

Reducing Neural Tube Defects : Consultation Document

Summary Analysis of Submissions

Background

In July 2004 the NZFSA and the Ministry of Health (MoH) released a joint consultation document, *Reducing Neural Tube Defects in New Zealand*. The consultation document consulted on two policy options to increase folic acid intake among women of child bearing age in order to reduce the prevalence of neural tube defects (NTDs) in New Zealand:

- Option 1: Continuation of the status quo – voluntary fortification
- Option 2: Introduction of a new policy – mandatory fortification

Stakeholder Representation

Stakeholder Representation	Number of Submissions	NZ	Overseas	Organisations	Individuals
Industry	7	4	3	7	
Health Agencies	15	15		9	6
Academic/health research	9	6	3	5	4
Professional Groups	11	11		11	
Consumers/Consumer Groups (include Advocacy Groups)	10	8	2	3	7

Approach

Assessment criteria

The following assessment criteria was developed for the purpose of identifying the most appropriate and effective mechanism for reducing NTDs in New Zealand.

- Will neural tube defects be effectively reduced?
- Will women of childbearing age be reached?
- Is there a risk of exposure to levels exceeding Tolerable Upper Intake Levels (TUIL)?
- Will consumer choice be protected?
- What is the impact on the food industry and government?

Weighting criteria

A weighting criteria was developed to assist the analysis of submissions. Factors considered as part of these criteria were:

- The extent of representation covered in the submission ie individual, all key groups (industry, consumer, public health, government);
- The level of impact of the policy options on the submitter ie direct impact, indirect impact, no impact;
- Equitable outcomes across all women of childbearing age regardless of socio economic, ethnic and educational differences;
- Cost of policy options on affected stakeholders.

Summary Analysis by Stakeholder Groups

Industry Submissions

Profile

Industry submissions covered a broad range of industry representation both from New Zealand (4) and Australia (3). New Zealand submissions were received from industry organisations that cover all of the key industries that would be directly affected by the proposed options.

The New Zealand Industry Submissions

The policy option considered by industry to be the most effective in reducing NTDs was voluntary fortification (status quo option) but with:

- broader permissions to permit folic acid fortification of a wider range of food categories, and
- a public awareness campaign/education programme on the benefits of consuming folic acid that targets women of child bearing age.

Key Issues Raised

1. Will women of childbearing age be reached?

Narrow range of products allowed to be fortified with folic acid (disincentive to industry)

Industry submissions generally supported a view that voluntary fortification has not been effective in reaching women of childbearing because of the narrow range of products allowed to be fortified with folic acid, and the absence of a public awareness campaign to promote the benefits of folic acid in reducing NTDs.

Voluntary fortification with broader permissions to fortify was viewed by industry as a more effective method than mandatory fortification because it provided an increased range of folic acid food sources that women can choose from.

Changeable consumer food behaviour such as the recent low carbohydrate diet fad was an issue. The availability of a small range of fortified products was seen to limit opportunities for effective targeting of women of child bearing age. In contrast, voluntary fortification with broader permissions was considered by industry to allow manufacturers to adapt to changing dietary trends more effectively and would more effectively target women of child bearing age.

2. Is there a risk of exposure to levels exceeding TUIL?

Concern was expressed about exceeding TUILs.

The risk the masking of B₁₂ deficiency associated with mandatory fortification was raised as an issue across most industry submissions.

3. Will consumer choice be protected?

Limited Consumer Choice

Most industry submissions raised concerns about the impact of mandatory fortification on consumer choice and how this might influence consumer purchasing and bring about a negative commercial impact on industry.

Out of concern about possible limitations to consumer choice, one key industry association has commissioned research in this area and has requested that the findings from this study should be included in any further decisions. NZFSA has been invited to participate in this study.

4. What is the impact on the food industry?

Substantial costs to industry

Industry submissions consistently raised concerns about increased costs to industry associated with mandatory fortification.

Several submissions stated that industry should not bear the cost burden of what is considered a public health issue.

Costs identified include:

- Capital Equipment – Fortification of flour will require flour mills to invest in micro feeders at approx. \$30,000 each. This issue is a particular concern to smaller flour mills, one of which stated mandatory fortification would force it to close.
- Manual handling issues – the manual handling of 'premix' bags into a micro-feeder in a flour mill raises OSH risks which are estimated to cost industry \$1,000,000 to eliminate them.
- Folate monitoring in the end product.
- Imported flours – Specialty flours produced offshore without the requirement for folate fortification would no longer be available to the NZ food industry and this would incur substantial reprocessing costs.
- Additional administrative costs to ensure flour-based products comply.
- The New Zealand Food Grocery Council estimated mandatory fortification involving flour would incur costs of \$2.5 million in the first year and \$80,000 - \$100,000 per year for the cost of folic acid. This would be in addition to the costs involved in changing the label of a single stock unit estimated to be between \$1,000 and \$10,000.
- On the basis of a previous submission on the costs of the changeover to the new food standards code in December 2002, the following costs were anticipated: a one off cost of \$A250 Million to Australian Food Grocery Council Members - 50 % label redesign 20% for legal compliance 20% write-off old label stock. In addition, one –off cost per product (A\$2500), ongoing monitoring for compliance costs of the folate addition to the premix if flour was the chosen vehicle.

Technical difficulties

The following technical difficulties associated with mandatory fortification were identified in industry submissions:

- The premix will contaminate the specific end use flour, which could compromise the performance of these flours.
- It is unknown if 'diverse processing' affects the efficacy of folate.

- It is technically difficult to separate out products destined for export markets.
- Qualitative testing will show the presence of folate but it will be costly to prove qualitative and homogenous addition across batches of flour ie 150 tonne of flour will require 210g of folate to be evenly distributed.

Several submissions requested provision of further time to undertake research to ensure folic acid does not have adverse effects on the end product.

Commercial impact of fortification

A key issue raised in several industry submissions concerned the commercial impact of folic acid fortification in industry. While manufacturers target both domestic and export markets, products fortified with folic acid may not be permitted in some countries. It was not considered cost effective for companies to maintain separate manufacturing runs for their export and domestic markets.

Folate awareness/education campaign (disincentive to industry)

The lack of a public awareness/targeted education campaign to support voluntary fortification was mentioned as a factor for voluntary fortification's current lack of effectiveness. Industry submissions largely supported a national public awareness campaign targeted at women of childbearing age.

Several industry submissions questioned whether mandatory fortification complies with FRSC's policy guideline on fortification as mandatory fortification was not considered the most effective public health strategy to address a public health issue.

The small and reducing numbers of NTDs in New Zealand were not generally considered to balance fortifying food consumed by the wider population.

5. Other key issues raised

Monitoring

A testing regime would be required to ensure correct folate levels were met in foods. This would include the installation of an electronic surveillance and control system to ensure correct folate addition.

One key industry association recommended that folate in food is analysed regularly whether fortification occurs under mandatory or voluntary conditions.

Other disincentives to industry

The current regulation of health claims was seen to limit opportunities for manufacturers to make health claims and this in turn acts as a disincentive to industry to fortify foods with folic acid. The issue was related to the length of time required for application to be processed according to the case-by-case approach followed by FSANZ.

A non-product by product approach is supported by industry as it was seen to enhance the number of fortified products available to the target group.

Health Agency Submissions

Profile

Health Agency submissions included those from the following areas: midwifery, nutrition, paediatrics, obstetrics, clinical medicine and nursing. These submissions were made either by individuals (6) or on behalf of organisations (9). Of the latter, 5 organisations supported mandatory and 4 organisations supported voluntary. Of the former, 5 individuals supported mandatory and 1 individual supported voluntary fortification. Within both groups of submissions, there was support expressed for a public health campaign.

KEY ISSUES RAISED

a) Submissions pro – mandatory fortification

1. Will women of childbearing age be reached?

There was agreement across this group of submissions that voluntary fortification was not effective in delivering folic acid to the target group generally for the reasons outlined in the discussion document.

Mandatory fortification was considered an effective option to deliver folic acid to the target group because it addressed barriers such as high rates of unplanned pregnancies and lack of awareness of the benefits of folic acid among the target group.

2. Is there a risk of exposure to levels exceeding TUIL?

Issues around excessive levels and masking vitamin B deficiency were viewed as manageable through the setting of appropriate fortification levels and a national awareness campaign which would provide necessary information about how to consume folic acid fortified foods. A risk management / risk communication strategy would also be recommended as part of a national awareness campaign.

3. Will consumer choice be protected?

Where the issue of mandatory fortification impacting on consumer choice was raised in submissions, the availability of some non-fortified products such as wholemeal flours would provide a level of consumer choice. It was also noted that consumers could source non-fortified food supplies from specific suppliers who do not use commercially ground flour.

4. What is the impact on the food industry?

Few submissions commented on the impact on the food industry. Where comments were included it was acknowledged industry would face initial costs for equipment. The possibility of small price increases to consumers was outweighed by the cost of reducing NTDs. The risk of products being unfairly targeted by the pure food lobbyists was thought to be unlikely.

5. Other key issues raised

Of those submissions that made reference to monitoring, key areas identified were: monitoring actual level of folic acid in the vehicle product, and the establishment of a

national peri-natal congenital malformation database which would include details of all terminated pregnancies.

b) Submissions pro-voluntary fortification

1. Will women of childbearing age be reached?

There was general agreement across this group of submissions that voluntary fortification has had limited effect in reaching women of child bearing age but that this was seen as resulting from a lack of knowledge of the benefits of folic acid. These submissions support voluntary fortification in combination with a national awareness campaign directed at the target group. Some of the submissions referred to the experience of Western Australia and argued voluntary fortification with a national awareness campaign could effectively reduce NTDs.

2. Is there a risk of exposure to levels exceeding TUIL?

The key argument against mandatory fortification raised in these submissions concerned the possible risk of exposing the wider population to levels of folic acid that exceed the TUIL and of the risk of masking vitamin B₁₂ deficiency among older people. It was generally agreed that there is insufficient knowledge/research on increased exposure at a population level.

The public health/safety impact of interactions between increased folic acid and antiepileptic and antifolate drugs were also raised.

Concern was raised about risks to specific population groups, particularly adolescent boys and people with TT MTHFR genotype.

3. Will consumer choice be protected?

Where issues around consumer choice were raised, mandatory fortification was considered to limit consumer choice and to potentially increase costs to consumers. There was some concern about increased costs of staple foods and the impact on people in lower socio-economic groups.

4. What is the impact on the food industry?

The financial impact on the food industry if mandatory fortification proceeded would result in increased costs to consumers as noted above.

5. Other key issues raised

Arguments against mandatory fortification included mandatory fortification removing personal responsibility for folate intake from individuals due to the passive nature of this option ie no motivation or knowledge is required.

The following monitoring was recommended:

- Continuation of MFD surveillance of voluntary fortified foods.
- Monitoring of overages in fortified foods.
- Annual random testing of folic acid fortified foods to determine actual folic acid levels.
- Improved and consistent monitoring of folic acid intakes and folate status.

Health Research /Academic submissions

Profile

Health research/academic submissions were made by either individuals (4) or on behalf of organisations (5) and covered the following areas: human nutrition, crop and food research, paediatrics, medical research, information medical systems, preventative medicine, child health research. Three submissions from overseas institutes were also received. Of the submissions on behalf of organisations, both NZ and Australia, three supported mandatory fortification and two supported voluntary fortification. Of the submissions from individuals, three supported voluntary and one mandatory.

a) Submissions pro-mandatory fortification

1. Will women of childbearing age be reached?

Across this group of submissions there was general agreement that voluntary fortification was not effective in targeting women of child bearing age primarily for the reasons presented in the discussion document. One submission pointed to the experience of Western Australia and noted that the 30 % fall in NTDs was confined to non-Aboriginal infants.

In contrast, mandatory fortification was supported as the most effective option in targeting women on the basis of evidence in Canada, United States and Chile. A key comment raised by supporters was that mandatory fortification would provide for a more equitable targeting of women of all socio economic groups and education levels.

Several submissions supported a higher level of fortification as was planned initially in Britain – 240ug per 100g flour.

Some submissions also pointed to the ‘secondary benefits’ of folic acid ie reduction of heart disease and some cancers – that have been indicated in emerging medical research.

2. Is there a risk of exposure to levels exceeding TUIL?

This question was not generally covered by this group of submitters. Reference was made to the masking of vitamin B₁₂ but this issue was viewed as a ‘theoretical risk’ which might be reduced through fortifying food products with folate and vitamin B₁₂.

In addition, the scientific basis of folic acid masking vitamin B₁₂ deficiency was questioned and the experience of Canada and USA did not show an increase in this problem area.

3. Will consumer choice be protected?

The submissions expressed support for consumers having the option of non-fortified products to provide for consumer choice. However, this issue was not generally viewed as a key issue. The submissions generally expressed the view that the impact on consumers would be beneficial both in terms of reducing NTDs and risks of cardiovascular disease and some cancers.

4. What is the impact on the food industry?

In the few submissions where this question was addressed, the two issues raised were that the food industry had raised no objections in principle to fortification of flour but that they needed to operate on a 'level playing' field and that there was a need for close collaborative relationships to be established between industry, regulators, health and government.

5. Other key issues raised

The following monitoring was recommended:

- Folate status of the general population (serum folate) before and after the introduction of mandatory fortification.
- Total rate of neural tube defects (termination due to suspected NTDs, live birth/stillbirth).
- Actual levels of folic acid in the vehicle product (ie flour) and produced foods (ie bread).
- Plasma homocysteine levels in a representative sample of adults.
- Prevalence of coronary heart disease and relevant cancers over time starting before fortification is introduced.
- Compliance with fortification and labelling and monitoring of consumer views.

b) Submissions pro voluntary fortification

1. Will women of childbearing age be reached?

Submitters in this group stated that the effectiveness of voluntary fortification has been limited. However, several barriers to its effectiveness were identified. These included the absence of a public health campaign to promote the benefits of folic acid, and the limited level of folic acid fortification currently permitted (100ug per serve).

There was support for the continuation of voluntary fortification but combined with a national awareness campaign. One submission supported the above with promotion of health claims.

One submission argued the 30 % reduction of NTDs in Western Australia was due to the effectiveness of the state campaign to promote increased folate rather than voluntary fortification.

Reference was made to one study of folate status on young women living in Dunedin which suggested voluntary fortification has been shown to have a measurable effect on the folate status of young women.

Several submissions recommended the level of fortification permitted should increase to 400ug per serve and manufacturers be encouraged to market products aimed at young women.

Dairy foods were raised in one submission as a viable product for voluntary fortification as these products are consumed by many women and may reach women who are currently limiting their intake of carbohydrate foods.

Folic acid supplementation with a targeted national awareness campaign was seen as a viable option. One submission suggested this could have the same outcome in terms of reducing as NTDs as mandatory fortification.

2. Is there a risk of exposure to levels exceeding TUIL?

A key concern about mandatory fortification raised across this group of submissions related to 'uncertainties' about safety concerns associated with mandatory fortification. These concerns related to the untargeted nature of mandatory fortification and difficulty controlling individual consumption of folic acid and managing excessive intake. Some young women would not receive any folic acid and others may theoretically consume excessive amounts.

Safety risks identified included: health risks associated with multiple births, masking of symptoms of vitamin B₁₂ deficiency; concerns about interference with anticonvulsants and chemotherapeutic drugs, concerns that may accelerate the progression of certain cancers, long-term consequences of prolonged exposure is not known.

Reference was made to a recent publication in the New England Journal of Medicine which indicated folic acid increased restenosis in patients undergoing coronary angioplasty.

Further reference was made to the US experiences. While mandatory fortification has been effective in delivering folic acid to the target group there have been three concerns identified: difficulty in controlling exposure, exposure has exceeded safety levels and the lack of good manufacturing practice ie practice of overage.

Vulnerable sub-population groups identified were infants, children, and older people.

Further modelling studies were requested prior to any decision on mandatory fortification proceeding and risk /benefit analysis comparing fortification options with dietary supplements.

3. Will consumer choice be protected?

Comments on protecting consumer choice were limited. Issues raised related to the need for a consumer education programme to gain the acceptance of consumers for mandatory fortification as well as increased costs to consumers. There was some concern expressed about the need to ensure women from low income households do not stop eating the fortificant vehicle because of price increases.

4. What is the impact on the food industry?

Comments on the impact on the food industry were limited. Issues related to the cost of equipment, quality control testing and monitoring and whether industry would be willing to bear the cost. Other comments included the lack of costing data provided in the consultation document. A question was also raised on where responsibility would lie should there be any litigation in the future related to possible safety concerns.

5. Other key issues raised

The following monitoring was recommended:

- monitoring of potential risks and benefits in terms of health impacts (masking of B deficiency/multiple births)
- regular sampling and testing scheme run by an independent laboratory
- monitoring of overages
- monitoring of the amount of added folic acid in addition to the total folate content of foods should be reported separately on the products' nutritional

- information panel labels – this was recommended because of the differences in bioavailability between added folic acid and naturally occurring food folate.
- HPLC analysis of folate.

One key issue raised was the need for the method of folate analysis to be validated in order for the analysis to be used as the basis of a health claim and of monitoring health claims. A recommended approach involved validating the analytical method on a wide range of reference materials that cover all possible matrix types (cereals, fruits, vegetable, meat). In addition, it was recommended the method should be tested in several laboratories by an interlaboratory trial.

Other issues

Supporting data from the US and China was questioned. In the US it was suggested the decline in NTDs occurred decades prior to mandatory fortification. China – the public health campaign in China established that the effectiveness of folic acid to prevent neural tube defects was substantially less, and possibly non-existent, where the background rate of NTDs was low as in NZ. The variation in decline in NTD between areas of high and low NTDs rates in Canada, US and Chile was viewed as consistent with this phenomenon.

Several submissions commented that the rationale for mandatory fortification did not support the FRSC policy guidelines on the fortification of the food supply with vitamins and minerals.

Professional Groups Submissions

Profile

Professional group submissions covered representation from general practitioners, midwives, dietitians and public health professionals, and business and professional women. These submissions were made on behalf of professional organisations and one individual. Of the 11 submissions received, 6 supported mandatory fortification and 5 supported voluntary fortification. Within both groups of submissions, there was support expressed for a public health campaign.

a) Submissions pro-mandatory fortification

1. Will women of childbearing age be reached?

This group of submissions expressed overall support for mandatory fortification as the most effective vehicle for targeting women of child bearing age. This position was primarily based on available evidence/research.

Reasons given why voluntary fortification has not been effective covered barriers already identified in the consultation document as well as the lack of support by industry for voluntary fortification.

2. Is there a risk of exposure to levels exceeding TUIL?

Submissions falling into this group generally minimised the risks associated with exceeding the TUIL. Referring to evidence from the USA and Canada one submission suggested that mandatory fortification with folic acid has been associated with folic acid intakes above the TUIL only among women who also consumed dietary supplements. In addition, doses both below and significantly above the TUIL have not shown to lead to adverse effects and significant increases in folic acid intakes have not been associated with changes in vitamin B₁₂ deficiency without anaemia.

Issues around the masking of B₁₂ deficiency were generally considered theoretical and one submission suggested a recent reassessment of the original reports indicated there has been misleading reporting of the studies.

Concern was raised in several submissions regarding the level of fortification. Mandatory fortification will be ineffective if the fortification level is too low or the food vehicle a non staple food.

A further argument for mandatory fortification relates to emerging evidence of additional health benefits associated with folate which would flow on to the wider population.

3. Will consumer choice be protected?

There were limited comments on protecting consumer choice. The general view was that only a few consumers would be affected and they would be able to source alternative food supplies.

Overall the impact on consumers was largely viewed as positive. More public information on the benefits of folic acid was required to alleviate any anxiety associated with mandatory fortification.

It was also mentioned that there would be additional potential benefits to consumers identified in emerging evidence.

4. What is the impact on the food industry?

Submissions acknowledged that there would be some additional costs to industry ie equipment. Several of these submissions made the assumption that this extra cost would not be an issue for industry.

5. Other key issues raised

The following monitoring was recommended:

- Measurement of folate levels in the population.
- An active surveillance and monitoring system for NTDs, including NTD defect termination numbers.
- Surveillance of mortality from strokes and heart attacks.
- Monitoring of the actual levels of folic acid in both the staple food and food products.
- Monitoring of clear and accurate labelling of foods fortified with folic acid.
- Monitoring of folic acid in the food supply.
- Folate and homocysteine status of target groups comprising: adult and younger women, middle-aged men should be surveyed before and after introduction. This should be combined with homocysteine levels.
- Registration of foods with folic acid fortification.

b) Submissions pro voluntary fortification

1. Will women of childbearing age be reached?

Submissions in this group generally considered the effectiveness of voluntary fortification in targeting women of child bearing age as limited but this was attributed to the women not being informed about the benefits of folic acid. There was broad support across these submissions for a public health campaign to raise awareness among the target group.

Other options for addressing barriers preventing voluntary fortification from being effective include:

- Public support for fortification from leaders of the community.
- Cost of setting up fortification to be covered by government.
- Assurance to industry from government of no liability if regulations are followed.
- Australia could have the same policy on fortification as NZ to minimise commercial repercussions of fortification policies.

2. Is there a risk of exposure to levels exceeding TUIL?

A key issue of concern raised in several submissions related to the adequacy of risk analysis/research on the safety of mandatory fortification, particularly relating to the effect of consumption of excessive levels on vulnerable groups and the wider population. There was a general call for further research into this area. While the effectiveness of mandatory fortification was generally acknowledged in most of this group of submissions, the issue of balancing the needs of a small sub-population against the rights of the wider population was widely raised. The general view expressed was that the risk to the wider population from mandatory fortification outweighs the benefit to the target group.

Specific concern was raised regarding the possible masking of vitamin B deficiency due to increased consumption of folic acid.

3. Will consumer choice be protected?

No specific comments on the need to protect consumer choice were made in the submissions. However, there were issues raised regarding the need to ensure the cost of mandatory fortification was not passed onto consumers as the food vehicle was likely to be a staple food item.

It was also noted that consumers need credible and consistent nutrition messages.

One submission compared mandatory fortification to mass medication and questioned the ethics of mandatory fortification.

4. What is the impact on the food industry?

Those submissions that responded to this issue generally agreed that mandatory fortification would incur costs to industry but that this issue needs to be addressed to avoid cost increases to consumers.

5. Other key issues raised

The following monitoring was recommended:

- Folic acid levels in foods must be monitored by a public agency every year, not by private companies
- Measurement of folate and B₁₂ status in the population, particularly vulnerable groups
- A monitoring programme should be initiated for pre-and post- intake of folate/serum folates estimates for the population and vulnerable population groups.
- Extensive monitoring of levels of fortification in the food supply.

Consumers/Advocacy Groups Submissions

Profile

Representation for this group of submissions covered individual consumers (7) and advocacy organisations (3). Of the former group, four submissions supported mandatory fortification and four submissions supported voluntary. Two submissions were made by advocacy organisations in Australia and both supported mandatory fortification. Of the latter group, three submissions supported mandatory and no submissions supported voluntary fortification.

Key Issues Raised

a) Submissions pro mandatory fortification

1. Will women of childbearing age be reached?

Submissions generally considered voluntary fortification to be ineffective primarily due to the reasons provided in the consultation document, and to the absence of a public health campaign to inform women of the benefits of consuming fortified foods.

The importance of voluntary fortification was also considered difficult to assess because there was no means of systematically monitoring who is having fortified foods, how much they are having and who is using supplements.

In addition, it was also noted that any increased reduction of NTDs through voluntary fortification would impact only on affluent and educated couples.

2. Is there a risk of exposure to levels exceeding TUIL?

The issue of intakes above TUILs was not directly covered in this group of submissions. The support for mandatory fortification was primarily based on evidence from overseas (US, Chile) supporting mandatory fortification as the most effective option to target women and reduce NTDs.

Two submissions raised new issues not covered in the consultation document that concerned the impact of mandatory fortification on women with coeliac disease,. Depending on the food vehicle chosen, it could be possible that folic acid would not reach this group of women.

There was limited reference to the risk of consumption of foods fortified with folic acid masking vitamin B deficiency.

3. Will consumer choice be protected?

The perceived need for mandatory fortification was seen as more important than issues around consumer choice. However, where choice was raised there was an acknowledgment of the need to provide a level of choice to consumers.

There was some general concern that the cost of fortified products may increase for consumers, and the impact of this on consumers.

Submitters considered the benefits to consumers outweighed the negatives. A public health campaign was needed to provide accurate information and alleviate anxiety among consumers.

4. What is the impact on the food industry?

Submissions noted that industry would incur compliance costs, particularly in the area of re-labelling and the purchasing of equipment. However, one submission suggested this could be managed through a change over period.

The need for a close working relationship between industry and the government was also noted.

5. Other key issues raised

The following monitoring was recommended:

- Comprehensive mandatory national birth defects register, including pregnancy termination data.
- Measures of important biomarkers which reflect nutritional status eg folate/vitamin B₁₂.
- Community awareness and attitude surveys would also provide important feedback to the food industry and Government.
- Levels of folic acid in foods would need to be monitored by NZFSA.
- Monitoring of effects of fortification on the general population and target population.
- Monitoring of health issues such as cardiovascular disease, cancer and anaemia.
- Research into the interaction of genetic and environmental factors

b) Submissions pro-voluntary fortification

1. Will women of childbearing age be reached?

This group of submissions support voluntary fortification as the most effective policy to deliver folic acid due to concerns about the safety of mandatory fortification.

2. Is there a risk of exposure to levels exceeding TUIL?

The key issues raised in submissions concerned known and unknown risks to the general population, such as the masking of vitamin B₁₂ deficiency.

Mandatory fortification was viewed as a form of mass medication and that this approach was unethical because the benefits of mandatory fortification were targeted at only a small sub-population and the rates of NTD were seen to be in decline anyway.

Mandatory fortification was viewed as not sufficient on its own as the level of fortification would need to be within the TUIL. The need for women to also take a folate supplement would mean that without a public health campaign, women's knowledge of folic acid would remain low.

3. Will consumer choice be protected?

There were limited comments on protecting consumer choice but there was concern that increased costs of manufacturing fortified products would be passed on to consumers.

4. What is the impact on the food industry?

Refer to response to question 3.

5. Other key issues raised

The following monitoring was recommended:

- Monitoring of increased folic acid in the food supply – adequate funding is required.
- Co-ordination between NZFSA and MoH on monitoring issues is required.
- Monitoring of increased costs to consumers.