Response to the Consultation on the COMA Report on Folic Acid and Prevention of Disease

The Committee on Medical Aspects of Food and Nutrition Policy (COMA) report Folic Acid and the Prevention of Disease was published in January 2000. A consultation on COMA’s report took place between July – October 2000 and sought views on how the Government should respond to the conclusions of the report. The consultation also sought views on other wider issues such as the impact on consumers and industry. The consultation sought responses to twelve questions and the following summary of the responses is structured around the questions posed.

The 166 respondents to the consultation included academics, expert and consumer groups, trade organisations and individual companies, health authorities, local government and individuals.

Desirability of fortification

Question 1: Is it desirable and acceptable to fortify all wheat flour (and by extension, all products made with wheat flour) with folic acid?

- Of the 141 respondents, 83 (59%) agreed with the proposal, 42 (30%) disagreed and 16 (11%) were unsure or had reservations.
- Consumer groups and individuals were the most likely to disagree with the proposal; academics and professional bodies were the most likely to agree.
- Most industry trade organisations declined to comment, feeling it was not for them to decide. Individual companies were mostly in favour of the proposal.
- Reasons for supporting the proposal were the high percentage of unplanned pregnancies, benefits to women and possibly the population as a whole and respondents believed the benefits out weighed the risks.
- While the majority was in favour of the proposal, it was deemed important to establish numbers at risk of Vitamin B₁₂ deficiency, establish the impact of higher intakes in children, evaluate the American experience and monitor the policy (if implemented).
- those who disagreed with the proposal commonly raised concern about the lack of information on the above issues. In addition there was concern about the lack of consumer choice.

Compulsory or voluntary?

Question 2: If fortification is considered to be desirable, should it be compulsory (i.e. be required by law), or should industry be encouraged to fortify on a voluntary basis?

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• In general, those who agreed with the proposal that fortification is desirable and acceptable (and stated a preference) were in favour of it being compulsory.
• In general, those who disagreed with the proposal (and stated a preference) said they would favour a voluntary approach, were fortification to be introduced.
• Limitations on consumer choice was key for those who disagreed with the proposal and an important reason for rejecting compulsory fortification.
• The importance of catering for those who consume little or no wheat (e.g. individuals with coeliac disease) was frequently mentioned.

Consumer choice and restriction on fortification of other products

Question 3: Compulsory fortification would have the effect of restricting consumer choice – is this acceptable? Should any provision be made for those who wish to buy wheat flour products without added folic acid?

• There were 110 responses to this question of which 78% (86) indicated that there should be consumer choice.
• Only 17% (19) did not think provision should be made for consumers who wished to buy wheat flour products without added folic acid.

Question 4: If compulsory fortification of flour were to be introduced should restrictions be placed on the level of folic acid that could be added to products other than flour on a voluntary basis? If so, what form should they take?

Options might include:
• Prohibition of voluntary fortification in some or all classes of products;
• Limits on level of fortification;
• A combination of these approaches, which limits the amount of folic acid that may be added to those classes of products where fortification is already widespread and prohibits the fortification of all other classes of product.

• The majority of respondents (71 out of 89), whether or not in they were in favour of fortification supported restrictions on the fortification of other products with folic acid.
• Of the 89 respondents who commented on the issue, only 15% (13) did not think there should be any restrictions.
• Respondents from industry were more likely to disagree with restrictions than other groups.
• Respondents who supported restrictions were most commonly in favour of a combined approach: prohibition on some products and limits on the level of fortification.

Labelling

Question 5: Should folic acid be included on the ingredient list of affected flour and products containing it?
• Of the 103 respondents who commented on this issue, 87% (90) thought folic acid should be included on the ingredient list of products containing it.
• It was commonly highlighted that labelling would be important for those who wished to avoid folic acid, or for comparison with unfortified (e.g. imported) products.
• While there was consensus on the need to label folic acid, views differed on where this should occur and the details to be provided.

**Supplementation and health claims**

*Question 6: Would fortification detract from the public health message on supplementation for women of childbearing age? Should claims on fortified products be restricted/prohibited to reduce the risk of this happening?*

• Rather than directly commenting on whether fortification would detract from the public health message on the need for additional supplementation for women of child bearing age, many respondents provided suggestions on how this scenario might be avoided.
• Of the 99 respondents who commented on this issue, 39% (39) stated that the existing education strategy should be continued or a new strategy implemented (as a solution or preventative measure).
• Only 13% (13) of respondents believed that the proposal would detract from the policy; the remainder of respondents was unsure about this issue.

*Question 7: If so, should the wording of the folic acid content and related health claims be the subject of guidance or controlled by statutory measures?*

• Of the 79 respondents who considered the area of health claims on fortified products, 62% (42) thought they should be controlled, a further 13% (10) thought they should be subject to guidance and 3% thought they should be “regulated”.

**Technical issues associated with fortification of wheat flour with folic acid**

The remaining questions were answered by relatively few respondents, mainly industry bodies.

*Question 8: Does the fortification of wheat with folic acid present any technical difficulties? And are there any technical difficulties associated with the use of fortified flour in the manufacture of products?*

• Virtually all responses (11) to this question were from industry – manufacturers and retailers. Technical problems with the addition of folic acid by millers appear to be minimal and relate to the even distribution through flour and the correct level of fortification to allow for “overage” – loss of folic acid during processing.
• Two respondents considered that the US experience of grain fortification with folic acid would provide useful lessons.
Question 9: What average is needed to achieve a level of 240µg of folic acid in the final product for every 100g of wheat flour used in the manufacture of individual products, taking into account any problems associated with adding folic acid at the milling stage, and potential losses during storage and during processing?

- 7 out of 8 respondents to this question stated that the target level recommended by COMA in end-products, other than flour, is impractical due to variable deterioration rates of folic acid in the processing of different products. One respondent suggested that bread, as the main flour–containing product, could be used as an assessment for an alternative higher level of fortification at source.

- Most respondents (5 of 8) considered that the fortification requirement should relate solely to fortification of flour and not to products in which flour used.

Question 10: What is the likely variability in the level of folic acid in the final product? Is this likely to be different in different types of products (e.g. bread, cakes, buns and pastries, biscuits, puddings)?

- Four out of the five respondents who answered this question considered that losses of folic acid during production of baked goods was of the order of 20% - 30%. The other respondent suggested losses could be as high as 35%.

Cost implications for industry and the consumer

Question 11: What are the cost implications of fortification for industry, and what is the likely impact on the cost of final products to the consumer?

- Costs for industry would relate mainly to labelling or packaging if labelling of folic acid addition was required. Some respondents mentioned raw materials and possibly more sophisticated feeding and quality control equipment. Only two respondents gave an indication of possible cost implications, one respondent quoted £350K, another £35 million, per year.

- One respondent noted that costs would vary depending on whether fortification was mandatory or voluntary and whether the requirements related to flour only or the products as consumed.

- The two respondents who mentioned the costs to consumers considered them to be negligible.

- Two respondents were concerned about the possible significant loss of export business if fortification was mandatory, particularly where countries do not permit fortification.

Timescale for compliance with compulsory fortification

Question 12: If compulsory fortification were to be introduced, how long would it be before industry could comply with the requirement, given the need to adapt processes, use up stocks of unfortified flour and introduce any necessary changes to product labels?
• All (7 respondents) agreed that the run-in period for introduction of mandatory fortification would need to take account of existing supplies of flour and current packaged stocks. The timescale varied between 12 to 18 months as reasonable, with 3 years leading to minimum costs.

Next Steps

The consultation responses have indicated a number of areas which point to the need for more detailed information. The Department of Health and the Food Standards Agency are currently undertaking the additional work necessary before a firm decision on fortification can be made. This work includes:

• Further research into the prevalence of Vitamin B₁₂ deficiency in the UK, which will give more information on the potential risks of fortification. Results are expected by July 2001
• Detailed discussions with various industry bodies to look closely into the technical aspects of fortification which they raised.
• Further estimates of folic acid intake from flour based on different options raised by respondents. This is also a key factor in quantifying the potential risks.
Table 1. Response to the Consultation by country of origin

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<td><strong>166</strong></td>
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</table>

¹ Respondents who stated that their response was applicable to the whole of the UK, or their organisation was a national one.
ANNEX A

List of respondents

Abbey Health Centre, Arbroath
Aberdeen City Council
Airedale NHS Trust (Consultant Paediatrician)
Airedale NHS Trust (Midwifery Manager)
ALJ Williams (Dr)
Andrew Robertson (Dr)
Andrews Flour
Anne Gibson (Dr)
Anne Wilks (Mrs)
Association for Spina Bifida and Hydrocephalus
Association of Bakery and Ingredient Manufacturers
Association of Local Authorities Northern Ireland
Ayrshire and Arran Health Board
Barbara Addison
Barking and Havering HA
Berry Ottaway and Associates Ltd
Biscuit, Cake, Chocolate and Confectionery Alliance
Borders General Hospital
Borders Health Board
Bradford Hospitals NHS Trust
British Dietetic Association
British Medical Association
British Nutrition Foundation
Burnley Healthcare Trust
Catherine Muller
Cliona Ni Bhrolchain (Dr)
Cochrane Collaboration Consumer Network
Coleraine Borough Council
Colin Wills
Consumers for Health Choice
Consumers’ Association
Co-operative Wholesale Society Limited
Cornwall and Isles of Scilly HA
Council for Responsible Nutrition
County Durham and Darlington HA
Coventry NHS HA
Craigavon Borough Council
David Bender (Dr)
Deborah Hall
Dilys Cluer
Dundee City Council (Education)
Dusan Obradovic
Dyfed and Powys HA
Ealing Hospital NHS Trust
Ealing, Hammersmith and Hounslow NHS HA
East Ayrshire Council
East Riding and Hull NHS HA
Eastern Health and Social Services Board
Edinburgh City Council (Education Support Services)
English National Board for Nursing, Midwifery and Health Visitors
Falkirk Council Development Services
Federation of Bakers
Felicity Mawson
Fife Health Board
Fiona AW Fyfe
Food and Drink Federation
Forth Valley Health Board
FSA Expert Group on Vitamins and Minerals
FSA Wales Advisory Committee
Gateshead and South Tyneside NHS HA
Geoff Brewer
George Maddicks
Glasgow City Council (Protective Services)
Gloucester HA
Grampian Health Board
Gwent HA
Gwent Healthcare NHS Trust
Health Development Agency
Health Food Manufacturers Association
Health Promotion Agency for Northern Ireland
Highland Health Board
Highland Primary Care NHS Trust
Incorp. National Association of British and Irish Millers Limited
Institute of Food Research
J Sainsbury PLC
Jacky Redfern
John Bowen
Jonathon Dixon
Judith Harris (Mrs)
Kensington, Chelsea and Westminster  HA
Kings College, London (Prof Seller)
L Dass (Mr) and G Dass (Mrs)
Lanarkshire Health Board
Law Society for Scotland
Lincolnshire NHS HA
Lothian Health Board
M Harbinson (Mrs)
Manchester HA
Marcus Williamson
Maternity Alliance (Margaret Wynn)
Meat and Livestock Commission
Medical Research Council
Morag McCluskey
MRC Cambridge (Dr A Prentice)
National Association of Master Bakers
National Childbirth Trust
National Consumer Council
National Council of Women of Great Britain
Niki Jakeman
North Derbyshire NHS HA
North East Devon HA
North Lanarkshire Council
North Staffordshire HA
North Yorkshire HA
Northern Health and Social Services Board
Northumberland NHS HA
Northumbria Healthcare NHS Trust
Nutrition Society
Pembrokeshire and Derwen NHS Trust
Powys Healthcare NHS Trust
Prof AV Hoffbrand (Royal Free)
Prof Martin Wiseman
Prof N Wald (Wolfson Institute)
Prof RW Smithells
RCM Edinburgh and District Branch
RCP, Faculty of Public Health Medicine
Richard Lockwood
Riverside Community Health Care NHS Trust
Rochdale Healthcare NHS Trust
Roche Products Limited
Rowett Research Institute (Prof Morgan)
Royal College of General Practitioners
Royal College of Midwives
Royal College of Midwives UK Board for Scotland
Royal College of Nursing – Scotland
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Pathologists
Royal College of Physicians of Edinburgh
Royal College of Physicians, London
Royal Pharmaceutical Society of Great Britain
Safeway Stores PLC
Sandwell HA (Chairman)
Sandwell HA (Community Development Team Leader)
Sandwell HA (Director of Public Health)
Sandwell HA (Food Policy Advisor)
Sandy Steel
Scottish Centre for Infection and Environmental Health
Scottish Crop Research Institute
Scottish Food Co-ordinating Committee
Scottish Spina Bifida Association
Sefton HA
Singleton Hospital (Swansea NHS Trust)
Society for Research into Hydrocephalus and Spina Bifida
Soil Association
Somerset Health Authority
South Glasgow University Hospital
Southern Health and Social Services Board
Sperrin Lakeland Health and Social Care Trust
Tayside University Hospitals NHS Trust
Unilever (Van Den Bergh Foods)
University of Aberdeen (Epidemiology Group)
University of Dundee (Anderson, Forsyth, Howie)
University of Glasgow (Prof Lean)
University of Sheffield (Centre for Pregnancy Nutrition)
University of Southampton (Dame Barbara Clayton)
University of Wales College of Medicine (CVD Research)
Vicki Sandy
Viv Mountford (Ms)
Waitrose Ltd
Wendy Green
West Kent NHS HA
Wigan and Bolton HA
Wolverhampton HA (Consultant Public Health Medicine)
Wolverhampton HA (Director of Public Health)
Women’s Food and Farming Union