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NEW ZEALAND FOOD & GROCERY COUNCIL

13 July 2012

Food Policy Team
Biosecurity, Food and Animal Welfare Directorate
Ministry for Primary Industries
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Dear Sir/Madam

Attached is the submission from the New Zealand Food & Grocery Council concerning the consultation on **The Future of Folic Acid Fortification of Bread in New Zealand**, MPI Discussion Paper No: 2012/02.

Yours sincerely

A handwritten signature in black ink that reads 'Katherine Rich'. The signature is written in a cursive style and is underlined with a simple horizontal line.

Katherine Rich
Chief Executive

Ministry for Primary Industries
The Future of Folic Acid Fortification of Bread in New Zealand
Discussion Paper No: 2012/02
16 July 2012

The New Zealand Food & Grocery Council (the “FGC”) welcomes the opportunity to make a submission on the Ministry for Primary Industries (MPI) Discussion Paper No: 2012/02 titled *The Future of Folic Acid Fortification of Bread in New Zealand* (the Discussion Paper).

The FGC represents the major manufacturers and suppliers of food, beverage, and grocery products in New Zealand. A number of these manufacturers and suppliers are major importers and exporters. FGC member companies supply over 95 percent of the processed food and beverages to the New Zealand grocery retail industry and over 70 percent of supermarket packaged good sales, including ‘natural health products’. Bread is a major category in the grocery retail industry, and FGC’s relevant members include George Weston Foods and Goodman Fielder. Fortification is, of course, an issue of interest for the whole food industry, particularly for categories such as breakfast cereals, dairy, and beverages.

The FGC understands that the Discussion Paper presents four options for the future fortification of bread in New Zealand, ranging from full mandatory fortification to full voluntary fortification.

The FGC has been an active member of the MPI Folic Acid Working Group over the past three years and has appreciated the opportunity to participate in the forum with colleagues representing a wide range of interests in the folic acid debate. We are appreciative of MPI’s approach to the Working Group which has been both professional and fair, and believe it has provided a mechanism for views to be aired, issues discussed, and research reported.

However, it is important that before Government decisions are made that this discussion returns to the fundamental question of whether in 2012, some decades after calls for mandatory fortification were first made and significant population health improvements have been made, mandatory intervention to dose an entire food category is appropriate in a modern nation. This is a particularly a valid question in light of statistics which show a dramatic decline in the number of Neural Tube Defects to a point over the last decade where some suggest the current New Zealand rate is already at a ‘floor’ level beyond which there is unlikely to be little improvement for the

target group, but potential harm for the non-target population. As academics Skeaff, Green and Mann aptly summarised the conundrum facing New Zealand decision-makers in New Zealand in their New Zealand Medical Journal paper in 2003¹, *“Preventing even one case of spina bifida is a priceless relief for the afflicted child or family, but is the prevention of four cases of spina bifida each year sufficient justification for accepting the risks of exposing four million people?”*

Estimated numbers of Neural Tube Defects and the New Zealand population have been updated nearly ten years later, but the question for officials and the Government remains exactly the same.

OVER-ARCHING COMMENT

The FGC supports voluntary fortification (Option 4) and believes this has been shown to be effective in achieving the Government’s aim to improve folate levels in women over the past two years. The implementation of the current voluntary programme was a significant initiative within the industry and has demonstrated that the industry is serious about helping the Government meet national health goals by targeting the relevant group in the population (women of child bearing age). In 2009, statements by the Prime Minister made it clear that if the Government was to decide to defer a mandatory standard then industry was expected to demonstrate good faith by implementing its own voluntary initiative. Industry took this message seriously and acted accordingly.

In light of the upcoming decisions concerning whether or not to mandate folic acid fortification it is important to recognise that since the 1990s, nutrition and awareness has improved and the rate of Neural Tube Defects (NTDs) within the community has dropped dramatically. NTDs are now at a point where some experts have suggested that New Zealand’s current rate of folate-sensitive NTDs is at a “floor level” and “that due to the already very good folate status in New Zealand any additional beneficial effect is probably limited”².

As an intervention, dosing an entire food category to reach a target population group of New Zealanders is a significant step. While the debate in favour of mandatory fortification has focused on NTDs, limited attention has been paid to potential effects on other New Zealanders, particularly men, children, and the elderly.

We note that supporters of full mandatory fortification dismiss suggestions that there is any potential health risk to the non-target population at all, but given the advice we have received and shared with the Folic Acid Working Group and MPI (as contained in A. David Smith and Helga Refsum’s literature review, *An update on folic acid fortification: benefits and risks 2012*), an outright dismissal is neither sustainable nor responsible. It is extraordinary that despite sharing recent reports and advice commissioned to inform the current process, no effort has been made to seriously

¹ <http://journal.nzma.org.nz/journal/116-1168/303/content.pdf>

² p1 *An update on folic acid fortification: benefits and risks 2012*, A David Smith and Helga Refsum, Feb 2012 available at http://www.fgc.org.nz/myfiles/An_update_on_folic_acid_fortification.pdf

consider the potential effects on other New Zealanders. Nor has there been discussion on seeking estimates of more recent data based on that gathered to date.

The significance of the step that might be considered to mandate fortification can also be informed by actions in other countries. The MPI consultation document notes that 59 other countries have mandatory fortification programmes in place to varying degrees. While the number of countries sounds significant, it is worth considering the list itself. With only a few exceptions the majority of countries are either Third World or developing countries with which New Zealand has little in common in terms of nutrition issues and general population health. This is the case, for example, with Uganda, Kazakhstan, Uzbekistan, Nigeria, Ghana, Guatemala, and Iraq. It's noteworthy that no countries in Europe have opted for mandatory fortification, while Ireland and the United Kingdom have currently stalled plans.

FGC members take their responsibilities very seriously and will work hard to ensure they follow the laws and regulations of New Zealand. Whether the outcome is voluntary or mandatory it is important to record that the resulting fortification programme is in response to the Government's clear direction on this issue. It would be hoped that voluntary fortification across a number of food groups would deliver the establishment of a base level of folic acid in the diets of the target population. While not fully protective, this is seen as a significant improvement over the alternative for some which could be very low even though it has been reported³ that "The folate status of NZ women is now the same as or better than, that of women in the USA several years after mandatory folic acid fortification."

Voluntary fortification does not carry the regulatory overheads that a mandatory programme necessarily entails. As well, by not taking a blanket approach to all bread products it provides greater choice for consumers, some of whom may wish to limit their folic acid intake.

Option 4 suggests a further review. The FGC is not supportive of a review in three years' time to assess ongoing effectiveness. It is important to decide on an approach so there is certainty. Rather, FGC suggests that annual reporting and monitoring provides the opportunity for regular refinement by agreement, and that such annual reviews, whether by meeting or through a desktop analysis of the available information by MPI, is the preferred and most cost-effective approach. Should the need arise, the Government can call for a review at any time.

The FGC is not opposed to mandatory reporting (Option 3) per se, but is opposed to mandatory reporting until a comparable voluntary reporting process has been devised by MPI and industry, and is implemented and evaluated. That is, mandated reporting should be considered only if voluntary reporting by industry is assessed as having failed. In a small country with a small number of participants, a reporting process can be agreed to and abided by without resorting to the law books.

³ p14 Ibid

DETAILED COMMENTS

Consumer and health impacts

The folic acid fortification debate has been active in New Zealand for at least the past two decades. The key issue is the impact on the rate of NTDs, the impact on the target population (women of child bearing age), the impact on other groups in the population (men, boys, and the elderly), and the impact on consumer choice.

Impact on the target population

The MPI Discussion Paper contains a table setting out the incidence of NTD-affected pregnancies in New Zealand between 2001 and 2008⁴. This states that the reported level was 34 NTD births or 5.4 per 10,000 births in 2008. This data is now four years old (the New Zealand Birth Defects Register now shows data for 2009 but the Discussion Paper does not use this) and does not reflect the position since the introduction of voluntary fortification of bread in 2009. The prevalence of NTDs in New Zealand was decreasing up to 2008 and may now have reached a significantly lower rate than that recorded in 2008.

The FGC believes that the decision on fortification should not be made in the absence of more recent NTD data. We understand that data for 2009-2011 is available. We strongly suggest that MPI request this information so decisions can be made based on the most current information. Even if this information is not yet appropriate for release in the public domain or is not finalised, estimated data should be used. MPI officials should ask to see the current information held by the New Zealand Birth Defects Monitoring Programme (NZBDMP) in confidence so the Minister for Food Safety is able to make decisions with the best information available.

It is our understanding that available non-published data will confirm that NTD rates have continued to trend downwards considerably, to what is probably a floor level for folate-sensitive NTDs, and to a rate that is likely to be the lowest in the developed world. The Minister must have the opportunity to make decisions based on the latest data rather than that which is four years old and does not include what is known to be a significant drop in the years following.

In any event, recent blood folate levels suggest that more than half of the women tested in research commissioned by MPI and conducted by the University of Otago had a blood folate status that would be associated with women taking a 400µg daily folic supplement⁵. Though this result cannot all be attributed to voluntary fortification of bread (since a range of breakfast cereals and spreads are also permitted to be fortified), the status in so many women is a very positive outcome.

Awareness clearly plays an important role and consumer awareness is relatively high. Again, this could be attributed to many elements, but the debate around fortification

⁴ p24 *The Future of Folic Acid Fortification of Bread in New Zealand*, MPI Discussion Paper No: 2012/02, May 2012 available at <http://www.foodsafety.govt.nz/elibrary/industry/fortification-bread-folic-acid/folic-acid-discussion-document.pdf>

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

over the past few years will have contributed to that awareness⁶. Research commissioned by the New Zealand Food Safety Authority shows that just over half (54%) of the total sample mentioned, on an unprompted basis, that folate and/or folic acid was needed before or during pregnancy⁷, while 95% of women had heard of folic acid⁸.

Impact on other groups in the population

Unlike other mandatory fortification programmes, the target for any potential folic acid intervention (women of child-bearing age) is a subset of the overall New Zealand population.

We do not doubt the sincerity of those who see mandatory fortification as a way of preventing rare birth defects. However, the significant issue that needs to be considered by Government decision-makers is what, if any, potential harm there might be to other New Zealanders from such an intervention.

Though little, if any, research has been conducted in New Zealand on the health effect of folic acid fortification on groups in the population other than the target group, research conducted overseas and reported in the literature review commissioned by the Bakers Research Trust and the FGC suggests there are risks in the consumption of folic acid by non-target groups such as the elderly (impacting on vitamin B12)⁹, and interactions with anti-folate drugs making them potentially less effective¹⁰. The more complex relationship is between folic acid fortification and cancer. As Smith and Refsum report¹¹, "Population studies in countries that have already fortified are difficult to interpret but a recent meta-analysis on 10 trials (38,000 people) ... show an overall 7% increased risk of new cancers, with a 24% increased risk in prostate cancer." The science continues to evolve so studies around folic acid fortification and cancer need to continue to be monitored over time.

Estimates of health costs of NTDs for families and individuals are not questioned, but it is important for Government decision-makers to take a whole-of-population approach to costs and to consider potential costs to other New Zealanders as a result of the non-target population potentially consuming too much folic acid in the diet. As the Smith and Refsum report concludes "although fortification might prevent up to 6 NTD pregnancies per year, thousands of people may possibly suffer harm"¹². Scientific study will continue to shed light on this issue, but certainly the evidence which underpinned concerns raised during the 2009 public discussion about unintended consequences of mandated folic acid fortification continues to firm.

Impact on consumer choice

Since voluntary fortification of bread with folic acid was implemented in 2009, choice has been preserved. There is a group of consumers who are strongly opposed to

⁶ *Awareness and Knowledge of Folate and Folic Acid: A Survey of New Zealand Women of Child-bearing Age*, Research New Zealand, February 2011 available at <http://www.foodsafety.govt.nz/elibrary/industry/folate-NZ-women.pdf>

⁷ p18 Ibid

⁸ p19 Ibid

⁹ p27 *An update on folic acid fortification: benefits and risks 2012*, A David Smith and Helga Refsum, Feb 2012 available at http://www.fgc.org.nz/myfiles/An_update_on_folic_acid_fortification.pdf

¹⁰ p28 Ibid

¹¹ p46 Ibid

¹² p56 Ibid

fortification just as there is a group of consumers strongly advocating fortification. Meeting the needs of both groups is about balance.

Consumers in New Zealand can choose to purchase fortified or unfortified breads since some 85% of production is not fortified. However, 34 packaged breads covering a broad range of the packaged breads sold in supermarkets are currently fortified.

Continuing Voluntary Fortification

As a Government-encouraged initiative, voluntary fortification of bread with folic acid is working: the range of breads fortified has greatly increased since 2009, blood-folate status levels of the at-risk population have increased, and the prospect is that the incidence of NTDs per 10,000 births has decreased.

Improving voluntary fortification

Voluntary fortification could be improved. The monitoring report commissioned by MPI showed that in five of the 17 breads tested the level of folic acid was low or negligible. The technical problems of adding folic acid to production in order to deliver the target level of 200µg per 100g of bread is difficult, but not completely unachievable.

Uptake might be expanded. Some 34 lines of packaged breads represents around 12.5% of total New Zealand production, suggesting there is still a lot of choice. A target level of uptake could be identified between MPI and industry that would increase the percentage of production fortified while retaining choice.

An industry Code of Practice would greatly assist in expanding uptake, but also in improving consistency of fortification. FGC is opposed to “an approved Code of Practice” being a feature of any future standard. There are several problems that reference in the standard entails:

- A legislative reference to a Code of Practice may or may not bring the Code of Practice itself within the ambit of the law (depending on the form of the standard) and thus expand the level of prescription of the standard significantly.
- A Code of Practice needs to be able to be flexible and reflect changes in technical applications as developments occur. This may or may not be possible if legislatively “approved”.
- More complex issues arise if the standard is to form part of the Australia New Zealand Food Standards Code (possibly as a New Zealand variation to the existing standard applying in the Australia) since the Food Standards Australia New Zealand Act provides for Codes of Practice but with limited regulatory application.

The bottom line is that if a Code of Practice is considered by industry and the Government to be a valuable tool for voluntary fortification – and this does seem to be the case – then it should be done. This is a practical step to take within the overall framework of voluntary fortification.

Cost of voluntary fortification

It is important to note that the preservation of choice for consumers rather than cost implications has been the primary industry concern during this consultation. However, in general, non-regulatory approaches to address issues are less costly than regulatory

measures because they do not carry with them the often high costs of administration, compliance, and enforcement. But to be effective there is a cost, and the cost of voluntary fortification is no exception. Direct costs are estimated at around half a cent per loaf of fortified bread produced. With the current level of fortification this amounts to direct ongoing costs of around \$155,000 per annum, noting that this excludes changeover, reporting, audit, and testing costs.

Monitoring and reporting in a voluntary scheme also costs. The MPI monitoring project costs would need to be factored into the ongoing data-collection process, as would reporting by industry and the cost of data collected by the New Zealand Birth Defects Register.

Reporting and monitoring

A standard industry reporting mechanism has not been developed/agreed by MPI and industry. Neither has a regular programme of monitoring. MPI commissioned research that was population specific to determine the impact of voluntary fortification. Part of this research necessarily involved a snapshot of the extent and level of fortification of the bread supply. The industry reported separately on its activities.

A standard reporting mechanism for the future could bring elements of these together to regularise the information that might be collected over time. This could be supplemented by regular (annual) testing of breads. Added to production reporting and test reports, the data on NTDs, whenever available (noting the current lag for the Birth Defects Register is over four years), would then provide an overall picture of the status and impact of folic acid fortification in New Zealand at any point in time. This level of information would, in turn, inform decisions over the next decade and beyond.

Though the FGC is not opposed to mandatory reporting (Option 3) per se, it is opposed to mandatory reporting until a comparable voluntary reporting process has been devised by MPI and industry, implemented and evaluated. That is, mandated reporting should be considered only if voluntary reporting by industry is assessed as having failed. In any event, FGC is opposed to mandating notices in bakeries setting out their position on folic acid fortification, as is suggested in the Discussion Paper¹³.

Future Evaluation

In order to monitor the breadth and impact of folic acid fortification over time, the following data is necessary:

- Up-to-date data on NTDs. It is concerning that major decisions are being made about the fortification of the New Zealand food supply without the most up-to-date and accurate data. Even if not published, such data could be presented confidentially to the Minister's office. The Government must make its decision based on the best data available.
- Industry reporting on production, sampling and testing of levels in breads.
- Data on that group in the population not receiving any folic acid and those receiving excessive amounts.
- Further monitoring of blood folate levels in women.

¹³ p28 *The Future of Folic Acid Fortification of Bread in New Zealand*, MPI Discussion Paper No: 2012/02, May 2012 available at <http://www.foodsafety.govt.nz/elibrary/industry/fortification-bread-folic-acid/folic-acid-discussion-document.pdf>

- Continued monitoring of the more complex relationship between folic acid fortification and cancer.

This data needs does not change between mandatory and voluntary arrangements. However, its completeness may vary and only through evaluation over time would this become evident and steps taken to address any failings. Similarly, timeliness of data is important and time lags in the supply of data needs to be factored into evaluation and subsequent decision-making.

Finally, the results of monitoring the impact of mandatory fortification in Australia are yet to be published. This data could also inform future developments in New Zealand. It would be interesting, for example, to review up to date Australian data on new prostate cancer cases if available.

The FGC does not support mandating a review of voluntary fortification within a specified period. Rather, FGC has suggested above that annual reporting and data collection from other sources should be implemented. Compilation and broader reporting conducted annually by MPI would deliver an added benefit: maintaining a level of interest and supplementing awareness activities every year. Should the data suggest the need for a more concerted review, the Government would be able to respond appropriately either by calling for such or seeking views of stakeholders through forums such as has been effected through the Folic Acid Working Group in the current period.

Conclusion

The FGC has set out the following as its preferred position on the future of folic acid fortification in New Zealand:

The FGC supports voluntary fortification, based on:

- Current trends in consumer health impacts.
- Level of voluntary uptake by bread manufacturers.
- Cost-effectiveness.

The FGC supports steps to improve voluntary fortification:

- Improving uptake by establishing a jointly agreed percentage of packaged breads sold by retailers at other than the place of manufacture that might be the target for voluntary fortification going forward.
- Improving consistency of application through the development of a Code of Practice by industry and MPI.
- Establishing standardised reporting by determining the form, content, and regularity of reporting that would best complement other data collected to provide the level of information necessary to assess, in an ongoing way, the effectiveness of a voluntary fortification programme.
- Publishing reports on the uptake, effectiveness and impact of voluntary folic acid fortification over time.

The FGC does not support:

- Mandatory fortification, since voluntary fortification has been proven possible and effective.

- Limited mandatory fortification, since a level of packaged bread that might be fortified has not been discussed, and until agreed and implemented voluntarily has not been shown to fail and therefore warrant mandating.
- A review at a specified time in the future, but supports reviews on an annual basis when data other than production data can be taken together for assessment.
- A legislatively approved Code of Practice for voluntary fortification of bread with folic acid, but supports the development of a Code of Practice agreed between bakers and MPI which could be updated as necessary to reflect enhancements and refinements to processes over time.
- Mandatory reporting by bakers on the scope of folic acid fortification, until an appropriate voluntary reporting scheme has been developed, agreed, implemented, and evaluated.

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