

Chair
Cabinet Economic Growth and Infrastructure Committee

FOLIC ACID FORTIFICATION OF BREAD

Proposal

1. This paper informs Cabinet of my proposed decision to replace the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 with a standard that permits voluntary fortification of bread.
2. It is for Cabinet's information as the decision to revoke the current Standard and issue a new Standard is my decision as the Minister for Food Safety under the Food Act 1981.

Executive Summary

3. I propose that the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (the Standard) be revoked and that I issue a new standard allowing for voluntary fortification of bread with folic acid. Folic acid is the synthetic form of folate, an essential B vitamin, which is converted into folate in the body.
4. The existing Standard will require that all bread baked in New Zealand (with some exceptions such as organic bread and unbaked bread) has folic acid added to it from 30 September 2012.
5. Consumption of adequate levels of folate before conception and during early pregnancy is proven to reduce the incidence of neural tube defects (NTD) such as spina bifida and anencephaly. Folic acid plays an important role in reducing the risk of NTD affected pregnancies.
6. Fortification of bread with folic acid must be part of a wider strategy to reduce the incidence of NTDs. There are a number of existing initiatives in place. They include the existing voluntary fortification of a range of other foods by industry and Ministry of Health initiatives such as education programmes and the subsidised folic acid tablets available on prescription.
7. The Ministry for Primary Industries (MPI) conducted a review of the Standard including an eight week public consultation between 22 May and 16 July 2012. The consultation document was supported by an extensive review of the science on folic acid fortification, its benefits and risks.
8. MPI consulted on four possible options ranging from 100% mandatory to voluntary fortification of bread. One hundred and thirty four submissions were received with 39 supporting 100% mandatory fortification and nearly all of the remainder supporting voluntary fortification.

9. Mandatory fortification of 100 per cent of bread reduces the most NTDs. However, during the consultation period, MPI conducted scientific modelling of the effect on NTD affected pregnancies of fortifying some bread. The modelling shows that fortifying a percentage of bread while increasing the concentration of folic acid has a significant impact on reducing NTD affected pregnancies. This approach would ensure bread contributes to the package of initiatives that aim to reduce NTDs while maintaining consumer choice.
10. The plant bakeries have made a commitment to work to fortify up to 50% of bread by volume at a higher concentration of folic acid. I consider that working with the bread industry to encourage them to achieve this level of fortification voluntarily is preferable to imposing a mandatory standard. I have taken into account that the bread industry does not directly contribute to the problem or benefit from fortification; bread is simply a useful vehicle for folic acid delivery.
11. Providing for voluntary fortification follows the Government Statement on Regulation which requires that new regulation should only be introduced when the problem cannot be adequately addressed through private arrangements and all practical options have been considered.
12. I consider that a voluntary standard that allows for bread to be fortified with a higher concentration of folic acid is the most appropriate approach because:
 - a. It recognises that fortification of bread is intended to be part of a wider strategy to reduce NTD affected pregnancies
 - b. The bread industry has committed to working towards voluntarily fortifying 50% of packaged bread which is likely to reduce NTDs by 9 – 13 NTDs compared to 14 – 20 NTDs under 100% mandatory regime¹
 - c. The response is proportionate because only a very small proportion of the population is at risk of having an NTD affected pregnancy – it is estimated that there are on average 80 such pregnancies per year
 - d. It would avoid the compliance costs imposed by a mandatory regime while still achieving a reduction in NTDs
 - e. It provides for consumer choice so those consumers that have expressed concerns and wish to avoid folic acid fortified bread can readily find alternatives
 - f. Within the existing permissions, a number of other food products are voluntarily fortified and this appears to be contributing to the improvement in folate levels
 - g. Women's red blood cell folate levels have increased under voluntary fortification. In 2008/09 26% of women had a red blood cell folate level associated with a very low risk of an NTD affected pregnancy compared to 59% in 2011.

¹ This is based on mandatory fortification of packaged bread only and so excludes small bakeries
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Background

Reducing neural tube defects and the role of folic acid

13. Fortification of bread is part of a wider package of initiatives to reduce the incidence of neural tube defects² (NTDs). The Ministry of Health has a policy objective to reduce NTDs and has initiatives such as information on the importance of folate and folic acid and the provision of registered folic acid tablets subsidised on prescription. Refer to Appendix 1 for information provided by the Ministry of Health on their other initiatives to reduce NTDs. Some other foods have been able to be fortified voluntarily in New Zealand since 1996. These foods are: bread, breakfast cereals, juices, legume and cereal analogue foods such as soy and rice milk. However, perhaps 30% of NTD-affected pregnancies are not related to a lack of folate so will not respond to folic acid supplementation.
14. NTDs result from the combined effects of genetic and environmental influences. New Zealand had an average rate for NTD-affected pregnancies of 12.9 per 10,000 births over the period 2005-09. That equates to a total of 80 NTD-affected pregnancies per year based on 19 live births, 14 still births, and 47 estimated terminations.
15. Consumption of adequate levels of folate and/or folic acid before conception and during early pregnancy is proven to reduce the incidence of NTDs such as spina bifida and anencephaly. Folic acid is a synthetic form of folate, an essential member of the B vitamin group, which is converted to folate in the body. Many foods, such as leafy green vegetables and unprocessed grains, contain folate.
16. Women who are planning to become, or are pregnant need more folate than the general population and it is difficult to get this level from dietary sources of folate alone. For this reason Ministry of Health advises that women planning on getting pregnant take a registered folic acid tablet. The *Growing Up in New Zealand*³ survey of women of childbearing age in New Zealand says 60% of the women had a planned pregnancy and that 38% of all women in the study reported taking folic acid tablets before the pregnancy.
17. Fortified food provides an additional source of folate for women who have an unplanned pregnancy or do not understand the importance of taking folic acid tablets before becoming pregnant.

Review of the standard

18. The New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 (the Standard) requires that all bread baked in New Zealand (with some exceptions such as organic bread and unbaked bread) has folic acid

² Neural tube defects (NTDs) are disruptions in the closure of the spine and skull in a fetus. A small number of NTDs occur as part of a syndrome and are not amenable to prevention with folic acid. The majority of NTDs result from inadequate folate status during early pregnancy. Within the New Zealand population there are genetic differences in the amount of folate required to prevent NTDs.

³ *Growing up in New Zealand: Before we are born*. 2010 p.43

<http://www.growingup.co.nz/media/12254/growing%20up%20in%20new%20zealand%20before%20we%20are%20born%20nov%202010.pdf>

added to it from 30 September 2012. Until then voluntary fortification is permitted.

19. The Standard was introduced to help reduce the incidence of NTD affected pregnancies in New Zealand.
20. In May 2012, Cabinet noted that MPI should conduct a public consultation and review the future of the Standard (CAB Min (12) 16/6 refers).
21. On 22 May 2012, the Ministry for Primary Industries (MPI) released *The Future of Folic Acid Fortification of Bread in New Zealand*, for public consultation on four possible options ranging from 100% mandatory to voluntary fortification of bread. The consultation document was supported by an extensive review of the science on folic acid fortification, its benefits and risks. This science paper - *Voluntary Folic Acid Fortification: Monitoring and Evaluation Report* - was released with the consultation document.
22. The MPI systematic review included an assessment of the risks of folic acid and cancer incidence. This work was reviewed by world-class researchers in the field of cancer epidemiology and public health nutrition epidemiology. The results show that folic acid has no significant effect on overall cancer incidence, particularly at the amounts provided from fortification of bread.
23. The four options proposed in the discussion paper were:
 - Option 1: Status Quo – 100% mandatory fortification from 30 September 2012 with or without a one year transition period or some other appropriate period, to allow businesses time to make the necessary changes to their production systems.
 - Option 2: Mandatory fortification of a limited range of breads from 30 September 2012 with or without a transition period.
 - Option 3: Mandatory reporting on voluntary folic acid fortification of bread where all bakeries would be required to report on whether they did or did not fortify their bread.
 - Option 4: Voluntary fortification of bread with folic acid without reporting but with or without a review starting in 2015 which would allow MPI to consider the findings from the review of the Australian mandatory standard.
24. MPI received 134 submissions with 39 supporting 100% mandatory fortification. Most of the remainder supported voluntary fortification.

Voluntary initiatives to fortify bread with folic acid since 2009

25. I convened a Folic Acid Working Group in 2009 to facilitate industry, public health representatives and government departments to work together on voluntary initiatives to fortify bread with folic acid.
26. Industry agreed to voluntarily fortify a wider range of bread. Since then, the number of voluntarily fortified packaged breads has increased from less than 10

to more than 30⁴ representing about 17% of current bread production. This is less than the target agreed by industry of about 30% of bread production.

27. A 2011 study commissioned by MPI of 288 women's blood folate levels showed 59% had a red blood cell folate measurement associated with a very low risk of an NTD affected pregnancy. This is more than twice the rate found in 2008/09. The authors concluded: "This suggests that voluntary fortification of bread has contributed to the increased folate status of women".⁵ Folate status indicates the effect of interventions including fortification.
28. The last Ministry of Health survey measuring blood folate status in women of child bearing age was undertaken in 2008/09. This survey predated the voluntary fortification initiatives put in place after the Standard was amended in late 2009. As a result, MPI commissioned research to measure the impact of these voluntary initiatives on blood folate. The Ministry of Health indicates it is working towards introducing biomedical tests (including blood folate) into the New Zealand Health Survey, but the timing and frequency of future blood tests will depend on the level of funding available.
29. The best way of measuring the success of any intervention is the change in numbers of NTD affected pregnancies, including live births, still births and terminations. This is difficult in New Zealand because of our small population and so the very small number of NTD affected pregnancies (estimated to be 80 per year).
30. Another difficulty in measuring changes in NTD affected pregnancies because detailed data on the reasons for terminations are not collected. The most recent data on NTD affected live births and still births are for 2011 and 2009, respectively (mortality data take longer to collate due to the extended length of time that some coronial inquiries take). The total number of NTD affected pregnancies has been estimated for 2009, using empirical data on live and still births and other data sources to estimate the number of NTD affected terminations. These data predate the post 2009 voluntary bread fortification initiative.

Current situation for the baking industry

31. The bread industry is made up of three major firms (\$100million+), about ten second tier firms (\$10-100million), and 2,000-3,000 small bakeries. The New Zealand Association of Bakers (NZAB) said in their submission that the bread market is in decline, with bread sales now lower than they have ever been despite an increase in population.
32. An industry-commissioned survey suggests almost 32% of consumers indicated they would move away from fortified products. However, an MPI commissioned study⁶ found only 1% of women of child-bearing age were consciously avoiding

⁴ Baking Industry Research Trust website <http://www.bakeinfo.co.nz/Hot-Topics/News/Companies-Respon-To-Voluntary-Fortification-of-Folic-Acid>

⁵ *Monitoring voluntary fortification of bread with folic acid* MAF Technical Paper No: 2011/103 p.32
<http://www.foodsafety.govt.nz/elibrary/industry/monitoring-fortification-of-bread-folic-acid.pdf>

⁶ *Awareness and Knowledge of Folate and Folic Acid A survey of New Zealand women of child-bearing age.* Prepared for NZFSA by Research New Zealand, March 2011. MAF Technical Paper No: 2011/8.
<http://www.foodsafety.govt.nz/elibrary/industry/folate-NZ-women.pdf>

food products fortified with folic acid and 19% were concerned about the lack of choice under a 100% mandatory fortification regime.

33. Industry puts the possible cost of lost sales of 100% mandatory fortification as \$5 million for each 1% lost sales per year from consumer opposition to the practice.

Comment

New information since the release of the consultation document

34. During the consultation period, MPI conducted scientific modelling of the effect on NTD affected pregnancies of fortifying sliced bread (but not all bread). The modelling shows that increasing the proportion of bread fortified and increasing the concentration of folic acid in bread has a significant impact on reducing NTD affected pregnancies.
35. The concentrations of folic acid studied were the Standard's 100% mandatory requirement of an average 135 micrograms per 100 grams of bread and the current target level for voluntary fortification of an average 200 micrograms per 100 grams of bread.
36. The modelling shows:
 - a. If 100% of women of child bearing age consume sliced bread that is fortified at 135 micrograms per 100 grams,⁷ it is estimated that between 14 and 20 NTD affected pregnancies per year could be prevented, but
 - b. If 50% of women of child bearing age consume sliced bread that is fortified at 200 micrograms per 100 grams, it is estimated that between 9 and 13 NTD affected pregnancies per year could be prevented.
37. The model only provides an estimate of the effects of fortification on health outcomes. Fortifying more than 50% of bread at the higher folic acid concentration modelled could bring an added risk of excess consumption of folic acid for some people, especially young children. However, while the tolerable upper limits for folic acid have a safety margin of five times the upper limit⁸ MPI prefers to take a conservative approach at this time.

Is bread an effective delivery vehicle?

38. Food Standards Australia New Zealand developed a joint standard covering the fortification of bread making flour with folic acid with the goal of reducing the incidence of NTDs in both countries. Bread was selected as the delivery vehicle in New Zealand because of the effects on third country trade for the limited number of flour millers in New Zealand.
39. The previously mentioned 2011 study⁹ commissioned by MPI shows that around 93% of women of child-bearing age consume bread. On average they (the target population) consume around two slices of bread a day.¹⁰

⁷ 135 micrograms folic acid per 100 grams of bread was the concentration used in the modelling studies when Food Standards Australia New Zealand (FSANZ) was considering establishing a standard.

⁸ Chapter 3 Issues Paper Mandatory Fortification with Folic Acid, April 2007, Food safety Australia New Zealand http://www.foodstandards.gov.au/srcfiles/P295_Issues%20Paper_UPDATED_13%20April%2007_FINAL.pdf

⁹ *Monitoring voluntary fortification of bread with folic acid*, p.17

40. The proportion of people benefiting from the addition of folic acid to bread is small compared to the total number of people who would consume folic acid in bread under 100% mandatory fortification. Only those women of child bearing age who do not follow the advice from the MoH about taking folic acid tablets would benefit.

The impact of socioeconomic factors on folate status

41. To achieve the maximum decline in NTD affected pregnancies, women need to have good folate status before they become pregnant. Women who do not take supplements (either through choice or because they are not aware of the need to take them prior to and in the early stages of pregnancy) and women with unplanned pregnancies (40% of all pregnancies) will benefit the most from fortified bread.
42. A recent scientific paper found New Zealand women's use of folic acid supplements¹¹ was lower amongst women who were younger, had more children, lower levels of education, lower income levels or belonged to minority ethnic groups. However, the small number of NTDs in New Zealand does not allow a strong link to be drawn.
43. The Australian Baseline Study¹² shows that women least likely to take folic acid supplements are also least likely to consume voluntarily fortified food. They are those at both extremes of maternal age, but more so among younger women; women living in areas of relative disadvantage; women living in remote areas; and women of Aboriginal and Torres Strait Islander origin.

International comparisons

44. Advocates of 100% mandatory fortification point to the many countries that already require mandatory fortification of flour as a justification for extending 100% mandatory fortification to New Zealand. Countries that require mandatory fortification of flour include the United States, Canada and Australia and many emerging economies. Conversely, opponents draw attention to the fact that no Western European country requires mandatory fortification with folic acid. Although most European countries permit voluntary fortification, some do not permit fortification at all.
45. In both the United Kingdom and Ireland, governments have received reports recommending mandatory fortification with folic acid. In 2009, Ireland decided to continue with voluntary fortification indefinitely because an updated study found that mandatory fortification could not be justified in light of the improved folate status of Irish women. The United Kingdom has not yet required mandatory fortification of flour.
46. One of the reasons for Ireland's relative success with voluntary fortification is likely to be the wide range and higher concentrations of folic acid fortified food which includes milk and margarine as well as cereal and bread.

¹⁰ MPI's modelling used an average consumption of about 60 grams of bread a day at an average concentration of 135 micrograms per 100 grams for an average folic acid consumption of 79.6 micrograms per day.

¹¹ Delaying mandatory folic acid fortification policy perpetuates health inequalities: results from a retrospective study of postpartum New Zealand women., Simonette R. Mallard, Andrew R. Gray, and Lisa A. Houghton. *Hum. Reprod.* 2012;27:273-82

¹² Neural tube defects in Australia: Prevalence before mandatory folic acid fortification. Australian Institute of Health and Welfare, December 2011

47. The *Australia New Zealand Food Standards Code - Standard 1.3.2 - Vitamins and Minerals* defines the existing permissions that allow fortification of specified foods with some vitamins and minerals in New Zealand. That Standard limits folic acid fortification to fewer food categories than Ireland permits.
48. It may be possible for New Zealand to seek to initiate a New Zealand-only proposal through FSANZ for the voluntary addition of folic acid of a wider range of food products. However, the specific product categories and proposed levels of fortification would need to be identified.

Summary of submissions

49. The discussion document identified four options for the fortification of bread. Of the 134 submissions received, 132 indicated a preference for an option:
 - a. 39 supported Option 1 (100% mandatory fortification of all bread),
 - b. 3 supported Option 2 (limited mandatory fortification),
 - c. 2 supported Option 3 (mandatory reporting), and
 - d. 88 supported Option 4 (continued voluntary fortification).
50. Most submissions that supported 100% mandatory fortification came from the medical and health professions and their professional organisations and families affected by NTDs. Reasons stated for supporting 100% mandatory fortification were:
 - a. It will achieve the maximum reduction in the number of neural tube defect affected pregnancies
 - b. It is an appropriate intervention given the high percentage of unplanned pregnancies
 - c. The costs to the health and education sectors of neural tube defects
 - d. The high emotional and financial costs to the families associated with NTD affected pregnancies.
 - e. Widespread lack of awareness of the importance of adequate folate consumption before and in the early stages of pregnancy
 - f. Use of folic acid supplements is low
 - g. Fortifying bread is safe
 - h. Many other countries have mandatory fortification of flour including Australia, the United States and Canada.
51. Those who did not support the fortification of bread were baking industry associations, individual bakeries, the Food and Grocery Council, and almost all consumers. Reasons people opposed 100% mandatory fortification were:

- a. It is a disproportionate response to address a problem that affects a limited proportion of the population
- b. It removes consumer choice
- c. Organic and non-yeast leavened bread (those not required to be fortified) are either hard to find or more expensive
- d. Increased costs to consumers for fortified breads passed on by manufacturers
- e. Objected to "mass medication" of the whole population and their right to refuse medical treatment
- f. A perception of possible risks to the health of the general population including increased cancer risk
- g. No European Union country requires mandatory folic acid fortification of any food
- h. Consumers are still clearly concerned about possible risks from folic acid and this could impact on bread consumption
- i. Consumers also expressed the view that rather than fortifying bread, the target group should be educated about the need to increase their folate consumption.

Advantages and disadvantages of the options

- 52. Folic acid fortification of bread (and other foods) will be most effective as part of a wider strategy to reduce NTD affected pregnancies. It is not sufficient on its own. The wider strategy includes health educational programmes on the importance of folate and dietary sources of folate and the provision of registered folic acid tablets.
- 53. Appendix 2 provides the summary of Benefits and Costs of Options from the Regulatory Impact Statement (RIS).
- 54. The benefits of avoiding NTD affected pregnancies are estimated using a twenty-year net present value for costs incurred averaged over all cases. The costs of individual cases may be higher than these averages.
- 55. MPI recognises that the addition of folic acid to bread is technically challenging. Most submissions from industry stressed that small bakeries would be poorly equipped to add folic acid and achieve a consistent distribution of folic acid in the bread. As small bakeries are estimated to account for perhaps 5% of all bread production, the following analysis assumes that small bakeries will not be required to fortify bread under any of the options.

Option 1 – 100% mandatory fortification of almost all bread

- 56. Mandatory (100%) fortification of almost all bread is estimated to prevent between 14 and 20 NTD affected pregnancies per year. Such an outcome would result in the highest benefits (costs avoided) in the health and education sectors and for the individuals and their families affected.
- 57. The incremental benefits of 100% mandatory fortification are estimated at between \$71 million and \$79 million per year. The estimated net benefits over

twenty years at a net present value are between \$920 and \$1,090 million. The great bulk of the benefit comes from the value of life and suffering rather than direct costs such as medical treatments. This option was very strongly, but not unanimously, supported by health professionals.

58. Mandatory (100%) fortification would also impose the highest costs on industry, and government. Monitoring and verification costs would be highest under this option as well as set-up and ongoing costs for industry.
59. These cost estimates include: one-off costs of \$1.5 million; an on-going increase in the cost of production of \$1.9 million per year; and increased compliance costs of between \$50,000-100,000 per year. The cost benefit analysis does not include an allowance for a possible decrease in the demand for bread at a cost to industry of \$5 million per each 1% drop in demand because it has not yet happened.
60. This option significantly impacts on consumer choice and increases the cost to consumers of finding alternative sources of bread if they do not want to consume fortified bread as well as absorbing any costs passed on by industry. The costs that may be passed on to consumers by industry are not significant and estimated in the regulatory impact statement as one cent per loaf. The other costs to consumers are not estimated. However consumers who want to avoid eating fortified bread will have to buy organic or non-yeast leavened bread which are more expensive. It may result in reduced bread sales if people switch to an alternative source of carbohydrates to avoid folic acid. If women reduce their consumption of bread, it may undercut the effectiveness of fortification and decrease the costs avoided by reducing NTDs.
61. The concentration of folic acid would remain at an average of 135 micrograms per 100 grams of bread for 100% mandatory fortification as this was the level modelled by FSANZ as safe and effective if all bread was to be fortified.
62. Submitters who were not in favour of 100% mandatory fortification argued that it amounts to "mass medication" of the population, is a disproportionate response to address a problem that affects a limited proportion of the population, and perceived there to be possible risks to the rest of the population.
63. Unlike iodised salt, 100% mandatory fortification of bread only benefits a small proportion of the population. As New Zealand soils are iodine deficient, all New Zealanders are at risk of goitre without some form of iodine supplementation.

Option 3 – Mandatory reporting with voluntary fortification

64. Mandatory reporting on voluntary fortification (option 3 in the consultation document) would require all bakeries to report on whether or not they fortify bread and provide for government and public monitoring of voluntary fortification initiatives. This option would impose record keeping requirement costs on industry and consumers with no guarantee that any bread would be fortified. It is considered the least effective option relative to the costs.

Option 2 Limited mandatory fortification and Option 4 Voluntary fortification

65. Under limited mandatory fortification (option 2) and voluntary fortification (option 4) it would be possible to fortify bread at a higher concentration without

introducing a risk that some population groups would exceed the tolerable upper limit¹³ for folic acid. The average consumption of folic acid would be reduced as some bread would not be fortified.

66. MPI modelling shows that the effectiveness of fortification depends on the percentage of bread that is fortified and the concentration of folic acid that is used. Limited mandatory fortification would need to be set at a higher percentage of breads than could be expected to be achieved with voluntary fortification to justify the additional costs of imposing a regulatory regime.
67. If either option were to be implemented at the higher concentration of 200 micrograms of folic acid per 100 grams of bread, more NTD affected pregnancies could be avoided for a lower percentage of bread fortified than is possible at the lower concentration of 135 micrograms of folic acid per 100 grams of bread. However, limited mandatory fortification would provide more assurance that any bread would be fortified. Both options allow consumers to choose whether to consume fortified bread.

Option 2 Limited mandatory fortification

68. Limited mandatory fortification was assessed based on MPI modelling using a concentration of 200 micrograms of folic acid per 100 grams of bread. If 50% of women in the target group consume sliced bread that is fortified at 200 micrograms per 100 grams, it is estimated that between 9 and 13 NTD affected pregnancies per year could be prevented.
69. Those NTD affected pregnancies avoided would result in benefits of between \$230-600 million per year from costs avoided in net present value terms.
70. Limited mandatory fortification imposes costs on industry and government that voluntary does not. Costs imposed on industry are estimated to be a one-off cost of between \$200,000 to \$400,000 and ongoing costs of between \$600,000 and \$1.1 million per year. Costs to government are expected to be similar to those for 100% mandatory fortification.
71. While the total costs under the limited mandatory fortification option are expected to be less than those for Option 1 (100% mandatory fortification), the per-loaf costs may be higher.

Option 4 voluntary fortification

72. Voluntary fortification provides both consumers and industry the most choice. It does not impose any costs on industry or consumers, although there will be costs to industry associated with voluntarily fortifying bread.
73. The disadvantage of option 4 (voluntary fortification) is that there is no guarantee as to the amount of bread that would be fortified with folic acid. It would rely on the baking industry implementing its commitment to fortification and government monitoring fortification and any improvement on blood folate levels and NTD affected pregnancies.
74. That uncertainty is reflected in the estimates, with this option (which is based on the current level of voluntary fortification of about 17% of bread by volume)

¹³ There is a safety margin built in of five times the upper limit.
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providing only between 1 and 2 fewer NTD affected pregnancies per year based on the existing level of folic acid fortification. The avoided cost for these NTD cases would be between \$3.7 and 5.0 million per year in net present value terms.

75. However, the plant bakeries have made a commitment to fortify 25% of their packaged bread at a higher concentration of folic acid and to work with large clients (such as the) to include private label bread products in the voluntary fortification programme which could bring the total volume of packaged bread fortified up towards the 50% mark. If industry reached its target of 50% of bread fortified, the number of NTDs avoided could rise to between 9 and 13 per year.
76. Industry and most consumers strongly supported voluntary fortification. Supporters of 100% mandatory fortification do not favour these options and drew attention to industry's failure to voluntarily fortify a significant proportion of bread.

Bread industry concerns

77. The bread industry opposed 100% mandatory fortification and expressed concerns about:
 - a. The cost to industry of lost sales. An industry-commissioned survey¹⁴ suggests almost 32% of consumers indicated they would move away from fortified products. However an MPI commissioned study¹⁵ found only 1% of women of child-bearing age were consciously avoiding food products fortified with folic acid although 19% were concerned about the lack of choice under a 100% mandatory fortification regime. Industry considers that a 5% drop in sales would be a conservative estimate.
 - b. A 5% reduction in bread consumption would cause a loss of \$25 million per year with accompanying loss of businesses and jobs
 - c. Bread sales are in decline despite an increase in population and
 - d. The cost burden of enforcement for smaller companies as this is likely to add minimal benefit given their small share of the bread market.

Bread industry proposal

78. The NZAB represents the plant bakers (manufacturers of packaged bread) in New Zealand. Packaged breads are defined as those produced for retail sale away from the manufacturing premises and therefore must carry a nutritional declaration (NIP).
79. The NZAB included in their submission a proposal for voluntary fortification of packaged bread supported by an industry code of practice. Each member company has agreed to fortify a minimum of 25% by volume of their branded breads with folic acid at a concentration of 200 micrograms of folic acid per 100

¹⁴ Consumer Link CATI Omnibus. December 2011 – February 2012) <http://www.consumerlink.co.nz/index.php?pageLoad=108>

¹⁵ Awareness and Knowledge of Folate and Folic Acid A survey of New Zealand women of child-bearing age. Prepared for FSA by Research New Zealand, March 2011. MAF Technical Paper No: 2011/8. <http://www.foodsafety.govt.nz/library/industry/folate-NZ-women.pdf>

grams of product. This is a higher concentration than is required by the 100% mandatory provision in the current Standard.

80. In addition, the NZAB on behalf of all its members agreed to:
 - a. Continue to work with large clients (such as) to include private label bread products in the voluntary fortification programme which could bring the total volume of packaged bread fortified up towards the 50% mark.
 - b. Commission an independent party to audit breads throughout each year to ascertain folic acid levels and if necessary work with MPI to refine these levels to optimise intake.
 - c. Provide MPI a report which outlines the range of breads containing folic acid (this would also be made available on the industry website) together with their combined percentage of total market.
81. In making this commitment the industry has indicated that it could take up to 12 months to ensure the industry fully achieves this target.
82. MPI modelling suggests that if NZAB were to fortify 30% of the volume of packaged breads, the estimated reduction in NTD-affected pregnancies could be between 4 and 9 per year.
83. The modelling further suggests that if NZAB members were able to reach the target of 50% of packaged breads, the estimated reduction in NTD affected pregnancies could be between 9 and 13 per year.

Proposed option

84. Folic acid fortification of bread will be most effective if it is part of a wider strategy to reduce NTD affected pregnancies. It is not sufficient on its own. The wider strategy includes Ministry of Health educational programmes and the provision of registered folic acid tablets subsidised on prescription.
85. While 100% mandatory fortification will bring the greatest benefits from reductions in NTDs, the analysis above suggests that in balancing reductions in NTDs with loss of consumer choice, costs to industry and effectiveness of alternative approaches, the best option is either option 2 (partial mandatory fortification) or option 4 (voluntary fortification).
86. Both options would allow the target concentration of folic acid to be set at 200 micrograms per 100 grams of bread¹⁶. MPI would need to conduct more extensive dietary modelling before recommending to me that more than 50% of bread be fortified at a higher concentration of folic acid. While the tolerable upper limits for folic acid have a safety margin of five times the upper limit¹⁷ MPI prefers to take a conservative approach at this time in regards to groups of consumers that might possibly be vulnerable.

¹⁶ MPI recommends a target of 200 micrograms of folic acid per 100 grams of bread but the Standard will establish a maximum permitted level of 250 grams of folic acid per 100 grams of bread to allow for manufacturing variants.

¹⁷ Chapter 3 Issues Paper Mandatory Fortification with Folic Acid, April 2007. Food safety Australia New Zealand http://www.foodstandards.gov.au/srcfiles/P295_Issues%20Paper_UPDATED_13%20April%2007_FINAL.pdf

87. In order to achieve the equivalent reduction in NTDs using the current Standard concentration of 135 micrograms per 100 grams of bread (the current 100% mandatory Standard concentration) more bread would need to be fortified. For example it would require more than 70% of bread fortified at the 100% mandatory concentration to achieve a reduction of 9 -13 NTDs. By comparison, it would take only 50% of bread at the higher concentration (200 micrograms) to achieve a reduction of 9-13 NTDs.
88. Partial mandatory fortification brings higher costs but more certainty of outcome for the same potential reduction in NTDs. However, if the NZAB achieves fortification of towards 50% of sliced bread under voluntary fortification as indicated as a possibility in their proposal, the costs would be lower for the same result.
89. I therefore propose that standard be changed to permit voluntary fortification of bread indefinitely with a maximum permissible level of 250 micrograms folic acid per 100 grams of bread. This will allow for manufacturing variance around a target concentration of 200 micrograms of folic acid per 100 grams of bread.
90. MPI will work with the baking industry to develop a voluntary code of practice to guarantee a minimum level of New Zealand breads be fortified with folic acid.
91. MPI will monitor folic acid fortification of the food supply generally and in particular of folic acid fortification of bread as part of its food safety responsibilities. This monitoring will occur within the next two to three years and needs to be considered alongside any changes to the blood folate status of women of child bearing age. Note that there will be a lag time between an increase in fortification of food and changes in blood folate status.
92. MPI will also ensure routine audits of bakeries under the Food Act (and in time, the new Food Act once the Food Bill comes into force) will include checks on bakeries' claims of adding folic acid to their products. Such bakeries would be expected to have adequate record keeping systems, evidence of supplies of folic acid and recipes that call for its use, and other supporting systems in place.
93. MPI will advise the Commerce Commission if it discovers that bread package labelling does not accurately reflect the folic acid fortification of bread.
94. I have asked MPI to keep me informed of the results of the monitoring and progress of voluntary fortification.

Trans-Tasman food regulation

95. As the Standard was originally developed through the joint Australia-New Zealand food regulation system, I will ensure that my Ministerial colleagues on the Legislative and Governance Forum on Food Regulation are kept informed of the proposals arising from this paper.
96. The actions I am proposing are within the scope of the *Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Food Treaty). Under the Food Treaty, New Zealand has undertaken not to make any legislation for matters within scope of

the Treaty, unless it is through the joint food standards system or by mutual agreement by both countries. Folic acid fortification falls within scope of the Food Treaty. Therefore it is necessary to consult with Australia on any changes to New Zealand regulation of folic acid in the food supply.

97. New Zealand 'opted out' of the joint standard for folic acid fortification of bread-making flour on third country trade grounds. Therefore, our folic acid fortification standard is a New Zealand-only standard, and so making changes to it does not have a direct impact on Australia.

I will write to my Australian counterpart, Hon Catherine King, to update her on my final decision in respect of folic acid fortification of bread in New Zealand.

Consultation

98. The following departments and agencies were consulted in the development of this paper: the Treasury and the Regulatory Impact Analysis Team (RIAT), the Ministries of Business Innovation and Employment, Health, Justice, Pacific Island Affairs, and Women's Affairs, Te Puni Kokiri, and the Commerce Commission.
99. Ministry of Health officials consider that the international evidence strongly supports the use of mandatory fortification of bread with folic acid for maximum health benefit and minimal risks to reduce avoidable NTDs. However, the Ministry would support continuation of voluntary fortification for two to three years, particularly given the commitments by industry to substantially increase the amount of product which is fortified, provided there is a robust review of its effectiveness at the end of this period, similar to the review being undertaken for mandatory fortification of flour in Australia. The Ministry of Health is concerned about the number of unplanned pregnancies for example, and considers that the effectiveness of any health initiatives to tackle NTDs will necessarily be limited. For this reason, Ministry of Health officials ultimately see mandatory fortification with folic acid as underpinning any other activities to reduce NTDs
100. The Department of Prime Minister and Cabinet and the Office for Disability Issues (Ministry of Social Development) were informed.

Financial Implications

101. There are only minor financial implications for MPI associated with the preferred option of voluntary fortification. These relate to monitoring and will be met within current food safety baselines.
102. As I am recommending voluntary fortification of bread with folic acid, government will not be imposing additional costs on the baking industry.

Human rights implications

103. Officials are not aware of any implications relating to the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993.

104. The Ministry of Justice commented: "The proposals in this paper appear to be consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993."

Legislative implications

105. A new Standard allowing for the voluntary fortification of bread with folic acid will need to be issued to replace the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007.
106. In order to avoid the existing Standard commencing on 30 September 2012, the new Standard needs to be submitted to the *Gazette* by 28 August 2012.

Regulatory impact analysis

107. The principles of the Code of Good Regulatory Practice and the regulatory impact analysis requirements, including consultation, were complied with in preparing the regulatory impact analysis.
108. "MPI's Policy Coordination and Regulatory Systems group has reviewed the Regulatory Impact Statement (RIS) prepared by MPI, and considers that the information and analysis summarised in the RIS meets the quality assurance criteria."
109. The regulatory impact analysis has been consulted with the Treasury.

Publicity

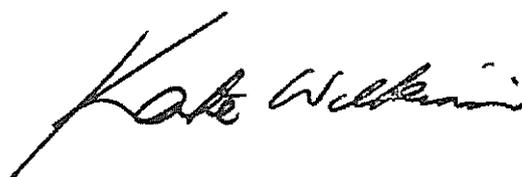
110. I intend to make a public announcement reflecting my decision on the Standard. I also intend that this paper should be published on the Ministry for Primary Industries' website.

Recommendations

111. The Minister for Food Safety recommends that the Cabinet Economic Growth and Infrastructure Committee:
1. **note** folic acid supplementation and fortification reduces the risk of neural tube defect affected pregnancies;
 2. **note** fortification of bread with folic acid must be considered as part of a wider strategy to reduce the incidence of NTDs which includes Ministry of Health initiatives;
 3. **note** that the New Zealand (Mandatory Fortification of Bread with Folic Acid) Food Standard 2007 will require almost all bread sold in New Zealand to have folic acid added to it from 30 September 2012;
 4. **note** that the Ministry for Primary Industries (MPI) conducted a review of the Standard which included eight weeks of public consultation and

mathematical modelling of likely outcomes of various fortification options to inform my decision;

5. **note** that I consider that a voluntary standard that allows for bread to be fortified with a higher concentration of folic acid is the most appropriate approach;
6. **note** that the plant bakeries have made a commitment to work to fortify up to 50% of bread by volume at a higher concentration of folic acid with 50% likely to reduce NTDs by 9 – 13;
7. **note** that I consider that Government working with the bread industry to encourage them to achieve this level of fortification voluntarily is preferable to imposing a mandatory standard and is good regulatory practice;
8. **note** that an amended or new standard will need to be submitted to the gazette by 28 August 2012 to avoid the 100% mandatory provisions of the current Standard coming into force;
9. **note** that the MPI and MoH will monitor the implementation of the standard for voluntary fortification of bread; and assess any potential further initiatives that would support the voluntary standard and increase folate levels for pregnant women;
10. **note** that the Standard requiring mandatory fortification of bread with folic acid will be revoked;
11. **note** that I propose to issue a new standard allowing for continued voluntary fortification of bread with folic acid with a maximum permissible level of 250 micrograms of folic acid per 100 grams of bread;
12. **note** that I propose to publish this Cabinet paper on the Ministry for Primary Industries' website.



Hon Kate Wilkinson
Minister for Food Safety

Date: 15 / 8 / 2012

Appendix 1: Ministry of Health provided the following information on their initiatives to address NTD affected pregnancies

The Ministry produces evidence-based recommendations for health practitioners on healthy eating during pregnancy (Food and Nutrition Guidelines for Healthy Pregnant and Breastfeeding Women: A background paper), which is the basis of advice on this issue. The Ministry also provides information for the public via its website and health education resources advising of the risks of NTDs and the benefits of taking folic acid. The advice is that all women should take folic acid tablets at least four weeks before becoming pregnant and for the first 12 weeks of pregnancy to reduce the risk of NTDs. These tablets are subsidised on prescription. District Health Boards are responsible for disseminating advice to pregnant women and health professionals and act independently of Ministry of Health.

In addition, the Ministry of Health funds initiatives which provide information to inform policy development and monitoring around this issue. For example, population-based health and nutrition surveys, the New Zealand Food Composition Database, the New Zealand Birth Defects Register, and the Growing up in New Zealand Study. The Ministry recognises the importance of good nutrition and a healthy start to life and is exploring options for improving health prior and during pregnancy and in the first few years of life.

Appendix 2: Summary of Benefits and Costs of Options

Option 1 – Full mandatory		Option 2 – Limited mandatory		Option 3 – Mandatory reporting only		Option 4 - Voluntary	
Benefits	Costs	Benefits	Costs	Benefits	Costs	Benefits	Costs
<ul style="list-style-type: none"> Between 14 and 20 NTD cases prevented per annum. Better reach to target population - will increase folic acid intake of women with unplanned pregnancies or who do not know about the importance of folic acid. 	<p>Industry</p> <ul style="list-style-type: none"> Increased costs of production: <ul style="list-style-type: none"> - One-off \$1.5m; - On-going \$1.9m p.a. Increased compliance costs \$50 -100,000 p.a. Possible decrease in demand for products: <ul style="list-style-type: none"> @1% = \$5m p.a. @5% = \$25m p.a. Reduced competitiveness <p>Consumers</p> <ul style="list-style-type: none"> Increased price @ 1c/loaf = \$1.8m p.a. Lack of choice <p>Government</p> <ul style="list-style-type: none"> Additional administration and enforcement (\$100,000/year) Adverse reaction from consumers to idea of "mass medication" of food supply. 	<p>Between 3 and 11 NTD cases prevented per annum</p>	<p>Industry</p> <ul style="list-style-type: none"> Increased costs of production. <ul style="list-style-type: none"> - One-off \$0.2m -0.4m - Ongoing \$0.6m-\$1.1m p.a. Increased compliance costs – higher than mandatory due to more complex record keeping and testing regimes. <p>Consumers</p> <ul style="list-style-type: none"> Increased price – but may be able to avoid this depending on industry pricing policies. Reduced choice (but more than under option 1) <p>Government</p> <ul style="list-style-type: none"> Additional administration and enforcement – likely to be around the same as for full mandatory. 	<p>Between 1 and 2 NTD cases prevented per annum.</p> <p>Consumers</p> <p>Choice preserved</p>	<p>Industry</p> <p>Increased compliance costs</p> <p>Government</p> <p>Monitoring costs to ensure reporting requirements complied with.</p>	<p>Between 1 and 2 NTD cases prevented per annum (based on current fortification of about 17% of bread by volume).</p> <p>Between 4 and 9 prevented per annum (if 25% of packaged bread is voluntarily fortified)</p> <p>Between 9 and 13 NTD cases per annum (if 50% of packaged bread is voluntarily fortified)</p> <p>Industry</p> <p>Any increased costs will be a business decision (retain control of marketing and pricing strategies)</p> <p>Consumers</p> <p>Choice preserved</p>	<p>Industry</p> <p>Adverse reaction from health professionals and disability groups.</p>



NOTE: Some material in Folic Acid Fortification of Bread has been withheld

The Ministry for Primary Industries has decided not to release certain short passages in this document.