous Options has been assumed for product manufacturers to take account these complexities.

Following the same standard cost methodology and using the same wage rates as the previous Options, the total one off familiarisation costs for industry in England are estimated at nearly £48,000, which translates to an equivalent annual cost of £5,568 over a ten year period (Table 13.)

Table 13: Total familiarisation costs to business by Equivalent Annual Cost and by Country

	Number of Food Business Operators	Total Familiarisation Cost	Equivalised Annual Cost
England	**1,581**	**£47,932**	**£5,568**
Wales	126	£3,836	£446
Scotland	163	£4,953	£575
NI	122	£3,709	£431
UK	1,992	£60,429	£7,020

Q40. Stakeholders are invited to comment on whether the assumptions outlined above are reasonable for Option 3b.

Change in manufacturer practices (one-off) – *This is currently a non-monetised cost.*

Food containing significant amount of flour such as bread will still be required to comply with mandatory fortification requirements and relabelling in line with FIR will be required. Current estimates suggest that only3-5%[19] of flour is used as a minor ingredient, so millers may choose to continue fortification, with related labelling implications. Therefore, providing unfortified flour may not be worth the capital and time investment that could happen in Option 3a. As a result, end users may decide to switch to imported unfortified flour for use as an ingredient incurring search and negotiation costs of switching to new suppliers.

Q41. Stakeholders are invited to comment on whether this assumption of switching to imported unfortified flour is reasonable. What would the scale of the costs in finding a new supplier?

Benefits

A more proportionate enforcement procedure for businesses – *This is currently a non-monetised benefit.* Same as Options 1 and 3a.

Consumers

Costs – There are no anticipated additional costs to consumers. We do not have sufficient information to identify those products which contain less than 10% flour as an ingredient within the modelling. However, given that this affects only 3-5%% of the flour market, we assume little change to market practices. Therefore, we assume that this will have no impact on consumer health.

Benefits – There are no anticipated additional benefits to consumers.

Government and local authorities

Costs

Familiarisation costs (one-off) – *This is a monetised cost.*

Same as Option 1, 2 and 3a.

Q42. Enforcement officers are invited to comment on whether the familiarisation assumptions above are reasonable.

[19] NABIM 2012 Milling Report

Benefits

Simpler enforcement procedures for enforcement officers – *This benefit is currently non-monetised.*

Same as Options 1 and 3a.

Q43. Is this a viable Option?

Q44. Is a threshold level of 10% realistic?

Summary of monetised costs and benefits of Option 3b

Table 14 provides a summary of the monetised costs and benefits for policy 3b. The net present value is around -£56,000 over 10 years. However, the business net present value is around -£48,000.

Table 14: Summary of monetised costs and benefits - Option 3b

	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total cost/benefit	Annual Cost or Benefits/EA	PV
COSTS													
Industry													
Familiarisation (transition)	£47,932	£0	£0	£0	£0	£0	£0	£0	£0	£0	£47,932	£5,568	£47,932
Total Industry Costs	**£47,932**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£47,932**	**£5,568**	**£47,932**
Government													
Familiarisation (transition)	£7,798	£0	£0	£0	£0	£0	£0	£0	£0	£0	£7,798	£906	£7,798
Total Government Costs	**£7,798**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£7,798**	**£906**	**£7,798**
TOTAL COSTS	**£55,730**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£55,730**	**£6,474**	**£55,730**
BENEFITS													
Government													
Total Government Benefits	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**
TOTAL BENEFITS	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**
NET BENEFIT													
Total Net (Benefit)	**-£55,730**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**-£55,730**	**-£6,474**	**-£55,730**
Total Net Business (Benefit)	-£47,932	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£47,932	-£5,568	-£47,932

Distributional effects

Under this Option, the distributional effects are not as large. It is possible that there could be a small shift in trade away from domestic fortified flour millers towards sources of imported unfortified flour. However, this is anticipated to be small and, therefore, having little or no impact on current market conditions.

Given the small proportion of flour used as a minor ingredient and the assumption that there will be little or no impact on market conditions, it has also been assumed that prices of these goods will remain approximately similar (after factoring other costs such as transport costs).

Q47. Stakeholders are invited to comment on whether this assumption of no price changes is a reasonable assumption.

Rationale and evidence that justify the level of analysis used in the IA (proportionality approach)

Risks and assumptions

Risks

There could be a detrimental impact on human health as a result of removal or reduction in fortification requirements. There is a risk that the devolved countries will not follow suit with different fortification requirements. Monitoring of intakes may be more difficult in a non regulatory situation, with various different levels of fortification being applied across the bakery industry. There could be greater risks to low income groups of removing all mandatory fortification particularly for calcium and iron. This is anticipated in Option 2. This is because low income groups tend to have lower intakes of these nutrients compared with the general population and tend to consume more bread (particularly white bread). There may also be regional differences in impact due to differences in consumption of bread and flour products again this is likely to be associated with Option 2.

Direct costs and benefits to business calculations

Regulatory Costs

Administrative burden costs and policy costs

Food Labelling is an administrative burden. Revocation of the rules would free up industry to make a voluntary decision as to whether to add nutrients to flour. Retention of the rules would not add any further burden as a result of retaining this policy.

Consultation

Informal consultation has been carried out prior to this consultation as part of the RTC exercise. The views of some stakeholders have been reflected in this IA. Stakeholders are regularly informed and updated on issues relating to bread and flour as well as the labelling issues which will affect the sector under the new FIR. Stakeholders have been made aware of the RTC exercise and have been kept updated on progress with this consultation.

A formal twelve week consultation is proposed to seek the views of all stakeholders on the deregulatory Options and impacts.

Enforcement

The current regulations are enforced by trading standards officers in local authorities and by environmental health officers in the London boroughs. If the Regulations are repealed then bread and flour will no longer need to be subject to checked for compliance with these rules therefore reducing the

regulatory burden. However resources devoted to the enforcement of these Regulations are minimal as flour is fortified at the mill in most cases. No additional resources will be required if the regulations are retained or amended.

Simplification

Simplification measures are proposed. Option 2 discusses removing regulation in this sector altogether leaving no rules for bread and flour. A further simplification measure is discussed in option 1 which would be to reduce the number of fortificants to be added from four to two. Options 3a and b are also forms of simplification requiring fortification of bread flour only or the setting of a minimum threshold where unfortified flour could be used in foods containing flour as an ingredient at less than 10%

Implementation

No preferred option is being put forward as the purpose of this exercise is to inform the decision making process. A joint decision by Defra and DH ministers will then be required on any future action. This will be informed by the responses to this consultation and the independent advice on the health impacts. Consideration will also be given to whether deregulatory action is beneficial if only applied in England. Any decisions will be put before the Government's overarching Reducing Regulation Committee (RRC) and Home Affairs Committee for agreement.

Implementation would be by way of an SI to either to replace or revoke the current Regulations in England. Depending on timings it may also be possible to revoke the regulations though an SI that is currently being prepared to provide for the enforcement of the Food Information Regulations.

Summary and preferred Option

Fortification of flour in the UK is a longstanding requirement dating back more than 50 years. The Governments deregulatory programme in England is currently reviewing the need for all regulation, particularly national ones. The purpose of this consultation is to seek the views of stakeholders on the continuing need for rules covering bread and flour in England particularly with regard to the fortification of flour the levels set within the regulations. These views will be used to inform the Government's decision regarding whether to revoke the rules on bread and flour and allow industry to choose whether to fortify or not. The Government's Scientific Committee on Nutrition have also considered the health impacts of removing mandatory fortification requirements and this will also be used in the coming to a decision.

At this stage no Option has been identified as preferred. The consultation process is being used to gather further evidence and views to support the identification of a preferred Option.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but, exceptionally, a longer period may be more appropriate. A PIR should examine the extent to which the implemented Regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR, please provide reasons below.

We have not currently made plans to carry out a PIR because the decision has not been taken whether to deregulate entirely the rules on bread and flour or to continue to regulate in this area as currently or in a reduced manner. This consultation has no preferred Option however a review will be necessary to consider the effects of any change in policy particularly any deregulatory one. If a deregulatory Option is chosen then as recommended by SACN procedures will be put in place to monitor the effect of deregulation. Monitoring procedures will be further elaborated at the time a decision is published. If the Regulations are amended then a five review clause would be built into the regulations as a matter of course. The Regulations would also contain a sunsetting provision under which the Regulations would cease to have effect seven years after they are made. At that stage, if the decision was taken, after the review, to remake the Regulations then new Regulations would be needed.

Annex 2: Specific Impact Tests – Statutory Equality Duties Impact Test

Race equality issues

No impacts on specific ethnic groups have been identified from the policy Options.

Gender equality issues

The deregulatory Option 2 is likely to have an effect on women and young girls. For iron, a high proportion of girls and women have low intakes and removal from flour is likely to result in an increase in the proportions below the LRNI

The removal of added calcium from flour would have adverse implications for bone growth and bone health in the population groups whose intakes are already low and of particular concern. Older children and young adults are particularly vulnerable to low calcium intakes at a key stage in their bone development. Failure to achieve peak bone mass will increase the risk of osteoporosis in later life. Osteoporosis is a major public health problem in the UK and this will continue because of the shifting demographics of the population as it ages.

Disability equality issues

No disability specific issues related to the policies have been identified.

Heath Impacts

The Department of Health has sought the advice of its expert Scientific Committee on Nutrition (SACN) on the removal of existing mandatory fortification of flour. Its detailed assessment can be found at Annex 4. SACN concluded that in order of public health nutrition importance, the case for maintaining the mandatory addition of calcium to wheat flour (other than wholemeal flour) is strongest, followed by iron. Evidence to continue the mandatory addition of niacin and thiamin to wheat flour (other than wholemeal flour) is much weaker. The effect of removing fortification required by the bread and flour regulations on the proportion with intakes less than the LRNI will be greater for lower socio-economic groups.There may also be regional differences in impact due to differences in consumption of bread and flour products.

Competition Assessment Impact Test

The proposed legislation currently applies to all relevant UK bread and flour manufacturers equally. However any changes proposed will only apply in England. We acknowledge there may be different rules applying in different parts of the UK should the deregulatory option be chosen. However it should not limit the number or range of suppliers either directly or indirectly or reduce the ability of or incentives to, suppliers to compete. Therefore, it is not expected to significantly impact on competition.

Small Firms Impact Test

We do not envisage these Regulations currently impose a significant or disproportionate burden on small businesses and a change in fortification requirements are not likely to disproportionally affect small business. We acknowledge that if there is no mandatory fortification requirement that a small numbers of SMES supplying the fortificants may be adversely affected.

Sustainable Development Impact Test

We do not envisage that the Options outlined in this IA will have a significant impact on sustainable development. There are no significant environmental impacts associated with this policy. There may be health impacts and we cannot say for sure that our actions will not have any impact on future generations.

Annex 3 – Calculations for familiarisation Costs

To calculate to the familiarisation costs to industry and Government, the following assumptions have been made:

1. Relevant wage rates :

The wages outlined in this impact assessment represent median gross hourly pay including overtime from the Annual Survey of Household Earnings, 2011, All Employees. Following standard cost model assumptions, the following wages are then uprated by 30% to account non-wage costs:

Regulatory affairs/production manager (proxy for production manager millers) - £25.39 per hour
Bakers and flour confectioners (proxy for bread and non-bread manufacturers) - £10.43 per hour
Inspectors of standards and regulations (local authorities) - £18.01 per hour

2. Number of familiarisation hours:

- The number of hours required by affected **millers** to become familiar with new BFR, and to ensure compliance = **1 hour**;
- The number of hours required by affected **micro and small** manufacturers to become familiar with new BFR, and to ensure compliance = **2 hours**;
- The number of hours required by affected **medium and large** manufacturers to become familiar with new BFR, and to ensure compliance = **1 hour**;
- The number of hours required by **trading standard officers** to become familiar with new BFR, = **1 hour**;

However, under Option 3b, an additional hour is added to manufacturers given the complexity of the new rules regarding fortification to a set threshold of flour content (in the case of Option 3b, it is less than 10 per cent).

Using the standard cost model approach, familiarisation costs are calculated by using the number of hours to familiarise and multiplied by the number of businesses affected by the hourly cost (wage and non-wage costs).

3. Disaggregation of familiarisation costs

Costs below are disaggregated by affected sector. Where possible, information has also been disaggregated by firm size. However, where information was not available, this has not been presented.

Data from the Inter Departmental Business register (IDBR) estimates that there are currently 1,935 firms that manufacture bread products or products requiring flour in the UK in 2010, the majority of which are micro and small size businesses. Of the total number of manufactures in the UK, nearly 80 per cent of the establishments are located in England.

All other figures estimates have been taken from the 2012 NABIM Report or through contacts from industry.

Familiarisation costs (under all Options except 3b)

	Total Familiarisation Costs for England
Industry	£31,974
Enforcers	£7,798
	£39,772

Enforcers

	Number of Local Authorities	Total Familiarisation Cost	Equivalised Annual Cost
England	**433**	**£7,798**	**£906**
Wales	22	£396	£46
Scotland	32	£576	£67
Northern Ireland	26	£468	£54
UK	513	£9,239	£1,073

All FBOs

	Number of Food Business Operators	Total Familiarisation Cost	Equivalised Annual Cost
England	**1,581**	**£31,974**	**£3,715**
Wales	126	£2,532	£294
Scotland	163	£3,284	£382
NI	122	£2,457	£285
UK	1,992	£40,247	£4,676

Premix suppliers

	Number of premix manufacturers	Total Familiarisation Cost
England	**1**	**25**
Wales	0	0
Scotland	0	0
NI	0	0
UK	1	25

Millers

	Number of milling companies	Total Familiarisation Cost
England	**50**	**1,270**
Wales	1	25
Scotland	3	76
NI	2	51
UK	56	1,422

Manufacturers

	Number of Manufacturers	Total Familiarisation Cost
England	**1,530**	**30,679**
Wales	125	2,506
Scotland	160	3,208
NI	120	2,406
UK	1,935	38,800

Familiarisation costs (under Option 3b only)

	Total Familiarisation Costs for England
Industry	£47,932
Enforcers	£7,798
	£55,730

Enforcers [no differences]

	Number of Local Authorities	Total Familiarisation Cost	Equivalised Annual Cost
England	**433**	**£7,798**	**£906**
Wales	22	£396	£46
Scotland	32	£576	£67
Northern Ireland	26	£468	£54
UK	513	£9,239	£1,073

All FBOs

	Number of Food Business Operators	Total Familiarisation Cost	Equivalised Annual Cost
England	**1,581**	**£47,932**	**£5,568**
Wales	126	£3,836	£446
Scotland	163	£4,953	£575
NI	122	£3,709	£431
UK	1,992	£60,429	£7,020

Premix suppliers [no differences]

	Number of premix manufacturers	Total Familiarisation Cost
England	**1**	**25**
Wales	0	0
Scotland	0	0
NI	0	0
UK	1	25

Millers [no differences]

	Number of milling companies	Total Familiarisation Cost
England	**50**	**1,270**
Wales	1	25
Scotland	3	76
NI	2	51
UK	56	1,422

Manufacturers

	Number of Manufacturers	Total Familiarisation Cost
England	**1,530**	**46,637**
Wales	125	3,810
Scotland	160	4,877
NI	120	3,658
UK	1,935	58,982