

THE FOOD STANDARDS AGENCY & COI

**consumer research on consumer
attitudes on options for increasing
the folate intake in young women**
(COI 274215)

FINAL REPORT

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Executive Summary and Conclusions

Background

Current Government advice is that women who may become pregnant should take a folic acid supplement to reduce the risk that their baby will develop a Neural Tube Defect (NTD) such as Spina Bifida. However, the policy of advice has not achieved a reduction in NTD rates in recent years.

In November 2005, the Independent Scientific Advisory Committee on Nutrition (SACN) agreed its draft report *Folate and Health*, in which it recommends that flour should be fortified with folic acid in order to achieve the desired reduction in NTD affected pregnancies¹. The Board of the Food Standards Agency discussed the draft SACN report at its April open meeting², and agreed to hold a public consultation on options to increase population folate intake (including mandatory fortification as recommended by SACN). In order to inform subsequent discussions, the Board also agreed that qualitative research should be undertaken to gather consumers' views on these options:

- Option 1: To continue with current Government advice
- Option 2: To run a public education campaign to encourage women to take folic acid supplements
- Option 3: To encourage food companies to fortify more foods with folic acid on a voluntary basis.
- Option 4: To introduce a legal requirement for flour to be fortified with folic acid.

The Research

The main challenge identified in the planning of this research was the high degree of technical detail necessary to enable an informed discussion among participants. A two-stage deliberative process was therefore developed, and was successful in allowing participants to be carefully briefed, and providing sufficient time for them to explore the issues in detail. Participants' views on the options were also tracked throughout the process, providing an insight into how views evolved as participants received further information and had the opportunity to reflect on what they had heard.

¹ www.sacn.gov.uk

² The Paper discussed by the Board can be viewed at www.food.gov.uk/multimedia/pdfs/fsa060405.pdf

Research outcomes

Participants' initial response was to view NTDs seriously, and there was a view that some action from Government was warranted. Throughout the deliberative process however, a small but consistent part of the sample favoured the status quo because they felt that this was a proportionate response given the number of people affected.

Participants were first introduced to the options towards the end of the first deliberative session, at which point they had been briefed on the benefits of folate in reducing NTD affected pregnancies, and on the possible risks associated with increased folate intake. At this stage, the option of a renewed public education campaign (option 2), had the most support, with less than 2 people per group on average favouring any kind of additional voluntary fortification, and only three people among the five groups favouring a mandatory approach.

Participants' preferences were checked again at the beginning of the second session, based on a questionnaire completed at home. By this stage, they had had the opportunity to read more detailed information provided in their briefing packs, discuss the issue with friends and family, and to reflect on the earlier session. There was a notable swing away from the education campaign (option 2) and towards mandatory fortification. It appears that the reason for this was that participants came to doubt that other options i.e. educational and / or voluntary options would be successful in reducing NTD rates rather than because their anxieties about fortification were completely resolved.

At the end of the second session, participants' final preferences were checked. There had been a further shift towards mandatory fortification, with more support for this than any other option, and with around two thirds of participants now favouring some kind of fortification. However, the strong opposition towards option 4 that had persisted among some participants throughout the process was maintained.

Discussions were extremely wide ranging, however three themes were frequent in the discussions, and impacted on participants' final preferences.

Participants spent a good deal of time attempting to gain a clear understanding of the nature and extent of the potential risks attendant on higher folate intake; and reaching a judgement on where (if at all) a balance could be struck between these and the more obvious benefits. There was a clear expectation among participants that these issues would be adequately considered by 'Government'.

These discussions suggest that it will be important to communicate to consumers not just the risk factors, but also that a rigorous and balanced risk assessment process has been conducted. It is clear that consumers would also expect the eventual policy to include active measures to manage these possible risks. This might include a programme of B12 and bowel cancer screening, particularly amongst older people, coupled with adequate monitoring of population folate intakes

The high proportion of unplanned pregnancies was consistently seen as an obstacle to the success of any policy reliant on behaviour change, and therefore instrumental in persuading the supporters of mandatory fortification. Many saw this as a compelling argument for a targeted, vigorous education campaign – aimed as much at reducing unplanned pregnancies *per se* as NTD rates.

Issues of consumer choice were discussed in two broad themes – that of the personal and practical; and in more broad terms related to mass medication and potential risks to people other than young women. There was an almost unanimous view that full labelling of fortificant folate was essential to enable those consumers who wished to avoid additional folate intake. For many participants this labelling was seen as answering any concerns relating to food choice inherent in mandatory fortification. It must be recognised however that in the event of mandatory fortification being taken forward, a small but significant minority would oppose it strongly on these grounds, whether or not they perceived there to be additional risks.

The sample specifically included respondents from Black and Minority Ethnic (BME) audiences. While there were some differences of view related to dietary and / or religious practices, the overall opinions of the BME audience in relation to the issue of folate fortification were not significantly different from those of the sample as a whole.

Implications of the research outcomes

The study showed that this is a complex issue and opinions of participants changed as time was spent considering the different options for improving the folate status of young women. The results suggest that the initial response of consumers may be overwhelmingly against fortification of foods, especially on a mandatory basis (option 4). However, access to further information and the opportunity to deliberate may persuade more consumers of the merits of further

fortification. However, even among consumers who have had the opportunity to reach an in depth understanding of the issues involved, more than half opted not to support mandatory fortification (option 4). Around a third of participants did not support any type of fortification (option 3 or option 4).

Summary

1. The research was successful in stimulating a highly informed discussion by participants with little or no previous knowledge of this complex and technical issue.
2. The majority of participants saw NTDs as a serious and significant problem, and supported (at least in principle) action by 'the Government' to address the issue.
3. By the end of the deliberative process, no single option was supported by the majority of participants. However, more participants supported mandatory fortification (option 4) than any other option, with the remaining support split fairly evenly among the other options.
4. There was a shift towards Option 4 as the research progressed. This was usually because participants came to believe that this was the most likely option to achieve the desired outcome i.e. (an improvement in NTD rates) rather than because their anxiety about the risks involved was satisfied.
5. Some participants retained a strong opposition to Option 4. In most cases this was because they considered the potential risks to those other than young women - involved to be unacceptable or because they felt strongly that consumer choice should be maintained.
6. Option 1 - maintaining the status quo - was supported by a number of participants, either because it brought no additional risks or because it was a low cost option. However, a large number came to reject this option as the research progressed, because they did not believe it would be effective in reducing the rate of NTD affected pregnancies.
7. Option 2 – an education campaign – received strong initial support. Support declined as the research progressed, and as participants became less convinced of its likely effectiveness. This option was also considered by many to be an important supporting element to option 3 or 4.

8. Option 3 – encouraging voluntary fortification - was favoured by some as a less risky and less radical option than mandatory fortification. Those who did not support this option were either opposed to fortification *per se*, or preferred the more structured approach of option 4.
9. Participants did not feel that the lack of consensus should prevent the Agency from moving forward on this issue. Participants recognised that, in a complex area such as this, consensus was not always possible.
10. It was clear that consumers would wish and expect to be informed of any significant change of strategy in this area, especially if mandatory fortification was chosen.
11. There was a clear expectation that any increase in fortification (whether on a voluntary or mandatory basis) would be monitored and regulated by an official body to prevent high folate intake by those consumers to whom potential risks may apply.
12. In the event of further fortification, whether on a voluntary or mandatory basis, there is a strong demand for the fortificants to be clearly labelled.

THE RESEARCH APPROACH

RESEARCH OBJECTIVES

In the initial planning of the research, the following research objectives were identified:

1. To encourage and facilitate informed deliberation amongst consumers on the possible fortification of flour with folic acid, and the attendant risks and benefits.
2. To gauge existing levels of understanding and knowledge about current fortification practice (i.e., both statutory and voluntary), including areas of confusion and concern.
3. To gather consumers' views on current practice, and on whether mandatory fortification is, in principle, an acceptable and appropriate way of tackling a public health issue.
4. To assess consumers' current understanding and awareness of NTD's and the benefits of taking folic acid supplements.
5. To gather consumers' views on the four options proposed by the Board and to identify consumer concerns likely to arise in relation to the four options.
6. To identify the key issues that influence opinion on these issues.
7. To explore issues of consumer choice in relation to the four options.
8. To identify differences between groups within the population in relation to these issues.
9. To make recommendations for a future communications strategy.

METHOD AND SAMPLE

The methodology aimed to address the significant challenges of this project, which included:

- ◆ the need to present consumers, having little or no previous knowledge on this issue, with a range of detailed and often technical information and evidence
- ◆ The lack of existing research on this issue, and therefore the lack of a “baseline” understanding of consumers’ likely response to the issue
- ◆ the potential sensitivity of some of the issues
- ◆ the need to balance the energy and mutual support of a group approach with the risk of ‘group effect’
- ◆ the requirement to include a wide range of consumers, including men and women, younger and older, and BME groups

The approach devised to meet these challenges involved:

- 5 workshops in 5 regions with ‘the general public’ which were reconvened 2 weeks later
 - ◆ each session lasting 3 hours
 - ◆ the period between was included to allow for reading of further briefing materials and deliberation
- 12 participants in each workshop
 - ◆ 6 women, 6 men
 - ◆ 3 Young People, 3 Family, 3 Older People, 3 Pensioners

- ◆ 6 ABC1, 6 C2DE
- ◆ none had close personal or professional experience of NTDs
- ◆ at least half the group personally responsible for food shopping and cooking
- ◆ all were eaters of bread
- ◆ representation of vegetarians / vegans

□ In addition, 4 paired depth interviews with BME consumers;

- ◆ the purpose of including participants from BME communities was to identify any indications of possible differences that may warrant further, more targeted investigation: it was not assumed that definitive conclusions could be made on the basis of this sub-sample
- ◆ sample comprised:
 - 1 pair of African origin, 1 pair of Caribbean origin, 1 pair Muslim, 1 pair Hindu
 - all female
 - representation of Young People, Family and Older People lifestages
 - other requirements as for workshops

STIMULUS MATERIALS

The workshops were structured so that spontaneous views of voluntary and mandatory fortification were gained initially before participants were presented with a range of information units, which set out some of the facts and issues for them to debate. (The information units are inserted at the appropriate points in the text of the Detailed Findings. See Appendix for Discussion Guide.)

- Session 1 – information units: Voluntary fortification
Mandatory fortification
The issue: Folic acid and NTDs
Folic acid
NTDs
B12 deficiency
The Options
- Deliberation Level 1 booklet (included in Appendix)
Level 2 booklet (available on request)
- Session 2 – further information: NTDs
Folic acid
Cancer risks
B12 deficiency
Target audience

Throughout two sessions, participants were given very simple self completion questionnaires on which to record their views on particular topics. These questionnaires were not designed to be an accurate quantitative measure of views but a qualitative insight into how participants' views either shifted or remained the same throughout the process and which options they gravitated towards.

Throughout the report, mention is made of our analysis of these questionnaires, but it must be remembered that any figures given are rough calculations and only intended to give a guide to where the weight of opinion lay, so they must be treated with extreme caution.

TIMING, LOCATIONS AND PERSONNEL

- Fieldwork locations
 - Sutton, Surrey (workshop)
 - Lewisham, London
 - Hounslow, Middlesex
 - Oldham, Manchester (workshop)
 - Edinburgh (workshop)
 - Glasgow
 - Cardiff (workshop)
 - Belfast (workshop)

- Fieldwork dates
 - 11th May – 12th June 2006

- Research team
 - Jeannette Croft
 - Freda Harris
 - Wendy Hayward

THE FINDINGS

SUMMARY OF FINDINGS IN RESPONSE TO THE RESEARCH OBJECTIVES

1. To encourage and facilitate informed deliberation amongst consumers on the possible fortification of flour with folic acid, and the attendant risks and benefits.

The structured two-stage methodology (described in Method and Sample section, pages 9 and 10) enabled participants to reach a high level of understanding of the folate issue and, in many cases, a subtle understanding of the risks and benefits involved. The methodology allowed participants the time to reflect on the information and enabled the views of participants to be 'tracked' by the use of simple questionnaires. The views of many of the participants shifted throughout the process, as they became increasingly informed and aware of the issues and as a result of the deliberation and reflection among the groups. It was clear that many participants were thinking not just of the implications for themselves, but were considering the implications for other groups in the wider society with a vested interest in the issue. A small number of individuals reached a view very early on in the process as to which option they preferred and maintained this view throughout. This was equally so amongst those who favoured some form of fortification as amongst those who vehemently opposed it.

The majority of participants entered into the deliberative process wholeheartedly. This was clear from the very good repeat attendance at the second sessions (97% overall); as well as the fact that nearly all participants had read the more straightforward level 1 'green book' and many had also read the much more complex level 2 'blue book'; and the high number who had discussed the issue with their friends and families, asking them to complete questionnaires.

2. To gauge existing levels of understanding and knowledge about current fortification practice (i.e., both statutory and voluntary), including areas of confusion and concern.

There was a moderate of awareness that some foods are fortified, with some food categories (e.g. cereals) being better known in this context than others. This did not appear to be an issue of great interest or concern to consumers, although there was surprise that there was not more detailed legislation in place to regulate this area. Following further discussion, it became clear that there was a significant degree of confusion about whether nutrients are 'added' or naturally occurring; and also what health benefits they provide. A minority of participants

conflated these nutrients with the broader category of 'additives'. Some expressed the view that they did not want their food to be 'messed around with' by the addition of any 'additives'.

Participants were quick to assume that voluntary fortification was driven by manufacturers seeking commercial advantage rather than for any concern about the health of the nation. Many claimed that 'fortification' had no influence on their purchasing decisions, although for many it could form part of some post purchase rationalisation, particularly for regular or habitual purchases. The majority of participants were not aware of the existence of mandatory fortification, although a minority of (usually older) participants knew that flour and margarine had been fortified on a mandatory basis to improve diets during the Second World War. Almost all respondents were surprised to learn that this practice was still continuing.

Overall, the distinction or choice between voluntary and mandatory was not one that consumers immediately make (at least in terms of their own shopping experience), as foods which are mandatorily fortified are not, we understand, labelled as such.

3. To gather consumers' views on current practice, and on whether mandatory fortification is, in principle, an acceptable and appropriate way of tackling a public health issue.

The current mandatory fortification of flour and bread (with iron, calcium, nicotinic acid and thiamin) was used as a case study to help focus discussion on the rationale for fortifying foods on a public health basis. While there is no doubt that the majority were surprised that the fortification of flour was still continuing, only a few objected on the grounds that it took away their individual right to choose. The majority recorded on their questionnaire that they were in favour of the current mandatory fortification of bread. In the second session they were given more information about the rationale for its continuation and they found this reassuring.

Participants reassured themselves that the mandatory fortification of bread must be acceptable because in sixty years there appeared to be no evidence of any resulting harm and because participants were persuaded of the health benefits for all. In particular, calcium and iron have well established health benefits and they could not remember them being associated with any 'bad press'. However, participants did not spontaneously leap to the idea that mandatory fortification could be used in other circumstances to deal with a public health issue.

4. To assess consumers' current understanding and awareness of NTD's and the benefits of taking folic acid supplements.

Almost all participants were aware of spina bifida, and knew that it affected babies at birth. Virtually none had heard of other aspects of NTDs such as hydrocephalus or anencephaly or the phrase 'neural tube defect'. A small number of participants were aware of a link between spina bifida and folic acid. Those who did know more often had young families and were often women rather than men. Consistently across the sample, older men knew very little, and sometimes nothing, about folic acid. There was also some debate as to whether medical advice had changed and that pregnant women were now advised to take folic acid rather than iron. While many women knew about the importance of taking folic acid supplements in the early stages of pregnancy, fewer knew about the need to take it when planning a pregnancy.

Having been provided with basic background information on NTDs and the role of folate in their prevention, around two thirds of participants recorded that they were in favour of some action being taken to address the issue. Learning more about NTDs confirmed the seriousness of the issue for many, although a minority (at least in the early stages of the discussions) remained either unconvinced about the need for action or specifically opposed to it.

5. To gather consumers' views on the four options proposed by the Board and to identify consumer concerns likely to arise in relation to the four options.

By the end of the deliberative process, no single option was supported by the majority of participants. However, more participants supported Option 4 than any other option, with the remaining support split fairly evenly among the other options.

Most participants shifted their position throughout the course of deliberation. In general, this shift was in the same direction: away from the more conservative options (Options 1 and 2) and towards the options involving fortification, particularly Option 4. This shift is apparently consistent with similar studies that have used a deliberative methodology, in which participants start from a 'conservative' stance and, as they move through the process and gain information, become less cautious in their suggested solutions, although often adding caveats and conditions.

Option 1 - Continue with current Government policies of advice.

Support for this option was relatively consistent throughout the process. At the end of the process it was the least supported of the four options. Most of those participants supporting this option appeared to do so because they did not consider the issue of NTDs (and the number of people affected) to be sufficiently serious to warrant an increase in Government action. Those participants who supported *some* action but did not favour fortification usually supported Option 2.

Participants supporting Option 1 considered it raised no additional risks and was therefore the safest way forward. For some, the absence of any additional costs was also a factor. Some participants felt that this option would allow time for further research to be conducted to investigate any potential risks related to increased folate intake.

This option also appealed to participants keen to retain their right to choose non fortified products.

Those who rejected it saw it as ineffective in reducing NTD affected pregnancies; ineffective in addressing the issue of unplanned pregnancies; and too reliant on individuals exercising good choices. Several felt that this option was almost immoral in its disregard for the rights of the unborn child.

Option 2 - Public Information campaign to encourage women to take folic acid supplements.

This option was often initially very popular but its appeal declined over the deliberative process. However, it was often selected as a 'back-up' to act in tandem with further fortification (whether mandatory or voluntary). This option was favoured by participants who felt unable to support further fortification – either because of issues of consumer choice or because they considered the potential risks to other sectors of the population to be unacceptable.

Those who chose it felt that, although past campaigns had been unsuccessful (in terms of behaviour change, if not awareness), this could be reversed by improved targeting or greater financial investment. A number of marketing ideas were suggested. This option was considered more pro-active than Option 1 but still relatively risk-free. For these reasons, it was often suggested as an initial measure that should be tried before moving to more radical action if necessary.

Those who were not in favour of this option or who moved away from it as their first choice, often doubted that it would be effective in reducing NTD rates. In this context, participants noted the evidence given to them from experience in the UK and other countries; the requirement for a change in behaviour amongst the target audience in addition to simple awareness and also the high percentage of unplanned pregnancies. They believed that it would also need to be run on an ongoing basis to catch upcoming generations of young women and would therefore be expensive. There was also the suggestion that the target audience would need to include parents (including fathers) of young women. This also led some participants to suggest that the campaign could be extended to the full population because of the general health benefits of optimum folate intake.

Option 3 - Encourage food companies to fortify more products with folic acid.

This option tended to become more popular as the process progressed, but also lost support among some people.

Those who did support it believed it would be effective in reducing NTD rates and it was felt by many to be less 'extreme' as well as less risky than Option 4. Some participants felt it could be tried before moving to a more regulated approach if necessary. Participants felt that this option provided purchasing choice for consumers and they viewed the marketplace as a tried and tested mechanism for stimulating product innovation and consumer demand. Relevant products would obviously need to be flagged (most probably by a labelling logo) to enable consumers to make an informed choice. Most felt that this option would also need to be supported by an education campaign to encourage uptake and to increase consumer awareness, both among women who could become pregnant and older people for whom high folate intake may present risks.

Those who rejected this option did so either because they opposed fortification *per se* (preferring Option 1 or 2), or because they favoured the more regulated approach of mandatory fortification. For those in the latter group, Option 3 seemed too indiscriminate. Firstly because of concerns about a consistent and appropriate "dose" being delivered to the target group, while avoiding over-consumption among potential at risk groups; and secondly the difficulty of monitoring the effect that increased consumption of specific products or categories of fortified foods might have on the NTD rate. It is interesting to note that even some participants who supported this option suggested refinements

aimed at making the approach less indiscriminate and which amounted to imposing a degree of regulation (either by specifying and proscribing which products should or should not be fortified, or by setting maximum and minimum levels). There was also a concern that the issue was too important to leave to the vagaries of the market place and required leadership from an official body.

Option 4 - To make the fortification of flour or bread with folic acid a legal requirement.

This option gained in popularity during the deliberative process as participants' doubts grew over the likely effectiveness of some of the other options. Participants who shifted their position towards Option 4 tended to do so because they came to the view that this was the only option likely to reduce NTD rates significantly, rather than because their anxieties about potential risks were completely resolved. However, for the minority who consistently supported it, this was simply seen as the right thing to do. Those who were adamantly against mandatory fortification at the outset tended to remain against it.

Some of those in favour of Option 4 were convinced by the evidence from other countries that mandatory fortification is effective in reducing NTD rates and, importantly, does not rely on behaviour change, thus addressing the issue of unplanned pregnancies. Many of the 'pro' participants supported their argument with the rationale that increased folate intake may deliver health benefits for the whole population. Bread was also considered as good a choice as any in the absence of any other more appropriate staple foodstuff. It is important to note that many of those who supported Option 4 added conditions to this option, designed to mitigate potential risks arising from an increased population intake of folate, especially amongst older people. Two most commonly cited were an effective screening programme for B12 deficiency as well as for bowel cancer; and the de-fortification of some foodstuffs that are currently fortified with folic acid on a voluntary basis. Most of the participants supporting this option also suggested the need for an education campaign about the specific benefits and risks of increased folic acid intake, as well as general health benefits for the whole population.

For those who rejected this option, two important themes emerged. Firstly, the right of purchasing choice – or rather the lack of it in this option - was a major objection. These participants objected to the 'medication' of the whole population seemingly for the benefit of a few. Secondly, a significant number of participants

remained worried by the evidence concerning the possible risks for older people due to B12 deficiency masking and some early scientific research evidence regarding the potential for accelerating the development of cancerous polyps in the bowel. These participants tended not to be reassured by any of the risk / benefit analysis included in the information, especially in the second session (NB. one as yet unpublished study). Some were also concerned about 'high consumers' of foods such as bread, spreads and cereals, which might include older people, those on lower incomes and students. Some participants who considered their own diets to be fairly 'ordinary' felt that even they might be liable to consume too much folic acid if bread were fortified. In addition, for these participants, the information that women planning a pregnancy would still need to take folic acid supplements undermined arguments for mandatory fortification.

There was an almost universal plea for more research and monitoring, both in terms of scientific research to investigate further the possible risks and research to investigate the effectiveness of interventions, particularly learning from the experience of other countries.

Those who felt unable to wholly support option 4, suggested possible alternatives, such as:

- Fortifying flour with a lower dose of folic acid and monitoring the effects, increasing the level if the evidence indicated clear benefits and manageable (or no) risks. Similarly, fortifying bread flour as opposed to all flour products was also suggested.
- Identifying a food typically consumed by young women but not the rest of the population, that could be fortified instead of flour or bread.
- Retaining an element of purchasing choice by encouraging industry to introduce variants branded 'fortified with folic acid' alongside unfortified products, or even introducing folic acid in low cost brands, so as to reach the core target market i.e. younger, often poorer women with poorer diets, unlikely to take supplements or to be effectively reached by health advice.

6. To identify the key issues that influence opinion on these issues.

Three key issues featured most prominently in discussions throughout the process and these were the greatest influence on which option participants eventually came to support. Participants' views on these issues as they relate to the specific options have already been discussed in detail above – some additional, more general, points are noted below:

Risks associated with increased folate intake

Many participants sought to establish a clear understanding of the risks attendant on increased folate intake and to find an appropriate balance between these risks and the benefits.

Many participants understood, from their own awareness, that scientific evidence is always developing and felt that that this can lead to “authoritative” health advice to the public changing frequently. Nevertheless, a sizeable number of participants felt unable to support further fortification without guarantees that increased folate intake would not cause harm to anyone in the population. Others took a more pragmatic approach and were prepared to make a decision based on what evidence was currently available, although this did not negate their desire for continued rigorous and comprehensive scientific investigation.

Participants demonstrated different strategies in attempting to find an appropriate balance of risks and benefits. Two that were debated (although not resolved) were: 1) focussing on the ‘hard’ numbers of cases of NTDs, B12 deficiency and bowel cancer and 2) taking account of monetary costs of all of these to the NHS and society.

Unplanned pregnancies

The high proportion of unplanned pregnancies in the UK convinced many participants that the only effective approach would be to increase fortification of frequently consumed foods (although not necessarily on a mandatory basis). The higher prevalence of NTD affected pregnancies among younger women and those on low incomes was also cited in this context.

Conversely, a minority of participants held the consistent and opposite view that young women should be the prime focus of any action to reduce NTD affected pregnancies, with some radical suggestions being made. This view was influenced to a degree by an assumption that the large number of unplanned pregnancies was the result of promiscuity and binge drinking among young women and teenagers.

Consumer choice

The issue of consumer choice was discussed both in broad ethical terms and in more personal terms where participants sought a means (either for themselves or others) to opt out of perceived risks. Some participants felt very strongly that mandatory fortification would severely compromise their freedom of purchasing choice, only to benefit what they saw as a minority target audience. Although no-one spontaneously used the phrase 'mass medication', some participants felt that it was not appropriate to 'medicate' the population as a whole.

Many participants remained concerned about retaining 'consumer choice' (particularly where they could not see any benefits for themselves from further fortification). Some participants attempted to find a compromise option offering an element of choice within mandatory fortification. Participants were almost unanimous in feeling that in the event of further fortification (on whatever basis) the added nutrients should be clearly labelled.

7. To explore issues of consumer choice in relation to the four options.

See discussion above.

8. To identify differences between groups within the population in relation to these issues.

The research was designed to gather the views of participants from a range of socio-economic sub-groups as well as from black and minority ethnic communities. The intention in this piece of research was to identify where there may be differences among these groups that warrant further investigation in further more specifically targeted research, rather than seeking to make definitive conclusions at this stage. Care should therefore be taken in interpreting the results of a relatively small qualitative sample and views by no means homogeneous within sub-groups.

In general, young people and young families were more in favour of some form of fortification than were older people and pensioners. Family participants were most in favour of mandatory fortification. Older people and pensioners were more likely to be in favour of targeting what they saw as the 'key' audience (i.e., young women).

The views from the interviews with black and minority ethnic consumers mirrored those voiced in the main sample in most ways, particularly in relation to the proposed solutions and, on the basis of this study, we would suggest that this did not warrant further targeted investigation. What is clear is that 'moral / social' and / or 'religious' views could inform personally held complex opinions about abortion and disability which are obviously pertinent to this debate but in a number of different ways (i.e. we are not able to generalise about their impact according to 'ethnic' or 'faith' group). In our opinion, these views were held across a wide cross section of the participants and not just by certain faith groups.

There also seemed to be little difference of opinion between men and women, or on the basis of socio-economic group. Responses to the questionnaires were analysed for these variables but no notable differences emerged.

As far as regionality was concerned, some participants in Northern Ireland (and in Wales) were aware of the higher prevalence of NTD affected *births* in their community. The issue of the non-availability of termination in Northern Ireland was also discussed, although there was a pragmatic understanding that women who wanted (or could afford) to do so, could travel to the mainland to obtain a termination. The issue of termination did not seem to greatly influence participants' views however, because the majority of participants in all groups saw NTD affected pregnancies as a very serious issue and discussions quickly moved to how increasing folate intakes among the target group could best be achieved. Certainly in no group was termination perceived as a 'solution' to the problem of NTD affected pregnancy.

In addition, there were some participants in all groups who were very cynical about Government interventions. This was particularly evident in Northern Ireland and, to a lesser degree in Wales. This cynicism was sometimes channelled into objections to fortification through questioning of policies, motives, efficacy, funding and priorities. In most other respects, regionality did not overtly play a strong role in the way participants approached the deliberations.

Overall, we feel that many differences in views between participants were more to do with the way people think as well as how this concords with their previously held (moral) views. We have proposed a number of segments which are explored in more detail in the body of the findings.

9. To make recommendations for a future communications strategy.

Before fieldwork started, this objective was prioritised below the others and in the event there was less time available to cover this in the sessions than would have been ideal. The following preliminary comments are therefore offered.

The issue of mandatory fortification is complex and requires consumers to consider the interests of many different interest groups. In addition there is clearly a significant challenge in the complexity of the issue and the amount of information consumers need in order to be able to fully understand and debate the issues from a 'rounded' perspective. It is difficult to see a way of shortcutting this process in the public arena, as the issue is far more complex than a more straightforward health benefit campaign, such as cutting down one's salt intake.

Comments relating to the communication of the specific options are:

Option 1 – Debatably, nothing needs to be done that is not being done already.

Option 2 – There is an argument for targeting everyone in the population alerting them to the general health benefits of folic acid, with young women and those planning a family as sub groups of the target audience. It is our feeling that if a campaign is directed solely at those planning a pregnancy then those who are not will rule themselves out. However, these are the very people who are a key audience in relation to the continuing high number of unplanned pregnancies.

Option 3 – An education campaign would be crucial in informing consumers of the benefits of folic acid, as well as the possible risks associated with increased intakes; and for supporting information systems, such as labelling, that would enable consumers to choose or avoid foods as appropriate.

Option 4 – This is the most complicated from several angles. Firstly, there may be some benefit in showing that a precedent for 'mass medication' already exists in bread, although this is also a risky strategy and could be a shock for some consumers who will need to be reassured as to why it is still happening. The current ethos for transparency and freedom of information also underlies this. Secondly, unlike the current fortification of bread, there are some very complex issues to be tackled, both in terms of specific risks and benefits and general health benefits for different population groups; and in terms of finding a mechanism for alerting consumers to the products that are fortified.

As we have mentioned above, we feel there are huge advantages in educating the whole population as to the health benefits of folic acid, but within this to target young women as a sub-group. We believe the message needs to be clearly relevant to all, otherwise we feel that women not planning a pregnancy will rule themselves out of any campaign message.

DETAILED FINDINGS

SESSION I

Voluntary fortification

Most participants were aware of voluntary fortification of various foods with vitamins and minerals *but* it was not especially top of mind *and* there was a significant degree of confusion around the issue.

Participants were 'pre-tasked' to bring one or two food products with added vitamins and minerals to the first session. Most had thought this would be an easy task, but many had found it surprisingly difficult as there were relatively few product categories where voluntary fortification was obvious. In particular, there was often confusion as to whether vitamins and minerals were naturally occurring in a product or whether they had been added, especially if the words 'added' or 'fortified with' were not present. Some participants also confused 'added vitamins and minerals' with 'additives' in general.

Among the products brought along, the most common were cereals, plus drinks, dried skimmed milk, processed cheese, children's tinned pasta, multigrain bars, cholesterol-lowering spreads, yoghurt with added omega 3 and probiotics.

Participants were agreed, in relation to the products they had identified as having 'added' vitamins and minerals, that these had been included at the manufacturers' behest, for their commercial advantage. They did not believe that this type of fortification was motivated primarily by concern for the health of the nation.

There was a **range of reactions to manufacturer led and voluntary fortification**. At best, it was felt to be 'a good thing', 'the more, the better' and sometimes even reassuring, especially if one had doubts about nutritional gaps in one's own or one's family's diet. At the same time it was also possible to think that fortification probably reflected perceptions that modern food is less naturally nutritious and more processed.

Participants also felt that it was hard to make a judgement about voluntary fortification, given what some perceived to be shifting advice on food and nutrition. It was also felt that it was hard to judge whether or not one was ingesting the 'ideal' amount of a particular vitamin.

At worst, there was cynicism and even a degree of paranoia about manufacturers' motivations. Some noted the presence of fortification claims on products they considered to be less healthy (e.g. cereals containing chocolate), on own brand equivalents of popular branded products, and on cheaper products. A minority expressed spontaneous concern about the possibility of ingesting too much of a particular vitamin, mentioning press coverage in the context of supplements in particular. A few expressed a strong preference for food which had not been 'messed around with' or food which was 'naturally' wholesome. Others were less concerned with the composition of their foods, with taste concerns and preferences taking precedence over nutrient content.

Hardly any of the participants had considered the **issue of regulation** in relation to voluntary fortification, but there was a fairly widespread assumption that some official body was probably 'keeping an eye on it' (e.g. by specifying RDAs and nutritional information on labels). The Food Standards Agency was mentioned in this context. However, some participants did spontaneously raise concerns about a presumed lack of control over voluntary fortification and that it would be difficult for any official body to regulate voluntary fortification, as it would be impossible to estimate / balance out any one person's daily intake.

The issue of **choice** in relation to voluntary fortification was not top of mind, but did emerge in comparison to mandatory fortification. However, choice in purchasing decisions was more apparent than real given the lack of clear labelling. Labelling in relation to vitamins and minerals was considered not to be very clear, with differing formats and confusion around RDAs and %s. In addition, there was a high degree of confusion and ignorance about the nutritional benefits of many vitamins and minerals.

For the most part, participants did not feel that they consciously looked out for fortified products, especially as aspects such as fat, sugar and calorie content were generally more top of mind, although there might be some post-purchase rationalisation if the fortification was noticed. However, fortification was more relevant for two sub-groups of consumer: children (especially if they were faddy eaters) and vegetarians or vegans.

At this stage, participants were asked to complete a questionnaire with their views of voluntary fortification. Overall, nearly a half of the sample recorded that they were 'definitely in favour' or 'on the whole in favour' of voluntary fortification. The bulk of the remainder were 'not sure', reflecting that this was a new issue for many participants.

Mandatory Fortification

There was very **low awareness** of the existence of mandatory fortification across the sample. The odd (older) person knew about it, in one or two instances in some detail in relation to bread and margarine. In addition, a few (usually but not always) older people recalled recent media publicity about the possible fortification of bread with folic acid. The vast majority knew nothing about mandatory fortification *and* were very surprised to hear about it.

Initial views about mandatory fortification were mixed, but with a significant degree of positivity. Participants recognised the possibility of a **public health justification** in that it would presumably be for the general good. Some also felt that it might especially benefit less healthy or more deprived members of society. They assumed that there would be a strong justification for such a significant action by Government.

To some degree, mandatory fortification fitted with the principle of a preventative approach to health issues. Participants considered that if it had been extant for some years, no-one seemed to have come to any harm in the process. In addition, it was not profit-driven, unlike voluntary fortification. There was also a belief that if it was Government-initiated, it would be regulated.

For those participants who could see the rationale, it was acceptable that Government take an active role in managing the health of the nation. This was reflected in the acceptability of the Government taking an interest in, for example: food labelling; consumer rights; research and the collation of evidence; health education, etc. However, there was some feeling that it was difficult to know where to draw the boundary between Government responsibility and individual responsibility for diet and health and that this is a 'fuzzy area'.

In addition, **a significant minority were more questioning** about the principle and practice of mandatory fortification. There were a range of objections, one of the key ones being a strong objection to the removal of individual choice when it came to their purchasing decisions. These were often the same people who were also resentful about the lack of information about current mandatory fortification available in the public domain. Others were also cynical about the motives of Government, some suspecting a possible tie-up with 'big business' and food manufacturers. Some were doubtful about Government's ability to manage and regulate fortification in order to prevent excessive consumption of folate. Across the sample, those participants in the 'choice-driven' segment often maintained their views throughout the consultative process, seeing it as matter of principle.

These questioning and negative views were especially prevalent in Northern Ireland (possibly because of especially deep-rooted cynicism around 'Government') but these views were also heard in other areas.

As most participants were unaware of mandatory fortification, they had **no idea which foods were fortified**. One or two participants were aware that bread and margarine were fortified mandatorily. Other suggestions included milk and baby food.

Bread was used as a 'case study', with details being given to participants in the groups on an information sheet, giving the history of mandatory fortification of bread, its justification and what it entailed.

AN EXAMPLE OF MANDATORY (by law) FORTIFICATION: FLOUR & BREAD

- The requirement to fortify flour was put into place during the Second World War. This was intended to reduce the number of children developing rickets, and because of a general concern that some people in the population might not get enough of these nutrients with food rationing in place. Having a healthy population was considered important for the war effort. Bread was chosen for fortification because it was eaten regularly by the vast majority of the population.
- There are legal rules in place (the Bread and Flour Regulations 1998) that require certain nutrients to be added to flour when it is milled:
 - Iron – which is important for making red blood cells
 - Calcium – which is important for strong bones
 - Thiamin – which is important because it helps the body make use of the energy in foods
 - Nicotinic acid – which is important to help make healthy cells
- The fortification requirements apply to brown flour and white flour, but do not apply to wholemeal flour. This is because the nutrients are found naturally in the husk of the wheat, which is extracted when milling white and brown flour resulting in most of these nutrients being lost. In the case of calcium, more is actually “added back” than was originally lost, resulting in brown and white flour containing more calcium than wholemeal.
- Also, the rules do not apply to flour that has been milled in the traditional way by grinding between stones (this is because the equipment needed to add the nutrients could not easily be fitted in the small mills and windmills producing this “stoneground” flour).

Most people were not surprised that bread had been chosen, given that it is a staple food, although there was some suggestion from personal experience that bread consumption may be going down in our diets.

It is also worthy of note that, among BME respondents, there were reports of both 'Asian breads' and 'Western breads' being eaten – the latter especially in the form of lunchtime sandwiches.

The justification for the introduction of mandatory fortification in wartime was widely accepted although some participants questioned why it was still considered necessary to fortify bread 60 years after the war. Others were prepared to assume that it must still be beneficial. All participants were (by sample definition) bread eaters and there were frequent comments that 'It doesn't seem to have done us any harm'. There was some confusion about the differences between brown, wholemeal and stoneground bread as explained in the information unit.

There were widespread requests for clearer labelling, to ensure that consumers were aware which breads were and were not fortified and, possibly, the nature of the nutrients which were added on a mandatory basis. There was also some discussion as to whether Asian flours conformed to the same requirements, especially when imported. Interestingly, one BME respondent brought to her second interview a label from an Asian flour product which stated that it was fortified with folic acid, although she had not noticed this prior to the research.

Interestingly, at this stage in the discussion, even where participants had strong objections to mandatory fortification, they rarely if ever said that their new knowledge would lead them to give up eating bread or confine themselves to non-fortified alternatives e.g. wholemeal.

Mention was also made by moderators of margarine as another product subject to mandatory fortification, leading to some concerns about the possibility that some heavy consumers of bread-and-spread might consume large amounts of the fortificants. However, many others were more accepting of its inclusion.

At this stage in the discussion, respondents were shown an information sheet which pulled together some of the issues around fortification, and the differences between mandatory and voluntary fortification.

FOOD FORTIFICATION

- Fortification means adding vitamins or other nutrients to foods during the manufacturing process.
- Bread and margarine / spreads are fortified by law – **mandatory**. These laws date from the 1940's and came into place because of concerns that people were not eating enough of some nutrients. The law specifies what nutrients should be added, and in what amounts, to ensure that people in general consume more of the nutrients.
- Many other foods are fortified on a **voluntary** basis – because the manufacturer chooses to do so, to make the product more attractive to consumers. Examples include some cereals and juice drinks. With voluntary fortification, the added nutrients may provide some health benefits, but some may have no proven benefits and sometimes they are nutrients which, although important in the diet, we should be careful not to eat too much of.
- There are two important differences between voluntary fortification and mandatory fortification:
 1. Voluntary fortification happens because manufacturers want to gain a commercial advantage by encouraging consumers to buy their product; mandatory fortification happens because Governments are trying to ensure that people get enough of certain nutrients.
 2. Consumers can choose whether or not they want to buy a product that has been voluntarily fortified, or a similar product made by a different manufacturer that hasn't; with mandatory fortification, consumers might not have that choice, because all manufacturers' products will be fortified in the same way.

Although lack of choice was an issue in relation to mandatory fortification, the sharpness of the differentiation between it and voluntary fortification was reduced by a number of factors; such as the presence of un-fortified breads and spreads in the marketplace but also the 'poor' labelling which precluded informed choice.

Again, it is interesting to note that at this stage in the discussion, no-one spontaneously suggested the use of mandatory fortification as a means of addressing other health issues.

Overall, a majority of the sample recorded on a self-completion questionnaire that they were 'definitely in favour' or 'on the whole in favour' of mandatory fortification. A significant minority were 'on the whole not in favour' or 'definitely not in favour' of mandatory fortification, often due to the choice issue. Negative views were especially prevalent in Northern Ireland (and, to a lesser extent in Wales) – perhaps again indicating the greater cynicism about Government activities in this location.

Folic Acid & Neural Tube Defects (NTDs)

Initial (Pre-Deliberation) Responses

Participants were given some **basic information** about folic acid and NTDs, and were told that the Government was considering a number of options (including but not only fortification).

THE ISSUE : FOLIC ACID & NEURAL TUBE DEFECTS

- The Government is considering options for improving the diets of young women in relation to folic acid.
- Getting enough folic acid during pregnancy makes it up to 70% less likely that the baby will develop a 'neural tube defect' (NTD) such as spina bifida – there is very strong evidence to support this
- Currently, women planning or starting a pregnancy are recommended to take a folic acid supplement to make sure they are getting enough folic acid.
- In the past, the Government has run 'education campaigns' advising women planning a pregnancy about the benefits of increasing their folic acid intake, by taking a daily supplement and eating more foods rich in folic acid
- This approach has had only a limited effect because around 50% of pregnancies are unplanned, and even where pregnancies are planned, only about 50% of women take folic acid supplements or change their diet to improve folic acid intake
- The end result is that there has been little decrease in NTD-affected pregnancies despite these campaigns
- The Government is considering a number of options, including continuing with the current policy, or possibly fortifying a food with folic acid
- Any option has its pros and cons, and the Government wants to hear consumers' views on this issue

Before any detailed discussion, participants individually recorded whether or not they thought 'something' should be done about this. In all, about two-thirds of the sample felt at this early stage 'definitely in favour' or 'on the whole in favour' of some action being taken.

A minority were unsure about whether action should be taken, usually because they felt they needed to know more before expressing an opinion. A few were against action being taken, usually because the preceding discussion led them to assume that fortification was implied (and they were against this) although the possibility of other options was emphasised in the ensuing discussion.

It should be noted that there had been **some spontaneous mentions** of this particular issue before it was formally introduced in the session, although in a cursory manner. Some of participants' pre-task products were labelled as being fortified with folic acid and, as a result of noticing this on pack, some (mainly women and some younger men) mentioned folic acid in the context of pregnancy during the general discussion of vitamins and minerals. At this stage in the discussion a few other participants (male and female) then recalled the recent media publicity re the proposal to fortify bread with folic acid. There was an acknowledgement by some people in both Northern Ireland and Wales that there is a higher incidence of Spina Bifida affected pregnancies in these locations than the national incidence.

Many of those who had heard of folic acid, but by no means all, linked folic acid with birth defects and specifically with spina bifida (although the phrase NTD itself was not used). Where participants knew about NTDs or spina bifida, they saw them as a significant issue. On the whole, women were more knowledgeable than men, and younger women or those with young families more than older women. This was primarily from their own experience, often of childbirth but also from the experience of relatives and friends and from seeing articles in magazines. Black and Minority Ethnic respondents were equally aware of the issue and knew about the need to take folic acid around the time of pregnancy in order to reduce the risk of NTD pregnancies.

At the other end of the age spectrum, some (older) men knew very little about Spina Bifida and especially of the beneficial link with folic acid. Some older people said the condition was not discussed as a problem when they were starting families, probably reflecting the fact that issues of disability in general were less discussed and disabled children were often institutionalised.

As a result of this pre-existing knowledge, women and younger men tended to understand and emotionally engage with the issue more easily, while older men had to work harder. However, across the sample, participants often found it difficult to take on board the fact that, for optimum effect, folic acid intake needs to be increased before conception and in the very early months of pregnancy. They also grappled with the information that 50% of pregnancies are unplanned, and to which type(s) of women this might apply.

Spontaneous suggestions for action made at this initial stage included:

- Action targeted at the 'needy' audience, often perceived to be young (and possibly ignorant) women or young girls who might become pregnant
- More and better education beginning in school
- Advertising on TV and in magazines
- Free folic acid supplements for (pregnant) women
- Linking folic acid – either literally or via marketing – with women's products e.g. sanitary protection, home pregnancy testing kits, condoms, etc
- Folic acid patches
- Persuading people to eat more green vegetables

- Add folic acid to a staple food eaten particularly by the prime target market – with suggestions including chips, burgers, crisps and even ‘alco-pops’

Within this, there were already debates in all the sessions around certain key issues, such as consumer purchasing choice as well as the likely effectiveness of action aimed at behaviour change.

Participants recognised that, at this stage in the deliberative process, they were giving their views based on limited information and they raised a number of questions to which they felt they would need answers before coming to a more definite view. These were **questions** that they generated spontaneously:

- What exactly are NTDs and what are their specific effects?
- Are there other causes of NTDs other than folic acid deficiency, e.g. genetic, age of mother?
- What is the size of the problem – how many NTD affected pregnancies and babies with NTDs are there?
- How do you know if you are taking in enough folic acid or too much?
- Is it possible to take too much folic acid and what might the effects of this be?
- Do the side-effects include cancer?
- What are the different options for addressing the issue and how effective would each of them be?
- What are the alternatives to fortification?
- Are there other benefits for improved folic acid intake, for instance in the general population, apart from its effect on NTDs?

- What are the natural sources of folic acid and how can we best utilise these e.g. is it destroyed by boiling vegetables?
- What are the costs of the various actions that might be possible and who will pay?
- Can we still have consumer purchasing choice?
- How good is the evidence about folic acid and NTDs, and what are the various options for action?
- What is the role of big business including pharmaceutical companies?
- Can action be targeted at those who really need it?

Participants were then given more detailed information about **NTDs**.

NEURAL TUBE DEFECTS ('NTDs')

- Neural tube defects (NTDs), such as spina bifida, hydrocephalus and anencephaly, are caused when the spinal cord or the bones of the spine surrounding it fail to develop properly. This leads to damage to the nervous system.
 - **Spina bifida** occurs when there is a gap or split in the backbone, exposing the spinal column, usually in the lower back. This can lead to varying degrees of paralysis; many people with spina bifida are wheelchair users and / or have no control over bladder or bowels
 - **Hydrocephalus** is caused when the fluid that is produced inside the brain doesn't get absorbed back into the bloodstream in the normal way. This leads to a build up of fluid, which in turn can stretch or squash the brain tissue. Children with Hydrocephalus may suffer from learning difficulties and eyesight problems
 - **Anencephaly** means that the brain fails to develop, leading to miscarriage or death of the baby soon after birth
- It is estimated that there were 700-900 pregnancies affected by NTDs in 2003 (this is about 10-13 in every 10,000 pregnancies). Many NTD affected pregnancies are ended by termination, although the numbers are difficult to estimate (and women living in Northern Ireland are not offered terminations). There are around 200 reported births of babies suffering from NTD each year in the UK.
- NTD-affected births declined until the 1990s, but there was little or no change throughout the 1990s and into 2000s.

Not all NTDs are caused by folic acid deficiency, but it is estimated that increasing folic acid intake could prevent about 40% (four out of every ten) of NTD-affected pregnancies. Food fortification programmes in USA, Canada and Chile have been successful in reducing the rates of NTDs dramatically. In each case, folic acid is added to bread and other grain and flour based products

For many this confirmed the serious nature of NTDs for the individuals affected. There was some question as to whether the incidence was 'high' or 'low' in relation to other birth defects and disabilities and, indeed, as to whether prevalence should influence the decision. There were also a few queries about

the cost-benefits of the issue: i.e. the cost of NTD-affected pregnancies set against the cost of action(s) to prevent these.

When discussed, **terminations of pregnancy** (ToP) were generally not seen as the 'easy solution' because these could be difficult and distressing for any prospective parent. They were mentioned on the odd occasion as a possible option by a lone participant.

Terminations also had particular resonance for Hindu, Muslim, Roman Catholic and Protestant participants. This is a complicated issue and we would not wish to imply the following comments are a comprehensive treatise on the issue from each perspective. We designed the sample to include certain ethnic and religious groups, but inevitably the numbers of actual participants are small. However, in each case, our participants reported that their religion usually frowned upon or even forbade terminations, as children are considered to be 'gifts from God'. However, they also reported that this orthodoxy might be overruled in private by the weight of personal considerations and individual choices. In the Hindu community, such individual action seems to be supported by the principle that one should not condemn others.

In Northern Ireland, many participants seemed to take a pragmatic attitude towards ToPs and acknowledged that these did happen, albeit one had to pay and go to England or elsewhere.

However, it is important to acknowledge that views on terminations, either for or against, might not be based on religious grounds but on personal, moral or social stances which could just as strongly influence deliberations on this issue.

Within many communities there are also cultural and social issues around the need for a healthy baby. Again, this can be so whatever one's ethnic or faith background might be, but some Hindu and Muslim women in particular spoke of the pressure to produce healthy offspring and of the potential repercussions of not doing so, such as husbands taking second wives, getting divorced, etc. Afro-Caribbean participants did not have distinctive responses to these issues.

At this stage in the pre-deliberative discussions, participants were given **more information about folic acid**, including the link with masking B12 deficiency and the potential risks in relation to other diseases.

FOLIC ACID

- Folic acid is used in the fortification of some foods and is also available in supplements. It is found naturally in green leafy vegetables
- The body cannot make folic acid for itself and therefore must get it from the diet. Also, because the body cannot store folic acid, people need to consume it regularly to maintain a good level in the bloodstream.
- Adults and children need folic acid to make normal cells (including nerve cells and red blood cells) and to prevent anaemia; some women of childbearing age and also the elderly do not have enough folic acid in their diets.
- Folic acid is particularly important during pregnancy: if a woman has a low folic acid intake before and during pregnancy, she runs a greater risk that her baby will be born prematurely, will have a low birth weight, or will develop a neural tube defect (NTD).
- There is evidence that where a person has a deficiency of vitamin B12, having a high intake of folic acid makes it more difficult to diagnose the B12 deficiency. B12 deficiency is reasonably common, with up to 10% of the elderly population being affected to some extent.
- Some recent studies have suggested that consuming high levels of folic acid can: reduce the risk of diseases including coronary heart disease, some cancers and bone diseases; but increase the risk that if you already have pre-cancerous polyps in the bowel, these will get worse. However, at the moment scientists agree that not enough studies have been carried out to establish whether folic acid does, or does not, have these effects.
- There is no evidence that an increased intake of folic acid presents any specific risk to children.

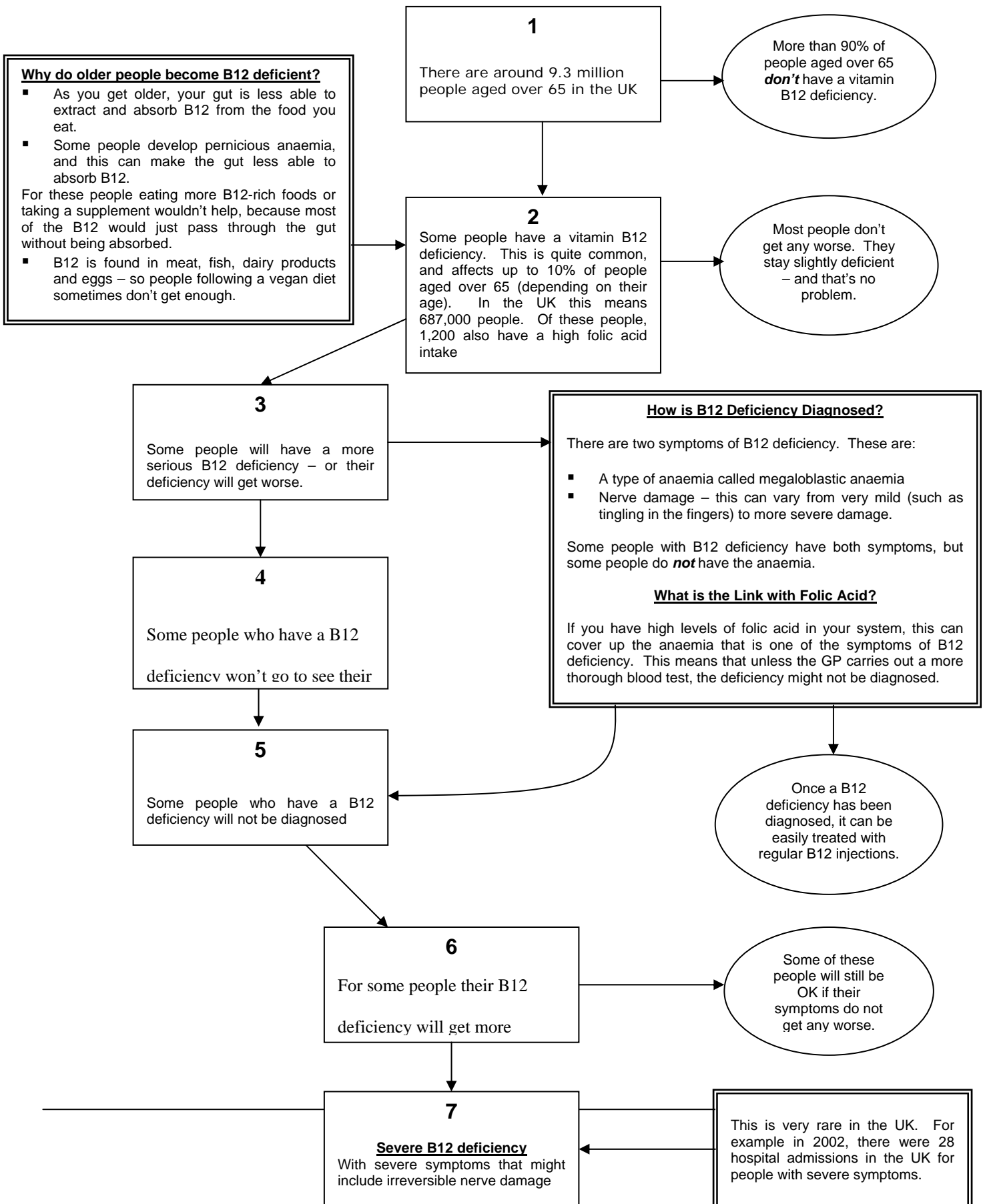
As noted earlier, folic acid and its benefits in relation to pregnancy were already quite well recognised among women and younger men and assumed to have a good evidence base. Initial responses to the information were as follows:

- ❑ **Everyone's need for folic acid** was reassuring for many, as well as the fact that folic acid is a water soluble vitamin and that the body excretes any excess
- ❑ The **B12 masking issue** was quite hard for many participants to engage with. Two older people in the sample had been prescribed folic acid for anaemia and so this was of particular interest to them but also to many of the older participants
- ❑ The brief information given at this stage about **cancer** was often (but not always) latched on to, especially in relation to bowel cancer, and was often viewed in a very negative light, particularly as bowel cancer was believed to be on the increase. It was usually assumed that there were more cancer sufferers than NTD-affected pregnancies, which was a factor for more statistically-minded participants.
- ❑ For some participants, the cancer risk was sufficiently worrying for them to say that no action should be taken to increase folic acid intake until the cancer evidence was clear. Others said that at this stage it was difficult for them to balance out the risks; that they needed more information and more time to think.
- ❑ One participant had heard that excess folic acid caused strokes in older people.
- ❑ The information that no specific risks to **children** had been identified was reassuring to most.
- ❑ **B12 deficiency** seemed already to be a recognised issue for vegetarian Hindus and other vegetarian groups and there were also queries as to whether chapatti flour would be fortified.

- Although some participants recognised that the B12 and cancer risks could be addressed by (better) screening, others were cynical about the likelihood of the Government and the NHS allocating sufficient resources and attention to this.

Participants were given more information about **the B12 deficiency masking issue** via a flow chart tracing the risks and numbers affected and to provide the context for how a case might progress in 'real life'.

Vitamin B12 Deficiency in Older People aged 65 and Over



As already mentioned, a few participants were already aware of this as an issue, but generally it was recognised that the 'science' and risk assessment was complicated and that it contained many 'ifs and buts'.

The main outcome, (i.e., 28 hospital admissions set against 9.3 million older people) was understood and was quite impressive, but with some caveats. Participants reckoned that presumably this proportion will increase, firstly - if folic acid intake goes up and secondly as the elderly population is known to be increasing.

Again, there was some recognition that this issue could be addressed by (better) monitoring and vigilance among health professionals, and (effective) treatment. However, as before there were doubts as to whether this would in fact happen. In contrast, NTDs were considered not treatable in the main. This information also triggered some recognition of a 'babies vs. old people' issue here and some early discussion of comparative cost-benefits. However, overall, at this stage there seemed to be rather higher levels of concern about cancer than about masking B12 deficiency.

It is important to note that the information given to participants at stage 1 about potential links to cancer and other diseases was rather brief for some serious consideration, especially compared to the amount of information given to them to digest about B12. This imbalance was remedied in the reconvened sessions.

Summing up, by the end of the **first sessions**, on the whole participants did see the issue of NTDs as a significant, serious one although some said that they needed to see more information and evidence to be sure.

In discussing the above topics, participants grappled with the issue of 'emerging evidence' willingly but with varying degrees of effectiveness. The idea that scientific knowledge is developing was given (not always positive) support by the well-known propensity for changes over time in the advice given about food and health. Some participants mentioned concerns about possible research bias and vested interests among food and pharmaceutical companies. Some participants

took a 'hard line' and said that significant actions (such as mandatory fortification of a staple food such as bread) should not be taken until the science was clear and sure. Others accepted that this might not be possible and that decisions would need to be taken on a balance of possibilities and risks. The fact that bread has been fortified for over 60 years without (apparent) ill effects was reassuring for some people in this context but with the important caveats that there were benefits for everyone and no known side effects.

Overall, most participants thought that trying to reduce the number of NTD-affected pregnancies was an appropriate issue for Government to concern itself with, the debate was more about how this could be achieved.

There were definite **pockets of 'outrage'** against the whole idea of mandatory fortification both on grounds of consumer choice and the principle of the greater population having to have folic acid added to their food seemingly for the benefit of only a few. However, on the whole, the idea of 'mass medication' was not unacceptable **if it could be proved to be effective and low-risk.**

It is interesting to note that, throughout the discussion, the views held between and by each individual were varied, often conflicting, sometimes changing, confused and contradictory, reflecting that some (if not all) participants still needed to think through the complex issues, from a number of different angles:

- ◆ for themselves and their families
 - ◆ for the rights of the unborn child
 - ◆ for older people
 - ◆ for society and the demands on the NHS
- and moral issues about the health of the nation which, for a very small minority, included disability rights

Others remained entrenched in their view that they could not support mandatory fortification on any grounds.

Towards the end of the first session, participants were presented with **the four options** agreed by the FSA Board as the basis for consultation:

FOUR POLICY OPTIONS

Option 1 – Continue with current Government policies of advice on folic acid

Option 2 - Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid.

Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis

Option 4 – Make the fortification of flour or bread with folic acid a legal requirement (mandatory)

After a brief discussion, participants were invited to record their views and preferences on a self-completion questionnaire. Their first preferences were as follows:

- Option 1 about one fifth * of the sample overall
- Option 2 about three fifths *
- Option 3 about one tenth *
- Option 4 about one twentieth *

* As already emphasised, these figures are shown to facilitate comparison and must be treated with caution.

These findings indicate that, at this early stage, a majority of participants favoured some action being taken, but went for a perceptually safe option because of their concern about and need to know more about the risks involved in more radical action.

SESSION II

Folic Acid & NTDs – Post-Deliberation Responses

At the end of the deliberation period, before returning for the second session, participants were asked to again record their views and preferences on a self-completion questionnaire on the basis of what they had read in their deliberation material and possibly had discussed with friends and family. A clear majority of the sample had changed their views over the deliberation period and first preferences were now as follows:

- Option 1 about one seventh – no significant change
- Option 2 about one third - decrease
- Option 3 about one fifth – slight increase
- Option 4 about one third - increase

At the beginning of the second session, participants were asked to report back on their preferences and to identify their main reasons or the main pieces of evidence that had influenced their choices.

Where participants had changed their views, this was sometimes because thinking about the information provided for the deliberative process had led them to look at matters differently *or* it was a reflection of their uncertainty about the issues and evidence and which option(s) to support. (It has been observed in other deliberative research settings that participants often start conservatively in their views and that, as they move through the process being given more information and effectively becoming more like 'experts', they turn to less cautious options, albeit with caveats).

Where participants had not changed their views, this was because they were convinced by the evidence that their original preferences had been correct (NB.

this could be either pro or anti mandatory fortification) *or* because the struggle to get to grips with the evidence had led them to become even more entrenched.

NB. In both categories, there were participants who appeared not to have thought in an evidence-based way but more on 'gut reaction' or in accordance with strongly previously held beliefs.

Others were still undecided having read much of the evidence and an acknowledgement that it was a complex subject with the weight of evidence difficult to evaluate.

Various different pieces of evidence were quoted to support people's preferences. From our impression, no one piece or area of evidence stood out as being especially striking in its effect. Different participants often gave different reasons or quoted different evidence for choosing the same option preference. Participants also interpreted the same pieces of evidence in different ways and also used their own personal experiences as evidence.

Overall, many people found the evidence in this instance to be complicated and sometimes conflicting, with the result that it felt like 'the balls are in the air' and that acquiring more information did not necessarily lead to more clarity! However, we were impressed that a majority of participants had persisted with their reading as was evidenced by their knowledge and marshalling of arguments in the second stage. Almost all had read the simpler Level 1 'green book' in full, but also in many instances tackling at least some sections of the far more complicated Level 2 'blue book'. In the sessions, most participants did their best to engage with the issues and the debate.

To generalise (and possibly to oversimplify) at this early stage in the reconvened discussions:

Options 1 & 2 appealed to those who were concerned with what they perceived as unacceptable and / or unknown risks, or who had strong views around choice.

"Carry on giving advice but with a stronger message"

(Oldham)

"Statistically there are more people that are at risk from having a higher amount of folic acid than there are at risk from having a low amount, and that's my main reason"

(Cardiff)

"My auntie died of bowel cancer, so it's in my family history ..."

(Belfast)

"Not enough research into it. And I'm 66, this B12 definitely alarms me, I have a heart condition"

(Belfast)

Option 3 was seen as a compromise, while also addressing choice issues.

"It offers choice and as long as there's no harm..."

(Edinburgh)

"Because I'm not really 100% on Option 4, but perhaps if they encouraged a bit more voluntary maybe that could help. Again a campaign to let people know why it is being added ... at least with voluntary it normally says 'with folic acid' so people know it is added, not it's just put in and people aren't aware of what they are eating"

(Sutton)

"If you put it in all of the bread, it is not really fair on the people who are going to have this vitamin B12 deficiency, so at least there's a choice. Because otherwise I would have said Option 4"

(Cardiff)

"The impression I got from the blue book was that there isn't enough clear evidence, there needs to be more research about the side effects and both the risks and the benefits of taking folic acid before anybody goes making it mandatory. I think people should have the choice"

(Belfast)

Option 4 was for those who were convinced that only this course of action would work, some giving it positive endorsement and others taking a more pragmatic view.

"Option 4 – they can screen for all the other things. Folic acid can't be made and any extra is excreted"
(Oldham)

"I went for Option 4, I'm definitely in favour ... I think today a lot of youngsters are so busy enjoying themselves that I don't really think they pay much attention to their diet. So if it is there, it's going to look after them whether they know it or not"
(Sutton)

"I went for Option 4, which is different from the original option that I went with. The main reason was I didn't think the other three had been that effective, although I would have preferred Option 1, 2, or 3 to have been my preferred option ... but it looked like the only one that was going to make a significant difference"
(Sutton)

"I think I read somewhere that it was proven in America, Canada and Chile that putting it in bread did reduce the number of children born with NTDs, so if it is proved there, why can't we do it here?"
(Cardiff)

Issues and Themes

After this initial sharing of responses, the session was thrown open to allow participants to raise and discuss the issues, concerns and questions which their deliberation had generated. Many of these issues had been raised in the first session but they were explored in more detail in the second session, hence their inclusion here. Participants spontaneously raised issues they wished to comment on and discuss further, which meant that not all issues were either covered in each discussion or across all the groups.

At various points during these discussions, participants were given additional information to answer queries or information gaps which had emerged in the first sessions. These are discussed specifically in a later section.

Research reflections on the deliberative process

In the course of this discussion, it became clear that virtually all participants had taken the deliberation process seriously and had fulfilled at least the minimum requirements requested of them. As noted earlier, all had looked at the level 1 'green book' and many had read it very carefully. Some had dipped into the level 2 'blue book', following up on aspects which interested them. Some had read the 'blue book' in depth and detail. A few had done their own internet searches on the topic and many had, as suggested, discussed the issues with family, friends etc.

There were inevitably variations in the rigour with which participants had examined the information and considered the issues. Some had been very thorough and tried to balance up the evidence as fairly as they could. Others had been more selective in what they read and took on board, to the extent that sometimes their views were based on partial or imperfect understanding of the evidence.

The sample was segmented to include a balanced range of ages, gender, life-stage, social class and region. However, despite this we believe that the differences in views were more to do with the way people think as well as the views they might already hold. Each participant tended to approach the task in her or his own individual way and hence we think it is possible to 'segment' participants in terms of their overall 'style':

- ❑ **Rationalists:** weighing up the evidence in a thoughtful way, looking at it from a number of viewpoints, probably better able to manage the risk issues, although this does not mean that all rationalists necessarily ended up in the same place or making the same choices of option.

- ❑ **Emotionalists:** responding to the more emotive aspects of the issue – "I just feel sorry for the babies".

- ❑ **Calculators:** emphasising the statistics, relying on data, e.g. more old people at risk than NTD pregnancies, these were usually male participants.
- ❑ **Moralists:** whose responses were based on their firmly held principles: this could be one or a number of principles, e.g. freedom of consumer purchasing choice; women should take responsibility for their own pregnancies; society should care about the unborn child, etc.
- ❑ **Selectors:** latching on to a small part of the evidence (e.g. the potential cancer risk) and using this to justify their stand.
- ❑ **Bargainers:** agreeing to a particular option *if* something else goes with it (e.g. Option 4 with screening, Option 3 with more Government regulation).

The atmosphere or dynamics of the workshops was somewhat different from the conventional 'focus group' and was often more thoughtful and reflective. We believe this reflects the nature of the deliberative process. Although people were being asked for their own views, this was within an explicitly social context. They were also being provided with a significant amount of information, some of it highly technical and the issues at hand were understandably complex.

The sessions were therefore quite hard work both for moderators and participants, albeit more obviously difficult for some than for others. However, while sometimes the atmosphere was 'cooler' than in an ordinary group, feelings did run high in some sessions, including arguments around principles (e.g. consumer purchasing choice vs. no choice) and there were some angry and emotional outbursts.

Participants' views on who is the target audience for folic acid

Stimulus and briefing materials made explicit mentions of 'women of childbearing age' and explicit links between folic acid and pregnancy. Within this context, some participants found it difficult to hold on to the evidence about the high proportion of unplanned pregnancies and the difficulties of achieving behaviour change. This was inevitably often reflected in their preference for education campaigns; their optimism about changing behaviour and their support for GP-led initiatives, etc.

Others were more pessimistic (and perhaps more realistic), mentioning both personal experience and citing the evidence that many women will not realise or acknowledge they are pregnant until the optimum time for folate intake has passed, as well as the past failure of health education programmes aimed at changing behaviour. Within this, there was a tendency for some (usually male) participants to stereotype (and stigmatise) the prime target audience as teenagers and young women who became pregnant as a result of irresponsible behaviour. This led some of them to suggest rather draconian measures such as the compulsory feeding of supplements to all schoolgirls, especially in Northern Ireland.

Others took a more generous view, believing that irrespective of the mother's behaviour, the baby should not be made to suffer and that the rights of the unborn child should be fought for and respected. Many of them also felt that it was not just young women who have unplanned pregnancies, and that unplanned pregnancies are not necessarily the result of irresponsible behaviour.

Some participants reacted to the challenge of reaching and influencing the target audience by pointing out that too much emphasis on pregnancy made it easy for women to 'opt out'. They could react to a health campaign about pregnancy and folic acid along the lines of: "I'm not planning to get pregnant, so this doesn't apply to me" while not being aware of the fact that 50% of pregnancies are

unplanned. Their suggestion was that folic acid should be 'de-coupled' from pregnancy and promoted as something which is **beneficial for all women**, which they understood from the evidence to be the case.

Arguably, this could be extended to consideration of the **whole population as the target audience for a folic acid health campaign**, much like campaigns around fat, salt, 5-a-day, etc. This would include men and older people who, again according to the evidence, need folic acid and can be deficient in it. This approach would particularly support Option 4 as it puts folic acid on a par with the other nutrients with which bread is fortified. It also gives it a broader justification in being clearly for the 'common good'. Importantly, women at potentially childbearing age would be an important part of the target audience but *not* the whole story.

Participants' views on balancing benefits to babies with risks associated with B12 masking in older people

When considering the evidence around the B12 masking and potential bowel cancer risk factors, some participants themselves raised the issue of making a choice between the interests of babies and of older people. This was, unsurprisingly, quite a difficult question and one with which not everyone could engage.

Some, including many older participants, expressed the view that, if it came to the crunch, babies' interests should come before older people: "They've got their lives in front of them". Another factor supporting this view was that B12 deficiency masking and potential cancer risks were (to a greater or lesser extent) seen as treatable or curable, whereas NTDs were less so. These participants tended to support Option 4.

Others, including some younger participants, felt that having to make such a choice was unfair and that everyone's interests should be protected. They

suggested a number of measures, such as not putting older people at risk in the first place by going ahead and adding folic acid to bread; delaying action until the science is clear(er); screening older people to minimise the risks, etc. Some of these participants pointed out that the elderly population is growing, so inevitably the proportion at risk will rise if fortification happens and therefore this challenge will need to be faced.

Participants' views on Disability

In general, participants across the spectrum looked on disability in a straightforward and conventional way. They characterised disability as a problem and as something to be prevented. They talked about feeling sorry for disabled people, even perhaps pitying them. As a consequence, they saw the intention to take action against NTDs in a positive light, thereby preventing damage to young lives and as part of the programme to help achieve healthy babies. They did not see it as eugenics, as a form of making 'designer' babies but as minimising as much as possible any health problems a child might experience.

They were therefore not surprised that organisations like Association of Spina Bifida and Hydrocephalus (ASBAH) supported mandatory fortification. Increasing intakes of folic acid in pregnancy was put on a par with advice to mothers to cut down on smoking and drinking. Given these views, most of them did not view the folic acid debate in terms of a 'disability rights' agenda. However, a minority did see some of the possible arguments from the disability rights angle. In one session where a (female) participant suggested using photos of babies with NTDs to 'shock' young women into taking folic acid, another (male) participant said that this was turning disability into a freak show and went straight on to ask which disability group would be the next one to be 'eliminated'.

One or two participants were concerned that if there were a significant reduction in NTD rates among the population, then those living with NTDs might face more problems in terms of acceptance and discrimination. There were a few comments that NTDs might act as a justification for terminations of pregnancy where the pregnancy was unplanned and unwanted.

There were also some issues around the 'meaning' of having a disabled child in some communities, though these were difficult to explore in depth with everything else that needed to be covered.

Participants' views on amounts and dosages of required folic acid

There was ongoing confusion about the amounts of folic acid needed to help prevent an NTD affected pregnancy. In addition, there was interest in the intake that fortification would achieve across the general population, both in relation to the benefits of folic acid for everyone, as well as the risks of high intakes and among particular at-risk groups.

This was not helped by some (apparently) conflicting information in the briefing materials. e.g. advice that women planning a pregnancy or in early stages of pregnancy should take a daily supplement of 400 micrograms vs. RNI for pregnant women of 300 micrograms.

The fact that, even with fortification, women would still be advised to take folic acid supplements was further support to those who were questioning the principle or practicality of fortification. Also, participants read in the material about the differing levels of fortification in different countries which raised yet more questions.

Basically, this was an area of questioning and concern, with participants wondering whether it was accurately known how much we need and what is the right level. Obviously this is especially pertinent in relation to mandatory fortification. Their concern was sometimes mollified by the takeout that the amounts did not look large 'per slice of bread' but it was asked why a staged approach could not be introduced whereby a small amount was initially added to bread to see what effect, if any, this would have in respect of NTDs, while hopefully not causing undue risk in other areas. Certainly, participants looked for a managed and monitored approach if increased fortification was selected as the way forward.

Participants' views on consumer purchasing choices

Like potential risk, the right of choice in issues to do with purchasing of foodstuffs was another 'big issue' for some participants, touching on something which they claimed was very important to them. As we have stated previously, these participants were very clear that they did not want their food 'messed with' (although some other participants saw this as a rather naïve view given the extent of modern industrial food processing). As well as possibly a well founded fear about what is done to food, it might also have been 'an excuse' to hang onto in the face of 'moral' arguments about the benefits of adding folic acid for the common good.

Whatever their real motivation, their views led them to reject any action where their individual choice was seriously compromised or removed. So, for example, they could support Option 2 and probably Option 3 but Option 4, mandatory fortification, was not acceptable if it meant that they were not able to buy bread that was not fortified. This option was only acceptable if only selected breads were fortified (thus arguably re-introducing the requirement for behaviour change and positive product choice).

Other participants took a more pragmatic approach, accepting that choice might have to be compromised in order to achieve the desired end, especially given that the unborn foetus does not have a choice. In addition, given that bread was already fortified it was accepted by some that a certain precedent had been set.

Risk assessment and management

This was a big issue for participants, one that they were often eager to learn more about and which was often a major driver in their option preferences. Some participants felt enlightened and reassured by the information provided, but many others still felt that the evidence was not 100% clear. While they might understand that scientific and medical evidence could never provide a total

answer, this still made it difficult for them to select an option where they perceived there was a significant risk, either to themselves or others. Some of these participants took an 'all or nothing' approach (if there's a risk, don't act), while others were able to think about strategies for addressing risks, such as screening.

Balancing risks and benefits and balancing the different kinds of risks, was a challenge for many participants. Some (especially men) tried to do it on a purely statistical basis by calculating the numbers at risk against the numbers who will benefit. Others felt that it was impossible, as they saw it, to reduce it to 'just numbers' and that if you can help prevent just one NTD baby, that in itself is worth it.

Both the B12 and the bowel cancer risks were seen as significant: B12 deficiency masking because of the numbers potentially involved amongst the older population and bowel cancer because of the understandable dread around the 'C-word' and because of its perceived increasing incidence.

Individuals had their own perspectives on which of these risks were more significant and overall it is difficult to say which one was more influential on people's deliberations. (See later for more detail)

Views on evidence from other organisations and countries

Some participants had read the submissions from **other organisations**, included in the Level 2 'blue book' and, in general, found this to be interesting in terms of their viewpoints and suggestions, such as co-fortification of flour with B12; the importance of addressing B12 deficiency in its own right; the GP's view that B12 deficiency and masking by folic acid could be effectively managed, etc. Views expressed by medical organisations and a GP were seen as particularly reassuring.

There were mixed views on the evidence from **other countries**. Some found this very persuasive, both in terms of the fact that three countries had already gone for mandatory fortification (presumably having gone through a process of 'risk assessment') and of the reduction in NTDs achieved. Others were less certain about this evidence, sometimes because of negative views about the specific countries (especially the USA), but also sometimes because they wondered whether conditions (e.g. in relation to diet) were similar enough to cross-compare. Some participants noted that there was no hard evidence from other countries re the risk factors (B12 deficiency, cancer) and felt that this detracted from the persuasiveness of other countries' experience to some degree.

Participants' views on the relative costs of different courses of action

Participants noted that there was limited information in the briefing documents about the costs, with the most prominent figure being the cost of fortification to manufacturers and the implication of a possible 1p rise in the cost of a loaf. They assumed that other costs would be taken into account in the final decision (i.e., by means of a cost-benefit analysis), and they would have been interested in knowing, for example, the cost to the NHS of lifetime care for a relatively small number of people with a NTD and the comparative cost of effective B12 and bowel cancer screening programmes for all older people.

Views on the Government and Public Health

This issue was the subject of explicit debate and was implicit in some of the attitudes and issues raised by participants. There was a widespread consensus that the issue of folic acid and NTDs was something in which the Government had a legitimate interest as there are clear public health issues. NTDs are (to quote several participants) 'horrible' and if it is possible to take action to prevent them, it is Government's responsibility to take the initiative. The desire to prevent NTDs fits with the trend towards preventative public health policies.

The big questions were precisely what action it should take and to what extent. Partly this was seen as an ethical and political issue which raised issues as to what were the appropriate boundaries for Government action. This linked in many people's minds to the debates around choice about what is in the food we buy and whether the Government can and should 'force' us to ingest certain nutrients.

It was also partly seen as a financial and pragmatic issue in terms of what was the most cost-effective way for the Government to spend the taxpayers' money and do the numbers of NTDs justify spending on this problem rather than on other public health issues.

For many participants, especially in Northern Ireland, to a lesser extent in Wales and a few in other locations, there were significant doubts and cynicism about the Government's 'delivery' in relation to its public health duties. This was partly based on participants' incoming 'baggage', for example, perceptions of discrepancies between stated policies and individual experiences. This meant that even if 'risk reduction' strategies (e.g. screening) were put in place, they were not confident that these would be delivered effectively.

Some participants picked up on the information given in the Level 2 'blue book' about the Food Standard Agency's seemingly differing stances over the years and this exacerbated the confusion about the Food Standard Agency's role in this issue. (Participants had not been informed that the Agency had funded and planned the research in which they were participating.) Participants took this to mean that the Agency, and therefore the Government, cannot make up its mind on this issue. This cynicism also came through in some participants' anxiety that mandatory action in relation to NTDs could be the 'thin end of the wedge' and they wondered on what issue the Government might next intervene.

More constructively, participants were also interested in what action the Government could and should take in tandem with the stated options, such as screening people at risk of B12 deficiency and bowel cancer; de-fortification of products to avoid excess intake; and producing communications and publicity campaigns.

Interestingly, while all were appreciative in principle of the opportunity to take part in this deliberative project, some questioned whether it was necessary or advisable, given the expense and the likelihood that it was a 'sham' exercise. A small minority felt that perhaps the Government is trying to offload its responsibilities so that it won't get blamed if there are problems.

For others, the exercise was viewed more positively, it was felt that we live in a democratic society, that our Governments are democratically elected and consultation is a praiseworthy process. However, the Government then has the responsibility to do what it thinks is right on the basis of what consultation it conducts and the access it has to other pertinent information, such as costs, other demands on resources, etc.

There was also some feeling amongst participants that the issue of mandatory fortification of flour is too difficult a decision for 'ordinary people' to make or to come to a consensus on and that, even though they might not agree with the decision, it is now up to the Government to do so. This is not just because of the difficulty in weighing up the evidence and balancing out the risks, but because of the large amount of information one needs to marshal in order to be reasonably acquainted with the issues would not lend itself to a relatively simple' and 'mass' consultative exercise.

If the Government did go ahead with mandatory fortification, participants were very clear that this move would have to be transparent and open.

Views on 'Marketing' activity

In relation to the effectiveness or otherwise of publicity and health education campaigns, some participants suggested additional strategies which could support these, sometimes borrowed from more commercial environments. These included offering folic acid supplements free to all; linked campaigns with 'women's products' e.g. sanpro; working in partnerships e.g. with family planning clinics, etc.

Participants' Responses to New Information

In response to queries raised by participants in the first sessions, new information was prepared for the second sessions. This was fed into the discussions at appropriate moments, either verbally or in written form. Overall, the information was welcomed, sometimes clarifying issues for participants while also sometimes reassuring them, as well as raising new queries.

Further Information on Folic Acid and Cancer Risks

- In Session 1 we spoke about new evidence coming to light that suggests that consuming high levels of folic acid can
 - increase the risk that if you already have pre-cancerous polyps in the bowel, these will get worse.
 - reduce the risk of diseases including coronary heart disease, some cancers and bone diseases; but
- In the UK, around 35,000 people are diagnosed with bowel cancer each year, and around 16,000 die as a result of bowel cancer each year.
- The likelihood of developing bowel cancer is strongly related to age. 8 out of 10 people who get cancer of the bowel are aged over 60.
- A national screening programme for bowel cancer is due to start this year. Everybody aged between 60 and 69 will be invited to go for testing once every two years.
- We are aware of eleven separate Scientific studies that have been carried out to look at possible links between folic acid and bowel cancer:
 - Two studies showed that higher intakes of folic acid made it less likely that a person would develop bowel cancer. However, this might have been because these people ate more fruit and vegetables and foods high in fibre.
 - Six other similar studies showed that there was no link between folic acid intake and bowel cancer risk.
 - One study suggests that taking folic acid supplements (especially if this leads to an intake above 1000 micrograms per day – the recommended daily intake for women planning a pregnancy is 600 micrograms a day) makes it more likely that if a person already has polyps in the bowel, these will get worse, and that this may lead to bowel cancer. This study has not been published.

(cont'd)

- One study showed that people with a high level of folic acid in their blood were less likely to develop bowel cancer. This effect could be due to these people eating more fruit and vegetables and foods high in fibre.
- Another similar study showed that having high levels of folic acid in the blood did not have any effect on the likelihood of a person developing bowel cancer.

- We are aware of six separate Scientific studies that have been carried out to look at possible links between folic acid and breast cancer:
 - Four studies looked at a possible link between eating more folic acid and the likelihood of developing breast cancer. These studies found no link.
 - Two studies looked at a possible link between having high levels of folic acid in your blood, and the likelihood of developing breast cancer. These studies found no link.

- We are aware of nine separate scientific studies that have been carried out to look at possible links between folic acid and Cardiovascular Disease (heart disease):
 - Three studies found no link between the amount of folic acid a person eats and their risk of developing cardiovascular disease.
 - Three studies found no link between the level of folic acid in a person's blood and their risk of developing cardiovascular disease.
 - Two studies found that a person with higher levels of folic acid in their blood was less likely to develop cardiovascular disease.
 - One study found that women with a higher level of folic acid in their blood were less likely to develop cardiovascular disease, but that for men there was no link.

The risks around cancer had been very worrying to some participants in the first session and on the whole the new information did provide a degree of reassurance. In relation to **bowel cancer**, the numbers of people diagnosed with, and deaths from bowel cancer were quite frightening, however the information about other risk factors (such as diet, smoking, obesity etc.) put the folic acid risk into context for many.

The information about the screening programme was reassuring and was potentially a counterweight to the risk element although, as in other contexts, there were some doubts and cynicism about the Government's real commitment to this. The fact that only 1 out of 11 studies proposed a link between folic acid intake and bowel cancer, was very reassuring and convincing for some, although others struggled with the complexity of the details of this evidence.

Overall, this information did lead some participants to lower their perceptions of the potential cancer risk, but others remained significantly concerned and took it into account when weighing up the options. Some felt the advice given in health matters was, as ever, contradictory in certain ways. (Shortly after completion of fieldwork there was media coverage of further research, which suggested that folic acid supplements can cause pre-cancerous lesions to shrink or even disappear.)

In relation to both **breast cancer** and **cardiovascular disease** the new information was reassuring and relatively convincing.

Re-cap about NTDs

Re-cap about NTDs

- Neural tube defects (NTDs), such as spina bifida, hydrocephalus and anencephaly, are caused when the spinal cord or the bones of the spine surrounding it fail to develop properly. This leads to damage to the nervous system.
- It is estimated that there were 700-900 pregnancies affected by NTDs in 2003 (this is about 10-13 in every 10,000 pregnancies).
- Many NTD affected pregnancies are ended by termination, although the numbers are difficult to estimate (and women living in Northern Ireland are not offered terminations). In some cases this will be a late term termination (at around the 20th week of pregnancy) and will involve labour.
- There are around 200 reported births of babies suffering from NTD each year in the UK.
- NTD-affected births declined until the 1990s, but there was little or no change throughout the 1990s and into 2000s.
- Not all NTDs are caused by folic acid deficiency, but it is estimated that increasing folic acid intake could prevent about 40% (four out of every ten) of NTD-affected pregnancies.
- Younger women are more likely to have an NTD affected pregnancy. This is not because of their age as such, but because in general younger women are less likely to eat a balanced diet (with good levels of folic acid) or to take folic acid supplements.
- Even if the decision were taken to fortify flour with folic acid, women would still be advised to take supplements, in order to get the best possible chance of avoiding an NTD affected pregnancy.

NTD RISK

From 1975-1999 NTD rates for women under 20 years have been consistently higher than for older age groups. This is not to do with any biological factor but is as a result of the fact that younger women are less likely to eat a balanced diet with good levels of folate and are less likely to take supplements, before and during pregnancy.

The additional information about terminations, i.e. that they can be late term and involve labour, was informative and unexpected, even amongst some mothers. It reinforced or brought home to many participants the importance and level of distress involved in this aspect of the NTD issue. It was especially poignant for parents who had gone through the anxieties and uncertainties of their own pregnancies and having to go through labour was seen as one of the worst types of termination. As noted earlier, terminations had particular resonance for those whose faiths or culture forbids terminations (albeit with the possibility that personal choice can be exerted).

The additional information about the (relatively young) age bias in NTD pregnancies and the reasons for this, was helpful and relevant to participants' deliberations about possible action strategies. However, in some instances it was interpreted as meaning *very* young mothers, and exacerbated a tendency to stigmatise women at risk of an NTD pregnancy.

While NTD pregnancies do often occur amongst young women of a lower socio-economic class, it was explained to participants that this was because they often had poorer diets, paid less attention to public health campaigns and were less likely to take (or be able to afford) folic acid supplements.

Re-cap about Vitamin B12 deficiency

Re-cap about Vitamin B12 Deficiency

- Vitamin B12 is needed by the body to form healthy nerve cells and red blood cells. It is found in virtually all meat, fish and dairy products.
- Around 5%-10% of people aged over 65 have low levels of B12 in their blood. The reason for this deficiency is that as we get older, our gut works less well and is less able to extract the vitamin B12 from the food we eat.
- Eating more folic acid does not cause a B12 deficiency, but if a person with a B12 deficiency has a high level of folic acid in their system, it could make their B12 deficiency more difficult to detect or diagnose.
- It is estimated that:
 - There are 9.3 million people in the UK aged 65 or over
 - 687,000 of these have a B12 deficiency (however mild)
 - Of these people, 1100 **also** have a high intake of folic acid
 - There were 28 hospital admissions for severe B12 deficiency in 2002
- To give an idea of how many more people could be affected by this possible extra risk – it has been estimated that if flour were fortified with folic acid at a level of 450 micrograms per 100 grams:
 - 4 out of every 10 NTDs would be prevented (this means around 300)
 - The number of older people with B12 deficiency (however mild) **and** a high folic acid intake would go up to 6700

This information was primarily 'revision' but the addition of the figure of 6,700 for older people with B12 deficiency **and** high folic acid intake did heighten anxiety in some instances.

Vitamins and minerals in Bread

VITAMINS AND MINERALS IN BREAD

The Bread and Flour Regulations require that flour should contain:

- not less than 0.24 micrograms **thiamine (vitamin B1)**,
- 1.60 micrograms **nicotinic acid** and
- 1.65 micrograms of **iron** per 100g of flour
- not less than 235 micrograms and not more than 390 micrograms of **calcium** carbonate per 100g of flour

Thiamine, nicotinic acid and iron are added to restore the natural levels in white and brown flours. Calcium is present in white and brown bread for historic reasons.

Current data suggests that the presence of calcium and iron in bread contributes significantly towards intakes in the UK. Removing it from flour may result in certain groups in the population being at risk of deficiency.

For example: white bread contributes towards approximately 10% of total iron intake and 11% of calcium intake in men in the UK.

Information that calcium and iron in bread contributes significantly towards intakes in the UK and that removing them might put some people at risk of deficiency, was supportive of the ongoing fortification of bread and to the principle of mandatory fortification. However, some were still not convinced by the possible health benefits that this might offer the general population.

The rationale that bread had been identified as the fortification vehicle because of it being the only food to be consumed evenly across the population was sometimes questioned. Young women are thought to be relatively low consumers of bread due to diet or weight considerations and participants were convinced that surely there must be a more 'targeted' food product suitable for the target market and fortification.

Consideration of this information also re-triggered thoughts about whether fortification should be of all bread, all flour, cakes, sauces etc. or just in particular flour products.

Required doses of folic acid

DOSE

Folic acid is a water-soluble B vitamin so you tend to excrete any excess. Too much over short term is unlikely to do you any harm.

It was helpful to remind participants about the fact that folic acid is a water soluble vitamin and that excess is excreted from the body, so that excess folate intake does not in itself present a health risk. However, some participants found it difficult to reconcile this with the information on risk factors.

FOLATE SUPPLEMENTS

Women of childbearing age will still be recommended to take a folic acid supplement to achieve optimal intakes even if fortification to increase intakes is implemented.

This is because, while fortification will increase the folate intake of the general population, it may not sufficiently increase the folate intake of individual women of childbearing age and there will be a proportion that will still be below the recommended levels of folate to prevent NTD-affected births. There may also be instances when women are not able to improve their folate intakes through eating fortified bread because of intolerance and the need to avoid cereals containing gluten.

Education campaign:

A health education campaign, which ran from 1995 to 1998, did succeed in increasing women's awareness from 9% to 49%. However, the fact remains that around 50% of pregnancies are unplanned, so although awareness increased there was not a significant change in behaviour. This is further supported by the fact that it is not recommended that all women of child bearing age take a supplement, only those planning a pregnancy.

The fact that women of childbearing age will still be recommended to take supplements even after fortification slightly undermined the case for fortification among its supporters and was a piece of useful evidence for fortification opponents.

The information about the lack of success of a previous health education campaign in changing behaviour was useful and convincing to an extent, but people could still support Option 2 in the hope that a future campaign would be 'better' or 'stronger', having benefited from all the sophisticated advertising that has been produced in the intervening years. However, it was recognised that any advertising campaign would need to be sustained throughout the 'upcoming' generations.

Thalidomide

THALIDOMIDE

This drug was distributed to pregnant women between 1958 and 1962 to relieve the symptoms of morning sickness. Those who took the drug gave birth to malformed babies who, most commonly, had two or more rudimentary limbs.

Thalidomide was only subjected to limited testing, whereas folic acid has undergone extensive testing.

This had been raised in the first sessions as an example of Government or scientists' ineffectiveness in identifying risks. The differences between this and folic acid were pointed out for clarification but it seemed less of an issue in the second sessions.

Detailed Reactions to the Options

This section draws together points made about each option during the free-flowing discussion in the first part of the second sessions and responses during a more structured examination of the options in the second half.

Each option was accompanied by a list of 'pros and cons' to aid full discussion, although many of these had already been spontaneously raised by participants.

Option 1 – Continue with current Government policies of advice on folic acid

This Option represented the 'status quo', though in fact some participants read more into it than this, to the extent that for them it started to overlap with Option 2. It was consistently chosen as first preference by up to a fifth of the sample.

Reasons for preferring or supporting Option 1 were:

- It is seen as a safe option, Government to continue with this while more research is done and evidence collected especially about the risk factors which may be the foundation for further activity later
- It appeals to those who are confused or uncertain
- It focuses on the (identified) target audience, i.e. the people perceived to have 'the problem'
- It appeals to those concerned with consumer purchasing choice

- It also appeals to the more disengaged (often older men?) who did not consider it worth spending money on anything else as it won't deliver effective results, especially as they felt there were not enough cases of NTDs to justify huge expenditure
- The 'pros and cons' information unit mentions offering benefits for food companies, which was accepted but not seen as a first priority

Reasons for not preferring or rejecting Option 1 were:

- The evidence shows that this option is not working and / or has reached a plateau
- It is seen as too passive a strategy
- It leaves too much to people exercising healthy choices
- It is ineffective in addressing the issue of unplanned pregnancies
- The feeling that there is a moral obligation to act where one can make a positive impact

Option 2 – Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid

This Option was initially first preference for two-thirds of the sample at the end of the first session; after deliberation, this reduced to less than a third, with some further diminution of support by the end of the second session. However, although it lost ground for first preferences, it was often participants' second choice and maintained a significant degree of support throughout as a back-up, often to those who chose Option 3 or 4.

Reasons for preferring or supporting Option 2 were:

- A safe option for a first step in a more active programme, relatively risk-free
- Such a campaign was considered necessary if participants' own acknowledged lack of detailed knowledge was anything to go by, either for the key target audience or casting the net wider
- It can be aimed at the (identified) target audience, this should include young teenage girls, to get them into the habit of taking folic acid and deal with unplanned pregnancies
- It is a flexible option as it could run in conjunction with other options or stand alone
- Previous failures do not mean a new campaign cannot be successful, it could just be done better, more creatively next time!
- A branded product aimed at women planning pregnancy is being advertised on radio at the moment. This seems to suggest that the commercial sector has faith in the ability to generate behaviour change
- It does not impinge on consumer purchasing choices, therefore it is acceptable for those for whom choice is an issue

Reasons for not preferring or rejecting Option 2 were:

- The evidence shows that it is unlikely to be effective

- In particular, it requires not only awareness raising and attitude change but changes in behaviour, which is a challenging brief for a campaign. Some participants felt that young and teenage women in particular were unlikely to take notice of health education initiatives (compared to older people who might respond well to a screening campaign re, for example, B12)
- It is likely to be costly (especially because it needs to be ongoing to catch every up-coming generation of young women), and was not considered to be justified by the likely benefits
- If the campaign stays within the 'childbearing women' envelope, it is unlikely to reach women who are not thinking of having babies but who are just as important as part of the target audience

There were also some unresolved issues and questions:

- As already mentioned, presumably the requirement would be for a series of (repeated) campaigns, to catch women entering the target audience all the time
- Could the target be broadened to include all women; indeed also parents (including fathers); and even everyone, given the benefits of folic acid across the population

Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis

This Option was initially selected by a small minority, but support rose to about a fifth of the sample at the end of the deliberative period and this level of support was sustained through to the end of the second session. However, although the

proportion of support was the same it would seem as if participants changed their views around this option, so different people supported it at different stages.

Most participants understood the difference between voluntary and mandatory fortification (because of the grounding given on this issue in the first session) but a few still showed some signs of confusion.

Reasons for preferring or supporting Option 3 were:

- It has potential and should be tried, possibly as an interim step
- It feels more comfortable than Option 4 for some participants; less extreme, less risky and a good compromise between doing nothing and doing too much
- It links well with Option 2 (prompted in the 'pros and cons' listed in the Level 1 'green book') or as possibly a next best step if Option 4 could not be implemented
- Some participants considered the marketplace to be an effective and trusted mechanism for providing fortified foods
- It allows purchasing choice for consumers as well as choice for companies
- Fortified products could and should be flagged up to increase consumer awareness, (although it seems likely that many consumers would still not know what the benefits of folic acid are and that everyone needs it in their diet)

Reasons for not preferring or rejecting Option 3 were:

- It seems too 'free form' with concerns expressed as to what foods would be fortified

- There were particular concerns around amounts and dosages, with questions about how would you know whether you were consuming the right amount
- It can also sound as if no-one is responsible for monitoring this (cf. Option 4, where although the same concern can exist, the assumption is that, with a mandatory approach, the Government is responsible for regulation)
- Some participants were suspicious about using 'the marketplace' for such a sensitive and important issue. Companies may be reluctant to get (more) involved in fortification because of the risk element. The fact that there was no plan to control fortified products was a concern, especially as the 'free market' might lead to clusters of inappropriately fortified products. It was felt that many manufacturers are primarily motivated by profit and that this seems inappropriate for this issue as they may enter and exit the market for the 'wrong' reasons. In addition, a partnership or endorsement between Government and particular brands also seemed questionable
- It will be difficult to tell if the target audience is being reached or if there is any improvement, as it will be difficult to monitor what specifically, if anything, had caused any improvement; i.e. which food, what level of fortification
- Any associated price rise with fortification might alienate the identified key target audience (younger, poorer women)
- Overall, this option seems to leave too much to chance

Some unresolved issues and questions were:

- Could the price of fortified products be subsidised to avoid price increases?
- Could this be run alongside an education campaign?

- Does Option 3 necessarily mean that there has to be 'light touch' Government regulation? Surely the Government can monitor or regulate even within a voluntary system?
- Some participants were suspicious that this issue had been presented in an inappropriately 'black and white' way in the information units in order to guide people towards Option 4!

Option 4 – Make the fortification of flour or bread with folic acid a legal requirement (mandatory)

When the options were initially seen, Option 4 was the first choice of a very small minority of participants. After deliberating, this rose to a third of the sample, and by the end of the second session it was the first choice of nearly half of the participants. Influential here was the recognition of the shortcomings of the other options. However, it should be noted that other respondents remained clearly and implacably against mandatory fortification.

Reasons for preferring or supporting Option 4 were:

- A firm belief that it will work on the basis of the scientific evidence and the evidence from other countries; i.e. it is evidence-based
- With a mandatory approach, the Government will be duty-bound to monitor and regulate the effects, both directly on NTDs and indirectly on any other potentially 'at risk' groups
- There will be increased awareness of the B12 deficiency issue, both amongst the public and doctors
- There is a good margin for error between the predicted intake level after fortification and the safe limit (1,500 vs. 5,000)

- It does not require behaviour change in the target group
- It will 'automatically' deal with the planned and the unplanned pregnancies, with both the conscientious and the careless
- It removes the risk of people making 'wrong' choices
- It has benefits for everyone, not just women of childbearing age
- It is for the common good, there is an element of altruism
- Bread sounds like a suitable vehicle as it is a staple item in the diet and there was no other real alternative

Some participants added 'riders' to their acceptance of this option:

- There should be effective screening for B12 deficiency
- Also effective screening for bowel cancer
- There should be an education campaign about the benefits and risks of fortification
- There should definitely be a programme of ongoing research and monitoring, both in this country but also using other countries' experience
- A minority of participants considered the co-fortification of flour with B12, although others were concerned as to what the risks of *this* option might be! *[NB – co-fortification with B12 would not in fact be effective because the majority of cases of B12 deficiency are the result of an inability of the gut to absorb the vitamin, rather than low B12 consumption per se.]*
- Some suggested the de-fortification of foods currently fortified, (e.g. spreads) to address concerns over excessive folate consumption.

Reasons for not preferring or rejecting Option 4 were:

- A desire to retain consumer purchasing choice, as a human rights issue. Perceived loss of their rights to buy unfortified flour or bread was seen as a very big disadvantage for some participants.
- To some degree this was linked with an objection to the idea of 'mass medication', expressed as 'Why should we all have to ingest something to help a small minority?' This made it impossible for them to accept Option 4 as it stood.
- In addition, they felt there were too many unknowns about fortification with folic acid, as well as too much conflicting evidence and too many 'ifs and buts', with not enough consideration given to possible unexpected side effects, especially in the long term.
- There was particular concern about the increase in health risks for others, especially older people. Although they understand and accept that folic acid masks B12 rather than causes the deficiency, there were still significant levels of concern. Similarly with bowel cancer, the information given (that so far only one, as yet unpublished, study out of eleven linked increased intake of folic acid with bowel cancer) was still not sufficiently reassuring for some.
- There was also some concern about 'extreme eaters' of bread, especially if spreads are not de-fortified. At-risk groups were seen as students; those with a 'poor' diet and older people
- Participants considered mandatory fortification an unnecessary measure because many foods already contain naturally occurring folic acid or are fortified with it. They felt it was just necessary to promote them more actively
- There was also concern re the rise in costs of staple items if fortification wasn't subsidised

- The need for women to take supplements if planning a pregnancy or in the early stages of pregnancy can undermine the rationale of this option
- The information materials noted the possibility of millers and bakers experiencing problems in exporting their products. This was noted by participants but was not an issue that they were concerned about.

Some unresolved issues and questions were:

- There was some suspicion that there was a 'conspiracy' here; were the sessions and the information set up to subtly pressurise participants into moving towards this particular option?
- There were suggestions that it might be possible to start fortifying with low levels of folic acid in bread, monitor the effects, and then increase levels if evidence emerged of clear good benefits and low or manageable risks.
- Some suggested an 'Option 4.5' incorporating a degree of selectivity, to retain consumer choice, while not undermining the rationale for the option, e.g. each brand could have fortified and non-fortified variants, or fortification could only apply to cheaper or own Label brands with the specific aim of reaching the core target group. These suggestions might be more acceptable than they initially might appear, given that the bread market is already very segmented.
- There were questions as to the possible omission of wholemeal bread from fortification and whether wholemeal has 'natural' folate content
- Some questioned whether bread really is such a good vehicle for fortification when looked at from an individual viewpoint rather than 'average consumption'

Final preferences

At the end of the second session, participants were asked again to record their views and preferences on a self-completion questionnaire.

About a third of the sample had changed their views during this session, reflecting the fact that the deliberative process was continuing, fed by new information and by other participants' views.

Participants took their own individual journeys through the process. While we asked them to put down 'markers' at various stages of the process, there were so many shifts and changes that it is not really possible to generalise about patterns or trends. The exception to this, as is shown below, is the trend towards Option 4 in most of the workshops (Northern Ireland being the exception, which tended to go more for Option 3).

Overall, the bulk of the change from initial to final preferences was represented by movement from Option 2 to Option 4 as a first preference, but it should be remembered that Option 2 remained popular and was often second preference as a 'back-up'. Participants' final first preferences were as follows:

- Option 1 about one seventh – no change (often same people)
- Option 2 about one quarter - slight decrease (often moved to Option 4)
- Option 3 about one fifth – no change
- Option 4 nearly one half – some increase

In summary:

- ❑ Participants who ended up preferring Option 1 were often very concerned about the risks and felt that more research and better evidence was required before any change was implemented
- ❑ Participants who ended up preferring Option 2 were also often motivated by perceptions of risk, but wanted at least some positive action taken, so they viewed Option 2 as the least risky
- ❑ Participants who ended up preferring Option 3 felt that more action than simply education was required, but preferred the voluntary approach mainly because it maintained consumer purchasing choice
- ❑ Participants who ended up preferring Option 4 were keen to see effective action taken and were convinced that Option 4 was the only one that would give significant results. However, they often added riders (e.g. the need for screening), indicating that they were not completely comfortable with some of the risks

Strength of feeling was tested by asking participants how they would feel if the two most 'extreme' Options: 1 and 4 were implemented. Most participants said they would take both 'in their stride' i.e. there was less celebration or outrage than might have been expected.

Option 1

- ◆ some would feel seriously disappointed
- ◆ a few said they might protest
- ◆ one participant said she would feel relieved
- ◆ others were more sanguine about the lack of action

Option 4

- ◆ most would accept, knowing that the decision had been made by a democratically elected Government, on the basis of the evidence and after consultation
- ◆ most would not change their eating habits, although a few might switch to wholemeal
- ◆ a few would protest or petition
- ◆ one would ask their GP for a B12 check

Differences between population sub-groups

Many variations in views and responses were noted throughout the discussions, but it was rarely possible to discern any consistent pattern by e.g. location, gender, lifestage, class. In terms of the slightly 'harder' data of participants' recorded preferences between the options, some differences within the sample were noted, but they must be treated with extreme caution because of the small sample size:

Participants in Northern Ireland were more likely to opt for voluntary fortification and less likely to choose mandatory fortification, than was the case in other **locations**, possibly another reflection of their cynicism re 'Government'.

There were no discernable differences by **gender** in relation to participants' final preferences.

As regards **life-stage**, Young People and Family participants were more in favour of Options 3 and 4 (fortification) than were Older People and Pensioners. Family participants were the keenest on Option 4. Older People and Pensioners were as likely to choose Option 2 as Option 4, and Pensioners were also as likely to choose Option 1, i.e. overall, older participants tended to be more conservative in their preferences.

In relation to **Social and Economic Status** there appeared to be no obvious differences.

Where differences occurred between **BME** participants and the mainstream sample, these have been noted in the earlier text but, overall, views expressed in the BME depths were very consistent with the rest of the sample.

Communications

The time needed to discuss the complexities of this issue meant that, as suspected, there was limited opportunity to discuss communications issues in full. However, communications was definitely seen as a challenge given the complexity of the issue. There were widespread requests for transparency and for consumers to be informed and educated if any action was to be taken, either via labelling or communications programmes.

Labelling could and should include not only products which have been fortified with folic acid but also those which naturally have a high folate content, to enable all consumers to make informed 'in the round' choices about their diet. It needs to both attract those who need to increase their folate intake (potentially all of us?) but also to warn those who need to be careful about their folate intake, (especially older people).

Any information or communications should include clear guidance on the benefits and risks of folic acid. Allied to this, participants requested that there be some education about the Recommended Daily Allowance (RDA) concept, with advice as to how to apply it.

Where discussed, participants suggested a wide range of possible **channels** for any communications, including: family planning clinics, GP surgeries, nurseries, leaflets in supermarkets, leaflets in sanpro packs, leaflets in contraceptive packs, etc.

In terms of **language and style**, the Level 1 'green book' was generally thought to be quite accessible and did seem to have been read and understood by most. However, allowance needs to be made for the 'motivation factor' of participating in a deliberative project, which probably enhanced their willingness to persevere with the task. Our judgement would be that if it was desired to communicate similar information at a similar level (e.g. on a website or in a leaflet), the language would need to be simplified 'a notch' for optimum accessibility and possibly reduced in volume to a degree.

The language and style of the Level 2 'blue book' was, as expected, quite challenging for many of the participants, but it would, we believe, be appropriate for 'second layer' information pages on a website.

APPENDICES

- Recruitment screener
- Workshops discussion guide
- Level 1 booklet (Level 2 booklet available on request)
- Self-completion questionnaires

RECRUITMENT SCREENER

Good morning/afternoon/evening, my name is and I am conducting a Market Research Survey on behalf of **forum qualitative**. Would you tell me if you or any members of your family or close friends work/used to work in any of the following professions or occupations.

Self

Close Family/Friends

SHOW CARD A

GROWING, PRODUCTION, MANUFACTURE,
 DISTRIBUTION, SALE OF FOOD
 ADVERTISING
 PUBLIC RELATIONS / MEDIA
 MARKETING, MARKET RESEARCH
 JOURNALISM
 CENTRAL / NATIONAL GOVERNMENT
 HEALTH PROFESSIONS
 e.g. doctor, midwife, nurse, physio, OT
 NUTRITION-RELATED PROFESSIONS
 e.g. nutritionist, dietician

V		V
X		X
0	CLOSE	0
1		1
2		2
3		3
4		4
5		5

	CODE	ROUTE
B) Have you <u>ever</u> attended a GROUP DISCUSSION OR IN-DEPTH INTERVIEW before?		
YES	V	ASK QC
NO	X	ASK Q1

C) How long ago did you attend a group discussion or in-depth interview?

D) What was the subject?

	How Many QC		What Subject QD	
Less than 6 months ago	<input style="width: 40px; height: 30px;" type="text"/>	CLOSE		CLOSE
Between 6 - 12 months	<input style="width: 40px; height: 30px;" type="text"/>	IF MORE THAN 2, CLOSE		IF SAME SUBJECT, CLOSE
1 - 5 years ago	<input style="width: 40px; height: 30px;" type="text"/>	IF MORE THAN 5, CLOSE	WRITE IN	

Q.1 Thinking about food and grocery shopping, what level of responsibility do you have for the shopping in your household?

SHOW CARD xx

Responsible for all / most of the shopping	V	
Responsible for about half of the shopping	X	CHECK
Responsible for less than half of the shopping	0	QUOTA
Not responsible at all for the shopping	1	

Q.2 And which of the following statements most closely matches your cooking arrangements?

SHOW CARD xx

I do all the cooking in our household	V	
I do at least half of the cooking in our household	X	CHECK
I do less than half of the cooking in our household	0	QUOTA
I don't do any cooking in our household	1	

Q.3 Can you tell me which of the following types of food you buy and / or eat regularly i.e. once a week or more often

SHOWCARD xxx

Cheese	V	
Fresh meat	X	
Bread	0	MUST CODE
Fresh fruit & vegetables	1	
Crisps & snacks	3	

Q.4 Do you or anyone in your household suffer from any of the following allergies / intolerances to the extent that you / they need to exclude certain foods from your / their diet?

SHOW CARD xx

Peanuts	V	
Dairy	X	
Wheat / gluten	0	CLOSE
Citrus	1	

Q.5 Are you or anyone in your household vegetarian or vegan?

Yes	V	RECRUIT
No	X	TO QUOTA

Use your discretion as to how you word this explanation:

I am now going to ask you some questions of a more personal nature. This is because some of the topics which may come up at the group may be sensitive for some people, so we need to know whether or not people have personal experience of them. Please be assured that any information you give me now is confidential and will not be passed on to anyone else.

Q.6 Use your discretion as to whom to ask this question:

(female) May I ask, are you currently pregnant?

(male) May I ask, is your partner currently pregnant?

No	V	
Yes	X	CLOSE
Not prepared to say	0	CLOSE

Q.7 Do you or does anyone close to you (family, friends) have personal experience of any of the following:

SHOW CARD xx

Motor Neurone Disease	V	
Downs Syndrome	X	CLOSE
Cystic Fibrosis	0	CLOSE
Neural Tube Defects		
(NTD - spina bifida, hydrocephalus, anencephaly)	1	CLOSE
Other genetic defects		
(e.g. muscular dystrophy, sickle cell anaemia)	2	CLOSE
Epilepsy	3	
Multiple Sclerosis	4	
Termination of pregnancy due to NTD	5	CLOSE
Termination of pregnancy for other genetic reason	6	CLOSE
Not prepared to say	7	CLOSE

Q.8 Which of these best describes your ethnic group?

SHOWCARD xxx

White British		V	
White Irish		X	
<u>Any other white background</u>		0	
White and Black Caribbean		1	
White and Black African	2		
White and Asian	3		
Any other mixed background		4	=
Indian		5	BLACK
Pakistani		6	&
Bangladeshi		7	MINORITY
Any other Asian background		8	ETHNIC
Caribbean		9	(BME)
African	V		
Any other Black background		X	
Chinese	0		
Other		1	

BME ASIAN PAIRED DEPTHS ONLY

Hindu	V
Muslim	X

FORENAME OF RESPONDENT: _____ SURNAME: _____

HOME ADDRESS: _____

TELEPHONE: _____

GROUP 1 – DATE & TIME _____

GROUP 2 – DATE & TIME _____

COMMITMENT

Please give respondent the introductory letter, and sign below that you have informed the respondent that they are making a commitment to attend a 3 hour group, to take away and look at information, and then to attend a second 3 hour group, on the specified dates.

Sign: _____

Date: _____

AUDIO RECORDING

Please sign below that you have informed the respondent that the groups will be tape recorded.

Sign: _____

Date: _____

Please give respondents an invitation and a thank you leaflet.

ENSURE THAT ALL THE RESPONDENTS CAN ARRIVE AT LEAST 5 MINUTES BEFORE START OF GROUP AND CAN STAY FOR THE FULL DURATION.

forum

qualitative

WORKSHOPS DISCUSSION GUIDE (final version)

Project Name: Castle

Project No: f094

N.B. This Guide indicates the areas to be explored in the workshops, the likely order in which topics will be covered and the kinds of questions and techniques which may be used.

It must be remembered that this is qualitative, deliberative research and that the approach will therefore be flexible depending on the dynamics of each workshop.

The process will include whole group discussion, discussion in sub-groups / pairs, and individual work, as appropriate to the process of the discussion and the group dynamics.

Throughout the discussion, responses will be explored both the issues and to the language / terms used.

WORKSHOP 1

INTRODUCTIONS / WARM-UP

- Moderator
 - ◆ introduction to the research, confidentiality, acceptability of different views etc.
 - ◆ reminder re workshop 2, work to be done in between
 - ◆ introduce observer(s) - FSA person to be introduced as 'from an organisation involved with the issues we're going to be talking about this evening'

- Respondents (paired) – name, personal / family / work details, 'added vitamins' pre-task
 - ◆ use examples to explore: which products have 'added vitamins', awareness of these before being asked to do task, initial feelings re 'added vitamins'

FORTIFICATION – BACKGROUND

- Build on pre-task discussion, verbally introducing the term 'fortification' (or use simple concept board with term and definition)
- Initial, spontaneous discussion
- More detailed discussion on issues such as
 - ◆ levels of awareness about fortification in general
 - ◆ levels of awareness about voluntary vs. mandatory fortification e.g. asking question – 'Do you think / guess / know whether the manufacturer chose to add this vitamin or was he legally obliged to?'
 - ◆ sources of awareness e.g. packaging, labelling
 - ◆ levels of interest in this issue
 - ◆ positive aspects – perceived benefits of fortification
 - ◆ negative aspects – perceived disbenefits of fortification
 - ◆ any confusion, concerns, worries
 - ◆ probe for views around 'Is more better?' – reactions to thought that 'More isn't necessarily better'
 - ◆ effects (if any) on shopping for food e.g. choose fortified products, avoid fortified products
 - ◆ awareness / understanding of regulation and who regulates – level of interest / concern in this area
- If voluntary vs. mandatory distinction has not emerged spontaneously in discussion, prompt this and probe reactions
- Then explain we are going to look at examples of each of these and will be interested in their views

FORTIFICATION – VOLUNTARY

- Pick up and expand on earlier discussion, focusing on **voluntary** fortification
- Present examples of voluntary fortification – BREAKFAST CEREALS
- Explore reactions e.g.

- ◆ awareness of fortification in this product field
 - ◆ reactions to fortification in this product field
 - ◆ awareness / understanding of rationale i.e. commercial benefit / not all have proven benefits / may be risks and reactions to this
 - ◆ perceived benefits
 - ◆ perceived disbenefits
 - ◆ areas of confusion, concern
 - ◆ influence on purchase process / decisions e.g. do they check whether fortified, will they now do so
 - ◆ review of thoughts around reactions to principle of voluntary fortification e.g. is it something that should be officially encouraged
 - ◆ show examples of communications around voluntary fortification e.g. packaging, advertising
- Give examples of other foods which are fortified on a voluntary basis e.g. mineral water, fruit juice, and explore reactions
 - Review of thoughts around rationale for voluntary fortification i.e. commercial benefit

FORTIFICATION – MANDATORY

- Pick up and expand on earlier discussion, focusing on **mandatory** fortification
- Present example / **case study** of mandatory fortification – BREAD (iron, calcium)
- Explore reactions e.g.
 - ◆ awareness of fortification in this product field
 - ◆ reactions to fortification in this product field
 - ◆ understanding of / reactions to rationale i.e. public health benefit – probe fully
 - ◆ perceived benefits
 - ◆ perceived disbenefits
 - ◆ areas of confusion, concern
 - ◆ influence on purchase process / decisions e.g. do they check whether fortified, will they now do so

- ◆ review of thoughts around / reactions to principle of mandatory fortification i.e. public health intervention – important area, probe as fully as possible e.g.
 - balance between how much government should do and how much is people's personal responsibility in relation to diet
 - is it appropriate for Government to intervene in this way
 - does Government have a right or responsibility to intervene in this way
 - what are the limits of Government responsibility
 - mass medication issue
 - (if raised) implied messages re disability

- Give examples of other foods which are fortified on a mandatory basis e.g. spread, and explore reactions

- As discussion proceeds, check for any changes in the way people feel about fortification per se and about voluntary vs. mandatory – are they more or less positive / negative, are they more / less confused, are they more / less concerned
 - ◆ what are the key issues and messages that influence opinion
 - ◆ explore and seek to understand differences of views within the group

- Review and sum up feelings re mandatory fortification
 - ◆ positives, negatives, concerns etc.
 - ◆ opinions on whether this (action by the state) is an acceptable / appropriate way of tackling a public health issue – why / why not / under what circumstances

- Review / sum up perceived key differences between voluntary and mandatory fortification
 - ◆ voluntary – manufacturer decides / commercial benefit / consumer has choice
 - ◆ mandatory – government decides / public health benefit / consumer has no choice (within specific product category)

- Show and / or talk through FORTIFICATION stimulus, pick up on any issues / points not raised spontaneously
 - ◆ especially probe / explore responses to voluntary / mandatory key differences (last bullet point)

- Use individual self-completion 1 to capture respondent positions at this stage and to allow for private expressions of sensitive positions – share responses and discuss

COFFEE BREAK

FORTIFICATION WITH FOLIC ACID – INITIAL DISCUSSION

- Introduce issue of folic acid and NTDs via stimulus THE ISSUE: FOLIC ACID & NEURAL TUBE DEFECTS
 - ◆ before any discussion, use self-completion 2 to record initial individual responses (or possibly paired discussion)
 - ◆ share responses from self-completions and discuss
- Spontaneous discussion of responses to stimulus
- Then probe in more detail, including
 - ◆ incoming awareness of folic acid, NTDs, the issue
 - ◆ check for understanding of issue and vocabulary used – (verbally) clarify any areas of confusion / misunderstanding
 - ◆ awareness of / reactions to recommendations re taking supplements
 - ◆ awareness of / reactions to education campaigns
 - ◆ awareness of / understanding of / reactions to specific issues e.g. % of unplanned pregnancies, % taking supplements, little decline in NTDs
 - ◆ assessment of seriousness of problem / issue
 - ◆ ethical / mass medication issues
 - ◆ initial thoughts re whether anything should be done, if so what, and by whom
 - ◆ link back to previous discussion re voluntary vs. mandatory fortification, comparison with earlier discussion – how might this be relevant here?
- As / when appropriate, show and / or talk through stimulus FOLIC ACID and NEURAL TUBE DEFECTS (NTDs), review and expand on earlier discussion
- Re FOLIC ACID, probe reactions to points re
 - ◆ B12 issue (more to come on this later)

- ◆ other studies – idea of ‘emerging evidence’ – ‘It doesn’t mean we’ve only just found out that x causes y, it means we have part of the picture, but until we find out more, it’s too early to reach a conclusion’

FORTIFICATION WITH FOLIC ACID – B12 / EVIDENCE ISSUES

- Explain that would like to explore issue of risks in more detail
- Introduce stimulus VITAMIN B12 DEFICIENCY IN OLDER PEOPLE (flow chart)
- Take respondents through flow chart step-by-step, checking for understanding and responses at each stage – also levels of interest / perceived importance / relevance
 - ◆ main point to communicate: there are things we know (about this issue) and things we don’t know – as compared with folic acid and NTDs where evidence is ‘as good as it gets’
- Review responses to B12 chart and effect on views re fortification with folic acid
- Remind respondents of ‘emerging evidence’ issue (discussed initially in relation to stimulus FOLIC ACID)
 - ◆ relevant to B12 and other issues e.g. heart disease, cancers
 - ◆ ‘It doesn’t mean we’ve only just found out that x causes y, it means we have part of the picture, but until we find out more, it’s too early to reach a conclusion’
 - ◆ main points to communicate
 - B12 is main issue with most evidence though still not conclusive
 - there are other issues but evidence is less good
 - medical evidence develops gradually and not everything has a definite conclusion
- Review responses to evidence issues and effect on views re fortification with folic acid
- Possibly repeat self completion questionnaire 2 here

FORTIFICATION WITH FOLIC ACID – THE OPTIONS

- Show respondents stimulus FOUR POLICY OPTIONS

- Gauge initial responses re options but avoid lengthy / detailed / heated discussion
- Use self-completion questionnaire 3 to record individual preferences after this initial discussion

ORIENTATION

- Remind participants of the next stage – read briefing materials, discuss with others etc.
- Show respondents briefing packs and talk them through role of different elements i.e. Booklet 1, Booklet 2, self-completion questionnaires
- Distribute briefing packs and ensure respondents are clear re their task
 - ◆ emphasise that we want them to think about what they **personally** would like to see happen in an ideal world i.e. not to pretend they work for the Government, they don't have to think about costs, practicalities, who might be 'upset' etc.
 - ◆ ensure they understand that if they have any queries they can contact either of the two facilitators of this workshop, or via recruiter if they prefer
- Confirm arrangements for Workshop 2 i.e. date, time, venue
- Distribute packs
- Thanks and close

WORKSHOP 2

RE-INTRODUCTIONS / WARM-UP

- Moderator
 - ◆ re-introduction to the research, reminder re confidentiality, acceptability of different views etc.
 - ◆ introduce observer(s)
- Check that respondents have completed and brought with them self-completion to record views after reading briefing pack materials
- Respondents individually to feed back on:
 - ◆ green self-completion - overall preference recorded re the 4 options
 - ◆ one thing that stood out from briefing materials

INITIAL DISCUSSION

- Initial spontaneous responses to the materials in the briefing pack (record on flip chart)
 - ◆ in this kind of situation, we have found it very helpful and instructive to let respondents 'go with the flow' at this very early stage – it is interesting to see the issues that come up spontaneously here, which may be a guide to priorities for consideration later in the group
 - ◆ explore how much of the briefing materials respondents actually read and why, and whether showed to / discussed with anyone else
 - ◆ explore areas of interest, approval, confusion, concern etc.
 - ◆ explore differences between responses, and reasons for these
 - ◆ comparison of responses recorded on green self-completions with responses recorded on Questionnaire 3, exploring reasons for any changes of opinion
 - ◆ deal with any queries (record on flip chart – some may be 'parked' for later discussion)
- Presentation of further information under 3 broad headings:
 - ◆ demographics of women with NTD affected pregnancies (to address stereotypes / assumptions)

- ◆ current evidence on the relationship between folic acid and different types of cancer – beneficial for some cancers, detrimental for other(s)
- ◆ summary of risks and benefits associated with consuming high levels of folic acid

DETAILED DISCUSSION

- Explore as much as possible spontaneously, then go through issues in a more rigorous way e.g.
 - ◆ respondents' awareness of and attitudes to NTDs and of the link to folic acid now, having read the briefing materials – how does this compare with their incoming / baseline awareness and attitudes
 - ◆ respondents' understanding of the issue – are there areas of confusion, and why?
 - ◆ respondents' recognition and understanding of terminations as a specific issue and their thoughts about the number of terminations (as against the number of live births) as a consideration
 - ◆ recap on public health issues / government intervention
 - balance between how much government should do and how much is people's personal responsibility in relation to diet
 - is it appropriate for Government to intervene in this way
 - does Government have a right or responsibility to intervene in this way
 - what are the limits of Government responsibility
 - how should Government proceed when there is an area of uncertainty
 - what questions should Government be asking
 - mass medication issue
 - (if raised) implied messages re disability
 - ◆ respondents' impressions of the advantages / benefits related to each of the options – and where did they learn these from?
 - ◆ respondents' impressions of the disadvantages / disbenefits of each of the options – and where did they learn these from?
 - we recognise that this will need careful management to ensure participants have a good understanding of

the scale and level of the possible risk surrounding B12 masking

- ◆ respondents' areas of concern in relation to each of the options – and why?
 - ◆ to what extent are there barriers / areas of resistance / opposition to each of the options – why
 - ◆ understanding of / reactions to reasons why flour could be an 'appropriate vehicle' – any issues around this
 - ◆ which elements of the briefing pack were interesting? helpful? persuasive? confusing? unbelievable? off-putting? etc.
 - ◆ which elements of language / terminology were clear, helpful, accessible, confusing, incomprehensible etc.
 - ◆ which elements of the briefing pack supplied 'good' evidence, and which elements were less believable / convincing
 - ◆ as always, explore respondent differences as well as areas of agreement
- ☐ Small groups exercise (in lifestages)
- ◆ preferred option for own lifestage (information confidential – each group records preferences but information not then shared in plenary session)

COFFEE BREAK

DETAILED REACTIONS TO THE FOUR OPTIONS

- ☐ Building on the earlier discussion, go through the four Options **one-by-one**, exploring for **each**
- ◆ understanding of what the Option entails, and reactions to this
 - ◆ understanding of the benefits associated with the Option, and reactions to these
 - ◆ understanding of the risks associated with the Option, and reactions to these
 - ◆ assessment of the balance between the benefits and the risks – and how they are calculating this
 - ◆ extent to which respondents are relying on Level 1 information, whether they read any Level 2 information about the Option – why / why not
 - ◆ how they feel about / respond to the evidence presented in relation to the Option

- ◆ the language and vocabulary of the Option
 - ◆ differences between respondents in their feelings about the Option, and why
 - ◆ where they stand in relation to this Option – is it acceptable, is it preferred, is it rejected – why
 - ◆ implications for choice with this Option – can I opt out
 - ◆ ethical / mass medication issues with this Option
 - ◆ implications for communications / labelling with this Option
- For Options 1 and 4 only
- ◆ if this Option implemented, how would they feel about the risks and benefits? Would they feel the need to take some action? If so, what? (e.g. switch to wholemeal bread / lobby their MP)
- For Options 1, 3, 4
- ◆ is there anything government should do alongside this Option? If so, what? (e.g. 'de-fortification' of certain products / better checks for bowel cancer / for vitamin B12 deficiency)
- For all Options
- ◆ issues around changes in behaviour required; feasibility of this; how could target group / others be helped
 - ◆ what if this Option did not work?

COMPARISON AND PREFERENCES

- Review the discussion and then ask respondents again to record their preferences between the Options on self-completion questionnaire, as before
- Share decisions / preferences / reasons, discuss, compare and contrast views
 - ◆ explore if consensus exists / possible – why / why not

COMMUNICATIONS – if time allows

- Explore issue of communications depending on which option goes ahead
 - ◆ should the public be informed of this – why / why not

- ◆ what do they feel the communication priorities should be e.g.
 - what would I / the public want to know?
 - what worries would I / the public have?
 - what might I / the public not understand?
 - etc.
- ◆ what information specifically should be made available
- ◆ recommendations for communications strategy

FINAL REVIEW AND RECOMMENDATIONS FOR WAY FORWARD

- Review learning from briefing packs, stimulus materials and discussion
 - ◆ what are the 5 key considerations the Government / Minister should have in mind when coming to a decision on this matter
- Final self-completion, rating each Option and putting in order of preference
- Review group's decisions and recommendations and summarise key conclusions

THANKS AND CLOSE

BOOKLET 1

Please do your best to read as much of this as possible before the next meeting.

Please feel free to mark the Booklet in any way you want, for example:

- **If there is something you do not understand, put a question mark beside it**
 - **If there is something you agree with, put a tick beside it**
 - **If there is something you disagree with, put a cross beside it**
- **If there is something that surprises you, put an exclamation mark beside it**

- or add any other comments you wish

After you have read the Booklet, and before you come along to the meeting, please fill in the green questionnaire.

**It would also be good if you could show it to family and friends, or discuss it with them.
If you do this, please ask them to fill in the yellow questionnaire**

PLEASE BRING THIS BOOKLET, BOOKLET 2 AND COMPLETED QUESTIONNAIRES TO THE MEETING WITH YOU

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A / 1 What is the issue?

- The Government is considering options for improving the diets of young women in relation to folic acid.
- Getting enough folic acid during pregnancy makes it up to 70% less likely that the baby will develop a 'neural tube defect' (NTD), such as spina bifida – this is an established fact
- Currently, women planning or starting a pregnancy are recommended to take a folic acid supplement to help make sure they are getting enough folic acid.
- In the past, the Government has run 'education campaigns' advising women planning a pregnancy about the benefits of increasing their folic acid intake, by taking a daily supplement and eating more foods rich in folic acid
- This approach has had only a limited effect because:
 - around half of pregnancies are unplanned
 - even where pregnancies are planned, only about 50% of women take folic acid supplements or change their diet to improve folic acid intake (and these women tend to have a more balanced diet anyway).

- The end result is that there has been little or no decrease in NTD-affected pregnancies despite these campaigns
- The Government is considering four options:
 - Option 1 – Continue with the current Government policy of advice to women on folic acid
 - Option 2 - Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid.
 - Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis
 - Option 4 – Make the fortification of flour or bread a legal requirement
- There are pros and cons for each of these Options, and the Government wants to hear consumers' views on this issue

B / 1 What is folic acid and what does it do ?

- Folic acid is used in the fortification of some foods and is also available in supplements. Folate vitamins are found naturally in many foods, especially green leafy vegetables (such as spinach, broccoli).³
- The body cannot make folic acid for itself and therefore must get it from the diet. Also, because the body cannot store folic acid, people need to consume it regularly to maintain a good level in the bloodstream.
- Adults and children need folic acid to make normal cells (including nerve cells and red blood cells) and to prevent anaemia.
- Folic acid is particularly important during pregnancy.
- Some women of childbearing age and also the elderly do not have enough folic acid in their diets.
- If a woman has a low folic acid intake before and during pregnancy, she runs a greater risk that her baby will be born prematurely, will have a low birth weight, or will develop a neural tube defect (NTD).
- There is no evidence that an increased intake of folic acid presents any specific risk to children.

³ To be exact, “folate” is an umbrella term for all the different forms of the vitamin, of which “folic acid” is only one. For the sake of simplicity though, we have used the words “folic acid” throughout this briefing pack.

- There is evidence that where a person has a deficiency of the vitamin B12, having a high intake of folic acid makes it more difficult to diagnose the B12 deficiency. B12 deficiency is reasonably common, with up to 10% of the elderly population being affected to some extent.

- Some recent studies have suggested that consuming high levels of folic acid can:
 - reduce the risk of diseases including coronary heart disease, some cancers and bone diseases; but

 - increase the risk that if you already have pre-cancerous polyps in the bowel, these will get worse.

- However, at the moment scientists agree that not enough studies have been carried out to establish whether folic acid does, or does not, have these effects.

C / 1 What are 'NTDs' and how common are they?

- Neural tube defects (NTDs), such as spina bifida, hydrocephalus and anencephaly, are caused when the spinal cord or the bones of the spine surrounding it fail to develop properly. This leads to damage to the nervous system.
 - **Spina bifida** occurs when there is a gap or split in the backbone so that the spinal column itself is exposed. This usually happens in the lower back, and can lead to varying degrees of paralysis of the lower limbs; many people with Spina Bifida are wheelchair users and / or have no control over their bladder or bowels
 - **Hydrocephalus** is caused when the cerebrospinal fluid (CSF) that is produced inside the brain doesn't get absorbed back into the bloodstream in the normal way. This leads to a build up of CSF, which in turn can stretch or squash the brain tissue. Children with Hydrocephalus may suffer from learning difficulties and eyesight problems
 - **Anencephaly** means that the brain fails to develop, leading to miscarriage or death of the baby soon after birth
- It is estimated that there were 700-900 pregnancies affected by NTDs in 2003 (this is about 10-13 in every 10,000 pregnancies)
- It is difficult to estimate how many NTD affected pregnancies are ended by termination. There are around 200 reported births of babies suffering from NTD each year in the UK. Also, women living in Northern Ireland are not offered terminations.
- NTD-affected births declined until the 1990s, but there was little or no change throughout the 1990s and into 2000s.

- Not all NTDs are caused by folic acid deficiency, but it is estimated that increasing folic acid intake could prevent about 40% (four out of every ten) of NTD-affected pregnancies.
- Food fortification programmes in USA, Canada and Chile have been successful in reducing the rates of NTDs dramatically. In each case, folic acid is added to bread and other grain and flour based products

D / 1 **What is 'food fortification'?**

- Fortification means adding vitamins or other nutrients to foods during the manufacturing process.
- There are laws already in place requiring the fortification of margarine and bread in the UK. These laws date from the 1940's and came into place because of concerns that some people in the population were not eating enough of some nutrients. The law specifies what nutrients should be added, and in what amounts, to ensure that people in general consume more of the nutrients.
- Many other foods are fortified voluntarily i.e., because the manufacturer chooses to do so (e.g. breakfast cereals). Manufacturers choose to fortify foods for commercial reasons – with the intention of making the product more attractive to consumers.
- Many of the foods that are fortified voluntarily contain added nutrients that might provide some health benefits. However, some foods are fortified with nutrients for which increased consumption does not have clearly established health benefits, or which are necessary in the diet, but we should be careful not to eat too much of.
- There are laws in place that prohibit the addition of some substances to certain foods (for food safety reasons), and other laws that set out the maximum amount of some substances (including some vitamins and other nutrients) that can be added to foods.

- There are also rules controlling what a food manufacturer can claim on the label about a food that has been fortified. For example, food manufacturers are not allowed to claim that a food (or one of its ingredients) can cure or treat an illness, and the label can only say that the food is a “source of” or “rich in” a particular nutrient if it contains at least a minimum level.
- There are two important differences between foods that are voluntarily fortified, and those that must be fortified by law (mandatory):
 1. Voluntary fortification happens because manufacturers want to gain a commercial advantage by encouraging consumers to buy their product; Mandatory fortification happens because Governments are trying to ensure that people get enough of certain nutrients.
 2. Consumers can choose whether or not they want to buy a product that has been voluntarily fortified, or a similar product made by a different manufacturer that hasn't; with mandatory fortification, consumers might not have that choice, because all manufacturers' products will be fortified in the same way.

E / 1 Vitamin B12 Deficiency in Older People (65+)

- Vitamin B12 is needed by the body to form healthy nerve cells and red blood cells. It is found in virtually all meat, fish and dairy products.
- Around 5%-10% of people aged over 65 have low levels of B12 in their blood. The reason for this deficiency is that as we get older, our gut works less well and is less able to extract the vitamin B12 from the food we eat.
- This means that for these people, eating more B12-rich foods does not help, and some will need regular injections of B12 to raise the level of B12 in their blood.
- Also, some people following a vegan diet have a B12 deficiency because they do not eat meat, fish and dairy products.
- Eating more folic acid does not cause a B12 deficiency, but if a person with a B12 deficiency has a high level of folic acid in their system, it could make their B12 deficiency more difficult to detect or diagnose.

How many people aged over 65 are affected by vitamin B12 deficiency?

- The chart on the next page explains more about how B12 deficiency develops, and gives an indication of the number of people estimated to be affected.
- It is estimated that:
 - There are 9.3 million people in the UK aged 65 or over
 - 687,000 of these have a B12 deficiency (however mild)
 - Of these people, 1100 **also** have a high intake of folic acid
- This does not mean that all these people will have their health affected by their folic acid intake, because some of them will have only a mild B12 deficiency, and some with a more severe deficiency will still be diagnosed. However, this is the best estimate we have of the number of people who currently face a possible extra risk.
- To give an idea of how many more people could be affected by this possible extra risk – it has been estimated that if flour were fortified with folic acid at a level of 450 micrograms per 100 grams:
 - 4 out of every 10 NTDs would be prevented (this means around 300)
 - The number of older people with B12 deficiency (however mild) **and** a high folic acid intake would go up to 6700.

G / 1. Arguments for and against different policy options

The tables on the next pages show the arguments for and against four options for addressing the issue of NTDs and folic acid.

- Option 1 – Continue with the current Government policy of advising women on folic acid
- Option 2 - Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid.
- Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis
- Option 4 – Make the Fortification of Flour / Bread with folic acid a legal requirement

Option 1 – Continue with the current Government policy of advising women on folic acid

What would this mean in practice?

- The current Government advice to women to take folic acid supplements would stay the same.
- There would be no new legal requirements that food companies would have to follow
- We could expect the number of products currently fortified on a voluntary basis to remain the same.

Pros

- It wouldn't cost food companies anything – because they wouldn't have to change.
- None of the potential risks associated with eating more folic acid would occur.
- Consumers could still choose whether or not to buy fortified products

Cons

- The number of neural tube defect (NTD) affected pregnancies would not decrease – there would continue to be around 700-900 each year in the UK.

Option 2 - Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid.

What would this mean in practice?

- The Government would pay for a public education campaign, to make women more aware of the need to take folic acid supplements.

Pros

- The campaign would focus on women of childbearing age (e.g., by putting adverts in women's magazines and TV programmes popular with younger women)
- It wouldn't cost food companies anything – because they wouldn't have to change.
- Consumers could still choose whether or not to buy fortified products

Cons

- This would probably not prevent very many NTD pregnancies – because it hasn't in countries where they have tried it. (including in the UK in the 1990's).
- Women on higher incomes, and those who have spent more time in education are usually more likely to follow the advice in campaign messages than women on lower incomes – but it is women on lower incomes who are most likely to have an NTD affected pregnancy.
- Around half of all pregnancies are unplanned – so it would make no difference in those cases.

Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis

What would this mean in practice?

- Work with food companies to find ways to encourage them to produce fortified products, and to highlight this, for example by designing a logo like the “folate flash” (previously developed by the Health Education Authority).
- This could include a range of food types, including bread
- Have a consumer education campaign at the same time to encourage women to buy these products.

Pros

- If food companies produce more fortified products, and these are bought by women, the number of NTD affected pregnancies is likely to go down.
- If more fortified products were made, consumers would have more choice about what products to buy.
- Food companies don't have to make any changes if they don't want to, and therefore they would not have extra costs forced upon them.

Cons

- Food companies in the UK can already do this if they want to. This has also been tried in other countries. There is no evidence that this has worked in reducing the number of NTD affected pregnancies.
- It is likely that fortified products would be more expensive than “normal” products. This might mean that women on lower incomes (who have a greater chance of having an NTD affected pregnancy) would be less likely to buy them.
- In general, people throughout the population eat roughly the same amount of bread. This is not the case for other foods. If food companies choose to fortify products other than bread people who eat less of those foods would get less benefit.

(continued)

- If food companies choose not to produce more fortified products, there would not be a significant reduction in the number of NTD-affected pregnancies each year.
- If food companies produce more fortified products, and these are eaten by lots of people other than women of childbearing age – then more people would face the potential risks related to high folic acid intake.
- Because a voluntary system would not be as closely controlled as mandatory fortification, and could affect a wider range of food types, there is a chance that some people would eat much more folic acid than we would like them to.

Option 4 – Make the fortification of flour or bread with folic acid a legal requirement

What would this mean in practice?

- Make a new law requiring food companies to fortify flour or bread with folic acid.
- At the moment the suggestion is that this would be all flour except wholemeal – but it could be a different approach.

Pros

- Up to four in every ten NTD affected pregnancies would be avoided.
- Consumption of bread and flour is roughly the same across the population. All women would therefore get the benefits of eating more folic acid. Also, women who currently eat the least folic acid would get the most benefit.
- Would also make a difference to all the pregnancies that are unplanned - which is about half.
- Because a mandatory system would be closely regulated, it would be easier to ensure that people don't have much too much folic acid.

Cons

- More people would face the potential risks associated with higher folate intake.
- Would cost food companies more (NB – Industry estimate costs at around £700K a year. This may result in a maximum increase in the price of bread of 1p per loaf).
- Might make it difficult for food companies who sell their products to other countries that don't have fortification.
- Consumers wouldn't be able to choose not to eat bread with folic acid in – unless they just ate wholemeal.

H / 1

Why fortify flour or bread and not a different food?

- Flour is a staple food that is consumed at about the same level across the population as a whole, and at steady rates through the year.
- By contrast, other foods that could be fortified are eaten more by some group of people than others (e.g., children tend to eat more breakfast cereal than older adults, while older adults tend to eat more margarine and fat spreads than children do.)
- Although hundreds of different foods contain flour, most of the flour in our diet we get through eating bread.
- Bread is eaten in large enough amounts that the added folic acid would make a significant difference to the total amount of folic acid we eat.
- For white and brown breads, the machinery is already in place to replace other nutrients lost during processing, and folic acid can simply be added in.
- The decision on whether all flour or only selected flours would be fortified is still to be made.
- Depending on this decision, foods which would contain fortified flour (and therefore be an additional source of folic acid) could include: bread, cakes, burger buns, biscuits, sauces
- Foods would not taste or look different if folic acid were added to them

- It is not yet clear who would pay for fortification, and whether the price of these fortified foods would rise
- The Government will also need to consider how to ensure that people on gluten-free diets (and therefore do not eat products containing flour) eat enough folic acid.

I / 1 What is the situation in other countries?

- Several countries have introduced laws requiring fortification of flour with folic acid, including the US and Canada (1998) and Chile (2000).
- Early evidence – especially from the US and Canada – shows a significant improvement in the ‘folic acid status’ of the population, and a corresponding reduction in the level of neural tube defect (NTD) affected pregnancies (between around 25% and around 50%).
- This does not necessarily mean that fortification would have **exactly** the same effect in the UK.
- In Europe, as in the UK, where the policy has been to recommend women to consume folic acid supplements, there has been no reduction in NTD-affected pregnancies
- Among countries currently moving towards fortification by law are the Republic of Ireland, Brazil, Israel

QUESTIONNAIRES – WORKSHOP 1

Name _____

Questionnaire 1

Please select one of the following which is closest to your feelings at the moment about the **voluntary** fortification of food with vitamins:

- I am definitely in favour of voluntary fortification of food with vitamins
- On the whole, I am in favour of voluntary fortification of food with vitamins
- I am not sure about voluntary fortification of food with vitamins
- On the whole, I am not in favour of voluntary fortification of food with vitamins
- I am definitely not in favour of voluntary fortification of food with vitamins
- I don't mind either way

Please jot down your main reasons for this opinion.

Please select one of the following which is closest to your feelings at the moment about the **mandatory** (by law) fortification of food with vitamins:

- I am definitely in favour of mandatory fortification of food with vitamins
- On the whole, I am in favour of mandatory fortification of food with vitamins
- I am not sure about mandatory fortification of food with vitamins
- On the whole, I am not in favour of mandatory fortification of food with vitamins
- I am definitely not in favour of mandatory fortification of food with vitamins
- I don't mind either way

Please jot down your main reasons for this opinion.

Name _____

Questionnaire 2

Please select one of the following which is closest to your feelings at the moment about whether anything should be done about folic acid and NTDs.

- I am definitely in favour of something being done about folic acid and NTDs
- On the whole, I am in favour of something being done about folic acid and NTDs
- I am not sure whether something should be done about folic acid and NTDs
- On the whole, I am not in favour of something being done about folic acid and NTDs
- I am definitely not in favour of something being done about folic acid and NTDs
- I don't mind either way

If you are in favour of something being done about folic acid and NTDs, and if you have any ideas at this point about what you would like to see done, jot down your ideas here.

Name _____

Questionnaire 3

Please give your current opinion on each of the Options.

Option 1 – Continue with current Government policies of advice on folic acid

- I am definitely in favour of Option 1
- On the whole, I am in favour of Option 1
- I am not sure about Option 1
- On the whole, I am not in favour of Option 1
- I am definitely not in favour of Option 1
- I don't mind either way

Option 2 – Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid

- I am definitely in favour of Option 2
- On the whole, I am in favour of Option 2
- I am not sure about Option 2
- On the whole, I am not in favour of Option 2
- I am definitely not in favour of Option 2
- I don't mind either way

Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis

- I am definitely in favour of Option 3
- On the whole, I am in favour of Option 3
- I am not sure about Option 3
- On the whole, I am not in favour of Option 3
- I am definitely not in favour of Option 3
- I don't mind either way

Option 4 – Make the fortification of flour or bread with folic acid a legal requirement (mandatory)

- I am definitely in favour of Option 4
- On the whole, I am in favour of Option 4
- I am not sure about Option 4
- On the whole, I am not in favour of Option 4
- I am definitely not in favour of Option 4
- I don't mind either way

Now please record your order of preference for the four Options. Put a 1 by your 1st choice, a 2 by your 2nd choice and so on.

Option 1 - Continue with current Government policies of advice on folic acid

Option 2 – Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid

Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis

Option 4 – Make the fortification of flour or bread with folic acid a legal requirement (mandatory)

Please jot down your main reasons for your 1st choice

QUESTIONNAIRE – BRIEFING PACK

Now that you have finished your reading, please select one of the following which is closest to your feelings now about each of the Options.

Option 1 – Continue with current Government policies of advice on folic acid

- I am definitely in favour of Option 1
- On the whole, I am in favour of Option 1
- I am not sure about Option 1
- On the whole, I am not in favour of Option 1
- I am definitely not in favour of Option 1
- I don't mind either way

Option 2 – Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid

- I am definitely in favour of Option 2
- On the whole, I am in favour of Option 2
- I am not sure about Option 2
- On the whole, I am not in favour of Option 2
- I am definitely not in favour of Option 2
- I don't mind either way

(continued)

Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis

- I am definitely in favour of Option 3
- On the whole, I am in favour of Option 3
- I am not sure about Option 3
- On the whole, I am not in favour of Option 3
- I am definitely not in favour of Option 3
- I don't mind either way

Option 4 – Make the fortification of flour or bread with folic acid a legal requirement

- I am definitely in favour of Option 4
- On the whole, I am in favour of Option 4
- I am not sure about Option 4
- On the whole, I am not in favour of Option 4
- I am definitely not in favour of Option 4
- I don't mind either way

Please record your order of preference for the four Options. Put a 1 by your 1st choice, a 2 by your 2nd choice and so on.

Option 1 - Continue with current Government policies of advice on folic acid

Option 2 – Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid

Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis

Option 4 – Make the fortification of flour or bread with folic acid a legal requirement

Please jot down your main reasons for this opinion.

QUESTIONNAIRES – WORKSHOP 2

Name _____

Questionnaire

Please give your current opinion on each of the Options.

Option 1 – Continue with current Government policies of advice on folic acid

- I am definitely in favour of Option 1
- On the whole, I am in favour of Option 1
- I am not sure about Option 1
- On the whole, I am not in favour of Option 1
- I am definitely not in favour of Option 1
- I don't mind either way

Option 2 – Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid

- I am definitely in favour of Option 2
- On the whole, I am in favour of Option 2
- I am not sure about Option 2
- On the whole, I am not in favour of Option 2
- I am definitely not in favour of Option 2
- I don't mind either way

Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis

- I am definitely in favour of Option 3
- On the whole, I am in favour of Option 3
- I am not sure about Option 3
- On the whole, I am not in favour of Option 3
- I am definitely not in favour of Option 3
- I don't mind either way

Option 4 – Make the fortification of flour or bread with folic acid a legal requirement (mandatory)

- I am definitely in favour of Option 4
- On the whole, I am in favour of Option 4
- I am not sure about Option 4
- On the whole, I am not in favour of Option 4
- I am definitely not in favour of Option 4
- I don't mind either way

Now please record your order of preference for the four Options. Put a 1 by your 1st choice, a 2 by your 2nd choice and so on.

Option 1 - Continue with current Government policies of advice on folic acid

Option 2 – Public information campaign to encourage more women to take folic acid supplements and eat more foods containing folic acid

Option 3 – Encourage food companies to fortify more products with folic acid on a voluntary basis

Option 4 – Make the fortification of flour or bread with folic acid a legal requirement (mandatory)

Please jot down your main reasons for your 1st choice

forum

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