

Submission to

**FOOD STANDARDS AUSTRALIA
NEW ZEALAND**

on the

DRAFT ASSESSMENT REPORT

PROPOSAL P295

**Consideration of Mandatory
Fortification with Folic Acid**

July 2006

ACA

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About ACA

The Australian Consumers' Association (ACA) is pleased to make the following submission to Food Standards Australia New Zealand (FSANZ) on the Draft Assessment Report (DAR) for Proposal P295 – Consideration of Mandatory Fortification with Folic Acid.

ACA is an independent, not-for-profit, non-party-political organisation established in 1959 to provide consumers with information and advice on goods and services, health and personal finances, and to help maintain and enhance quality of life for consumers. ACA provides consumer education, conducts surveys into consumer attitudes, lobbies for improved conditions for consumers and distributes unbiased consumer advice.

Independent from government and industry, it lobbies and campaigns on behalf of consumers to advance their interests. ACA is primarily funded through subscriptions to its magazines and website, fee-for-service testing and other related expert services. There is no government funding for normal running expenses of ACA, and no commercial sponsorship or advertising.

ACA has been involved in the debate around folate fortification since the 1990's. ACA was a member of the expert stakeholder advisory group that participated in the development of the policy guidelines for fortification. ACA is also a member of the FSANZ Fortification Standard Development Advisory Committee.

Health Impacts of Mandatory Folate Fortification

ACA appreciates the arguments for and against both mandatory and voluntary fortification of foods with folic acid, in an effort to prevent neural tube defects (NTDs). We can also understand the strengths and weaknesses of various strategies to increase folate consumption.

There is no question that NTDs are a serious health problem that have devastating social, emotional and financial consequences for families affected by them. ACA supports strategies that will successfully target women of childbearing age whilst protecting vulnerable and non-target groups from any potential negative impact of increased folate consumption. Ideally, folate fortification would reach women of childbearing age regardless of whether or not they were planning a pregnancy. In particular, folate fortification should reach women from low-socioeconomic groups who may not be able to afford folate supplements.

Mandatory folate fortification of bread making flour is a population-wide solution to a problem that affects only a small number of women. FSANZ estimates that the proposed fortification will reduce the incidence of NTDs by between 14 and 49 pregnancies each year, yet the mandatory folate fortification will affect 20 million Australians.

There is insufficient evidence to suggest that mandatory folate fortification of bread making flour will reach the target group. In fact, the DAR suggests that most women will not be able to achieve a daily intake of 400µg of folic acid – the amount

recommended to reduce the risk of NTDs – through food consumption alone. FSANZ states that women will still need to take folic acid supplements to achieve this level of folate consumption.

This suggests that mandatory fortification will not be successful in increasing the folate consumption of women of low socio-economic groups who cannot afford to buy folic acid supplements, nor those women who aren't planning a pregnancy and therefore taking supplements or seeking out foods rich in naturally occurring folate or synthetic folic acid.

ACA acknowledges that it is impossible to predict and prevent all adverse effects of increased folic acid consumption among all population groups. However, ACA believes that there is still sufficient scientific uncertainty about the risks associated with increased consumption of folic acid to postpone mandatory folate fortification.

The data presented in the DAR suggests that adding folic acid to all bread making flour will significantly increase the levels of unmetabolised plasma folic acid among some young children. On this basis, and given continuing uncertainty about the health effects of increased levels of unmetabolised plasma folic acid, ACA does not support the FSANZ proposal to fortify bread making flour with 200µg of folic acid per 100g, particularly when FSANZ has not presented any other potential food vehicles for consideration.

Food Vehicles

Based on information presented in the DAR it appears that FSANZ's consideration of potential food vehicles for mandatory folate fortification is limited to bread making flour. While Section 6 outlines the Codex criteria for selecting appropriate vehicles and justifies FSANZ selection of bread making flour as a vehicle for mandatory folate fortification, there is no evidence that FSANZ has considered any alternatives or conducted dietary modelling of other potential food vehicles for mandatory fortification before arriving at the conclusion that bread making flour is the most appropriate vehicle.

Without presenting information and dietary modelling for a variety of potential food vehicles, stakeholders are unable to make an informed and considered decision about mandatory folate fortification of bread making flour. ACA is concerned that the choice of bread making flour as a vehicle will increase the unmetabolised plasma folic acid levels of some young children. We would like to see dietary modelling of other vehicles that would minimise the impact on non-target groups. This might include adding folic acid to certain breakfast cereals (excluding children's cereals) or other cereal products, and low fat milk or dairy products.

ACA is also concerned that FSANZ has no plans to reconsider voluntary permissions for folate fortification. If mandatory fortification of bread making flour is implemented, this would not prohibit future applications to voluntarily fortify other foods with folic acid. Increasing voluntary permissions makes it more difficult to ensure that non-target groups do not consume excessive amounts of folic acid. FSANZ has established that some young children may have very high intake of folic

acid if bread making flour is fortified. ACA believes that FSANZ must reconsider current permissions for voluntary fortification such as the addition of folate to children's breakfast cereals and the levels at which products can be voluntarily fortified.

Another concern is that mandatory folate fortification of bread making flour will not reach members of the target population who are unable to consume wheat-based foods. The DAR does not present options for increasing the folate intake of women of childbearing age whose folate intake is unlikely to increase as a result of mandatory folate fortification of bread making flour.

Consumer Choice

ACA acknowledges that mandatory fortification may limit the capacity for consumers to avoid fortified foods if they wish to do so, or are advised to do so for health reasons. In principle, we support mandatory fortification as a way of addressing significant deficiencies and public health problems, provided it does not place other consumers at risk of health problems associated with excessive consumption of a particular nutrient.

However, ACA is not confident that the evidence presented in the DAR provides adequate assurance against the negative impacts of increased levels of unmetabolised plasma folic acid on non-target populations. Given this uncertainty and the fact that this is a population-wide measure to address a health problem that impacts on a small number of consumers, ACA believes that concern about restricting consumer choice is warranted. The proposed fortification of bread making flour would make it difficult for consumers to seek out non-fortified products.

Labelling

FSANZ states that folic acid would appear in the ingredients list of any product fortified with folic acid. Currently, any product making a nutrition or health claim about folate must list folate in the nutrition information panel. If mandatory folate fortification is introduced, ACA supports the inclusion of folate or folic acid on nutrition information panel of all fortified products. This would assist consumers to monitor their own or their family's intake of folic acid.

Monitoring and surveillance

Dietary modelling in the DAR is based on data from the 1995 National Nutrition Survey. This data is now 11 years old and the food supply has changed substantially in this time. Perhaps one of the most significant changes relevant to the current proposal is the permission of voluntary folate fortification of a range of foods.

ACA's support for any mandatory fortification is dependent on commitment to an extensive monitoring and surveillance program being established. A monitoring and surveillance program should include:

- Collection of baseline data before mandatory fortification is introduced
- Collection of data on folate intake and folate status of target and non-target groups
- More up-to-date data on consumption of the proposed vehicles by the target group
- Monitoring the incidence of NTDs (pregnancies, terminations, live births and stillbirths)
- Retrospective dietary intake assessment of women with NTD pregnancies
- Collection of data on potential negative effects of increased folate consumption e.g. twinning, masking of vitamin B12 deficiency, elevated levels of unmetabolised plasma folic acid
- Commitment of funds to enable ongoing collection of data to monitor the impact of fortification on target and non target populations and the success in reducing the incidence of NTDs

At this point there appears to be no funding committed to an extensive and ongoing monitoring and surveillance program. ACA believes it is irresponsible to consider implementing a population-wide fortification program without such a commitment. We are therefore unable to support the current proposal without assurance that adequate monitoring and surveillance will occur.

Education

Any strategy to reduce NTDs will not reach its full potential unless accompanied by appropriate education strategies. Consumers – more specifically, the target group – need to be aware of NTDs, the role of folate in preventing NTDs and how they can increase consumption of folate. Such a campaign needs to be running over the long term with women of childbearing age receiving a clear and consistent message from a variety of sources – media, GPs, nutrition education, food labelling etc.

Regardless of whether the decision is made for mandatory fortification, voluntary fortification or no fortification at all, consumers need to be aware of how they can increase folate intake through the consumption of folate supplement, foods rich in naturally occurring folate and food fortified with folate. If mandatory fortification is seen as the most effective public health strategy to reduce NTDs, then all consumers should be told of the impact folate fortification on target, non-target and vulnerable groups.

FSANZ acknowledges that to be most effective, education must be sustained. The report also indicates that FSANZ will collaborate with other organisations to inform stakeholders (including consumers) about any new standard for mandatory folate fortification and the importance of increased folate consumption among women of child-bearing age. However, the DAR provides no detail on the proposed communication and education strategy, and it is unclear whether any funding has been allocated specifically for the purpose of consumer education or whether agencies and organisations must take it on in addition to or at the expense of other work.

Resources and funding for education should be allocated prior to a decision on mandatory fortification. While we understand that FSANZ's capacity for consumer

education is limited, it is important that consumer education focuses not just on the fortification standard but the impact of folate consumption on target and non-target groups.

Preferred regulatory option

As noted above, ACA appreciates the devastating impact that NTDs can have on individuals and families affected by them. However, we do not believe that this is sufficient justification for the reduced consultation process and a hasty decision on the need for mandatory fortification, particularly as mandatory fortification of bread making flour will have consequences for the broader population. ACA is also disappointed that only two regulatory options were proposed in the DAR.

While not theoretically opposed to the concept of mandatory fortification, in the absence of any firm commitment of funds to undertake research and evaluation, and given the increasing body of literature urging caution in the face of unknown and unintended impacts of folate fortification, ACA does not support the current proposal for mandatory folate fortification of bread making flour at a level of 200µg per 100g.

In its submission to the FSANZ Initial Assessment Report, ACA's preferred regulatory approach was to postpone further folate fortification decisions until more data was obtained about folate consumption, the prevalence of NTD among different groups of women and the costs and benefits of folate fortification, including the capacity to reach target groups. ACA also supported increased health promotion and education. This continues to be ACA's preferred regulatory approach.

Before making a final determination on mandatory fortification of bread making flour ACA calls on FSANZ to:

- give further consideration to new research that has come to light since the release of the draft assessment report; and
- conduct dietary modelling of alternative food vehicles.

Health Ministers must also ensure sufficient funds are available for baseline data collection and ongoing monitoring and surveillance of mandatory folate fortification, as well as an extensive health promotion and consumer education campaign.

Once again, ACA appreciates the opportunity to provide these comments and trusts they will be given adequate consideration during the final stages of the standard development process.