

# Project Resource

*Project resources are materials which were originally produced during support from the Business Innovation Facility team to a specific inclusive business project. They include inputs provided as part of technical assistance and summaries of findings and outputs. They are adapted for wider use so that other practitioners can also make use of the material.*



**Business  
Innovation  
Facility**



## Commercial Home Fortification Products

### Bangladesh Political Economy Mapping

#### *What is this resource?*

*This document is about the political and economic landscape in Bangladesh with respect to home fortification products. These are products designed to address malnutrition and micro-nutrient deficiency in the first 1,000 days of an infant's life by enabling mothers and care givers to ensure that the local food they use to complement breast feeding is providing the necessary vitamins, minerals and proteins. It is based on a study undertaken by the Business Innovation Facility that will inform any company that wishes to enter the home fortification market in Bangladesh. It was produced by Garth Smith of PricewaterhouseCoopers who worked on this Business Innovations Facility project from October to December 2012. The information is taken from primary interviews with key stakeholders and desk research.*

#### *Why is it interesting?*

*There is a lot of interest in commercial products that address nutrition for infants and children, but it is a complex and sensitive environment for a company to understand and navigate, and it is essential to identify the key opinion formers (KoFs) and the relevant legislation and regulations.*

#### *Who is it for?*

*This document will be useful for companies who are planning to develop a home fortification product in any country, as many of the underlying issues are similar as in Bangladesh, and for policy makers to understand the implications of legislation relating to such products in terms of stimulating or repelling the private sector.*



<b>BFF</b>	Bangladesh Breast Feeding Foundation
<b>BINP</b>	Bangladesh Integrated Nutrition Plan
<b>BMS</b>	Breast milk substitutes
<b>BRAC</b>	Bangladesh Rehabilitation Assistance Committee
<b>BSTI</b>	Bangladesh Standards and Testing Institute
<b>CIDA</b>	Canadian International Development Agency
<b>CIP</b>	Country Investment Plan
<b>CGAIR</b>	Consultative Group on International Agricultural Research
<b>CODEX</b>	Codex Alimentarius
<b>DGDA</b>	Directorate General of Drug Administration
<b>DFID</b>	UK Department for International Development
<b>FANTA III</b>	Food and Nutrition Technical Assistance Programme
<b>GAIN</b>	Global Alliance for Improved Nutrition
<b>HKI</b>	Helen Keller International
<b>HPNSDP</b>	The Strategic Plan for Health, Population & Nutrition Sector Development Program
<b>ICDDR</b>	International Centre for Diarrhoeal Disease Research, Bangladesh
<b>INFS</b>	Institute of Nutrition and Food Science
<b>IPHN</b>	Institute of Public Health and Nutrition
<b>IFPRI</b>	International Food Policy Research Institute

<b>IYCF/N</b>	Infant and Young Child Feeding/Nutrition
<b>KoF</b>	Key opinion former
<b>LNS</b>	Lipid-based Nutrient Supplement
<b>MDG</b>	Millennium Development Goals
<b>MNC</b>	Multi national company
<b>MNP</b>	Micronutrient powder
<b>MoFDM</b>	Ministry of Food and Disaster Management
<b>MoHFW</b>	Ministry of Health and Family Welfare
<b>MoWCA</b>	Ministry of Women and Children's Affairs
<b>NNP</b>	National Nutrition Plan
<b>NNS</b>	National Nutritional Service
<b>NNSC</b>	National Nutritional Steering Committee
<b>NPAN</b>	Bangladesh National Plan of Action for Nutrition
<b>REACH</b>	Renewed Effort Against Child Hunger and Undernutrition
<b>RUTF</b>	Ready to use therapeutic food
<b>SUN</b>	Scaling up Nutrition
<b>UNICEF</b>	United Nations Children's Fund
<b>USAID</b>	United States Agency for International Development
<b>WFP</b>	United Nations World Food Programme



# Contents

## Key Opinion Former Environment

Nutrition Context

Policy Context

Political Environment

Key Stakeholders – NGOs and Programmes

Key Stakeholders – Major Donors

Key Stakeholders – Multilateral Agencies

Key Stakeholders – Research Organisations

Private Sector Actors – Micronutrient Powders

Social Distribution Channels

Collaborative Groups

Overview of challenges and success factors

## Regulatory Environment

Overview

Pharmaceutical regulation

Product Standards

Breast Milk Substitute Regulations

New Breast Milk Substitute Legislation

## Wider Social Benefits

Social Value Chain

Thematic Social Benefits



# Introduction

---



## HOME FORTIFICATION

The first 1,000 days of pregnancy and a child's life are crucial for healthy development. A lack of adequate vitamins and minerals during this stage will have significant and irreversible impacts on a child's development and health later in life.

Malnutrition through a lack of these necessary nutrients is still a major global problem - the WHO estimates that world-wide, 190 million infants and young children suffer from vitamin A deficiency and 293 million suffer from anaemia for example. Exclusive breast feeding for the first 6 months and continued breast feeding up to 2 years are crucial for addressing this malnutrition, but it is equally important that infants aged 6-24 months receive adequate complementary foods with the right nutrient balance.

Fortification of common foods such as oil and flour and single vitamin or mineral supplements are long established methods of addressing these problems, particularly in areas where it is difficult for children to get the necessary vitamins and minerals from local complementary foods.

More recent developments in technology have led to several products being created which provide ways for mothers and families to fortify their traditional meals at home after they have been prepared. These products often take the form of powders or spreads that are added to food once it has been cooked just before eating.

## INCLUSIVE BUSINESS APPROACH

A number of private sector organisations have been exploring the potential for commercial development of home fortification products in various developing countries which have high levels of malnutrition and micronutrient deficiencies. These products are generally intended to be affordable to those near the base of the pyramid and whilst the margin on individual products is small, a sustainable profit is seen through the large volume of potential sales. A range of small scale studies indicates both an acceptability of these types of product in relevant communities and a willingness to pay if the price point is right.

As a result, these commercial approaches present an ideal opportunity for the development of inclusive business models which the Business Innovation Facility has a mandate to seek out, given the positive impact that they can have on the health and nutrition of low-income communities as well as the associated economic and social benefits that are seen throughout the value chain of such products.

This report is intended to outline the political economy in Bangladesh in relation to such home fortification products, identifying some of the key challenges and the key stakeholders in this area. It will be useful for organisations who are looking at developing a home fortification product which supports adequate complementary feeding of children and infants aged 6 to 24 months in Bangladesh.

# Key Opinion Former Environment





# Nutrition context in Bangladesh

## CHILD MALNUTRITION

Under nutrition and malnutrition are a very serious concern in Bangladesh with mothers and young children are particularly at risk. The rates of child stunting are particularly severe with 8million children (around 41%) suffering due to chronic malnutrition. The first two years of life show a significant peak in malnutrition in Bangladesh which has significant negative knock-on effects for healthy development.

Single and multiple micro nutrient deficiencies are also common with vitamin D, iron and iodine deficiencies prevailing . As a result, there are very high levels of anaemia, particularly among young mothers and their children.

Child malnutrition in Bangladesh is seen proportionally less in urban areas than in rural areas, although within urban slum areas rates can be very high, and significantly more so than average rural areas. Even so, there are still relatively high levels of malnutrition and stunting for those in higher socio-economic groups.

The impact of such high rates of chronic and acute malnutrition has knock on effects for children's ability to fight disease, develop properly or learn effectively. Alongside the human cost, many studies have estimated the significant knock on financial effects this has for Bangladesh's economy.

## CAUSES OF MALNUTRITION

With a largely rice based diet, children in Bangladesh often suffer from a lack of protein or nutrient rich food in their diets, particularly in rural areas.

Exclusive breast feeding rates are relatively high, at around 89-93% for the first two years, although early breast feeding, exclusive breast feeding for 6 months and adequate complementary feeding are still generally poor.

For the poorest third of the population, food security can be an issue, and families do not have the physical or economic means to access sufficient nutritious food through channels available to them. This is particularly true in the off-season when crops and employment are not available to the ultra-poor.

For the rest of the population who have access to food, there are still relatively high levels of child malnutrition and stunting. This suggests that there are deeper issues around lack of diverse food, poor information or education on nutrition or entrenched behaviours of not feeding children with sufficiently nutritious food.

Maternal nutrition is also a key driver in child malnutrition with high levels of adolescent marriage and pregnancy and poor diets leading to low birth weights which are often associated with higher levels of stunting.

## PROGRESS ON NUTRITION

There has been some strong progress on malnutrition in Bangladesh in certain areas, although serious issues still exist which have seen little improvement.

Low birth weight is still a major issue and to date, Bangladesh still has the lowest average birth weight of any country in the world.

Exclusive breast feeding rates for under 6months had stagnated for the past decade but studies in 2011 showed a marked improvement above government targets. complementary feeding rates where children are receiving adequate nutritious food at the right frequency, however, have remained consistently low.

Some micro nutrient deficiency campaigns have been particularly successful with Vitamin A deficiency being significantly reduced and iodised salt seeing strong country-wide coverage. There have been concerns over the quality of fortified foods however, with estimates of as much as 50% of iodised salt having either too little or too much iodine .

Within the ultra poor, levels of wasting have not improved over the past decade and remain significantly high at around 15%. Iron deficiency has also remained a problem leading to consistently high rates of anaemia among both mothers and children.



# Nutrition context in Bangladesh

**1/3** of the population face food security issues



of the world's underweight problem is in Bangladesh



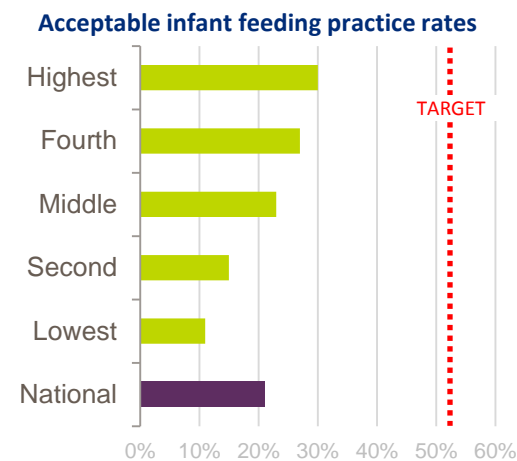
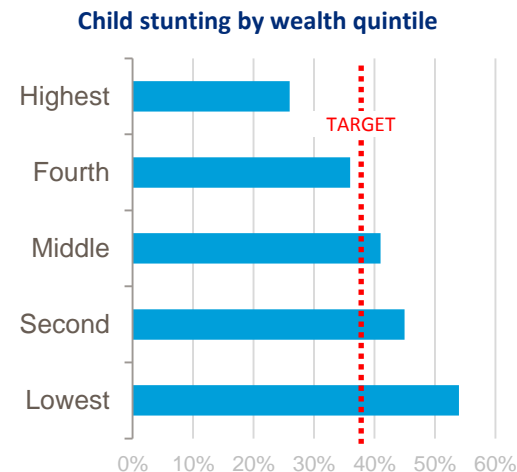
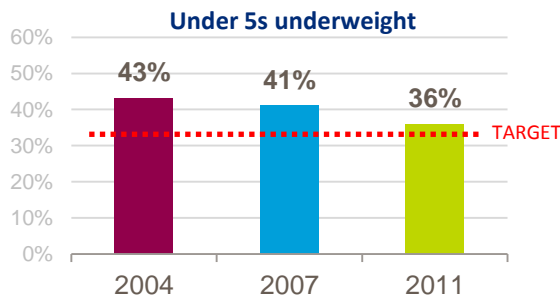
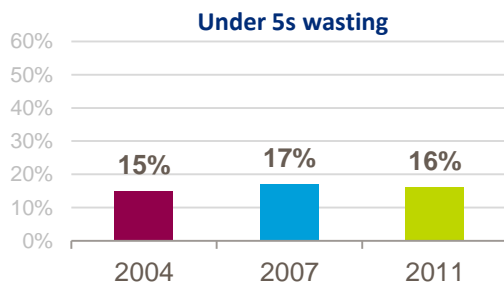
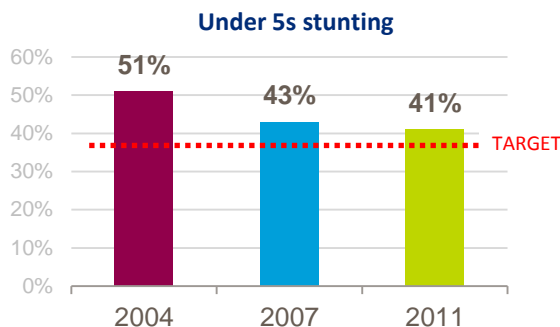
**41%**

of under 5s have stunted growth



**47%**

infants and pregnant mothers have anaemia







# Policy context in Bangladesh

## HISTORICAL CONTEXT

Over the past three decades, the Government of Bangladesh has developed a number of major initiatives to try and coordinate and implement a nutrition policy across the country

In the 1980s, the then Bangladesh National Nutrition Council developed the first co-ordinated policy through the National Plan of Action for Nutrition (NPAN). This was not implemented until 1995 however, as the Bangladesh National Integrated Nutrition Plan, involving ministries across the government for delivery.

In 2002 due to a number of monitoring, coordination and policy issues, the BNIP was developed into the National Nutrition Programme (NNP) with support from the World Bank.

**13** ministries involved in implementing nutrition policy

The NNP was abandoned in 2012 due to major governance and co-ordination issues, with 13 ministries all involved in implementing the programmes.

The World Bank has again recently supported the Government to develop the HPNSDP which is intended to mainstream nutrition and bring coordination under one effective body.

## HPNSDP 2011-2016

The Health Population and Nutrition Sector Development Programme (HPNSDP) is intended as a refresh of the Government's sector wide nutrition policy and is being led out of the Ministry of Health and Family Welfare. This policy specifically recognises the high malnutrition and micronutrient deficiency rates and has a number of relevant key attributes:

**Mainstreaming** – there is a focus on integrating nutrition services into mainstream, regular activities of the DG of Health Services and DG of Family Planning.

**Prevention** – the policy calls for a greater focus on preventative approaches to communicable and non-communicable diseases including malnutrition.

**Co-ordination** – there is an intention for greater service coverage through co-ordinating public, NGO and private sector organisations.

**Nutrition Activities** – HPNSDP sets out the need for better nutrition education and nutritional supplements to reduce micronutrient deficiency. The strategic plan does focus on specific supplements (Vitamin A, Zinc, Iron) rather than multi-micronutrients, however.

HPNSDP is supported and part funded by DFID, USAID, SIDA, AusAid, CIDA, SIDA and the World Bank among others.

## NUTRITION POLICY IMPLEMENTATION

The [Institute of Public Health and Nutrition](#) (IPHN) within the MoHFW is generally regarded as the key government organisation in terms of setting and developing government policy

In order to co-ordinate the various ministries, the [National Nutrition Service](#) (NNS) is responsible for the implementation of the HPNSDP. The NNS is chaired by the director of the IPHN, Dr Md Eklhasur Rahman.

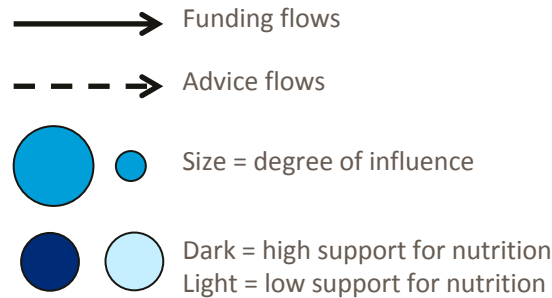
In 2012, the [National Nutrition Steering Committee](#) (NNSC) was set up to oversee the NNS and provide guidance on policy issues, and has relatively strong backing from the MoHFW. The NNSC has representatives from all the key government bodies and the major donors/agencies involved in nutrition as well as very active support from the Centre for Nutrition Studies at ICDDR,B. Most representatives have suggested that it is unlikely that private sector representation would be possible on the NNSC, but its representatives from government and donors are in general willing to engage closely with the private sector.

To date, the focus of implementation of the HPNSDP has been on expanding community clinics to provide therapeutic services to those suffering from Severe and Acute Malnutrition, but is being reassessed by the NNSC and NNS.

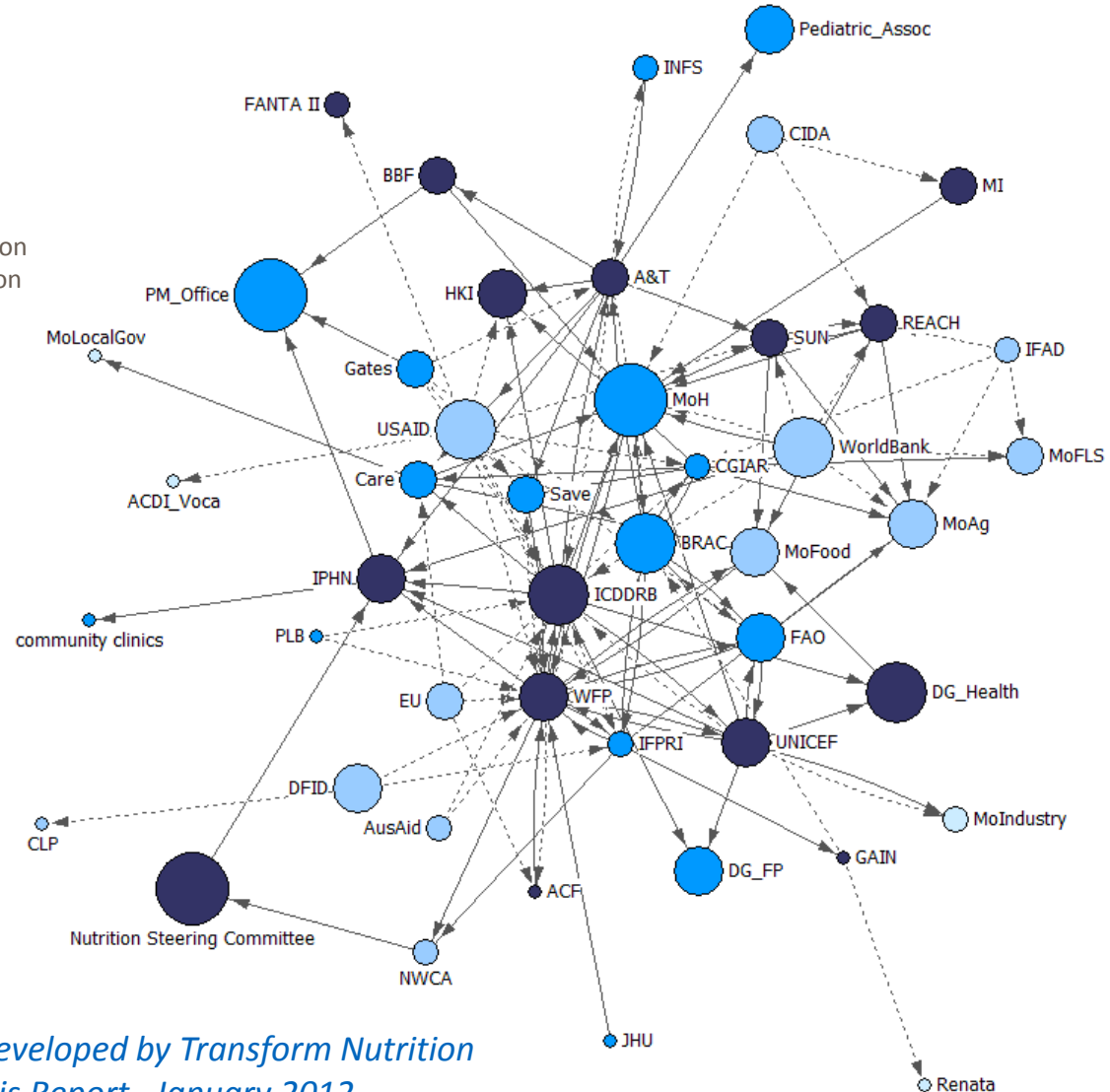




# Political environment: nutrition stakeholders



*This map sets out the key organisations and structures who are involved in the overall nutrition agenda in general in Bangladesh.*





# Political environment: home fortification stakeholders

## NGOs and Programmes

CARE Bangladesh	Save the Children
Eminence Bangladesh	Alive and Thrive
FANTA III	Helen Keller International
BRAC	Micronutrient Initiative

## Multilateral Agencies

UNICEF	UN World Food Programme
Food and Agriculture Organisation	World Bank

## Central

Government of Bangladesh
Bangladesh Judiciary

## Collaborative Groups

Scaling Up Nutrition
REACH Network
Nutrition Working Group

## Research

ICDDR,B
IFPRI

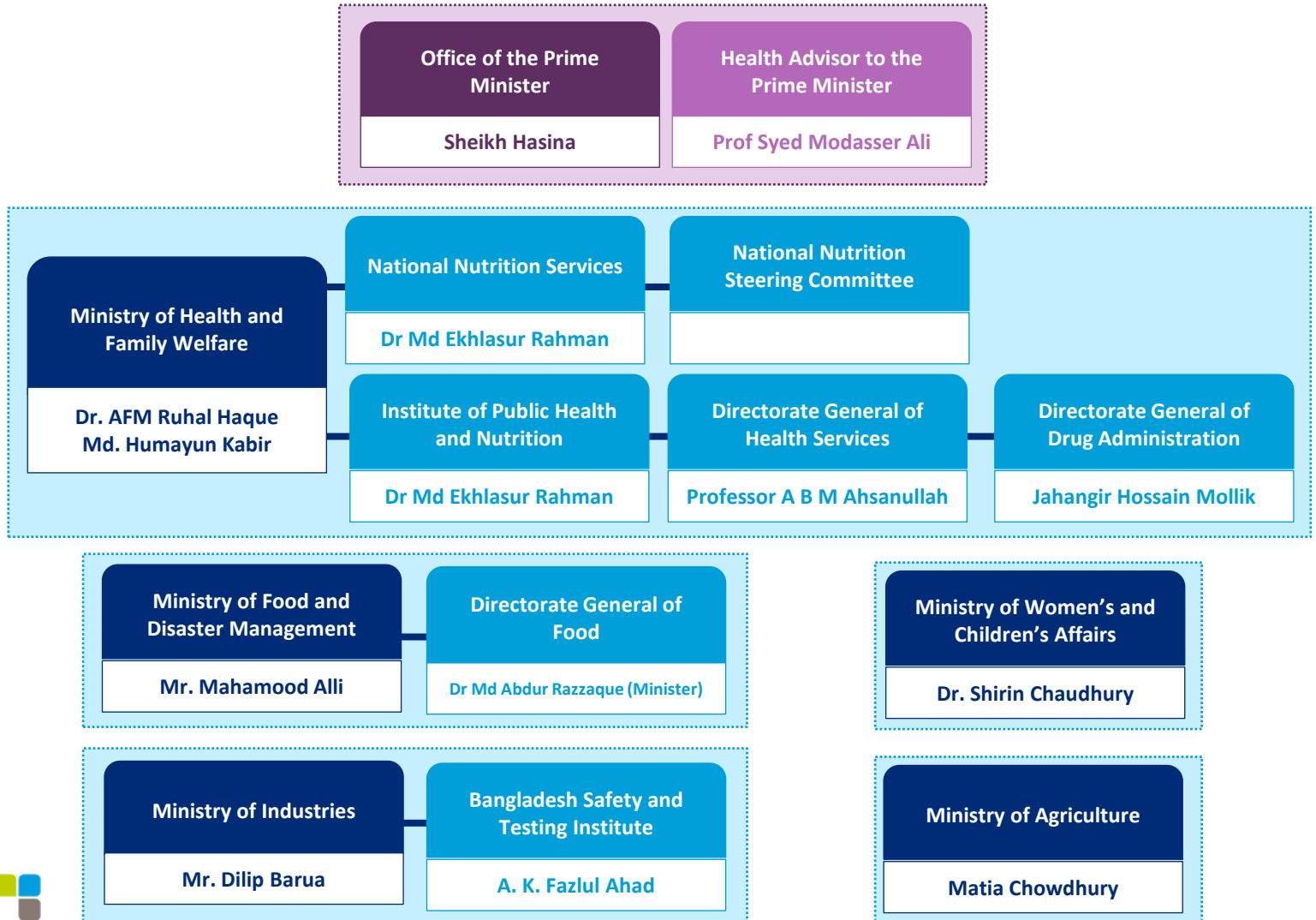
## Major Donors

DFID (UK Aid)	USAID
CIDA	Gates Foundation
SIDA	AusAid

## Civil Society

Bangladesh Breast Feeding Foundation (BFF)	IBFAN/IBFAN Asia
National Paediatric Association	National Human Rights Commission

# Political environment: key government structures



# Political environment: context



## CURRENT POLITICAL ENVIRONMENT

The **Ministry of Health and Family Welfare** is one of the major ministries within the government and naturally the key ministry on nutrition policy. The Minister and Senior Secretary have both regularly called for a greater focus on exclusive and continued breast feeding to help address under nutrition issues.

The **Ministries of Agriculture, Industries, Children and Women's Affairs and Food and Disaster Management** all play a role in setting and implementing government nutrition policy, and are relevant to a home fortification product. They are generally seen as less influential than the MoHFW, however, particularly over matters as sensitive as infant and young child feeding where the MoHFW will generally set policy in conjunction with the Prime Minister's Office.

In a **Parliamentary** context, stakeholders have suggested that nutrition is not a major issue and garners relatively little debate, except on issues that play well with the electorate, such as basic food provision.

A 2012 Institute of Development Studies (IDS) report found that a major issue across both parliamentary and ministerial contexts was a general lack of understanding of the key issues of nutrition beyond food security.

## GOVERNMENT INFLUENCES

Nutrition in Bangladesh has been regarded as an area that draws in ideological responses from all sides, which could have a tendency to distract from productive or effective approaches.

**Prime Minister** – The Prime Minister is very powerful in Bangladesh and is advised on health and nutrition issues by her health advisor. She is a strong proponent of the need for better breast feeding.

**Civil Society** – The Bangladesh Breast Feeding Foundation has strong influence on Government on child nutrition issues and advises both the MoHFW and the Prime Minister's office

**Donors** – Bilateral donors do play a role in supporting nutrition policy and implementation, although stakeholders say they generally only have a moderate influence over government bodies. The World Bank is significantly involved in this area due to its major investment in nutrition policy, but by no means sets the policy.

**International Agencies** – WHO regulations and guidance are particularly influential on the Government, directing a number of policies and BSTI standards for example. UN organisations such as UNICEF and WFP are actively involved in nutrition policy, but the government has on occasion criticised them on key ideological issues such as the use of non-local RUTFs.

## ELECTION in 2013/14

The current parliamentary term is due to expire on 29<sup>th</sup> December 2013, meaning an election should be held by January 2014 at the latest.

Bangladesh has two main parties, the AL and the BNP and the electorate tends to swing between the two over election periods, with the opposition increasingly taking opportunities to call the government to account on any issues it can.

In the run up to the next election, it is likely that more controversial or more publically resonant issues will take centre stage in a policy context. IDS found that curative and treatment approaches to nutrition and basic food provision (as opposed to nutrient intake) were regarded by policy makers as more 'visible' to the electorate and likely to be focussed on during a campaign.

The last change in government had big impacts on nutrition policy in general, with the incoming AL party keen to differentiate itself from the outgoing BNP by adopting new programmes and policy initiatives. There was also a significant amount of policy stalling around the election period, and a focus on highly politicised issues.

Given the sensitivity around infant and young child nutrition (IYCN) and home fortification products, this is a key risk to an organisation taking a product to market.

# Political environment: civil society advocacy



## BREAST FEEDING ADVOCACY

The [Bangladesh Breast Feeding Foundation](#) campaign and lobby to highlight the need for exclusive breast feeding to 6 months and continued breast feeding up to two years, and actively monitor for marketing infringements

**Natural, local foods** - the organisation has traditionally been opposed to any food products which could reduce the need for breast feeding and tend towards a food-only approach to preventing and treating malnutrition.

**Private sector** – in line with organisations such as IBFAN, the BFF has been distrustful of the private sector's involvement in child nutrition, given ethics issues around milk powder and formula. They are willing to engage in discussions with private sector organisations, however.

**Political patronage** – the organisation is highly respected and has a high degree of influence over the Bangladeshi government. The group's chair is seen as an influential figure in infant and young child nutrition in Bangladesh.

**MNPs** – The organisation had initially expressed concerns around MNPs but following collaborative discussions with ICDDR,B and organisations involved, are receptive to MNP-5.

The [Bangladesh Paediatric Association](#) is the primary organisation representing doctors involved in paediatrics and has been active in arguing against the use of imported RUTFs in the country. The organisation also has strong links with the Breast Feeding Foundation and strongly supports the need for improved breast feeding.

## INTERNATIONAL ADVOCACY

IBFAN is the key international network of organisations advocating on the need for breast feeding. They regularly influence and play a part in World Health Assembly regulations and discussions.

**Private Sector** – IBFAN takes the view that the private sector should *never* have a role in nutrition education as there will always be a conflict of interest.. They have criticised organisations such as GAIN and SUN for looking to seek partnerships with private sector organisations

**Activism** – IBFAN has a history of 'naming and shaming' organisations it considers are in violation of its views and regularly produces briefs on breast milk substitute marketing code violations by Danone and Nestle. They have also publically criticised major donors such as USAID for being willing to engage in discussions with companies who have violated the code in the past.

## HUMAN RIGHTS DISCOURSE

Across South Asia, there is a growing trend to see access to adequate food and prevention of malnutrition as fundamental rights which must be protected.

**National Human Rights Commission** – the NHRC is a quasi judicial body in Bangladesh tasked with protecting basic rights. It has been active in calling for food and nutrition to be recognised as necessities.

**State accountability** – A key demand of this movement is that states should be accountable and transparent in their approach to food and nutrition and there are calls for improvements in monitoring and evaluation of nutrition efforts.

**Judicial action** – The courts in Bangladesh have been more willing to support moves made by civil society groups and the government on food rights issues. The government has successfully prosecuted four organisations for violations of breast milk substitute marketing regulations and PRAN, one of the country's leading food manufacturers, is currently facing major court action on alleged unsafe juice products. The Indian supreme court has also issued rulings recently upholding that food and nutrition are basic human rights which the government is legally bound to protect and uphold.

# Political environment: RUTFs in Bangladesh



## OPPOSITION TO RUTFS

Ready to use therapeutic foods (RUTFs) are used to treat severe acute malnutrition (SAM) in countries around the world. They are a paste which contains the necessary nutrients, protein and energy intake that can be given to children in emergency situations.

RUTFs are generally not intended to be marketed to the general public but have faced opposition in Bangladesh on a number of fronts even as treatment used by NGOs. Opponents often cite the bans on RUTFs in India and Malaysia and draw on five main arguments against their use in Bangladesh:

**1. Opposition to processed foods** – A number of stakeholders have publically stated that the focus in Bangladesh should be naturally occurring foods. Many have called for the focus of support and finance to be on helping farmers grow a diversified food base and educating mothers on how to give their children a naturally diverse and nutritious diet.

**2. Opposition to non-Bangladesh foods** – Many have particularly opposed imported RUTFs and argue that the country should find local solutions to malnutrition which will improve food security and agriculture.

**3. Opposition to breast milk substitutes** – Many also argue that RUTFs are a threat to breastfeeding as they act as a total substitute and their promotion would undermine efforts to promote exclusive and complementary breastfeeding to mothers during the first two years of a child's life

**4. Economic cost** – RUTFs, particularly imported ones, are seen as an expensive solution to malnutrition and there would be better value for money and greater reach to spend the money on nutrition education and diversified food bases.

**5. Commercialisation of nutrition** – some opponents liken RUTFs to milk powder and argue that manufacturers are more concerned with profit than reducing malnutrition to the extent that they will promote their products even where they are not needed.

## A WORKABLE SOLUTION

A number of agencies and NGOs are working with the government help find a workable solution to developing a treatment for SAM and for emergency situations. This could include softening of restrictions on importing RUTFs in certain situations or more likely the development of a locally produced RUTF.

## IMPACT FOR HOME FORTIFICATION

The opposition to RUTFs, particularly those that have been imported, highlights the importance that the Government and many influential members of the health sector attaches to local, natural, home made food. Home fortification products could face similar opposition if they are not local and natural.

This also highlights the benefits that home fortification products can have, however, in that unlike RUTFs, they require and can champion natural, local complementary foods and could be used to educate mothers on how to prepare appropriate diets for themselves and their children.



# Stakeholders in detail: NGOs and programmes



## CARE Bangladesh



CARE is one of the major poverty reduction NGOs working across many development areas in Bangladesh. CARE has been involved in a number of nutrition programmes in recent years, including a Danone funded project to improve food security for marginalised children. CARE has a history of engaging and working in partnership with the private sector in Bangladesh including with major multi-national corporations

**Window of Opportunity** – CARE's campaign focussing on the first 1,000 days has included social marketing campaigns to educate mothers on appropriate breast feeding and complementary feeding. They have also promoted the use of MNPs to support complementary feeding

**JITA network** – CARE has developed a rural sales programme in Bangladesh which is currently run as an independent social enterprise. Through this network, women sell a basket of products door-to-door in rural areas, ranging from health products to cosmetics. The company intends to scale up to 12,000 sales staff over the next three years.

**Fortified flavouring** – CARE has recently begun working with the Mitsubishi Corporation to pilot the development of a nutrient rich flavouring, Furikake, which can be added to local foods. This is intended to be distributed through the JITA network and CARE has been undertaking research and focus groups in rural communities to test acceptability with positive results.

**Market development** – CARE and the JITA network have expressed support for working with private sector actors on further nutrition programmes, including with home fortification products. They are particularly keen to work with the private sector in both understanding and developing markets for social products and for the JITA network.

## BRAC



Initially set up in Bangladesh, BRAC is the largest NGO in the world, working across most areas of development. BRAC is currently running a number of initiatives relevant to Home Fortification products

**Sprinkles Programme** – In collaboration with Renata and GAIN, BRAC is implementing a micronutrient powder scheme to provide home fortification opportunities to families in rural communities. The project is being implemented in 61 districts in Bangladesh and primarily distributed through 80,000 healthcare workers who sell a basket of essential social products door to door.

**Awareness raising** – To support their sprinkles programme, BRAC has undertaken to develop awareness of the need for fortified and nutrient rich food and promote Pushtikona as a product. This is a multi-actor approach, trying to reach, mothers, care givers, health professionals, community health workers and other influencers

**Alive and Thrive** – BRAC has been working closely with the Gates' funded Alive and Thrive programme to improve exclusive breastfeeding in the first 6 months and effective complementary feeding up to two years. This has been implemented through community counselling and coaching, demonstrations and social marketing.

**Political influence** – BRAC is generally highly respected in Bangladesh and has previously been involved in advocating and advising the Government of Bangladesh on health and nutrition issues. The chairperson of BRAC has also been appointed this year to the Scaling up Nutrition (SUN) initiative by the UN Secretary General and the organisation has been strongly involved in the launch of the Civil Society Alliance SUN network in Bangladesh, providing its secretariat function.



# Stakeholders in detail: NGOs and programmes



## EMINENCE BANGLADESH



Eminence is an Bangladesh based NGO which works across health, nutrition, human rights and climate issues, conducting research, programme activities and advocacy

**Infant and Young Child Feeding Programme** – One of Eminence’s core programmes is focussed on improving feeding practices for children aged under two years of age. The programme is initially focussed in urban areas surrounding Dhaka and is intended to adopt an approach that works both directly with mothers but also in co-ordination with community structures and stakeholders to improve awareness and feeding influences.

**Behaviour change communication** - Eminence has expertise in developing and delivering behaviour change communications and social marketing campaigns on a range of social issues, both at a mass media level and through community volunteers and care workers.

**Advocacy** – is active in networks such as the SUN Civil Society networks and the Bangladesh Nutrition and Food Security Network, and has advocated for create awareness and importance to be given to nutrition in general and appropriate feeding of young children. The organisation has noted the importance of working collaboratively with the private sector in previous policy briefs, but has cautioned on the need to avoid conflicts of interest if the private sector is involved in social programmes.



## ALIVE AND THRIVE



Alive and Thrive (A&T) is a Gates funded programme set up to improve infant and young child nutrition by increasing exclusive breast feeding within the first 6 months and complementary feeding up to 2 years.

**Programme:** 2009-2014, **Target countries:** Bangladesh, Ethiopia, Vietnam

**Community interventions** – A&T works with BRAC’s health worker network to improve skills in educating, coaching and demonstrating suitable feeding practices and delivering behaviour change communications.

**Mass media communications** – A&T has worked closely with the Government of Bangladesh to develop mass media campaigns aimed at improving maternal and infant young child nutrition. Through Bangladeshi national television channels, they have achieved a penetration of 67% of rural households. These communications are tested and refined to improve impact using traditional mass advertising approaches.

**Hand-washing** – A&T is running parallel behaviour change campaigns to improve hand-washing during maternal and infant feeding times as poor hygiene is seen as a major contributor to poor child nutrition. This campaign is run through community and national communications

**Advocacy** – A&T advocates at a national and international level to highlight the importance of Infant and Young Child Nutrition. In Bangladesh, the organisation is working closely with the Government and the Scaling up Nutrition Network.

**Home fortification** – In line with a commitment to improving complementary feeding, A&T has expressed interest in exploring home fortification in situations where food security or other barriers prevent adequate feeding.

**Partners:** FHI 360, BRAC, GMMB Advertising, IFPRI (M&E), Save the Children (Vietnam), University of California, World Vision (Ethiopia)

# Stakeholders in detail: NGOs and programmes



## FANTA III



The Food and Nutrition Technical Assistance programme is a USAID funded initiative and is currently entering its third phase. The programme is set up to provide advocacy and technical assistance to initiatives looking to improve nutrition for mothers, infants and young children

**Home fortification trials** – FANTA has been heavily involved as a technical partner in an acceptability trial of LNS and MNP products in Bangladesh and is currently launching an efficacy trial in conjunction with ICDDR,B and the University of California.

**Local production** – in line with many other NGOs, FANTA sees local sourcing and manufacture as a key issue, both to help with political positioning but also to strengthen the local supply chains and improve food security.

**Marketing** – FANTA has expressed that a key role for the private sector in nutrition is to help develop the market through communications and traditional marketing to help consumers understand why nutritious products are necessary and to create demand.

**Hygiene** – FANTA has strong links with the Gates funded Alive and Thrive programme and is also calling for nutrition interventions to include a greater focus on hand-washing and hygiene factors to improve their effectiveness, particularly in rural areas.

## HELEN KELLER INTERNATIONAL



Helen Keller International (HKI) is a major international NGO working in Bangladesh. It has two core missions in its target countries - preventing blindness and reducing malnutrition.

**Food fortification** – Fortification is one of HKI's key project focuses and it has been involved in a number of campaigns world wide to support agricultural-fortification and the distribution of home fortification products including MNPs, vitamin A capsules and iron supplements.

**Micronutrient powders** – HKI has been involved internationally in a number of micronutrient powder schemes including working with the Government in India, local health centres in Cambodia and a pilot in Nepal in conjunction with Alive and Thrive.

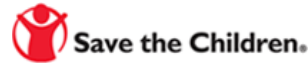
**Extreme poor** – HKI has been heavily involved in the DFID funded SHREE programme in Bangladesh which aims to improve lives of the extreme poor through targeted interventions and economic empowerment. Much of HKI's work on nutrition has been targeted at this group for maximum impact

**Private sector collaboration** – Internationally, HKI is open to working closely with the private sector, and is currently involved in a partnership with Heinz to deliver and take to market and distribute a micro nutrient powder product across Africa, Asia and Central America.

# Stakeholders in detail: NGOs and programmes



## SAVE THE CHILDREN



Save the Children is one of the leading children's rights and development organisations operating in Bangladesh. The majority of their work has focussed on improving children's human rights, improving labour standards, social protection and responses to disasters.

**Nutrition work** – Save the Children has been active in supporting malnourished children, and has been focussing on the poorest 10%, reaching 11,000 children through aid programmes to provide nutrition interventions and treat severe and acute malnutrition. The organisation has also responded to cyclone and flooding disasters.

**Treatment of SAM and RUTs** – Save the Children has been advocating to the government over the need to have an adequate treatment for severe and acute malnutrition that meets WHO guidelines.

**Future work on nutrition** – Save the Children is currently exploring its approaches to supporting children in Bangladesh in the best possible way and has expressed some interest in further understanding how the private sector and market based solutions could fit into improving health and nutrition for children in the country. Internationally, Save the Children has previously worked in partnership with major MNCs on various issues.

## MICRONUTRIENT INITIATIVE



The Micronutrient Initiative (MI) is a major NGO working across the world to reduce vitamin and mineral deficiencies. The organisation provides 75% of the Vitamin A supplements used by governments in developing countries and is involved in other fortification and supplementation programmes

**Key programmes** – To date, MI has attracted a seen successful programmes and campaigns with iron, zinc, and iodine supplementation. Globally the organisation is also looking at micronutrient powders designed through local markets and has been working with commercial channels in Haiti.

**Hard-to-reach populations** - The MNI in Bangladesh has been advocating with government and donors over the need for campaigns to reach those who are out of reach of usual health and nutrition interventions. This involved working directly with NGOs to identify and access those most at risk and working with the government to include these populations within their strategy.

**Advocacy** – The MNI is heavily involved in a number of forums and working groups and calls on government and civil society to recognise the need for interventions to address micro-nutrient deficiency as much as a simple lack of food.

# Stakeholders in detail: multilateral agencies



## UN WORLD FOOD PROGRAMME



WFP is the key UN body tasked with providing food aid and improving food security around the world.

**Improving Maternal and Child Nutrition** – WFP’s core activity include providing targeted and emergency fortified supplementary food to those in need whilst engaging in behaviour change communications to help them access adequate food in the future.

**Collaborative groups** – WFP is heavily involved in the co-ordination of REACH (the Renewed Efforts Against Child Hunger and Under nutrition) and the SUN (Scaling up Nutrition) multi-stakeholder groups.

**Working with the private sector** – WFP has been active in pursuing private sector collaboration opportunities within Bangladesh. They have previously worked with Heinz on developing the Bangladesh nutrition country strategy and are currently looking at how to work with local food manufacturers to develop a commercial market for fortified biscuits that will improve quality and supply.

**Project Laser Beam** – PLB is a major private sector initiative in Bangladesh and Indonesia aiming to eradicate child malnutrition. Founding partners include DSM, GAIN, Unilever and Kraft who provide both funding and technical support.

**Supplementary feeding products** – WFP is working with John Hopkins University and local food manufacturers to develop a locally sourced supplementary feeding product that can be used to prevent and treat malnutrition. This is largely in response to oppositions by the Government to imported RUSFs and RUTFs.

## UNICEF



UNICEF is strongly active in providing humanitarian assistance and development for children and mothers issues in Bangladesh. They are also active in supporting policy development in country and conducting research and evaluation on programmes including nutrition interventions.

**RUTFs** – UNICEF is one of the largest global purchasers of RUTFs as a treatment for severe and acute malnutrition. It has been working in partnership with ICDDR,B to look at ways of developing locally made RUTFs or RUSFs in Bangladesh that can be used as effective SAM treatment given the opposition from the government to imported versions.

**Breast feeding** – UNICEF is a strong proponent of the need for early and exclusive breastfeeding and adequate complementary feeding up until two years but is pragmatic in its approach. They are also active in monitoring baby formula products for violations of the WHO breast milk substitutes marketing code.

**Micronutrients** – micronutrient deficiency in children is one of UNICEF’s core global focus areas and in Bangladesh they have been a key player in developing the government’s vitamin A supplement programme. They have also worked closely with GAIN on products such as fortified cooking oil in country and have been working on providing micronutrient supplements to at-risk communities in the Chittagong Hill Tracts.

**Private sector** – UNICEF has expressed an openness to exploring further opportunities to engage with the private sector on developing approaches for solving child malnutrition



# Stakeholders in detail: multilateral agencies



## FOOD AND AGRICULTURE ORGANISATION

The FAO is the UN agency focussed on improving food security and the agricultural supply chains across the world.

**Food security** – the FAO’s core mission is to improve food security in Bangladesh and it is working towards more resilient, diverse agriculture that can provide adequate food and nutritional inputs for those who need them. They take a food-centred approach to nutrition, looking at how agriculture can be used to improve health across the country.

**At risk populations** – FAO focuses on some of the most at-risk populations who often rely purely on subsistence farming for their food intake. Their default position is that fortified products generally are not much benefit to these populations, and agricultural diversification and education are more appropriate solutions.

**Emergency safety nets** – the FAO is working strongly to improve the safety nets in Bangladesh in the event of a disaster so that victims can easily gain access to necessary food and nutrition.

**Private sector** – working with agricultural supply chains, the FAO naturally is keen to engage with private sector entities and to look at ways of improving economic empowerment in agricultural and food settings. They are likely to be supportive of fortification products made or grown in country but less so of those imported. FAO has previously shown some interest in home fortification products in general, but generally works towards improving food security and diversity first and using food fortification products as a secondary option.

# Stakeholders in detail: research organisations



## ICDDR,B



The International Centre for Diarrhoeal Disease Research in Bangladesh (ICDDR,B) is the primary research body around health and nutrition issues in the country, undertaking research studies, clinical trials, training and programme activities.

**Centre for Nutrition and Food Security** – The CNFS has strong links with the National Nutrition Steering Committee and works closely with the various ministries and governmental organisations. The centre is generally receptive to working with the private sector and to exploring innovative ways of delivering nutrition interventions but is strongly guided by medical research and published evidence.

**Micronutrient deficiency** – The CNFS is in the process of conducting research into micronutrient deficiency across the country and is intending to disseminate results to key figure and more widely in January 2013

**RUTFS/RUSF** – Given opposition to imported RUTs the organisation has been exploring and testing locally grown and manufactured products to be used as a treatment for Severe Acute Malnutrition with some success. There is some suggestion that future government policy could include these, although the area is still politically sensitive.

**Home Fortification Products** – The CNFS has been supportive in convincing government of the benefits of MNPs in the past and is currently undertaking a study into MNPs and LNS supplements in conjunction with University of California, Davis and FANTA III. Acceptability results were generally very positive and a full efficacy trial has just launched in 2012

## IFPRI



The International Food Policy Research Institute is a US-based research organisation that focuses on policy analysis and strengthening and research on key food and nutrition interventions.

**Micronutrient powders** – IFPRI has been involved in studies with a number of micro nutrient powders including in Bangladesh and Haiti, undertaking field research into uptake and baseline studies on the effectiveness of supplements in rural communities to inform policy debates.

**Transform Nutrition** – IFPRI is one of the key members of Transform Nutrition, a DFID funded initiative to undertake research and policy analysis and devise ways of improving the nutrition sector across Bangladesh.

**Scaling up Nutrition** – IFPRI is involved at a global level in the DFID effort to improve the quality and technical research attributes of the Scaling Up Nutrition movement. This will involve developing M&E networks and providing technical guidance which will be disseminated down to country offices.

**Alive and Thrive** – IFPRI is the research partner attached to the Gates funded Alive and Thrive programme and is responsible for evaluating cost effectiveness and impact of co-ordinated approaches to infant and young child nutrition interventions.



# Stakeholders in detail: major donors

## DFID (UKAID)

DFID is one of the key bilateral donors in Bangladesh and sees nutrition and one of its key strategic priorities, particularly for the extreme poor and those who are food insecure.

**Political influence** – Along with other donors, DFID participates in a number of NGO and Government forums on health and nutrition and jointly chairs the Health, Nutrition and Population Working Group which brings together donors, NGOs and ministries.

**Programme activity** – The majority of DFID's core funding and programmatic activity set aside for nutrition in 2011-2015 is intended to be spent on extreme poor programmes and used to support the development of the public health sector in general.

**Private sector development** – DFID is keen to expand its private sector development initiatives in Bangladesh and is currently reviewing how it spends funding and technical assistance for the coming years on working with the private sector or in market led approaches. Nutrition is generally seen as a potential focus sector for inclusive business funding in Bangladesh by donors.

**Advocacy** – Along with other donors and agencies, DFID has been working closely with the government and NGOs to find a solution to developing a treatment for severe and acute malnutrition that is suitable and politically acceptable in Bangladesh. DFID is also supporting Transform Nutrition, an initiative to understand and develop the nutrition sector in Bangladesh through policy and stakeholder analysis.

## USAID

One of the largest bilateral donors in Bangladesh, USAID is particularly active in the health and nutrition sector and has a relatively high level of influence due to the funding that it provides.

**Agricultural focus** – USAID's key work is focussed on funding agricultural approaches to improving nutrition. The current three main areas are Rice fortification, Zinc enriched fertilisers and improving milling processes, all of which are intended to improve the nutritional component of locally grown foods. Whilst generally supportive of home fortification products, LNS type products do not currently fit in USAID's main areas of focus due to the political sensitivities surrounding other LNS products such as RUTFs.

**Advocacy** – USAID is working with the government and advocating for the need for products which treat severe and acute malnutrition in emergency situations

**Programme activity** – USAID is currently funding two key programmes, (1) FANTA III which is aimed at improving the sector through directed technical assistance to the Government and NGOs; and (2) the Social Marketing Company, a social business which markets and distributes products including MoniMix micronutrient powders.

**Marketing Health for Innovation** – USAID is beginning a new programme in 2012 which is awarding \$15million to one or more organisations to look at how innovative approaches can be used to improve health and reach new beneficiaries through private sector approaches.





# Private sector: micronutrient powders

## SOCIAL MARKETING COMPANY (MoniMix)

The Social Marketing Company is partly funded by USAID and set up to market socially beneficial products to the majority of the populations. They aim to deliver products that are affordable and accessible to those who need them and also help to develop a market through appropriate marketing and behaviour change communications. The primary distribution channels are Pharmacies (35%) and general retail outlets (65%) and SMC has a distribution and warehouse network to keep rural locations stocked as necessary. Examples of the types of product marketed include contraceptives, zinc tablets and oral rehydration sachets.

In 2008, the Social Marketing Company brought to market a micronutrient powder under the name of MoniMix., intended for mothers to fortify meals at home for their children. SMC has faced initial barriers in regulation with bans on any advertising or product placement outside of pharmaceutical settings. At an early stage they were able to secure approval from the Directorate General of Drug Administration to produce social marketing on the importance of iron enriched foods in general, but not specifically on MoniMix.

MoniMix Micronutrient Powder		
Producer Renata	Distributor SMC	Type MNP-5
Volume sold 7m (FY11)	Target age 6mo – 2 yrs	Price c.2.25Tk

## RENATA (IN PARTNERSHIP WITH BRAC)

Renata is a pharmaceutical manufacturer based in Bangladesh. Alongside producing the MoniMix micronutrient powder, Renata has partnered with BRAC and GAIN to produce Pushtikona Micronutrient Powder. The product is currently distributed through BRAC’s community health workers in a basket of social products that they sell door to door, as well as through Renata’s network of 1,110 medical representatives.

During initial development, there was some opposition to micronutrient powders from civil servants in the MoHFW, in part due to a lack of understanding of the product. Government figures have suggested that this led companies to approach and eventually secure approval on MNPS from the Ministry of Food and Disaster Management, which may have created tension in the MoHFW.

Renata has subsequently faced opposition and delays of up to a year in moving from Micronutrient Powder 5 to Micronutrient Powder 15 and the government and civil society officially now only endorse MNP-5 for use in everyday situations unless further evidence can be provided on the use of MNP 15 in South Asia.

Pushtikona Micronutrient Powder		
Producer Renata	Distributor BRAC	Type MNP-15
Volume sold TBC	Target age 6mo – 5 yrs	Price c.2.25Tk

# Social distribution channels



## BRAC – COMMUNITY HEALTH WORKERS

Reach – 80,000 health workers

BRAC manages a very large network of community health volunteers, Shasthya Shebikas across Bangladesh who are trained to provide health education immunisations, basic treatments and referrals. The network extends over both rural and urban areas

**Sales channel** - These health volunteers are able to supplement their income by selling health commodities and medicines in the areas that they work. The products tend to be pharmaceutical in nature, including medicines and contraceptives for example.

**Pushtikona** – BRAC has entered into a partnership with Renata and GAIN to distribute and sell the Pushtikona micro nutrient powder through these health workers. Detailed results of success have not yet been published on the effectiveness of this as a channel.

**Health education** – The health workers are trained to provide education on a range of health and hygiene issues. BRAC has been working with A&T to develop effective education and training on breast feeding and adequate complementary feeding with nutritious food, as well as the importance of hand-washing during feeding times. The health workers also distribute reminders and leaflets to support the education, all of which are Government branded to ensure a consistent message.

## CARE – JITA NETWORK

Reach – 3,000 rural workers, 18 districts

The JITA network began as the Rural Sales Programme piloted by CARE in 2004, and through demonstrated success was scaled up into a separate social business in 2011. There is an intention to scale to 12,000 sales workers with access to 10 million customers by 2014

**Social marketing** – JITA is also involved in marketing and supporting market creation through social marketing and education campaigns, including supporting Danone with developing a market for fortified yoghurts

**Market research** – JITA is currently in the process of expanding its offering for corporate partners into market research and testing, helping to identify opportunities for new social products. This is something that they have also expressed an interest in developing with commercial partners.

**Social impact** – JITA is working to measure and report the impact of the network. A four year study by Oxford University was published in March 2012 which argued that the programme did generally empower and provide financial benefits for the sales women and their families.

**Structure** – JITA is a joint venture between CARE International and Danone Communities.

**Current partners** – Unilever, Danone, Square, Bata, Grameen Foods, BIC, Lal Teer Seeds

# Social distribution channels



## GRAMEEN DISTRIBUTION

Reach – 44 districts (urban) 20 districts (rural)

Grameen Distribution Limited (GDL) is a subsidiary of the Grameen Bank group of companies and exists as a social business to provide products throughout Bangladesh that have a social impact

**Urban Distribution** - GDL has access to the 2,500 district offices and branches of both Grameen Bank and Grameen Telecom, providing coverage in urban areas in 44 districts across the country.

**Rural Marketing** – The Grameen Marketing Network (GMN) is the rural sales programme of GDL, aimed at opening up marketing to the rural poor and providing income opportunities for underprivileged workers. The system works on a micro franchise model with hubs distributing through a female network selling door-to-door mostly to women and a male network selling in village markets mostly to men. The network currently has distributors in 20 districts.

**Partners** - The organisation has previously worked in partnership with companies including Nokia, Danone and Canadian Solar

## SOCIAL MARKETING COMPANY

Reach – 12 districts, 220,000 outlets

The Social Marketing Company (SMC) is funded by USAID and intended to act as a social business developing and distributing socially beneficial products through various channels and marketing them effectively.

**Traditional distribution** – SMC adopts a more traditional distribution model to BRAC, Grameen or JITA and focuses on getting products to market through retail outlets and pharmacies via its 12 regional hubs.

**Distribution of MoniMix** – the MoniMix micronutrient powder is distributed through the Social Marketing Company's pharmacy channels due to its classification as a drug product. There is some suggestion that further capacity building may be needed to education healthcare and pharmacy professionals on the benefits and use of home fortification products.

**Social marketing** – Alongside distribution, SMC is also active in developing behaviour change communications and social marketing campaigns that are intended to create the market for the products that it distributes.

**Future collaboration** – The organisation has expressed an interest in working more collaboratively with private, public and NGO organisations in the nutrition and home fortification areas to help develop the market and address some of the technical and regulatory challenges faced by organisations.

# Collaborative groups



## SUN MOVEMENT

The Scaling Up Nutrition Civil Society Alliance was formally launched in Bangladesh at the end of October 2012 by the Bangladesh Senior Secretary for Health following a number of months of drafting the Terms of Reference and establishing the network.

**Multi sectoral group** – in line with the global SUN framework, the CSA is intended to act as a multi sector network bringing together expertise across each sector in line with the global SUN movement. The launch was heavily attended by senior figures across government, major bilateral donors, key NGOs involved in Nutrition and international agencies including UNICEF.

**Political patronage** – the launch of the SUN CSA has been championed by senior figures across government including at ministerial level from the Ministry of Health and Family Welfare and the Ministry of Family Planning. The chairperson of BRAC and the Prime Minister have both been invited to be representatives on the central SUN initiative by the UN Secretary General.

**Infant and Young Child Nutrition** - the Government of Bangladesh has also called for the network to explicitly focus on the first 1,000 days agenda for maximum impact in improving nutrition.

## REACH

Reach is the Renewed Effort Against Child Hunger and Under nutrition campaign which acts as a multi organisational body to help coordinate UN efforts on child malnutrition and facilitate effective working with other organisations and sectors.

Within Bangladesh, REACH is hosted by the WFP and has worked to bring organisations together to address malnutrition. The network has acted as a driving force behind the SUN CSA network which follows the framework that REACH developed for strengthening a country's approach to malnutrition.

## BCSNPN

The Bangladesh Civil Society Network for Promoting Nutrition is another forum for bringing together NGOs in Bangladesh to discuss approaches to improving nutrition.

The network is predominately made up of national NGOs and lobby groups and is chaired by the director of the Bangladesh Breast Feeding Foundation. The group is linking with the SUN Civil Society Alliance as it forms.

## LOCAL CONSULTATIVE GROUP

The Health Nutrition and Population Working Group (HNPWG) is one of the Local Consultative Groups which are set up to act as a forum for bringing together the major donors, foreign missions, agencies, NGOs and government organisations working in Bangladesh.

The group has representatives from all the major donors and international agencies such as UNICEF and WFP and meets on a monthly basis. It is currently chaired by the Ministry of Health and Family Welfare and DFID. Stakeholders have suggested that it is focussed with procedural issues more than substantive policy discussion.

## INDUSTRY COLLABORATION

Numerous other networks and groups exist, but there is currently no centralised, coordinated environment for private sector actors to work collaboratively on infant and young child nutrition, either between themselves or in conjunction with the Government or NGOs.

A number of organisations have expressed an interest in further collaboration between such organisations to help address some of the technical and regulatory challenges faced by the industry, to share learnings and to help create consumer demand for nutritious products.

# Overview: key success factors

---



In order to enable the successful launch of an home fortification product by a commercial organisation, stakeholders have indicated that there are a number of key success factors which should ideally be in place. If all of these are not present, this will not necessarily be prohibitive to launching a product, but an organisation should have a clear position on why they have adopted a different approach and be aware of the opposition that may be presented.

- Ministry of Health and Family Welfare engaged at a senior level early in development
- Wider collaborative bodies (SUN, REACH, Nutrition Working Group) and other stakeholders engaged and supportive
- Clear consistent messages on why the product is needed and why alternatives are not suitable
- A clear articulation of how home fortification products can be used to support locally grown foods and improve food security
- Demand created at a consumer level for nutritious products
- A product that can reach all segments of the population and a strategy for traditionally hard-to-access groups
- Regulatory bodies engaged early to support understanding of the product
- Localised sourcing and production
- Localised evidence on acceptability and efficacy of home fortification products
- A strategy to monitor and evaluate the product's effectiveness in the market
- Ethical marketing and education of consumers and the public on nutrition and adequate infant feeding



## Overview: potential opposition to home fortification products

The statements below represent a summary of the key arguments that have been presented against commercial MNP and LNS products by various individuals and organisations in Bangladesh. Any attempt to bring to market a home fortification product should have clear positions on each of these:

### Local food security

- ❓ The product does not use locally sourced ingredients
- ❓ The product is not locally manufactured
- ❓ Processed products should only be used in emergency situations, and the focus should be on developing the food chain for everyday situations

### Private sector role

- ❓ It is a conflict of interest for the private sector to play a role in health or nutrition education or to influence policy
- ❓ Private sector companies pushing products will lead to a rise in over nutrition
- ❓ The product will be promoted by private sector companies or sales people even when it is not needed

### Nutrition education

- ❓ Supplement products will give people the impression nutrition comes from a packet, not a natural food
- ❓ Supplement products will lead to mothers thinking that they no longer need to breast feed their children for the 6 months to 2 years period or be used to replace breast feeding.

### Safety and impact

- ❓ The product is not proven effective and safe in local clinical trials
- ❓ Those most at risk of malnutrition will not be able to afford or physically access the product due to cost and distribution channels



# Regulatory Environment

This section is based on discussions with key stakeholders and perceptions of the wider regulatory environment. It does not constitute professional, legal or regulatory advice. You should not act upon the information contained in this publication without obtaining specific professional advice. No representation or warranty (express or implied) is given as to the accuracy or completeness of the information contained in this publication, and, to the extent permitted by law, PricewaterhouseCoopers LLP, its members, employees and agents do not accept or assume any liability, responsibility or duty of care for any consequences of you or anyone else acting, or refraining to act, in reliance on the information contained in this publication or for any decision based on it.



# Overview



Very few home fortification products have been taken to market either by NGOs or by private companies within Bangladesh to date and so the legal and regulatory environment is still uncertain to some degree. Micronutrient powders (Pushtikona and MoniMix) have had some success in getting to market and do present some insight into the regulatory issues. There are four key regulatory aspects that need to be considered in launching a commercial home fortification product in Bangladesh aimed at infants and young children:

1

## Pharmaceutical Controls

Products which are deemed to be drugs are subject to regulations on marketing and distribution and approval requirements. Micronutrient powders have been classed as drugs by the Government of Bangladesh due to their high micronutrient content, although there is no precedent for whether other home fortification products would be similarly classed.

2

## National Standards

Certain products are required to be tested and certified by the Bangladesh Standards and Testing Institution (BSTI) prior to launch and are subject to restrictions on composition and packaging/labelling. Most BSTI standards come directly from the international Codex, although there are currently no local or international standards covering LNS home fortification products.

3

## BMS marketing Act

The Bangladesh Breast Milk Substitutes (Regulation of Marketing) Ordinance, 1984 places blanket restrictions on the advertising or marketing of anything classed as a BMS, and requires that the product is registered with the Government every three years. The Bangladesh definition of BMS also includes complementary food, which is any food used to complement Breast Milk

4

## New BMS Act, 2013?

The Ministry of Health and Family Welfare is in the process of drawing up replacement legislation on Breast Milk Substitutes, which may be sent to parliament in the near future. The content of the Bill is unconfirmed, although it is reported to apply all elements of the WHO Code on the marketing of BMS and subsequent WHA resolutions. This could result in tougher marketing conditions for any food product to under two



# 1. Pharmaceutical Regulation

---

## CONTEXT

Products which are classed as ‘drugs’ in Bangladesh are regulated by the Directorate General of Drug Administration (DGDA) a body that sits within the Ministry of Health and Family Welfare and which is responsible for their testing and regulation.

Relevant definitions of ‘drugs’ which could affect home fortification products include<sup>1</sup>:

- ⑦ “All medicines for internal or external use of human beings or animals, and all substances intended to be used for or in the treatment, mitigation or prevention of diseases in human beings or animals, not being medicines and substances exclusively used or prepared for use in accordance with the ayurvedic, unani, homoeopathic or biochemic system of medicine.”
- ⑦ “Such substances (other than food) intended to affect the structure or any function of the human body...”
- ⑦ “Any other substance which the Central Government may, by notification in the official Gazette, declare to be a drug for the purposes of this Act”

Such products require license for manufacture, and approval for import or distribution and have restrictions placed on their marketing and promotion. They can generally only be distributed through pharmacies or healthcare professionals who are licensed.

Micronutrient Powders have in the past been classified as drugs due in part to their high micronutrient content. Both examples on the market have been produced by a local pharmaceutical company (Renata) however which may have influenced the classification.

There has been significant debate around the use of Micronutrient Powder 15 (MNP-15) vs Micronutrient Powder 5 (MNP-5) and government has argued that MNP-5 should be sufficient for everyday complementary feeding, whereas MNP-15 should only be used in emergencies.

## CASE STUDIES

The Renata-BRAC Pushtikona partnership and The Social Marketing Company (SMC) have both faced high barriers in getting MNPs to market as they have been classed as pharmaceuticals rather than food. At times, this has restricted their sale and distribution to registered pharmacies and health workers. Pushtikona has had some limited success in securing waivers for marketing and promotion through other channels and SMC is looking at scaling up innovative distribution models.

Companies have also faced significant delays of many months when introducing Micronutrient Powder 15 (MNP-15), having previously used MNP-5, due to the regulatory difficulties of securing the necessary approvals. The government has also subsequently confirmed that it does not endorse MNP-15 which may lead to further regulatory and approval issues.

## 2. BSTI and Codex Standards

---



### CONTEXT

The Bangladesh Standards and Testing Institute (BSTI) is responsible for regulating the certification of products in Bangladesh. Certain products require MANDATORY certification prior to launch\* and are tested against existing composition and packaging requirements.

There is currently no standard for the majority of home fortification type products in Bangladesh, but three standards exist for other infant food and nutrition products which require mandatory approval:

- **Infant formula** - a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate
- **Processed cereal-based foods** - those prepared primarily from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis
- **Follow-up formula** - prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.

### KEY RISKS FOR HOME FORTIFICATION PRODUCTS:

- With no applicable standard, the Government or Judiciary could deem that other home fortification products should be classed under one of the existing standards which would require extensive restrictions on product composition and packaging.
- If there is no BSTI standard, this could also encourage regulators to consider that home fortification products are pharmaceuticals and be subject to the restrictions associated with them.
- A new standard for individual types of home fortification product could subsequently be introduced which requires changes to the composition of packaging of the supplements. Most BSTI Standards come directly from the Codex and work is currently underway to develop an international standard for LNS



## 3. Breast milk substitute marketing legislation

---

### DEFINITIONS OF BREAST MILK SUBSTITUTES

The Bangladesh *Breast Milk Substitutes (Regulation of Marketing) Ordinance, 1984* (amended in 1990) sets out the legal position on marketing or promoting any breast milk substitute (BMS). Two key definitions may be relevant for determining whether nutrition supplements fall under the definition of the Act. There is currently no tested legal position within Bangladesh on whether home fortification type products would be included within these definitions.

- **s2(aa)** “breast-milk supplement or weaning food” means any food manufactured or locally prepared to be used as a complement to breast-milk or infant formula, when either becomes insufficient to satisfy the nutritional requirements of infants;]
- **s2(b)** “complementary food” means any food represented as a complement to breast-milk or [infant formula, and includes any breast-milk supplement or weaning food];

### RESTRICTIONS ON BMS PRODUCTS

If a product is considered to fall under the definitions contained within the Act, a number of restrictions exist:

- The product must be registered and approved by the Government every three years
- There is a blanket ban of an advertisement that promotes the use of the BMS or implies that it is in any way superior to breast feeding
- There are also a number of strict requirements on packaging and messaging outlining the importance of breast feeding

### KEY RISKS FOR HOME FORTIFICATION PRODUCTS

**Home Fortification products as complementary Foods** - MNPs in Bangladesh are the only precedent for this type of product and they have not been considered foods and so not subject to the provisions of the Ordinance above (although subject to other restrictions as pharmaceuticals). There is no clarity and little domestic or international precedent to suggest how different formulations of home fortification products may be classed. If they are considered as foods due to their composition on positioning, they could therefore be classed as complementary foods and attract all the restrictions of a breast milk substitute.

**Home fortification products as pharmaceuticals** - If a home fortification product is not classed as a food, this may also point to it being classed as a pharmaceutical by default with the restrictions which that entails.



## 4. A new Breast Milk Substitute Act 2013?

---

### CONTEXT

The Government of Bangladesh is in the process of drafting a new Breast Milk Substitute Act to replace the existing 1984 legislation. Timescales and exact content of the new Act have not been made public, although it is anticipated that the Cabinet will be presented with a version in late 2012 or early 2013.

The MoHFW has courted opinion of NGOs and Civil society groups including the Bangladesh Breast Feeding Foundation (BFF) and the Health Minister announced in August that it was intended to enact tough new laws against “aggressive marketing” of baby food companies.

Informally, the Ministry of Health and Family Welfare has indicated that the new Act will simply be designed to implement the WHO code of Marketing of Breast Milk Substitute in its entirety along with all subsequent World Health Assembly (WHA) resolutions passed since 1984.

### NEW RESTRICTIONS ON MARKETING

The drafting of the Act will be crucial in determining the legal impacts but WHA resolution 63.23 (2010) has proven restrictive in other countries for private sector wishing to engage in developing nutrition supplements for infants and may apply even if the product is not defined as a BMS:

*WHA 63.23 – requires that countries “end inappropriate promotion of food for infants and young children, and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex Alimentarius standards or national legislation;”*

The scope of this is as yet uncertain although with conservative interpretation, this could prevent any marketing or any health claims for any food products to children under the age of two.

WHA Resolution 65.6 (May 2012) called for the Director General to clarify the meaning of ‘inappropriate promotion of food’ and provide an update on the work of the Codex Commission in relation to 63.23.

### OTHER CHANGES TO THE LAW

Reports also suggest that a number of other new provisions may be contained within the new Act. These may

- Prevent healthcare professionals from attending events organised by baby food manufacturers
- Require large mandatory warnings on all breast milk substitute packaging that the product is not germ free
- Enact tougher penalties on violation of the Act for companies and individuals

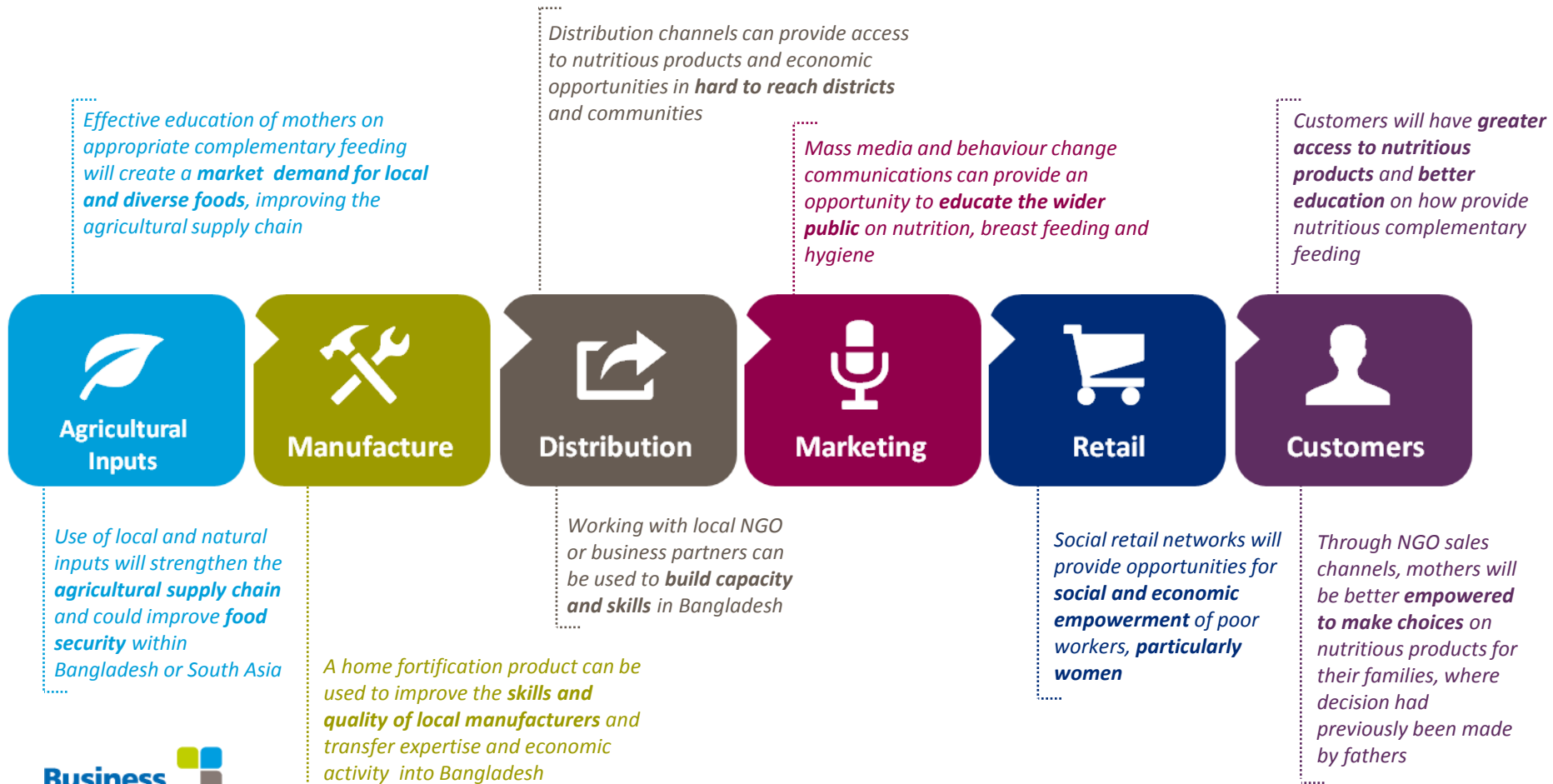


# Wider social benefits of Home Fortification Products

# Social benefits through the value chain



The value chain below identifies other key social benefits that a commercial home fortification product could potentially have depending on decisions taken on sourcing, manufacture, distribution and marketing.







# Social benefits: key themes

Alongside the nutrition impact, there are several key themes in the social value chain that can be highlighted to help to create the enabling environment for home fortification products, and build support with various stakeholders. These will depend on specific decisions taken and channels used for manufacture, distribution, marketing etc and would need to be monitored and evaluated.



A commercial home fortification product can be used to improve food security within Bangladesh or South Asia, depending on supply, manufacturing and marketing decisions. The greatest impact can be had through either use or subsequent development of the agricultural and manufacturing sector to develop local inputs. In the event of a product being manufactured elsewhere, however, effective social and mass-media marketing will help educate the public on nutritious foods and complementary feeding, leading to a greater consumer demand for diverse agricultural products, improving security within the local region.



Home fortification products could have benefits for women's empowerment in two main ways. The first is through employment in social distribution and retail sales. These initiatives have been shown to empower women both socially and economically. Secondly, mothers can be empowered through an increased ability to demand and purchase nutritious products. Traditionally fathers have purchased much of a family's food intake and adolescent mothers in particular have little choice over what they eat. NGO distribution channels have been seen as a way of opening markets directly to mothers. There is some anecdotal evidence that this has led to mothers asking for products such as contraceptives to be sold through these channels so they have access to them.



Any new product could provide increased economic opportunities for all organisations and individuals involved as well as revenue for Government through associated taxes. A new home fortification product can particularly be used to provide economic empowerment at the base of the pyramid, however, through distribution and retail channels which involve those traditionally excluded from market-led approaches. There has been evidence to suggest that rural sales programmes provide economic empowerment for men and women and can transfer income from urban to rural areas.



Through the development and sale of a new home fortification product, beneficial impacts can be seen across the supply chain in terms of transfer of skills and knowledge into Bangladesh, capacity building and quality improvements. Further, if a PPP or partnership model is implemented, skills such as marketing and business case development can be shared between NGOs, central bodies and private sector companies to build the capacity. The Bangladesh Ministry of Industries is particularly keen to improve the strength of Bangladeshi industry and improve quality throughout. The Ministry of Agriculture is also keen to pursue opportunities to improve the agricultural supply chain, skills and diversity.



### Additional resources:

You will find more ideas, information and resources on innovation and inclusive business on the **Practitioner Hub:** [www.businessinnovationfacility.org](http://www.businessinnovationfacility.org).

There is useful blog by Tom Harrison on definitions and terms used in the area of nutrition:  
<http://businessinnovationfacility.org/profiles/blogs/understanding-nutrition-terms-definitions-doses-and-diets>

### Further interesting resources on this topic include:

Frequently asked questions from the Home Fortification Technical Advisory Group: <http://hftag.gainhealth.org/faq>

A report on supplements by Food and Nutrition Technical Assistance and USAID:  
[http://www.fantaproject.org/downloads/pdfs/Bangladesh\\_LNS\\_Acceptability\\_Feb2012.pdf](http://www.fantaproject.org/downloads/pdfs/Bangladesh_LNS_Acceptability_Feb2012.pdf)

A short report by the Global Alliance for Improved Nutrition:  
[http://www.gainhealth.org/sites/www.gainhealth.org/files/Renata\\_BRAC.pdf](http://www.gainhealth.org/sites/www.gainhealth.org/files/Renata_BRAC.pdf)

An update report on In-Home Fortification with Micronutrient Powders from Sight and Life  
[http://www.sightandlife.org/fileadmin/data/Magazine/2012/26\\_2\\_2012/positions\\_statements\\_in\\_home\\_fortification\\_with\\_micronutrient\\_powders.pdf](http://www.sightandlife.org/fileadmin/data/Magazine/2012/26_2_2012/positions_statements_in_home_fortification_with_micronutrient_powders.pdf)

The Business Innovation Facility (BIF) is a pilot project funded by the UK Department for International Development (DFID). It is managed for DFID by PricewaterhouseCoopers LLP in alliance with the International Business Leaders Forum and Accenture Development Partnerships. It works in collaboration with Imani Development, Intellectap, Renaissance Consultants Ltd, The Convention on Business Integrity and Challenges Worldwide. The views presented in this publication are those of the author(s) and do not necessarily represent the views of BIF, its managers, funders or project partners and does not constitute professional advice.

We welcome feedback on our publications – please contact us at [enquiries@businessinnovationfacility.org](mailto:enquiries@businessinnovationfacility.org)

January 2013