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REVIEW OF REGULATORY MONITORING SYSTEM FOR FORTIFIED FOODS IN NEPAL



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ABBREVIATIONS

ADB	Asian Development Bank
CCO	Canadian Cooperation Office
CDO	Chief District Officer
DHS	Department of Health Services or Demographic and Health Survey
DFTQC	Department of Food Technology and Quality Control
EDTA	Ethylenediaminetetraacetic acid
EU	European Union
FAO	Food and Agriculture Organization
FFI	Flour Fortification Initiative
GON	Government of Nepal
HACCP	Hazard Analysis and Critical Control Points
HPLC	High-performance liquid chromatography
ISO	International Organization for Standardization
MI	Micronutrient Initiative
MOHP	Ministry of Health and Population
NFMA	Nepal Flour Millers Association
PPM	Parts per million
QA/QC	Quality assurance/quality control
SPS	Sanitary and phyto-sanitary
STC	Salt Trading Corporation
UIE	Urinary iodine excretion
UNICEF	United Nations Children's Fund
VAT	Value added tax
VDC	Village development committee
WB	World Bank
WFP	World Food Programme
WHO	World Health Organization

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This work would not have been possible without the dedicated efforts of the nutrition community in Nepal, which offered valuable support to this endeavor. These partners included the Ministry of Agriculture and Cooperatives (including the Department of Food Technology and Quality Control), the Ministry of Health and Population, the Ministry of Industry, the Nepal Salt Trading Corporation, the Nepal Roller Millers Association, flour mill owners in Kathmandu and Nepalgunj, the Micronutrient Initiative, UNICEF, the World Food Programme and other members of the Nepal Nutrition Group. Their contributions improved significantly this review and are much appreciated.

1. Executive Summary

Salt and wheat flour are the two main foods/condiments that are fortified with vitamins and minerals on a large scale in Nepal. The objective of this exercise was to review and document the regulatory monitoring systems (legal framework, internal, external and commercial monitoring) for fortified salt and wheat flour in order to draw lessons that could identify constraints and weaknesses and develop recommendations for changes that will improve the efficiency, effectiveness and sustainability of the systems in Nepal and also provide valuable lessons for other countries. A summary of this review served as the basis for a Nepal case study which was used to facilitate the meeting on Regulatory Monitoring of Fortified Foods organized by various partners¹ and hosted by WHO in Manila 27-29 September 2011.

The review was carried out by two consultants using the Framework for Monitoring and Evaluation of Food Fortification.² It consisted of a desk review of available documents on the regulatory monitoring systems in Nepal, including in particular, all past reviews and analyses of these industries and fortification programs. The desk review was followed by a country visit to interview the main stakeholders including salt and wheat flour producers, relevant departments of the Ministries of Health and Population and Department of Food Technology and Quality Control, Ministry of Agriculture and Cooperatives, at national, regional and district levels.

Following are the main findings of the review:

Food Fortification Legislation and Standards

The legal and regulatory framework in Nepal that governs the food control system has the proper mechanisms in place to introduce regulations and mandatory standards for foods and processing of foods. However, the current political instability in Nepal has created an environment that is not conducive for legislative amendments. The current design of the system is considered to be a sound model for the food control system in the country but it experiences delays due to the political instability.

The Food (Third Amendment) Act 2052 (1995)

The original Food Act of 1966 was established to provide the mechanism for the Government of Nepal to be able to control the food supply system in the country. The current Food Act enables the Government to prohibit production, sale and distribution of unsafe foods, to establish Quality and Standards of Food, to establish

¹ Global Alliance for Improved Nutrition (GAIN), Flour Fortification Initiative (FFI), Micronutrient Initiative (MI), UNICEF, World Bank and WHO.

² *World Health Organization & Food and Agriculture Organization Guidelines on Food Fortification with Micronutrients, 2006.*

a Food Quality Standards Committee, the inspection and testing of food, and to take enforcement action. The lead Ministry is Agriculture and Cooperatives.

The Food Regulation, 2027 (1970) and the Food (Fourth Amendment) Regulation, 2054 (1998)

The Food Regulation specifically identifies the Ministry of Agriculture and Cooperatives as being the lead government department for the development of food standards and food regulations and for the operation of the food control system including inspection, sampling and testing of food products and food commodities such as cereals, pulses and oils including salt and wheat flour. In August 2011, under the Food Regulation, the government issued a notice requiring the fortification of all flour milled by roller mills to be fortified with iron, folic acid and vitamin A. This is the result of several years of joint efforts of government, roller mills and public health agencies, in particular the MI. However, only about 20% of the wheat flour supply in Nepal is currently milled by roller mills; the rest is milled by small scale chakki and water mills. In addition a 9.75% VAT is imposed upon refined (maida) flour, as it is treated as a processed food, whereas wholemeal (atta) flour produced by small mills is not similarly taxed as it is not packaged, labeled and considered processed. Roller mills are also competing with imports of cheaper flour from India. While the proportion of wheat flour fortification that is currently regulated in Nepal remains low, this is likely to increase as the food processing sector modernizes and more of the wheat flour consumed in Nepal is milled by large roller mills. Cost-effective models for regulating the fortification of the flour milled in small mills in Nepal have yet to be developed.

The Iodized Salt (Production & Distribution) Act 1999.

The lead ministry for the administration of the act is the Ministry of Health and Population. This is different from the Food Act where the Ministry of Agriculture and Cooperatives is the lead ministry. Despite the fact that the Act has been in place and gazetted since 1999 the standards and regulations related to this Act have not yet been gazetted, which means that the salt iodization standards have not been made mandatory yet. It is noteworthy, however, that there is a mandatory technical regulation in the Food Act that specifies that salt must be iodized.

Salt is imported by the Salt Trading Corporation (STC), the sole quasi-public enterprise authorized by the government to import and distribute iodized salt throughout the country. Virtually the entire quantity of salt is imported from India and salt is iodized in India itself. The Nepal standard of 50 parts per million (ppm) differs from that of the exporting country (India), in which it is 30 ppm. In addition, some amount of iodized salt is imported illegally by others, mainly from India. Non iodized salt is permitted for agricultural and industrial purposes only.

Internal Monitoring

The large scale food industry is estimated to represent approximately 20-30% of the total food processing capacity in the country. The majority of the food processing is carried out in small scale industries scattered throughout the country. The current Food Act does not apply to small scale enterprises where the product will not be packaged and therefore labeled. However, local governments have a role in monitoring small scale food services under the Food Act which they are currently not playing.

The large scale food industry is well aware of the need to have good internal monitoring and quality systems in place in order to compete with imported foods and for export purposes. This includes the roller flour mills and STC. The industry has invested in establishing QA/QC and food safety systems that meet global requirements. There is, however, a lack of internationally accredited third party laboratories due to the lack of an accreditation system in Nepal. However, there are local laboratories accredited by the Nepal Bureau of Standards that large scale industry can utilize, including for analysis of iodine content in salt and iron content in flour.

External and Commercial Monitoring

The lead agency for this is the Department of Food Technology and Quality Control under the Ministry of Agriculture and Cooperatives. The DFTQC has offices and laboratories in Kathmandu but they are severely constrained due to lack of basic infrastructure such as electricity and water. There is also a lack of personnel for undertaking inspections.

Due to limited resources, the focus of the food control system is on those food products that present significant public health hazards if they are not processed and controlled properly. These include processed water, milk products, oils and more recently, imported foods from Japan that could be affected by radiation. Consequently the control of fortified foods is not high on the priority list of DFTQC. The current food control system places heavy reliance on finished product sampling and testing.

Consumer Awareness and Nepal Business Forum

It was beyond the scope of this review to undertake a detailed review of consumer awareness regarding fortified foods in Nepal. However, low consumer awareness appears to be a concern as it was raised in most of the interviews conducted. While consumer awareness of iodized salt appears to be generally high -- and there is evidence that increased awareness through a “two child logo” has increased the use of iodized salt where that awareness creation strategy was adopted – this is not yet the case for fortified wheat flour or other fortified foods in Nepal.

While increased consumer awareness should translate into a “demand pull” for policy reforms, measures also need to be taken to facilitate dialogue between the

private sector and the government on regulatory matters. The Nepal Business Forum has yielded some good results in terms of implementation of proposed reforms in Nepal and has the mechanisms both at the working level and at the policy level to bring together appropriate government and private sector stakeholders. The Nepal Business Forum could be one of the options to help advance some of the regulatory reform issues outlined in this report.

Overview of Strengths and Weaknesses of the System

Strengths

- The system is logical and the roles and responsibilities of each of the applicable government departments in the development food regulations and food standards are clearly defined.
- The system allows for the development of food regulations and standards under existing Acts, which do NOT need to be adopted and passed into law by the Parliament.
- The Technical Committee formed for the development of regulations and standards under the Food Regulations has wide stakeholder representation from both government departments and the food industry itself – if slightly biased towards Government (Ministries of Agriculture and Co-operatives; Health and Population; Industry; Commerce; Supplies; Home; Law and Justice) - with a Food Industry Representative nominated by Federation of Industries and Commerce, a Consumer Representative nominated by Ministry of Supplies and the Chief, Department of Food Technology and Quality Control. The Committee is chaired by the Secretary of the Ministry of Agriculture and Cooperatives.
- Many large companies have food quality systems in place based on ISO 9001, Registered HACCP and in some cases ISO22000 (HACCP).

Weaknesses

- There are no time limits set for each stage in the development of both the regulations and the food standards. In the current politically unstable environment the lack of a specified time tables can allow special interests or political interests to stall the whole process.
- The current flour standard does not meet the WHO recommendations and there is still no mandatory standard for salt (which limits the efforts made to salt monitoring).
- Insufficient priority and resources are allocated to regulatory monitoring of fortified food as it is not considered a safety issue; despite the fact that micronutrient deficiencies are proven to significantly constrain national development.
- Fortified food monitoring is end-product focused, concentrating on packaged foods, with indications of a lack of control relating to imports of wheat flour and salt. The fines and penalties for contravening the regulations and standards have not been changed since 1966 and any amendment to be

passed by the Parliament. A change in the Food Act will be required and should ensure that periodic revisions to the level of fines can be increased to punitive levels to ensure compliance.

- The food control regulations do not have any provision for the food industry to be required to implement food safety systems that meet internationally recognized standards such as ISO 9001:2008 Quality Systems and/or food safety standards such as ISO 22000 Hazard Analysis and Critical Control Points HACCP.
- The role of the consumers associations to make a significant contribution to the overall food control system is considered to be weak due to in-fighting between the various associations that purport to represent the consumer in Nepal.
- The system for filing and executing legal cases for contravention of the regulations and standards has been devolved to the Chief District Officer, CDO. The CDOs are responsible for the administration and enforcement of more than 50 acts. This requires them to prioritize legal cases on the basis of severity and risk. In the case of food, CDOs will fast track cases related to food safety and urgent public health issues. Due to lack of resources in personnel and finance, cases relating to food fortification are not considered high risk and therefore not urgent.
- There is a lack of third-party food quality testing laboratories and even the DFTQC laboratory does not have accreditation. The DFTQC has implemented a process to get accreditation under ISO 17025 standards but it will take 3-5 years before the process is completed. Thus, food samples from the industry have to be sent out of the country at significant increased cost for both local and export markets.
- Non iodized salt is permitted for agricultural and industrial purposes, which may lead to leakage.

Recommendations

- The Food Act 2032 (1966) should be updated to incorporate time limits for each step of the process and provision for increasing penalties for non-compliance.
- A more in-depth study of the inspection regime should be conducted, to understand better the mandate of DFTQC, human resource management issues, staff performance, accountability, etc.
- A systematic monitoring program, which is centrally co-ordinated, should be developed taking into account the current capacity limitations and concentrating on food processors rather than at market or retail level.
- Personnel responsible for regulatory monitoring should be given adequate training in the management of all aspects of the food control system, including inspection, sampling and laboratory analysis.
- The procurement process for laboratory equipment and supplies should be updated to ensure that unreliable suppliers are excluded from the bidding

- process by providing conditions of guarantees of performance, testimonials from other customers and reference checks in the tender documents.
- The third party accreditation process for laboratory capacity at the government institution, DFTQC, and private sector levels in Nepal should be accelerated through the provision of ISO 17025 technical experts.
 - Additional social marketing activities and awareness creation of the benefits of iodized salt should be carried out particularly in the districts of the Terai border with India.
 - Salt iodization should be made mandatory either by implementing the special Salt Act 1999 or by removing the standard for common salt under the food regulation.
 - A survey of the iodization levels throughout the supply chain should be carried out to determine the extent/coverage of non-iodized and inadequately iodized salt.
 - Additional technical support should be provided to roller millers on the fortification process.
 - The standard for wheat flour fortification should be amended to bring it in line with WHO guidelines, especially in the area of more bio-available iron such as ferrous fumarate or, preferably, sodium iron EDTA.
 - The Ministry of Finance should reassess the imposition of VAT on wheat flour produced in large roller mills within the country to reduce the incidence of unofficial imports of flour which can come in as unfortified flour and to assist the milling industry in bearing the additional cost of more effective premixes (assuming the standard is changed).
 - The Government of Nepal and its development partners should engage the various consumer groups within the Consumer Forum on the right to safe and healthy foods and the importance of consuming fortified foods with emphasis on salt and wheat flour products.
 - Explore the Nepal Business Forum as a means to facilitate the regulatory reforms outlined in this report.
 - The Government of Nepal should expand the use of approaches that are shown to increase consumer awareness of fortified foods, such as the “two child logo” for iodized salt.

2. Background and Methodology

Salt and wheat flour are the two main foods/condiments that are fortified with vitamins and minerals on a large scale in Nepal. A Special Iodized Salt Act was promulgated in Nepal in 1999 but it has not been enforced as the Regulation has not been passed by the government yet. At present, iodized salt is regulated by the general Food Regulation but according to this, salt iodization is not mandatory. However, there is a technical regulation in the Food Act regarding iodized salt and that is considered mandatory once it has been gazette. The Nepal government has a Universal Salt Iodization program that requires that all salt distributed in Nepal be iodized. The salt iodization program was introduced in Nepal in 1973. The preliminary report of the Nepal Demographic and Health Survey (NDHS) 2011 indicates that 80% of households consume adequately iodized salt. These data are semi-quantitative and would need to be confirmed with quantitative testing, but they would indicate an improvement in the quality of salt iodization in recent years.

Wheat flour fortification has become mandatory in Nepal in 2011, following a period of a few years of voluntary fortification by wheat flour millers with free supply of vitamin and mineral premix by the Micronutrient Initiative. However, sufficient system capacity to enforce mandatory wheat flour fortification may not yet exist in Nepal. Discussions are currently underway as to whether the premix currently used should be changed to take into account WHO recommendations that were made after the selection of the premix in Nepal. In addition the Micronutrient Initiative and the Asian Development Bank are currently supporting pilot projects to test the feasibility and scalability of fortification by small scale water/chakki mills in one district.

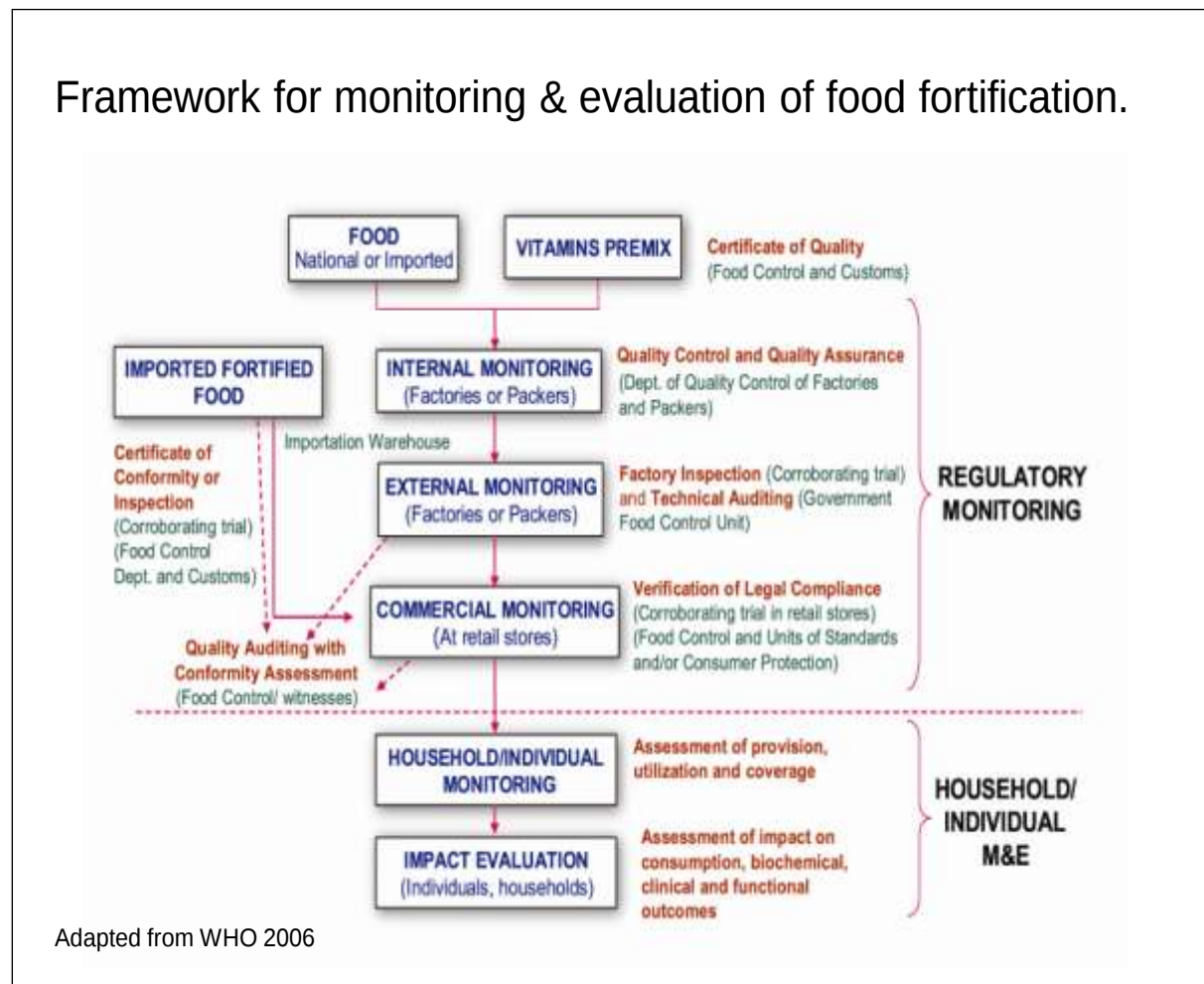
The WHO and FAO *Guidelines on Food Fortification with Micronutrients, 2006* distinguish two main categories of monitoring: regulatory monitoring and household/individual monitoring. The former, regulatory monitoring, encompasses all monitoring activities conducted at the production level (ie factories and packers), as well as monitoring at customs warehouses and at retail stores, by concerned regulatory authorities as well as by producers themselves, as part quality control/assurance programs. The primary aim of regulatory monitoring is to ensure that the fortified foods meet the nutrient, quality and safety standards set prior to program implementation.

The objective of this exercise was to review and document the regulatory monitoring systems (legal framework, internal, external and commercial monitoring) for fortified salt and wheat flour (focus on roller mills) in order to draw lessons that could identify constraints and weaknesses and develop recommendations for changes that will improve the efficiency, effectiveness and sustainability of the systems in Nepal and also provide valuable lessons for other countries. A summary of this review served as the basis for a Nepal case study which was used to facilitate the meeting on Regulatory Monitoring of Fortified

Foods organized by various partners³ and hosted by WHO in Manila 27-29 September 2011.

The review was carried out by two consultants using the Framework for Monitoring & Evaluation of Food Fortification.⁴ It consisted of a desk review of available documents on the regulatory monitoring systems in Nepal, including in particular, all past reviews and analyses of these industries and fortification programs. The desk review was followed by a country visit to interview all relevant stakeholders including salt and wheat flour producers, relevant departments of the Ministries of Health and Population and Department of Food Technology and Quality Control, Ministry of Agriculture and Cooperatives, at national, regional and district level.

2.1 Framework Diagram



³ Global Alliance for Improved Nutrition (GAIN), Flour Fortification Initiative (FFI), Micronutrient Initiative (MI), UNICEF, World Bank and WHO.

⁴ World Health Organization & Food and Agriculture Organization Guidelines on Food Fortification with Micronutrients, 2006.

Interviews were carried out with the main stakeholders involved in the food control system in Nepal as well as with external development partners with knowledge of food fortification. Stakeholders included Government of Nepal departments, such as Child Health Division, Ministry of Health and Population, Department of Food Technology and Quality Control, Ministry of Agriculture and Cooperatives; food industry stakeholders represented by the Nepal Flour Millers Association, the Chaudhary Group, and the Salt Trading Corporation; and external development partners such as UNICEF, the World Food Programme, the Micronutrient Initiative, and the World Bank.

3. General Food Laws and Regulations

The legal and regulatory framework in Nepal that governs the food control system is reasonably well structured and has the mechanisms in place to introduce regulations and mandatory standards for foods and processing of foods. However, the current political instability in Nepal has created an environment that is not conducive for legislative amendments. The current design of the system is considered to be a sound model for the food control system in the country but it currently experiences delays due to the political instability. The process flows for the development of acts, regulations and standards are considered to be reasonable and in line with the FAO/WHO guideline documents on food control systems FAO/WHO publication *Guidelines for Developing an Effective National Food Control System* (1976) and *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems* (2003).

The following laws and regulations are used to provide the framework for the food control system in Nepal:

3.1 Acts and Regulations

The following acts governing food and food control are currently in effect in Nepal. These Acts provide the legal framework which allows the relevant Departments of the Government of Nepal to prepare and enact the appropriate regulations, standards and activities which are used in the country's food control system. In addition, they provide the legal framework for laws regulating iodized salt and the regulations for by which other fortified foods can be made mandatory.

3.1.1 The Food (Third Amendment) Act 2052 (1995)

The original Food Act of 1966 was established to provide the mechanism for the Government of Nepal to be able to control the food supply system in the country. The Food Act has been amended three times since 1966 with the latest amendment coming into effect in 1995. The Act was designated “**An Act to maintain purity in foodstuffs**” and covers the following:

- **Prohibition on production, sale or distribution** of adulterated foodstuff or sub-standard foodstuff and **prohibition on sale** of foodstuff by lying or misleading
- **Powers to withhold** foodstuffs
- **Licenses** to be obtained to produce, sell, distribute, store or process foodstuffs
- **Punishments** and fines
- **Liability of crime** committed by a firm or body corporate
- Powers to set **quality and standards** of foodstuffs
- **Analysis** of foodstuff
- Establishment of **Food Standards Committee**
- Government to be the **plaintiff** in legal cases
- Adjudicating authority to be **Chief District Officer**
- **Appeal**
- Power to frame **Rules (regulations)**

The key words and phrases are listed in bold above. These key words and phrases then enable the applicable regulations to be developed and implemented. The Food Act enables the system to prohibit production, sale and distribution of unsafe foods, to establish Quality and Standards of Food, to establish Food Quality Standards Committee, the inspection and testing of food, and to take enforcement action.

The following food regulations have been brought into effect using the Gazette Process⁵:

3.1.2 The Food Regulation, 2027 (1970) and The Food (Fourth Amendment) Regulation, 2054 (1998).

The Food Regulation specifically identifies the Ministry of Agriculture and Cooperatives being the lead government department for the development of food standards and food regulations and for the operation of the food control system including inspection, sampling and testing of food products and food commodities such as cereals, pulses and oils.

The Food (Fourth Amendment) Regulation, 2054 (1998) covers the establishment and duties of the following entities:

- Central Food Laboratory
- Food Inspectors
- Analysis of Foods
- Establishment of Food Standard Fixation Committee
- Labels of packaged foods
- Use of Colours & Preservatives
- Licenses

⁵ The Gazette Process is the method used to publish the Laws, Rules and Regulations in Nepal which once published makes them official and in effect from the date of publication.

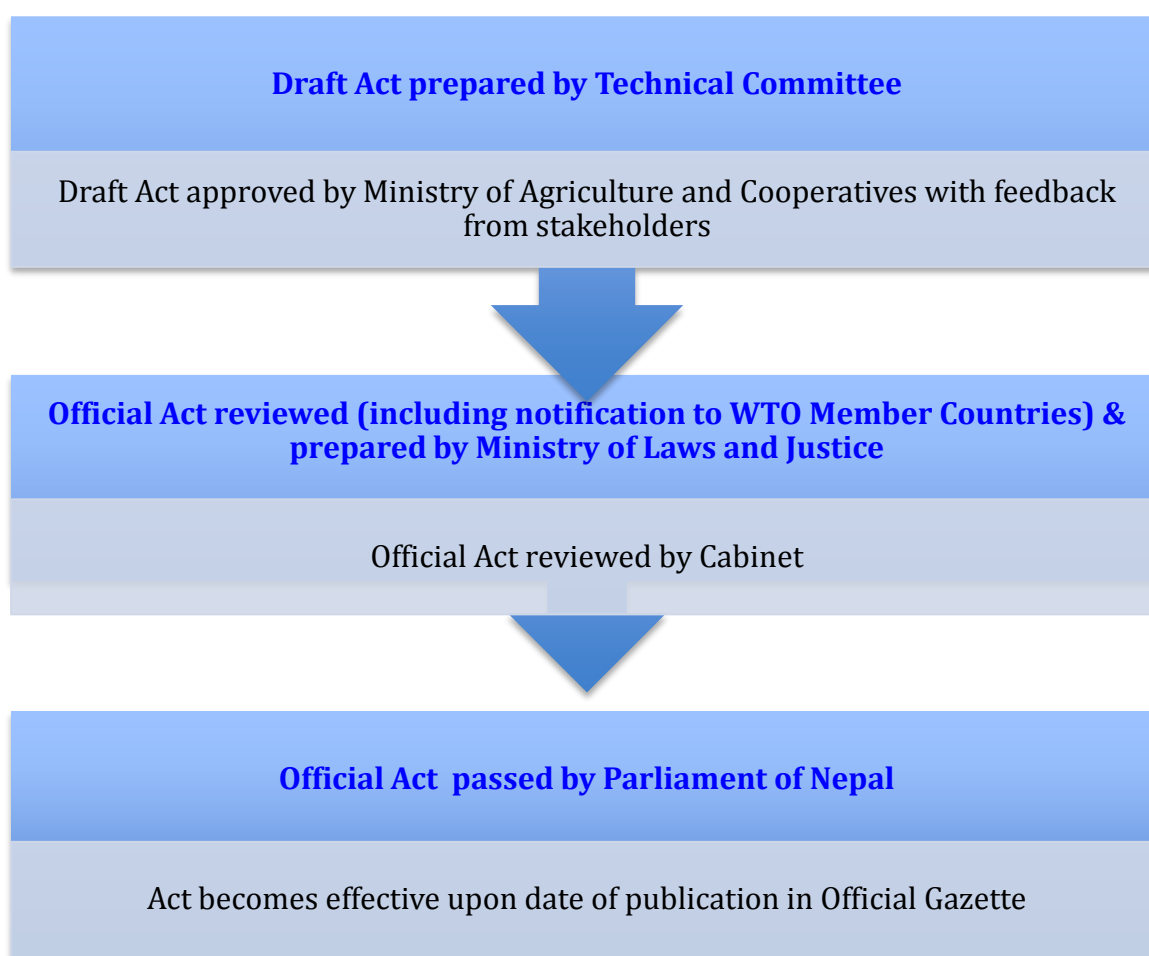
- Schedules covering identity of inspectors, samples taken including sample size and method of securing samples, definitions of micronutrients including vitamin A, B group vitamins, folic acid, vitamin C, vitamin K, calcium, iodine, iron, phosphorus, colours, preservatives as Class 1, Class 2, license for itinerant sale, license to open retail shop or wholesale business, license for food industry.

3.2 Process Flows for the Development of Laws, Regulations and Standards for the Food Control System

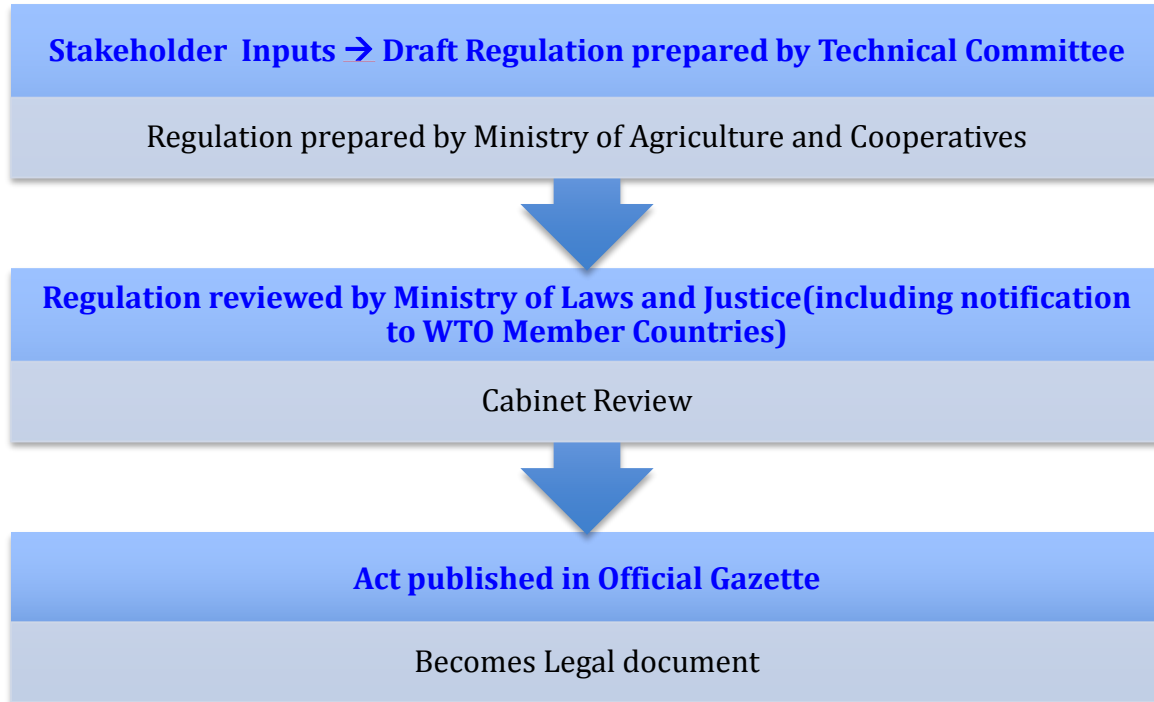
The following sections represent in diagrammatic form the process flows for the development of laws regulations and standards for the Food Control System in Nepal.

3.2.1 Diagram Flow Sheet of the System for Developing and Promulgating Acts of Parliament.

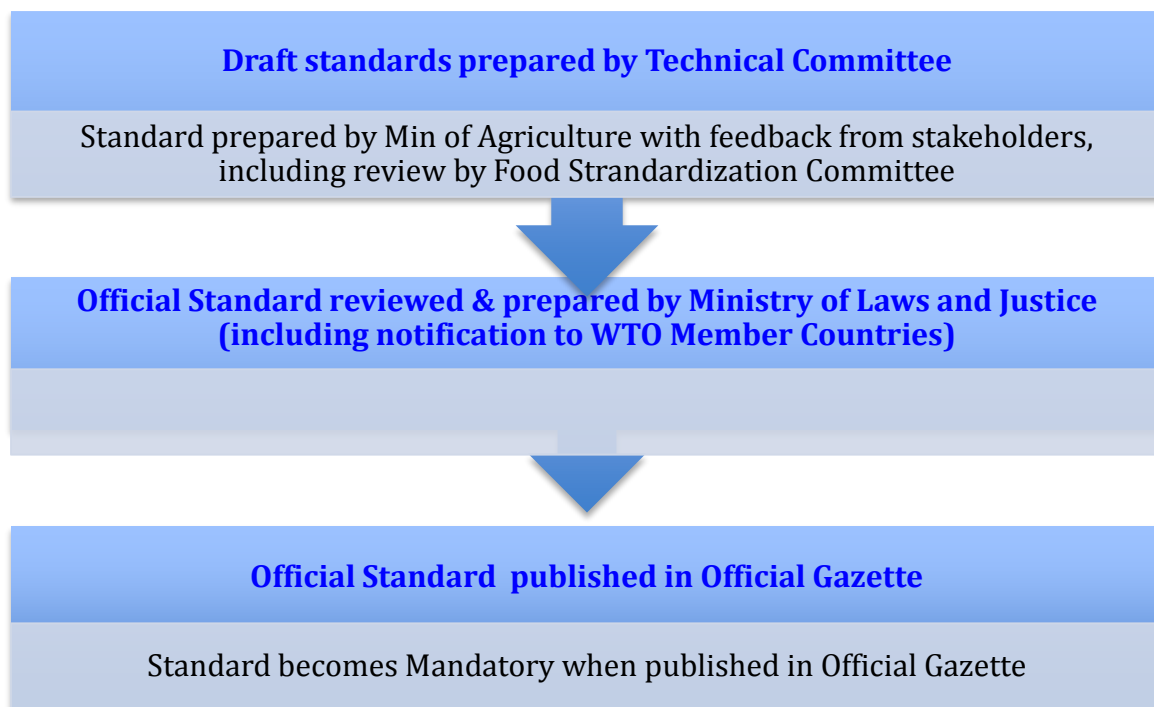
The following diagram illustrates how the system for developing Acts of Parliament flows in Nepal:



3.2.2 Diagram Flow Sheet of the System for Developing Regulations



3.2.3 Diagram Flow Sheet of the System for Developing Food Standards



3.3 Other Acts & Regulations

The following is a list of other acts and regulations that can be used in the food control system.

3.3.1 Mother's Milk Substitutes (Control of Sale and Distribution) Act 2049 (1992) Mother's Milk Substitutes (Control of Sale and Distribution) Rules, 2051 (1994)

These are specifically to control the sale and distribution of breast milk substitutes. They are based on the WHO international guidelines for breast milk substitutes. The Government of Nepal is required to form a Breastfeeding Protection and Promotion Committee to supervise whether this Act is being complied with, to protect and promote the breastfeeding and to control the sale and distribution of the product.

3.3.2 Animal Slaughterhouse and Meat Inspection Act, 2055 (1999)

This act governs the licensing and control of slaughterhouses and the inspection of meat by qualified meat inspectors.

3.3.3 Export and Import (Control) Act, 2013 (1957)

This Act empowers the Government of Nepal to control the import and exports of foods as well as other products in Nepal.

3.3.4 Essential Commodities Control (Authorization) Act, 2017 (1961)

In addition to the Food Law and Regulations that are currently in effect, the Government of Nepal promulgated an Essential Commodities Control Act which permitted the Government of Nepal to control essential commodities. The following table lists the basic commodities that are controlled by the act.

Controlled Commodities
Salt
Paddy, rice, wheat, maize, barley, millet and their flours
Sugar
Linseed, mustard seed, sesame seed and their oils
Vegetable oil, vegetable oil ghee
Milk and milk products including butter
Pulses including gram, lentils soybeans
Any other food specified by Government of Nepal

The important feature of the Essential Commodities Act is that it allows for the Government of Nepal to control the supply of the essential commodities listed above so that in times of food insufficiency the Government of Nepal can control the sale and distribution of them including price control mechanisms. Typically, this means that it can prevent the export of the essential commodities during times of insufficiency. Nepal used to be self sufficient in food supplies but is now considered to be a food deficit country.

3.3.5 Consumer Protection Act 2054 (1998)

This act has been formulated by the Government of Nepal in order to preserve the health, benefit and economic condition of the consumers, and to protect the right of consumers to gain the specified or intended use of the product.

This act has the provision of food control by an inspection team including representatives from consumers association(s). If the food items are not found of appropriate quality or quality claimed in the label, the consumers can complain to the concerned authority for such food products, services and quality standards.

3.4 Review of the Current Legal and Regulatory Framework

During the mission an assessment was made of the strengths and weaknesses of the legal and regulatory framework in the current system.

3.4.1 Strengths

The following strengths of the system were identified:

- The system that is to be followed is clear and is logical. It is built on the same system that was developed by the United Kingdom and which has been adopted in most Commonwealth and some other countries. The development of food regulations and food standards has to be in accordance with the Food Act itself.⁶
- The roles and responsibilities of each of the applicable government departments in the development food regulations and food standards are clearly defined.
- The system allows for the development of food regulations and standards that do NOT need to be adopted and passed into law by the Parliament. This is considered to be a major advantage.⁷
- The Food Standardization Committee that is formed for both the development of regulations and standards under the Food Regulations has wide stakeholder representation from both government departments and the food industry itself. The following government departments are represented on the Food Standardization Committee:
 - Ministry of Agriculture and Co-operatives (chaired by Secretary of MoAC)
 - Ministry of Health and Population
 - Ministry of Industry
 - Ministry of Commerce
 - Ministry of Supplies
 - Ministry of Home
 - Ministry of Law and Justice

⁶ This is similar to the food control system in effect in Canada where the Food and Drug Act is a short document of 5 pages. The Food and Drug Regulations number more than 3,000 pages.

⁷ By contrast, in India food standards were embedded in the Pure Food Acts of 1947 and 1954 which requires that any changes in standards have to be passed by Parliament through an Amendment of the Act.

- Food Industry Representative nominated by Federation of Industries and Commerce
- Consumer Representative nominated by Ministry of Supplies
- Chief, Food Control Laboratory
- Invitees: Specialists or experts from different sectors

The Consumer Protection Act make provision for consumers to play an active role in the food control system by allowing them to complain to the relevant authorities and government departments about food quality and food safety issues.

3.4.2 Weaknesses

The following weaknesses of the system were identified:

- There are no time limits set for each stage in the development of both the regulations and the food standards. This means that the process can be held up for an indefinite period.⁸
- In the current politically unstable environment the lack of a specified time tables can allow special interests or political interests to stall the whole process.
- The fines and penalties for contravening the regulations and standards have not been changed since 1966. For example, the current fines for an offence range from only NRs 50 – NRs1000 (US \$0.71 - \$10) for itinerant sellers to NRs 1,000 – 10,000 (US \$14 - \$140) for manufacturers, retailers and importers of adulterated foods.
- In the case of foods which cause serious illness (“irreparable damage”) the fines range from NRs 10,000 – 25,000 (US \$ 140 - \$350) and up to 3 years imprisonment and up to NRs 100,000 (US \$1,400) compensation to the victim or heir.
- In addition to the low fines of the Food Act 2023 (1966), any changes will require a change in the Act that will require the amendment to be passed by the Parliament. A change in the Food Act will be required and should ensure that periodic revisions to the level of fines can be increased to punitive levels to ensure compliance.
- The food control regulations do not have any provision for the food industry to be required to implement food safety systems that meet internationally recognized standards such as ISO 9001:2008 Quality Systems and/or food safety standards such ISO 22000 Hazard Analysis and Critical Control Points HACCP. The implementation of internationally recognized food quality assurance & quality control systems is becoming the norm for countries around the world. Many importing nations will not permit imports from food

⁸ By comparison, in European Union countries, North America and other countries once the process has been started there are a limited number of days before the proposed draft regulation and standard has to be passed on to the next stage in the process. Typically, the time frame for each stage is between 60 and 90 days.

companies unless they adhere to internationally recognized systems for food safety.

- The role of the consumer associations to make a significant contribution to the overall food control system is considered to be weak due to in-fighting between the various associations that purport to represent the consumer in Nepal.
- The system for filing and executing legal cases for contravention of the regulations and standards has been devolved to the Chief District Officer, CDO. The CDOs are responsible for the administration and enforcement of more than 50 acts. This requires them to prioritize legal cases on the basis of severity and risk. In the case of food, CDOs will fast track cases related to food safety and urgent public health issues. Due to lack of resources in personnel and finance cases relating to food fortification are not considered high risk and therefore not urgent.

3.4.3 Recommendations

- **That the Food Act 2023 (1966) be updated so that the following amendments can be made.**
 - **Establish time limits for each step in the development and review process of regulations, standards and laws. Based on international good practice, a proposed time limit for each stage would be 60 days upon official publication.**
 - **Penalty provisions in the Food Act need to be upgraded so that penalties for infractions against the law can be increased on a regular basis.**
- **That a more in-depth study of the inspection regime be conducted, to understand better the mandate of DFTQC, human resource management issues, staff performance, accountability, etc.**
- **That additional awareness training be provided to CDOs and their staff on the importance of a safe food supply so that priority be given to cases of infractions against Food Act where the public health status may be at risk or in danger.**

4. External Monitoring System

External monitoring refers to the inspection and auditing activities carried out at production centres (factories and packers) and importation custom sites. *Governmental authorities are responsible for external monitoring*, which is implemented as a mechanism to assure compliance with standards and regulations.

With financial and technical assistance from external development partners, Nepal has upgraded and modernized the infrastructure and capital assets of the food control system, particularly at the Department of Food Technology and Quality Control offices and laboratories in Kathmandu. Despite these investments, the national weaknesses in basic infrastructure such as electricity and water supply

hinder the efficiency of the Central and Regional Laboratories. In addition, the management of the system is considered to be weak with inefficiencies in the operations of the laboratories and the procurement process for equipment and supplies.

The total budget for the DFTQC in FY2010/11 ending 30 June is NRs 92 million. The amount allocated for food control activities was not available for review.

Due to limited financial resources the focus of the food control system is on those food products that are perceived to present significant public health hazards if they are not processed and controlled properly. These include processed water, milk products, oils and more recently, imported foods from Japan that could be affected by radiation (due to the March 2011 earthquake and tsunami which damaged the nuclear power plants). Given the low level of awareness of the long term consequences of micronutrient deficiencies, the control of fortified foods is not high on the priority list of DFTQC despite the fact that the long-term consequences of micronutrient malnutrition for the country are as important as short-term consequences of food safety issues of other foods⁹.

The current food control system has placed heavy reliance on finished product sampling and testing. This system of food control does not take into account the importance of consistent processing procedures and controls to ensure food safety as well as product quality. On a worldwide basis, there has been a strong move away from relying just on finished product testing to the inspection of the whole food production process and the use of Hazard Analysis and Critical Control Points HACCP systems. Food control systems based on HACCP principles have been adopted in several EU countries and North America.

4.1 Responsible Agency DFTQC

The Ministry of Agriculture and Cooperatives has the responsibility for the operation of the food inspection system and food testing in the country. The Department of Food Technology and Quality Control, DFTQC, within the Ministry of Agriculture and Cooperatives is the agency responsible for administering the food control program in Nepal.

4.2 Structure of DFTQC

The DFTQC has the following divisions:

- **Food Quality Control Division**

This division is responsible for the development of food standards, the certification of food industry companies, the food inspection unit for food control and for oversight of the Food Safety system, export/import quality inspection and certification, and consumer awareness.

⁹ Economic losses due to micronutrient deficiencies are estimated to represent 2-3% of GDP.

- **National Nutrition Programme**

This division is responsible for the management of the National Nutrition Programme. The National Nutrition Programme provides information to the population on the benefits of good nutrition, raising awareness of the benefits of the consumption of nutritious foods including fortified foods.

- **Food Technology Development and Training**

This division is responsible developing and conducting training courses on food technology for food entrepreneurs, the regional laboratory staff and other training programs on food technology for the food industry and other ministries including Ministry of Industry, Ministry of Health and Population and other departments within the Ministry of Agriculture and Cooperatives.

- **Central Food Laboratory**

This division has a number of laboratories for analyzing foods. These laboratories include chemical, microbiology, instrument, and reference laboratories. The Central Food Laboratory is responsible for carrying out analysis of samples taken from food inspections, food analysis and investigation of food quality and safety in the food supply chain.

- **Sanitary and Phyto-Sanitary Entry Point**

The DFTQC is the Sanitary and Phyto-Sanitary (SPS) Enquiry Point which functions to respond to enquiries regarding existing and proposed national legislation and food standards from other countries under the World Trade Organization, WTO, rules. Any country that wishes to export foods to another country can make enquiries about the national standards.

- **Regional Food Technology and Quality Control Offices**

There are 5 Regional Food Technology and Quality Control Offices and 4 Food Quarantine Offices and one food inspection unit at the international airport in Kathmandu. In addition, there are 20 District Food Inspection Units that report to the 5 Regional Food Technology and Quality Control Offices. All these offices are located mainly in the Terai and foothills areas of Nepal.

- **Supporting Offices**

In the DFTQC main office there are additional administrative offices providing support such as Planning, Administration, Finance and Legal services.

4.3 Official Function of DFTQC

The functions of DFTQC, as specified in Section 7.2 (Part II) of the Food Act, are as follows:

- To analyze food samples collected during inspections
- To assist the Food Standardization Committee in generating scientific data to be used to set standards for food products

- To carry out food inspections at all points in the distribution system from point of manufacture to point of sale to determine whether adequate control measures are in place
- To conduct food inspector training
- To issue licenses for the production, distribution and sales of foods
- To inspect and certify export/import food products
- To conduct consumer awareness promotion activities

4.4 Food Inspection Staffing

The DFTQC has 40 food inspectors to cover all 75 districts in Nepal. Based on the Annual Bulletin highlights for 2009/10, (see below) this translates into 28 inspections per inspector per year of food industry companies and food service establishments. In addition, 68 official samples per inspector per year were taken for analysis from food industry companies, food service establishment and food markets and or shops.

The number of inspections and sample taking per inspector appears to be low, but it must be noted that there are very limited resources allocated for transportation purposes for inspectors to carry out their duties. This means that not all food establishments and markets can be visited on an annual basis. In addition, the focus tends to be on markets and shops, with emphasis on expired and or mislabeled products.

4.5 Annual Bulletin 2066/67 (2009/10) of Activities under the DFTQC Mandate

The DFTQC is mandated to produce an Annual Bulletin of their activities. The latest bulletin for 2009/10 had the following highlights:

- Development of standard for fortified wheat flour
- Testing of 214 samples of iodized salt with 3 being substandard. Types of salt analyzed included common salt, crystal salt and triple refined salt. Salt inspections were approximately 200 in the current year taken mainly from the market place such as stalls, shops and smaller warehouses in the distribution chain.¹⁰
- Draft guidelines for production of processed drinking water and dairy products
- 1107 inspections of food/feed industries
- 1040 inspections of food service establishments i.e. hotels, restaurants, sweet shops
- 4113 official samples were taken and analyzed at the Central Laboratories, of which 416 (10.11%) were found to be substandard or defective

¹⁰ The Salt Trading Corporation is responsible for internal quality assurance and quality control testing. The DFTQC carries out a monitoring assessment of the main STC facilities on an occasional basis.

- 32.23% of food samples tested for microbiological safety were found to be defective
- 18955 samples were analyzed by the regional and central food testing laboratories for food industry companies, and government ministries
- 18 training programmes were carried out on food technology and food processing for 353 food industry entrepreneurs
- Implemented the process to have the Central Laboratory certified under ISO 17025 for proximate analysis of foods (moisture, protein, fat, and fibre)
- Nutritional analysis and Food, Nutrition Education and Communication activities

4.6 Current Situation and Challenges

During the review, the consultants visited both the DFTQC central office and the regional office and laboratory in Nepalgunj on the border with India. As a result of the visits and discussions the following points were noted:

- **Infrastructure** -- The DFTQC's ability to function adequately is suffering from basic infrastructure issues related to inconsistent water and electrical supply. Both of these reduce the number of analyses that the Central Laboratory can carry out. In addition, the lack of simple voltage stabilizers in each facility increases the risk of damage to sensitive equipment such as computers, HPLCs, GCs, spectrophotometers, etc. The regional laboratory in Nepalgunj is in a similar situation and condition as the other 4 regional laboratories according to the director of the regional laboratory in Nepalgunj. One of the consequences is that any new equipment that could analyze a much larger number of samples will not operate properly. An example of this would be a Chinese iodine checker machine to test iodized salt samples. Due to unreliable power supplies the laboratory at the regional level has to use simple titration methods.
- **Financial Resources** -- The 2010/11 budget (year ending 30 June 2011) for the DFTQC is NRs 92 million. The breakdown and allocation for the food control was not available at the time of the mission. However, during the mission DFTQC personnel advised that the DFTQC is constrained by the lack of adequate budgets and funding to be able to maintain the existing equipment and future equipment needs. Capital equipment donations and funding from development partners is not usually matched by adequate allocation of finances to maintain and repair the equipment. In the case of the UV/Visible Spectrophotometers, procured by DFTQC with funding support from MI to analyze iron in fortified wheat flour at the Central Laboratory and at the Regional Laboratories, these machines were sourced from an Indian supplier and have not worked properly. Efforts were made to contact the supplier/manufacturer, but it is thought that the company no longer exists. The procurement process requires that the least costly supplier

wins the contract tender without having adequate condition clauses and other safeguards in the tender documents to ensure that the potential supplier is reliable and its business is viable.

- **Laboratory Staffing and Management** -- The DFTQC management advised during the mission that due to budget constraints, the laboratory is understaffed and some staff are inadequately trained to be able to carry out its full mandate under the Food Act. At the time of the visit it was not possible to confirm what the actual financial constraints are.
- **Food Safety Priorities** -- The DFTQC has to prioritize its inspection and testing activities using risk assessment practices. At the top of the priority list are those foods that present the greatest food safety risk due to microbiological and other contaminations. The following foods are deemed by DFTQC management to be the highest risk and take priority over other foods: milk products, processed water, baby foods, meat products, and any product complaint received from consumers. The Annual Bulletin confirms that the use of risk assessment methods and assignment of priority foods shows the extent of the problems. 33.3% of processed water samples and 29.8% of milk product samples tested were found to be contaminated with coliforms and pathogenic bacteria (*e.coli*). In addition 26% of the water samples were substandard due to chemical standard not being met such as high pH, high ammonia and high iron content. Pesticide residue analysis of the food supply in Nepal has increased in importance with specific reference to exports where countries have regulations covering pesticide residue limits.
- **Fortified Foods** -- DFTQC currently focuses its attention on the testing of fortified foods that have mandatory standards. In this case salt is the main food. The responsibility of the quality assurance system for the routine salt iodization process lies with the Salt Trading Corporation. The DFTQC activities on salt testing are focused on the sampling and testing of salt in the markets and limited inspections at the STC salt warehouses, repacking and iodization plants. However, in the case of the Nepalgunj regional office of DFTQC the inspectors do visit the STC warehouse which has a re-iodization plant in it. Samples of salt are taken from the STC on a monitoring basis. As flour fortification at roller mills has become mandatory, DFTQC is expected to increase its efforts towards the analysis of fortified flour.
- **Regional Laboratory, Nepalgunj** -- During the visit to the DFTQC Regional Office and Laboratory in Nepalgunj, the Regional Inspector advised that the office covers 4 districts on a regular basis and an additional 15 districts in Western Nepal from the Terai to the Mountain region and border with Tibet, China. The regional laboratory has the

capacity to carry out basic analysis in a small overcrowded room. They analyze about 1100 samples per year including about 200 samples received from the Customs quarantine area at the border crossing in Nepalgunj. The office inspects mostly small processors and markets, taking samples during the inspections. There are only 4 large processors including two flour mills, an oil plant and complementary food plant (making UNILITO a fortified complementary blended food made from maize and or wheat and soybeans for the UN World Food Programme). The majority of the inspections are random market inspections in market stalls and food shops, followed by license renewal inspections 70 per year and 40-60 small dairy inspections. The most frequent issue that the office encounters is foods being sold passed their expiry date. The regional inspector sits on the CDO's monitoring committee that meets monthly. Other representatives on the committee chaired by the CDO are the municipality representatives and animal inspectors.

4.7 Recommendations

- **That a detailed review be carried out of the current inspection practices to determine where efficiencies in inspection practices can be achieved so that the coverage of inspections (in numbers of inspections) can be increased from the current relatively low numbers of inspections per inspector.**
- **That the current inspection plan be refocused on food industry companies as the priority rather than inspection and sampling at the market and retail shop level.**
- **That additional support be provided to give adequate training in the management of all aspects of the food control system, inspection, sampling and laboratory. The training should include the development of risk assessments for different types of foods so that the foods that have the highest levels of risk have the most focus within the food control system.**
- **That the procurement process for laboratory equipment and supplies be updated to ensure that unreliable suppliers be excluded from the bidding process by providing conditions of guarantees of performance, testimonials from other customers and reference checks in the tender documents.**
- **That the introduction and training on HACCP systems for food safety be considered to make the current food control system more effective.**
- **That development partners advocate more assertively for the need to ensure that adequate attention is paid to the food control of fortified foods by DFTQC.**

5. Internal Monitoring System

Internal monitoring refers to the quality control and quality assurance (QC/QA) practices *conducted by producers, importers and packers.*

The large scale food industry in Nepal is well aware of the need to have good internal monitoring and quality systems in place in order to compete in the domestic market with imported foods and for export purposes. The industry has invested in establishing quality assurance/quality control (QA/QC) and food safety systems that meet global requirements. However, there is a lack of strong technical support for internationally accredited third party laboratories due to the lack of an accreditation system in Nepal. As Nepal take steps to join the World Trade organization (WTO) the need to invest in proper systems and facilities has become more urgent to provide for sound technical support to the food industry.

The large scale food industry represents less than 20% of the total food processing capacity in the country. The majority of the food processing in Nepal is carried out in small scale industries scattered throughout the country, mainly in the Terai, hill regions and Kathmandu valley. The current Food Act does not apply to small scale enterprises where the product will not be packaged and therefore labeled. This will include small scale mills, rice mills, dairies. The local governments have a role in monitoring the small scale food services as per the Food Act but they are not playing this role. The lack of inspection of small scale food processing enterprises represents a potential problem for the food safety system in Nepal. Many food processing and other enterprises are small scale businesses and the total number in Nepal is large.

5.1 Large Scale Industries

The main large scale industries in the country are made up of 20 wheat flour roller mills, 4 rice mills, the Dairy Corporation of Nepal, 8 instant noodle plants, several large processed water companies, and 6 complementary blended food plants. The per capita consumption data for wheat in Nepal is 37.9 kg/capita/year which translates into flour (75% extraction rate) consumption of 28.4kg/capita/year or 77.9 grams/capita/day.

The instant noodle market using wheat flour has grown significantly as seen by the increase in numbers of instant noodle plants from 2 in 2005 to 8 in 2011. Based on discussions with the Nepal Flour Millers Association the estimated consumption of wheat flour as instant noodles is 13.5 – 15.5 grams/capita/day and growing.

Many of these large companies already have good quality systems in place based on ISO 9001, Registered HACCP and in some cases ISO22000 (HACCP). The decision to have a registered certified quality system is driven by commercial considerations such as meeting international agency (e.g. WFP) requirements for quality systems and export customers in the South Asian sub-continent. These companies and

industries consider the need for registered quality systems to be a part of the cost of doing business. The Food Act does not encompass the HACCP and ISO2200 certification system but DFTQC is promoting voluntary compliance under the support of UNIDO. Consequently it is probable that foods from the largest food companies in Nepal are able to meet the relevant national and international standards for their food products. The food control system will still need to carry inspections and license renewal inspections of these large food industries. It should be noted that the relative risk for sub-standard foods from these companies will be significantly lower than smaller companies. Those that supply export markets and UN agency requirements will continue to need the services of an internationally recognized analytical laboratory to provide the quality analysis of their food products.

5.2 Lack of Independent Food Quality Testing Labs

One of the challenges that the large scale food industry faces is the lack of registered third party food quality testing laboratories in Nepal. Multinational testing laboratory companies that have tried to set up branches in Nepal have been unable to attract business from the private sector because the GoN has not registered and accredited the private sector laboratories. Without official accreditation and registration any analysis is not deemed official and not considered valid for international trade. Part of the problem is that the GoN laboratories are also not accredited for analyses under ISO17025 standards as yet. Secondly, officials consider that the official accredited laboratory should be a GoN institution such as DFTQC Central Laboratory and not independent third party laboratories. The DFTQC has implemented a process to get accreditation under ISO 17025 standards but it will take 3-5 years before the process is completed. One of the challenges that the food industry is facing is that samples now have to be sent out of the country at significant increased cost for both local and export markets.

5.3 Recommendations

- **That the third party accreditation process for laboratory capacity at both the government institution, DFTQC, and private sector levels in Nepal be accelerated.**
- **That the development partners support this process by providing technical experts who can prepare laboratories for ISO 17025 accreditation through training, skills transfer and funding for this process.**

6. Salt Iodization

Nepal's salt iodization programme was started in 1973 and in 1999 the "Iodized Salt (Production and Distribution) Act 1999" was approved by the government and gazetted. However, the standards and regulations under this Act have not been

gazetted and as such, salt iodization is not considered mandatory. Virtually all salt in Nepal is imported, mainly from the Indian states of Gujarat and Rajasthan, by the Nepal Salt Trading Corporation (STC), which also controls the salt trade and distribution. The STC was founded in 1973 and is a joint venture between GoN and the private sector. The GoN has a 23% ownership share with 77% share by the private sector.

The STC supplies the following types of salt to Nepal:

- Triple refined iodized salt sold in 1kg bags (introduced in 1990)
- Crystal salt iodized
- Non-refined crushed salt iodized

However, non-iodized salt is also available in the country, for agricultural and industrial purposes. It is possible that some of the industrial salt does become part of the edible salt supply. Non-iodized salt is used as a chemical feedstock for industrial purposes such as textiles and dyeing, animal hide and leather processing, pharmaceuticals, pigments, ceramics, soaps and detergents. One of the challenges that face the food control authorities is that non-iodized salt does not look any different from iodized salt. There is a standard for edible non-iodized salt under the Food Regulation of Nepal. In a meeting on regulatory monitoring of fortified foods held in Manila in September 2011, it was agreed within the Nepal delegation to cancel this standard so that only the standard for iodized salt remains, resulting in mandatory salt iodization in the country under the Food Regulation.

The STC has the responsibility of providing salt to all parts of Nepal including the mountain region and other remote areas. In order to ensure that the salt is available at a reasonable price in these areas the STC also implements iodised salt supply scheme of the government in 22 remote districts under which iodised salt is distributed at subsidized rates (as transport cost is borne with funding support from government).

Because of the centralized nature of the salt industry in Nepal, high coverage of iodized salt was rapidly achieved, despite the fact that it is not mandatory.¹¹ The government policy is to import and distribute only iodized salt throughout the country and the STC has been implementing this policy, as the Universal Salt Iodization Programme, since 1973. In 1998, 82.5% of households had iodized salt. However, in that same year, only 55.2% of households consumed adequately iodized salt (ie >15ppm of iodine).¹² In 2005, coverage with iodized salt increased to 95% but coverage with adequately iodized salt remained virtually unchanged at 58%.¹³

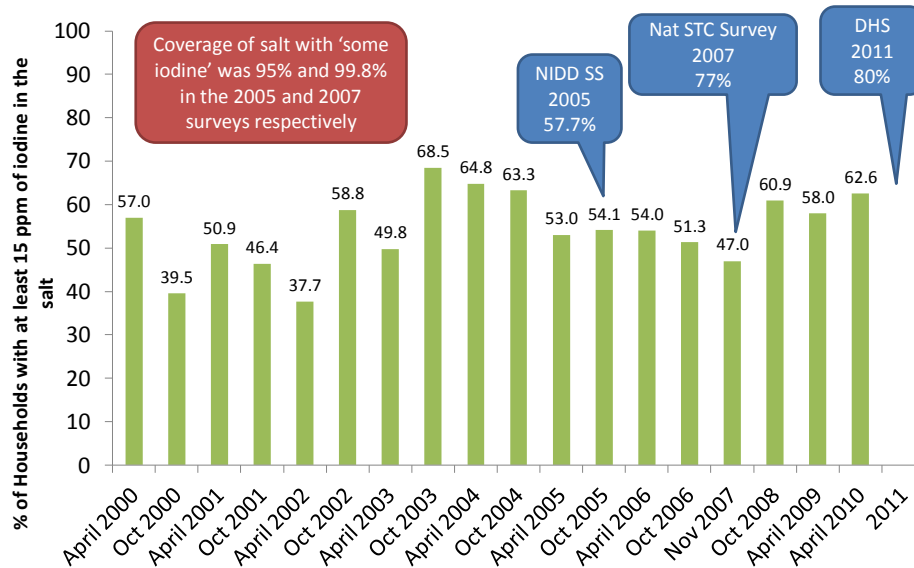
¹¹ Although there is lack of mandatory legislation as such, the policy of the Government of Nepal has been to import and distribute only iodized salt. STC has been authorized to import and distribute only iodized salt through the country by the government under the Import Export Control Act of Nepal.

¹² Nepal Micronutrient Status Survey 1998. MOHP, UNICEF, WHO, MI

¹³ Nepal Iodine Deficiency Disorders Status Survey 2005, MOHP, MI

As shown in the figure below, data from the Micronutrient Surveys suggest that coverage of adequately iodized salt has been about 50-60% for the last ten years and more. However, a survey undertaken by the Governments of Nepal and India in 2007 found that coverage of adequately iodized salt had risen to 77%.¹⁴ This improvement seems to have been confirmed by data from the DHS 2011 Preliminary Report which indicates that coverage of adequately iodized salt was 80%.

Figure 27: Coverage of Adequately Iodized Salt



Ref: Green bars - Micronutrient Survey April 2010. Blue boxes - Nepal IDD Status Survey 2005 and National Survey, Impact Study for IDD and Availability of iodized Salt in Nepal 2007 and DHS 2011 (Preliminary Report)

As a result of the high iodized salt coverage, Nepal has an adequate iodine status as assessed by urinary iodine excretion (UIE) levels; median UIE in 2007 (the most recent data available) was 202.8 µg/L, up from 188 µg/L in 2005 and 143.8 µg/L in 1998.¹⁵ WHO categorizes a median urinary iodine level of 100 and 199 µg/L as “adequate” and notes that although levels of 200-299 are “above requirements”, this level of iodine intake (as measured by iodine excretion) is “likely to provide adequate intake for pregnant/lactating women, but may pose a slight risk of more than adequate intake in the overall population”.¹⁶

The most recent data on urinary iodine is from 2007 and the most recent data on and iodized salt coverage is from the DHS 2011 Preliminary Report. However, data on iodized salt coverage has also been collected by the Living Standards Survey

¹⁴ National Survey and Impact Study for Iodine Deficiency Disorders and Availability of Iodized Salt in Nepal 2007. Govt of Nepal, Govt of India and Alliance Nepal.

¹⁵ 1998 data is from the 1998 Nepal Micronutrient Status Survey quoted above, 2005 data from Nepal Iodine Deficiency Disorders Status Survey 2005 and 2007 data from National Survey and Impact Study for Iodine Deficiency Disorders and Availability of Iodized Salt in Nepal 2007.

¹⁶ Assessment of iodine deficiency disorders and monitoring their elimination: A guide for programme managers. Third edition. WHO, UNICEF, ICCIDD 2007

2011 and according to this around 73% households were consuming adequately iodized salt in the country in 2010. It should be noted however that none of the past surveys except the one conducted in 2007¹⁷, and the Living Standards Survey, included a quantitative measurement of the iodine content of the salt. In all cases only rapid salt test kits were used to assess iodine content. This assessment is semi-quantitative at best and considering that a major problem of the program is inadequately iodized salt, there would be considerable benefit in getting a quantitative assessment of the salt iodine content at the next opportunity.

As noted above, the current regulatory process for salt iodization in Nepal has been stalled at the regulation development level: the regulations and rules that will make salt iodization mandatory have not been prepared and published in the Official Gazette. This stalemate has been going on for 11 years. This indicates that the issue is likely to be political and not technical. Part of the problem may lie with the assignment of the Ministry of Health and Population as the lead agency in the Iodization of Salt Act rather than the Ministry of Agriculture and Cooperatives who are the designated lead ministry in the Food Act. In addition, the monopoly situation of the Salt Trading Corporation is also perceived to play a role in the stalemate.

The recent Supreme Court ruling dated 4 January 2011 (see Salt section below) may provide an opportunity for the international agencies to take more action and re-engage in the process.

6.1 STC Import Point at Nepalgunj

The STC imports salt from India through two entry points into Nepal. There used to be five entry points but these have since been reduced to two. The STC depot in Nepalgunj was visited as part of this assessment. The depot has inside warehouse space and outside storage for the imported salt. The iodized crystal salt is stored outside in 50kg bags and covered with tarpaulins for protection from the weather. At the time of the visit triple refined iodized salt was being repacked in 1kg bag sizes using a manual bagging and sealing system. The STC Nepalgunj location has a quality control (QC) laboratory which is used to test all incoming shipments of salt for iodine content. There is a re-iodization process in place with iodizing equipment so that any shipments below the standard of 50ppm iodine can be re-iodized. The staff advised that they had recently re-iodized one truckload due to low iodine content in the salt. During the visit by the consultant they were re-iodizing the shipment and the STC QC lab records showed that the shipment was being re-iodized successfully to meet the current standard of 50ppm. Based on the QC records and a meeting with the manager of the STC facility the percentage of shipments (based on truck numbers) needing re-iodization was between 5 to 10%.

¹⁷ The proportion of households consuming adequately iodized salt was 77% based on the results of quantitative analysis (titration) of around 17% sub-samples of salt collected from survey.

6.2 Informal Salt Trading Channels

Because of the long 1500km border between India and Nepal with limited control points there are informal imports of both iodized and non iodized salt that come into the country. The length of the open border and the lack of full border controls means that it is not possible to have a closed market for salt. The informally imported salt coming from India may be fortified or unfortified. If it is fortified and informally imported, it will be fortified at the India standard of 30 ppm compared to the Nepal standard of 50 ppm. A program by the Ministry of Health and Population and UNICEF of promotion of a “two child logo” over the last few years has contributed to reducing the consumption of non-iodized salt in the districts that border India.

Due to the long southern border with India it is relatively easy for individuals to bring small quantities of unfortified salt into Nepal on a regular basis. This salt will not find its way into the formal shops and markets but more likely get distributed through informal channels in the border districts of the Terai. Under these circumstances the current food inspection and control system will not detect non fortified salt coming into the country by inspection and sampling in markets and shops. There are two explanations that were given to the consultant by the regional office in Nepalgunj why non-iodized salt is coming into the country. First, there is the lack of awareness of the benefits of iodized salt by the population located in the districts of the Terai adjacent with the border with India and second the price of lower quality salt (with more impurities) from India was NRs 2-3 per kg cheaper than STC iodized salt.

6.3 Salt Iodization Legislation

With support from external development partners the GoN developed a policy for introduction of mandatory salt iodization. The Iodized Salt (Production & Distribution) Act 1999 was endorsed by the GoN which included the proposed levels of fortification with iodine for the different types of salt used in Nepal. The following are the key elements in the legislation:

- The lead ministry for the administration of the act is the Ministry of Health and Population. This is different from the Food Act where the Ministry of Agriculture and Cooperatives is the lead ministry.
- The act covers the requirements for the production, importation and distribution of iodized salt.
- The standard for iodization of salt at the point of iodization is 50 parts per million of iodine.
- The salt to be covered is common salt in two forms, the first in fine refined form and the second in crystal form. Crystal salt is in large pieces about 1-2 cm size cubes.

- The right to test the quality of salt including iodization levels is given to the DFTQC.
- The technical committee is chaired by the Secretary MoHP with two other MoHP representatives including one officer who acts as the Committee Secretary. The committee is mandated to meet 4 times per year.

6.4 Current Situation

Despite the fact that the Act has been in place and gazetted since 1999 the standards and regulations have not yet been gazetted which means that the salt iodization standards have not been made mandatory yet. The fact that this situation has been going on since 1999 indicates that these delays are not due to technical issues but are at both the political and the organizational level. The regulations and rules are still stuck at the Technical Committee level which is right at the beginning of the process of regulations development. Part of the problem is that the food control provisions for salt have been given to the MoHP instead of the usual role played by the Ministry of Agriculture for food control.

However, there has been a recent development which may move the process forward. On 4 January 2011, the Supreme Court handed down a decision which instructed the MoHP, Ministry of Supply to issue regulations that would bring the Salt Iodization Act into effect “at the earliest possible date”. The decision was copied to the Bar Council of Nepal, the Attorney General and the Chief Secretary of the Cabinet. It is understood that the action was brought by the Consumer Forum. It is not certain that there has been any official response at the time of this assessment. Until the regulations required by the act are published in the official gazette the current standards for iodization of salt are not mandatory.

There are different types of salt being procured by the STC, triple refined and crystal salt. There does not appear to be any stability studies or iodine retention studies that have been carried out recently to determine how effective the iodization process is in the supply chain within Nepal. The storage buildings for salt in the supply chain within Nepal are frequently inadequate which means that the salt can suffer from moisture contamination that reduced the iodine levels in the salt. In addition the informal importation of salt by individuals in the Terai districts can result in improperly iodized and non-iodized salt entering the country.

6.5 Recommendations

- **That the development partners follow up with the Ministry of Health and Population as a result of the Supreme Court ruling to help restart the process of regulation development.**
- **That additional social marketing and awareness creation activities on the benefits of iodized salt be carried out, particularly in the districts of the Terai bordering India.**

- **That salt iodization be made mandatory either by implementing the special Salt Act 1999 or by removing the standard for common salt under the food regulation.**
- **That a survey of the condition of salt in the supply chain facilities within Nepal be carried out, including measuring iodine levels at the different stages.**
- **That a sample survey of unofficial salt imports from India be carried out at border crossings by the food inspectors of DFTQC using rapid test kits to determine the extent of importation of non-iodized (and inadequately) iodized salt into the country.**

7. Wheat Flour Fortification

Nepalis consume approximately 78g of wheat flour per day. This calculation is based on a per capita consumption of wheat of 37.9kg per day and an extraction rate of 75%. Wheat flour is consumed directly through foods such as chapattis (local bread) which are made in the home and through processed foods such as biscuits, bread and instant noodles. Instant noodle consumption is rising rapidly and Nepal has 8 domestic productions in 2011, compared to only 2 in 2005. Nepalis ate an estimated 730 million packets of instant noodles in 2010, up from 430 million in 2007.¹⁸ The 2010 figure calculates out as approximately 15 packets per person per year on average.¹⁹ The Nepal Flour Millers Association estimates that average consumption of wheat flour as instant noodles is 13.5-15.5g/capita/day and growing. The consumption of such processed foods is higher in urban areas but overall, consumption of such foods is rising. An unknown amount of maize flour is also consumed.

Wheat and maize flour in Nepal is milled from locally grown and imported wheat and maize. Detailed information on the milling industry is not available but the best estimate is that 20-30% of all wheat flour and 8% of total cereals (wheat, maize and millet) is milled in about 20 large scale commercial roller mills throughout the country. The remainder is milled in small scale village mills known as chakki or water mills. It is likely that the flour milled in the large mills can be cost-effectively fortified and in August 2011 a Notification was passed under the existing Food Act making fortification of all roller mill flour mandatory. While the proportion of wheat flour fortification that is current regulated in Nepal remains low, this is likely to increase as the food processing sector modernizes and more of the wheat flour consumed in Nepal is milled by large roller mills. Cost-effective models for regulating the fortification of the flour milled in small mills in Nepal have yet to be developed.

¹⁸ World Instant Noodles Association. (Accessed 17 October 2011)
<http://instantnoodles.org/noodles/expanding-market.html>

¹⁹ Based on estimated population of 28,043,744 in 2010 (2001 census estimates)

The Micronutrient Initiative (MI) has, over the past few years, supported the industry to start wheat flour fortification (with iron, folic acid and vitamin A) by providing training and technical support, free fortification premix and some machinery. The new legislation is largely the result of MI support for roller mill flour fortification and strong commitments from government and roller mills. The roller mills of Nepal are thus currently preparing to implement this new law with the support of the Nepal Roller Millers Association.

Besides support for initiating fortification in roller mills, MI has also been providing support for piloting fortification by small scale mills such as chakki and water mills operated in rural areas. In 2007, MI started a pilot on small mill fortification in 10 VDCs of Lalitpur district. MI developed an innovative gravity-powered fortification device suitable for water mills which is provided to the mills. The pilot also involves support to the small mills in the form of seed money for premix revolving fund, training and awareness creation. The programme is monitored by a paid NGO at community level. MI is evaluating the impact of this pilot project and the results are expected in December 2011. In a separate activity, an NGO, Project Healthy Children, is adapting the fortification device developed by MI, to make it more suitable for electric chakki mills.

In light of the success of the MI pilot, the Asian Development Bank (ADB) has recently provided a US\$ 1.8 million grant to the Government of Nepal (GoN) for Flour Fortification in Chakki Mills. The program will work in 65 VDCs in one district to support and encourage small mills to fortify. A revolving fund for premix will be created though the premix will be procured by the MOHP. Appropriate equipment, principally microfeeders, will be provided, together with training. Social mobilization will aim to encourage the small mills to participate and the community to accept the fortified flour and pay the incremental fortification cost. The VDCs will establish structures to work with the mills, monitor implementation of the program, and collect the fortification fee for the premix. Quality assurance checks will be carried out by health post staff. The project was started in 2011 and will last three years.

The current form of iron (electrolytic) used in the premix for roller mill fortification may not be sufficiently bio-available when used in noodles and in atta flour to show efficient impact. Based on the WHO Consensus Statement on the fortification of wheat and maize flours, the current premix of vitamin A, iron and folic acid has levels that may need to be adjusted to have a more effective and faster impact. However, the increased cost of a new vitamin and mineral premix has implications for the flour price. Using a premix with different iron sources and more vitamin A and folic acid will have higher costs ranging from \$3.83 to \$4.90 per MT of flour compared to the current premix cost of \$1.67 per MT of flour.

The current wheat flour fortification standard that was used for the supply of premix can be found in the table below.

Micronutrient	Amount Added, ppm
Vitamin A, as Retinyl Palmitate, cold water soluble	1
Iron, electrolytic powder	60
Folic Acid	1.5

The DFTQC was provided with funds to purchase UV/visible spectrophotometers so that the regional laboratories and the central laboratory can measure iron in flour quantitatively.

The original plan was to provide this assistance while the mandatory standard for wheat flour fortification was proceeding through the official channels. However, the legal process was delayed so that the premix that was supplied to the mills has been used and many mills had stopped flour fortification by the time it became mandatory in August 2011. It should be noted that the Flour Millers Association has a number of important issues and constraints that are hurting the profitability of the mills in the country. So for many mill owners voluntary fortification is not an activity that has great priority. They are trying to bring these issues to the attention of the GoN. These issues include:

- The imposition of 9.75% VAT on maida flour that has encouraged smuggling and formal flour imports from India. Maida flour is considered by the GoN to be a prepared processed food which is used by the food industry to make baked foods and therefore should be subject to VAT as are other inputs taxed.
- Atta flour made by the small scale mills in Nepal is not considered to be a processed food because it is not packaged and labeled nor is it used by the food industry and therefore is not subject to VAT.
- Lack of control at the border for informal maida flour imports from India (Indian flour mills are larger and enjoy economies of scale which make the flour cheaper).
- Flour imports have reduced the operating times of mills in Nepal by 10% that has a significant impact on flour milling costs.
- Insufficient electricity supply to produce flour. Currently in Kathmandu valley the supply per day is only 10 hours.
- Imposition of duty on premix imports.

7.1 Vitamin and Mineral Premix Options

While the introduction and official publication of the mandatory flour standard will require the millers to fortify, these other issues will continue to be a major concern for the mill owners and will need to be addressed between them and the GoN. Based on the WHO Consensus Statement on the fortification of wheat and maize flours the current premix of vitamin A, iron and folic acid has levels that may need to

be adjusted to have a more effective and faster impact. The following table shows the different options for the premixes using the recommended levels and the different types of iron compound.

Options	Vitamin A ppm	Folic Acid ppm	Iron ppm	Iron Type	Fortification Cost \$ per MT
Current premix	1	1.5	60	Electrolytic	\$1.67
Option 1	3	2.6	60	Ferrous Fumarate	\$3.83
Option 2	3	2.6	40	NaFeEDTA	\$4.90

However, the increased cost has implications for the flour price. Using premixes with different iron sources and more vitamin A and folic acid will have higher costs ranging from \$3.83 to \$4.90 per MT of flour compared to the current premix cost of \$1.67 per MT of flour. The costs for the more expensive options for premix could be offset by the elimination of VAT on flour.

In the case of pilot small scale fortification project, the whole cereal flour (mainly maize) is fortified with iron (25 ppm) in the form of NaFeEDTA, folic acid (1.5 ppm) and vitamin A (1 ppm).

7.2 Recommendations

- That external development partners provide additional technical support for additional miller training on fortification process control.
- That external development partners provide additional technical support for regulatory staff training on production process monitoring once the mandatory fortification regulation is published.
- That the options for using more bioavailable sources of iron such as ferrous fumarate and sodium iron EDTA in the premix be reviewed by the Ministry of Health and Population with technical assistance from external development partners as required.
- That the Ministry of Finance re-assess the imposition of VAT on wheat flour produced in large roller mills within the country to reduce the incidence of unofficial imports of flour which can come in as unfortified flour and to assist the milling industry to bear the additional cost of more effective vitamin and mineral premixes.

8. Consumer Awareness and Nepal Business Forum

It was beyond the scope of this review to undertake a detailed review of consumer awareness regarding fortified foods in Nepal. The level of consumer awareness on the importance of safe and healthy foods including fortified foods appears to be low in Nepal, except for iodized salt. There is evidence that increased awareness

through a “two child logo” has increased the use of iodized salt where that awareness creation strategy was adopted.

The concern about low consumer awareness was raised in many of the interviews carried out for this review. The low level of awareness is likely due to the paucity of public nutrition awareness programs, coupled with low levels of education and literacy, and the politicization of consumer groups in the country. Civil society organizations that are properly informed can be powerful advocates to create demand for safe and healthy foods. In addition, school children can become powerful advocates for safe and fortified foods and healthy lifestyles once they have been sensitized. For example, in Morocco the use of salt test kits and the iron spot test for wheat flour were introduced as part of the science curriculum. The introduction of strong anti-smoking campaigns in the schools in Canada has resulted in a significant drop in tobacco use in the country. Consumers that are well informed can create demand for superior products such as fortified foods. The commercial private sector will then have a stronger incentive to meet the demand for such foods.

While increased consumer awareness should translate into a “demand pull” for policy reforms, measures also need to be taken to facilitate dialogue between the private sector and the government on regulatory matters. The Nepal Business Forum has yielded some good results in terms of implementation of proposed reforms in Nepal and has the mechanisms both at the working level and at the policy level to bring together appropriate government and private sector stakeholders. The Nepal Business Forum could be one of the options to help advance some of the regulatory reform issues outlined in this report.

8.1 Recommendations

- **That government and external development partners re-engage with the various consumer groups within the Consumer Forum on the right to safe and healthy foods.**
- **That government and external development partners consider expanding the use of the “two child logo” for iodized salt and develop similar approaches to increase consumer awareness for wheat flour and other fortified foods.**
- **That the focus of efforts be on the importance of consuming fortified foods with emphasis on salt and products wheat flour.**
- **That the Nepal Business Forum be explored for its potential to facilitate dialogue between the private sector and government around the regulatory reforms proposed in this report.**
- **That innovative schemes such as those listed above be considered to raise awareness of safe and healthy foods within schools in Nepal.**

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