Fortification of the food supply with Vitamins and Minerals

Summary Analysis of Submissions

The summary analysis of the submissions includes all submissions received by the 5 February 2004 deadline and submissions up to and including the 11 February 2004 that were granted an extension beyond the deadline date.

The analysis of the submissions is presented in two parts:-

- a list of the companies or organisations that made a submission
- a written summary of all submissions

List of Submission (Attachment B1)
Each submission was categorised into one of the following groups:

- Industry and business
- Consumers
- Public Health
- Government

Information regarding a submission was recorded for reference. Information recorded includes the date of the submission, organisation and a contact name. Each submission was assigned a reference code.

Summary

NB Opinions, views and comments made in submissions are presented in this summary as statements irrespective of the validity of the position.

Submission breakdown

• Total number of Submissions	60
• Total number of submissions from NZ	22
• Total number of submissions from Australia	38
• Industry and business groups	25 (41.67%)
• Consumers and Consumer Groups	6 (10.00%)
• Public Health and Professional Groups	20 (33.33%)
• Government Groups	9 (15.00%)

Summary By Groups

Industry and Business Groups
Mandatory Fortification:
Of the 25 submissions from Industry and Business groups: 14 supported the policy to permit mandatory fortification 1 submission did not support mandatory fortification

A number of submissions, including the submissions that support mandatory fortification, indicated that it should be a “last resort”.

All submissions that supported mandatory fortification generally agreed with the following conditions to permit fortification:

- Science-based evidence
- Excessive intake of vitamins and minerals should be managed through upper limits based on upper tolerable intake levels, providing there is no chance of excessive intake for the target or the general population.
- There is high probability that mandatory fortification will address the

deficiency and, therefore, be a benefit

and

- other feasible options have failed or been assessed as less effective.

Issues Raised/Comments made

Health and safety is a key issue and it is important that a comprehensive assessment be conducted, especially in regards to the impact on non-target population groups.

Food vehicles should be considered against nutritional guidelines, however, the most appropriate and effective food vehicle should be used.

Consideration should be given to the bioavailability of the added vitamin/mineral in the food vehicle as poor bioavailability will not deliver the desired outcome.

Concern that mandatory fortification could limit consumer choice.

If permitted any form of mandatory fortification should be supported with consumer education programs.

Concerns that mandatory fortification will require considerable investment and cost, however, people should not assume any increase in production costs would be passed onto consumers.

Need for mandatory fortification permissions to be reviewed and monitored at regular intervals to determine their effectiveness. Essential to undertake regular national nutritional surveys.

Governments should provide specific guidelines on mandatory fortification and assist industry in covering the costs of mandatory fortification.

Consumers should be provided with sufficient information in order to make informed choices. The label must clearly identify that the food has been fortified and provide the reason why the food has been fortified. Research needed to evaluate consumer understanding of nutritional benefits, before any additional information is supplied.

Voluntary Fortification:

Of the 25 submissions from Industry and Business groups:

2 support option 2 (potential benefit)

3 support a combination of options 2 & 3 (potential benefit/minimum risk of public health)

19 supported policy option 3 (minimum risk to public health)

Submissions that support option 3 provides industry with the incentive to support vitamin and mineral research, product innovation and fair trade, while still maintaining the high order principle of public health and safety.

Submissions that supported a combination of option 2 & 3 did not support option 3 fully because this approach would not be appropriate for nutrients where the risk level is unclear.

A number of submissions commented that consideration should be given to an extension of the fortification policy to include other bioactive substances. This extension could remove the need for a standard for Food-Type Dietary Supplements. This would also be similar to the EU proposed regulations.

Issues Raised/Comments made

Some submissions commented on the difficult and impractical concept of the

restoration of vitamins and minerals to pre-processing levels. Nutritional equivalence should include alternative foods rather than just specific substitutes for core foods.

The credibility of the food industry must be maintained and any addition of vitamins and minerals should not be permitted if there is a risk to public health. Tolerable Upper Intake Limits should be used as a safety measure in the context of total dietary intake.

Foods that are fortified should support national nutrition policies, however nutritional polices are only relevant to the total diet and cannot relate to a specific food. It was noted that the management of nutritional policies might change as dietary patterns are continually changing.

Any food vehicle in the mainstream diet should be seen as being suitable however some foods, for example foods containing alcohol, should be excluded. Assessment of suitable food vehicles needs to be robust and is an issue during standard development.

The bioavailability of the added vitamins and minerals in the food vehicle is important and should be based on the amount and rate of the vitamin and mineral. Accurate information on the level of fortificant is crucial and any determination of level should be based on approved methods.

The prospect of consumers being limited to highly fortified foods is unlikely as there will always be a demand for non-fortified foods. However the market dynamics would determine this and further consumer research will be required in the future.

Voluntary fortification could be expensive and therefore would only be considered if there was a benefit to both the consumer and the manufacturer. It was noted that there was little evidence to support increased costs to consumers and the cost of fortified food would probably still be less than complementary medicines. Consumers should be given adequate information through basic nutritional education programs to ensure informed choices are made.

Monitoring and a strong regulatory framework was seen as essential and should include clear partnerships between Governments, industry and consumers.

Foods that have been fortified must be clearly labelled and should be allowed relevant nutritional and health claims providing they are “truthful” and not misleading. Foods that have been fortified should not be allowed to make comparative claims stating nutritional equivalent to another foods. The additions, and levels of additions, in fortified foods should be included in the NIP.

Public Health Groups

Mandatory Fortification

There were 20 submissions from Public Health Groups:

- 16 supported mandatory fortification
- 1 did not support mandatory fortification

Several submissions suggested that it would be more useful to make natural sources of nutrients more readily available to all consumers and provide appropriate education in increasing the intake of these.

Key issues raised included

- the requirement for fortification to be based on risk factors associated to specific target populations.
- based on scientific evidence.
- only used when all other viable options have been considered
- should be in foods already naturally containing the specific nutrient.

Issues Raised/Comments made

Fortification should aim to increase the nutrient intake of the target population to as close as possible to the RDI.

Unintended effects on groups outside of the target population, food & nutrient intake, disease states relating to the particular nutrient, and impact on health status should be monitored. Decision should be evaluated for efficacy or any negative effects.

General comments on the Government's role in mandatory fortification were that public health information needs to be available on the benefits of fortification so as to counteract any negative publicity and that it is imperative all costs of fortification are balanced against health benefits. Consumer education campaigns were supported with the focus being on health promotion and keeping consistent nutrition messages.

Significant concern that mandatory fortification would increase the cost of products to consumers, thereby disadvantaging low socio-economic populations. One submission commented on the cost to industry, claiming cost, and the technical impact on industry need to be considered. Government should cover the costs of mandatory fortification, or at least fund the programs.
There was a general consensus that labelling should be compulsory on foods that undergo mandatory fortification. The vitamin/mineral added needs to be included on the NIP and consumers should be informed as to why the food is fortified. Labels should be clear and indicate any risks associated with the fortified nutrient. Claims about fortified foods should be aimed at food groups as a whole, not a specific brand.

Voluntary Fortification

Of the 20 Public Health group submissions:

2 preferred option 1(restoration & equivalence only)
1 suggested option 1a (restoration & equivalence and the public health need)
3 supported a modified option 2 (a demonstrated need instead of potential nutritional benefit)
5 option 2 (potential benefit)
1 preferred option 3(minimum risk to public health)

All voluntary fortification was opposed in a couple of instances.

Several submissions also indicated that fortification, whether voluntary or mandatory fortification should be in line with Codex principles.

Most submissions questioned the concept of "potential nutritional benefit and requested clarification is important as to what this actually means.

Issues Raised/Comments made

Voluntary fortification should be implemented in cases where commercial preference doesn't take precedence over public health and unbalanced diets or potential nutritional imbalances will occur.

Health and safety assessment should ensure no risk from excessive intake, potential for maximum health benefit, scientific evidence showing sub/clinical deficiency, long term effects should be known and the way fortified nutrients, and those already present in the food, interact with each other.

Comprehensive and current scientific evidence is required to inform this policy decision as the only dietary intake/food compositional information information available is ten years old.

Consistency with nutrition guidelines should be maintained. Voluntary fortification shouldn't affect the integrity of the food supply. Food vehicles should have dis/qualifying criteria, not contain high levels of sugar, fat, salt and so on, they should be at least a moderate source of the nutrient being fortified and be consumed by the 'at risk population".

Nutrients not in their natural context do not confer the expected benefit – ie. their bioavailability may not be as great. General comments on key issues included that pro-oxidant effects of high vitamin/mineral intake need to be considered.

No link between consumer choice and public health outcome and fortification will actually decrease consumer choice, as the availability of non-fortified foods will become limited.

Concern that voluntary fortification will result in increased cost to consumers and the perceived benefits will not reach those with less market power.

Education campaigns should inform of changes to the food supply and consequences regarding food choices. The potential for diets to become distorted in favour of fortified products is of concern.

Governments should be responsible for the monitoring of voluntary fortification in terms of levels of fortification, realisation of benefit and claims made by manufacturers. There also needs to be a regulatory framework supported by all groups involved – industry, public health groups, government and consumers alike.

Labelling of food products that have been voluntarily fortified require clear statements of the vitamin/mineral fortified, levels of the fortificant and any risks which may be associated so consumers know exactly what they are purchasing. Claims should be truthful, concise and not inflated claims of benefit. All current labelling requirements should be applied.

Consumers and Consumer Groups:

Mandatory Fortification:

Of the 6 submissions from Consumers and Consumer groups:

- 2 directly supported the policy to permit mandatory fortification
- 2 submissions indicated that they would support mandatory fortification providing there was no risk of public health and based on the Codex principles of fortification.

One submissions directly support the immediate introduction to mandatory fortify foods with Selenium

Issues Raised/Comments made

Governments should have the capacity to mandate fortification of a specific food and the food vehicle chosen should address the need.

Food should not be fortified when there is a proven risk to public health and safety and the food should be consistent with dietary guidelines.

Concerns were expressed regarding the bioavailability of the vitamin/mineral as there was little point fortifying a food if the body cannot utilise the fortificant.

Consumer education campaigns were important especially if consumer choice is restricted.

Governments should also develop and maintained monitoring programs of the fortified vitamin or mineral.

Consumers must be informed that the food has been fortified through labelling. Any information provided should be clear, accurate and informative. Information should include the type and level of the fortificant and specify the whether it is a natural source.

Voluntary Fortification:
Of the 6 submissions received:

1 submission was strongly opposed to option 3 and favoured a policy between option 1 and option 2. (restoration, nutritional equivalence and public health need)
1 submission supported option 2 if demonstrated need not potential benefit
1 submission supported option 3 (minimum risk to public health)

Issues Raised/Comments made
Submissions expressed concerns regarding the long-term adverse effects of excessive intake of vitamins and minerals. One submission was particularly concerned with excessive intake of sodium in the diet and suggests consideration of the need to develop policies to reduce the intake of sodium. Other submissions had concerns that if too many foods were fortified there would be a risk that USL will be exceeded.

2 submissions commented on the need for food vehicles to be consistent with nutritional policies. Foods that are of poor nutritional value must be avoided for example food products that are high in fat, sugar and sodium. The fortificant in the food vehicles must also be able to be absorbed by the body otherwise consumers will be mislead.

2 submissions commented on the need for better consumer nutrition education to help make informed decisions regarding food choices. Issues regarding consumer choice were raised however limiting food vehicles could ensure consumer choice.

1 submission commented on the need for Governments to monitor dietary patterns for excessive intakes of vitamins and minerals. 2 submissions mentioned that there is a lack of current data on consumption patterns and updated nutrition surveillance necessary.

Submissions indicated that consumers must be aware of foods that have been fortified. The label of the fortified food must specify the fortificant added and the amount and percentage of RDI in the food. Health claims should not be allowed on fortified foods and strict labelling requirements regarding statements should apply.

1 submission commented on the current differences between the New Zealand dietary supplementary regulations and the Food Standards Code and mentioned it was important that this loophole was closed.

Government Groups

Mandatory fortification:

Of the 9 Government submissions:

3 submissions directly supported the policy to mandate fortification of food

Issues Raised/Comments made

Submissions commented that foods should not be fortified when there is a proven risk to public health and safety and chosen food vehicles must reach the target population.

2 submissions noted the need for industry to manage the technical feasibility and the quality control issues of fortification and indicated that industry will have possible cost implications and may have to absorb the cost of fortification.

Most submissions commented on the need for monitoring the program. Monitoring should be through national nutrition surveys and the use of up to date food compositional information. A number of submission noted that the fundamental element of a fortification policy should be up to date information on dietary intake and to collect data before considering mandatory fortification.

1 submission commented that the monitoring process should include assessing information accuracy regarding the fortification program and nutrition and health claims made on labels. Governments will bear the cost for enforcement and monitoring programs.

Submissions indicated that the responsibility for consumer education and evaluation rests with Governments.

Some submissions indicated that the ingredient lists should include the vitamin/mineral added as per current requirements and any claims should be inline with the claims policy. Three submissions suggested as extended NIP and on suggested claims should not be allowed.

2 submissions commented on the need to include a statement on the label as to why the food has been fortified and the desired outcome of the fortification.

Voluntary Fortification:

Of the 9 submissions from Government groups:

1 submission supported option 1

3 supported option 2

1 supported a modified option 2 (a demonstrated need instead of potential nutritional benefit)

1 Supported maintaining the status quo until the necessary diet/food compositional data on which to base decisions was available.

1 submission supported option 3 (minimum risk to public health).

Issues Raised/Comments Made

The submissions supporting option 2 indicated that any fortification policy needed a demonstrated population need as well as no risk of excessive intake to the population. They also commented that only core foods should be allowed to be fortified for restoration purposes. 1 submission commented that any fortification policy would need clearly defined parameters.

A number of submissions commented on the lack, or inadequacy of, current dietary/food composition data and questioned the ability to make evidence or science based decisions on inadequate or excessive intake and dietary patterns.

Most of the submissions commented on emerging evidence that there could be a risk of excessive intake of some vitamins and minerals.

3 submissions supported restriction of fortification vehicles to foods consistent with dietary guidelines and only where the vitamins/minerals occur naturally in the food. Foods of poor nutritional qualities should not be allowed to be fortified.

It was noted that an expanded fortification system could blur the current distinction between the drug and food regulation systems.

A number of submissions commented on the likelihood that consumers would pay a premium price for the fortified food. The possible increase in price may provide a barrier to low social income groups.

Governments were also concerned that availability of a broad range of fortified foods may potentially further direct consumers away from eating habits encouraged by dietary guidelines. The integrity of the food supply must be maintained to ensure consumer choice.

Consumer education programs will be needed as consumer confusion could increase because of industry marketing. Education programs should convey the specific role of the fortificant in food and its overall context in the diet. Education and health promotion will need to be funded by Governments.

1 submission commented that the monitoring process should include assessing information accuracy regarding the nutrition and health claims made on labels. Governments will possibly bear the cost for enforcement and monitoring. It was noted that if voluntary fortification were left uncontrolled the food supply would become distorted. Voluntary fortification also has the potential to direct funds away from other public health strategies.

Most submissions indicated that the ingredients lists should include the added vitamin/mineral as per current requirements and any claims should be inline with the claims policy. Two submissions suggested that advisory statements should be included on the label. The submissions indicated one advisory statement should be related to RDI and a balanced diet and that another advisory statement should be included for specific nutrients or vulnerable population groups. Submissions also recommended that fortified foods be clearly identifiable from non-fortified.

List of Submitters to Fortification Consultation Paper

Queensland Health
Western Sydney Health
Western Australia Dept of Health
New Zealand Food Safety Authority
Cadbury Schweppes
Australian Self Medication Industry
Parmalat Australia
PB Foods
Murray Goulburn
Food Technology Association of Victoria
National Heart Foundation of Australia
Bower & Stanley
Australian Academy of Science National Committee for Nutrition
Public Health Association of Australia
Coalition for a Health Australian Food Supply
Rollins School of Public Health
Dietitians Association of Australia
Australian Food and Grocery Council
Wrigley company Pty
Australian Soft Drinks Association
Dairy Australia
Fonterra Co-operative
Sanitarium Health Food Company
Beer Wine & Spirits Council of NZ
New Zealand Nutrition Foundation
H.J. Heinz Australia + New Zealand
Public Health Dietitians- Auckland Regional Public Health Service
NSW Health and SafeFood NSW
Nestle Australia
Campbell Arnott's
ASBHA
Kraft Foods Ltd
Confectionary Manufacturers of Australia
Spina Bifida Association of WA
Australian Consumers Association
ACT Health
SA Department of Human Services
Queensland - Department of Families
Spina Bifida Association of VIC
DSM Nutritional Products
AA Clinical Geneticists
National Foods
SIGNAL
National Centre of Excellance in Functional Foods
Consumer Institute
University of Otago

Capital Coast Health
Griffins Foods Ltd
Crop and Food Research
CCS
NCWNZ
NZ Ministry of Health
Agencies for Nutrition Action
The National Heart Foundation of NZ
New Zealand Dietetics Association
San Miguel
New Zealand Food & Grocery Council