

report

MANDATORY FOLIC ACID FORTIFICATION OF BREAD MAKING FLOUR IN AUSTRALIA

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**by Gerard McMullen for
G P McMullen Consulting**

Specialising in technical support to the grain and agriculture industries in areas of grain quality management, food safety and hygiene systems and training packages

Contact Details:

Gerard McMullen
GP McMullen Consulting
76 Bruce Street
Coburg VIC 3058

Ph 61 3 8300 0108
Mob 0419 156 065

Email: gerardmcmullen@optusnet.com.au

ABN 28457020743

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1 EXECUTIVE SUMMARY

1.1 General

The objective of this Report is to provide Food Standards Australia New Zealand (FSANZ) with advice on the technical and compliance issues faced by the flour milling industry (Industry) associated with mandatory folic acid fortification of bread making flour (BMF).

FSANZ has proposed to introduce legislation mandating the fortification of BMF with folic acid at the level of 230-280ug/100g of flour.

The method of fortification and the products to be fortified has created a diverse view of opinions as the Industry does not agree with the current proposal from FSANZ for mandatory folic acid fortification of BMF.

The tight tolerances recommended for fortification of flour with folic acid cannot be met using existing fortification equipment in Australian flour mills. Industry will be required to replace existing fortification equipment.

At present there a limited number of flour based products fortified with folic acid on a voluntary basis. All flour for bread making is fortified to a minimum level with thiamin however as the regulatory controls are considered minimal, Industry applies limited controls over application and monitoring of levels in the fortified flour.

Overseas where fortification of flour with folic acid in the mill has occurred in a number of countries, retro-fitting of mills with fortification equipment to meet the desired levels has been relatively cheap. That said, as most countries have only introduced minimum levels of folic acid in their regulations, the costs involved in setting a target range as proposed in Australia, are unable to be accurately determined from that experience.

1.2 Meeting the Fortification Proposal

Industry Views

On many occasions, Industry indicates they cannot determine the end-use of the flour. Therefore they may be required to fortify flour that is not used for bread making purposes. Bakers themselves may create a BMF from a range of flours and ingredients, thus creating a product that does not contain the required level of folic acid.

Industry also has a significant concern with their liability in exceeding the maximum levels of folic acid in the flour produced and subsequent exposure at some future time to legal action.

The range of fortification with folic acid proposed by FSANZ is considered by Industry as presenting an unrealistically tight tolerance, requiring significant upgrades to their current milling operations in terms of equipment and processes.

From a Quality Assurance perspective, Industry indicates they will be required to meet the tolerance levels of folic acid on outturn of every BMF consignment. This may be a group of flour bags outturned or a single bulk tanker. The requirement for control of folic acid levels in each consignment is based on their QA systems and desire to achieve world's best practice in terms of supplying a product that meets customer expectations.

For these and other reasons, Industry has advised the costs of restructure of their milling operations will be in the vicinity of \$22 million initially with ongoing annual costs of \$12 million. These costs are considered by some sectors of Industry to be conservative.

Author Views

Based on experience overseas, there is feeder equipment available that will enable Industry to fortify flour with the required range of folic acid. This equipment is relatively simple to install and operate based on existing mill operations and equipment configuration.

Existing feeders will need to be removed and replaced with the updated feeders. Limited modifications to the flour streams and infrastructure will be required to meet the proposed range of fortification based on a lower level of monitoring for compliance on flour outturns than that projected by Industry. The monitoring level proposed is once or twice a year, assuming Industry introduces appropriate practices and continuous improvement to meet the proposed range of fortification throughout their milling operations.

The above also assumes Industry QA procedures and systems can be adopted to enable this level of monitoring for compliance to be acceptable.

With the introduction of new feeders, the range of fortification proposed by FSANZ in the Draft Assessment Report is achievable. However, as Industry is not experienced with the range of fortification proposed by FSANZ, it is recommended to increase the range of fortification to +/-20%. This equates to a range of 200-300ug/100g of flour.

This range is proposed on the basis that initial Industry discussions indicated 20% variation was acceptable. Consideration could be given to reduce this range over time.

The cost of new equipment is relatively small compared with the expected benefits to the general population. Based on advice from suppliers and international experts in fortification, the total capital set-up cost is estimated at \$1.35 million. Ongoing and other operational costs are not included as it is assumed these costs will be part of ongoing milling costs.

This cost is significantly lower than that projected by Industry and should not prohibit implementation of the proposed regulations. In reality as each mill will require a different set-up, the true costs to Industry may not be fully determined until detailed plans for each mill are generated, fortification is implemented and an analysis is conducted post-implementation. For this reason, it is expected that the true cost of folic acid fortification within the range to be introduced by FSANZ is someway between the above estimates.

Note that a range of actions are outlined in this Report to assist Industry to implement the regulations.

2 INTRODUCTION

2.1 Background to the Report

This Final Report is in response to a request for consultancy services by FSANZ.

In May 2004 FSANZ was asked to investigate mandatory fortification with folic acid as a possible means of reducing the incidence of neural tube defects.

Through various consultative mechanisms, FSANZ engaged industry and other stakeholders to determine the most suitable option for such a scenario. BMF was determined as a suitable food vehicle for mandatory folic acid fortification in Australia and New Zealand.

A Draft Assessment Report was provided to the public and invited submissions in mid-2006. In October 2006 FSANZ released a Final Assessment Report Proposal P295 with the decision:

Mandatory fortification of bread with folic acid is the preferred approach in Australia and New Zealand to further reduce the incidence of NTDs. The proposed level of mandatory fortification is 80-180 micrograms (μg) of folic acid per 100 grams of bread.

In November 2006, Ministers requested FSANZ review this recommendation on the basis of a number of issues including technical, compliance and cost. FSANZ was also asked to reconsider the fortification of BMF in Australia.

2.2 Ministerial Request

During industry consultations it became apparent there were a range of views on the decision regarding health, consumer choice and how industry could implement the decision.

More specifically, the Industry raised concerns with the decision in terms of their ability to fortify flour within the range described and compliance issues associated with folic acid fortification of BMF.

With the above in mind, FSANZ sought the services of the Author of this Report to assist in the task of further reviewing Industry's ability to implement the decision.

2.3 Project Objectives

The project is in two parts with a Preliminary Report and a Final Report required.

A Preliminary Report outlining findings by the Author during Industry consultations as at the end of February 2007 was provided.

The objective of this Final Report is to provide FSANZ with advice on the technical and compliance issues associated with folic acid fortification of BMF. This task includes:

- An overview of the Australian flour milling industry and current fortification practices;
- A review of flour segregation for bread-making purposes;
- Investigation of the technical and compliance issues for Industry associated with the proposed approach to mandatory folic acid fortification;
- Provision of advice on an achievable prescribed range of fortification; and
- Advice on infrastructure requirements and compliance costs associated with a prescribed range of mandatory folic acid fortification.

The task of the Author and this Final Report does not look at any of the health or associated issues with folic acid fortification, other mechanisms to increase the folic acid intake of the population, or mechanism for cost recovery by Industry.

2.4 Scope and Limitations of this Report

This Final Report highlights information gleaned from discussions and visits to industry. It also includes relevant material in submissions previously provided by Industry to FSANZ during the consultation phase prior to publication of the FSANZ Final Assessment Report and a further report provided by Industry in February 2007.

Where possible individual comments made by or the operation of particular mills are not referred to in this Report. Many comments and statements made in this Report are of a general nature considering the diversity of operation of mills in Australia. Thus comments may not be applicable to a particular flour mill or all Industry participants.

A range of issues of concern to Industry were identified during interviews and these have been included in this Report. Views of the Author of this Report on issues raised by Industry have been included and identified when stated. In addition, international expert comment was provided on this Report¹.

Industry provided a high level of cooperation in discussions on the issues to be addressed both during and subsequent to interviews. A range of views and data were provided. Of note are a relatively small number of Industry stakeholders who did not provide access to the equipment or milling operations or detailed information regarding their operations. In those instances, interviews were conducted and the accuracy of information provided cannot be fully guaranteed.

¹ Quentin Johnson

Where possible, the Author of this Report has highlighted any instances where findings may be based on incomplete data.

This Report only deals with the proposed fortification in Australia. It does not include the proposed fortification in New Zealand.

2.5 Methodology of Data Collection

A series of discussions between the Author and FSANZ lead to the compilation of a list of potential Industry stakeholders to be contacted in conducting this project. In addition, the list was further enhanced via the knowledge of the flour milling industry by the Author.

This study has taken into account the views of all Industry stakeholders identified and contacted as being relevant to the project objectives.

An interview template was developed outlining questions to determine the operations of Industry stakeholders and whether they were relevant to the project. Initial telephone interviews with these Industry stakeholders were conducted to gather data and views and to determine whether an on-site visit was required. Based on the initial contact, further follow-up discussions occurred. On some occasions, details of additional Industry stakeholders requiring to be contacted were provided.

In addition, the Author has also made contact with a number of technical specialists including fortification experts, health authorities, suppliers of fortification equipment and analytical testing laboratories. Access to relevant material from those parties was obtained through that consultation phase.

Some sectors of Industry have previously supplied a large amount of data on relevant costs to FSANZ regarding potential changes to their operations to meet the proposed regulations. This data was not provided to the Author of this Report but should be considered in the overall assessment of benefits and costs to industry.

The Author wishes to thank Industry for its high level of co-operation in providing assistance to this project.

2.6 Disclaimer

The information contained in this Report is based on sources believed to be reliable. However, GP McMullen Consulting gives no warranty that the said sources are correct, and accepts no responsibility for any resultant errors contained herein and any damage or loss, howsoever caused, suffered by any individual or corporation.

3 DEFINITIONS

The following definitions are used in this Report:

Author	The Author of this Report, Gerard McMullen
Bakers flour	General term for flour produced in a flour mill for general baking use, often for bread manufacture
Batch	A definite quantity of flour produced under conditions that are considered uniform. In general the flour is considered to be formed during the same process or in one continuous process and having identical characteristics throughout
BMF	Flour produced from the milling of wheat for the purposes of making bread. See Report for further detail
Bread	The product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water
Bulk Flour	Flour stored in large storage units and outloaded by road transport in a single large unit
Cereal	Seeds of flowering plants of the grass family cultivated for the food value of their grains. Includes wheat, barley, oats, triticale, rye, sorghum, maize and rice
Commercial Testing Laboratories	Analytical laboratories offering a range of testing services, operating on a commercial basis
Composite Sample	Is a sample representing the entire consignment. Compiled by obtaining representative sub-samples of each individual load (container, truck etc) based on the tonnage each represents and combining these samples to form one sample
Consignment	A quantity of flour outturned in bags or bulk at the one time

Elliott Report	Report produced in February 2007 by Richard Elliott and commissioned by the FMCA on behalf of Industry entitled “Addition of folic Acid to Flour for Making Bread”
Flour	Flours means the products of grinding or milling of cereals, legumes or other seeds
Flour Mill	Facility used to process cereal grain into flour
Flour Milling	The process by which cereal grain is ground into flour or meal
Flour Products	The cooked or uncooked products, other than bread, of one or more flours, meals or cereals
FMCA	Flour Millers Council of Australia
Folate	Folate is a water-soluble vitamin. The term folate is used generically to refer to the various forms of the vitamins, both naturally-occurring and synthetic, and their active derivatives
Folic Acid	Folic acid (pteroylmonoglutamic acid) is the most common form of synthetic folate. It occurs rarely in foods but is the form most often used in vitamin supplements and in fortified foods
Fortification	The addition of an ingredient for the purpose of enrichment
FSANZ	Food Standards Australia New Zealand
Grist	Grain intended to be ground or milled
Industry	In this Report, the members of the flour milling sector that operate flour mills
Mandatory Fortification	As specified in the FSANZ Food Standards Code, food manufacturers must add an essential nutrient (e.g. thiamin) to a specified food at a specified rate
Manual	Flour Mill Quality Manual

NATA	National Association of Testing Authorities is Australia's national laboratory accreditation authority
Outturn	Process of loading flour from a storage unit or directly from the mill into a transport unit, for eventual delivery to a domestic or international customer
Overage	Amounts of folic acid or thiamin added in excess of the required dose to ensure compliance with the minimum content requirements
Procedure	A documented, verified and auditable Sample Collection and Testing procedure
Quality Control	Those actions that control the attributes of an analytical process, system, or facility according to predetermined quality requirements
Quality System	A structured and documented management system describing the policies, objectives, principles, organisational authority, responsibilities, accountability, and implementation plan of an organisation for ensuring quality in its work processes, products and services
Retrofit	Installing new equipment and systems to existing flour mills
Returns	Return of flour from outside sources (customers) mainly due to incorrect flour quality characteristics or fortification levels
Running Sample	A sample obtained via sub-sampling each batch produced or delivered into a segregation and is usually compiled based on a tonnage figure. The sample may then be analysed for quality parameters to determine if individual batches produced or delivered into a segregation met specifications
Sampling	A manual or automatic process whereby a sample is taken at a pre-determined rate from a batch of flour
Speciality Flour	Flour produced and used for a specific purpose that is not considered bakers flour

Tolerance

The total amount by which a quantity is allowed to vary from nominal; thus, the tolerance is half the algebraic difference between the maximum and minimum limits

Voluntary Fortification

As specified in the FSANZ Food Standards Code, food manufacturers have the choice of adding an essential nutrient (e.g. folate) to a specified food up to specified rate

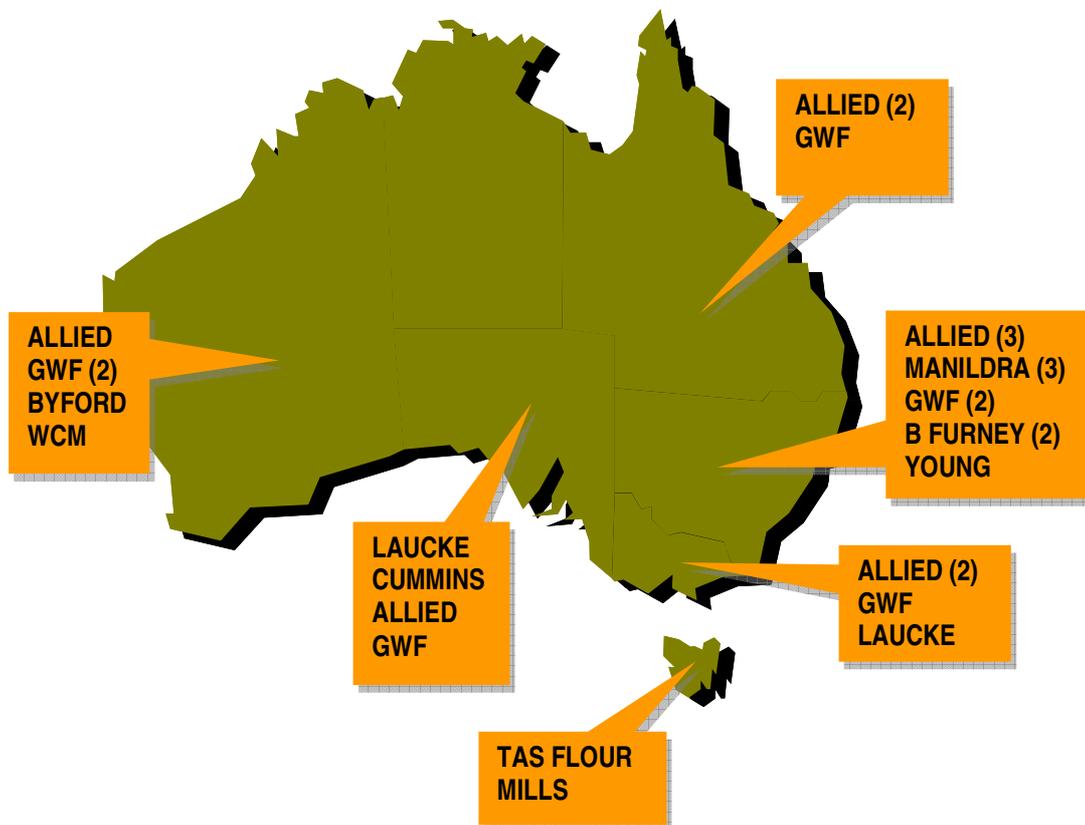
4 CURRENT AUSTRALIAN MILLING INDUSTRY

4.1 Mill Size, Location & Flour Production

4.1.1 Size and Location

The size and complexity of flour mills varies depending on a range of factors. There are approximately 28 mills in Australia, with the geographic spread of many of these depicted in the following diagram.

Figure 1: **Flour Mills in Australia** (Producing BMF)



The purpose of a mill is to grind grain through various processes to produce the major product flour. The rate of extraction of flour from the grain is termed the extraction rate. The higher the extraction rate, in general, the higher the efficiency of the mill in extracting value from the grain. That said there are several products of high value produced using a lower extraction rate.

Flour mills produce flour at rates varying between 0.5 to 25+ tonnes per hour depending on a range of factors including grain type, customer requirements and mill set-up. In general flour mills can be classed as small, medium or large based on the theoretical tonnage per hour of flour produced:

- 0.5-5 tonnes per hour 9 mills
 - 6-14 tonnes per hour 12 mills
 - 15+ tonnes per hour 7 mills
- 28

Small mills may be owned by individual companies and operate as sole operations or be owned by larger companies with more than one flour mill. The degree of technology used to control the milling operations is somewhat limited, relying on manual systems rather than complex computer control.

The medium to large mills are generally owned by large companies with mills in one or more of the Australian states. In general the medium mills are a mixture of gravity and pneumatic fed. These mills may have undergone recent refurbishment and upgrading, relying to some extent on computer controls.

The large mills tend to have been upgraded in recent years and are highly automated. The milling process and pathways in the milling process are automated and tend to be controlled by computer systems rather than rely on manual controls by labour resources.

Industry advised their current segregation capacity by mill is limited. While limited, it is adequate to meet current milling operational needs and supply customers with the required quality flour. Advice was that folic acid fortification may require additional segregation capability or other changes such as a decrease in the lines of flour each mill produces.

4.1.2 Milling Operations

The objective in milling varies by company but could generally be described as “To maximise flour produced from the mill, with all processes controlled to achieve the desired outcome of meeting customer expectations”.

Mill operations are manual to fully automated with combinations of technology levels. They are highly capitalised, with modifications made to improve operations and thus profit.

The different size, complexity, modifications & upgrades for each mill must be considered when resolving the proposed fortification of BMF with folic acid. Every mill in general is designed differently, thus requiring a different solution and mill set-up. The complexity of operation needs to be taken into account when designing a new fortification set-up for a particular product.

Mills rarely have shut-downs for extended periods, with large mills running almost continuously. Smaller mills may shut-down for a short period for various reasons, including lack of flour storage space.

Wheat may be blended together into a grist depending on customer quality requirements, the quality of the grain and millers experience. The grain then undergoes a number of cleaning processes that involves the removal of foreign material. The grain is conditioned involving the addition of water. The grain then moves into the mill and is milled, producing flour and other products.

Mills have a number of flour streams along which the flour passes. Depending on the size of the mill and the flour quality required, these flour streams may be blended at varying rates to produce the final flour.

Once in the mill, there is a limited opportunity to alter quality to any significant extent. Thus the grist and pre-conditioning stages are vital to ensure the correct milling process occurs and the flour produced will meet the customer requirements.

The preferred approach of mills is a limited amount of blending of flours prior to or on outturn. Such blending operations may add cost and be difficult to achieve given the infrastructure existing in the mill site. Generally there is no real need to blend prior to outturn as the grist and the milling process, which may involve blending of flour streams, is used to control the quality of the product. That said individual mills may blend flours after the flour leaves the mill depending on individual circumstances.

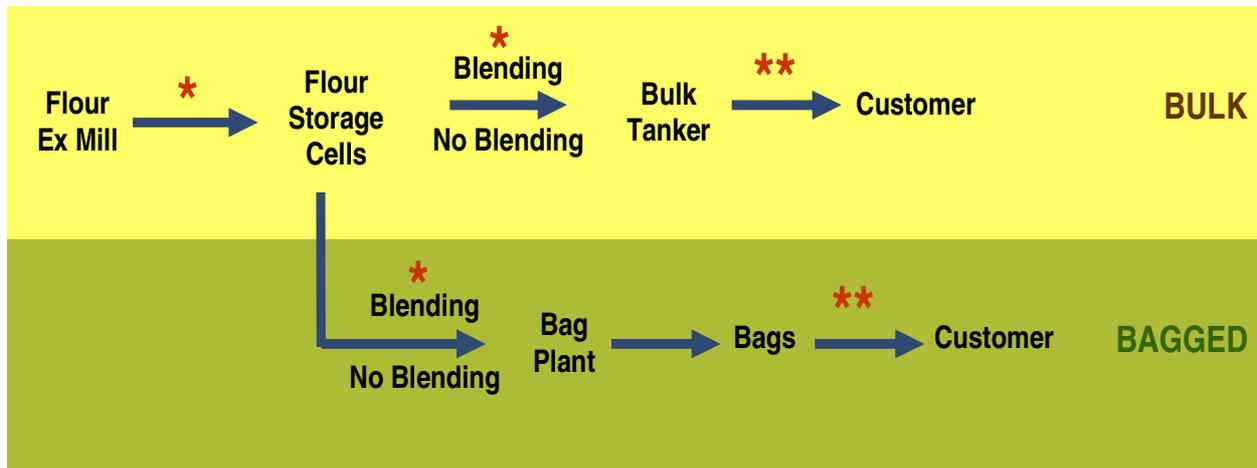
Where a grist is not used, there may be a requirement to mill a single wheat variety for the production of specialised flours. In this instance again the quality of the grain is paramount. Monitoring during the milling process will occur to ensure flour quality requirements are met. Thus on outturn, blending of flour if milled correctly is limited.

Depending on the flour type and customer requirements, generally “like” flours are milled following similar flour. Thus any potential contamination of the second flour with carryover with the first will have a limited effect on the quality. Changeover bins are generally used such that the first hour or two of milling is blended from this bin at a controlled rate in the subsequent flour stream. Thus minimal effect on quality occurs.

Special runs of very different flour, such as organic are appropriately timed to keep potential contamination and milling interruptions to a minimum.

While variations exist depending on the flour type, customer and mill operation, in general this process can be depicted as in figure 2 below.

Figure 2: **Typical Flour Production & Outturn**



- * Sampling / testing points
- ** Depending on customer contract

Specific times are allocated for production of each flour type. An example is Bakers flour which is often the major product of a mill. Some mills produce this flour during evening/night shifts as:

- Lesser resources may be needed to control the milling of this “general quality” flour
- Night operations may be cheaper to operate than day operations
- Specialty flours, requiring greater controls over milling and blending may be done during the day when more applicable resources may be available

Indications are the fortification of Bakers flour with folic acid may require a change in this practice. Comments were received from Industry that additional resources may be needed at night to monitor the fortification process and conduct testing, thus adding costs.

4.1.3 Storage & Segregation Capacity

Wheat is generally brought in on a just-in-time basis, as there is limited storage capacity. Storage is used for generating the grist and processing the grain prior to milling. Thus milling operations revolve around wheat in and processed as soon as practically possible. There is limited capacity and desire for long term storage of wheat.

Flour is rarely outloaded immediately it is produced. Generally flour remains in the mill (storage) for a minimum of 4-6 hours (green flour). Then flour may be outloaded

following tests. Flour may be stored for up to 7 days but on average may be outloaded after 24-48 hours. In some large mills, flour trucks may outload over 4 loads a day.

Mills have bulk or bagged outturn, with many mills having a combination of both. Bagging plants on site may mean flour is stored for longer periods up to months depending on the product and mill customers.

Industry consensus is there is limited capacity and desire for storage for lengthy periods awaiting results of analytical testing. Note that bakers have limited storage. Thus flour milling timetables are tightly controlled in line with customer logistic operations.

Large Mills

The larger mills tend to operate on a day to day basis. That is, grain is milled one day for outloading the following day. These mills may have one or two major customers requiring flour daily in the hundreds of tonnes.

Segregation capacity in these larger mills is limited via the storage space available. Generally there are 3-4 large flour bins, at least two outloading bins and where applicable, storage area in the bagging plant.

Large storage bins are generally allocated to the main production lines, often with one or two bins allocated to particular customers. A bin may be used for a major line such as Bakers flour.

The outloading bins are not used for long term storage, with rapid movement of product through these bins into road transport. The bagging area is where a large number of bagged flour lines are stored. The storage area is limited and again, product turnover is rapid.

Small Mills

Smaller mills also have a tight control over the milling process and how long flour is stored. In many instances, storage space is considered tighter in these mills than in the larger mills. There may be as few as 4 flour bins or up to 10 bins depending on the size and complexity of the mill. Any delays in outloading stock may have the impact of causing the milling operations to cease until flour storage space is made available.

Some flour may be turned over within 8-16 hours, on average all flour is turned over within 24-48 hours. Some flour is held over as a base for the premix made on-site. Similarly some flour may be held over for a longer period for bulk outturn customers.

In general, both bulk and bagged flour turnover is rapid, generally less than 2 weeks.

4.1.4 Flour Production Statistics

Australia has generally relied on our own production of flour for consumption. However one Industry source stated the level of flour imports is increasing. This has important implications for imported product and the requirement to meet the proposed fortification standards.

Australian Domestic Market

By far the majority of flour, including BMF is used for domestic markets. Production statistics are well known although the range varies depending on the source of the information. In general, flour production is estimated at up to 1.1 million tonnes per annum, of which up to 750,000 million tonnes may be BMF.

Significantly, individual mills vary in the tonnage of BMF produced, ranging from nil (one mill) to approximately 75%. The average is difficult to determine as production varies, but is estimated at 50%.

Australian Exports

A relatively small market exists for export flours. Where required, the flour is fortified with whatever additive required by the importing country government or customer.

A number of countries have developed regulations requiring fortification of flour with folic acid. This is mainly focussed on domestic flour usage however the same folic acid levels are required to be met when flour is imported.

Other countries have mandated that folic acid fortified flours are not permitted in imports. Where export markets occur, Industry provides a product that meets the importing country requirements through specific milling runs to prevent unintended contamination.

Imports into Australia

Currently specialty flours are imported as required, generally in a time of shortfall such as a drought. If flour imports are required following implementation of the proposed folic acid fortification regulations, the marketer would need to arrange fortification of the imported flour with folic acid if it was to be used as BMF. This would normally be stipulated in the supplier contract but Industry pointed out the difficulties of this requirement. As the Australian market is small and the requirement to import flour infrequent, the logistics of the overseas supplier fortifying the flour for Australia only within the required range may be difficult “if not impossible”.

In instances where the flour could not be fortified in the exporting country, a possible scenario is fortification on arrival in Australia and re-bagging of the product. This would significantly add costs, but may not be as high as Industry suggests given the product may require to be re-labelled in Australia for marketing purposes.

4.1.5 End-uses & Types of Flour

Grain Source

Although the majority of bread is made from wheat flour, a wide range of other flours are also used. This may include:

- Cereals – wheat, barley, rye, triticale, oats, buckwheat, spelt, corn, rice
- Pulses – lupins, soybeans, field peas
- Oilseeds – sunflowers, linseed

Mills may operate solely by milling wheat but there are also a number that mill these other grains.

While the tonnage of these other grains being milled may be low, they must be considered when reviewing fortification of BMF for human consumption. While no accurate figures are available, the Author of this Report considers the total milled of these other grains is less than 10%. Based on anecdotal evidence it appears that the majority of this flour goes into bread production.

These other grains are milled by Industry stakeholders interviewed during this project, or by small specialty mills operating as “boutique” millers. The number and extent of operations of the latter is unknown although the volume produced is considered insignificant compared to the volume produced by the mills cited in this Report.

There is also a growing organic wheat flour market. Part of this production is also used for bread making. An estimate could not be made of the size of this market. Fortification of this flour may be applicable provided it is accepted in the community with a “non-organic” or man-made additive such as folic acid.

Flour Types Produced

The flour milling operation produces the main product flour. In addition to flour, mill by-products are also produced. These include bran and germ, with these products sometimes blended back into the flour either at the mill or by the customer such as at a bakery.

The main flour that is produced is Bakers flour. This is produced by all but one Australian flour mill. This flour is generally used for bread making and is considered by Industry as a general purpose flour rather than a speciality flour. It may have a different name depending on the company producing the product.

Large mills may produce over 30-40 different flour products. These have a range of quality specifications depending on the customer.

As with the larger mills, small mills produce a range of products. Of the small mills, at least one is closely associated with their own plant bakery. This takes a large percentage of the milled product. In general small mills tend to have a larger percentage of their

overall range of flours as specialty flours compared to the larger mills and potentially have a greater knowledge of the end-use of the flour. That said large mills also produce a wide range of specialty flours.

Specialty Flours are produced as required by individual mills in a number of different ways. This may involve one or a combination of:

- Special grist
- A specific run for that product
- Blending of flours

Speciality flours are considered differently than bulk flours. As with all flours, speciality flours are produced at a time that is planned to minimise disruption to the “normal” milling operations. They may not be produced every day, only as required. Pre-planning may be required:

- For cleardown of the mill beforehand
- For receipt of the speciality wheat or generation of the grist
- For blending of the flours post-milling
- For outloading in a manner that causes minimal disruption to the “normal” operations of the mill i.e., bulk flour production

Some customers require guarantees folic acid is not present in flour they receive. Industry indicated the fortification of flour with folic acid will increase the complexity of creating these specialty flours.

Wholemeal flour may be produced in different ways:

- Bringing mill streams together post the grinding phase
- Having separate mill streams or flours and relying on the bakery to blend the products
- A combination of the above

Both small and large mills may use a mixture of both these processes, depending on the customer.

Consumer choice, gluten intolerance and a range of other factors are influencing consumer choice on the type of products such as bread they choose to eat. In response, millers and bakers are increasingly providing specific flours and bread for this sector of the market. The levels of production at present are low, estimated at less than 10%, but growth potential is quoted by industry as significant.

End-use of Flour

Flour is used for many purposes that vary from human consumption to industrial uses. Common human consumption uses include bread, cakes and pasta. Industrial uses include building materials.

Bakers flour is used in a wide range of products and is not solely used for bread making purposes:

- Bread
- Cakes
- Pasta
- Muffins
- Pastry
- Coatings
- Crumbs
- Crumpets
- Scones
- Pikelets
- Crepes
- Pizza bases

Other uses include:

- Soup
- Binders
- Building materials, etc

Some of the above products such as cakes, pasta and pastry are mainly produced with flours specific for that end-product. Bakers tend to purchase specific flours for these end-products based on flour quality specifications. Most flours would generally not have appropriate quality characteristics. Thus the use of BMF in the manufacture of these end-products is limited.

Contracts with buyers stipulate functional quality characteristics and not the end-use of the flour purchased. From this information it is difficult for the miller to confidently determine the end-use of the flour. When Industry sells products such as Bakers flour, they don't distinguish it as a BMF, as the bakeries make that distinction. In addition, a baker may formulate their own flour mix for making bread.

That said, as millers do know the buying habits and locations of where the flour is sent to, they can make educated guesses as to the end-use of the flour and whether it may or may not be used as BMF.

More accurate data on what constitutes a BMF and the content of this flour could be obtained from bakers.

If all BMFs were to be monitored from all mills, cereals such as rye and triticale that are used in breads would also require fortifying. This would also include the small commercial boutique millers.

4.2 Definition of Bread Making Flour

As part of this project, the Author was responsible for proposing a definition of BMF.

4.2.1 Production of Bread Making Flour

BMF was recently estimated by industry sources as being 50% of total flour production in Australia². Production has declined according to recent ABS figures to 42%. Thus some uncertainty occurs on the exact production figure.

Bread may be made from:

- Bakers flour made solely from wheat
- Other flours made from wheat
- Flour from other grains as listed above
- A combination of wheat flour and flour from one or more of these other grains

In addition, bread may contain other products including those products from the milling of grain.

As with all flours, only certain flour quality characteristics make it suitable for bread manufacture (or other products). Whether the flour is wheat based, organic or made from non-wheat sources, the flour characteristics must be suitable for bread manufacture. Thus there is a limit on what flours can be made into bread.

4.2.2 Definition of Bread Making Flour

FSANZ

The Food Standards Code defines the following:

- bread means the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water
- flour products means the cooked or uncooked products, other than bread, of one or more flours, meals or cereals
- flours or meals means the products of grinding or milling of cereals, legumes or other seeds

The third dot point indicates flour may arise from the traditional current method of milling or as a meal made by grinding the grain. The addition of meals or flour from this process may alter the final level of folic acid in the bread once the flour is fortified.

² Brooke-Taylor & Co.

Distinction needs to be made whether flour from whole grain milling is the sole intent of the regulations or other processes used to grind and produce meals that may end up in bread are to be included.

The Food Standards Code also states “Flour for making bread must contain no less than 6.4 mg/kg of thiamin”. This section of the Food Standards Code uses the same definition of flour as described in the dot points above. Thus it is recommended that the regulations for folic acid fortification use the same definition of flour.

To a flour miller, BMF is considered to be that flour used by a baker for the purpose of making bread. Industry considers their Bakers flour made from wheat is used for this purpose.

Industry

The majority view of Industry is that BMF should only refer to flour produced from wheat. Other grains should not be included in the definition for several reasons, including:

- difficulty of manufacturing various lines with and without folic acid based on customer needs
- increased segregation required
- increased complexity of operations
- cost considerations

In addition, the cost benefit of fortifying flour from all grains with folic acid may not be warranted given the relatively low percentage of the non-wheat flours used for bread making purposes.

The general Industry view as understood and the Author of this Report recommends that BMF be defined as “**Flour used for bread making that comes from the cereal grain wheat**”.

Although there are a number of flours from grains that could be used for making bread, only wheat flour used for bread making should fall within this definition.

Industry has highlighted several issues with this definition, including:

- Mills do not know the end use of the flour. The wheat flour may not be used for bread making and thus other products may be fortified with folic acid
- Fortification of flour not ultimately used for bread making will add unnecessary costs to Industry
- Fortification of this flour may lessen consumer choice

- Bakeries may use flour other than wheat Bakers flour to make bread that is not fortified with folic acid. Thus the bread will not contain folic acid, or may contain folic acid at lower than desired levels

Of note is that Industry is currently fortifying their wheat Bakers flour with thiamin as per FSANZ regulations. Thus Industry is recognising wheat flour that is ultimately being used for bread-making purposes.

4.3 Fortification – Current Australian Industry Practice

4.3.1 Industry Views on Proposed Mandatory Fortification

A range of views were expressed by Industry on fortification in general. Many comments fall outside of the scope of this Report and have not been documented.

Relevant comments received from Industry that relate to the current issue of mandatory fortification of BMF with folic acid include the following:

- The need for fortification must be based on scientific grounds – the rationale being that the costs to Industry must be justified
- Fortification levels must consider food safety issues – the rationale being that Industry must accurately meet proposed levels otherwise run the risk of causing food safety issues in certain sectors of the population or being open to liability issues. This also has implications on the ability of Industry to implement procedures to meet the desired folic acid levels.
- From a technical perspective, bakeries are micro-managing ingredients in their products. Thus folic acid fortification to a specific range with small tolerances may be better managed by that sector rather than rely on a system that essentially handles a bulk product i.e., fortification of flour at the mill.

For ease of management a small number of mills voluntarily fortify all their flours with thiamin. Mills fortify other flours based on customer requirements. From this it could be deduced that Industry is not opposed to fortification, as they can see the benefits either from a commercial or health viewpoint.

4.3.2 What Flours are Fortified

Fortification occurs in a number of overseas countries but only on a relatively limited basis in Australia. There is only limited voluntary fortification of flour.

In Australia there is no mandatory fortification of any flour or flour product with any other vitamin other than thiamin.

Thiamin

As previously stated, the Food Standards Code stipulates “Flour for making bread must contain no less than 6.4 mg/kg of thiamin”.

Most of Industry stated they fortify their straight flours and wholemeal flour products with thiamin. These are the flours generally used for bread making. There are mills that fortify some of their non-bread flour products with thiamin at the request of their customers.

A low number of small mills fortify all their flours due to the logistical difficulties in the mill of only fortifying their BMFs. Thus flours used for production of products other than bread may be fortified with thiamin.

Folic Acid

While most Industry sectors can see the need for an increase in folic acid intake by the general population, there is only a limited amount of folic acid fortification of flour or flour based products.

One major flour miller currently fortifies with folic acid their bulk export flour to an overseas market (Indonesia) that has mandatory fortification specifications in their Government regulations and thus customer contract. Fortification is set at a minimum 2ppm in flour for this market.

A limited number of products on the domestic market are also fortified. However one major baking company uses folic acid fortified flour in their bread production.

Based on Industry calculations, the fortification levels proposed by FSANZ will result in lower levels of folic acid than is currently present in some of these products. No confirmation has been conducted on this claim.

4.3.3 Customer Contract Requirements for Fortification

Thiamin

For those domestic customers requiring flour purchased to be fortified with thiamin, contracts are in general terms. Contracts do not specify tolerances, only that fortification is required. Similarly, based on Industry information there are no requirements for certification, sampling or testing as further confirmation that fortification levels have been met. While no contracts were sighted, Industry advice is that in most instances, actual fortification levels to be met are not listed.

Findings suggest this also to be the case for customers purchasing BMF where there is a mandatory requirement for fortification with thiamin. Bakery customers generally only specify flour quality characteristics of relevance to the end-use of the flour. They are not generally concerned with the level of thiamin, other than the thiamin is present at levels that meet regulatory requirements.

As Industry have openly stated that in general wheat flour for bread-making purposes may contain levels of thiamin higher than the regulatory requirement, this indicates customers such as bakers are not overly concerned with levels of thiamin in the flour they purchase.

Folic Acid

Where flour is fortified with folic acid for the export market, findings also suggest the customer is only concerned that the flour contains folic acid at levels that meet the

regulatory requirements. While contracts were not sighted, Industry advice is that no tolerances around the minimum level are stated.

In future, given the tight tolerances that are required for folic acid fortification, the current view of Industry is that customers may place greater focus on the levels of folic acid in flour for bread making. Contracts may state actual levels required and customers may require some form of certification as confirmation.

4.4 Where & How Fortification Occurs

In general the location of fortification with thiamin or folic acid is in a similar position in the milling process in each mill. Although variations do occur in some instances, in the main thiamin or folic acid is added in the main elevator or conveyor taking the flour to the flour storage bins.

Fortification generally does not occur following storage of the flour or immediately prior to outturn. Nor does fortification occur at packing. Industry prefers not to fortify in the storage or packing areas as it is too costly to develop separate systems for fortification. It is more cost effective, given the level of controls required on current fortification to fortify in the main flour conveyor.

Crude feeders are used to fortify flour with thiamin or folic acid.

In a typical small mill, a premix is generated using a base flour. This may involve creating a 1:500 premix, being 1kg thiamin and 500kg flour. Bags of this premix are then placed into a hopper. The feeder discharges the premix at a predetermined rate depending on the mill stream flow rate. The rate of feeding the premix approximately equates to the minimum level required as per legislative requirements, however overages are factored into the rate.

In larger flour mills, a similar process and equipment is used. However there may be a more automated mechanism used to control the flow rate.

In both small and large mills, flour fortification with thiamin tends to be a relatively low priority. Industry indicated this is mainly due to the legislation only requiring a minimum level to be complied with and the virtual “absence of legislative enforcement”. Findings were the equipment used is relatively crude and the level of monitoring could be described as minimal compared with other QA processes such as monitoring quality characteristics of flour outturned to customers.

There is no deliberate mixing after fortification to ensure levels are homogeneous within the flour. However by their very nature, the existing conveyors tend to mix to some extent the flour stream. On outturn further mixing also occurs as the flour is moved, further assisting creation of a homogenous product.

4.5 Fortification Levels

Industry advice is that when thiamin fortification regulations were introduced, significant efforts were made to ensure processes were implemented to meet the minimum levels of thiamin. A significant level of sampling, testing and ongoing monitoring occurred. Over time, as millers became familiar with the equipment and processes, the quality controls have been reduced to the extent of those today.

As stated, Industry has developed an attitude that limited controls over thiamin fortification are necessary to meet the current regulations. Findings were that this has led to a lack of focus on fortification processes, overages and testing for compliance other than what is the minimum required. That said some mills do place a greater emphasis on the process than others, mainly a reflection of adhering to their own internal QA system and procedures.

A range of tolerance levels for thiamin input were provided by Industry, although these were based on estimates in many instances. Industry does not appear to place a great deal of effort on measuring thiamin input over time and altering fortification processes on that basis. There are none to limited links between the feed rate of the mill and feed rate of thiamin feeders for in-line adjustment during milling. In most mills there is little monitoring during the milling process of thiamin levels.

Nevertheless the processes employed appear to be effective. Thiamin levels in the flour are controlled in a number of ways including:

- Knowledge and skills of the operators
- Setting equipment flow rates at the start of milling
- Monitoring as required during the milling operation
- Limited testing

No rates of overages in the thiamin premix were provided.

Industry indicated the current QA processes and equipment applied to thiamin fortification are not appropriate for folic acid fortification. Similarly they consider the current frequency of monitoring thiamin fortification is incompatible and not appropriate for the proposed levels of folic acid fortification.

All agree a significantly higher level of sampling and monitoring will be required, as will a tighter tolerance of folic acid concentration for both the premix applied and the resulting flour coming from the mill. This is discussed further in Section 5 of this Report.

4.6 QA Controls in the Mill

Mills are generally highly sophisticated operations where small changes to inputs and processes are used to alter the quality of the flour and thus profit from those operations. QC controls have been developed over time so that the milling operation is highly technically controlled using manual operations or via use of computer technology.

Sampling and testing to maintain flour quality occurs at defined stages of milling. Due to the controls used on the grist and the milling operation itself, in general a low level of confirmatory testing is required upon completion of milling and upon storage of flour prior to outturn.

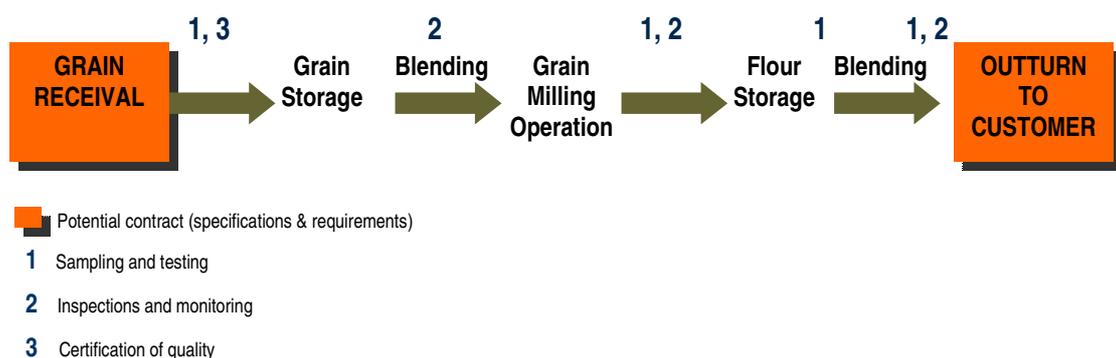
4.6.1 Overview

Most mills implement ISO9000 and/or HACCP Quality systems, as Industry recognise that flour production is a key element in the food chain and food safety issues must be controlled. The processes implemented are highly controlled and have evolved over a long period of time.

Each company and mill site implements internal procedures based on their company policy, location and design of the mill. Thus milling operations are not considered a generic process and are adjusted as required. In the case of folic acid fortification, each mill would similarly implement varying methods to achieve the desired outcome.

A typical QA process in a flour mill is depicted in figure 3. Variations exist depending on a range of factors and not all processes occur in all mills on every occasion.

Figure 3 : Typical QA Processes in a Mill



Contracts may stipulate testing and certification required. Based on factors such as risk assessment, mills may sample and test product.

4.6.2 Control of Production

The production cycle itself, while controlled, is highly automated and is described by the Author as designed for throughput based on known parameters. Industry advised it will need to change its thinking if fortification is required to the levels required in the Draft Assessment Report. The levels of fortification will need to be tightly managed during milling.

Most modern mills are fully automated and few staff are involved in the milling operation itself. Operations are generally computer controlled with staff monitoring operations and taking samples at strategic locations within the mill. The emphasis is generally on as few staff as possible with computers controlling operations where available.

For speciality flours, as a greater degree of control may be required than for bulk flours, generally higher staffing levels are required. Industry advised these flours tend to be milled during the day rather than incur expensive staff outside of normal day hours. Thus it could be inferred that milling at night and thus the fortification process, incur a lesser degree of control than non-fortified product.

Most processes to control the quality of the flour in the mill occur before the product is created. Controls over wheat selection, segregation of wheat, testing, grist and conditioning are all up-front of the milling operation.

Variations such as the conditioning of the wheat and extraction rate will require the miller to vary the mill flow rate. Based on these variations modifications to the feeder premix flow rate would be required to meet tight tolerances. Millers indicate they cannot rely on the addition of a finite level of an ingredient such as thiamin/folic acid. The feeder equipment flow rate will need to be actively controlled. That said the controls appear appropriate for current thiamin fortification.

When milling specialty products or producing flours according to customer specifications, Industry indicated the level of contamination of flour with another needs to be considered. This also applies to contamination with fortification premix. Industry closely monitors potential contamination areas and scenarios and via use of changeover bins, can modify products and keep them within customer specifications.

4.6.3 Outturn

Similar to the tight controls on flour production, there are also tight controls over the outturn of flour. Industry advice is that no flour is released from the site unless the quality is known to meet the requirements of the end-user as specified in the contract.

4.6.4 Overages

Most of Industry aim for a slight overage but an accurate estimate could not be given by Industry.

Based on information supplied by Industry, findings were that overages may be up to 30% where some degree of control applies. Where mills have less control, the level may increase to over 100% on some occasions. This applies particularly to small mills where interruptions to flour streams may be more frequent than in larger mills due to be shutdowns between milling different products.

Mill operations in large mills are virtually continuous with minimal shutdowns. This has an effect on the accuracy of fortification levels and generally the more shutdowns, the greater the variation in fortification levels that arise. An overage rate in larger mills similar to small mills was estimated by Industry.

For commercial reasons, Industry advised the least amount of thiamin is added as possible in order to achieve the minimum level. Thus generally there are no overages or these are reduced to the barest level as thiamin addition above the minimum costs the companies involved.

Those comments are at odds with the following comments received from other Industry stakeholders that imply levels of thiamin may be relatively high in some instances on outturn of the flour:

- Mill chokes causing high levels in the flour as the thiamin feeder may often be running throughout much of that period
- New product runs where flow levels are still being “bedded down”
- Variations in flour flow rates as a result of quality issues
- Minimal QA based on “lack of regulatory rigour”
- Thiamin goes into “everything”
- “We never underfeed”

That said, comments such as “occasionally the feeder bin is found to be empty” indicate required fortification levels may not be met for some flour outturned for bread making purposes.

These conflicting comments highlight the uncertainty of levels in flour and the general lack of rigour of fortification processes in some mills.

4.6.5 Sampling and Testing

Testing occurs to a lesser extent at the major stages during the milling process itself to monitor the quality of the product produced.

Only limited testing of the final product is required generally using laboratory analysis on site at the mill where available. These confirmatory tests are readily able to be conducted in a short timeframe using the available staff. As noted before, blending of flours may also occur to alter the quality to that required by the customer.

Industry advised that initially they set up their feeders and took samples to ensure the minimum standards were being met. A significant number of samples were obtained and forwarded to laboratories for analysis. Adjustments were made and gradually over time, sampling and testing to any great extent were not considered to be required by Industry. The result is that relatively little sampling and testing now occurs compared with when regulations were implemented.

Findings indicate the primary concern of Industry appears to be testing for customer flour quality specifications, with legislative requirements a lesser priority.

Industry advised they do not generally conduct thiamin testing in-house, but rely on external commercial laboratories to test samples at varying rates:

- Randomly
- Every week
- Once or twice a year

While commercial laboratories are generally used for analysis of thiamin, there were no indications from Industry that laboratories must be certified and accredited for that test. That said, as most of Industry operate their mills under a QA system, there may be a requirement to use only appropriately accredited laboratories. In addition, knowledge of the Author indicates that most commercial laboratories have recognised QA systems and operate to relevant international Standards by default.

4.7 Re-processing Flour

Flour may be required to be re-processed either due to:

- Flour produced out of specification
- Flour rejected and returned to the mill by the customer (returns)

No data on the causes and levels of flour requiring re-processing or returned were received from Industry.

Industry advised their mills are not readily set-up to receive large tonnages of returned flour, as their main purpose is to despatch flour, not receive it. In general where small tonnages are received this can be adequately managed with existing equipment. However where large tonnages may be involved, additional equipment for handling and processing of the flour in the storage and bagging areas was stated as being required.

No mill indicated they were adequately set-up to receive large tonnages of such material although their returns system is adequate for most current scenarios they encounter.

4.7.1 Flour Quality Issues

If an issue did arise during milling or following outturn, the larger mills indicated they do have some ability to blend flour. There may be several large flour bins on site which enable the blending of flour on outturn, depending on the availability of those bins. Smaller mills with less storage have a greater issue than larger mills.

When flour is required to be re-processed before leaving the site or returned, the mill must determine:

- The quality of the flour to determine why it is out of specification and to enable a decision on whether the flour quality can be rectified;
- Their ability to re-process it to meet the original product specification; or
- Whether the flour must be blended into some other product

The flour must be separately stored while the remedial action is determined. Industry advised that in many situations, the mill will attempt to blend off the product into other flour provided there is no detrimental effect on the quality of the resulting flour. In extreme cases, the mill may be required to re-process the flour in some other manner as this strategy may not be an option.

Depending on the tonnage, this may have major disruptions to the current mill operations. No data was provided by Industry on the level of re-processing however

given the tight control over milling processes this is not expected to occur to any significant extent.

4.7.2 Fortification Level Issues

Similar to the above processes, flour for bread making that is fortified with thiamin and/or folic acid must be returned to the mill for re-processing if there is a quality issue or if levels of thiamin or folic acid are not adequate. As per the discussion above, no data on flour returned solely due to incorrect fortification levels was provided although this is expected to be rare given the relative lack of concern with fortification levels discussed previously in this Report.

When fortified flour was returned, as per flour returned for quality considerations, it would need to be stored separately until a decision could be reached on appropriate remedial action. Thus fortification and quality considerations would need to be taken into account in making the final decision on a method to rectify the flour specification.

Similarly, Industry advised that folic acid fortified flour would need to undergo the same decision making process. Industry advice is that the level of accuracy required for folic acid content would add a further degree of complexity to this decision making process. They advise remedial options would be reduced and storage for longer periods would be required until the flour could be appropriately blended into another product. Industry advice is this would add significant costs.

Equipment would need to be significantly modified and further equipment purchased where required to re-process large tonnages of returned fortified or non-fortified flour. Industry has designed such systems as discussed in the following Section on the basis that up to 13 mills would require this returns set-up. This alludes to large tonnages falling out of specification leaving the mill.

4.8 Costs of Fortification

An accurate cost of fortification is difficult to determine given the limited fortification conducted by Industry at present other than thiamin. For thiamin, as mills vary greatly and fortification is not a high priority, it is difficult to determine a cost of fortification.

The general view from Industry is the cost is relatively insignificant in the overall milling process and thus detailed cost analyses have not been conducted. Previous comments by Industry on overages support this view.

International data shows that costs vary depending on the milling operation³. For the USA where minimum levels are set voluntarily, as opposed to mandatory for thiamin in Australia, a brief range of costs are outlined as follows:

USA – thiamin

- Is classed in the same group as Zn, vitamin B-6 and B-2
- All are classed as having the lowest cost of all the fortification ingredients
- Cost range of US\$0.08-0.25 per metric tonne

USA – folic acid

- Is classed in the same group as niacin and B-12
- Are all classed as having an intermediate cost of all the fortification ingredients
- Cost range of US\$0.18-0.60 per metric tonne

³ Omar Dary

5 PROPOSED MANDATORY FLOUR FORTIFICATION

It is the view of the Author that there is no need for a complex system as advised by Industry costing “millions of dollars” for the proposed mandatory fortification of flour with folic acid. This is based on a limited amount of regulatory enforcement and enforcement agencies working with Industry when issues with fortification levels arise, rather than pursuing the legal options in all scenarios.

That said Industry has raised genuine concerns regarding two key issues:

- Their legal liability in future should any food safety issues arise and it has been shown the required range was not met for all outturns
- Their obligations under their Procedures and Quality Systems to meet the proposed regulatory limits for all outturns

These items are discussed in further detail in this Section with options outlined to find a satisfactory solution for Industry and government.

In addition comments on the Elliott Report⁴ from overseas experience and from the Author are outlined in the following Section.

The following Section relates to the proposed mandatory fortification of BMF with folic acid. It does not deal with Industry proposals or comments relating to voluntary fortification.

5.1 Proposed Industry Fortification Process

5.1.1 Industry Proposal

Industry advises they would prefer to add the folic acid and thiamin in the one process. As per current procedures, fortification would involve adding folic acid and thiamin to flour as a premix.

Most of Industry indicated in future they may only fortify particular products requiring thiamin or folic acid, potentially reducing the amount of voluntary fortification that currently occurs or may occur in future without the proposed mandatory fortification regulations.

Industry would fortify BMF during transfer of the flour from the mill to the bulk storage bins prior to packing, blending or holding within the storage area.

⁴ Richard Elliott Milling Consultant Service Pty Ltd, February 2007

In the Elliott Report for small mills, it quotes that as the flow rate varies, a transit bin is required to receive BMF from the mill. As the flow rate from this new bin can be controlled, flour will be fortified as it flows from this bin back into the existing mill pathway. Non BMFs will bypass this new system and only flow down the existing system.

For large mills the Elliott Report states that flour for bread making purposes will also be directed to a transit bin. Flour will also be fortified as it flows from this bin. The fortified flour will then be stored awaiting test results. Upon receipt of test results, the fortified flour will then be returned back into the existing packing pathway or bulk outloading transfer system. As the flow rate is significant a number of new flour storage bins will be required awaiting test results before the flour will be released for packing or outloading.

In summary form, Figures 4 & 5 depict the Elliott Report proposed pathway of fortification for small and large mills respectively.

Figure 4 : Industry Proposal for Fortification in Small Mills

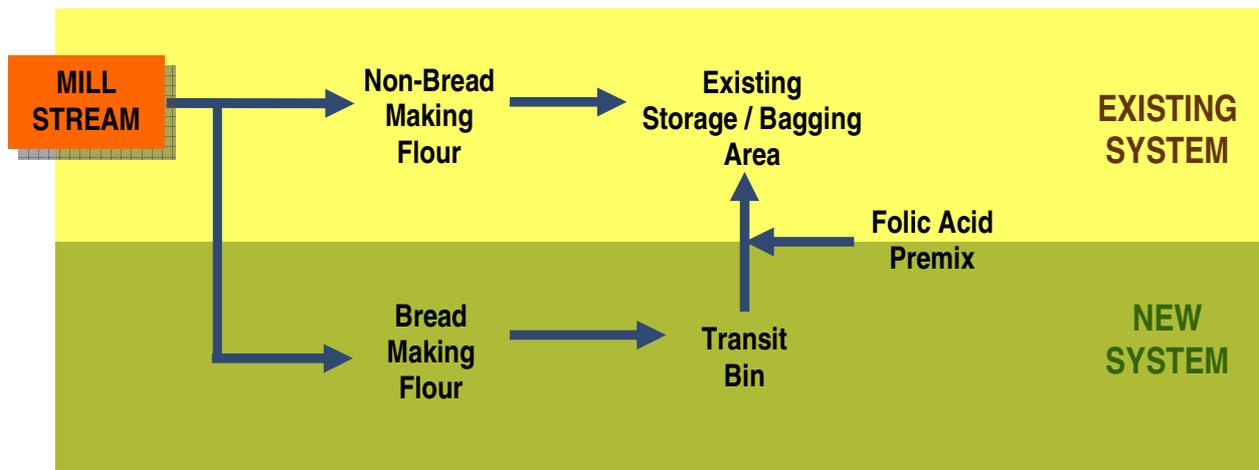
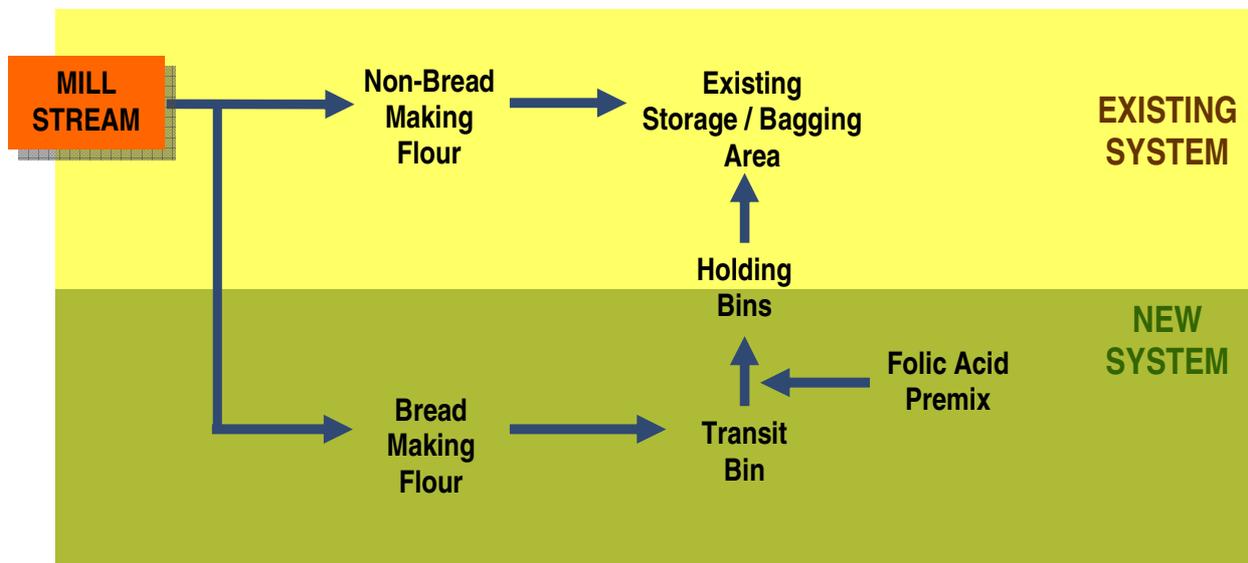


Figure 5 : Industry Proposal for Fortification in Large Mills



Industry considered using a transit bin would provide for greater accuracy as opposed to adding the folic acid immediately following the milling process in one of the existing flour streams. The system would be set up with a link from the flour feed ex the transit bin to the premix feed for accurate dosage, leading to no significant under-dosing or over-dosing and fortification within the required range.

The Industry view is that fluctuations in the mill flow rate would not enable sufficient control without the use of the transit bin. Likewise, mixing conveyors of sufficient length would be required to achieve a homogeneous mix of the fortified flour before returning to the existing mill stream. For both the small and large mills, the processes would require a significant alteration to the mill and flow path and add significant cost, as described in the Elliott Report.

5.1.2 Expert Comments on Industry Proposal

Industry uses a wide array of mills to produce BMF, from unsophisticated to highly sophisticated. Overseas experience in North America and a number of other countries with fortification indicates many relatively unsophisticated mills are able to successfully fortify flour with folic acid. Personal communication with a fortification expert⁵ who has fitted these systems in many countries indicates it is feasible to meet the range required by FSANZ in Australian mills.

⁵ Quentin Johnson

Based on that information, most Australian mills should be able to be retrofitted with feeders quite easily. This is at odds with the Elliott Report that indicates a significant upgrade to the feeder area and flour streams would be required in most mills.

Many mills in developing countries have retrofitted feeders of the type outlined in Appendix 2. Expert advice indicates the most important point in meeting fortification specifications in these scenarios is the correct installation of feeders.

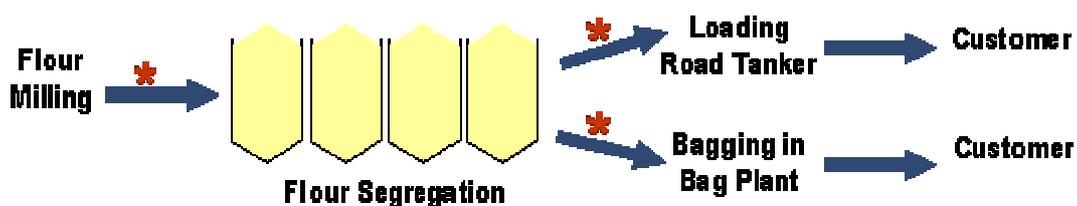
Flour holding bins until folic acid levels are analysed are considered as not required. With controls on the feeder rate based on flour flow rates, the levels proposed by FSANZ are achievable. Thus flour will not be required to be held until each consignment is certified to meet the proposed range.

5.1.3 Author Alternate Proposal

The Elliott Report provides an overall summary of the most suitable set-up for a small and large mill and identifies in reality that a range of set-ups will be needed depending on the size and complexity of the mill. This is a valid assumption and generalisations on the set-up are made in this Report. However given the experience from North America and other overseas countries, major modifications may not be required.

The following describes an alternative option to that proposed by the Industry through the Elliott Report. Figure 6 depicts a simplified diagram of the proposed points of fortification.

Figure 6 : Potential Folic Acid Flour Fortification Point



* Folic Acid fortification
NB Flour segregation/storage could be bypassed

Note that fortification will only occur at one point in each mill. While the most suitable could be expected to be as flour immediately leaves the mill, as currently occurs, an alternative fortification process could occur after flour storage and immediately prior to

outloading. However as this option is more costly than the previously mentioned process, this is not recommended.

A separate stream for BMF would not be required. Existing thiamin feeders would be replaced on the current flour streams.

It is acknowledged that all mills including the small mills would require a greater degree of control than currently exists for thiamin. Sensors with automated controllers would be required on the feeder and the flour flow path. For modern mills, this would be via automated plc controllers already existing in those mills. For smaller or older mills, manual control of the flow rates may not suffice and mills may need to install new controllers.

The sensors would need to be able to detect changes in BMF flow rate and alter the folic acid feeding rate as per the required dosage. The feeders in Appendix 2 are cited as having a feed rate and compatibility with the addition of the necessary controller equipment where this degree of control can be achieved.

In North America and in many overseas countries, fortification feeders are usually placed on top of the existing flour collection conveyors. These conveyors in part act as blending mechanisms as fortified flour is transferred using pneumatic systems or conveyor systems into storage bins. Flour transfer into the packing area or into outloading bins for loading bulk flour trucks provides additional mixing. Thus it is considered an additional mixing system post fortification as outlined in the Elliott Report is not required.

Action No. 1 The solution from Industry outlined in the Elliott Report to set-up transit bins and a new production line is reviewed by international fortification expert(s) to determine the need for such a system given the limits required for folic acid levels in BMF. Include a case study of the feeder system set-up in both a small and a large mill to determine the accuracy limits of feeder units applicable to each mill set-up.

5.2 New Infrastructure and Equipment required for Mandatory Folic Acid Fortification

5.2.1 Vitamin Premix

Industry Views

The majority of mills already have a premix plant on-site and make their own premix for fortification of flour with thiamin and folic acid where appropriate. The complexity and degree of control over the premix produced varies. However, the process is considered “accurate enough” by Industry to enable them to meet the current regulatory limits for thiamin and customer requirements for folic acid where stipulated.

Most mills consulted stated they would make the premix on-site as they would not rely on commercial bodies to supply premix with folic acid and/or thiamin within the correct tolerance levels required.

One miller stated they would not be prepared to transport folic acid premix to their other mills across the country as the logistics would be difficult. Thus folic acid premix would be made on site at each of their milling operations. This is a reasonable assumption given the large tonnages involved and issues with timeliness of delivery.

During consultations there was a view among several Industry stakeholders that as the capacity of each mill varies, no single premix could satisfy requirements of every mill for the folic acid range required for their BMF. When sourcing the folic acid/thiamin premix from a commercial company, a second premix stage may be required to ensure the premix has the appropriate level of folic acid. As this issue has not been subsequently raised in the Elliott Report, this view no longer appears valid.

For on-site premix production, mills would need to source appropriate quality folic acid. The purity of the folic acid must be specified by the supplier, but is quoted by one supplier as 100%.

No estimates were sought from industry on the degree of accuracy required when making the premix.

Expert Views

Premix is a key component in ensuring the tolerance levels are met. In North America, mills generally purchase the premix for fortification of flour. Generally premix manufacturers specify a 5-10% tolerance for vitamin content in the premix. This is acceptable to the industry and does not add to the complexity of the fortification process implemented by each mill.

Author View

The Elliott Report only stipulates costs for the creation of 2 new premix plants for the proposed folic acid fortification. Current plants in other mills are assumed to be able to

compile the premix to the correct specifications or smaller mills would have access to suitable supplies.

Industry stated one reason why they would make their own premix was that they could not rely on the accuracy of premix produced by commercial suppliers. Although there is no evidence to support or negate this view, it does not appear to be a valid argument given normal commercial practices. Overseas experiences indicate suitable premix is able to be supplied.

Of note in the Elliott Report is that the cost of premix supplies (Appendix F) assumes a (profit) margin of 20% for the entire production of premix required by all Industry. It could be assumed from this that all premix supplies would be drawn from commercial suppliers. This is at odds with advice from Industry.

There were no indications from Industry that:

- Development of a thiamin/folic acid premix was a complicated process
- Mills would have difficulty in producing a premix with the required levels of thiamin and folic acid or a separate premix with either vitamin where required

The production of suitable premix does not appear to be a significant impost to Industry nor beyond their technical capability.

5.2.2 Feeders

Industry Views

All industry acknowledged the current feeders are inadequate for meeting the tolerances proposed by FSANZ. The type of feeders being used do not render them suitable for upgrading or adjusting to meet the tolerances and feed rates required for folic acid fortification. Thus they will be required to be replaced with more accurate feeders.

Industry indicated “pharmaceutical feeders” would be required and that the feeders would not be totally suited to a bulk flow pathway. Two different set-up types would be required as depicted in summary form in figures 4 & 5. While these depict the proposed pathway of fortification and location of feeders for small and large mills respectively, in reality each mill set-up may be different.

The Elliott Report indicates 20 mills would fall into Category A, being a less complicated and thus expensive system than 7 mills that would fall into Category B, requiring a significant upgrade to their mill flow paths including feeder area.

For accuracy, a weight loss system would be needed, along with a range of associated equipment.

Expert Views

Output from feeders may be based on:

- Volume. This system assumes the ingredients within the premix are at a constant volume. This is not necessarily so with some substrates but considered satisfactory for vitamins.
- Weight loss. This system requires flour scales and a greater degree of sophistication of set-up.

Sources expert in fortification⁶ indicate either system may be suitable. The greater control of a weight system may be advantageous however these will cost significantly more. Overseas volumetric feeders have been used in both large and small mills, with similar flour production rates as those in Australia.

The set-up time and complexity⁷ varies depending on a range of issues such as:

- Number of feeders per mill
- Whether the mill is pneumatic or gravity fed
- The point of application of the premix
- The type of feeder desired
- Amount of technology required on the feeder such as loss in weight, motor controls

An example is outlined based on a simple feeder installation with one feeder on a gravity feed placed above the flour conveyor with a remote start/stop slaved to the mill plc. This would be very simple and would require only cutting an access hole in the top of the conveyor, and running the electrical and communication to the mill plc. For this method for 1 to 5 feeders, it would be 1-2 days to install.

Pneumatic installations would add an extra 1-2 days depending on length of distance between feeders and discharge point. The amount of obstacles to pipe around may add time.

For the Model 70 feeder in Appendix 2 the lead time for 28 feeders is approximately 6-8 weeks. The Micro-fuser feeder being a more advanced feeder of the screw type design is currently the most popular used world-wide because of the design and technology applications. This feeder has a 12 week lead time.

The feeder once installed can be checked every shift if required by collecting the output from the feeder for a specific period and weighing the premix. The rate of feed can then be calculated.

⁶ Quentin Jonson

⁷ Research Products Company

Author Views

As noted previously the feeders currently used for fortification of flour in Australian mills are relatively crude, with QC on their use at the minimum required to meet regulatory and customer needs. They are not suited to the proposed range of fortification of BMF with folic acid.

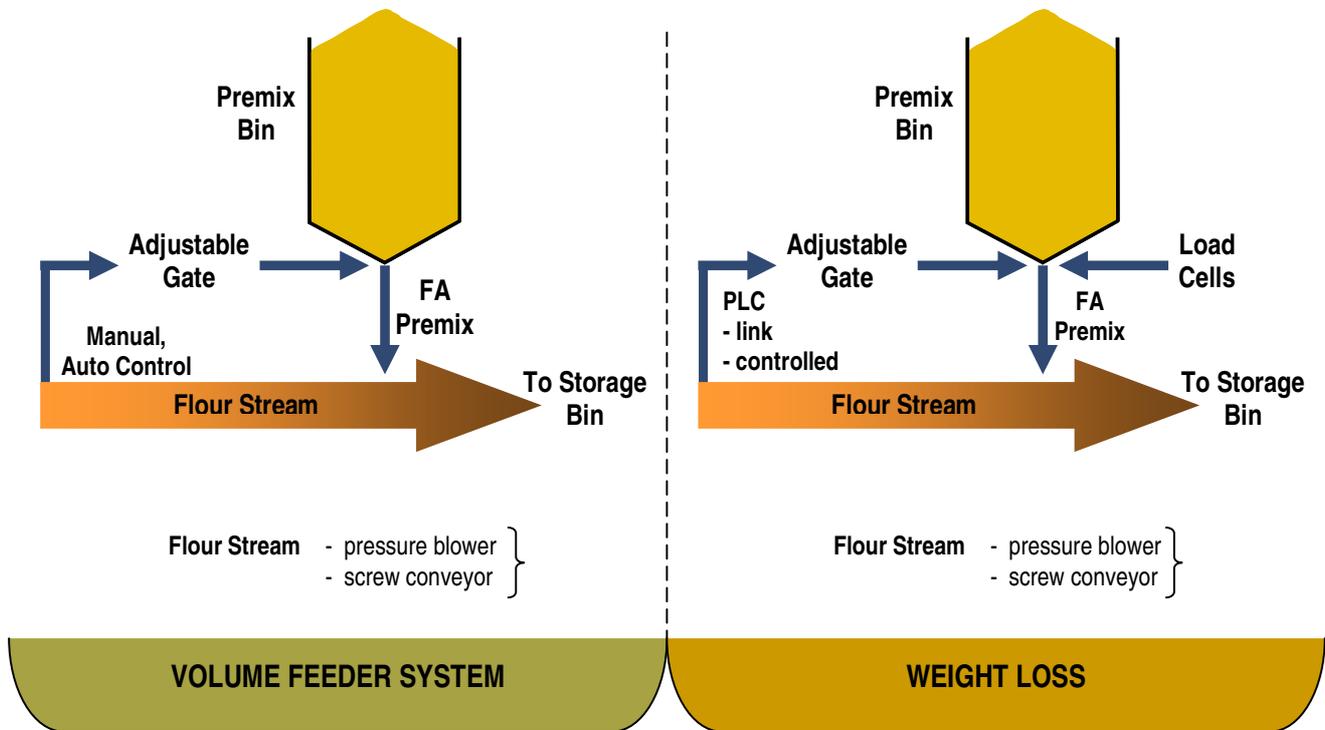
Although the feeders are crude in nature they do meet the task required for thiamin and where applicable, the minimum levels required for export customers sourcing flour fortified with folic acid.

The type of feeder outlined in Appendix 2 is generally in use by many overseas mills that are fortifying flour in the mill to a minimum level with folic acid. Other equipment manufacturers with suitable equipment are also included.

No estimate on the number of feeders per mill would be required but it is assumed one for folic acid would suffice.

A typical set-up is generalised in figure 7. Note that variations in individual mills may preclude the use of one or both options. For example, physical space within the feeder area may not enable complex weigher, screw auger systems or additional transit bins to be added. In the Elliott Report the feeder areas have been completely re-designed. The practicality of this in each mill has not been determined during this project.

Figure 7 : Feeder Systems Available



The feeders outlined in Appendix 2 have a flow rate between 113g to 27kg per hour. This adequately meets the flow rates defined in the Elliott Report of 300-900 gm per hour for mills between 10-30 tonnes per hour. The variation around these flow rates is not provided however overseas experience identifies the systems are easily adjustable and accurate.

These feeders can be sourced from the manufacturer and supplied to the mill within approximately 6-12 weeks of placing an order for approximately 28 units depending on the unit type. Installation can usually be done in 1-2 days with set-up, calibration and testing a further 1-2 days.

For other manufacturers listed in Appendix 2, the delivery time has not been sourced but is assumed to be similar.

Suitable feeders are available for use in fortification of BMF with folic acid and should not require a significant modification to milling areas for installation.

5.2.3 Sampling & Laboratory Testing

Sampling and testing of fortified product to confirm fortification levels will require access to testing facilities through a laboratory on-site at the mill, at another mill location or an external commercial laboratory.

Industry Views

Industry advises that sampling in real time during flour production whenever fortification occurs will be needed. No product will be permitted to leave the mill unless it complies with the regulatory limits for folic acid. Flour must be stored until results are known. To minimise disruption to milling operations sample test turnaround must be rapid.

No views on the mechanism of sample collection were sought however as current operations are mainly manual, this is expected to continue for folic acid.

The level of sampling and subsequent testing will be determined by the relative risk and QA processes implemented by each mill. This cannot be determined at this stage. Industry sources indicate a range of testing from every hour to up to “6 months”, with the former being more favourable.

Industry considers the transfer of samples to external laboratories for folic acid analysis impractical for a number of reasons including:

- The impracticality of organising large numbers of samples
- The logistics of organising sample pick-up, despatch and receipt of results on a 24 hour basis
- The long timeframes involved in the provision of results based on timeframes for sample pick-up, despatch, result generation & review, receipt of results by the mill

At present no mill can test for folic acid on-site and samples are sent to commercial laboratories for analysis of thiamin and / or folic acid as required.

Mills indicated they would need to store the fortified flour until cleared for outturn. To minimise storage space required and due to issues outlined above, many mills advised they would install on-site laboratories for testing of folic acid levels. The Elliott Report indicated 19 mills would provide their own folic acid testing facilities and dedicated testing equipment. It is assumed the others would use commercial testing services.

The Elliott Report includes labour, running, maintenance and interest costs in their final estimate of costs assuming the mills would purchase the Biacore folic acid testing unit. The level of testing in these mills is higher than for those mills using commercial testing services.

The high level of testing as proposed by Industry with on-site facilities will require:

- Training in sampling techniques or use of automatic samplers
- A sufficient sized and fitted laboratory
- A method for sample provision to the laboratory
- Resources to conduct testing, including provision of training
- Testing equipment and consumables
- Storage of product until results are known

It is unclear if the level of testing will reduce over time as per that which has occurred for thiamin. However some views were expressed that testing would occur for all BMF leaving the mill, implying the levels of testing would be maintained while the mandatory folic acid regulations were in place.

Expert Views

Based on overseas experience, mill set-up required calibration of equipment and testing of folic acid levels in the fortified flour. Once experience was gained, the level of testing could be reduced.

This level of testing varies by mill. In North America, no mill conducts folic acid analysis⁸. Samples are sent to one of up to 5 commercial laboratories that test for the entire milling sector, although there are reportedly only 2 main laboratories used.

The Biacore system test method is not recognised officially internationally, nor is the most common test method using HPLC. However the HPLC method is currently being progressed through that process.

Based on experience the sampling rate for North American mills is significantly lower than that proposed by Industry in the Elliott Report. Generally samples are taken and sent for analysis every 2-4 weeks.

Simple spot checks are also done as required. This involves collection of a sample from the mill stream post fortification every 2-4 hours. This sample is taken at the same time as samples are taken for other flour quality tests, thus no additional resources are required. It is a semi-quantitative test to indicate if premix is in the fortified flour.

Author Views

Industry has stated that no product will be permitted to leave the mill unless it complies with the regulatory limits for folic acid. As outlined previously, this is a conservative view by Industry based on their approach to legal liability concerns and internal QA systems and procedures.

Sampling of fortified flour may be manual or automatic depending on the degree of control required by the mill. Manual sampling would be sufficient for most mills as the

⁸ Quentin Johnson

cost of installing automatic systems would not be justified. This is based on the following assumptions:

- The expected low level of monitoring for compliance by regulators
- The intention of regulators to monitor samples over a relatively long period of time through compositing of samples collected
- Mills monitoring relatively infrequently
- Collection of samples for folic acid analysis at the same time as collection for analysis of other quality parameters i.e., the same sample can be used

Should any of the above assumptions alter, the cost benefit of installing automatic samplers would need to be reviewed.

It is assumed thiamin could also be tested where required, although not at the same high rate as for folic acid.

Timeframes for testing folic acid in commercial laboratories are considered too long by Industry under the proposed fortification scenario. Commercial laboratories have indicated these timeframes could be reduced⁹, although this is not based on any detailed analysis and no timeframes are able to be quoted at this stage based on the methods used.

Several mills indicated they have relatively rudimentary laboratory systems or have no laboratory at all, with some testing equipment physically located within the mill itself. Mills indicated they may have neither the capacity nor resources to undertake folic acid testing and would need to purchase the necessary equipment and in some cases create suitable laboratory facilities. It is assumed these mills in the Elliott Report are the 9 that will send samples for commercial testing rather than set-up their own laboratory.

Based on overseas experience, investment in HPLC or other testing equipment such as the Biacore is not necessary at the individual mill level. Instead, a reputable commercial laboratory will need to be identified or a large milling company could purchase equipment and test samples for a range of its mills depending on location.

The frequency of testing overseas is indicative of the minimum standards set however even with mandatory regulations covering a range of folic acid levels, indications are the level of testing would not increase significantly.

Thus Industry should implement a significantly lower level of testing than indicated in the Elliott Report, based on acceptance of low levels of monitoring required by industry to indicate to regulators compliance with the folic acid regulations. The level of testing cannot be determined at this stage, as that will be determined by each mill as part of its risk strategy. However based on overseas experience mills should accept a low risk

⁹ Australian Analytical Laboratories

profile and only be required to sample and test on a relatively infrequent basis if all other monitoring processes and controls are in place as described previously.

It is recognised that initially, testing frequency will be relatively high given the uncertainty by Industry of the fortification process. However with experience and the benefit of test results, this is expected to be lowered significantly over a relatively short period of time.

If mills are to conduct their own testing, it is reasonable to assume they would purchase the Biacore equipment, as this is the quickest test at present and appears to be reasonably accurate¹⁰. That said, further work on the test method for folic acid in flour may be required given the method has not yet been published or approved internationally. Unfortunately this is the most costly of all testing units.

Action No.2 The method of testing for folic acid content in flour using the HPLC method and potentially the Biacore system is approved internationally.

5.2.4 Storage Areas

Industry Views

Industry indicate in the Elliott Report that folic acid fortification would involve active monitoring of the flour fortification process and setting flour aside to test for the folic acid levels before release from the mill. This would require new flour storages.

At large mills this would involve a minimum of 32 hours of additional storage, with less at smaller mills.

Expert Views

Based on overseas experience, control of processes such as premix folic acid levels and flow rate during fortification, accurate levels of fortified flour can be produced. Mills do not store this flour until test results are generated, nor have they created additional storage for this purpose.

Author Views

As outlined throughout this Report there is a high degree of variation between the proposal by Industry and that considered adequate through overseas experience. The change in mill set-up including additional flour storage areas outlined in the Elliott Report

¹⁰ Biacore Life Sciences

would only be required if every consignment leaving the mill is required to meet the proposed fortification range. This does not appear to be required, as outlined in this Report.

These additional storages are not required at the number and volume noted in the Elliott Report and implied during industry discussions. Some level of additional storage may be required:

- Initially as mills set-up their mills and run the fortification process. Over time as they gain experience less holding of flour will be required
- No process is ever “perfect”. At present mills may hold some level of flour over until further testing is conducted to determine quality or fortification levels. Given the degree of accuracy required, it is realistic to expect this added quality parameter to add further complications to the milling process. Thus some increased level of holding flour may be needed

Large and small mills alike will need to go through the initial bedding down stages. Rather than include some level of additional storage, in this initial bedding down period additional testing may need to be conducted. Only as a last result, should mills consider installing costly additional flour storage.

Note however that these requirements cannot be estimated at present until detailed plans are drawn up by each mill.

No additional flour storage is required to hold flour until each batch is analysed for folic acid content.

5.2.5 Re-Processing Area

Industry Views

For non-compliant product there needs to be a process for rectification of the levels of folic acid by for example:

- Re-processing or blending of product to meet the required levels prior to or on outturn
- Altering the end-use of the fortified flour to a non-regulatory use
- Receipt of rejected product (returns) and re-processing at the mill premises in some manner

Either one of these options will require storage of flour until the process can occur. It may also require re-configuration of flour streams to enable activities such as blending.

Generally Industry have advised they would have one try at adding folic acid to the required tolerance and that's it – they cannot re-process to any great extent other than limited blending under their current mill set-up. Thus the Elliott Report proposes a significant modification to the returns area for 13 mills. The returns area for the remaining mills is assumed to be adequate.

When receiving returns and re-processing flour, the flour could not go through the existing pathway as it may undergo a double-dosing of folic acid. A mechanism to bypass this system would be required and a process has been outlined to return this flour into the pathway for non-fortified flours.

Expert Views

The level of returns of fortified flour predicted by the Elliott Report was considered a significant over-estimation based on overseas experience¹¹. Returns were not considered a significant issue. Comments received included:

- The current returns area in mills is used for rectification of quality and fortification issues. This would appear adequate for future fortification returns
- The high level of QA and control of processes employed in Australian appears at odds with the expected level of returns of folic acid fortified flour and re-structuring of the returns areas as outlined in the Elliott Report

Author Views

The Elliott Report indicates 13 mills will need a new returns area. It is assumed the other mills have adequate returns processes. This is considered a high number of mills requiring a new returns process to the extent outlined given current and future QA controls employed by Industry during flour production.

It should be noted that existing returns are thought to occur for reasons of quality and / or fortification levels. This arises despite extensive QA systems in each of the mills and testing of flour along the milling pathway. Conversely the relatively limited controls on fortification have also been described and acknowledged by Industry.

With greater control of fortification and thus focus on QA systems, it could be reasonably expected that the level of product out of specification identified before leaving the premises or returned should be reduced and thus not be as high as expected by Industry. However as noted previously, Industry has taken a conservative approach in this regard.

It is unclear from the Elliott Report the extent of returns needing to go through the fortified or non-fortified pathway. The current level of returns was not provided in that

¹¹ Quentin Johnson

report or through discussions with individual mills as this is thought to be considered commercially sensitive information.

5.3 Overages & Tolerance Levels

5.3.1 Premix

Industry Views

Industry did not state what their requirements would be in terms of accuracy of premix or any level of overages in this premix. However comments received related to:

- The need for highly accurate levels of folic acid in the premix
- Consistent levels of folic acid in the premix
- Uncertainty of commercial suppliers to meet Industry needs for premix production
- Production of premix on site

Expert Views

Based on overseas experience, premixes are made with folic acid with overages accepted by all industry. In the United States for example, the overage included into the formula by premix manufacturers is 10-15%¹². This overage takes into consideration that folic acid contains 8.5% moisture in addition to moisture in the flour and there is some degree of inaccuracy in the analysis of folic acid in flour (note no analytical method could be considered 100% accurate).

Author Views

While Industry did not state what their requirements for tolerance levels and overages would be, an estimate has been made. There does not appear to be any valid reason why overseas experience could not apply to suppliers of folic acid premix in Australia whether they are commercial suppliers or mills make their own premix on-site.

This view is also supported by the Elliott Report indicating only 2 mills would require a new premix facility, with existing facilities and procedures considered suitable for the purpose.

At present there are a limited number of suppliers of folic acid premix to the Australian market. The major supplier to existing mills fortifying with folic acid appears to be Bronson and Jacobs Trading. Note this company also supplies a premix containing thiamin.

5.3.2 Flour Production

The Draft Assessment Report requires a range of 230 – 280 ug folic acid/100 g of BMF. A residual level (i.e., level in the flour after baking) of 200 ug folic acid/100 g of flour was selected as the recommended level of flour fortification.

¹² Quentin Johnson

Having decided on the level of 200 ug folic acid/100 g of flour, there needed to be a tolerance for:

- Addition of the folic acid to the flour
- Baking losses

Plus 20% was allowed for baking losses, and +/- 10% was allowed for the point of addition of folic acid to the flour. The final figure for fortification was therefore concluded to be 230 – 280 ug folic acid/100 g flour.

Industry Views

For commercial reasons, the amount of overages is kept to a minimum whilst still meeting customer or regulatory limits for fortified flour. Levels must also be considered in light of the practicality of meeting the proposed fortification range by batch and production run. As yet there is no indication on what the jurisdictions will implement, however as indicated previously Industry has determined its own interpretation of this requirement.

Industry has stated that no flour will leave the mill unless it meets the regulatory limits for folic acid and this will involve the extensive modification to mill equipment and processes outlined in the Elliott Report. By implication, this infers processes must be accurate to meet the range by consignment, being 230-280ug folic acid/100g flour.

No indications were received from Industry on variations around those levels or the levels of non-compliance permitted other than general comments such as “the levels must be achieved” for all consignments.

The degree of rigour for current thiamin fortified flour leaving the mill was less than that stated by Industry for future folic acid fortified flour.

Expert Views

In considering the appropriateness of overages in general, the variability of the analytical method and sampling errors must also be recognised. For practical purposes, this means that an unrealistically tight specification could not be used (e.g., $\pm 5\%$) and then use an analytical method that had a higher variability.

As previously stated, there are a number of overseas countries that set minimum mandatory fortification levels. The minimum level in the USA is approximately 10% higher than that proposed in Australia. 10% is the usual level of overages in North America based on their extensive experiences with fortification of flour. Similar figures apply in other countries that have recently introduced folic acid fortification.

While adding a maximum limit in Australia will increase the complexity of compliance for Industry, advice is that in reality this should be readily able to be met given previous considerations.

For example, in the US, the specifications for addition of folate to some of the cereal-grain categories that are fortified with folate are provided as ranges:

- 154-308 micrograms/100 g for enriched rice
- 198-264 micrograms /100g for enriched macaroni products

Author Views

Initial industry discussion indicated in general that 20% variation in folic acid levels in BMF flour should be acceptable. At that time no extensive analysis had been done on equipment required to meet this variation. Since then the Elliott Report has provided an indication of the equipment and expected costs, however there is no indication of the expected or proposed tolerance.

With the introduction of new feeders, the range proposed by FSANZ in the Draft Assessment Report of folic acid of 230-280ug/100g of flour is achievable. This relatively limited range will require the introduction of new equipment and processes, with a greater degree of QA controls than currently exists in mills.

Given that Industry is not experienced in fortification of flour at the levels proposed by FSANZ, potential exists to increase the range of proposed fortification to +/-20%. This variation equates to a level of folic acid in the range of 200-300ug/100g of flour.

Consideration could be given to reduce this range over time. Alternatives could also be investigated, including setting a minimum level with the potential to set an upper limit to meet the proposed range after a period of time.

As expected when thiamin regulations were first introduced in Australia, several mills had difficulty initially in meeting the minimum levels on a consistent basis without suffering excessive costs. Advice is that mills soon learnt to modify procedures based on experience and through assistance where required.

Similarly, when individual mills first fortified flour in North America, overages were quoted as up to 50%¹³. The main area of difficulty appeared to be with feeder set-up, not the technology itself. Over time these levels dropped significantly. It must also be recognised that North America has over 60 years experience with fortification. Fortification may involve up to 5 different feeders in the one mill.

As stated previously, folic acid fortification in Australia is minimal and involves relatively limited controls. Industry is not experienced in meeting the range proposed by FSANZ. The increased range proposed above by the Author (+/-20%, being 200-300ug/100g of flour), would provide greater flexibility for Industry to comply with the folic acid regulations.

¹³ Quentin Johnson

For these reasons, a phase in period in Australia and an increase in the range specified by FSANZ is recommended.

In many developed and developing countries, fortification has been successfully introduced in both small and large mills, being a mixture of “unsophisticated” to “sophisticated”, with good results achieved in the majority. In one mill classed as relatively unsophisticated, the accuracy of fortification was rapidly reduced to 3% of the level of projected input soon after implementation.

Given flour production is a “bulk process” and by taking a spot sample at some point following fortification, it is unrealistic to expect all flour in every parcel or consignment meets the folic acid range proposed by FSANZ. Industry indicated they do not meet these levels for all thiamin consignments. Advice was not received on the current compliance levels for folic acid.

Allowance must be made for inherent variations within flour and the figure of +/-20% appears reasonable.

As an added benefit of the Industry proposal, it is presumed thiamin fortification will undergo an increased level of rigour and achieve similar accuracy levels.

A range of fortification of bread making flour with folic acid at the level of 200-300ug/100g of flour is recommended.

Action No.3 Consideration is given to reducing this range over time.

5.4 Contractual Issues with Flour Customers

Industry Views

Customers of mills such as plant bakers have little if any storage facilities. They generally rely on just in time supply of product prior to processing. Flour from different products they make is purchased based on quality specifications. Industry has advised that this sector of industry would prefer to receive the product already fortified.

Most mills stated that customers would require alterations to contracts to ensure the correct product is being provided within the desired range of folic acid once legislation was introduced. There is not expected to be any tolerances mentioned in the contract, with the supplier expected to meet the range. It is unknown if the customer would chose to sample and test the flour for compliance.

Industry advice is that customers are expected to demand:

- Monitoring of folic acid addition to flour
- Sampling and testing of the flour to ensure compliance prior to leaving the mill
- Certification of the delivered product

Expert Views

Based on overseas experience¹⁴, few contractual issues have arisen following fortification. That said, as much of this information is considered commercially sensitive, little data has been provided or investigated. However based on experiences with mills and industry in general, the fortification of flour has not significantly altered relationships within the milling industry or lead to significant levels of contractual disputes.

Author Views

The level of testing and certification (by batch etc) is unknown however most mills indicate it would be significantly more frequent than current certification processes.

All these changes come at a cost to Industry and increase the complexity of the milling operation.

There are existing processes to manage contracts, alterations to contracts, dispute mechanisms and procedures for mills to monitor product for compliance with contract requirements. Folic acid fortification of flour is not expected to create any significant issues that cannot be managed within that existing commercial process.

¹⁴ Quentin Johnson

5.5 QA and Monitoring Requirements

This section outlines potential controls Industry will need to place over the fortification process and monitoring options for both Industry and Government.

5.5.1 QA Systems & Monitoring

Monitoring (auditing) is assumed to include review of documents and physical sampling and testing of fortified flour, by either Industry or Government (State Jurisdictions).

Industry Views

All the processes of fortification must be documented as per the requirements of the mill QA system. This provides a pathway for education and training of staff and an auditable pathway for verification of all processes. Staff will need to be trained in aspects of fortification, sampling and testing as applicable.

Industry advice is that to ensure fortification regulations and their own internal QA system and procedural requirements are met, the following processes must occur:

- Control over folic acid input specification
- Control over folic acid added to a base flour to generate a fortified premix
- Testing of folic acid in the premix
- Control of flour and folic acid feeding rates throughout the entire flour production pathway
- Control over blending of flours post-fortification
- Testing of fortified flour for folic acid levels
- Procedure for rectification of inappropriate folic acid levels
- Documentation and auditing of all procedures

As stated on many occasions by Industry, all the above will need to be implemented with a greater focus on each than currently occurs to ensure all consignments meet the proposed regulations. The Elliott Report describes the significant mill upgrades required to support these processes.

Industry advised they implement most of the processes listed in the above dot points during fortification of flour with thiamin. However greater focus is placed on certain aspects over others even though current thiamin fortification is mandated in regulations.

However Industry advice is that if regulations are only based on minimum folic acid levels, few alterations to current processes and systems may be required or the scope of each activity listed above could be greatly reduced.

From a monitoring perspective, the main issues of concern to Industry were:

- The level of monitoring by State Jurisdictions
- Different monitoring processes across States

The level of monitoring will have a direct impact on costs to Industry. A higher level of monitoring by State Jurisdictions will require more resources from Industry and potentially a higher level of monitoring internally. That said, Industry have stated the degree of changes to systems and monitoring they have proposed in the Elliott Report will need to occur despite State Jurisdiction involvement.

As several mills may be operated by the one company across more than one State, there are also concerns that different approaches by State Jurisdictions will lead to additional costs of compliance by Industry. It was stressed that the same approach must be adopted in all States.

State Jurisdictions do acknowledge they should be more proactive in this area where there are legislative controls in place e.g., thiamin in BMF. This lack of monitoring in the past is of concern to Industry. Industry has expressed a desire for auditing where mandatory fortification has been imposed.

Expert Views

Based on overseas experience, with proper location, calibration and checking of feeders, few other changes to mill processes are required. Changes required are based on monitoring of feeders and fortified flour to ensure adequate premix doses.

The existing staff are able to undertake monitoring of fortification activities within their existing work roles.

Industry has stated that their own monitoring and testing would be at very high levels to ensure compliance. This is at odds with overseas experiences.

The following advice was received from the USFDA “*We do not have a formal monitoring program in the U.S. for folic acid or other vitamins in enriched flours. If a need to analyse folic acid or other vitamin in flour or other enriched products arose, then one of the Food and Drug Administration’s field laboratories would undertake that analysis.*”¹⁵

As a guide, overseas mills implement one or more of the following:

- Weekly or monthly verification of premix utilisation rates with flour production records

¹⁵ United States Food and Drug Administration, Dr Barbara Scheenman

- Routine 4-6 times per day semi-quantitative spot test in the laboratory
- Monthly quantitative analysis of composite flour samples by an outside commercial laboratory

Advice is that “In North America and other countries that have recently implemented flour fortification these key points are not considered to be burdensome from a mill operation and additional cost viewpoint”.¹⁶

Author View

No further comments have been made in this section on the proposed changes by Industry to systems as this has been discussed in detail in other sections of this Report.

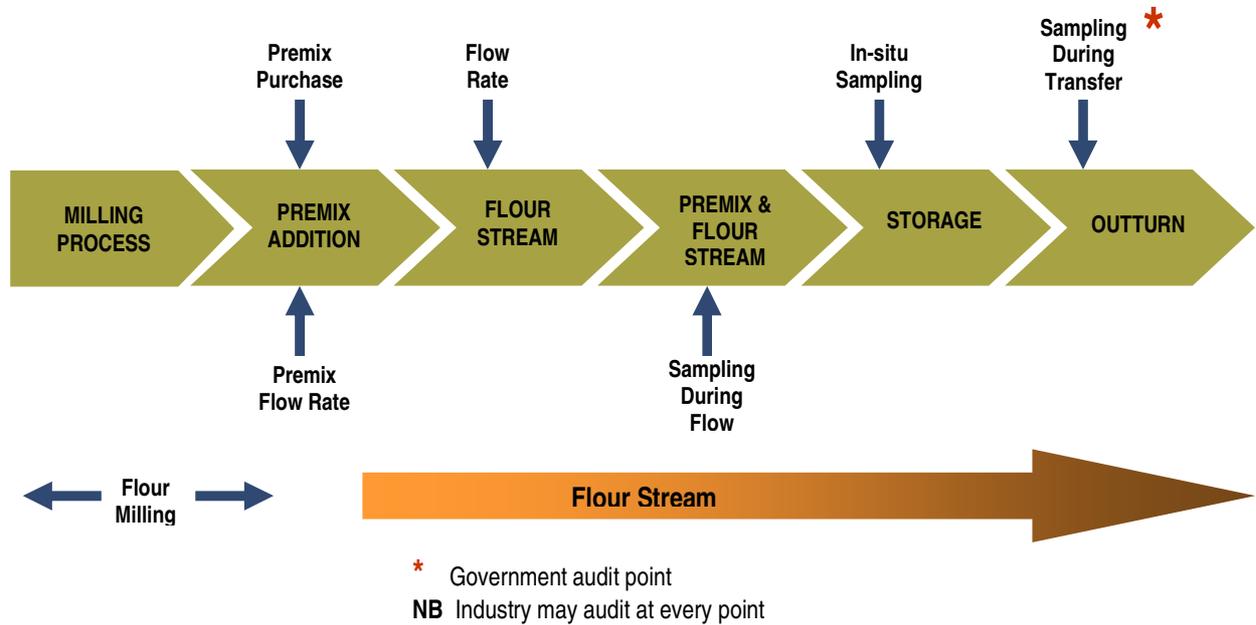
Auditing and / or monitoring compliance with fortification levels are expected to occur by both Industry and Government. There is potential for independent auditing processes to be done by third parties where customers require, however this is not expected.

As yet the Government has not finalised the level and type of auditing for compliance with the regulations. From information advised by FSANZ, enforcement is the responsibility of the State Jurisdictions. That said it is understood FSANZ may make recommendations to the State Jurisdictions and encourage consistent implementation.

The following diagram depicts potential auditing points in the flour production supply chain.

¹⁶ Quentin Johnson

Figure 8 : Potential Auditing Points (Industry & Government)



Government auditing may occur at varying stages, but the final endpoint provides greater certainty over the end-use of that flour as a BMF. The rate of sampling and auditing needs to be determined. For example sampling one bulk tanker may not provide a true account of the ability of the mill to fortify the BMF and achieve the desired folic acid range versus a composite sample collected over a longer period of time.

As stated previously the timing and frequency of these processes will have a significant impact on Industry practices and their ability to meet the required folic acid range. Similar to changes to mill infrastructure and systems, the Elliott Report proposes a significant increase in monitoring by Industry compared with overseas experiences.

Informal indications from State Jurisdictions are that they would audit the mills through one or a combination of:

- A review of the equipment used to fortify the flour
- Audit of mill processes and documentation
- Taking some samples for analysis

Local Government auditors would potentially be used and where possible a local Government laboratory used for analysis of samples. The level of skill required, the number of samples and a wide range of other details have not been determined at this stage.

The auditing level would be different to a food safety plan where QA systems would be needed to demonstrate compliance. Thus the auditing process would need to vary based on Industry issues at the time.

The type of mill operations are thought to dictate that sampling would need to be sequential rather than one off. However it is recognised this could add to costs of labour where physical samples were needed to be collected over that period. Nevertheless the frequency of auditing would be significantly less than that proposed by Industry in the Elliott Report.

Similarly, the level of auditing required by Industry can only be determined following finalising the regulations by FSANZ and review of requirements of State Jurisdictions. A joint Government and Industry approach to this task is thought to lead to more a consistent approach across States and not impose an overly burdensome task on Industry.

Action No.4 During transition/implementation State Jurisdictions and Industry jointly develop an appropriate and consistent auditing strategy that reflects the accuracy of folic acid in BMF required within the regulations.

5.5.2 Industry Assistance

Industry Views

During discussions with Industry, indications were that a significant lead-time was required for Industry to successfully revise their milling operations before they would be confident of meeting FSANZ regulations. This implies a significant education program within the Industry and within each mill. Staff will need to be trained in all aspects of the revised fortification process.

Appropriate external resources will be used where required for this task.

Expert Views

Guidelines have been used successfully overseas to assist industry in meeting the proposed fortification levels. These guidelines have included:

- How to set up the mill and feeders
- How to run the fortification process
- How to monitor and conduct QA/QC operations

Author Views

Provisions of assistance and advice to Industry before, during and after the regulations were implemented would:

- Aid their understanding of the tasks involved
- Increase understanding of the reasons for the changes
- Potentially lead to a quicker uptake and level of compliance

In most cases, feeder equipment suppliers have stated they could assist with the set-up and running of the equipment within the mill. State Jurisdictions could assist in how to monitor and conduct QA/QC operations.

Action No.5 Assistance for Industry is considered in the areas of how to implement the proposed fortification and monitor fortification levels in BMF.

5.6 Thiamin Implications

Author Views

While not discussed with Industry, as a consequence of the introduction of the folic acid regulations, there is potentially added benefit to Industry and the population as a whole. Through mills developing their own thiamin/folic acid premix, having tighter control over fortification through more accurate equipment and monitoring processes, an improvement in the accuracy of levels of thiamin fed into BMF may also occur.

During discussions with Industry it became apparent the distinction is being made by Industry between food safety (maximum levels) and what could be termed good industry or QA practice (minimum levels). That is, maximum levels indicate to Industry that compliance for all consignments outturned is mandatory. This requires a full modification to operations as previously discussed.

However for thiamin fortification as there is only a minimum level set in regulations, the degree of concern with compliance apparently is less, requiring less robust systems and processes. This is despite the regulations being in place and mills having internal QA processes and systems.

It is suggested that mills review thiamin fortification practices in light of their views on folic acid fortification.

Note that improvements to the accuracy of thiamin levels in fortified flour may only be achieved if the same processes and equipment used for folic acid fortification were used for thiamin fortification.

Action No.6

At some future point in time, Industry provides details of the levels of thiamin in BMF as a consequence of complying with folic acid regulations. This information can be used to inform any review of mandatory fortification of BMF in the future.

5.7 Timing of Changes

Industry views

The timing of changes required to set the system up and a further period of implementation and bedding down of the system to achieve an accurate outcome varied by mill. These ranged from as little as 6 months to over 4 years. These extensive lead-times relate to the degree of changes proposed by Industry and the desire for full compliance before regulations were officially adopted and enforced.

The shorter period was generally quoted by the smaller mills whereas the longer period was cited by the larger mills given the large number of mills they would have to alter.

The larger companies advised that as they have several mills, the above process would be a significant impost on their current operations. Planning and implementation would be difficult given the limited number of suitably skilled resources to spread across their entire operations.

A staged implementation could assist in this task, albeit in consideration of the practical difficulties of supplying product from different mills with different fortification levels. This includes issues associated with labelling raised by Industry in their submissions to FSANZ.

It should also be noted these timeframes were quoted prior to the detailed analysis outlined by the Elliott Report. Thus these timeframes may increase following further discussions with Industry.

Expert Views

From experience overseas, a relatively short timeframe is needed to implement the fortification proposal. This is based on the limited amount of change required to mill design and systems. Some lead-time is required, less than 12 months.

Author Views

Based on preliminary discussions with FSANZ, a transitional period is proposed before the regulations are enforced. Clarification is required on what regulations apply and when the changeover to requirements for the product occurs – that is, flour produced as of a certain date or flour leaving the mill as of a certain date. This has implications for the mill, label changes, stocks of BMF and contracts with customers.

Industry has advised in the Elliott Report and also during consultation with the Author that setting up mills for accurate fortification of BMF only with folic acid is a significant capital project. Requirements would include, but not exclusively:

- Planning of mill design and operations
- Raising of capital

- Approval to re-design from Council where required
- Purchase of equipment
- Delivery
- Set-up with minimal impact on mill operations
- Testing of the system
- “Going live”
- Associated activity planning such as re-packaging materials etc
- Ongoing monitoring and testing

A long period such as that proposed by Industry is only relevant given extensive modifications to mills as per the above. The introduction of new feeders and bedding of that process should be able to occur within a relatively short period. Suppliers of equipment outlined in Appendix 2 indicated between 8-12 weeks for equipment. Thus allowing for planning and post-implementation monitoring, a minimum of 6 months should be set.

Based on overseas experiences and the relatively small changes to mill operations, a lead-time of 1-2 years should be sufficient for Industry to be able to fully comply with the folic acid regulations. This would also enable all old stocks of labels etc to be modified and potentially used.

Action No.7 A staged implementation process is developed by FSANZ in consultation with Industry in order to achieve the most suitable fortification strategy and outcome as early as possible.

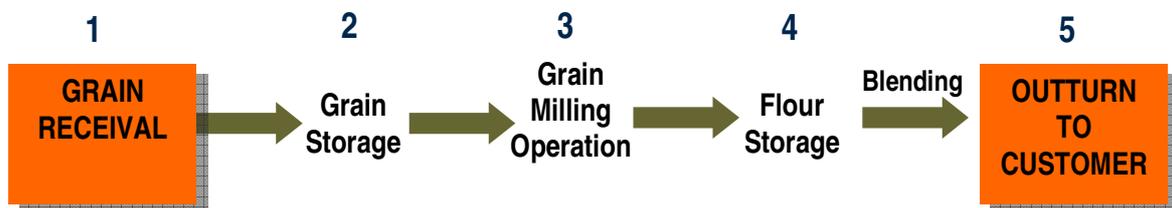
5.8 Costs of Fortification

5.8.1 General

Costs are a major issue for individual flour mills with processes designed to minimise cost yet produce a product within contractual requirements. The final cost of fortification will vary depending on the mill and type of equipment.

Typical cost points in fortification are outlined in the following diagram.

Figure 9 : Typical Cost Points for Fortification in a Mill



- 1 JIT, contract terms
- 2 More storage, better management
- 3 Premix, premix contract, premix storage, premix feeder, premix bin setup, feedback controls, staff, testing, monitoring, mixing
- 4 New storage bins, testing, blending, re-work pathway
- 5 Customer specification, certification auditing, testing

To accurately identify costs of fortification within the proposed range is difficult given the relative lack of fortification with folic acid in Australia and the unique range that is proposed for BMF compared with that overseas.

Some sectors of Industry have previously supplied detailed costs of most of their operations to FSANZ. These were not made available to the Author. Subsequently, industry understood that the mandatory fortification proposal was changed to incorporate a fortification range, which industry viewed as substantially increasing compliance costs. These costs were not included in the earlier cost benefit analysis.

The FMCA on behalf of Industry engaged a consultant to write a report (Eliott Report) detailing a range of costs based on the latest proposal by FSANZ. This report was based on the assumption of a high risk profile for Industry.

A summary of costs (rounded) outlined in the Eliott Report versus the findings of this review are outlined in the following table. There are many generalisations that make up this table and further details as outlined in the following Section of this Report should be

reviewed when assessing the table. A full analysis of costs was not conducted by the Author due to incomplete information from Industry.

Cost Item Description	Eliott Report Cost (\$)	G McMullen Cost (\$)	Comment
<i>Premix plant</i>	<i>385,000</i>	<i>unknown</i>	<i>2 plants require construction</i>
<i>Premix</i>	<i>227,000</i>	<i>100,000</i>	<i>Using \$2.50 /kg for GMc</i>
<i>Feeder, Mill setup, flour storage</i>	<i>15,000,000</i>	<i>1,350,000</i>	<i>Assume \$50,000 for GMc</i>
<i>Staff</i>	<i>Not set</i>	<i>Not set</i>	
<i>Analytical Testing</i>	<i>4,900,000</i>	<i>Not set</i>	
<i>Returns system</i>	<i>1,800,000</i>	<i>Not set</i>	
<i>Other costs</i>	<i>25,000</i>	<i>Not set</i>	

It should also be noted that during Industry discussions, comments were received that their costs included all costs associated with fortification. No details of items included in these figures were provided however the estimates ranged from:

- \$1m plus for a small mill
- \$30-\$160 per tonne for larger mills
- \$600,000-\$1,500,000 for large mills

The Eliott Report indicates a capital set-up cost of \$22 million (\$29 per tonne) and ongoing costs of \$12 million (\$16 per tonne) on the basis of 750,000 tonnes of Bakers flour. Since those figures were provided, many in Industry consider them to be very conservative.

5.8.2 Folic Acid Premix & Plant

Industry Views

The Eliott Report indicates 2 mills will require a premix plant to be built at a cost of \$192,400 each. Ongoing costs have also been included. For other mills with existing plants used for making the premix, the ongoing cost of their operation has not been included in the analysis.

The total cost of premix to the Australian milling industry is based on 25t of premix required as per the following (calculations summarised):

23t tonnes flour	\$12,000
2 tonnes folic acid	\$119,000
Production cost	\$50,000
Testing costs	<u>\$9,000</u>
Total including margin (20%)	\$227,000

Expert Views

Based on overseas experience, the majority of mills purchase pre-made premix from a number of commercial suppliers. The cost of the premix is deemed to be relatively insignificant compared to the cost of other inputs such as wheat or the price received for the flour.

Author Views

As stated previously, as no costs for modification of existing premix plants have been included in the Elliott Report, it is assumed that current plants are adequate for making the folic acid premix and storage for use as required – albeit storage time would be minimal.

The cost of the folic acid premix varies on the basis of the supply of the folic acid and whether the mill makes their own premix or purchases the product ready-made at the correct concentration for their mill.

The cost may also alter depending on whether the premix contains other additives such as thiamin. Most mills indicated that the premix would include both thiamin and folic acid, as they would not be able or willing to manage two premixes. It is not apparent from the Elliott Report whether this has been factored into the costs. In addition, creating this premix may alter the cost structure quoted in the Elliott Report.

It is unknown which two mills are cited in the Elliott Report as requiring a premix plant to be constructed, however it is worth noting that more than one mill advised the Author they would make up the premix in their laboratory. This places in question the total cost of building a premix plant to the degree of complexity cited in the Elliott Report. Note this previous Industry view may have altered since the Elliott Report was commissioned.

Due to the lack of commercial suppliers, no additional estimates of the cost of folic acid premix could be determined. However based on overseas figures, the cost of folic acid premix is quoted as \$2.20 to \$2.50 per kilogram. This figure differs significantly from the figures provided in the Elliott Report that equates to approximately \$9 per kilogram.

Comparisons are difficult given the different industries and companies making the premix. However even allowing for different production costs and profit margins, the range of \$2.50 to \$9.00 would not be expected to be that large all things being equal.

Of note is the differing prices quoted for supply of folic acid. Rates of \$40/kg plus GST from China to \$115/kg from Europe have been obtained from a local supplier compared with the Industry quote of \$57/kg. The rate from China was quoted as a high rate based on an initial quote and the company have advised a better rate could be obtained. This

rate is significantly better than that quoted by the Elliott Report and would bring the cost of premix down estimated by Industry by approximately \$35,000, to \$8 per kg.

5.8.3 Feeder, Mill Set-up & Storage

Industry View

Industry modifications to mill premises are well documented and are estimated at \$22 million initially. Ongoing costs are \$12 million based on the ongoing requirement for folic acid fortification of BMF.

The Elliott Report indicates two dosing systems are required, one for small mills and one for larger mills. The total costs are listed at \$15 million capital and \$3.7 million ongoing. This includes extensive modifications to the feeder area and separate flow paths for folic acid fortified flour. As discussed previously, these costs are based on highly controlled fortification processes and are considered conservative by some Industry sectors.

The Industry view is that extensive modification to flour storage will also be required and this is included in this figure.

Expert Views

Based on overseas experiences, installation costs are estimated at 10-15% of the feeder cost assuming no additional equipment would be required or existing equipment would not need to be modified.

This is a reasonable assumption given the fortification process overseas and level of compliance generated from those mills.

Author View

The feeder, mill set-up and additional flour storage (if required) costs vary depending on the set-up and the degree of control of the flow rate. The manufacturer of the feeder units outlined in Appendix 2 indicated each feeder costs in the vicinity of \$5,000-\$30,000.

As some additional equipment would be required, including weighers where industry requires a greater degree of control, this figure will increase. No estimate can be made unless individual mill set-up is costed. For practical reasons the \$30,000 has been increased conservatively to \$50,000 assuming one flour stream line only per mill is set up with the new feeder equipment.

Even with the expected costs based on overseas data increasing to \$50,000 per mill, there is a significant difference between this figure and that quoted in the Elliott Report. This difference has been explained previously given the different risk profiles taken.

Of note is that there may be opportunities for Industry to reduce the cost for folic acid fortification by including benefits of improved fortification with thiamin, assuming the same equipment is being used.

5.8.4 Staff

Industry View

There is no allocation of costs for additional staff in the Elliott Report other than for a new staff member in the laboratory. Ongoing costs include an allowance for additional labour based on using existing staff.

During night shifts some mills indicated that staffing levels are trimmed to “the minimum” and thus sufficient numbers would not be available to monitor the fortification process at their desired levels.

During discussions Industry also indicated staff numbers were relatively low and costs were minimised based on commercial practices. To increase staffing levels would add costs to the milling operation.

Expert Views

When feeders are supplied and installed in the mill, existing mill staff are trained in the fortification process. This includes those nominated by the mill however the feeder suppliers generally recommend both millers and QC staff are trained in its operation. This ensures a suitable level of qualified and experienced staff are available at most times should they be required.

Overseas experience shows staff would be present at all times including night shifts. With some pre-planning, fortification should be able to proceed with the desired degree of control.

In the experience of milling experts who have implemented such systems in a range of mills overseas, “*there is no need to add additional staff for flour fortification*” as the process is relatively simple when using volumetric feeders.

Author Views

No costs have been included in this Report given information that additional resources were not required in overseas mills. However it is recognised some additional staff may be required and mills may need to re-allocate time from staff to the fortification process. Thus in reality costs for staff may increase marginally. These costs can only be accurately determined following introduction of the fortification process and analysis of total costs.

5.8.5 Analytical Testing

Industry View

The Elliott Report indicates a maximum testing cost of \$200 each, being \$45,000 annually for those mills seeking external analysis of samples. This Report indicates two samples a week would be analysed in these laboratories, in conflict with other comments from Industry that “the frequency of testing would be very high and no product will leave the site unless it meets the required levels”.

For the remaining mills the Elliott Report cites testing would occur on-site, thus testing units would be needed. The proposal includes the development of 19 on-site laboratory facilities with testing equipment at a significant cost of \$4.9 million and ongoing costs of \$5.7 million.

Expert Views

In North America, a small number of laboratories conduct folic acid testing on behalf of industry and virtually no mills conduct testing in-house. Costs of testing are relatively high compared with those quoted for Australia, being up to US\$500 per test.

Author View

The cost estimates for folic acid testing in flour range depending on the type of test sourced. In summary the costs of testing by commercial laboratories are listed in the following table. Further discussion on the options is outlined in Appendix 4 of this Report.

Test Type	Test Cost per Sample (\$)	Basis of Cost
<i>HPLC</i>	<i>121 - 195</i>	<i>Testing in Australia</i>
<i>Biacore</i>	<i>236.50</i>	<i>Testing in Australia</i>
<i>HPLC</i>	<i>50 - 120</i>	<i>Overseas testing costs in Nth America</i>
<i>Unknown</i>	<i>nil</i>	<i>Feeder suppliers offer free services up to a certain number of tests</i>

Note that commercial providers of this testing service are limited at present due to the lack of commercial testing needed. Should Industry require a significant number of tests in future, some commercial laboratories that were approached indicated they would significantly upgrade their services and offer services that would meet the needs of the Industry.

The most acceptable unit for testing by Industry appears to be the Biacore unit however the Author received a cheaper quote of \$195,000 per unit versus the Elliott Report quote of \$256,000.

The Elliott Report also assumes mills have suitable laboratory facilities. While a number of mills indicated that laboratories were rudimentary or non-existent, no numbers in each category were provided.

The Elliott Report indicates ongoing costs of \$5.7 million, being costs of testing and other associated costs such as staff and test kits. The number of tests quoted appears at odds with previous advice cited. However the final cost of testing will be significant on the basis of the advice of the high frequency of testing from Industry.

5.8.6 Returns Area

Industry View

As previously discussed, the returns area is for rectification of out of specification product. Costs incurred vary depending on the type of mill and a range of other factors. Mills produce a number of specialty products. They plan their milling production so that similar products follow each other and flours produced meet customer expectations.

The Elliott Report indicates up to 13 mills will require a new separate returns system for Bakers flour. As per previous cost estimates, ongoing costs are included in this estimate. The costs involved are listed as \$1.8 million capital and \$250k ongoing.

Expert Views

No advice on cost of returns by mill based on overseas experience was received.

Author View

For those mills requiring a new or modified returns area, the capital and ongoing costs listed in the Elliott report indicate a significant modification to the existing system for these mills due to the expected large volume of returns. Other mills are expected to have an adequate returns area.

No estimate could be made by the Author on modifications required due to the lack of information provided by Industry on the level of returns, as indicated previously.

5.8.7 Other Costs

The Elliott Report indicates other costs may be incurred, including labelling and losses on returns. Industry also advised during discussions the costs of changing labels is significant. These costs varied from Industry being over \$4 million for one company. As further changes to labels are required in the foreseeable future, these costs may be able to be minimised through a staged and planned implementation phase as previously discussed.

The level of loss on returns could not be estimated but the Elliott Report only indicates 1900 tonnes of returns would incur the loss. This is a low figure compared with the degree of alteration and costs necessary to re-configure the returns areas proposed in the report.

5.9 Other Considerations

Industry Views

During discussions with Industry, the Author was asked to provide the following comments to FSANZ. These comments have also already been provided in other forums and through other mechanisms:

- Industry preference is for no mandatory folic acid fortification of BMF
- If introduced, mandatory folic acid fortification should occur through the setting of minimum levels only
- Should the option of minimum levels not be accepted, a significantly higher tolerance level than that proposed in the Draft Assessment Report should be set

The actual minimum level and higher tolerance proposed above were not discussed with Industry.

Some sectors of Industry have advised that costs of fortification cannot be passed onto the baker or consumer as there is no market for folic acid fortification of BMF. Thus costs would be borne by Industry. Others indicated mills may have a competitive advantage over others given the level of complexity and modifications required to establish systems to meet the proposed regulations

There were many other issues discussed with Industry regarding fortification options that were not relevant to the scope of this project and have not been included in this Report.

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- SGS Australia

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- Draft Assessment Report of Proposal P295
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Appendix 2 – EQUIPMENT SUPPLIERS

A. FEEDERS

1. REPCO® Model 70 Ingredient Feeder (ex Research Products Company)

The REPCO® Model 70 Ingredient Feeder is a volumetric feeder engineered and built specifically for the feeding of dry, free flowing powders and other finely divided materials. The rate of feeding is easily adjustable from a low of 113.4g to 27.21kg per hour. Depending on density of flow characteristics, higher feed rates can be attained. A standard design feeder is equipped with a 0.02 cubic metre hopper. A larger capacity hopper is also available.

- Weight 39.0kg
- Construction Cast aluminium base. Heavy gauge standard steel hopper. Optional polished stainless steel hopper
- Lubrication None required
- Measurement Width 35.56 cm, Depth 57.79 cm
- Height 57.15 cm with 0.02m³ hopper
- Height 87.63 cm with 0.07m³ hopper
- Accessories Feeder stands complete with discharge hoppers and air manifolds for pneumatic or gravity addition of ingredients
- Feeder blower packages

2. The REPCO® Model 202 MicroFuser® (ex Research Products Company)

The REPCO Model 202 MicroFuser Feeder is a volumetric feeder that can be used for a wide variety of products. Ingredient is moved down into a helix by external agitation of the Vinyl Flex Hopper and is then conveyed through a discharge nozzle. The only moving part inside the ingredient hopper is the Helix. A variety of accessories are available including gravity discharge hoppers, multiple unit control panels, feeder stands, and complete pneumatic ingredient dispensing systems - all manufactured to customer specifications.

- Feeder Hopper Capacity 0.02m³
- Feeder Extension Hopper 0.07m³ (Optional 0.14m³)
- Dimensions 54.9cm L x 54.9cm W x 39.4cm H (1.77-2.54cm level adjust)
- Discharge Nozzle Protrudes 17.8cm from face of feeder
- Weight Approximately 68.04kg
- Rates From 1-160 RPM/.0008 – 48.32 cubic feet/hr

3. Acrison International, 27 Maria Road, Woodcliff Lake, NJ 07675 USA Telephone +1 201 476 0577 Fax +1 201 476 1053

4. Agromatic AG, Goldingstrasse 30 CH-8637 Laupen/Zurich, Switzerland. Telephone +41 5525-62100 fax +41 5525-62111 Contact U. Deiner info@agromatic.com
www.agromatic.com

5. *American Ingredients Company, 3947 Broadway, Kansas City, MO 64111, USA. Telephone +1 816 561 9050 Fax +1 816 561 0422 Contact Bill Gambel. bgambel@americaningredients.com www.americaningredients.com
6. Buhler AG, 9240 Uzwil, Switzerland. Telephone +41 7195 51111 Fax +41 7195 53742 Contact Martin Schlauri mu.buz@buhlergroup.com www.buhlergroup.com
7. Codema Inc. 11790 Troy Lane N., Maple Grove MN, 55369-9377 USA Telephone +1 763 428 2266 Fax +1 763 428 4411 Contact Heinz Baecker codema@aol.com www.codemainc.com
8. Gericke SA, 7, rue GuyMoquet, Z.I du Val d'Argent, F-95100 Argenteuil, France Telephone +33 1 39 98 29 29 Fax +33 1 39 82 29 74 gericke.fr@gericke.net www.gericke.net
9. Golfetto/GBS Group Via Temanza, 1, 35134 Padova, Italy Telephone +49 049 894 9494 Fax +49 049 894 9400 info@golfetto.it
10. Jaymark, (Division of BDI Inc,) 74 Dorchester Close, St. Catherines, ON L2M 6V2 Canada Telephone +1 905 938 2882 Fax +1 905 938 2772 Contact Darryl Tateishi tateishifamily@sprint.ca
11. K-Tron, International Inc., Pitman, NJ 08071-0888 USA Telephone +1 856 589 0500 Fax +1 856 589 8113 ka@ktron.com www.ktron.com
12. Muhlenbau, 490-G, IV Phase, KIADB, Peenya Industrial Area, Bangalore 560 058 India. Telephone +91 80 836 3744/45 Fax +91 80 836 3346 Contact S.K. Ramaprasad muhlenbau@hotmail.com or eskaram@vsnl.com
13. *Muhlenchemie GMBH, Kornkamp 40, D-22926 Ahrensburg, Germany./ Telephone +49 4102 239301 Fax +49 4102 239323 Contact L info@muehlenchemie.de www.muehlenchemie.de
14. Ocrim SPA, Via Massarotti, 76, Cremona, 26100 Italy. Telephone +39 0372 4011 Fax +39 0372 412692 Contact Luciano Bolzoni info@ocrim.com www.ocrim.com
15. *Research Products Co., PO Box 1460 Salina, KS 67402, USA Telephone +1 785 825 2181 Fax +1 785 825 8908 Contact Monte White montewhite@researchprod.com www.researchprod.com
16. Satake USA Inc., 9800 Townpark Houston, TX 77036 USA Telephone +1 713 772 8400 Fax +1 713 772 8484 Contact Chuck Vincent vision@satake-usa.com www.satake-usa.com
17. Schenk Accurate Inc., 746 E.Milwaukee St. PO Box 208, Whitewater WI 53190-9972 USA Telephone +1 414 473 2441 Fax 414 473 4384 info@sarinc.com www.sarinc.com

18. Technomight Engineers: Contact: Muhammad Sarwar Mirza, Usman Flour Mills Building, Jhang Road, Altaf Ganj Chowk, Faisalabad, Bus: (041) 654903-5
Home: (041) 611127 – 640652, Mobile: (0300) 720 4740, Bus Fax: (041) 654915

B. PREMIX

1. AMERICAN INGREDIENTS, 3947 Broadway, Kansas City, MO 64111, USA.
Telephone +1 816 561 9050 Fax +1 816 561 0422, Contact Bill Gambel.
bgambel@americaningredients.com or Brent Adams badams@americaningredients.com
WWW.AMERICANINGREDIENTS.COM

2. EUROGERM, 5 Rue des Artisans, Quetigny 21800, France
Tel +33 80 73 07 77, Fax +33 80 73 07 70, Contact Bruno Vesignie, Export Manager
WWW.EUROGERM.COM or contact@eurogerm.com

3. LESAFFRE AT HYPERLINK WWW.LESAFFRE.COM" WWW.LESAFFRE.COM
Or fld@lessafre.fr

4. NICHOLAS PIRAMAL WWW.NICHOLASPIRAMAL.COM
Or vfd@nicholaspiramal.com

5. Muehlenchemie, Muehlenchemie GMBH, Kornkamp 40, D-22926 Ahrensburg, Germany., Telephone +49 4102 239301 Fax +49 4102 239323
Contact L Kutschinski E-mail: info@muehlenchemie.de or www.muehlenchemie.de

6. FORTITECH, Riverside Technology Park, 2105 Technology Drive
Schenectady NY 12308 USA, Tel +1 518 372 5155, Fax +1 518 372 5599
www.fortitech.com

7. WATSON FOODS COMPANY INC., 301 Heffernan Drive, West Haven CT 06516
US Fax +12039328266, Mary Watson, Mary.watson@watsonfoods.com

8. Hashtgerd Co. Contact: Jalali, Abdol-Hossein, E-mail: sjalili@hashtgerd.com
No. 4, First Floor, West Entrance, Arain Bldg., Mirdamad Blvd., Tehran, Iran
Bus: +98 (21) 2256278 & 2256238, Bus Fax: +98 (21) 2252530

9. Hexagon Chemicals Solution Provider, Contact: Shewale, Ramesh
Plot No. 92, PO Unandanagar, Lakhmapur, Tal. Dindori Dist. Nasik, India
Bus: (02557) 250079, Bus Fax: (02557) 250015, E-mail: hexagonnsk@sancharnet.in
List of premix producers in China

10. Beijing Long Age Vita Nutritious Products Co.,Ltd, Contact: Dr. Huo Junsheng,
G.M. jshuo@mail.263.net.cn www.sjvt Phone:86-13501152782,Fax: 8610-83132317

11. DSM (China) Limited, Contact: Gao Xi, xi.gao@dsm.com Tel. 8610-65885353, Fax: 8610-65886711, Cell; 86-13601370115

12. RICHEN Food Industry Co.,Ltd, Shanghai, Contact person: Jeff Chen, Managing Director richen@online.sh.cn www.richenchina.cn Phone:8621-52845388, Fax: 8621-52845368

13. Fortitech Co.,Ltd, Contact person: Piri Chen, Account Executive piri.chen@fortitech.com Phone: 8621-65976790, Fax:8621-65976791

14. Tianjin Sihuan Nutrition Products Factor, Contact: Li Shengtan, Position: Manager ammsihem@public.tpt.tj.cn Cell: 86-13602056003, Phone: 8622-23308286

15. Beijing Tiantian Vita Co.,Ltd, Contact: Li Qiang, Manager, liqiang678@china.com Tel. 8610-67471750, Fax:8610-67473835, Cell, 13910107651

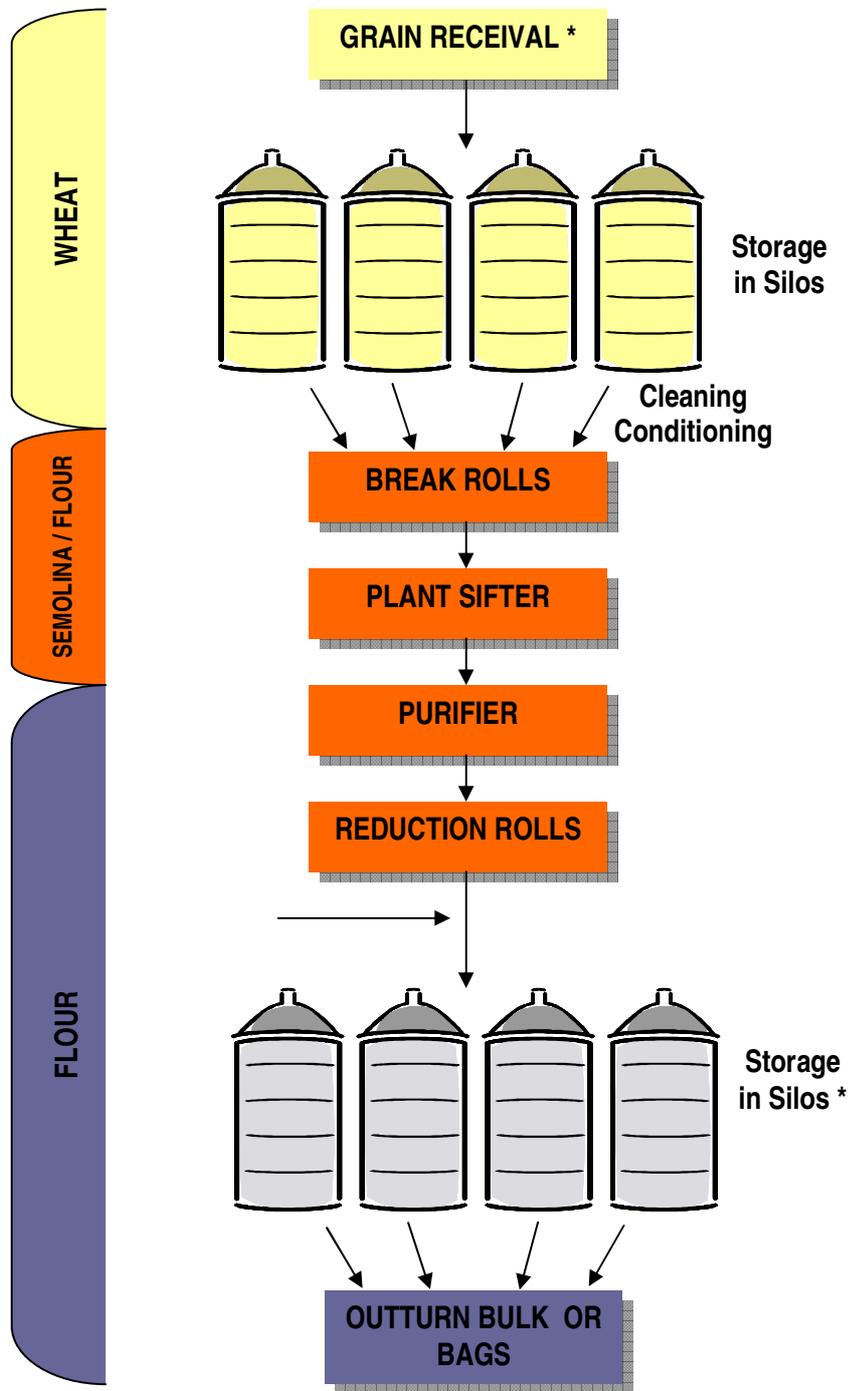
Appendix 3 - FLOUR MILLING PROCESS

General

Flour is most commonly made from wheat, but also maize, rye, barley, and rice, amongst many other cereals grasses and non-grain plants (including many Australian species of acacia). Flour can also be made from legumes and nuts, such as soy, peanuts, almonds, and other tree nuts.

A generalised view of the flour milling process is depicted in figure 10.

Figure 10: Simplified Diagram of Milling Process



* Major sampling points testing

There are many different types of mills producing flour, but the two main types are:

- Pneumatic
- Gravity fed

The former is more commonly used in modern mills, as this process is more sophisticated and able to utilise modern technology to control flow paths and flow rates.

Gravity mills rely on the flow of the commodity using gravity. This process is more common to the older mills still in operation. However many of these older styles mills have had their operations modernised through the use of computer controls etc where available and economical to introduce.

Pre-Milling

Grain is received and classified. The grain may be further tested by milling and baking a small amount to determine end-use qualities. The results from these tests determine how the wheat will be handled and stored. Millers may blend different wheats to achieve the desired end product. The wheat will then be stored at the mill in large bins.

Before the milling process begins, the wheat is cleaned and then tempered (conditioned). Weed seeds, dirt and other foreign materials are removed by the cleaning equipment. The processes may involve one or more of the following:

- Magnetic Separator - the wheat first passes by a magnet that removes iron and steel particles
- Separator - vibrating screens remove bits of wood and straw and almost anything too big and too small to be wheat
- Aspirator - air currents act as a kind of vacuum to remove dust and lighter impurities
- De-Stoner - using gravity, the machine separates the heavy material from the light to remove stones that may be the same size as wheat kernels
- Disc Separator - the wheat passes through a separator that identifies the size of the kernels even more closely. It rejects anything longer, shorter, more round, more angular or in any way a different shape
- Scourer - the scourer removes outer husks, crease dirt and any smaller impurities with an intense scouring action. Currents of air pull all the loosened material away

In the conditioning process, the moisture content of the wheat is increased to toughen the bran coat, assisting in the separation of the endosperm. The increased moisture also mellows the endosperm allowing for more efficient reduction into flour. Conditioned wheat is stored in bins from eight to 24 hours, depending on the type of wheat. Blending of different wheat may be done at this time to achieve the best flour for a specific end-use.

Milling

In the mill, the wheat is sent through a system of corrugated steel grinding rolls and sifters. This process of grinding and sifting is repeated until all of the endosperm is removed and only the bran remains. The particles of endosperm are graded through the sifting process, according to size, and are sent to the appropriate part of the system for further reduction.

The reduction system consists of smooth steel rollers and sifters that reduce the endosperm particles into finished flour. Throughout this process the miller has the ability to collect or divert specific flour streams, which differ analytically, in order to produce specific finished flour.

The rolls are paired and rotate inward against each other, moving at different speeds. Just one pass through the corrugated "first break" rolls begins the separation of bran, endosperm and germ.

The miller's skill is demonstrated by the ability to adjust all of the rolls to the proper settings that will produce the maximum amount of high-quality flour. Grinding too hard or close will result in bran powder in the flour. Grinding too open allows good endosperm to be lost in the mill's feed system.

The miller must select the exact milling surface, or corrugation, on the break rolls, as well as the relation and the speed of the rollers to each other to match the type of wheat and its condition. Each break roll must be set to get as much pure endosperm as possible to the middlings rolls. The middlings rolls are set to produce as much flour as possible.

From the rolls, the grist is sent away to drop through sifters. The grist is moved via pneumatic systems that mix air with the particles so they flow, almost like water, through tubes.

The broken particles of wheat are introduced into rotating, box-like sifters where they are shaken through a series of bolting cloths or screens to separate the larger from the smaller particles.

Inside the sifter, there may be as many as 27 frames, each covered with either a nylon or stainless steel screen, with square openings that get smaller and smaller the farther down they go.

Up to six different sizes of particles may come from a single sifter, including some flour with each sifting. Larger particles are shaken off from the top, or "scalped," leaving the finer flour to sift to the bottom.

The "scaled" fractions are sent to other roll passages and particles of endosperm are graded by size and carried to separate purifiers.

In a purifier, a controlled flow of air lifts off bran particles while at the same time a bolting cloth separates and grades coarser fractions by size and quality.

Four or five additional "break" rolls, each with successively finer corrugations and each followed by a sifter, are usually used to rework the coarse stocks from the sifters and reduce the wheat particles to granular "middlings" that are as free from bran as possible. Germ particles will be flattened by later passage through the smooth reduction rolls and can be easily separated. The reduction rolls reduce the purified, granular middlings, or farina, to flour.

The process is repeated over and over again, from sifters to purifiers to reducing rolls, until the maximum amount of flour is separated, consisting of approximately 75 percent of the wheat.

There are various grades of flour produced in the milling process. The remaining percentage of the wheat kernel is classified as millfeed - shorts, bran and germ.

"Reconstituting" or blending back together all the parts of the wheat in the proper proportions yields whole wheat flour. This process produces higher quality whole wheat flour than is achieved by grinding the whole wheat grain. Reconstitution assures that the wheat germ oil is not spread throughout the flour so it does not go rancid so readily.

The flour may then be enriched or fortified. It may be tested for various quality parameters at various stages throughout the milling process.

Finally, the flour millstream flows to the packing room or into hoppers for bulk storage.

Appendix 4 – COMMERCIAL TESTING SERVICES

Test Providers

In Australia there are no mills or laboratories associated with milling companies or baking operations that are capable of analysing flour or products of flour for folic acid.

There are currently a small number of laboratories within Australia capable of analysing flour or flour products for folic acid to some extent:

- PathWest Laboratory Medicine, Royal Perth Hospital
- University of New South Wales
- AgriQuality (in New Zealand)

Royal Perth Hospital laboratory is accredited by NATA to ISO/IEC 17025 (1999) in the field of Biological Testing (accreditation number 14671). This accreditation covers the microbiological assay of vitamins in food.

Sample Provision

For all laboratories, samples are analysed on the basis they represent the product being tested.

Sample Analysis

Royal Perth Hospital laboratory

The Royal Perth Hospital laboratory conducts duplicate tests and provides customers with the range of results detected. The method used is based on the AACC method 86-47 “Total Folate in Cereal Products – Microbiological Assay Using Trienzyme Extraction”. This method conducts a total folate analysis however the laboratory will conduct free folate analysis if requested (free folate is defined as the amount added to the sample by industry, being that over and above the amount naturally in the commodity analysed).

A sample of 10g is required to allow for a duplicate analysis and further assessment if required. For each test, 1g of sample only is required.

A two week turnaround time is quoted for routine analysis. The laboratory requests advice if the sample has been fortified as this will ensure an appropriate starting point for specimen dilution and will improve turn around time. At present, a general cost per test of \$110 plus GST is quoted however this may vary based on a range of factors including number of samples. This price is thought to be the cheapest in the world, with USA laboratories quoting up to US\$500 per sample.

There is no tolerance quoted to customers on the accuracy of the test. As the laboratory is NATA certified all duplicate tests must show a variation of less than 10%, other tests must be repeated before results are released. The level of detection (LOD) is cited as 40ng/g.

Issues with Testing

Folic acid tends not to be homogenous within a sample taken from an end-product or flour. Laboratories stressed the need for several samples to be taken by the provider of the samples. The laboratories then combine those samples and conduct the analysis. From experience, even though folic acid may be added to the flour in a measured amount, the amount detected in each batch varies considerably. The range of variation could not be estimated however by analysing in duplicate, the Royal Perth Hospital laboratory provides industry with the range of folic acid detected.

When assessing samples, the Royal Perth Hospital sought indications from the customer on the expected range of folic acid within the sample. This information is used to modify the method of analysis and will alter the timeframe of analysis. On most occasions the laboratory indicated industry predicts less folic acid in the sample than detected, as folic acid is also present in other ingredients and these levels are frequently not considered.

Where high levels of folate are present, such as when the samples are saturated, analysis by the AACC Method 86-47 is difficult. An example is tablets for medicinal purposes. In these instances analysis by the HPLC method is recommended.

The Royal Perth Hospital laboratory indicated the number of samples they currently analyse is relatively small. To increase their capacity to cope with the potential large number of samples, significant lead-time to enable resource acquisition and capacity build-up would be required.

Should samples from New Zealand be required to be tested, Western Australia's quarantine laws would need to be considered. Due to quarantine, imports into Western Australia are relatively difficult and require a permit from the Government.

AgriQuality

This laboratory currently does not analyse for folic acid in Australia. They do conduct the analysis in their Auckland laboratory with an average turnaround time of 7-10 days, which may be reduced in a greater number of samples were required.

The detection limit is 7ug/100g and testing is accredited to an equivalent NATA Standard. A 20g samples would be required.

National Measurement Institute

They have conducted some analyses in the past for organisations such as FSANZ. Now mainly outsource the testing to Royal Perth Hospital.

Appendix 5 – BIACORE TEST OVERVIEW

The Biacore testing kit enables a rapid assessment of folic acid, and a range of other vitamins and substances of relevance to industry. It includes a Biacore Q system and the Qflex Kit Folic Acid.

As yet, the method for flour assessment of folic acid levels is not internationally recognized by organizations such as AOAC. Note however that AgriQuality uses the method provided by Biacore, with some modifications. This method has been accredited in their laboratory.

Indications are that the test equipment and results generated are suitable for use in the international milling industry.

Biacore testing units have been quoted at \$195,000 without resources and ongoing costs. This does also not include any potential discounts.

A kit is valued at \$1,079 and expires only after 6 months. This same kit is used for folic acid analysis. The kit does 88 samples, more if the full 16 standards are not done.

There appears to be excellent repeatability in the range of 3-5% CV and reproducibility values in the range of 5-10% CV. Comparisons with that of standard microbiological based assays shows a high level of correlation across a range of concentration values. An LOD is approximately 4ug.

For each batch of 20 samples, the time taken to report results is up to 6 hours.