



# Fortification of Bread with Folic Acid

## Summary of Submissions

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Requests for further copies should be directed to:

Publications Logistics Officer  
Ministry for Primary Industries  
PO Box 2526  
WELLINGTON 6140

Email: [brand@mpi.govt.nz](mailto:brand@mpi.govt.nz)  
Telephone: 0800 00 83 33  
Facsimile: 04-894 0300

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# 1 Introduction

One hundred and thirty four submissions were received on the Ministry of Primary Industry's (MPI) discussion paper: *The Future of Folic Acid Fortification of Bread in New Zealand* (discussion paper). Thirty nine were in favour of mandatory fortification. Eighty eight submitters supported voluntary fortification or were against mandatory fortification. Three submitters supported limited mandatory fortification (option two) and two supported mandatory reporting (option three). Two submitters did not indicate which of the options in the discussion paper that they supported. Submitters focused on the benefits and risks associated with fortifying bread, the costs and the fortification option that they supported.

Submitters who favoured mandatory fortification considered that the benefits of fortification outweighed the costs and said the risks to the general population were minimal or non-existent. Submissions favouring mandatory fortification were mainly from professional medical associations, doctors and families affected by a neural tube defect (NTD) pregnancy.

Those submitters who did not support mandatory fortification were concerned about the risks associated with adding folic acid to bread, questioned the proportionality of the response (fortifying all bread when only a very small subset of the population would benefit) and objected to the lack of choice mandatory fortification would impose on consumers. Submissions favouring voluntary fortification were mainly from individual consumers, industry associations and individual bakery firms.

MPI has undertaken an evaluation of selected scientific issues raised in the submissions, in addition to updating the systematic review on folic acid and cancer which was published alongside the discussion paper. This is available as the *Scientific evaluation of comments on submissions received on the future of folic acid fortification in New Zealand (MPI Technical Paper No: 2012/25. August 2012)*. In general, the results report that folic acid has no significant effect on overall cancer incidence. The evidence does not suggest that there is an increased risk of colorectal adenomas but remains inconclusive with regards to the risk of advanced adenomas in high risk individuals consuming high folic acid containing supplements. There is also some evidence of a protective effect for breast cancer.

Masking of B<sub>12</sub> deficiency and cognitive decline in the elderly have been raised as possible negative effects of folic acid fortification. The risk of masking of vitamin B<sub>12</sub> deficiency is considered negligible and the totality of evidence to date does not suggest that supplementation with B vitamins leads to either a positive or negative effect on cognition in the elderly. The evidence to date does not indicate that folic acid influences the incidence of asthma.

## 2 Submitters who supported mandatory fortification of bread

Thirty nine submitters supported the mandatory fortification of bread (option 1 in the discussion paper). These submitters supported mandatory fortification because they said it:

- would prevent/reduce the number of NTD affected pregnancies;
- was safe/low risk;
- was the most effective approach;
- would reduce the costs to the health and education sectors as well as families affected by NTD pregnancies.

These submitters supported the mandatory fortification of bread because of the high number of unplanned pregnancies in this country. They said a number of women in the target group are not aware of the need to take supplements prior to becoming pregnant as well as during the early stages of pregnancy or do not take the folic acid tablets as prescribed. The public health benefits of mandatory fortification of bread outweighed the costs that would be incurred by the industry, according to these submitters. They also said that fortification of food is not without precedence in New Zealand using the example of iodised salt.

### 2.1 NTD PREGNANCIES REDUCED OR PREVENTED BY MANDATORY FORTIFICATION

Submitters who supported the mandatory fortification of bread said it was the most effective way of reducing the number of NTD pregnancies and that other countries that have introduced mandatory fortification have been very successful at reducing the rate of such pregnancies. They referred to other countries (stating as many as 70 countries including Australia) that had mandatory fortification and said New Zealand's rate of NTD pregnancies could reduce to the international floor level seen in countries where there is mandatory fortification such as the USA and Canada. If this were to occur the number of NTD pregnancies would reduce from an estimated 70-90 per year to 40-50 per year.

### 2.2 FOLIC ACID FORTIFICATION IS SAFE

Submitters who supported mandatory fortification of bread said it was safe. They said that there was clear scientific evidence that shows that the addition of folic acid to bread flour is safe for all bread consumers and that a large pooled meta-analysis using high dose folate supplements showed no association with incidence or mortality of cancer or longer duration treatment. The concerns relating to cancer risks come from folic acid supplement trials but the applicability of these trials to food supplementation is very poor. These submitters said that there were no safety concerns in the countries that had already introduced mandatory fortification.

The opinion that folic acid may (or would) cause several hundred cancer cases is speculation, is completely unjustified and not based on scientific evidence, according to a couple of submitters. Another submitter said that there was probable evidence that foods containing folate reduce the risk of pancreatic cancer, that there was limited suggestive evidence of oesophageal and bowel cancer and that cohort studies suggest that high folate intake may reduce the risk of post menopausal breast cancer. Another said that there was an increasing body of evidence that dietary folate has a range of health benefits for all, including the potential to reduce stroke deaths by an estimated 164 cases a year in New Zealand.

Masking B<sub>12</sub> deficiency was not considered to be a significant issue. A submitter questioned why concerns were raised about mandatory fortification when voluntary fortification at the same concentration was allowed and considered to be safe. The objection to mandatory fortification was, according to this submitter, solely on the grounds of financial cost and compulsion. These submitters dismissed the public concerns about adding vitamins to food which occur naturally, such as folate, but are stripped out by processing.

## **2.3 MANDATORY FORTIFICATION OF BREAD IS THE MOST EFFECTIVE APPROACH**

These submitters said that mandatory fortification of bread was the most effective way of reducing the incidence of NTD pregnancies and that it had worked well in other countries such as the USA, Canada and Chile. They did not support continuation of voluntary fortification because they said the bread industry had not delivered on its targeted fortification programme (total volume of bread fortified is currently identified by MPI as 12.5 percent) and that very few of the breads that had been fortified were the budget lines that are likely to be consumed by the highest risk population groups.

These submitters thought that mandatory fortification of bread was the most effective approach because of the high number of unplanned pregnancies in this country and because of the number of women in the target group who do not consume a diet rich in folate and who are not aware of the need to take folic acid tablets prior to becoming pregnant as well as during the early stages of pregnancy.

These submitters said that mandatory fortification of bread was the most effective way of increasing folate status and preventing inequities between socioeconomic groups. One submitter, for example, said that more than one third of all infants presenting to the Starship neurosurgical unit for initial surgery for meningomyelocele between 2002-2008 were Maori and that Maori are disproportionately represented in many adverse health outcomes that reflect social disadvantage.

Voluntary fortification of bread was not considered to be an effective response to reducing the incidence of NTD pregnancies by these submitters. They said it was unlikely to provide sufficient folic acid throughout New Zealand and that food that was voluntarily fortified was likely to be more expensive, which would mean that women in the lower socio economic groups would be less likely to purchase fortified products and would not benefit. Another said if fortification remains voluntary there is no guarantee that manufacturers will increase the volume of products fortified and may choose to reduce or cease fortifying bread altogether.

Another submitter said that mandatory fortification in Australia had been more effective at increasing the folate status of the target group than New Zealand's voluntary approach.

## **2.4 REDUCED COST TO THE HEALTH AND EDUCATION SECTORS AND TO THE NUMBER OF FAMILIES AFFECTED BY NTD PREGNANCIES**

These submitters said that the mandatory fortification of bread would reduce the number of preventable NTD pregnancies. Such prevention would reduce the costs to the health services of terminations and treating children affected by a NTD as well as costs to other sectors such as special education. A submitter said that the cost of tertiary hospital inpatient care (only) is approximately \$1million per child for the first two decades of care (does not include regional hospital care or GP care costs). If adult surgical costs, lost family income, special education

and disability sector costs are included the cost could double for each individual with a NTD who survives to adulthood.

Reducing the number of NTDs would also reduce the emotional costs to families and children affected by such pregnancies (including terminations and still births) as well as hidden costs such as mothers not returning to the workforce because of their children's high level of need and fathers working reduced hours.

Individuals with spina bifida experience ongoing pain, disrupted home and school life from frequent infections and hospitalisation, physical limitations, lost opportunities (including more limited employment opportunities) and stress on their families and themselves. NTD affected pregnancies also impact on families caused by, for example, the challenge of caring for a teenager or adult affected by bowel and urinary incontinence.

Some of these submitters did not think that the cost of reduced demand for bread should be included in any assessment of the costs of fortification. This was because in other countries where bread was fortified reduced demand had not occurred. These submitters did not think that consumers' purchasing decisions were made on the basis of whether a product had been fortified or not. They also said that cereal manufacturers producing fortified products had not experienced a reduction in sales and that the addition of vitamin C to fruit juices had not put consumers off buying juice. A submitter said it was a small minority of the public who were against compulsion of any kind or public health measures that target the whole population in order to benefit a few.

The costs to industry, consumers and government of mandatory fortification were outweighed, these submitters said, by the significant public health tradeoffs and long term savings to the public purse of reduced numbers of NTD pregnancies.

## 2.5 EDUCATION AND PROMOTIONAL CAMPAIGNS

As well as mandatory fortification of bread, some of these submitters said that there also needed to be education campaigns addressed to women in the childbearing age group focusing on the importance of good nutrition prior to and during pregnancy. Promoting folic acid tablets and the period during which they need to be taken as well as making them free for the target group was also considered necessary in order to reduce the number of NTD pregnancies. As well as campaigns directed at the target group, a submitter said that the education campaign accompanying mandatory fortification should cover the costs and impacts of NTDs on affected individuals and families and the health sector as well as reassuring the public that folic acid is safe, that it replenishes an essential vitamin removed during processing and that there are early indications of other health benefits.

## 2.6 MONITORING OF FORTIFICATION

Some of these submitters thought the fortification of bread should be accompanied by monitoring of the effectiveness of the intervention by measuring the overall incidence of NTD pregnancies (number of births, still births and terminations) and the blood folate status of the target population. They also thought that the folic acid levels in bread should also be monitored.

Although these submitters thought the risks of fortification of bread were low, a small number said that mandatory fortification should be accompanied by an on-going scientific review focusing on the possible harm or side effects as well as the benefits.

## 2.7 OPTION SUPPORTED – MANDATORY FORTIFICATION

These submitters supported option one- mandatory fortification with some saying that there should be no delay while others saying that a transition period of a year could be used to allow the bread industry to adjust to the requirement of having to fortify their bread. A small number said that option two – proportional mandatory fortification- would be acceptable if 95 percent of bread was fortified, which would still give consumers a choice while still providing a public health benefit.

Consumer choice was not considered a sound reason for delaying fortification according to some of these submitters. Consumer resistance they said was due to fear and a lack of information (or mis-information) about the risks and benefits of fortification.

Although these submitters did not support voluntary fortification, a small number said that if this was the approach that was taken, the breads that should be fortified are those that are most likely to be purchased by the target population (that is low cost white and multigrain breads). Another said that if the proportional mandatory was the approach taken, it should be the lower cost breads should be targeted.

### 3 Submitters who supported the partial fortification of bread

Three submitters supported the partial fortification of bread. Two submitters indicated that this option balances consumer choice while at the same time reduces the incidence of NTDs.

A submitter suggested that a minimum of 80 percent of bread should be fortified. This submitter said that bread that was fortified should be clearly labelled, that lists of fortified breads should be available in shops and that information on how folic acid reduces NTDs should be available on line and in store. They also said that regardless of which option is chosen they would like to see increased health promotion and education strategies to promote an increase in folate consumption through diet, supplementation and fortification in the target population. They also said that they would like to see monitoring of the folic acid levels in bread, the monitoring of dietary and blood folate levels of the general population and the target group and monitoring of NTDs (live births, still births and terminations).

The other submitter who supported this option did so because they said it would reduce the number of NTDs and the consequential effects that they have on individuals and families. They also thought that the health care costs associated with caring for patients with preventable NTDs could be better spent in other health areas. As New Zealand has a high number of unplanned pregnancies this submitter said that the use of folic acid tablets at the correct time during pregnancy was likely to be mixed.

### 4 Submitters who supported mandatory reporting

Two submitters supported mandatory reporting. One said that they strongly oppose mandatory fortification, that consumers should be able to choose whether they want to eat fortified bread or not and that there should be no “one-size-fits-all” prescription. The other submitter who supported this option also thought consumers should have freedom of choice and that while NTDs were tragic they were not a population-wide problem. This submitter thought fortification would be problematic for small bakeries and said that funding health and awareness campaigns would be a better way to address NTDs than bread fortification.

## 5 Submitters who supported the voluntary fortification of bread

Eighty eight submitters supported voluntary fortification of bread (option 4 in the discussion paper) or were against mandatory fortification. Reasons given for not supporting mandatory fortification were the:

- risks to the non target groups in the population;
- use of bread as the vehicle;
- lack of choice for consumers;
- proportionality of response;
- medication of the whole population;
- extra costs that would be imposed on industry and consumers;
- difficulties for industry of fortifying bread.

These submitters thought more data about the folate status of the target group and the number of NTD pregnancies was needed before a decision could be made about the mandatory fortification of bread. They also said that this lack of data would mean that the effectiveness of fortifying bread could not be measured. These submitters thought that rather than fortifying all bread, the target group should be educated about the need to eat a diet high in folate and the need to take folic acid supplements.

Three submitters viewed mandatory fortification as a nanny state approach, which they objected to and another said that with only a few exceptions most of the countries that fortify are either Third World or developing countries with which New Zealand has little in common in terms of nutrition issues and general population health. A submitter said that voluntary fortification has worked in Ireland and so there is no reason why it would not be successful in New Zealand where the diet is similar.

A submitter said that fortification of bread was being considered so that this country conformed with FSANZ and followed Australia and that the government and public servants have taken this approach so that they fell into line with Australia rather than have our own policy. Another said that the FSANZ Act section 10, objective 1(b) would not be met if any particular food or subgroup is mandatorily fortified. Section 10 (1) lists the objectives in developing food regulatory measures; objective 1 (b) is the 'provision of adequate information relating to food to enable consumers to make informed choices'.

### 5.1 RISKS ASSOCIATED WITH FORTIFYING BREAD

Submitters who did not support the mandatory fortification of bread with folic acid considered that the risks to the non target groups (children, men, the elderly) in the population were too high. They were particularly concerned about colorectal and prostate cancer and masking of vitamin B<sub>12</sub> deficiency (in the elderly).

They considered that any benefits from fortification would accrue to only a very small proportion of the population, while there would be risks to the much larger non target population.

These submitters considered that there was a lack of information about the side effects and long term harmful effects of fortifying bread with folic acid and believed that it was simply not true to categorically state that there is no potential risk from folic acid. They thought that more research on the safety and potential risks of folic acid was needed before bread was mandatorily fortified.

Concerns were raised about excess consumption of folic acid that could be ingested, particularly by children and the elderly if bread was fortified. Excess consumption was regarded as a possibility as folate naturally occurs in some foods and there are other foods that are voluntarily fortified with folic acid.

Two submitters were concerned about the synthetic nature of folic acid with one saying that synthetic products are generally not as effective as natural products and there is also the unknown that comes from synthetic product – namely the safety and consistency of manufactured products.

## 5.2 USE OF BREAD AS THE DELIVERY VEHICLE FOR FOLIC ACID

Bread was not seen as the right delivery food vehicle to use in order to target women of child bearing age by these submitters. This was because women are not the biggest consumers of bread and also because some women avoid bread because they have celiac disease, are gluten intolerant, or want to limit their carbohydrate intake. Two submitters identified that not all ethnic groups consume bread and Asian women, for example, are more inclined to consume rice.

Five submitters thought encouraging women to eat lots of bread was poor health advice given the rising rates of obesity, diabetes, and celiac disease.

Other reasons given for questioning the use of bread as the delivery vehicle included the difficulty in getting a consistent amount of folic acid throughout a loaf of bread and the need to eat large amounts of bread (around 11 slices) in order to consume enough folic acid.

The industry was also concerned that people would avoid purchasing bread because of perceived risks if it had been fortified. In a survey conducted on behalf of the New Zealand Association of Bakers (NZAB) nearly 32 percent of respondents indicated that they would move away from fortified products.

These submitters did not think that a staple food product should be fortified because:

- the potential risks to the whole population are not fully understood or are too high;
- only a small portion of the population would potentially benefit;
- the international science community has yet to agree on the contentious issue of the cancer risk associated with fortification.

They thought that before bread was mandatorily fortified, the Government would need to be absolutely confident that it would be effective, that there would be no harmful effects in the long term, and that there was no better way of achieving the desired outcome of reducing the number of NTD pregnancies.

## 5.3 LACK OF CHOICE/LACK OF CONSENT

Mandatory fortification of bread was not supported because it removed the right of individuals to decide whether they wanted to consume folic acid or not. These submitters thought that consumers should have the right to choose whether they ate fortified bread or not. By making the fortification of bread mandatory, this right would be taken away. Mandatory fortification was seen as an imposition by government and a removal of individual human rights.

Two submitters said that they were not able to tolerate folic acid or purposely ate a low level of folic acid while another said it caused depression and seasonal affective disorder (SAD).

Fortified bread was not supported by submitters who wanted to ingest naturally occurring folate rather than the synthetic folic acid. These submitters wanted to avoid additives and consume natural foods and said that the milling process for white bread removed naturally occurring folate, which was still available in wholegrain breads. One submitter wanted wholemeal bread removed from any fortification programme (mandatory or voluntary).

## 5.4 PROPORTIONALITY OF RESPONSE

Submitters who did not support mandatory fortification of bread questioned why all the population should have to consume fortified bread for the benefit of a small proportion of the population – women giving birth. Consuming folic acid under a mandatory fortification standard was considered to be something that the rest of the population would be subjected to for the benefit to a few. Four submitters said it was the responsibility of women having children to make sure that they consumed the right diet and questioned why the rest of the population should have to consume fortified bread when other people’s pregnancies were not their responsibility. Two submitters did not support the mandatory fortification of bread, in part because it did not eliminate the risk of NTD affected pregnancies.

A submitter said that it was unclear whether there was widespread public support for mandatory fortification and that whole-of-population interventions should not proceed unless there is widespread public support for such interventions particularly because most of those that are affected by the policy (bread eating consumers) will derive no direct benefit.

## 5.5 MASS MEDICATION

Mandatory fortification of bread was viewed as mass medication by eighteen submitters who did not support this option. Implementation of such a Standard was seen as setting a dangerous precedence (nine submitters) with six submitters saying such an approach would breach the Bill of Rights Act and the Medicines Act. Questions were raised about why people who would not give birth needed to be medicated and how fortifying bread would ensure that the target population would receive the right dose of folic acid.

## 5.6 COST

Submitters who did not support mandatory fortification were concerned about the extra costs that would be imposed on consumers and the industry. The costs to consumers that were identified were the removal of choice and the extra expense associated with purchasing organic bread, which is generally more expensive.

Costs for the industry were identified as lost sales, the cost of adding folic acid, training staff, updating packaging, product redevelopment and monitoring and testing. The direct costs of adding folic acid were estimated at between a half and a few cents a loaf. Industry calculated that for every 1 percent sales loss (1.8 million loaves @\$2.79 average value) the wider industry would lose over \$5 million per annum in sales revenue. The industry estimated that the risk of lost sales to be 5 percent or \$25 million. A potential loss in sales was seen as a real concern, as the bread market is already in a state of decline with bread sales now lower than they had ever been despite an increase in the population.

## 5.7 LABELLING

Different views about labelling were expressed by the submitters who favoured voluntary fortification. One said that the labelling requirements to identify that bread contains folic acid should not be too onerous as bread that is manufactured and sold on the same premises is not required to be labelled. Five others wanted fortified bread to be clearly labelled so that consumers could make an informed choice about the bread that they purchase and avoid fortified bread if that was their preference.

One submitter who did not identify whether they thought bread should be fortified or not said that manufacturers would need to ensure that their labels on fortified bread were not misleading.

## 5.8 PROBLEMS FOR INDUSTRY

Mandatory fortification of bread was seen as problematic for small scale bakeries. Twenty four small bakers said it would be very difficult for them to comply. Errors in accuracy may occur with regards to the correct dosage because of the minute volumes of folic acid that would need to be added to some of their bread mixes. These small bakers as well as the large plant bakers were concerned that some consumers would remove bread from their diet altogether rather than consume fortified bread.

Twenty five submitters said that voluntary fortification would allow bakers to provide a range of products so that consumers could make the appropriate choice if they wanted to consume fortified bread or need to increase the amount of folate in their diet. A small baker noted, however that they had never been asked by a consumer to include folic acid in their bread and they believed that there is no customer desire for fortified bread.

## 5.9 LACK OF DATA

The lack of data (or old data) on NTD affected pregnancies in this country was seen as a problem by submitters who opposed mandatory fortification. They considered that this data problem meant that it would be difficult to assess whether the number of NTD affected pregnancies had already reduced to such an extent that mandatorily fortifying bread would not lead to any further reduction. They also said that the effectiveness of any fortification programme would not be able to be measured as New Zealand has insufficient baseline data. Five submitters also said that the New Zealand has as good or better folate levels as the US has after fortification and that almost all folate sensitive NTDs may have already been prevented.

A submitter said that implementation of voluntary fortification (before mandatory fortification) resulted in a 26 percent reduction in NTDs in Australia but mandatory fortification has not resulted in an additional reduction in the number of NTDs.

## 5.10 EDUCATION

Those who did not support mandatory fortification thought that there should be more emphasis on educating the target group on the need to take folate acid tablets and eat a diet high in naturally occurring folate. These submitters thought that there should be comprehensive education and promotional campaigns directed to the target group. One submitter said that consumer awareness of the need for folic acid prior to and during pregnancy was high and referred to research conducted by NZFSA.

## 5.11 SUPPLEMENTATION

A number of submitters who did not support the mandatory fortification of bread thought promoting the use of folic acid by targeting women in the child bearing age group who intended to have children was a better approach. Seven submitters said that women who were intending to have children should plan carefully, get expert advice, take personal responsibility and take folic acid supplements while trying to conceive.

## 5.12 OPTION SUPPORTED – VOLUNTARY FORTIFICATION

These submitters supported option four - voluntary fortification of bread. They did not think that the voluntary system had been in place long enough to ascertain its effectiveness nor did they think that there was enough evidence to show that mandatory fortification would significantly reduce the number of NTD pregnancies in New Zealand. Some submitters also commented that the response was not proportional to the size of the problem in terms of the number of NTD affected pregnancies. Two submitters were not in support of having a review but rather proposed that industry report to MPI on an annual basis. The baking industry said that if a voluntary fortification approach was adopted, they would undertake to participate in a Code of Practice developed with MPI to guarantee a minimum level of breads fortified.