

UNICEF/FFI Joint Workshop, Ankara 14-15 June 2012
Addressing Micronutrient Deficiencies Through Flour Fortification
In the CEE/CIS Region



Flour Fortification: Legislation and Standards
Quentin Johnson, Coordinator
Training & Technical Support Group FFI



Core Messages


1. Standards should be based on the best public health science. The best public health science is offered by the Recommendations
2. The Recommendations focus on average nutrients added not levels in Regulatory Standards
3. Standards should be of a form consistent with Codex standard structure and be clear about what is required
4. The legal minimum (and maximum) should be developed recognising what you want to achieve but also realising milling's technological limits and variations - together
5. Not basing standards on the best science available could leave the way open to trading partners challenging the standard through WTO

Food Legislation

- Objectives are:
 - protection of health
 - protection of consumers' rights
 - facilitation of trade in safe and healthy food
- Based on risk analysis principles
 - based on Codex standards, codes and guidelines which have been developed based upon a thorough risk assessment
 - or based on independent, objective and scientific risk assessments
- Developed, evaluated and revised in an open and transparent manner, involving public consultation and trading partners

The Codex Alimentarius Commission

- Codex sets international standards for national governments to consider
- Flour standards
- Labelling requirements for fortified/enriched including declarations
- Claims that can be made
- These have all been established






Address  <http://www.codexalimentarius.net/>

FAO/WHO Food Standards ENGLISH | FRANÇAIS | ESPAÑOL

CODEX alimentarius

ABOUT CODEX MEETINGS AND EVENTS OFFICIAL STANDARDS

[Forthcoming Codex Meetings](#)
[Reports](#)
[Archive Reports](#)



Welcome

The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

Warning: This is the only official website of the Codex Alimentarius Commission. Unofficial websites using similar domain names (URLs) exist. The information contained in unofficial websites is not guaranteed by the Codex Alimentarius Commission nor by FAO or WHO and in no way commits the Commission, FAO or WHO.

Joint FAO/WHO Food Standards Programme
Codex Alimentarius Commission

Twenty-seventh Session,
International Conference Centre, Geneva (Switzerland),
28 June - 3 July 2004

SIDE EVENTS

Executive Committee of the Codex Alimentarius Commission


RELATED CODEX LINKS

- JECFA
- JMPR
- JEMRA
- Biotech assessment
- Expert consultations

EXTERNAL LINKS

- WTO
- OIE
- IPPC
- WHO

FAO/WHO
TRUST FUND
FOR PARTICIPATION
IN CODEX



Food Law and Fortification

- Food Law:
 - states powers, offences and penalties
 - allows for the setting of regulations to achieve the purpose of the Law or Act
- As laws/acts are subject to interpretation, it may be necessary to specifically allow for regulations on fortification
- Depending on what legal system operates, it may be a Law/Act itself with implementing rules and regulations.
- Examples:
 - Canadian Food and Drug Act (5 pages)
 - Canadian Food and Drug Regulations and its implementing rules and regulations (2500 pages)

Mandatory Regulations and Standards

- Enable legislation to be adequately understood by consumers, industry and regulators
- Identify what is required of suppliers, processors and imported food and traders
- Facilitate enforcement by regulators
- Create an expectation of the need for adding health value to food

WHO Consensus Statement Recommendations on Addition of Nutrients to Flour

Nutrient	Flour Extraction Rate	Compound	Level of nutrient to be added in parts per million (ppm) by estimated average per capita wheat flour availability (g/day) ¹			
			<75 ² g/day	75-149 g/day	150-300 g/day	>300 g/day
Iron	Low	NaFeEDTA	40	40	20	15
		Ferrous Sulfate	60	60	30	20
		Ferrous Fumarate	60	60	30	20
		Electrolytic Iron	NR ³	NR ³	60	40
	High	NaFeEDTA	40	40	20	15
Folic Acid	Low or High	Folic Acid	5.0	2.6	1.3	1.0
Vitamin B ₁₂	Low or High	Cyanocobalamin	0.04	0.02	0.01	0.008
Vitamin A	Low or High	Vitamin A Palmitate	5.9	3	1.5	1
Zinc ⁴	Low	Zinc Oxide	95	55	40	30
	High	Zinc Oxide	100	100	80	70

Revising or Establishing Standards

Revising or Establishing Mandatory Standards in Line with Recommendations

- **Changes would require**
 - Understanding wheat flour consumption, particularly among the vulnerable populations
 - Understanding which flours would fall into low and high extraction rates
 - Understanding bioavailability and stability of micronutrient compounds to select optimum for circumstances
 - Understanding the purity of the permitted compounds
- **Consider**
 - Incorporating Codex standard guidance on flour itself
 - Minimum level standards mean that industry must add more than the minimum requirements to avoid not meeting regulatory requirements at the point of regulatory control
 - Maximum levels may also be prescribed but shouldn't be needed if GMP is in place and monitored
 - Tolerances or deviations may also be prescribed

Standards Can Apply at Different Points in the Food Production Chain

- For countries not processing flour, standards might apply at the point of import
- Pre-mix standards
- Milling process standards
- Flour standards at point of sale

Converting Recommendations To Standards for Pre-mix

- Requirements on pre-mix will vary according to mixing ratios so difficult to set one on all unless every miller mixes at same ratio
- A possible pre-mix standard could refer to the pre-mix's capacity to achieve a specified level in flour when mixed at a given mix ratio
- Would need to include mandatory requirement that pre-mix is monitored along with mixing proportions to achieve a specified level in flour
- **Nutrients would be at higher levels than those expressed in the Recommendations**

Converting Recommendations To Standards for Pre-mix

- Advantages of pre-mix standards include:
 - Higher concentrations of nutrients to be detected
 - Equal playing field for pre-mix suppliers
 - Possible for regulators and millers to require pre-mix suppliers to provide certificate of analysis from an independent laboratory
 - Possible for regulators and millers require QA certification
 - Can specify purity of chemicals used in pre-mix
- Possible disadvantages include:
 - Regulators cannot be confident that pre-mix is mixed at correct rate by all millers
 - Regulators are not monitoring what users (public/bakers etc.) are being supplied
 - Pre-mix standards do not allow for assessing losses from subsequent handling

Converting Recommendations To Standards On Flour During Milling Process

- As governments move to placing greater responsibility on businesses ensuring the safety and quality of food, Process Standards make more sense
- SOPs would require millers to identify, monitor and record pre-mix specifications, process controls and compliance with Process Standards
- Regulatory authorities could set national Process Standards focused on total nutrients in flour
- Can be integrated with QA/HACCP systems requirements

Converting Recommendations To Standards On Flour During Milling Process

- Advantages of process standards include:
 - Less reliance only on end point testing
 - Greater focus on responsibility of businesses to monitor and control processes
 - Regulators could focus on a limited number of milling establishments
- Disadvantages could include
 - Process standards alone may not be ideal for controlling imported flour
 - May be difficult to accurately assess some of the nutrients once diluted in flour
 - Regulators are not monitoring what public/bakers etc. are being supplied at the point of supply

Converting Recommendations To Standards On Flour At Point Of Sale

- Regulators could require that retail and processing businesses establish and monitor buyer specifications consistent with flour standards
 - Example – Food & Drug Administration for bakers and processors
 - Businesses obtain proof that product received complies
 - certificates of analysis on pre-mix
 - QA monitoring records
 - occasional analysis of their incoming raw materials
- Regulators can establish flour standards for inspectors to monitor through
 - Sampling and analysis
 - Auditing QA systems

Converting Recommendations To Standards On Flour At Point Of Sale

- Advantages of standards on flour include:
 - Regulators can monitor what public/bakers etc **are being supplied** with at the point of supply/sale
- Disadvantages include
 - Too many businesses for regulators to control
 - Regulators often have inadequate resources to focus on sampling and analysis of flour
 - Smaller businesses might not be able to effectively control what they receive
 - Tests cannot readily determine the compound used to provide the iron
 - Tests unable to accurately assess nutrients present in smaller quantities

Standards for Wheat Flour

Flour Mills must demonstrate compliance with standards, and have available to food control inspectors the following:

- Pre-mix specifications
- Certificates of analysis of pre-mix that demonstrate compliance to specification.
- All other records that demonstrate safety and quality of the product.
- Compliance with the standard

Food processors, wholesalers and retailers using flour must demonstrate compliance with standards and have available to inspectors the following.

- Evidence that they are monitoring their millers to ensure the flour is in compliance with this standard
- All other records that demonstrate safety and quality of the product
- Compliance with this standard

Conclusions - Standards

- Standards should be of a form consistent with Codex standard structure and clear about what is required.
- The legal minimum (and maximum) should be developed recognising what you want to achieve but also realising milling's technological limits and variations
- Focus should be at the milling industry for nationally produced flour
- Focus should include process control during fortification at the mill
- Focus should be at the point of import for flour imports

Trade Considerations

- Must ensure compliance with international agreements e.g. World Trade Organization Sanitary & Phyto-Sanitary and Technical Barriers to Trade agreements

What are the rights and obligations under the SPS agreement?

Rights of Signatories under the SPS Agreement

- ❑ WTO Members are allowed to adopt or enforce measures necessary to protect human, animal or plant life or health

- ❑ However these measures are not to be applied in a manner which would constitute
 - ✓ arbitrary or unjustifiable discrimination between Members
 - ✓ a disguised restriction on international trade

Obligations of Signatories under the SPS Agreement

- Members are to base their measures on international standards wherever possible
 - Base their SPS measures on an assessment of risk
 - Ensure measures are necessary to protect health
 - Not unjustifiably discriminating to foreign sources of supply
 - Promote the review and development of international standards

Costs/Benefit Considerations as Part of Regulatory Impact Assessment

- Need to assess the extent to which standards protect public health
- Need to assess costs to consumers
 - higher prices and/or
 - reduced choice of product
- Food business costs
 - Ingredients, processing, storage, technological
 - Documentation, monitoring records, analysis and certification
 - Inspection services
- Regulators costs

Core Message

Not basing standards on the best science available could leave the way open to trading partners challenging the standard through WTO

Country A sets mandatory standard for electrolytic iron it will therefore exclude imports of flour with ferrous fumarate from Country B – Potential consequences under WTO

Next Steps

Next Steps for Standards

1. Industry needs to take greater responsibility for food safety and nutritional quality
2. Need to put in place mechanisms for partnership between government and industry
3. Identify what standards would look like to comply with recommendations
4. Assess the public health consequences of taking or not taking action to apply the recommendations to voluntary or mandatory standards
5. Analyse the broader cost/benefits of both voluntary and mandatory standards

Next Steps for Standards

6. If mandatory standards are considered the preferred option consider the WTO implications and assess the public health impact vs trade barriers – ensure principles of SPS are applied
7. Use Codex guidance and national standards development process to draft standards
8. Consider the benefits of harmonizing in the region e.g. EU
9. Share draft standards with industry and consumers for input
10. Share draft standards with WTO Members and trading partners for input
11. Train industry and regulators before standards in place

Core Messages

1. Standards should be based on the best public health science. The best public health science is offered by the recommendations.
2. The Recommendations focus on average nutrients added not levels in Regulatory Standards
3. Standards should be of a form consistent with Codex standard structure and clear about what is required
4. The legal minimum (and maximum) should be developed recognising what you want to achieve but also realising milling's technological limits and variations
5. Impact on Trade: Not basing standards on the best science available could leave the way open to trading partners challenging the standard through WTO

For additional information, visit:

www.FFInetwork.org



Flour Fortification Initiative

A Public-Private-Civic Investment in Each Nation