12 November 2019

Consultation: Folic Acid Fortification
Ministry for Primary Industries
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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council (NZFGC) wishes to present on *Folic acid fortification: Increasing folic acid availability in food – New Zealand Food Safety Discussion Paper No:2019/08 October 2019.*

Yours sincerely

Katherine Rich
Chief Executive

Folic acid fortification: Increasing folic acid availability in food – New Zealand Food Safety Discussion Paper No:2019/08

Submission by the New Zealand Food & Grocery Council

12 November 2019

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the ***Folic acid fortification: Increasing folic acid availability in food – New Zealand Food Safety Discussion Paper No:2019/08 October 2019*** (the Discussion Paper).

2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

OVERARCHING COMMENTS

3. NZFGC is cautious about supporting a mandatory folic acid fortification programme and asks officials and decision makers to consider fully the potential effects of a fortification programme that purposely and knowingly results in child over-consumption. In relation to health impacts, the key concerns are the impact of:
   - over-consumption by children 1 to 8 years old;
   - the interaction of folic acid and B12; and
   - the circulation of unmetabolized folic acid.

4. With recent research and inquiry developments in major countries particularly Australia and the US, on the health impacts of folic acid fortification, we strongly believe application of the precautionary principle be applied in terms of timing of implementation especially in relation to the US National Institute of Health (NIH) review. There are health-related mitigation measures that could be taken that NZFGC would support:
   - Adding B12 fortification at the same time as folic acid fortification – in view of evidence from like countries
   - Using methyltetrahydrofolate in order to avoid problems associated with circulating unmetabolised folic acid. L-5-methyltetrahydrofolate is a natural substance is commercially available and could be added to flour
   - Assess the impact of overconsumption by children aged 1 to 5 years and factor this into the decision
   - Defer implementation until the US NIH review report has been published.

5. Our primary support is for continued voluntary fortification as an interim measure until the issues related to health impacts are better addressed. We could then support a mandatory system that was implemented in the most cost-efficient way, taking account of removing duplication across businesses and minimising the cost to them and other means of fortifying bread than to bread-making flour if that is more cost-effective.

DETAILED COMMENTS

Neural tube defects and folic acid

6. NZFGC recognises that neural tube defects (NTDs) affect. In the March 2018 year, there were over 73,000 pregnancies (comprising around 60,000 live births, 200 still births and 13,000 abortions) in New Zealand of which 64 were pregnancies affected by NTDs (0.09%). We are advised that some of these NTDs will also be insensitive to folate or folic acid. This is a quite

rare occurrence but one which we know has costs even while not all the affected pregnancies result in live births – to the families, whanau, the community and New Zealand generally.

The problem and voluntary fortification to date

7. There is little dispute that fortification of food with folic acid could reduce the number of NTD affected pregnancies. The issues have been safety for the population not needing folic acid fortification, choice of food to fortify, efficacy, cost and consumer choice.

8. Voluntary fortification of bread was widely negotiated with the New Zealand bread industry in 2009. On average, around 38% of non-organic, packaged sliced breads are fortified. According to the Discussion Paper, this approach is not increasing "folate status adequately for the optimal reduction of NTDs". MPI suggests over 80 countries mandate folic acid fortification, the closest example being Australia which recorded a 1.5% decrease in NTD rates over a period of three years.

Health risks

9. The key health risk, not covered in the Discussion paper but covered in supporting documentation, is over-consumption by non-target population groups, most New Zealanders. Two other health risks not covered in the Discussion Paper and difficult to locate in other consultation documentation relates to the interaction of a high folate status and low vitamin B12 with respect to cognitive function and the impact of unmetabolised folic acid circulating in the blood.

Over-consumption

10. Over-consumption by a non-target population group increases with each option from none for the status quo to 5-36% for the option of fortifying all flour. This is of concern since the discussion Paper states that "… there is no conclusive evidence that folic acid in the amount recommended for fortification purposes has any harmful effects on health". The potential over-consumption is only referred to for 5 to 8 year olds not younger. Evidence is emerging of harm. The question is when is it conclusive and should we apply caution in the interim. This and other health risks were considered by the US NIH in August 2019. It would be sensible and responsible to consider the report of that enquiry before proceeding.

Interaction of a high folate status and low vitamin B12

11. There has been concern of folic acid consumption masking the neurological consequences of B12 deficiency but that generally the phenomenon does not occur at the level of fortification generally applied. The emerging issue is the interaction of a high folate status and low vitamin B12 status concerning the increased risk of cognitive impairment in the elderly. This issue is not mentioned in the Discussion Paper and the supporting document (p10) states that the Prime Minister's Chief Science Advisor's report prepared in 2017 found no evidence to link the use of folic acid supplements or fortification to increased risks of neurological /cognitive decline…". However, several papers have raised this (Morris et al 2007, Moore E et al 2014, Castillo-Lacellotti C et al 2015) including in Australia. While this is only from three countries, they are most likely to have the resources to monitor and research impacts. Caution is therefore suggested.

    The significance of these findings is that those at risk have biomarkers indicating that it is interaction rather than masking that is the problem with B12. At a potential rate of around 4% of a growing population of elderly, a solution is to fortify with B12 as well.

Impact of unmetabolised folic acid circulating in the blood

12. The MPI supporting document does not consider unmetabolised folic acid circulating in the blood as an issue and the Discussion Paper does not mention it. After fortification in the USA, folic acid has found in the serum of more than 95% of a sample of nearly 3,000 people between 1 and 60 years old (Pfeiffer et al 2015). There is evidence of possible harm

associated with unmetabolised folic acid from several other studies, (eg Paniz et al 2017) which suggest that folic acid that involves circulating unmetabolised folic acid harms the nervous system. We note a solution for this in the concluding paragraphs.

Options for future

13. The Discussion Paper sets out three broad options for increasing folic acid in the food supply (1. Status quo; 2 Enhanced voluntary fortification; and 3 Mandatory fortification) and a further three options for mandatory fortification (3a – non-organic bread; 3b – non-organic bread making flour; 3c – all non-organic wheat flour).

Option 1. Status quo

14. Folic acid would continue to be added to bread at the bakery stage and while delivering no increase in NTD rate, there is no appreciable reduction. The industry has committed to voluntarily fortify to 50% but a rate of 80% is needed to deliver an NTD reduction. There is no over-consumption under this option.

15. NZFGC recognises that while there has been an impact from voluntary fortification, uptake has been slow.

Option 2 Enhanced voluntary fortification

16. Folic acid would continue to be added to bread at the bakery stage but the industry would be asked (tasked) to commit to increasing the voluntarily fortification to 80%. At this rate, an NTD reduction would result. Although the risk of over-consumption is not identified under the 'health impacts' of this option in the Discussion Paper, it was presented at public consultations as around 1-2% of children aged 5-8 would exceed the Upper Limit (UL).

17. NZFGC notes that the need to more than double voluntary fortification is a substantial commitment that may not be reached even over the next decade. The additional cost to industry would be around $100k per year. The most important consideration is the over--consumption.

18. On balance, NZFGC considers the over-consumption low on the way to the target level, the additional cost is low but that the likelihood of achieving the 80% threshold is perhaps also low.

Option 3 Mandatory fortification

19. All mandatory options have higher levels of over-consumption by a non-target population group, deliver greater prospects of NTD reduction, limit consumer choice and cost more for industry.

Option 3a – Mandatory fortification of non-organic bread

20. This Option proposes the mandatory fortification of all non-organic bread. Around 1-6% of children aged 5-8 years old would exceed the Upper Limit (UL) but there would be greater prospects of NTD reduction.

21. Consumer choice would be reduced (over the status quo) and the cost for industry would be substantially higher. Each large bread manufacturer participating, has to date, worked out its own method of fortification meaning that systems to fortify have to be duplicated in each facility.

22. NZFCG is uncomfortable with the level of overconsumption by 5-8 year olds and very concerned at the prospect of younger children being even more exposed to exceeding the UL. This latter issue is not covered in the Discussion Paper.

Option 3b – Mandatory fortification of non-organic bread making flour

23. This Option proposes the mandatory fortification of all bread-making flour. A little less than 1-6% of children aged 5-8 would exceed the Upper Limit (UL) under this Option but there would be greater prospects of NTD reduction.

24. Consumer choice would be reduced (over the status quo) and the cost for industry could be less than for Option 3a since only the bread-making flour supplier would be required to fortify.

25. NZFCG remains uncomfortable with the level of overconsumption by 5-8 year olds and very concerned at the prospect of younger children being even more exposed to exceeding the UL and considers these should be re-considered. Delivering the fortificant effectively by the bread-making supplier would provide relief from setting up individual systems by SMEs. This could be through the flour or another bread ingredient depending on cost-effectiveness.

Option 3c – Mandatory fortification of all non-organic wheat flour

26. This Option proposes the mandatory fortification of all non-organic wheat flour. A much greater percentage of children aged 5-8 years old would exceed the Upper Limit (UL) under this Option (5-36%) but there would be a significant and positive change in the prospects of NTD reduction.

27. NZFCG does not support an option that purposely sets out to raise the consumption of folic acid of non-target groups. NZFGC is very uncomfortable with the level of overconsumption by 5-8 year olds and very concerned at the prospect of younger children being even more exposed to exceeding the UL. We understand that ultimately this is a decision for officials and the Government, but we do ask that both consider this issue separately and in detail – parents and grandparents in particular will want to be assured that Government ministers have considered all available science and evidential trends.

Conclusion

28. NZFGC has two key concerns – health and cost. We consider that more summary health impacts might have been brought forward into the Discussion Paper for ease of consideration. However, in relation to health, the key concerns are the impact of:
    - over-consumption by children 1 to 8 years old;
    - the interaction of folic acid and B12; and
    - the circulation of unmetabolized folic acid.

29. With recent research and inquiry developments in major countries particularly Australia and the US, on the health impacts of folic acid fortification, we strongly believe application of the precautionary principle be applied in terms of timing of implementation especially the in relation to the US NIH review. There are also mitigation measures that could be taken that NZFGC would support:
    - Adding B12 fortification at the same time as folic acid fortification – in view of evidence from like countries
    - Using methyltetrahydrofolate in order to avoid problems associated with circulating unmetabolised folic acid. L-5-methyltetrahydrofolate is a natural substance is commercially available and could be added to flour
    - Assess the impact of overconsumption by children aged 1 to 5 years and factor this into the decision
    - Defer implementation until the US NIH review report has been published.

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