



FEED THE FUTURE BUSINESS DRIVERS FOR FOOD SAFETY

Cooperative Agreement No. 720BFS19CA00001

BD4FS Pre-HACCP Validation Audit and Badge Program - Nepal

Technical Learning Note

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Photo Credit: Preparing for the audit. Food Enterprise Solutions

Disclaimer

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BD4FS Auditor engaging with employees at Pawan Dairy Udhyog in Chitwan.
Photo Credit: Food Enterprise Solutions.

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Proper food handling at Muna Krishi Limited, Laitpur, Nepal. Photo Credit: Food Enterprise Solutions.

Key Terms

BD4FS: Business Drivers for Food Safety (created by FES)

BRC: Brand Reputation through Compliance (BRC)

CODEX: The Codex Alimentarius, or "Food Code", is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission. The Commission, also known as CAC, is the central part of the Joint FAO/WHO Food Standards Program and was established by FAO and WHO to protect consumer health and promote fair practices in food trade. It held its first meeting in 1963.

FES: Food Enterprise Solutions

FSSA: Food Safety Situational Analysis (FSSA) a survey/mapping tool that targets the challenges that small to medium food companies encounter. FES designed the FSSA with a business lens to survey and collect intelligence about key challenges and gaps in; infrastructure, service, academia, policy/regulatory, natural resources, and available financial services.

GFB: A Growing Food Business is a small- to medium-sized enterprise that seeks to expand by adopting a business model that incorporates food safety practices.

GMP: Good Manufacturing Practices

HACCP: Hazard Analysis and Critical Control Points, or HACCP, is a systematic preventive approach to food safety against biological, chemical, and physical hazards in production processes that can render the finished product unsafe and designs measures to reduce these risks to a safe level.

Key Message: A key message contains essential information that decision-makers can use to make changes in personal actions, policies, management decisions, etc. Key messages can be via internet, social media, phone apps, radio, television, public awareness campaigns, etc. BD4FS has created a phone app where a caller can listen to multiple key messages using an interactive voice system.

PRPs (Prerequisite Programs): Prerequisite programs (PRPs) are the basic conditions and activities required to sustain food product hygiene and a clean, hygienic environment throughout the food chain. The prerequisites and procedures are necessary to ensure the safety of food operations. In developing PRPs, growing food businesses (GFBs) should consider relevant information, including regulatory and legal requirements, official instructions, national and international standards, guidelines, and the codes of practice in the Codex Alimentarius'. Prerequisites are applicable for the delivery, production, handling, packaging, and transportation of food products. PRPs are at the center of the food safety management system.¹ (See Annex _A for a list of the specific PRPs that BD4FS promotes through in-person and online training)

SME: Small and medium-sized enterprises

TOC: Theory of Change

USAID: United States Agency for International Development

WHO: World Health Organization

ZOI: Zone of Influence.

¹ Food Enterprise Solutions, 2022. Food Safety Pre-HACCP Training Course for Growing Food Businesses, P.4

Introduction

Food safety is a term that includes many aspects of supplying consumers with safer foods. It starts with safe inputs, fertile uncontaminated soil and feed, clean water, safe on-farm practices, and other important pre-requisites along the supply/value chain until it reaches consumers. Unsafe food impacts countries' economies and populations in several ways; public health, human productivity, postharvest losses, use of the natural resource base, medicine, nutrition, private sector growth, trade, and many others. It is an overwhelming and daunting issue to address and is now a major global issue as more food is commercialized and traded across the globe than ever before.

In developing countries, barriers to effective food safety systems include prohibitive costs, a lack of surveillance programs, and limited opportunities for employee education/training to name a few. There are many organizations in the nonprofit, public and private sectors addressing food safety. Most efforts target large companies looking for lucrative export markets. Few affordable/quality services are available for small- to medium- sized enterprises (SMEs). These businesses provide a substantial amount of food for local populations, and a good percentage enters the export market by way of large wholesalers and logistics firms. The mission of Food Enterprise Solutions (FES) is to energize the global food system to better balance global needs and profit. FES leverages the powers of business, entrepreneurship, and innovation as key drivers in the global fight against hunger and malnutrition. To that end, FES partners with SMEs to provide safe, nutritious, and affordable foods that are commercially viable and environmentally sustainable.

The World Health Organization (WHO) has estimated that 600 million – almost 1 in 10 people in the world – fall ill after eating contaminated food and 420,000 die every year, resulting in the loss of 33 million healthy life years (DALYs).² Furthermore, the dietary transition and associated market transformation have increased food safety risks. At the local level, SMEs supply a significant amount of food/nutrition to local populations, and many are suppliers to export supply chains as well. They play a significant role in the overall contribution to consumers' health, protection, and advancement of food regulations and standards. However, not all food companies, particularly SMEs, are able to follow demands highlighted by international and local standards and regulatory bodies. Many developing countries/emerging economies lack the resources to participate in international trade because of the difficulties in complying with the requirements of food safety standards. Often, this extends to their local food supply as well. The broad underlying reasons for this are: outdated and/or unclear laws, lack of knowledge and training, limited coordination between the private and public sectors, food loss and waste, under-funding of national research institutes, lack of awareness of standards and quality, and inadequate infrastructure.

Feed the Future Business Drivers for Food Safety (BD4FS), funded by USAID and implemented by FES, is a multi-country (Senegal, Ethiopia, and Nepal) project that works alongside SMEs, or as they are referred to in the BD4FS project, "growing food businesses" (GFBs) to co-design and implement incentive-based strategies to accelerate the adoption of food safety practices in local food systems. The BD4FS theory of change (TOC) proposes that by co-creating with GFBs to address food safety challenges and by delivering targeted training and technical assistance, and promoting business-to-business facilitation programs, GFBs will be better prepared to adopt improved food safety practices that reduce the risk of food safety hazards. Through its applied research and implementation of BD4FS, FES has developed a preparatory stage for these companies to be better prepared to participate in the broader, more difficult, and more expensive certifications to comply with both local and international trade laws. This can enable GFBs in developing markets to reduce key risks in growing a sustainable food business to meet the ever-increasing demands, needs, expectations, and trust of government food safety regulators and consumers. By focusing on the role of local food businesses in improving food safety, the FES team has added to USAID's knowledge base regarding strategies and methodologies for enterprise-level assistance in food system strengthening, developed best practices and lessons learned, and generated success stories from collaborating with entrepreneurs to improve food safety. Stakeholder engagement also raises national awareness around the issue of food safety and lays the foundation for the promotion of a "food safety culture" among all actors in a national food system.

² <https://www.who.int/news-room/fact-sheets/detail/food-safety>

BD4FS designed and implemented a Food Safety Situational Analysis (FSSA), which was first implemented in Senegal and then in Nepal and Ethiopia. Utilizing the International Livestock Research Institute (ILRI) format for collecting and analyzing information, FES designed a survey/mapping tool that targets the challenges that most SMEs face in emerging economies in upgrading their food safety standards and practices. In general, the FSSA uses a “business lens” to look at a country’s infrastructure, policies, political will, private sector approaches, and services (both agronomic and financial) targeting SMEs. The FSSA also analyzes the dynamics of specific value chain systems, especially the regulatory structure and enabling environment that affects food safety. Additionally, the FSSA touches on the main hazards, risks, and burden of public health outcomes from food-borne diseases deriving from the targeted value chains. In collaboration with the local USAID Missions, the FSSA was designed to target specific production-to-consumption corridors or “zones of influence” (ZOI).

Through this process, BD4FS identifies key actors, stakeholders, institutions, donors, etc. involved in food safety of targeted ZOIs. GFBs are the key stakeholders/clients who provide the business and social capacity to improve food safety. Key stakeholder surveys, meetings, and focus groups are held with public sector officials, policy and regulatory offices and agencies at different levels of government (local, regional, national), universities and food science programs, engineering/agriculture groups, food safety testing facilities/labs, civil society actors, private sector food companies and service providers, as well as financial institutions that provide financial and non-financial services, capital investors, consumer advocacy groups, etc.

This process allows BD4FS to identify the principal constraints; technical knowledge base, cultural, financial access, infrastructure, policy, business and consumer awareness, and regulations that impact GFBs. Data and information collected are analyzed and used to co-design strategies and activities that help businesses accelerate the adoption and use of technologies and practices that improve food safety and reduce food loss to retain the nutritional value of foods in the marketplace.

Brief History of Food Safety & HACCP

Broadly, HACCP is a preventive-based system for improving/assuring food product safety. Biological, physical, and chemical hazards can be prevented, reduced, or eliminated through this system. The HACCP concept was first developed in the 1960s by the U.S. National Aeronautics and Space Administration (NASA), working with Pillsbury, to ensure that crumb and pathogen-free food had extensive shelf-life properties for space travel. This was the first pathogen monitoring and measurement requirement imposed on the food industry (Lachance, 1997).

Between the 1970s and early 1990s, there were landmark food-borne outbreaks in both Europe and the United States which spawned a series of national as well as international meetings, conferences, regulatory laws, etc. In 1983, the WHO released a report on HACCP and its use to slow food born illness. In 1993, CODEX issued the first international HACCP guidelines. Since then, the international food trade has expanded to such an extent that food importers/exporters need a certification to gain a market share, like HACCP, as well as other audit/certification programs, like International Standards of Operation (ISO) which has various subcategories like ISO 22,000, ISO 9001, Brand Reputation through Compliance (BRC), etc.

The United States has fully embraced HACCP both as a part of a successful business plan as well as a regulatory requirement in meat and poultry production since the implementation of the Pathogen Reduction, HACCP Systems Final Rule in 1996. The E.U. has proactively adopted food laws for its 28 member countries that apply to other countries that trade with member nations to the E.U. The European Food Safety Authority (EFSA) was established by the General Food Law in 2002 and is responsible for risk assessment (European Food Safety Authority, 2018).

Development and adoption of food safety systems is very inconsistent among developing countries. Emerging economies are still in an evolutionary stage and there are several barriers to successfully implementing HACCP or other food safety systems. Some countries have required partial adoption of HACCP in their processing plants, whereas others have struggled. Red meat production in China has grown

at a rate of 5.8% annually. However, less than 10% of their production facilities are HACCP certified. As of now, in Latin America and the Caribbean (LAC), Africa, and in parts of Asia, there is limited formal reporting of outbreaks of food born illnesses and transparent tracking of contaminated food. Developing countries still struggle with uniform regulatory implementation of food safety standards. To continue to decrease foodborne illness worldwide, focus needs to be expanded on increasing implementation of these proven systems in developing countries, particularly at the SME level.

BD4FS Methodology

The BD4FS FSSA discovered significant food safety challenges for Nepalese GFBs. Some of the most critical are the need for more accessible and affordable training as well as auditing and certification services on the functional implementation aspects of food safety within an emerging economy context. This need led to the design of the “BD4FS pre-HACCP Validation Badge.” Based on the analysis from the FSSA, FES’ knowledge of SMEs, key FES staff and food safety experts, the BD4FS team reviewed multiple food safety standards and certifications and selected certain aspects from these that GFBs could adopt and improve upon to provide safer foods for consumers without major financial investments. Knowledge of the SME context was applied as a “lens” to create a model that BD4S could test. The Food Safety team reviewed multiple food safety pre-requisites, standards of operations, local regulations, hazard analysis critical control points or “HACCP,” BRC (Brand Reputation through Compliance), good manufacturing practices (GMPs), food safety checklist from the International Finance Corporation’s Food Safety Handbook, and many others, all which are based on the United Nations Codex Alimentarius requirements and best industry practices and standards. Additionally, the Nepali policy and regulations for food safety were thoroughly reviewed and applied to the method to ensure local compliance. This methodology is used in other BD4FS countries as well.

BD4FS Audit Objectives: Evaluate the implementation of the BD4FS Pre-HACCP Validation training program and uptake by GFBs on food safety practices and applicable technologies.

BD4FS Creating Incentives to Improve Food Safety in Nepal

GFB Identification & Selection

Working in partnership with local USAID Missions priorities, BD4FS focuses on values chains that are important to USAID’s “zone of influence.” FES uses a systematic and efficient approach in identifying growing food businesses for the BD4FS project. Of the 23 companies that were audited, three were woman owned and six had female managers. FES developed a series of workshops, focus groups, and surveys where companies learn about BD4FS, and the services provided. From there, companies self-determined if they want to join. Those that agreed sign MOUs with BD4FS and then participate in the BD4FS pre-HACCP Validation Badge program. Potential GFB participants were selected from:

- Contacts in BD4FS studies (e.g., FSSA),
- Networks of the BD4FS team: trade organizations, etc.,
- Research and recommendations from institutional organizations and local partners.

From there, the selection process is based on several factors but the most important being the “will” of the owner/operator to embrace food safety improvements within their business. To participate in the BD4FS pre-HACCP Validation Badge program, potential GFBs must meet the following criteria as collected in the FSSA and workshops:

- GFB must have growth potential,
- An autonomous company (no government ownership),
- Have a brand name, or building a brand name or have respected products in the market,
- Have minimum qualifications; a physical space, basic business systems (bank account, business plan, etc.) and a clientele,
- An owner/operator dedicated to improving food safety for business acumen and consumer safety,
- Have linkages with supply/value chain actors (at various levels of production, processing, distribution, and marketing),

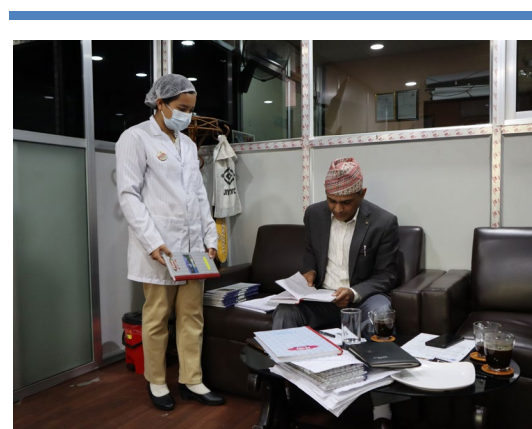
- Working in perishable food value chains (fresh fruit & vegetables (FFVs), meat, poultry, dairy, and fish) as perishable foods face higher food safety risks, postharvest losses, and are nutrient dense.
- Willing and capable of investing time in trainings & audits,
- Size of company: cannot be a multinational, or a “large” company as defined by the World Bank and local financial definitions,
- Must have a domestic focus, but can include products for export,
- Staff profiles can include operator/manager, any food safety experts on staff, laboratory staff, laborers, etc.

It is important to note that the audit and gaining a BD4FS validation badge is not a certification, nor does it ensure that all products are risk-free. Rather, the audit validates that the business is implementing the correct processes to provide safer food and decrease the risk of foodborne illnesses. BD4FS staff communicates this with the GFBs prior to signing an MOU.

Audit Process

The BD4FS team works with our partner Brighthouse, to select a professional auditor with an extensive background working with large certification companies but who also had knowledge and experience working with GFBs in a developing economy context. The team worked with the auditor to draft the BD4FS Pre-HACCP “conformity document” based on standard certification audits and a “pre-audit” checklist for the GFBs. This was shared with the GFBs two weeks ahead of the audit to give them time to prepare. The audit calendar/schedule and allotted time for each GFB was determined and scheduled.

The BD4FS audit team carried out twenty-three (23) audits to validate the GFBs implementation of the BD4FS Pre-HACCP training standards as laid out in the conformity document. Each audit took between 2-4 hours (3 hours on average) depending on the size of the GFB. While the audit process was difficult for some, all twenty-three companies expressed their appreciation of the auditor’s professionalism and that the BD4FS training and audit process was very professional and did not make them feel like the recipient of a giveaway program.



Documentation review during the BD4FS Pre-HACCP Validation Audit (QC In-Charge and Auditor).
Photo Credit: Food Enterprise Solutions

“The primary achievement from the BD4FS program / FES is empowerment through knowledge on food safety. It helped us to better engagement of our team members for assuring food safety. We have observed that the processes for safer food have become more systematic and efficient.”

GFB owner on BD4FS technical assistance leading up to the audit.

Figure 1 Profile of the 23 Companies

Company Industry	Audit Date	Scale* (micro, small, medium, etc.)
1. Fruits and Vegetable Processing	4 September 2023	S
2. Fruits and Vegetables Processing	4 September 2023	S
3. Dairy Processing	5 September 2023	M
4. Meat Processing	5 September 2023	S
5. Dairy Processing	7 September 2023	M
6. Dairy Processing	7 September 2023	S
7. Meat Processing	8 September 2023	M
8. Fruits and Vegetable Processing	8 September 2023	S
9. Meat Processing	11 September 2023	M
10. Fruits, Vegetable, Cereals and Legumes Processing	12 September 2023	M
11. Fruits and Vegetables Processing	12 September 2023	M
12. Fruits and Vegetables Processing	13 September 2023	S
13. Dairy Processing	13 September 2023	S
14. Dairy Processing	20 September 2023	M
15. Dairy Processing	20 September 2023	M
16. Dairy Processing	21 September 2023	S
17. Dairy Processing	21 September 2023	S
18. Meat Processing	22 September 2023	S
19. Meat Processing	22 September 2023	S
20. Meat Processing	23 September 2023	S
21. Meat Processing	23 September 2023	S
22. Meat Processing	24 September 2023	S
23. Meat Processing	24 September 2023	S

*BD4FS Nepal uses the Asian Development Bank definition of Small and Medium Enterprises as having a maximum of 50 employees

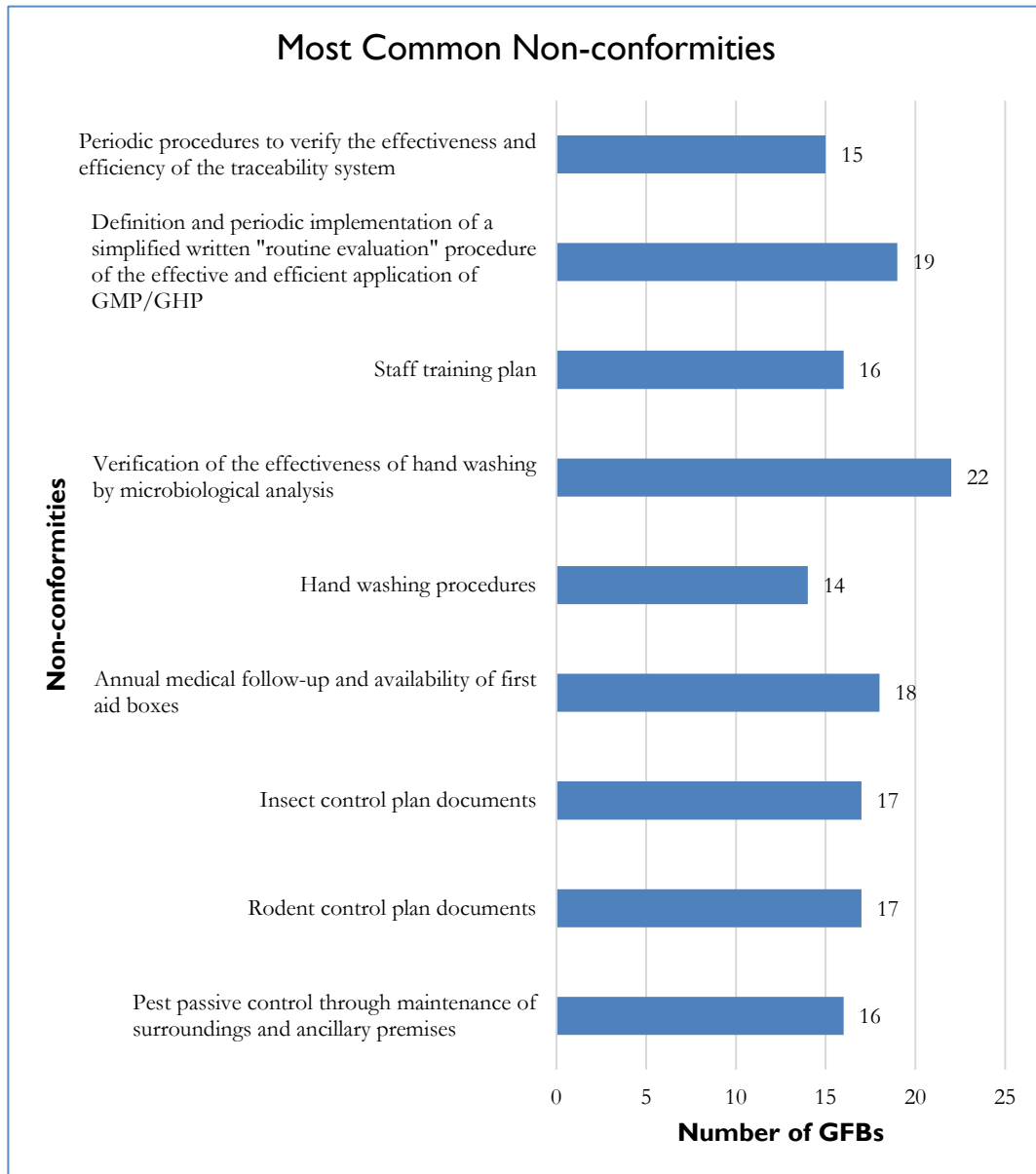
Post Audit – Validation

BD4FS Nepal gave each GFB a confidential audit report that included a grading system for each prerequisite, Standard Operating Procedures (SOPs), etc., along with pictures that showed any conformity issues the company may have had. BD4FS Nepal received help from a photographer to document conformity issues accurately and clearly. There were several conformity issues that were cross-cutting:

1. Validation of cleaning effectiveness
2. Pest Control

3. Medical Health Checkup
4. Establishment of documented information (procedures)
5. Conduction of analytical tests

Figure 2: Most Common Non-conformities



The GFBs that did not pass the initial audit were given 30 days to rectify both major and minor non-conformity issues. The Nepal Food Safety expert reviewed their updated conformities and shared these with the auditor to decide pass/fail. The auditor determined that 16 out of the 23 GFBs passed the audit and earned the BD4FS Pre-HACCP Validation Badge. This is a commendable pass rate of 69.5% successfully meeting the required standards.

The GFBs documented the following impacts, both immediate and forthcoming, of earning the BD4FS Pre-HACCP Validation Badge.

Benefits

- Enhanced knowledge on food safety
- Compliance with the regulatory food safety requirements
- Realization of importance of documentation and record keeping
- Strengthened operational processes.
- Recognition / brand reputation through acquiring the badge.
- Identification of the lapses related to food safety.
- Planning for the improvement of food safety implementation.

Risks

- Higher costs to address the food safety requirements require financial investments.
- Negative image in case of discontinuation of the badge recognition
- Requirement of competent technical personnel
- Traditional infrastructures that is difficult to re-structure

Analysis

As stated, the aim of the BD4FS Pre-HACCP Badge program is to train GFBs in basic food safety PRPs, SOPs, use of technologies and verify the level of implementation via a professional audit. BD4FS awarded successful GFBs a badge that they can display on their “storefront” and in their branding/promotional material. The BD4FS Pre-HACCP Validation process provides a “preparatory” phase to better prepare, understand and correct major food safety non-conformities. The badge serves as a sign of accomplishment for the GFB and can inform consumers that the GFB’s efforts have been validated to produce safer products compared with competitors. Again, it is important to note that the BD4FS validation badge is NOT a certification, nor does it ensure that all products are risk-free. Rather, the badge signifies that the business is implementing the correct processes to provide safer food and decrease the risk of food born illnesses. The BD4FS Pre-HACCP Validation program addresses Nepal’s need for validation and training but does not usurp the authorities in the country.



BD4FS Pre-HACCP Validation Badge.
Photo Credit: Food Enterprise Solutions

NEPAL ADHERES TO THE CODEX ALIMENTARIUS’ STANDARDS AND HAS A NATIONAL CODEX COMMITTEE RESPONSIBLE FOR REPRESENTING NEPAL AT CODEX MEETINGS AND NEGOTIATIONS, ADVISING, AND SENSITIZING THE GOVERNMENT AND PRIVATE SECTOR INTEREST GROUPS TO CODEX FOOD SAFETY STANDARDS AND THEIR APPLICATIONS.

Company Feedback

Assistance prior to audit

BD4FS Pre-HACCP Training was the initial phase of food safety implementation which was effective in creating awareness among the food handlers and harmonizing momentum for strengthening the food safety culture. Further, technical assistance prior to the audit assisted the GFBs in ensuring proper implementation of the prerequisite programs. Participating GFBs reported that the periodic technical assistance – physical as well as virtual – with the food safety experts helped GFBs to intervene in the constraints for the implementation of food safety management. The internal audit checklist for the self-assessment provided the GFBs with the opportunity to self-check and address the basics of food safety requirements. GFBs that participated in the audit reported that they are glad they were a part of the program and that it can help them enter new markets.

In response to BD4FS training and technical assistance, many businesses that participated in the audit have already made investments to improve their food safety practices. Such improvements include new testing laboratory equipment, infrastructure changes, cleaning and sanitation practices, using appropriate equipment and tools, proper uniforms, proper handwashing stations, measuring and monitoring equipment calibration, etc. Some investments were less expensive but still highly effective; these include reorganizing a facility's workflow, cleaning practices, establishment of procedures and formats for record keeping, and following a strict operational parameter.



Site tour during the audit of the fruits and vegetables processing GFB. Photo Credit: Food Enterprise Solutions

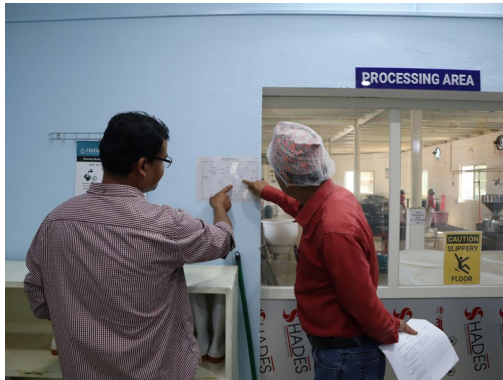
“Working with BD4FS Program/FES increased the awareness level of our team on food safety which has resulted in proper implementation of food safety management system within the processing facility. We have been able to provide quality assurance to our customers and we are sure that we have been able to meet and exceed their satisfaction level.”

GFB owner on how the team benefited from the BD4FS training and audit.

Improving the BD4FS Pre-HACCP Audit Process

After completion of the audit, BD4FS Nepal Team reviewed the overall audit program and its findings. Outcomes of the interaction with GFBs were considered during the review process.

- Extended support for establishment of proper documentation
- Extensive in-house trainings to the food handlers
- Frequent visits of the experts before the scheduled audit



Discussion on food safety aspects during the audit.
Photo Credit: Food Enterprise Solutions

“Continuous support from the experts through training and technical assistance has helped us to establish and implement a robust food safety system within the organization. We could formalize the food safety practices and establish a proper documentation system. Furthermore, we are confident that we can proceed for HACCP implementation and certification as well.”

GFB owner on the impact of BD4FS Program in their business.

The BD4FS Pre-HACCP Validation Badge program has been perceived by the GFBs as an effective tool for identifying and addressing critical food safety issues. The commitment of the participating GFBs was appreciable. As the certification to HACCP and other recognized food safety standards are quite expensive, the badge program has been regarded as an ideal program to self-assess the status of food safety implementation of the food businesses and to leap towards continual improvement in the system. Furthermore, the provided BD4FS badge has been expected by GFBs to be equally helpful for recognition of the brand, which will increase demand and provide better market access opportunities.

Major challenges faced by the Nepali GFBs for the proper implementation of food safety systems seems to be establishment and implementation of documentation (including record keeping), and the infrastructural aspects. Rigorous technical assistance for establishment of documentation and formats for record keeping and orientation on the proper documentation will help GFBs maintain sound food safety systems. Consultation with the food safety experts while designing or restructuring the food establishment will help to overcome most of the GFB's food safety issues.

The Pre-HACCP validation program emphasizes the implementation of prerequisites and control of operational processes rather than overly documented food safety management systems and it is affordable unlike other expensive food safety standard certifications. These sorts of validation programs will help harmonize the establishment, implementation,

maintenance, updating and improvement of the food safety management system within the business. The external validation from food safety experts will help to enhance the knowledge of food handlers on food safety and the identification of any nonconformities in the system during the assessment will be addressed, thereby ensuring critical food safety standards are applied and food safety systems are strengthened.

APPENDIX A

BD4FS Pre-HACCP Validation Badge PRPs

PRP is the term used for food safety prerequisites. Below is the list of PRPs that are provided in the BD4FS training (each is supply/value chain specific):

- Module 1: Cleaning and Disinfection Procedures
- Module 2: Preventing Cross-Contamination
- Module 3: Personal Hygiene and Employee Facilities
- Module 4: Equipment Cleaning and Maintenance
- Module 5: Waste Disposal
- Module 6: Utilities: Clean Water, Air, and Energy
- Module 7: Premises and Workspaces
- Module 8: Design and Construction of Establishments
- Module 9: Supplier Management
- Module 10: Pest Control
- Module 11: Reprocessing
- Module 12: Withdrawal and Recall of Products
- Module 13: Warehousing and Storage
- Module 14: Product Information
- Module 15: Food Defense, Vulnerability and Threats
- Module 16: Cold Chain Technology, Heat Treatment Technology, Food Formulation
- Module 17: Allergens Control
- Module 18: Control of Foreign Bodies
- Module 19: Document Management

APPENDIX B

AUDIT OF THE IMPLEMENTATION OF PRPs IN A GFB

Presentation of the GFB

Name of company:		
Business sector:		
Owner's name:		
Manager's name:		
Full Address:		
Telephone:	- email address:	
Number of employees:	female:	male:

Audit Details

Date of the audit:	
Scope of audit:	
Auditor's name:	
Start time:	End time:

Audit Objectives

1. Evaluate the implementation of the BD4FS pre-HACCP prerequisites program
2. Identify major non-conformities and minor non-conformities
3. Identify corrective actions

People met during the audit:

Full name	Function

Characterization of findings:

- Minor Non-conformity: Where a clause has not been fully met but based on objective evidence, the safety of the product is not in doubt.
- Major Non-conformity: When there is a substantial failure to meet the requirements of any clause of the training standards or a situation is identified which would; based on available objective evidence; raise significant doubt on the conformity of the product being supplied (in orange on the grid).

The criteria applied are derived from:

- Applicable Nepali hygiene regulations,
- Codex Alimentarius CAC/RCP 1-1969, Rev 4-2003

Food Safety Badge Grading Criteria

This grading criterion is used in conjunction with the BD4FS Food Safety Audit Checklist, to validate that a GFB, upon receiving HACCP PRP training by FES, has understood, and implemented safety standards to a level that warrants awarding a BD4FS Pre-HACCP Validation badge. The grade is determined by the number and severity of non-conformities identified at the time of the audit.

<u>Grading system</u>		
STANDARD	NON-CONFORMITIES	
	MAJOR	MINOR
Pass – Gold Level	0	≤16
Pass – Silver Level	2	≤ 16
No Pass Improvements needed	^ 2	^ 16

Procedures for handling non-conformities and corrective actions

Following the identification of any non-conformities during the audit, the GFB must take corrective action to remedy the immediate issue (correction). Then, the GFB must undertake an analysis of the underlying cause of the non-conformity (root cause) and develop a preventative action plan to address the root cause and prevent a recurrence.

In the case of GFBs not meeting the passing criteria, they shall implement corrective action and close out the non-conformities within a minimum of 28 calendar days. Confirmation of non-conformity closeout can be presented to FES in the form of evidence (photos, video, records, updated procedures, or invoices of work undertaken) or by a follow-up site visit by FES staff.

BD4FS PREHACCP AUDIT GRID

I. Premises and workspaces

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
1.	1.1. Conformity of the premises: general organization <i>Conformity of the establishment's immediate surroundings</i> <i>Areas subject to flooding or pest infestation</i> <i>The presence of solid or liquid waste that is difficult to dispose of</i>			
2.	1.2. Doors in sufficient number: <i>Raw material door</i> <i>Worker door</i> <i>Finished products door</i> <i>Waste door</i>			
3.	1.3. Compliance with the onward flow principle <i>Products move forward with no turning back</i> <i>From 'less developed' to 'more developed' and from less safe to safer zone</i>			
4.	1.4. No crisscross of the production lines			
5.	1.5. Separation of cold zone and hot zone			

C= compliant; NC= Not compliant; NA= Not Applicable

I. Premises and workspaces

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
6.	1.6. Separation of clean sector and unclean sector			

	<i>Immediate and direct disposal of the waste to its storage area (bin room). Immediate transfer after use of materials to the dishwasher</i>		
7.	1.7. Water supply potability <i>-In sufficient quantity -Of quality satisfied -Potable and non-potable water are clearly separated and identified</i>		
8.	1.8. Sewage disposal system		
9.	1.9. Floors: <i>-Floor covering smooth, light-colored, washable, resistant -waterproof -Anti-slip -Rot proof -Slightly inclined to facilitate the removal of wash water to a drainage system with grids and traps -Floor grids and U-bends to collect wastewater</i>		

I. Premises and workspaces

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
10.	1.10. Walls <i>-Wall coverings: smooth, light-colored, washable, impervious -Floors and walls jointed by round gorge assemblages -Rot proof -Shock-resistant -Compliance of doors and windows</i>			

11.	1.11. Ceilings: <i>-Washables</i> <i>-smooth</i>		
12.	1.12. Ventilation devices <i>-Ventilation devices ensure steam and smoke elimination</i>		
13.	1.13. Lightings: <i>-Bright</i> <i>Neutral in color</i>		
	Number of MINOR non-conformities		
	Number of MAJOR non-conformities		

II. EQUIPMENT SUITABILITY CLEANING AND MAINTENANCE

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
14.	2.1. Material: -Smooth -Washable -Rot proof -Inalterable -Authorized without prohibited items			
15.	2.2. Work surfaces: -Smooth -Light colored -Washable -Rot proof -Inalterable -Impervious -Authorized without prohibited items			
16.	2.3 Furniture: -Inalterable -Authorized without prohibited items			
17.	2.4. Machines: -Made with durable materials -Easy to disassemble -Easy to clean and disinfect			

II. EQUIPMENT SUITABILITY CLEANING AND MAINTENANCE

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
18.	2.5. Maintenance plan <i>-Cold installations-preventive maintenance</i> <i>-Equipment-preventive maintenance and calibration</i> <i>-Operators have skills to identify maintenance tasks to plan</i> <i>-Predictive and corrective maintenance saved</i>			
	Number of MINOR non-conformities			
	Number of MAJOR non-conformities			

III. PEST CONTROL

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
19.	3.1. Pest Passive control through maintenance of surroundings and ancillary premises <i>- Insulated storage of unused materials and equipment</i> <i>- Tidy and clean outdoor spaces</i> <i>- Interior surfaces kept tidy and cleaned so as not to be used by nutrients for insects</i> <i>- Installation of screens on doors and windows</i> <i>- Strict management of waste containers (frequently washed and maintained closed even full)</i>			
20.	3.2. Pest Active control* Visual detection of pests <i>Insects</i> <i>Rodents</i>			

*Visual detection of pests can be classified as major or minor NC at the discretion of the auditor and the country guidelines

III. PEST CONTROL

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
21.	3.3. Rodent control plan documents -Technical data sheet of products used -Mapping of the trap -Follow-up procedure -Corrective action procedure			
22.	3.4. Insect control plan documents -Technical data sheet of products used -Mapping of the insect killer devices -Control procedures of the operations -Corrective action procedure			
	Number of MINOR non-conformities			
	Number of MAJOR non-conformities			

IV. SUPPLIER MANAGEMENT

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
23.	4.1. Raw material specifications -Criteria for acceptance of batches -Supplier evaluation -Labelling requirements -Microbiological standards -Toxicological standards -Purity standards (foreign object control)			
24.	4.2. Control of raw materials received -Temperature control of raw materials (Compliance with specified criteria for each product) -Receiving records -Respect of shelf life -Labelling compliance with official food safety marking rules (authorization FRA) -Coding procedure for traceability system -Cleanliness of the delivery vehicles			
	Number of MINOR non-conformities			
	Number of MAJOR non-conformities			

V. EMPLOYEE HYGIENE

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
25.	5.1. Annual medical follow-up and availability of first aid boxes			
26.	5.2. Sanitary facilities <i>Toilets designed to provide good hygiene</i> <i>Changing rooms with showers for the production staff</i>			
27.	5.3. Hand hygiene Washstands: <i>In sufficient numbers</i> <i>Placed near work stations</i> <i>Equipped with non-manual operating valves</i> <i>Equipped with a bactericidal soap dispenser</i> <i>Equipped with a synthetic nail brush</i> <i>Equipped with a disinfectant dispenser</i> <i>Equipped with a single use drying system</i> <i>Accompanied by a poster reminding people of the hand washing rules</i>			

V. EMPLOYEE HYGIENE

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
28.	5.4. Hand washing procedures <i>-Clearly written</i> <i>-Presented and explained to all the staff</i>			
29.	5.5. Other hygiene restrictions <i>-Smoking in work clothes</i> <i>-Eating or chewing gum while in work clothes</i> <i>-Wearing watches, rings, or jewelry in the production area</i> <i>-Wearing long nails or nail polish</i>			

30.	5.6. The use of foot baths or boot washers (fixed or mobile) containing an antiseptic solution before entering the production area		
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V. EMPLOYEE HYGIENE

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
3	5.7. Clothing hygiene -standard work clothing supplied by the company -washing of clothing by the company or under its responsibility -management of clean and dirty clothes –lockers with two compartments -boots/shoes washstands in conformity with standard			
	Number of MINOR non-conformities			
	Number of MAJOR non-conformities			

VI. CLEANING AND DISINFECTION

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
32.	6.1. Material hygiene: the cleaning and disinfection plan			
33.	6.2. Establish written cleaning and disinfection procedures			
34.	6.3. Cleanliness of tools during production <i>Tools are regularly replaced in hot water (82°C) or cleaned at regular fixed intervals by an equivalent method</i>			
35.	6.4. List the detergents and disinfectants used (datasheet)			
36.	6.5. Separate lockable storage of detergent and disinfectant			

37.	6.6. Recording of operations and verification of cleaning efficiency (visual cleanliness and microbiological control of surfaces)		
	Number of MINOR non-conformities		
	Number of MAJOR non-conformities		

VII. COLD CHAIN

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
38.	7.1. Refrigeration <i>-Compliance with the temperature of refrigerated products (raw materials, partially processed products, finished products)</i>			
39.	7.2. Good manufacturing practices for the use of positive cold rooms <i>-Protective packaging of stored goods -No stacking of unprotected foods -Storage of raw materials and finished products in separate refrigerators -Respect of the FIFO (“first in – first out”) -Strict adherence to expiry date -No ground storage -Regular cleaning of ventilation systems (refrigeration units and sleeves) -Regular monitoring and recording of temperatures</i>			

VII. COLD CHAIN

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
40.	1.3 Products cooled rapidly by the freezing operation -Frozen products kept at -18°C (or other T° for certain products) $\pm 2^{\circ}\text{C}$			
41.	7.4. Good manufacturing practices for the use of negative cold rooms: -Regular monitoring and recording of temperatures -Respect of the FIFO "first in-first out" -Do not freeze products in negative cold storage			
42.	7.5 Thawing procedure to avoid any temperature rise that may cause a health risk			
	Number of MINOR non-conformities			
	Number of MAJOR non-conformities			

VIII. HEAT TREATMENT

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
43.	8.1. Rules specific to cooking: -Temperature and cooking time defined and controlled for each product -Core temperature of products $\geq 63^{\circ}\text{C}$			
44.	8.2. Rules common to pasteurization and sterilization -Definition of a scale (time and T°) previously validated for all products to obtain a sufficient "sterilizing value" -Control and recording of the application of the sterilization scale for each production batch			

	-Control of the tightness of the seals and packaging		
	Number of MINOR non-conformities		
	Number of MAJOR non-conformities		

IX. SELF CHECK

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
45.	9.1. Prevention of physical contamination by foreign items: <i>-Installation of metal detectors (metal particles)</i>			
46.	9.2. Prevention of contamination by packaging: <i>-Selection of non-toxic materials (see also point 4.1)</i>			
47.	9.3. Verification of the effectiveness of hand washing by microbiological analysis.			
48.	9.4. Checking the effectiveness of cleaning and disinfection			

IX. SELF CHECK

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
49.	9.5. Sampling and analysis plan <i>-Establish and carried out under contract with a laboratory -Applied to finished products (and possibly raw materials and in-process products)</i>			

	-Referring to microbiological criteria (qualitative and quantitative)		
50.	9.6. Microbiological control plan for water and ice		
51.	9.7. Temperature control of products during the process		
	Number of MINOR non-conformities		
	Number of MAJOR non-conformities		

X. TRAINING

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
52.	10.1. Staff training plan			
53.	10.2. Timetable and contents of training activities			
54.	10.3. Provisional timetable for implementation			
55.	10.4. An individual sheet per operator, summarizing the training received			
56.	10.5. Definition and periodic implementation of a simplified written "routine evaluation" procedure of the effective and efficient application of GMP/GHP			
	Number of MINOR non-conformities			
	Number of MAJOR non-conformities			

XI. TRACEABILITY

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
57.	<p>11.1. The labelling shall comply with Codex requirements for pre-packaged foodstuffs, and with the regulatory requirements of the country where it is marketed with at least:</p> <p><i>The components of the product in descending order</i></p> <p><i>The registration number of the establishment (agreement, FRA...)</i></p> <p><i>The use-by date or the expiration date</i></p> <p><i>The production batch number</i></p>			
58.	<p>11.2. Finished products containing declarable allergens must be declared in accordance with the legal provisions in force. The labelling of incidental and trace allergens must be based on a risk analysis</p>			
59.	<p>11.3.A traceability system shall be in place, allowing for the identification of product batches and their relationship to raw material batches, packaging in direct contact with food, and packaging intended for or intended to be in direct contact with food. The traceability system should include all relevant production and distribution records</p>			
60.	<p>11.4. Traceability must be guaranteed at all stages, including in-process production, reprocessing, and recycling</p>			

XI. TRACEABILITY

	Items to check	Findings and objective evidence	Compliance level	
			C	NC
61.	11.5. Periodic procedures to verify the effectiveness and efficiency of the traceability system: <i>Carrying out upstream traceability simulations</i> <i>Carrying out downstream traceability simulations</i>			
62.	11.6. Procedures of the withdrawal and recall of foodstuffs that may present a risk to the consumer <i>Drafted in advance and available in the establishment</i> <i>Know and understood by operators concerned and by the management</i>			
	Number of MINOR non-conformities			
	Number of MAJOR non-conformities			

Summary

Total number of MINOR non-conformities	
Total number of MAJOR non-conformities	
DECISION	

Corrective actions or follow-up plan (see an example on the following page)

OBSERVATION	ACTION PLAN	P	TIME
Floor, wall, ceiling is constructed of cement easy to clean but some cracks existed in the floor.			
Wall/floor junction of the processing area and receiving area was not curved.			
Garbage bin does not exist and the only one is not covered and not identified.			
Hand washing area is available for the company, soap or sanitizer was not available.			
Water taps were hand-free and sanitizer not available			
Water tanks are not available, their usage is rarely and water from is government sources but no analysis for water.			
Inspection programs were not available, and their records non-existent.			