MANDATORY FORTIFICATION OF BREAD AND FLOUR WITH FOLIC ACID – ADVICE TO SCOTTISH MINISTERS

Report by Charles Milne, Director Scotland

1 SUMMARY

1.1 This paper sets out advice to Scottish Ministers on the action the FSA deems necessary in relation to folate fortification in Scotland. The Board is asked to:

- **Agree**: the recommended advice to Scottish Ministers and
- **Agree**: that the Chair write to Scottish Ministers accordingly, copying in the CMOs and respective Ministers in the other 3 UK countries;

2 INTRODUCTION

2.1 Following consideration of advice from the Scientific Advisory Committee on Nutrition (SACN) in 2007, the FSA recommended the mandatory fortification of bread or flour with folic acid in order to reduce the risk of neural tube defects (NTDs) in foetuses. Health Ministers across the UK, were advised of the recommendations and parameters were set to reduce the incidence of NTD affected pregnancies and improve the overall average folate intake levels for the population, whilst ensuring the numbers exceeding the Guide Level / Upper Level (GL/UL) for folic acid didn’t increase.

2.2 In March 2013, the Board reflected on the lack of progress in this matter, noting, that although the FSA no longer had responsibilities for nutrition in England and Wales, it did in Northern Ireland and Scotland and agreed that Ministers in those countries should be reminded of the Board’s previous advice that mandatory fortification of bread or flour should take place.

2.3 In response, the Minister for Public Health in Scotland asked the FSA to provide further advice on the action it deemed necessary in relation to folate fortification in Scotland.

3 STRATEGIC AIMS

3.1 Business compliance is effectively supported because it delivers consumer protection. This will include a focus on effective, risk-based and proportionate regulation and enforcement.

4 EVIDENCE

4.1 NTDs are thought to be caused by failure of the neural tube to close within the first 28 days after conception. They result in a range of serious medical conditions, including infants who are stillborn, or who die a short time after birth, and individuals whose quality of life is significantly impaired through physical disability.
There is conclusive evidence that folic acid supplementation in the first few weeks of pregnancy can prevent NTDs.

4.2 Health Departments throughout the UK advise that women planning a pregnancy should supplement their diet with folic acid prior to conception, until the 12th week of pregnancy. Less than half of mothers from socio-economically deprived areas, follow this advice for a planned pregnancy and only half of all pregnancies are planned, which limits the value of the recommendation.

4.3 In 2006, SACN concluded that the public health advice on supplementation was not fully effective. To address this, they recommended that mandatory fortification of flour with folic acid would improve the folate status of these women, with the caveat that this should only be introduced if accompanied by action to reduce intakes from voluntarily fortified foods and supplements, along with measures to monitor intake levels, because of concerns about increased population exposure to levels above the GL/UL.

4.4 The most up to date available data on NTD-affected pregnancies across the UK show that the average rates and total numbers of cases per year have not significantly declined in the interim period, indicating that the case for mandatory fortification remains.

4.5 SACN's advice on the need to reduce intakes from voluntarily fortified foods, was based primarily on the need to ensure that the possible masking of clinical signs of vitamin B12 deficiency, which can happen at exposure levels above the GL/UL, would not occur.

4.6 There was concern from the Chief Medical Officers (CMOs) that some scientific studies suggested an association between high intakes of folic acid and increased risk of colorectal cancer, particularly amongst those predisposed to this risk. SACN concluded on reviewing this evidence, in 2009, that there was no reason to change its previous advice.

4.7 In 2007, the FSA commissioned qualitative research into the ethics of fortification, and health and lifestyle in pregnancy. The reports from these studies supported the option of introducing mandatory fortification, so long as adequate controls are in place to limit exposures to folic acid above the GL/UL.

5 DISCUSSION

Models for Implementation

5.1 The Board previously recommended that bread or flour would be the most appropriate vehicle for mandatory fortification, and identified parameters for an approach which reduced the incidence of NTDs, whilst ensuring the numbers exceeding the GL/UL did not exceed the levels at that time.

5.2 Initial modelling work, in 2007, identified interventions which could meet all of the outcomes agreed by the Board, and indicative support was received from
representatives of the food industry to reduce the levels of foods they voluntarily fortified, to help ensure GL/UL levels were not exceeded. However, representatives of the food supplement industry were less convinced over the need to require restrictions from their sector. Overall, industry representatives expressed a preference for a level playing field across the UK for any new measure being introduced.

5.3 A legal mechanism has been identified by which Scottish Ministers might introduce legislation requiring the mandatory fortification of bread or flour sold in Scotland. However, there is no legal mechanism within Scottish Ministers’ competence to impose restrictions on businesses who are currently voluntarily fortifying foods with folic acid, in compliance with the existing harmonised EU legislation. This is outlined in more detail in Section 8.

5.4 It will be important to reach agreement with the food Industry over the required restrictions on foods which are currently voluntarily fortified. Given the preference from the industry for a UK-wide approach and the potential difficulties associated with imposing voluntary controls in Scotland alone for products with a traditional UK-wide distribution pattern, it would be preferable if Ministers across the UK could agree a uniform policy.

Wider context - UK and beyond

5.5 In 2007, many countries in North and South America had introduced mandatory fortification of flour and reported significant reductions in NTDs as a consequence. In the interim period, a number of other countries - including Australia, New Zealand and South Africa - have introduced mandatory fortification and have reported success in reducing rates of NTDs without any apparent negative consequences.

5.6 However, no EU countries have so far introduced mandatory fortification, and the Commission have not brought forward any proposals relating to mandatory fortification. Current EU rules only concern circumstances where industry has decided to voluntarily fortify foods.

5.7 Of the other EU Member States, only Sweden (2007), and more recently Ireland (2013), have determined their policies, and both have decided not to apply mandatory controls. In the case of Sweden, the decision was based primarily on their relatively low levels of neonates with NTDs, and the difficulty with determining accurately the level of improvement which might be realised by mandatory fortification. In Ireland, the Food Safety Authority of Ireland (FSAI), who had previously considering fortifying bread with folic acid, concluded that based on blood monitoring, the levels of folate due to voluntary fortification are sufficient.

5.8 In the UK, there is currently no up to date available data to identify blood folate levels, but new data on the folate status of the population from the National Diet and Nutrition Survey (NDNS) is due early this year and Scottish specific data is anticipated to be available by May.
5.9 A legal mechanism has been identified which is considered to be within Scottish Ministers’ devolved competence and, in principle, capable of delivering mandatory fortification in Scotland. However, some practical technical issues have been identified which would have to be overcome before delivery of the overall policy objectives could be confidently realised. There are two key areas:

- Securing the necessary support from industry, across the UK, to introduce the required controls on voluntary fortification and supplement use, to counterbalance potentially adverse effects from exposure to levels above the GL/UL following mandatory fortification.

- The need to initiate new monitoring arrangements, required to evaluate success against policy objectives and mitigate the possibility of negative public health impacts from exposures above the GL/UL and to provide targeted advice to at risk groups as recommended by SACN.

These issues would ideally be addressed at a UK wide level by moving forward with a uniform approach across the UK. This would also ensure the important public health benefits could be realised on a UK-wide basis.

6 IMPACT

6.1 Evidence from scientific research, and the experience of those countries who have introduced mandatory fortification of flour, have demonstrated significant reductions in the number of NTDs, thereby improving both the public health status of the population and reducing costs associated with managing the resulting debilitating conditions.

6.2 The FSA consultation exercise in 2007 highlighted an industry preference for modification of the pre-existing fortification arrangements for flour at the milling stage, as the best, least negatively impacting mechanism to achieve the required fortification levels for folic acid. However the effected millers and bakers expressed a preference for a uniform UK approach, to minimise the financial impact associated with the need to produce more than one production stream and additional labelling requirements.

6.3 Discussions with representative bodies for businesses voluntarily fortifying foods and manufacturing food supplements took place in 2007. Those representing the voluntary fortification sector indicated support. However, some industry stakeholders expressed concern over additional costs of product labelling. The supplements industry also expressed concerns over practical difficulties with the use of advisory statements on small packages.

6.4 The current levels of voluntary fortification and supplement use are not known, and the impact of restricting mandatory fortification in the UK to the Scottish market has not yet been established. A full impact assessment would be required to accompany any legislative proposals.
7 CONSULTATION

7.1 The FSA advice in 2007 was the subject of consultation with all relevant stakeholder groups.

7.2 Colleagues across the FSA have had input into this paper, as have relevant officials in other interested Government Departments.

8 LEGAL / RESOURCE / RISK / IMPLICATIONS

Legal Competence of Scottish Ministers to act.

8.1 Legal advice has confirmed a mechanism by which the Scottish Ministers might require the mandatory fortification of flour sold in Scotland. Competence is derived from the vires contained in Section 16 (1) of the Food Safety Act 1990 (the 1990 Act). Under that section, the Ministers may make provision for requiring, prohibiting or regulating the presence in food or food sources of any specified substance, and generally for regulating the composition of food. Requiring the fortification of flour with folic acid would require the presence of a specified substance (folic acid) in a food, flour. The Bread and Flour Regulations 1998 were made under section 16 (1) of the 1990 Act, and this power is exercisable by the Scottish Ministers by virtue of section 53 of the Scotland Act 1998.

8.2 The simplest effective mechanism to introduce mandatory fortification is would be to amend the existing UK Bread and Flour Regulations to extend the nutrients already covered (calcium, iron, niacin and thiamine) to include folic acid. Whilst such a change would require to be prior notified to the European Commission, it is not anticipated that this would be problematic, since the only grounds for rejection would be if the provision presented a risk to public health, or a barrier to trade, neither of which would be triggered by this proposal.

8.3 Legal advice is that it is not considered to be within Scottish Ministers competence to legislate to restrict businesses that are voluntarily fortifying foods in accordance with the harmonised EU rules in this area contained within Regulation (EC) No 1925/2006.

Risks

8.4 There is a risk that the food industry might not be prepared to voluntarily reduce the levels of folic acid in the foods which are already fortified. This risk might be mitigated if a uniform approach to fortification could be secured across the UK.
9 DEVOLUTION IMPLICATIONS

9.1 The FSA retains policy responsibility for matters associated with diet and nutrition in Scotland and Northern Ireland, on behalf of Ministers in those countries.

9.2 Ministers in Northern Ireland have indicated their support, in principle, for mandatory fortification. However, they are not currently considering the possibility of using Northern Irish legislation and would prefer, in the first instance, to further explore the possibility of a UK-wide solution.

9.3 Following the Westminster machinery of government changes, the FSA does not have the policy lead for diet, nutrition and food supplementation in England and Wales. However it retains an interest in how the most appropriate solutions for Scotland and Northern Ireland might be achieved.

9.4 Decisions on mandatory fortification in England and Wales rest with the health departments in those countries. Westminster Ministers decided to wait until all the relevant scientific research on the potential negative effects of exposure to high levels of folic acid were in the public domain, before reaching a final decision. This was achieved in 2013. They are now considering the case for mandatory fortification of flour with folic acid and will reach a decision when they have considered new data on the folate status of the population due early this year.

10 CONSUMER ENGAGEMENT

10.1 The FSA’s 2007 advice on mandatory fortification of flour was informed by a significant amount of consumer engagement, including targeted and quantitative research on the behaviours and attitudes of consumers relating to mandatory fortification.

10.2 Should Scottish Ministers decide to proceed with flour fortification in Scotland, it would be appropriate to carry out further targeted consumer engagement work during the consultation process.

11 CONCLUSIONS AND RECOMMENDATIONS

11.1 This paper identifies a competent legal mechanism by which mandatory fortification of white and brown wheat flour can be delivered in Scotland, in line with the FSA’s advice to Ministers across the UK in 2007. No new evidence has come to light which would necessitate a change in the Board’s 2007 advice.

11.2 However, a number of practical technical issues and knowledge gaps have been identified which will require to be addressed before delivery of policy objectives could be confidently realised. These are highlighted in Sections 5.2, 6.3 and 6.4 of the paper.

11.3 These difficulties would best be addressed by moving forward with a uniform approach across the UK.
11.4 The Board is therefore asked to:

Advise Scottish Ministers:

- the FSA’s previous recommendation about the benefits of mandatory fortification of foods to reduce NTDs across the UK, is still valid in Scotland;

- they have the legal competence to require mandatory fortification of flour manufactured in the UK and sold in Scotland, so long as products freely circulating in other Member States are not restricted;

- that there may be practical difficulties in securing policy objectives unilaterally in Scotland, in particular securing the necessary support from industry to restrict fortification levels in products which are currently voluntarily fortified in compliance with EU law;

- that these difficulties may be mitigated if agreement could be reached to introduce mandatory fortification uniformly across the UK.

- of the legislative process, with indicative timescales, which would need to be followed for implementation of mandatory fortification in Scotland.

Recommend that:

- Scottish Ministers enter into discussions with other administrations across the UK, in an attempt to secure agreement to a consistent UK approach.

- should this be unsuccessful, they invite the FSA in Scotland to enter into discussions with industry across the UK to establish current levels of support for mandatory fortification, and explore the scope for securing agreement to implement the necessary controls in Scotland on a unilateral basis;

- Scottish Ministers require that arrangements are put in place to establish the necessary baseline data and to carry out monitoring and evaluation in line with previous advice from SACN, before any legislation be introduced in Scotland.

Agree: that the Chair writes to the Scottish Ministers welcoming their interest in implementing the previous FSA advice on fortification, and outlining the advice and recommendations above;

Agree: that the letter be copied to the CMOs and respective Ministers in the other UK countries.