# The Ethical Implications of Options for Improving the Folate Intake of Women of Reproductive Age

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# 1: Summary

1. This report develops an ethical framework to support the Board of the Food Standards Agency (the Agency) in considering options for improving the folate intake of women of reproductive age including mandatory fortification of wheat flour with folic acid[1]. It draws on scientific information from other reports previously commissioned by the Agency and relevant research in peer-reviewed journals. The ethical approach is based on the 2005 United Nations' *Universal Declaration on Bioethics and Human Rights*.

2. The central question is: would it be ethically defensible for the Agency to recommend the mandatory fortification of wheat flour products in order to reduce the number of neural tube defect (NTD) births in the UK?

3. While an increased intake of the vitamin folate prior to conception and during the first 12 weeks of pregnancy has been shown to reduce the risk of NTD development, approximately 50% of UK pregnancies are reported to be unplanned. This implies that at least 50% of women who become pregnant have not been able to make an informed decision about modifying their diet to increase folate intake. Other studies have found efforts to increase the folate intake of women of child-bearing age, through public health education, to be relatively ineffective,

[1] Folic acid is a synthetic form of folate.

particularly among younger women and those from socio-economically disadvantaged backgrounds.

4. Evidence suggests that mandatory fortification of flour will reduce the number of NTD births, or terminations by reason of NTD, but may potentially result in an increased risk to those who suffer from an undiagnosed vitamin B12 deficiency. Other, currently inconclusive, evidence has suggested a possible link between folic acid intake in excess of the guidance safe levels of intake and certain cancers (SACN, 2006).

5. The principal ethical conflict to be addressed by the Agency is between the ideal of *personal autonomy*, which requires that an individual should always retain control over any decisions relating to her own health and medical treatment, and the ideal of *social responsibility* and *justice*, which proposes that societies have a duty of care to work, mainly through governments, towards the greatest level of health and happiness for their members, particularly those who suffer from social and economic disadvantage.

6. The objectives of *beneficence* and *non-maleficence* are also relevant. These relate to the goal of achieving benefits without simultaneously inflicting harms.

7. Other possible government health actions, such as adding fluoride to drinking water or compelling vaccination against childhood infectious diseases, raise parallel ethical issues. A review of these may be helpful in policy-making.

8. This report outlines the ethical issues that the Agency might consider in reaching its decision. It does not offer conclusive answers. However, our analysis of the four courses of action presented is that:

(a) Option 1 (*no change*), while preserving individual autonomy, breaches the social responsibility and equality principles. There is also a strong difficulty with the failure to prevent an identified harm.

(b) Option 2 (*increased public education*) has been shown to be largely ineffective. For this reason, it would not significantly remedy the breaches of social responsibility and equality presented by option 1. Moreover, it may create additional stigma for those populations already affected by NTDs.

(c) Option 3 (*voluntary industry fortification*) may also be ineffective, based on the previous failure of option 2 and current existing levels of voluntary fortification. In addition, it may pose additional health risks due to uncontrolled voluntary fortification. An action that is not likely to prevent harm, but may actually cause it, is difficult to defend ethically.

(d) Option 4 (*mandatory fortification*) poses difficult questions regarding the restriction of autonomy and the balancing of potential harm to one group over the prevention of harm to another. However, the scientific

evidence available to the Agency presents a strong argument that, in this instance, individual autonomy may reasonably be limited to benefit specific vulnerable groups, provided that parallel attention is given to minimizing the potential for harm to others. Because there are opportunities to 'opt-out' (for example by choosing wholegrain bread), the reduction of autonomy is less than in comparable scenarios.

# 2: Table of Contents

# 3: Introduction

9. In 2006, the Agency conducted a public consultation on options for improving the folate intake of women of reproductive age. Some respondents questioned the ethical implications of this action. In response, the Agency commissioned the Institute for Science and Society (ISS) at the University of Nottingham to develop a framework within which the ethical arguments for and against mandatory fortification could be considered.

## Background

10. This report draws on previous reports commissioned by the Agency including:
    (a) The Scientific Advisory Committee on Nutrition's (SACN) 'Folate and Disease Prevention' report (2006), which contains the Committee's findings on the benefits and possible risks of folate fortification;
    (b) Define's 'Health and Lifestyle in Pregnancy' report (2006) on the views of mothers living in deprived communities on options for improving folate intake;
    (c) Forum's 'Consumer Research on Folates' report of 2006 on qualitative research with a population sample of consumers on options for improving the folate intake of young women;
    (d) Lynn Stockley & Associates' 'Folic Acid: influencing low-income groups' report (2006), which reviews the available literature regarding past programmes to

increase folic acid intake among women of childbearing age.

11. This report also considers relevant information and findings published in peer-reviewed journals, particularly those devoted to public health and social policy.

12. The ethical framework used to structure the analysis is based on the Universal Declaration on Bioethics and Human Rights (the Declaration on Bioethics), signed by the General Assembly of the United Nations Educational, Scientific and Cultural Organization (UNESCO) on 19 October, 2005.

## Methodology

13. Part 4 of this report explains the principles laid out in the Declaration on Bioethics and offers some context for their application to health care and public health decision-making.

14. `Part 5 of this report gives more detailed consideration of the ethical principles most relevant to issues of population-wide health programmes.

15. Part 6 of this report introduces two medical case studies: mass-fluoridation of drinking water and childhood vaccination. These involve many of the same ethical issues as folic acid fortification. A review of similar

fortification schemes conducted in other countries is also provided.

16. Our analysis of the four options offered to the Agency Board and their ethical implications is contained in Part 7 of this report.

17. Finally, Part 8 offers conclusions based on the evidence and analysis covered in this report. ISS has not been asked to make specific recommendations regarding a best course of action for the Agency.

18. Appendix 1 contains a table comparing the four available courses of action against relevant ethical principles.

# 4: Ethical Principles

19. In 2005, UNESCO's General Assembly signed the Declaration on Bioethics which attempts to offer a cohesive and unified structure for ethical decision making by member states. Its principles are drawn from many regional and national frameworks. They are intended to allow flexibility for local practice and custom within a broad consensus over the limits of acceptability.

20. Some of the principles included in the Declaration are not relevant, or only peripherally relevant, to consideration of the options for improving the folate intake of women of reproductive age and have not been included here.

21. It is also important to note that different ethical principles may carry varying weights depending on circumstance and situation. Policy makers must decide on the weight given to each relevant principle in light of the decision being made. Thus, the order in which the ethical principles are listed here does not imply that one principle is a priori any more important than another.

22. Descriptions of the principles given here have been adapted in some cases to relate more closely to the options for improving the folate intake of women of reproductive age.

## Principles

23. **Human Dignity and Human Rights**: Full respect for the inherent dignity of the human person, human rights and human freedoms must be maintained at all times and the interests and welfare of the individual must always prevail over the sole interest of science or society.
24. **Equality, Justice and Equity**: Any action should consider the fundamental equality of all human beings in dignity and rights and attempt to ensure that they are treated justly and equitably.
25. **Benefit and Harm:** actions concerning health or bodily integrity must only be undertaken if they are of active benefit to the individual concerned. Every attempt should be made to avoid causing harm to any individual or group.
26. **Non-Discrimination and Non-Stigmatisation:** No individual, family, group or community should be subject to discrimination based on any grounds that might infringe their human dignity, human rights or fundamental freedoms.
27. **Respect for human vulnerability and personal integrity:** Human vulnerability should be taken into account when considering actions concerning health or bodily integrity. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.
28. **Autonomy and Individual Responsibility:** The autonomy of persons to make decisions, while taking responsibility for

those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

29. **Consent:** An action concerning health or bodily integrity is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent.

30. **Social Responsibility:** The promotion of health and social development for their people is a central purpose of governments that all sectors of society share. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, decisions in health care and public health should consider and advance:

    (a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;

    (b) access to adequate nutrition and water;

    (c) improvement of living conditions and the environment;

    (d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;

    (e) reduction of poverty and illiteracy.

# 5: Population-Wide Health Programmes

31. The considerations raised by the decision whether or not to enact mandatory fortification are similar to those involved in bioethical discussions about systems of 'mass medication' in that both affect the health of the population as a whole and raise similar issues about informed consent and the interests of the vulnerable.

32. This section considers some characteristics of population-wide health programmes and draws some parallels with the decision regarding folic acid fortification. By population-wide, we imply that the programme is intended to reach all, or a large majority of, members of a state or population regardless of their existing health status.

33. Enacting health programmes on a population-wide basis poses several ethical challenges. What constitutes an appropriate health programme for one individual may not be the best for another, which raises questions of potential harm. In the present case, it becomes necessary to ask whether appropriate supplementation for one individual, who might not otherwise receive it, sufficiently justifies the possibility of imposing unnecessary supplementation on another.

34. Additional conflicts may arise if a society or population as a whole stands to benefit from the effect of the

programme on the individual. In such situations, it may prove necessary to overrule the personal autonomy of the individual in order to prevent harm to the society. In instances where the possibility exists that the individual may be harmed by the programme, however, additional constraints apply. The benefit to society may only outweigh harm to individuals in extreme cases.

35. Population-wide programmes largely invalidate the principle of consent since there is no way each individual can be offered an opportunity to give explicit consent. Informed consent is generally considered one of the fundamental tenets of any health-related or medical discipline.

36. For these reasons, the implementation of health programmes on a collective basis has often been contentious.

## Consent and Opting-out

37. Due to past abuses, consent to medical treatment and experimentation is considered the cornerstone of medical ethics. National and international law, as well as all codes of medical practice, require that informed consent procedures are followed except in the most extreme emergencies.

38. Over the years, this tenet has expanded to include all aspects of healthcare, including nutrition. In essence, any substance that has a physical or mental effect on the

physiology of an individual must only be administered with that individual's informed consent. Consent is thus equally necessary in matters of medication and matters of food fortification.

39. Authorization for all forms of healthcare should be obtained in accordance with the best interest of the person concerned and domestic law. The person concerned should be involved to the greatest extent possible in the decision-making process of consent, including refusing or withdrawing consent.

40. Most health programmes involve opt-in procedures. The default state is not participating; the individual, or someone empowered to act for the individual, must take specific action in order to participate.

41. Informed consent requires that the individual should not be permitted to opt-in unless he, or his representative, has received all relevant information pertinent to the programme, its outcomes and known risks. Further, the individual must have the opportunity, in as much as it is medically possible, to leave the programme at any time and to withdraw consent. Where possible, informed consent should be acquired in written form.

42. By contrast, population-wide health programmes are opt-out procedures. The default state is participation in the programme. In order to stop participating, the individual,

or someone properly empowered to speak for the individual, must take specific action.

43. The process of opting-out may take many forms, depending on the contents of the programme and the delivery vehicle used. However, opting-out procedures must have three definitive characteristics:
    (a) They must be known to everyone participating in the programme. It is the responsibility of the programme administrator to ensure that all participants are fully aware of the opt-out procedures.
    (b) They must require conscious and concerted action on the part of the individual. Opt-out programmes from which it is possible, or likely, that the individual may opt-out accidentally or without informed choice are not effective.
    (c) They must be equally attainable, without undue hardship, by all members of the affected population. Opt-out procedures that are only available to one segment of a population, or are more available to one segment of a population than another, are invalid.

44. Even with effective opt-out procedures, however, population-wide programmes pose problems in as much as they remove the possibility of informed consent. A high threshold of justification must be reached before opt-out procedures may be implemented.

## Vulnerability and Diminished Autonomy

45. Modern codes of ethical professional practice include a clause providing that extra care and consideration must be given to vulnerable populations.

46. This means that in any given decision, extra weight is accorded to the needs and potential harms to vulnerable populations. Policies should be aimed at relieving vulnerability.

47. Groups or populations of people may be vulnerable in two ways: procedurally and physically.

48. Physical vulnerability implies that the group is more exposed to the possibility of harm by virtue of biological factors. Common examples of physically vulnerable populations are the elderly and those with existing medical conditions, which may easily be exacerbated.

49. Procedural vulnerability refers to groups of persons who are systematically disadvantaged or incapable of giving appropriately informed consent. Children and people with mental health problems are two common examples of procedurally vulnerable groups.

50. Physical vulnerability is often easier to recognize and treat than procedural vulnerability because procedural vulnerability is generally systematic and endemic. Causes of procedural vulnerability may include illiteracy, diminished mental capacity, lack of education, extremely

low socio-economic status and a lack of personal autonomy.

51. Children and potential children are generally considered the most vulnerable population because they are both physically and procedurally vulnerable. Potential children, unborn foetuses and infants, in particular suffer from total vulnerability. For this reason, many ethical difficulties arise in decision-making for these groups.

52. Most societies attempt to resolve these difficulties by granting control over decision-making on behalf of children and potential children to their parent or parents. A parent is generally authorized to speak for the child until the child reaches majority. But children acquire increasing autonomy as they mature and it is widely accepted in developed countries that, from the age of about seven, their opinions should be sought and, to the greatest extent possible, respected in medical decisions.

53. However, the case of potential children and unborn foetuses poses a greater dilemma. While the pregnant woman is generally accorded full rights to make decisions about her own health and that of a foetus, many states restrict this right where it impacts too heavily on the eventual health of the foetus. In some states this extends to the outlawing of abortion.

54. At the core of such debates is the question of whether the foetus should be accorded full status as a person or

whether it is a potential person. A potential person may have value by reason of their eventual status as a citizen but the duty of the state must first be directed to its current citizens.

55. Current UK policy suggests that the foetus is to be regarded as a potential person after a certain period of development has occurred. A potential person should receive all possible care and treatment with the understanding that, if all goes well, the foetus will eventually become a full person at which time any medical concerns will become the concern of the state (Department of Health, 2000; Warnock, 1985).

56. However, exception may be made to this understanding in cases where concern for the health of the potential person causes harm to the health of a current citizen. Thus, abortion in cases where the health of the mother is at stake is generally legal.

57. This debate is relevant to the folic acid fortification decision because it implies that the choice being made is between the health of potential persons and the health of another vulnerable population, those with B12 deficiency. In addition, the evidence seems to suggest that those potential persons in greatest danger of NTDs are concentrated among lower socio-economic groups who may also be procedurally vulnerable.

## Benefit and Harm

58. The debate over what constitutes a potential harm versus a positive benefit has long troubled bioethical debates. Liberal political ideals traditionally hold that the role of the state should be limited to preventing harm to individuals from outside sources – whether the outside source is natural, such as disease or natural disaster, or involves the actions of another individual in society. In a strict libertarian reading, the state has no role in preventing the individual from causing harm to himself, nor in bringing about active benefit to the individual.

59. However, this interpretation is complicated by the need to define where the line between active benefit and active harm lies. If one places the line at the state in which the individual in question finds himself at the time of the ethical decision, then improving his current state would be seen as an active benefit, but doing nothing to improve his state would be considered ethically neutral; even if the individual is in imminent danger of harm.

60. Many philosophers argue, however, that this interpretation is unfair in that it waits until the individual is in a position of danger to begin weighing ethical imperatives. Instead, they argue, the benefit and harm an individual is likely to encounter should be measured against a baseline of 'normal' health and safety (Feinberg, 1984). Under this view, active intervention to prevent an imminent harm counts not as attempting to confer

benefit, but simply as bringing that individual back to 'baseline' status by preventing an imminent harm (Dare, 1998).

61. To give an example; a GP encounters a patient who is severely anaemic but does not suffer, at present, any adverse effects. The libertarian view argues that the doctor, in this case considered as a representative of the state, has no duty to the patient. By offering medical intervention, he would be raising the patient above his current status and offering him an active benefit, which is not his role. By doing nothing he is not changing the patient's status at all. He is neither causing harm nor failing to prevent harm.

62. Under the second view, however, we would measure that patient against other individuals in society and argue that he is 'below baseline' in that he suffers from a potential danger that others do not suffer. In this instance, the doctor has a duty to offer treatment in order to bring the patient back to baseline status. He has a duty to prevent harm, even though it also involves active benefit to the patient.

63. Most doctors would argue that their duty must lie in the second scenario; otherwise there would be no ethical compulsion to perform a great many life-saving medical interventions. However, on a state level, where limited resources must be weighed and balanced, the first view is often compelling. This is particularly true of the

presumption against active benefit when equal resources could go to the avoidance of active harm.

64. Although there are many gradations inherent in the harm/benefit analysis, much current ethical thinking supports the following hierarchy: 1) The first priority must be not to cause harm, 2) the second to prevent harm where possible and 3) the third to bring about benefit where possible.

# 6: Case Studies

65. In this section we examine several population-wide health programmes which have been debated in recent years. Although some of these cases are medical in nature, they have been chosen because they share certain key ethical dilemmas with the question of folic acid fortification of wheat flour and may therefore offer guidance on how decisions of this nature have previously been conducted.

## Fluoridation

66. Sodium fluoride has been shown to have beneficial effects through the reduction of tooth decay in children (Petersen & Lennon, 2004). In areas where naturally occurring water supplies are low in sodium fluoride, many local governments or similar authorities have elected to add a fluoride supplement to publicly supplied drinking water (Clarkson & McLoughlin, 2000).

67. Proponents of water fluoridation (British Medical Association, 2006; World Health Organisation, 2001; Dept. of Health, 2006; British Fluoridation Society) regard it as a safe and simple means of preventing dental decay (World Health Organisation, 2004; Secretary of State for Health, 1999). , particularly in areas where lower socio-economic groups may not have universal access to dental care (Jones et al, 1997). However, studies have linked ingestion of fluoride with dental fluorosis, a condition that causes

discolouration and potential weakening of the tooth enamel (McDonagh et al, 2000). Although other studies have proposed linkages between fluoride ingestion and a variety of illnesses including osteoporosis and cancer, the quality and quantity of such evidence has not been conclusive (McDonagh 3 et al, 2000; Medical Research Council, 2002; Demos et al, 2001).

68. Many groups nevertheless object to fluoridation and argue that it is an ethical violation to force individuals to consume a potentially harmful substance without their consent (Cross, 2003). Critics contend that, even if fluoridation does benefit some individuals, it should not be administered on a mass level regardless of whether the consequence might be an increased rate of tooth decay among some sections of the population (All Parliamentary Group Against Fluoridation; Green Party; Britain Against Fluoridation).

69. In this instance, not adding fluoride to the water may cause a relatively large harm to one section of the population, i.e. children who inhabit areas serviced by water supplies with low fluoride content, but may also cause harm to a potentially larger section of the population – those who may contract dental fluorosis.

70. The opt-out procedure for fluoridation involves either purchasing and using a water filtration system or drinking only bottled water. It could be argued that both these

options favour individuals of higher socio-economic groups (Diedendorf, 1997).

71. Proponents argue that the scientific evidence in support of the benefits of fluoridation is more robust than that linking it to harmful effects. Further, those who benefit most from fluoridation tend to be from socio-economically disadvantaged sections of the population who may be unable to afford other treatments such as advanced dental care and alternative fluoride supplements (Jones & Worthington, 1999).

72. Arguably, society as a whole also benefits from the fluoridation of water and the reduction in cases of tooth decay because prevention of dental caries is considerably less resource-intensive than treatment of diseases that may result from fluoride deficiency. This argument is stronger in countries, like the UK, which have state-sponsored medical care; limited NHS funding may be preserved for less preventable but potentially more health-threatening medical situations.

73. In the US, fluoridation of drinking water is mandatory. In the UK, communities are granted the right to decide whether they wish to fluoridate their water (UK Water Act, 2003). A recent amendment to the Water Act states that water providers must commence fluoridation at the community's request. Although the measure passed overwhelmingly, the decision process was fraught. There

appear to be no plans to implement mandatory fluoridation in the UK at this time.

## Immunization

74. Vaccination is considered by many to be the greatest health achievement of modern medicine. Concerted efforts towards vaccination in countries in Europe and the US have resulted in the virtual elimination of diseases such as polio and greatly decreased the drain on health resources caused by outbreaks. In order for vaccination to be most effective, it must occur in infancy or early childhood (Ulmer & Liu, 2002).

75. There is considerable evidence to suggest that immunization only works to eliminate most diseases if all members of a society receive vaccination. In order to negate the possibility of an outbreak of most diseases, approximately 98% of the society must be immunized. If the percentage of individuals vaccinated falls too far below this level, evidence suggests that vaccination is no longer effective (Meissner et al, 2004).

76. For this reason, many have argued that the vaccination of children should be mandatory. Vaccination is not only necessary to prevent harm to the individual child but also to preserve the health of society as a whole Vermeersch, 1999). Vaccination not only prevents harm to the child but

prevents the child from causing harm to others through infection (Feudtner et al, 2001).

77. However, vaccines vary in efficacy and safety. Some vaccines have been shown to reduce or eradicate instances of a disease with few negative side effects. Others have been linked, albeit in small numbers (Govaert et al, 1993; Peltola et al, 1986; Relyveld et al, 1998), to instances of the disease they are intended to prevent or severe allergic and follow-on reactions that may cause permanent damage (Pywell, 2002).

78. The question is particularly difficult because it deals with the treatment and health of children. Children are seen as a quintessentially vulnerable group because they are generally most susceptible to diseases and they are not considered capable of full consent until they reach a certain age.

79. There is a strong premise that parents should retain autonomous decision-making powers over medical treatment for their children. However, the state has, in the past, reserved the right to interfere in this process if it believes that the welfare of the child is sufficiently at stake (Isaacs et al, 2004).

80. Thus, vaccination raises three very difficult ethical questions:

(a) Is it justifiable to risk causing harm to the child in the service of possibly preventing greater harm at a later date?

(b) Is the case for vaccination strong enough to overcome the autonomy of a parent in their capacity to make decisions on behalf of their child?

(c) Can the benefit to society as a whole outweigh the risk to an individual child?

81. States have answered these questions in varying ways. In countries such as Sweden, Denmark and New Zealand, vaccination records are *required* upon entry to the school system (Hodge & Gostin, 2001-02). Vaccination is not mandatory but the parent is required to make a clear decision either in favour of vaccination or concretely against it (Dare, 1998). In the US, vaccination is compulsory in all states but some allow conscientious objection on the grounds of strongly-held religious or philosophical beliefs (Salmon & Siegel, 2001).

82. In the UK, vaccination is not mandatory, although relevant vaccination records are *requested* upon entry to the school system and in the event of immigration (Griffith, 2003). There is also a very strong social pressure towards vaccination which some groups claim is already coercive (Hobson-West, 2007).

83. Perhaps more tellingly, the UK is one of the few states to offer financial compensation for adverse medical outcomes as a result of recommended vaccinations. This creates the impression that the government is willing to take responsibility for vaccinations, even though it has not made them mandatory. Compensation implies that the family is being remunerated for risks taken on behalf of the overall health of the society.

## Other Fortification Schemes

84. The UK currently requires the fortification of flour with calcium, thiamine, iron and niacin and the fortification of margarines with vitamin A and vitamin D. Several other countries have initiated, or are considering implementation of mandatory fortification programmes. This section provides a brief review of other food fortification programmes.

### The USA

85. The US implemented mandatory fortification of flour products with riboflavin, iron, niacin and thiamine in 1942. The US Food and Drug Administration (FDA), noted at the time that it did not support indiscriminate fortification but acknowledged that fortification was mandated to correct deficiencies in "the general population, or of significant...geographic, economic or racial segments.( Committee on Foods and Nutrition of the NRC, 1951)."

86. Mandatory folic acid fortification commenced in 1998, following clinical research linking increased intake of folic acid with a reduction in NTD births.

87. Unlike debates over fluoridation, the rhetoric of discussions over the implementation of folic acid fortification focused primarily on safety and efficacy and does not appear to have been framed within the context of ethical debate, per se (US, FDA, 1996). However, concerns over the advisability of fortifying the entire population in order to target a relatively small population eventually led the FDA to mandate fortification at a lower level than originally intended (Backstrand, 2002).

## Canada

88. In Canada, mandatory fortification with folic acid came into effect in November 1998 following several government studies on the current folate status of the Canadian population. Again, the debate over whether or not to implement mandatory fortification appears to have centred on the safety and efficacy of suggested fortification levels rather than on ethical issues. However, concerns over potential negative effects on population members over 60 years of age led the government to conduct a post-fortification study of folate levels in the Canadian population.

89. The study found that mandatory fortification had significantly improved the folate levels of population groups that had previously been most deficient in folic

acid and at highest risk of NTD births. There were no reports of those over 60 exceeding the recommended intake of folic acid. The percentage of persons over 60 who showed biochemical signs of vitamin B12 deficiency declined by approximately 7%. These results suggest that mandatory fortification resulted in a strong prevention of harm to women of childbearing age without evidence of increased harm to the population over 60.

90. However, results also showed that there remained a significant correlation between household income and folate levels, with women and those over 60 who lived in households below the government-mandated poverty line showing the lowest levels of folate intake (Public Health Agency of Canada, 2004).

## Australia

91. Australia currently permits the voluntary fortification of milk, yoghurt and dairy products with vitamin D but vitamin D deficiency appears to remain a problem, particularly in women (Nowson & Margerison, 2002). Iodine fortification is currently voluntary but Food Standards Australia New Zealand (FSANZ) is currently considering the mandatory fortification of salt with iodine (FSANZ, 2006(2)).

92. Voluntary fortification with folic acid has been ongoing in Australia since 1996. However, studies show that while folic acid intake is higher than in years prior to the commencement of voluntary fortification the greatest increase is strongly correlated with educational and

socioeconomic status. Of particular concern is the status of the aboriginal population, who are a highly vulnerable segment of Australian society. In 2004, based on studies which argued that mandatory fortification would be the most equitable approach to achieving sufficient folate intake, the Australia and New Zealand Food Regulation Ministerial Council agreed that mandatory fortification should be considered a priority (Bower & Stanley, 2004).

93. In public consultation with various interest groups in Australia and New Zealand, issues of autonomy and the protection of vulnerable populations have been raised (FSANZ, 2006(1)). Nevertheless, mandatory fortification has been actively promoted by FSANZ although the measure has not yet been passed (FSANZ, 2006(3)).

# 7: Consideration of the four options for improving folate intake

94. In this section we use the ethical framework laid out in the previous sections to examine the four courses of action that the Board has been asked to consider and their ethical implications.

## Option 1: No Change

95. The first option proposes no changes to the current course of government action with respect to folic acid fortification. Current efforts to encourage folic acid supplements in women planning to become pregnant would continue but no additional programmes would commence.

96. The scientific evidence presented to the Agency indicates that this course of action would result in a continuation of current levels of disability, early deaths and pregnancy terminations due to NTD. This course of action would not increase the current rate of folic acid over-supplementation, nor the number of undiagnosed vitamin B12 deficiency cases.

97. With respect to ethical principles, this option would continue to respect the autonomy of the individual by

permitting a choice as to whether or not to take folic acid supplements. Because folic acid supplementation would remain an opt-in procedure, systems of consent would remain intact. Individuals would implicitly consent to folic acid treatment by means of purchasing and consuming folic acid supplements or folate-rich foods.

98. However, consent requires adequate information in order to be valid. Studies provided to us by the Agency suggest that many members of the target population who do not choose to ingest sufficient levels of folate have not made an informed choice for one or more of the following reasons:

(a) They are unaware that they are likely to conceive.

(b) They are unaware that folic acid is necessary to foetal health. This may be due to a failure of education or a lack of access to appropriate public health services.

(c) They lack the financial resources to purchase supplements or folate-rich foods.

(d) They have access to the necessary education but they do not find the available evidence sufficiently credible to undertake self-fortification.

99. In as much as consent to opt-in to a medical procedure may be invalidated procedurally due to a lack of information, a lack of consent to nutritional supplementation may suffer from the same failure. This would indicate that informed consent is not maintained by this course of action in a pure form. The situation is exacerbated by the fact that, while consent in this

instance is unlikely to harm the individual, a lack of consent may do so. Where the opposite is true, such as in examples of medical experimentation, a very high standard is usually applied to ensure that the individual is making a truly rational choice.

100. Issues of consent are exacerbated when the outcome affects more than the individual involved. In this case, because a failure to opt-in to voluntary folic acid fortification may result in an NTD in a potential child, the burden of making medical decisions remains with the mother. As discussed in the immunization example, bioethicists generally support the right of the parent to make medical decisions on behalf of her children. However, this tenet has exceptions in cases where the decisions of the mother, particularly non-informed ones, are likely to result in active harm to the child.

101. A threat of active harm to both the mother and any potential children is of concern because, as stated in the Declaration on Bioethics, it is the duty of a government or society to work towards the best possible level of physical and mental health for *all* its members, particularly those who are most vulnerable. In particular, if a governing body is aware that certain vulnerable sections of its population are under direct threat from a potentially preventable medical condition and takes no action, it is in breach of the ethical tenet of social responsibility.

102. The corollary to this argument is that by not offering an easily available treatment for a potential illness a responsible authority, be it a physician or a governing body, is both failing to prevent harm to those to whom it owes a duty and failing to benefit them. Potential children who are in danger of NTD births or terminations are not operating at the baseline enjoyed by the potential children of women with sufficient folic acid fortification. The state may have a duty to adjust this inequality.

103. If, as the evidence suggests, the effects of folate insufficiency in women of childbearing age are more likely among the young and economically disadvantaged then there is an equality argument to be made as well. The care and treatment of those suffering from NTD is costly in terms of both financial and emotional resources. A course of action that allows this burden to be concentrated on those with the fewest resources would not accord with notions of equality and justice.

104. Finally, however, this option would not cause any additional harm to those suffering from vitamin B12 deficiency. Current rates of diagnosis and treatment of this deficiency would continue. Because evidence has shown that the potential masking effect of folic acid on vitamin B12 deficiency would be most highly concentrated in those individuals over 65 (SACN, 2006), this option would effectively prioritize the health of these individuals, who may also be considered a physically vulnerable population.

## Option 2: Increasing Public Awareness and Education

105. This option involves increasing the intensity of current programmes and investigating potential new programmes to educate the public on the benefits of folic acid supplements and the necessity of ingesting sufficient levels of folate-rich foods.

106. The evidence presented to the Agency suggests that previous efforts in the UK, as well as similar programmes elsewhere, have been largely ineffective and have not resulted in an increase in the number of women consuming the recommended amount of folic acid (Lynn Stockley & Associates, 2006). Where improvement has been shown , it is concentrated among women of higher socio-economic and educational status.

107. In addition, evidence on the number of unplanned pregnancies suggests that, even if educational campaigns succeed in stressing the importance of folic acid fortification in achieving a healthy pregnancy, the net change in the number of NTD affected foetuses may not be significant.

108. Thus, continuing with, or increasing, current education and awareness programmes is likely to have a negligible effect on the number of NTD births and terminations.

109. In light of this data, option two becomes ethically very similar to option 1. A duty to prevent harm and recognize social responsibility cannot be fulfilled through actions that the state has evidence to believe are ineffective.

110. As discussed above, there is a presumption that additional resources, where available, should go towards benefiting the most vulnerable in any situation. Because data on similar folic acid education programmes suggests that such programmes largely benefit higher socio-economic and educated groups, this option does not significantly improve on the inequalities presented by option 1.

111. Worse, there is a possibility that this option might create additional inequality. Strong efforts to increase the uptake of folic acid in women by publicly stressing the undesirability of NTD in children may have the effect of stigmatizing and marginalizing those who already suffer from NTDs and their families. Clearly people with NTDs can live full lives, whether or not the defect can be surgically repaired. At the same time, many pregnancies with NTDs miscarry and others result in children born with defects that are incompatible with life. The precise outcome cannot necessarily be predicted at the time of screening. Our understanding of the scientific evidence is that fortification will reduce rather than eliminate the risks of NTD births, some of which seem to be due to other, as yet unknown, errors of foetal development. As such, maternal behaviour and lifestyle choices are unable to prevent these and the

appearance of an NTD pregnancy is not something for which a woman should be held accountable.

112. An additional concern stems from the use of state resources, funded by taxpayers, for programmes which do not promise significant improvement in the overall health of the population. This potentially compromises the ethical basis of taxation, that compulsory transfers of income or property will be used in ways that are efficient and effective.

113. That said, this option continues to preserve the ideals of autonomy and informed consent. Indeed, by attempting to increase the level of information available, this option may result in more informed consent among those it reaches.

114. Similarly, it is unlikely that this action would result in a greater folic acid uptake in people over 65 suffering from vitamin B12 deficiency and so no additional harm would be caused to these individuals.

115. It is possible that new programmes could be developed to encourage the use of folic acid supplements using information gathered from the failures of past programmes and that these might result in a more effective outcome. This is, however, speculative and may be hard to use as a justification for a policy decision.

116. In summary, there is little to distinguish this option from the previous one in the absence of evidence that there are more effective measures of education and outreach in relation to folic acid supplements than have yet been used.

## Option 3: Voluntary Food Fortification by Industry

117. This option proposes encouraging the flour and bread-product industry voluntarily to increase the amount of folic acid contained in flour products in the UK. Although guidelines as to suggested amounts would be offered, no regulation, beyond those safety regulations already in place, would be instituted.

118. A certain amount of voluntary fortification with folic acid already occurs in the UK, particularly among producers of breakfast cereals and some fat spreads. Existing data on fortification levels, including current incidence rates of NTDs, take into account folic acid intake from these sources. Plans to increase voluntary fortification would involve extending voluntary fortification to other food manufacturers (SACN, 2006).

119. Widespread voluntary fortification programmes have shown some success in the past (Hickling et al, 2005). However, the greatest success is often shown when the public understands that the fortification substance is of benefit to all members of the population and is actively seeking to purchase it (Bower et al, 2005). Past consumer

outreach programmes involving voluntary fortification and subsequent advertising have not shown this to be the case with folic acid in the UK (Forum Qualitative, 2006). This raises significant questions as to the number of businesses likely to undertake voluntary fortification.

120. If voluntary folic acid fortification and subsequent advertising were to be effective in raising sales of bread products it can be assumed that such sales would be concentrated among those who are already aware of the benefits of folic acid and are seeking to ingest more of it (Crane et al, 1995). Presumably, such individuals have already benefited from the results of education and awareness programmes as discussed in option 2. But this does not address the issue of those who have not benefited from such programmes and remain unaware that folic acid is a beneficial supplement.

121. Of further concern would be the lack of regulation inherent in this action. Because manufacturers would be fortifying voluntarily no relevant health authority would be supervising the quantity and quality of the fortification substance. Given unregulated levels of fortification it is possible that some individuals may unknowingly consume too much folic acid, which may have adverse effects, or may believe that they are receiving adequate levels of folic acid fortification when in fact they are not. This may prevent them from taking other action to ensure sufficient fortification.

122. The implication is, then, that option 3 is unlikely to result in a significant increase in folic acid intake in the most vulnerable populations. It would therefore have little net impact on the number of NTD cases.

123. As such, option 3 shares many of the ethical difficulties found in option 2. While in this instance, the potential cost of the action is shifted on to industry rather than the taxpayers, the state would remain in a position of attempting to undertake its duties of social responsibility through actions it has insufficient reason to believe successful.

124. Nor does this option avoid the equality and justice difficulties found in option 2; the benefits appear likely to be concentrated among those of higher socio-economic and education status rather than more vulnerable populations.

125. It is possible that some of the difficulties inherent in this option could be overcome with strategies such as government subsidies for fortification and possibly by combining it with option 2. However, the ethical justification in support of this option remains weak.

## Option 4: Mandatory Fortification

126. This option suggests that the government amend current regulations for the fortification of flour products in the UK to

include levels of folic acid calculated to result in optimal fortification for as many individuals as possible.

127. The evidence made available to us by the Agency suggests that widespread fortification of flour products will result in a lower incidence of NTD cases in the population as a whole. It is most likely, given current occurrence rates, that the greatest reduction will occur among lower socio-economic groups.

128. Decreasing instances of NTD overall may be considered of benefit to society because this allows reallocation of medical resources to less preventable conditions. It would also contribute to the advancement of social justice by actively working to increase the health of the population as a whole, particularly women and children.

129. Increasing average folic acid intake may also be seen as preventing harm to certain areas of society. As discussed above, potential children of those who do not receive the recommended level of folic acid supplementation face greater health risks than the potential children of those who do. According to the 'baseline' model of ethical reasoning, there is therefore an ethical imperative to rectify this imbalance.

130. Similarly, the decision to terminate a pregnancy, even one which may not result in a live birth, is a difficult and traumatic one which can often lead to long term mental

and emotional damage. The avoidance of this choice may be counted as a prevention of harm.

131. In addition, the mandatory fortification of flour products would result in a more even distribution of folic acid intake across the population. This would ameliorate certain inequalities in the level of health enjoyed by different sections of society.

132. However, this option also suffers from several of the most common ethical difficulties inherent in population-wide health programmes. If all wheat flour based products in the UK are fortified then there is a strong likelihood that many individuals will consume products fortified with folic acid without their prior informed consent. Although it is assumed that information about folic acid fortification will be provided on product labels it is inevitable that this information will not be read by all.

133. The opt-out procedure in this instance would be the avoidance of wheat flour based products. Alternatives would involve those wheat flour products made from whole grains and those manufactured outside the UK. In order to accord with the requirements for opt-out procedures laid out in section 5, the following actions would be required in the case of folic acid fortification of wheat products: a) a public announcement that mandatory fortification had been implemented and the possible implications for the consumer, b) an update of relevant food labelling to reflect the change and c)

monitoring to ensure that the price differential between fortified and unfortified foods remains negligible.

134. Greater than recommended doses of folic acid have been linked with other illnesses, including possible cardiovascular disease and cancer. At present, analysis by SACN shows that the evidence on such linkages is inconclusive. However, SACN recommended that, along with mandatory fortification of wheat flour with folic acid controls on voluntary folic acid fortification of other food products be put in place. In that case, the proportion of people exceeding guidance levels on safe intake would be similar to, or less than, now thereby potentially reducing this risk.

135. There is also evidence to suggest that intake of folic acid above recommended amounts for persons over 65 may have the effect of masking the occurrence of vitamin B12 deficiency. In some cases, prolonged vitamin B12 deficiency may result in neural damage and, in severe cases, disability. Should mandatory fortification be implemented, separate consideration of the management of the vitamin B12 status of vulnerable persons over 65 would be required.

136. Mandatory fortification may therefore cause potential harm to people over 65, many of whom are likely to be physically vulnerable. An issue thus arises as to whether the prevention of harm to potential children and their parents should be prioritized over the possibility of harm to persons,

a large percentage of whom are elderly, who suffer from or may suffer from vitamin B12 deficiency.

137. In attempting to resolve this issue it may be helpful to consider that there are variables of treatment associated with both groups of persons. Instances of NTD are highest among groups of people who have been shown to have lower than average contact with health care systems. And because so many pregnancies are unplanned, and others may go unrecognized until the crucial period for adequate folate intake has passed, folic acid is most effective only if recommended levels are maintained at all times during the childbearing years.

138. By contrast, those over 65 tend to have higher than average contact with health services systems (Bowling et al, 1991). A significant percentage live in long-term care facilities and medical observation of people over 65 is generally more intensive than that of healthy young women. Moreover, public health education programmes regarding the benefits of folic acid supplementation have proved largely unsuccessful, but dissemination of information amongst the medical community regarding the best diagnostic technique or treatment mechanism for medical conditions is generally quite efficient.

139. This means that although the strongest weight is generally placed on not causing harm, the potential harm caused to people over 65 is likely to be easier to avoid than finding another method of preventing harm to

potentially pregnant women and potential children. In practical terms, it is likely to be easier to encourage a limited group of professionals in health care of the elderly to be aware of B12 deficiency as a possible diagnosis than to encourage an indefinable group of women to be nutritionally prepared for the risk of pregnancy inherent in all sexual encounters.

140. A final difficulty arises, however, if we consider the effect that active campaigns to eliminate NTD cases may have on those children already suffering from NTD and their families. As with the course of action in option 2, this course of action may encourage the belief or impression that those individuals who suffer from NTD are of less value than those who do not. It may also send the message that women whose children suffer from NTD are somehow at fault because they did not follow recommended health guidelines during pregnancy. Aside from the fundamental tenet that all individuals are of equal value, creating such an impression or allowing it to persist may violate the principle of non-stigmatization and lead to additional inequality.

141. In summary, the evidence suggests that option 4, unlike options 1, 2 and 3, is likely to result in a lower incidence of NTD cases in the population and that the greatest reduction would occur in lower socio-economic groups. Thus it fulfils the objectives of social responsibility, benefit to individuals and society, protection of vulnerable young women and reduction in health inequalities. However, this

option, like option 3, has some potential to harm older people and, like option 2, may breach the principle of non-stigmatization. In addition, despite the availability of opt-out, it suffers from the difficulty of not unfailingly preserving individual autonomy.

# 8: Conclusion

142. The brief does not require the authors to make a recommendation to the Food Standards Agency. However, the report has identified the primary issues the Agency will need to weigh up in reaching its decision.

143. If the Agency takes a strong libertarian view, holding that autonomy and individual choice are pre-eminent values, then its thinking should be led towards the first option, of no change. This action would be consistent with past government decisions on the subject of immunization and fluoridation. However, this decision would impose a burden on a particularly vulnerable social group, young women from socially disadvantaged backgrounds and their potential children, that might properly be criticised on grounds of equality or justice.

144. Option 2 (increased public awareness) would be similar to other Agency campaigns to warn of health dangers such as the risks inherent in excess salt consumption. However, given the empirical evidence that option 2 has already proved ineffective in achieving the desired outcome, there is little to distinguish it from the first option, except for the marginal increase in informed autonomy among those who choose to follow the recommendations.

145. Similarly, the lack of evidence of effectiveness for option 3 (voluntary industry fortification) would place it alongside option 2, with the additional concern of a negative impact on socially disadvantaged groups if the costs of fortification result in price disincentives for them to consume supplemented products. Option 3 also poses an additional risk of unregulated fortification resulting in greater numbers of persons consuming higher than recommended levels of folic acid.

146. The Agency may conclude that it would be more consistent to adopt a strong libertarian position than to weaken the position in ways that would make little practical difference to the outcome.

147. The Agency might also consider whether its mandate includes a responsibility to advance justice and equality through its regulatory interventions. Option 4 would further this objective at some cost to autonomy. However, the opt-out procedures, such as purchasing wholemeal flour products, largely comply with the ethical requirements and mandatory fortification would ensure that there were no price disincentives to disadvantaged consumers. The risks of harm would be transferred from a group who would find them difficult to identify and prevent – young women who are not intending to become pregnant – to a group that tends to be under greater medical surveillance. However, introduction of controls on voluntary fortification alongside mandatory fortification of wheat flour could potentially reduce this risk.

148. However, if option 4 is adopted, the Agency should be careful to ensure that its decision cannot be represented as a devaluation of the personhood of those already born with NTDs or as a criticism of the competence of their mothers.

# Appendix 1 - Table of Options

| *Principles* | *Option 1* | *Option 2* | *Option 3* | *Option 4* |
|---|---|---|---|---|
| **Autonomy** | High | High | Mid | Negative |
| **Equality/Justice** | Low | Mid | Mid | High |
| **Non-Stigmatization** | High | Negative | Low | Mid |
| **Protection of Vulnerable – young women** | Negative | Low | Low | High |
| **Protection of Vulnerable – older people** | High | High | Mid | Mid |
| **Benefit** | Negative | Low | Mid | High |
| **Prevention of Harm** | Negative | Low | Mid | Mid |
| **Consent** | High | High | Mid | Negative |
| **Social Responsibility** | Negative | Low | Low | High |

**Table 1: Available options and Ethical Principles (see paras. 95-141)**

1. In considering this table, it is probably helpful to review each row independently and to consider how much weight should be attached to each principle in turn. Once each principle has been separately evaluated, the weights can be aggregated and discussion then directed to the trade-offs (i.e how much autonomy should be given up to increase justice?)

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