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Productivity Commission
Regulatory Burdens – Manufacturing & Distributive Trades

The Flour Millers' Council of Australia ('FMCA') is the peak body for the Australian flour milling industry. We represent the views of the industry and seek to communicate the industry's concerns to governments, statutory authorities and other organisations.

We write to express our concerns in relation to the 13 September 2007 gazettal of changes (under FSANZ Proposal P295) to the Australia New Zealand Food Standards Code ("the Food Standards Code") which will impose a mandatory legal obligation on flour millers to fortify bread-making flour with folic acid at a set concentration.
From 13th September 2009 it will be illegal for a flour miller to supply flour for bread making that has not been fortified with folic acid

What is the legislation?

From the 13th of September 2009 wheat flour for making bread will be required under Clause 4(2) of Standard 2.1.1 of the Australia New Zealand Food Standards code to contain "no less than 2 mg/kg and no more than 3 mg/kg of folic acid". This is separate to and additional to the current requirement that wheat flour for making bread also contain "no less than 6.4 mg/kg of Thiamine".

What is the background and intention / underlying objective?

A study was commissioned by FSANZ and was conducted for FSANZ by Professor Carol Bower of the University of Western Australia. The study found that at the amount of fortification recommended by FSANZ (which is aimed at increasing a person's daily intake of folate by 100 µg), an estimated 27 cases of Neural Tube Defects in babies will be prevented in Australia out of a total of between 125 cases and 153 cases of Neural Tube Defects per year in Australia (based on historical data).[1] **This is based on the assumption that the fortification of bread at the levels prescribed by FSANZ will increase everyone's daily intake of folate by 100 µg**. This assumption means that the estimate of 27 prevent cases of NTD's per year will become incorrect if a proportion of the population does not consume bread. The claimed benefit of mandatory folic acid fortification in Australia is therefore less than 27 babies per year in a country with a population of over 21 million people and with a current annual birth rate of approximately 105,000 babies.

As mentioned above, FSANZ has not considered the extent of possible adverse health effects of excessive consumption of folic acid from folic acid fortification. It must be noted that while the benefits are limited to a maximum 27 babies whose mothers must also have

[1] Carol Bower, *et al*, "Assessment of the potential effect of incremental increases in folic acid intake on neural tube defects in Australia and New Zealand" *Australian and New Zealand Journal of Public Health* 30(4) (2006) 369 – 374.

consumed fortified bread products prior to and during pregnancy, the risks of adverse health effects from excessive consumption of folic acid will be borne by the entire Australian population of over 21 million. It would only take a very small percentage of people to suffer from the adverse health effects of excessive folic acid consumption to offset the benefits to the 27 babies.

What is the problem?

In setting this standard FSANZ has continually neglected advice from the flour milling industry that a micro addition between an upper and lower level with range of 1ppm is beyond the capability of the flour milling process.

Flour Millers worldwide have a long history of fortification of flour, based on achievement of a minimum standard. This is achieved by allowing a conservative overage in addition so that the legislated minimum level of addition is achieved. It is a unique requirement to expect that in the flour milling operation that control within a finite range of 1mg/kg (1 part per million) can be achieved in the flour milling process.

The Flour Millers' Council of Australia obtained expert opinion[2] that detailed capital and ongoing costs that would be incurred by the flour milling industry in Australia if it was to make a best endeavours' response to meeting the legislative requirement. Even so, given the technical, operational and logistical constraints, for flour mills to continuously meet customer supply, this standard is not achievable in the high volume, macro environment of the flour mill.

To achieve micro ingredient additions such as for bread improvers, concentrates and bread mixes, batch mixers are used. This is high cost and low throughput and only applicable to high-value concentrates. Folic acid could easily be included as an ingredient in these mixes.

The flour milling industry must be able to go about its business of flour milling to continuously supply customers unimpeded by fortification requirements. This is currently the case with the equipment and systems used to fortify with thiamin to a minimum requirement only. Fortification in the flour mill by necessity must be incidental to the main business of flour milling.

Another major problem with this legislation is that the reason well announced by FSANZ to include an upper limit of addition for this legislation is for health & safety reasons. There are a number of health concerns associated with excess intake of folic acid. FSANZ has used this form of legislation to alleviate challenges to health & safety concern. Since the miller is unable to continually satisfy this limit millers are subjected to the potential consequence of future legal liability due to non compliance. If at some point in the future the potential health risk actually becomes subject of a class action & millers are unable to demonstrate legal compliance with the legislation they will be liable. This is further exacerbated by inability to either get insurance to cover this potential liability or premiums which are not affordable.

What failings are identified?

FMCA has obtained expert legal advice which states;
'We believe that the decision to change the Australia New Zealand Food Standards Code to introduce mandatory fortification of wheat flour for bread-making was made through a decision-making process that was legally flawed because;

[2] Eliott, Richard "Addition of Folic Acid to Flour for Making Bread", *FMCA Report* (Feb. 2007)

- The procedures required by the Food Standards Australia New Zealand Act 1991 and Ministerial Council directions were not followed
- There was a bias and certainly apprehended bias in the way in which the decision was made
- The assessment of the safety of the proposal was incomplete and based on flawed assumptions
- There was a failure to make any assessment that addressed the practicalities of implementation'

The Australia New Zealand Food Regulation Ministerial Council ('the Ministerial Council'), prior to gazettal of the new Food Standard, had raised concerns over FSANZ's previous assessment of the Proposal and had requested a review of FSANZ's recommendations. Yet, this "review" by FSANZ has failed to address the initial concerns of the Ministerial Council and has certainly disregarded all of the concerns of the Australian flour milling industry.

Despite a long and costly process and despite expert advice from the flour Milling industry throughout the consultative process Food Standards Australia and New Zealand (FSANZ) has recommended legislation which is internationally unique and not achievable in commercial milling practice.

The Australian & New Zealand flour milling and baking industries have overlap in that key players operate in both countries, the industry structures, technical operations and other aspects of the industries are similar, yet New Zealand opted out of the legislation and implemented it so that folic acid is not added at the flour mill but at the bakery. There is no reason why this should be different for Australia.

Of great concern is the selective use of consultant reports by FSANZ throughout the process. Non recognition of the Eliott report has been referred to. A consultant's report on the Australian & New Zealand baking industries that acknowledged that fortification at the bakery (via concentrates/improvers) was preferred to the flour mill was also dismissed. A thorough evaluation of risk and cost effectiveness was carried out by Professor Leonie Segal[3], for some reason at such a late point in proceedings that it was not available at the time of circulation of the First Review Report (May 2007) and become available later. This excellent cost effectiveness comparison of a range of options for delivering the benefits of folic acid fortification to the target population was in reality not available for genuine consideration as part of the consultative and decision making process.

Quantify the burden, cost, restriction

In its First Review Report, FSANZ recognised that, as a result of mandatory fortification, there will be significant costs to industry. FSANZ estimated such costs to industry as $7.9 million up-front and $1.1 million per year, but this estimate was based on FSANZ's flawed assumption that there will be no need to change any of the flour milling process. FSANZ also disregarded the industry costs of new monitoring, audit and analysis methods that will be required by all flour millers in order to ensure compliance. The FMCA had submitted to FSANZ in July 2006 a cost estimate of $28.6 million up-front and $12.1 million per year to the milling industry to make best endeavours approach to comply with the indicative legislation. These figures were produced in the four weeks provided for submission to a proposal which included the concept of upper & lower control levels for the first time.

[3] Segal, "Informing a Strategy for increasing folate levels to prevent neural tube defects: A cost-effectiveness analysis of options", *FSANZ Report* (13 April 2007)
FSANZ website: http://www.foodstandards.gov.au/_srcfiles/P295_Attachment_4_Professor_Segals_Report.pdf

To support and confirm industry concerns in this regard FMCA contracted an independent milling consultant to provide a totally costed proposal for mills to make a best endeavours attempt to meet proposed legislation. These figures for the Australian Milling industry were; Capital cost $22.1 million up front and $11.9 million per annum. The approach taken by Eliott was subsequently supported by an independent report commissioned by Australian Food & Grocery Council (AFGC) through BRI Research[4].

FSANZ supposedly used international comparisons as the basis for measuring the likely cost in Australia of implementation for the Australian flour-milling industry (First Review Report p 52-53). Yet aside from international cost figures being irrelevant to the Australian position, FSANZ itself did in fact acknowledge that the Australian mandatory Standard will be different from the position in every other country because all other countries simply set a minimum level of fortification and not a strict range (First Review Report p 53). Moreover, FSANZ failed to recognise the significance of this difference on the likely costs of implementation. Where a minimum level is set, manufacturers can simply add more than the required amount to ensure compliance with the Standard, but where a strict range is prescribed, this means there is also a maximum limit on fortification that must be met in order to meet compliance. Therefore, there is a need to employ extra equipment, and more analytical testing needs to be conducted to ensure compliance, particularly where there is a risk that excessive amounts will lead to adverse health effects.

What would Best practice consist of?

An outcome based standard that would deliver the intended result to the target population with minimum detrimental impact on the non target population with minimum cost and burden to industry and consumers is clearly an ideal outcome.

What is required to be delivered is an average intake of folic acid over time with bias towards the target population. This requires removal of prescriptive limits and appropriate selection of carrier foods stuffs. It also requires that Government Health Departments monitor consumption patterns over time and relate results to the intended Health Outcome, reduction of Neural Tube Defects. In this way targets and practices can be reviewed over time. Again ideally Government and industry could work co-operatively to achieve the desired outcomes.

Consumer choice should be preserved. This has effectively been eliminated. FSANZ have precluded organic bread from the standard and claim that consumers can choose to avoid folic acid by buying organic bread (this is considerably less than 0.5% of production).

Are there other reissues?

The new Food Standard is bad law and policy because:

1. Food prices will increase substantially because of FSANZ's decision to introduce this new Food Standard.
2. The new Food Standard cannot be enforced except at great cost to industry and consumers and the tax-paying community.
3. **The new Food Standard will make bread unsafe for many consumers.**

[4] McCorquodale, "An Evaluation of Two Reports on the Proposed Mandatory Fortification of Flour with Folic Acid in Australia", *BRI Research Report* (April 2007) **Commercial in Confidence**

4. There are insufficient benefits when weighing up the requirements of this new Food Standard against the health risks and retail price uplift and additional industry costs.
5. The FSANZ decision to require mandatory fortification of flour with folic acid is inconsistent with FSANZ's legislative objects.
6. The decision will adversely affect Australia's export opportunities.

FSANZ's safety assessment of the mandatory fortification Standard is based on the assumption that folic acid can in fact be consistently added at levels within the prescribed ranges. Given evidence in the US that mandatory fortification has led to most fortified products containing more than the regulation amount of folic acid,[5] and given that FSANZ has stated that enforcement agencies have indicated that the new Standard will not be strictly enforced, the safety assessment needs to be extended to situations where excessive amounts of folic acid (within reasonable limits) have been added to the flour.

There are insufficient benefits when weighing up the requirements of this new Food Standard against the health risk and retail price uplift and additional industry costs

Further, FSANZ decided that bread-making flour would be the most effective carrier for folic acid despite admitting that the real target population consumes does not consume a large amount of bread. At page 54 of Attachment 7 of the First Review Report, FSANZ stated:

> *"Generally**, lower proportions of women of child bearing age with low folic acid intakes consumed breads**, breakfast cereals, yeast extract spreads, milks, fruit juices and soy beverage than those with high folic acid intakes. Additionally, women of child bearing age with low folic acid intakes, on average, consumed lower amounts of these foods than those with high folic acid intakes. There did not appear to be a food consumed preferentially by women of child bearing age with low folic acid intakes that was feasible to fortify. The one possible exception was **natural yoghurt and reduced or low fat flavoured yoghurt, which was consumed in greater amounts by Australian women in the low folic acid intake group**, as was diet/low fat yoghurt in New Zealand, **but by a relatively low proportion overall of the women of child bearing age** (<10%) so did not meet the criteria for a suitable mandatory fortification vehicle[31]. However these data would support the consideration of low and reduced fat natural and flavoured yoghurt as a suitable food for voluntary fortification permissions in the future in addition to those currently in place, as it is intended under the current mandatory fortification proposal that voluntary permissions to add folic acid to certain foods remain in the Code"*

Males

Another issue to consider is that the fortification of bread with folic acid does not have any demonstrated benefit for males. There is no evidence of any folate deficiency amongst Australian males and no scientific evidence that folate deficiency amongst males can considered a serious public health concern. If the new Standard is allowed to take effect, it would seem that the entire male population is unnecessarily being put at risk of excessive folic acid consumption without any real demonstrated benefit.

The FSANZ decision to require mandatory fortification of flour with folic acid is inconsistent with FSANZ's legislative objects

[5] Rader, et al, "Total folate enriched cereal-grain products in the United States following fortification" *Food Chemistry* 70 (2000) 275-289

Section 18 of the *Food Standards Australia New Zealand Act 1991* states:

The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:

> *the protection of public health and safety; and*
> *the provision of adequate information relating to food to enable consumers to* ***make informed choices****; and*
> *the prevention of misleading or deceptive conduct.*

Considering the lack of a significant public health benefit (especially for male consumers) and considering the possible risk of adverse health effects from excessive consumption of folic acid, there does not seem to be any justification for FSANZ to have ignored legislative objectives of FSANZ in developing or reviewing food regulatory measures.

The decision will adversely affect Australia's export opportunities

The decision by FSANZ to require mandatory fortification of bread-making flour is likely to have an impact on the export markets of the flour industry as well as the bread industry.

The Australian mandatory fortification Standard set by FSANZ requires folic acid fortification at a level higher than the maximum levels in many other countries (including the US). There are even some export partners that do not allow fortification of bread or bread-making flour. Fortification at this level, therefore, will mean that unless the flour millers can produce one batch of flour for export and a separate fortified batch for the local market, Australian bread-making flour will no longer be allowed into many of Australia's export markets.

Are there alternatives?

There are alternatives to mandatory fortification with folic acid as well as alternatives to the point of introduction of folic acid in the supply chain.

Irrespective of fortification of the food supply with folic acid women of child bearing age must still take a folic acid supplement to achieve the recommended minimum level of folic acid intake.

An industry proposal for an enhanced voluntary fortification with folic acid to an enhanced range of products better targeted to women of child bearing age was shown to give an outcome close to that of mandatory fortification but with greater cost effectiveness (Segal) and lesser health consequence for non target populations. This option was eliminated from consideration by FSANZ during the consultative process.

Folic acid can be easily incorporated into a number of manufactured foodstuffs. It can be incorporated in bakery concentrates & improvers and complete bread mixes which are all high value ingredients including made up of a range of high cost ingredients included at low concentration at accurate levels. These are manufactured by precise weighing of ingredients and mixing in batch mixers with relatively low output volume. Concentrates, improvers and bread mixes are included in bread doughs at the bakery.

General comment on the food regulatory system

The flawed nature of the FSANZ standards setting process is certainly reflected in the whole manner of introduction of this standard for mandatory fortification of bread-making flour. However it may well be an example of a systematic problem in FSANZ whereby FSANZ appears to have become reticent about undertaking rigorous scientific assessments.

In the past year senior personnel of FSANZ have publicly admitted that carrying out a scientific assessment into food safety might not be possible and that FSANZ accordingly will act merely in accordance with what it perceives to be the policy position of the Ministerial Council. The following quotation from the annual report of FSANZ written in June 2007 by the then acting chief executive of FSANZ is quite revealing in this regard.

> 'we recognize the value of the food industry to the national economy and the need to facilitate , innovation and trade. There is no magic formula to getting the balance right… but of a leader most effective feedback on whether we have succeeded in getting the balance right comes from the Ministerial Council... getting the balance right is more of an art than a science. However, our processes and culture allow us to do better than expose a wet finger to the wind. There is method even in our subjectivity.'

We believe that this approach by FSANZ demonstrates a serious failure. As a government scientific risk assessment body with a primary objective of the protector of public health and safety, FSANZ ought to be independently assessing the impact of regulatory measures on the public using recognized scientific methods. The approach taken by FSANZ in setting the flour mandatory fornication standard (Clause 4 (2) standard 2.1.1) not only compromise the independence of FSANZ has the potential to cause a serious loss of public confidence in the FSANZ standard-setting process and the food standards generally.

A flawed process in the introduction of the standard certainly has exacerbated the risk of an imminent loss of confidence by Australian consumers in the National food safety assessment processes. Given the raison d'etre of FSANZ and the Australia New Zealand food standards code and the objects of the legislation under which FSANZ and the ministerial Council operate, the ministerial Council, if not FSANZ itself, needs to review the current standard before implementation proceeds.

20 March 2008