Department
for Environment
Food & Rural Affairs

www.defra.gov.uk

# Bread and Flour Regulations 1998

## Consultation

### January 2013

This document is also available on our website at:

www.defra.gov.uk/corporate/consult/open

Any enquiries regarding this document should be sent to us at:

Food Policy Unit, Department for Environment, Food and Rural Affairs

Area 7E Millbank, 17 Smith Square, London SW1P 3JR

## Contents

# Part I – About this consultation

## Topic of this consultation

This consultation is seeking views on the continued need for the Bread and Flour Regulations 1998 and whether there is still a need to mandatorily fortify flour with four specific nutrients in England.

## Scope of this consultation

Defra is seeking views on possible deregulatory measures regarding the mandatory fortification of flour which is currently required by the Bread and Flour Regulations 1998. The aim is to reduce the regulatory burden on industry by considering whether these rules could be revoked without compromising public health. An assessment of the options including the effects on industry and the health implications of removing or amending the current fortification requirements in England is considered.

## Geographical extent

Food and health matters are devolved issues therefore this consultation relates to England only. Any changes agreed as a result of this consultation will apply to England only. Scotland, Wales and Northern Ireland will be considering any actions separately although at present there are no immediate plans to consult on this. It is noted that the majority of flour mills are situated in England and changes to fortification practices may also directly impact on Scottish, Welsh and Northern Irish consumers. In addition, many of the larger companies have more than one site spread across the four nations which could result in different rules applying in different parts of the UK.

## Impact Assessment

An impact assessment is available online at www.defra.gov.uk/corporate/consult/open

## Audience

Anyone may reply to this consultation. Defra would like to hear from anyone with an interest in this issue, including industry, local authorities, consumer organisations, health practitioners and the general public.

A list of organisations that we have approached directly for views accompanies this consultation and is available alongside this consultation document at

www.defra.gov.uk/corporate/consult/open . However we would welcome views from any interested party or individual.

## Body responsible for the consultation

Defra's Food Policy unit is responsible for this overall consultation however the Department of Health has responsibility for health related matters.

## Duration

This consultation started on **16 January 2013**

This consultation closes on **13 March 2013**

## How to respond, or make an enquiry

Enquiries and responses may be directed to:

**Bread & Flour Regulations Consultation**

**Food Policy Unit**

**7E Millbank**

**c/o 17 Smith Square**

**London SW1P 3JR**

**Email**: breadandflour@defra.gsi.gov.uk

## Additional ways to become involved

As this is a complex issue it will be a purely written exercise.

## After the consultation

When this consultation ends we intend to put a copy of the responses in the Defra library at Ergon House, London. This is in line with Defra's policy of openness, so that the public may see them. Members of the public can ask for a copy of responses under freedom of information legislation. Copies of the consultation responses to personal callers or in response to telephone or email requests will be supplied by the Defra Information Resource Centre (020 7238 6575), defra/library@defra.gsi.gov.uk. Wherever possible, personal callers should give the centre 24 hours notice of their requirements. An administrative charge will be made to cover any photocopying and postage costs.

A summary of the responses to this consultation will also be published and placed on our website at www.defra.gov.uk/consult. This summary will include a list of names and organisations that responded but not people's personal names, addresses or other contact details.

If you do not want your response- including your name, contact details and any other personal information to be publicly available, please say so clearly in writing when you send your response to the consultation. Please note, if your computer automatically includes a confidentiality disclaimer, that won't count as a confidentiality request.

Please explain why you need to keep details confidential. We will take your reasons into account if someone asks for this information under freedom of information legislation. But, because of the law, **we cannot promise that we will always be able to keep those details confidential.**

If you have any comments or complaints about the consultation process please addresses them to:

**Defra Consultation Co-ordinator**

**Area 2D, Ergon House**

**17 Smith Square**

**London SW1P 3JR**

**Email: consultation.coordinator@defra.gsi.gov.uk**

# Part II

## Background

Defra made a commitment to review rules around fortification of flour as part of the Red Tape Challenge (RTC) which seeks to reduce regulatory burdens on business. The Government is committed to reducing regulation and removing rules which are no longer needed. The Bread and Flour Regulations 1998 are national rules which have come under increased scrutiny as part of the Hospitality Food and Drink sector and the review of regulations relating to food composition and labelling.

Under these regulations all wheat flour (except wholemeal flour) is required to have added to it certain specified quantities of four nutrients, namely iron, calcium, thiamin and niacin. The rules date back to post war times when nutrient deficiency particularly for calcium and iron was of significant concern. Flour is a basic commodity which is widely consumed and therefore an excellent vehicle for fortification with desired nutrients. Fortification of flour is also a relatively straightforward process which is carried out easily during the final milling process.

Three of the nutrients, iron, niacin and thiamin are added back for restoration purposes to bring the levels of these nutrients back up to the amounts naturally present in the wheat before the milling process. Calcium is added for fortification purposes at levels higher than naturally present.

The current consultation is looking at whether, 60 years on, fortification is still necessary for the nutritional health of the UK population and, whether the current rules on mandatory fortification of flour are still required with a view to scrapping these national rules (as they apply to England) if no longer needed. Removing such a requirement however is not something the Government is considering lightly and the associated Impact Assessment considers in detail the implications of removing any existing fortification requirements. In particular advice on the health implications of changing existing fortification practices has been sought from the Department of Health's Scientific Advisory Committee on Nutrition (SACN) who considered the issue at its meetings in February and April 2012. A summary of its conclusions was published in June 2012 and these can be found at www.sacn.gov.uk

The views of all stakeholders are important to help inform our further decision making on this issue and as part of this overall review of these Regulations.

## The Regulations

The Bread and Flour Regulations 1998 lay down specific labelling and compositional rules for bread and flour produced in Great Britain. Separate rules apply in Northern Ireland. Under these rules white and brown flour is required to have added to it specified quantities

of iron, calcium, thiamin and niacin, at the levels indicated in the table below. The Regulations also lay down chemical specifications for those mandatory nutrients.

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, more than half a century 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 treatments agent have now been removed and are contained in separate horizontal rules controlling the use of additives. The primary purpose of the Bread and Flour Regulations is therefore almost entirely in relation to the fortification requirements and the reason these rules still exist. If fortification is no longer necessary then these rules could be repealed.

Table X: Nutrient requirements for flour

| Nutrient | mg/100g flour |
|---|---|
| Calcium (calcium carbonate) | ≥235 to ≤390 |
| Iron | ≥1.65 |
| Thiamin (thiamin hydrochloride) | ≥0.24 |
| Niacin | ≥1.60 |

Additional restrictions on the use of the terms ‘wholemeal’ and ‘wheat germ’ are also contained in the current regulations Wholemeal flour is also required to have niacin, thiamin and iron naturally present at the levels indicated. In addition self raising flour with a calcium content greater than 0.2% is exempt from the calcium requirements.

## Industry practices

All white and brown flour produced in the UK is currently fortified late in the milling process via a premix which has been proven to be the most straightforward approach to fortification. The industry is generally content with the current mandatory provisions required by the regulations which have existed for over half a century. Such provisions also help provide a level playing field for industry by ensuring all flour is manufactured to the same criteria.

Some concerns have been raised about forthcoming changes to existing labelling rules which will mean that from 2014 the current labelling exemption that allows these added nutrients not to be indicated in the ingredients list will fall when the new Food Information Regulations come into force. The current derogation is an under implementation of EU rules and the new Food Information Regulation agreed in 2012 will in future require bread, flour and any products using flour as an ingredient to be labelled with these added nutrients. Some sectors of industry, particularly those using flour in small quantities as an ingredient in their products are concerned about the effect of these future labelling requirements. 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. 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.

The requirements of the Bread and Flour Regulations are not optional and so they place an added burden on UK industry to fortify flour while other countries in the rest of Europe and the EEA are not required to fortify and can legally export their goods to the UK.

## Health Aspects

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. 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. Thiamin deficiency in developed countries is associated with alcoholism where low intake can result in alcoholic neuropathy (nerve damage).

Data from years 1 & 2 of the National Diet and Nutrition Survey (NDNS[1]) 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. Full details of SACN's assessment of the nutritional aspects of bread & flour fortification can be found at Annex 4 of the accompanying Impact Assessment or at www.sacn.gov.uk.

### Calcium

Low calcium intakes are already seen in a substantial proportion of older children (11-18 years) 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

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

Intake (LRNI)[2] (from 15% to 21% for girls; from 8% to 12% 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 (growth) 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.

There is evidence therefore that withdrawing calcium fortification would increase the proportion with intakes below the LRNI and the corresponding risk of inadequate calcium intakes in the population particularly for women and low income groups. This implies an increased risk of deficiency which has been associated with poor bone health and subsequent osteoporotic fracture.

**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 increase the proportion of the population with low intakes. However, 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 and there is low uptake of iron in the form added to wheat flour by the body.

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

**Niacin**

Modelling suggests that the removal of niacin from wheat flour would still result in mean intakes remaining well above the RNI and less than 2% would have intakes below the LRNI in any age/sex group. Niacin is widespread in the diet and non-wheat flour sources include meat and meat products, breakfast cereals, and milk and milk products. Evidence on the niacin status of the UK population is unavailable and therefore only intakes can be monitored to assess potential deficiency. Clinical deficiency of niacin is rare in the general UK population.

**Thiamin**

Modelling shows that the effects of the removal of thiamin from wheat flour (other than wholemeal) are small. Mean intakes remain well above the RNI and less than 5% would

[2] 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 are 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.

have intakes below the LRNI in any age/sex group. In practical terms where the population of people with intakes less than the LRNI is below 5%, this is not considered to be of concern. Concern increases as the percentage of a population with intakes rises above this level. Thiamin is widespread in the diet. Non-wheat flour sources include meat and meat products, vegetables and potatoes and breakfast cereals and clinical deficiency of thiamin is rare in the general UK population.

**Conclusions from the 2012 SACN report on Bread and Flour (www.sacn.gov.uk)**

In 1981 the Committee on Medical Aspects of Food and Nutrition Policy (COMA) report on the Nutritional Aspects of Bread and Flour concluded that the addition of calcium and the restitution of iron, thiamin and niacin to flour should no longer be mandatory. The 1998 the COMA report on Nutrition and Bone Health recommended that calcium fortification of flour be retained to ensure that intakes did not fall below the then current levels. The evidence presented in this paper shows that repealing the UK bread and flour regulations will decrease intakes of thiamin, niacin, calcium and iron, and increase the proportion of the population with intakes less than the LRNI (for calcium and iron in particular). The LRNI has been set as a threshold of increased risk and therefore an increase in the proportion of the population with intakes less than the LRNI implies an increased risk of diseases associated with nutrient deficiency. The evidence also shows a downward shift in population intakes, particularly for calcium, indicating a change in risk across the population. For calcium, the evidence presented in this paper supports the assessment made previously by COMA in the 1998 Nutrition and Bone Health report

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.

There is evidence that withdrawing calcium fortification would increase the proportion with intakes below the LRNI[8] and the corresponding risk of inadequate calcium intakes in the population particularly for women and low income groups. This implies an increased risk of deficiency which has been associated with poor bone health and subsequent osteoporotic fracture.

Removing iron currently added to wheat flour (other than wholemeal) would decrease iron intakes in the population and increase the proportion of the population with intakes less than the LRNI[8]. However, the impact of this is unclear due to uncertainties associated with the ability of the body to adapt to low iron intakes and low intestinal uptake of iron in the form added to wheat flour (other than wholemeal).

The effect of repealing the bread and flour regulations on the proportion with intakes less than the LRNI[8] will be greater for lower socio-economic groups.

The effect of any amendments made to the current mandatory addition of thiamin, niacin, calcium and iron to wheat flour (other than wholemeal) should be adequately monitored and evaluated to determine effects on nutrient intake and status of the general population.

If the Regulations are repealed guidance on voluntary fortification for industry should be considered. Voluntary fortification of breakfast cereals would require particular attention as these are a notable source of nutrients currently added to wheat flour (other than wholemeal).

Guidance to manufacturers on appropriate levels to be added on a voluntary basis should be considered. Discontinuing voluntary fortification of products currently fortified with nutrients added to wheat flour (other than wholemeal), or reducing the levels added would increase the proportion of those at risk due to low intakes. Conversely, an increase in the levels of voluntary fortificants added may lead to excess intakes above guidance levels.

Bread is a widely consumed food and is thus an important vehicle for fortification with other nutrients. No other food is as universally consumed (including those already fortified voluntarily, such as breakfast cereals). Repealing the Regulations would create difficulties for extending the practice of fortification to improve population health, for example with folic acid to reduce the incidence of neural tube defects.

**Other relevant aspects**

There has been a long term decline in bread consumption but it remains an important source of the fortificant nutrients, particularly calcium. The SACN report also concludes 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. Regional differences are also likely across England, Wales, Scotland and Northern Ireland in line with differences in bread consumption and a reflection of socio-economic variations.

**Overall Health Issues Summary**

In order of public health nutrition importance, the Scientific Advisory Committee on Nutrition (SACN) concludes that 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. There is evidence that withdrawing calcium fortification would increase the proportion with intakes below the LRNI and the corresponding risk of inadequate calcium intakes in the population particularly for women and low income groups. This implies an increased risk of deficiency which has been associated with poor bone health and subsequent osteoporotic fracture. Removing iron currently added to wheat flour (other than wholemeal) would decrease iron intakes in the population and increase the proportion of the population with intakes less than the LRNI. However, the impact of this is unclear due to uncertainties associated with the ability of the body to adapt to low iron intakes and low intestinal uptake of iron in the form added to wheat flour (other than wholemeal).

## Objectives for intervention

The Government is committed to scrutinising regulation and where possible removing or reducing redundant regulation. As part of Hospitality, Food and Drink sector theme of the Government's Red Tape Challenge exercise there was a commitment to rationalise and simplify existing food labelling, food standards and compositional rules. National rules on bread and flour have been scrutinised to consider whether these are still necessary and whether any deregulatory moves could benefit industry without compromising public health. Defra as owner of the Regulation in conjunction with the Department of Health made a commitment to hold a formal public consultation on whether there is a continuing need for government intervention requiring mandatory fortification of flour. The views of stakeholders will form part of the overall decision process as to whether there is a continued need for the Bread and Flour Regulations

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. The Department of Health has been fully involved in the development of the Impact Assessment supporting this consultation. The Scientific Advisory Committee on Nutrition (SACN), the independent advisory committee to the Department of Health on nutrition matters, has provided a risk assessment on the health and nutrition impacts of removing the current fortification requirements for white and brown flour, which can be found at Annex 4 of the Impact Assessment

## Costs of fortification

**TABLE 1: 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.

The cost of fortifying with all four nutrients is currently around 0.71p per tonne. Fortifying with calcium and iron only for example would be 0.61p per tonne, a saving of 0.10p per tonne.

## Summary of Options

A brief summary of the baseline and possible options being considered is given below. The consultation process is being used to gather further evidence and views to support the identification of a preferred option.

**Baseline - 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.

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 in flour. This is not a deregulatory measure and will not reduce any burdens on industry. Flour millers have not voiced any concerns at the current fortification requirements. However, they have raised concerns relating to the future labelling requirements of the four nutrients once the new rules on food labelling come into force at the end of 2014.

**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 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. Reformulation of the premix will be required if industry chooses not to add niacin and thiamin. Should industry choose to continue voluntarily with niacin and thiamin fortification then the existing niacin levels required in the regulations would not meet the 15% RDA requirements. Hence reformulation would still be required with niacin added at higher levels. Labelling of iron and calcium will be required.

**Option 2- No fortification**

Removal of mandatory fortification requirements for all four nutrients through repeal of the existing Bread and Flour regulations in England.

This will end the compulsory fortification of flour for all 4 vitamins and minerals in England only. It would then be for 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.

Any continued voluntary fortification would need to meet the 15% RDA EU requirement. Larger amounts of two of the nutrients (iron and niacin) than those set by existing requirements would therefore be required. 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 (11-18 years) (8% below the LRNI increasing to 12%) and women (increase from 6% below the LRNI to 9%). For iron, removing fortification of wheat flour would result in the proportion of older girls (11-18 years) below the LRNI increasing from 44% to 50% and from 22% to 25% for women.

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 across the UK and millers may find it more problematical to have different demands from their customers. Opening up the requirements could conceivably put extra burdens on the millers.

It will be harder to monitor the population's intake of these nutrients as it will be entirely up to industry whether they fortify or not. A mechanism would need to be put in place to review the effect of this option.

**Option 3a - Continue with some fortification requirements but for bread flour only.**

This 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 where separation of bread flour from other types of flour may not be a simple matter.

**Option 3b - Exempt fortification of flour for ingredient use at < 10% level.**

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 the total ingredients. This would have the advantage of retaining fortification requirements and protecting intakes of the four nutrients although it is not possible to accurately model the impact of this option. This option may need further exploration and a threshold level would need to be agreed. Informal views suggested 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. Production of fortified and unfortified flour may complicate matters for millers. The onus of fortification would then fall to the product manufacturers to ensure they were using the correct flour and may result in added burdens on the manufacturing industry.

# Impact Assessment

An assessment of the cost and benefits of each of the possible options has been provided in the accompanying consultation stage Impact Assessment. Possible effects on industry, consumers and local authorities have been identified. However, we would welcome further input from stakeholders on the costs and benefits associated with the options discussed. In addition we have asked a number of both general and specific questions throughout the IA which we would welcome more information on. These are outlined below and should be read in the context of the accompanying IA. In addition if you have any views on the effect that repealing the Regulations would have for example on no longer controlling the terms “wholemeal” or “wheat germ”. If you have any other comments or points to make in relation to the Bread and Flour Regulations we would be happy to receive these.

# Questions asked as part of this consultation

## General

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 (other than those associated with implementing the FIR’ since this is outside the scope of the consultation) and if so, could you please quantify them.

Q2: (millers, vitamin manufacturers and manufacturers using flour) Will the new Regulations 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) Will there be any other effects of the new Regulations for your business or those that you represent? If so, could you please quantify them.

Q4: (enforcement agencies) 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 of the IA).

## Specific Questions

### Option 1 - Partial fortification with calcium and iron only

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

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

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

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

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

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

Q15. In what way would an Improvement 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.

### Option 2 - No fortification

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

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

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

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.

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?

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

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

Q29. Stakeholders are invited to comment on whether the time saving assumptions above are reasonable for Option 2.

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 3a - Fortification of bread flour only**

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

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

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 with quantifications.

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

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

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?

**Option 3 b- Exempt fortification of flour used as an ingredient at levels <10%**

Q40. Stakeholders are invited to comment on whether the assumptions outlined in Annex 3 to the IA are reasonable for option 3b.

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?

Q42. Enforcement officers are invited to comment on whether the familiarisation assumptions outlined in Annex 3 to the IA are reasonable

Q43. Is this a viable option?

Q44. Is a threshold level of 10% realistic?

## Enforcement

The existing 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 compliance with these rules will no longer be required thereby reducing the regulatory burden on industry. This will mean one less set of food regulations to comply with and enforce. However resources devoted to the enforcement of these Regulations are fairly minimal as flour is fortified at the mill in most cases and enforcement is therefore targeted at the 56 UK mills. It is anticipated that no additional resources will be required if the regulations are retained or amended.

## Next Steps

We want to hear from industry and other interested parties about what impact any changes might have on them and on the health of the population.

We'll look carefully at all responses we receive to the consultation before we make any 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 and way forward.

Implementation of any agreed course of action is likely to 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 the SI that will provide for the enforcement of the Food Information Regulations.

Following completion of this consultation Ministers will make a final decision, taking into account the responses to this consultation, and the views of independent advice on the health impacts of any policy change on the population. Consideration will also be given to the views of the devolved countries and whether a deregulatory approach is in our best interests. A final recommendation will be put before the Government's overarching Reducing Regulation Committee (RRC) for agreement.