



THE PAEDIATRIC SOCIETY OF NEW ZEALAND

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PSNZ Submission: The Future of Folic Acid Fortification in New Zealand July 2012

Part 1

Prepared by Andrew Marshall, Paediatrician, Wellington Hospital, and endorsed by PSNZ membership through an e-mail based consultation process.

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Summary:

The Paediatric Society of New Zealand **strongly supports Option 1: Mandatory fortification of bread with folic acid** as per the Food Standard 2007.

PSNZ believes mandatory fortification will be **effective** in reducing Neural Tube Defect pregnancies, and bring the numbers of such pregnancies down from an estimated 12-14 per 10000 (70-90 per year in NZ) to the international "floor-level" seen in countries with mandatory fortification, such as USA and Canada, of 7-9/10000 (40-50). This would prevent approximately 30 Neural Tube Defect pregnancies per year.

PSNZ recognises that mandatory fortification is **safe**. No safety concerns have been raised regarding the current voluntary fortification regime. No safety concerns have been reported in countries where a mandatory fortification programme has been introduced and monitored. Purported safety concerns are not supported by consensus scientific opinion despite exhaustive study, and only relate to high-dose folic acid supplementation trials, not to the dose of folic acid delivered in NZ bread.

PSNZ acknowledges that the costs of mandatory fortification will be small compared to the cost-savings achieved in preventing NTD and other health consequences of folate deficiency.

Voluntary fortification since 2009 has resulted in health benefits and likely reduction in NTD rates through raising the blood folate levels in the population. MPI commissioned research (Bradbury and Skeaff 2011) show that double the number of women had red blood cell folate levels in the optimum range for preventing neural tube birth defects (NTD) like spina bifida in 2011 compared to 2008/2009 (from 26% to 59 % having RBC folate 906 nmol/L or above). However, international evidence confirms that the best reduction in NTD rates occurs with a mandatory programme.

Part 1 of this submission states the PSNZ position in support of mandatory fortification, and provides a summary of the benefits and a discussion of the costs to support this position.

Part 2 of this submission provides a critical analysis of the paper “*An update on folic acid fortification: benefits and risks 2012*” A David Smith and Helga Refsum, which was commissioned by the New Zealand Baking Industry Research Trust and New Zealand Food and Grocery Council in February 2012. This critical analysis is necessary due to the combination of

- Vocal opposition of these two groups to mandatory fortification in the 2009 consultation.
- Significant bias and methodological flaws in the paper they have commissioned which lead to unsupported overstatement of risks associated with folic acid fortification, such that the paper would never be accepted by any peer-reviewed scientific publication.
- The likelihood New Zealand Baking Industry Research Trust and New Zealand Food and Grocery Council will seek to misinform the NZ public and the Government using this publication.
- That such use could undermine a democratic and thoughtful implementation of a significant public health policy.

Introduction:

The Paediatric Society of New Zealand is a multidisciplinary organisation with a membership of more than 500 child health professionals.

The aims and objectives of the Society are to stimulate interest in and to promote the scientific study of child health and Paediatrics in New Zealand, and to engage in all activities which, in the opinion of the Society, may be necessary from time to time in the interests of child health, and to engage in the following activities which promote the welfare of New Zealand children:

- Encourage and promote the study and advancement of the science and practice of paediatrics, child health nursing and other professional practices involved with child health
- Generally to promote the health and welfare of children in New Zealand consistent with the United Nations Convention on the Rights of a Child.
- Advocate for children on all issues related to their health at a local, regional and national level.
- Provide information to the public of New Zealand on all matters that concern the health and welfare of children.
- Advance public education and awareness of the science and practice of paediatrics, child health and welfare of children.
- Maintenance of the highest possible level of the scientific and ethical practice in the health care of children in New Zealand.

The Paediatric Society of New Zealand has consistently advocated for mandatory fortification of flour/bread in New Zealand. PSNZ has contributed positively through previous submission processes, and has worked cooperatively with the Ministry of Primary Industries and its predecessors in providing data, information and support to inform government policy on this issue, including constructive participation on the Folic Acid Working Group.

Members of the PSNZ have and will continue to work tirelessly at the medical front-line providing excellent care to children with Spina Bifida. Expert knowledge of this devastating condition and its consequences for the individual, family / whanau and society informs PSNZ policy, and members' expertise in critical analysis of medical research methods and results provides confidence in interpretation of the safety and efficacy of folic acid fortification.

Cost-Benefit Analysis:

Efficacy:

The **efficacy** of pre-conceptual folic acid in preventing Neural Tube Defect has been established since the 1980s, and the efficacy of a public health approach, namely the mandatory fortification of flour to reach the whole population has been proven. Meta-analyses demonstrate a reduction in NTD prevalence of 41% ^(Blencowe et al 2010) and 46% ^(Imdad et al 2011) following mandatory fortification.

PSNZ believes mandatory fortification will be effective in reducing NTD pregnancy rates down from an estimated 12-14 per 10000 (70-90 per year in NZ) to the international "floor-level" seen in countries with mandatory fortification, such as USA and Canada, of 7-9/10000 (40-50). This would prevent approximately 30 Neural Tube Defect pregnancies per year.

In 2009, media coverage of the folic acid fortification debate focused on the contention from the baking industry that to be effective in raising folate levels to the RDI (recommended daily allowance), 11 slices of bread a day would need to be consumed. Yang et al (2010) have demonstrated that mandatory fortification of flour in the USA has provided most Americans about 135 micrograms of folic acid a day. This additional folic acid is less than the recommended daily allowance, but prevents the vast majority of folic acid preventable spina bifida, at a dose that is perfectly safe. This dose is present in less than 100g or 3 slices of NZ fortified bread a day.

Mandatory folic acid fortification is clearly the most effective public health strategy to address the problem of reducing the risk and therefore incidence of neural tube defects. *If* almost all women in New Zealand planned their pregnancies *and* consulted a Health Professional prior to embarking on unprotected sexual activity *and* took appropriate folic acid supplements consistently while trying to become pregnant, then mandatory fortification would not be necessary.

However, more than half of all pregnancies in New Zealand are unplanned. Unplanned pregnancies occur in the more disadvantaged sectors of the community, especially younger women including teenagers, and women in low socioeconomic groups. These women are more likely to have a diet low in naturally folate rich foods and less likely to be taking folic acid supplements. Therefore a public health approach is necessary to reach these women.

More than a third of all infants presenting to the Starship neurosurgical unit for initial surgery for meningomyelocele 2002 – 2008 were Maori. Maori are disproportionately represented in many adverse health outcomes that reflect social disadvantage.

Benefits:

The **benefits** of preventing NTD pregnancies through mandatory folic acid fortification include:

- Reducing the burden of living with spina bifida to the individual and their family. Individuals with Spina Bifida experience ongoing pain, disrupted home and school life from frequent infections and hospitalisations, physical limitation, lost opportunities, and stress on their families and themselves.
- Reducing the grief of perinatal loss of a baby with anencephaly,
- Reducing the numbers of women who face the agonising decision to terminate a NTD pregnancy.
- Financial benefits: Bowkett and Deverall ^(NZMJ 2012) calculate hospital costs alone in spina bifida patients by age 21 are nearly 1 million dollars. Add the adult surgical costs, the lost family income, the community, special education and disability sector costs, and the price could easily be doubled for each individual with a neural tube defect (NTD) who survives to adulthood.

Additional **benefits** of mandatory fortification of bread include:

- Preventing at least 20 babies being born with congenital heart lesions
- Preventing 164 stroke deaths in NZ per year (statistically significant decrease in stroke deaths of 12900 per 314 million in USA per annum since mandatory fortification introduced). *See Part 2 for discussion and references.*
- Financial benefits to the health system in preventing these congenital heart lesions and strokes, and reducing the social and emotional burden of these medical conditions on the individuals and families.
- Aligning NZ policy and practice with Australia with who we share joint food standards, and with approximately 70 other countries.

Costs:

The **costs** of mandatory fortification of bread are minimal.

- Financial costs to the baking industry of adding folic acid to bread (calculated by MPI at ½ cent per loaf).
- Financial costs to the baking industry in reduced bread purchased. This cost has been reported publically as a significant concern by the industry, with a belief that many people will refuse to buy bread because it is vitamin-enriched. However, analysis of this argument reveals;
 1. Industry is largely responsible for publicity suggesting safety fears (which are unfounded), so bears some responsibility for suggesting to the public bread is unsafe when it is not. Industry therefore carries the consequences of their own misinformation.
 2. Industry have failed to provide evidence that in Australia since 2009 (when mandatory fortification was introduced), there has been a reduction in bread sales due to mandatory fortification, and in excess to the incremental reduction in bread sales each year due to consumer purchasing trends. It is beholden on industry to prove their contention that bread sales will be affected by comparison with Australia.

3. The history of public health initiatives in NZ suggests industry often predicts exaggerated negative consequences to themselves that do not eventuate (ie the liquor industry predicting drinking in bars would dramatically reduce with smoke-free legislation).
4. There has never been a suggestion that addition of vitamin C to fruit juices has put consumers off buying juice. Adding folic acid to bread equally is unlikely to have any effect on consumers, the vast majority of whom are unlikely to care. Most consumers buy products with a great many artificial additives and preservatives which are not known to have any beneficial effect on health, unlike folic acid which is known to be beneficial to health. There has been no resistance to the mandatory use of iodized salt in bread to prevent thyroid deficiency.
5. There has been a significant increase in voluntary consumption of folic-acid fortified cereals in NZ since 2008, leading to the majority of the increase in population folate levels in 2011 ^(Bradbury et al 2011). Cereal manufacturers therefore have not experienced any risk that addition of folic acid will harm their sales.

In summary, there is no evidence to support the industry contention that bread sales will be adversely affected.

- Financial costs to government in ensuring baker's compliance. Compliance will be easy to ensure for the 95% of breads that are produced by the 4 large bakeries, but may be more difficult for small owner-operated bakeries.

In summary, the costs of implementing mandatory fortification are substantially less than the costs of delaying mandatory fortification, in terms of the providing medical and social support to those born with neural tube defects, congenital heart defects and those excess adults suffering stroke.

Safety:

Mandatory fortification of bread with folic acid is **safe**. No safety concerns have been raised regarding the current voluntary fortification regime. No safety concerns have been reported in countries where a mandatory fortification programme has been introduced and monitored. Purported safety concerns are not supported by consensus scientific opinion despite exhaustive study, and only relate to high-dose folic acid supplementation trials, not to the dose of folic acid delivered in NZ bread.

Folate deficiency is associated with cancer risk. Sufferers of spina bifida have a very high lifetime cancer incidence due to their high exposure to radiation (multiple CT scans and X-rays) and bladder augmentation surgery using bowel wall which has a high rate of malignant transformation ^(Bowkett and Deverall 2012). Therefore mandatory fortification is likely to decrease cancer incidence, not increase it. This is confirmed in the USA experience of mandatory fortification where the rate of all cancers decreased post-fortification ^(Kohler et al 2011).

There is an obvious contradiction in the position that voluntary fortification of breads and cereals is safe (and is allowed by the government and supported by industry because it is safe and yields health benefits) but mandatory fortification at the same levels is unsafe. This stance is clearly illogical and highlights that "safety" is being used by industry as an argument against mandatory fortification when in fact this is not a legitimate argument, and the objection by industry to mandatory fortification is solely those of financial cost and compulsion.

A full discussion of the safety of fortification of bread with folic acid occurs in Part 2 of this report below, as safety is the key focus of the Smith and Refsum report, as safety concerns are the principal means by which the baking industry and the Food and Grocery Council seek to prevent mandatory fortification to be introduced, despite the contradictory position of being comfortable adding folic acid to up to 1/3 of breads currently.

In summary, the cancer registry of the USA demonstrates a **decrease in all cancers** since the introduction of mandatory fortification.

Safety of folic acid is likely to be related to dose. The only safety concerns which are reported and are controversial relate to high-dose supplementation, not to low-level population fortification. Two large meta-analyses (Clarke et al 2010, Wien et al 2012) with overlapping research populations demonstrate a trend towards increased risk of cancer which **is not** statistically significant, and occurs in the context of high-dose supplementation, not fortified food.

Another pooled study in Norway (Ebbing et al 2009) demonstrated that in older men who smoke, taking high dose folic acid and Vitamin B12 supplements somewhat increases risk of lung cancer. The dose of folic acid required to give this risk was on average in the studies 700 micrograms per day. At a fortification level of 140 micrograms/100g bread, the dose of bread required to give this overdose effect would be **nearly one loaf (500 g or 12 slices per day)**.

Barriers:

The barriers to mandatory fortification are:

- Industry resistance due to inconvenience and minor financial cost,
- Public concerns about additives in food of any kind. This is despite the fact that the initiative proposed involves replacing a natural and essential vitamin stripped from our diets by poor choices and excess processing. There is no public concern at the addition of Vitamin C to fruit juices, yet the scenarios are equivalent.
- A philosophy in a small minority of the public against compulsion of any kind. This philosophy states that no public health measures that target the whole population, in order to benefit a few, are justified, due to the primacy of individualism and autonomy. This philosophy rejects of the notion of the responsibility individuals in society have to each other, to the greater good. The doctrine of individual rather than collective responsibility has little interest in society's responsibility to the disabled.

Why not continue voluntary fortification, with an industry-monitored code of compliance?

Option 4, continued voluntary folic acid fortification of bread with an industry-regulated code of compliance is **not** a viable option in prevention of NTDs and other health risks associated with folate deficiency, and is **not** supported by PSNZ:

- Voluntary does not yield the full benefits in prevention of NTD pregnancies. In the latest MPI-sponsored survey (Bradbury et al 2011), 41% of women did not have RBC folate at the optimum level for preventing NTD of 906 nmol/L or above despite voluntary fortification. In that 2011 survey period, almost all women (93%) ate bread that week, but only 18% had eaten brands known to be fortified. The PSNZ estimates we have around 70-90 NTD pregnancies a year in NZ, and any voluntary programme is going to reach around half the people it needs to. A voluntary programme might reduce numbers of NTDs to 60, but not to the international optimum of 7-9/10000 per 10000 (40-50 per year in NZ terms) found in countries with mandatory fortification.

- Industry has made an effort since 2009 to introduce folic acid into some bread lines, despite their public opposition in 2009 to the introduction of mandatory fortification. This is because there was a **strong incentive** for industry to do this on a temporary basis, in the knowledge that a two year period of voluntary fortification was being monitored for efficacy by MPI. To prevent mandatory fortification being implemented in 2012, it was in the interest of industry to demonstrate voluntary fortification was successful, and so they had a significant incentive to add folic acid to bread lines.
- However, if industry is successful in preventing the 2007 Food Act requiring mandatory fortification to be introduced, they will have no further incentive to add folic acid, and given their opposition to fortification, it is likely that a **diminishing proportion** of breads will be fortified under a voluntary programme. This is likely to increase the number of women with deficient folate levels.
- There is already evidence that this trend has started. Industry undertook to fortify up to 1/3 of breads. However, this was implemented as 1/3 of bread lines (i.e. products) not by volume of bread produced. Total volume of bread fortified is currently identified by MPI as 12.5% (MPI discussion paper, page 20).

Conclusion:

The Paediatric Society of New Zealand strongly recommends the introduction of mandatory fortification, as planned in 2007 but deferred by two years in 2009, and further deferred this year. This would bring us in line with Australia, Canada and USA and more than 70 other countries that have successfully introduced mandatory folate in the food chain, and are now reaping the health benefits.

Mandatory fortification is effective, safe, and easy. Barriers exist to implementation but these are minor, and manageable with a public education campaign. PSNZ recommends that such a public education campaign be carried out at the time mandatory fortification is introduced, with the goals of:

- a. Raising the level of awareness of the nature and impact of Neural Tube Defects on affected individuals and their families
- b. Increasing the understanding of the negative economic effects on the Health Services in New Zealand, and the implications for availability of funds for other Health Services
- c. Correcting the misinformation that folic acid is a “medication” that is being added to bread, and ensuring the public understand that fortification with folic acid replenishes an essential vitamin that has been removed during processing
- d. Reassuring the public that folic acid is safe and that there is no clear evidence that folic acid fortification at the proposed level causes cancer, and that it may indeed be protective against some cancers
- e. That there are early indications of other possible health benefits.

PSNZ calls on the government to act now, and not to further delay this important health initiative.