#### **Annexure-A**

File No: TIC/1/2024-IMPORTS-FSSAI

Food Safety and Standards Authority of India

(A Statutory body under Ministry of Health & Family Welfare, Government of India)

(Trade and International Cooperation Division)

FDA Bhawan, Kotla Road, New Delhi-110002

Dated: 13 September, 2024

#### Office Order

Subject: Implementation of "Agreement" signed between FSSAI, Ministry of Health and Family Welfare, Government of India and Bhutan Food and Drug Authority (BFDA) -reg.

This is to inform that an "Agreement" is signed between FSSAI, Ministry of Health and Family Welfare, Government of India and Bhutan Food and Drug Authority (BFDA), Ministry of Health, Royal Govt. of Bhutan, at Thimphu on 21 March, 2024. The Agreement aims to recognize the official control exercised by BFDA on Food Business Operators (FBOs) as equivalent to FSSAI's requirement and the BFDA shall issue a Health Certificate as proof of compliance with the requirements prescribed by FSSAI, for export of food products to India.

- 2. For compliance and smooth implementation of the above said agreement, it is informed that all the concerned officers shall ensure the compliance of following requirements:
  - I. If the Imported food consignment from the Bhutanese manufacturer with the scope of approval as per the list attached, is accompanied with the prescribed Health Certificate duly issued by the BFDA Competent Authority, then NOC may be given to the consignment based on the duly complaint accompanied Health Certificate. Enclosures as below:
    - a. Copy of approved Health Certificate
    - b. Copy of signatures of the Authorized signatories issuing the Health Certificate
    - c. List of approved establishment of Bhutan with scope of approval
- 3. This issues with the approval of the Competent Authority.

Encl: As above

(Manvesh Kumar, IRS)
Director (Imports)
dir-imports@fssai.gov.in

To:

- 1. Authorized Officers, FSSAI- for information and to ensure compliance
- Customs Officers notified as Authorized Officers- for information and to ensure compliance

Copy for information to:

- 1. PS to CEO, FSSAI
- 2. PA to ED (TICD), FSSAI
- 3. Regional Directors, FSSAI (All)- for sensitization of concerned importers

### **Annexure-B**

SN	FSL Client	Approval Number  (Food Safety License Number)	Product Scope	Validity of Food Safety License
1	Zimdra Food Pvt Ltd, Chukha	FSL-C/17/A001	Fruit Juices & UHT Milk	The License has no validity; however, it is subjected to annual surveillance inspection based on risk score (risk-based inspection planning)
2	Namgay Artisanal Brewery, Paro	FSL-PA/17/A002	Beer & Apple cider	-do-
3	ICE Beverages Pvt. Ltd, Samtse	FSL-S/18/A003	Fruit Juices & Packaged Drinking Water	-do-
4	Veen Waters Bhutan Pvt Ltd, Samtse	FSL-S/18/A004	Natural Mineral water	-do-
5	Bhutan Spring Penzogyam, Thinleygang, Punakha/Wangdue	FSL-PU/18/A005	Packaged Drinking Water	-do-
6	Gelephu Distillery, AWPL, Gelephu	FSL-SG/18/A006	Alcoholic Beverages	-do-
7	Samtse Distillery, AWPL, Samtse	FSL-S/18/A007	Alcoholic Beverages	-do-

8	Kinjore Brewery Pvt. Ltd, Chukha	FSL-C/19/A012	Beer	-do-
9	Serbhum Microbrewery, Thimphu	FSL-TH/19/A014	Beer	-do-
10	Living Water of Bhutan Pvt Ltd, Thimphu	FSL-TH/20/A019	Packaged drinking water	-do-
11	Chuniding Foods, Thimphu	FSL-TH/19/A020	Fruit & Vegetable products, Spices, Grains, Cereal products, Ciders & vinegars	-do-
12	OGOP Unit, Motithang, Thimphu	FSL-TH/19/A024	Assorted dried and processed food products	-do-
13	Bhutan Agro Industries Ltd, Mongar	FSL-M/20/A025	Fruits and vegetable products & packaged drinking water	-do-
14	Bhutan Herbal Tea, Shaba, Paro	FSL-PA/20/A026	Herbal Tea	-do-
15	Druk Honey, Bumthang	FSL-B/20/A027	Honey	-do-
16	Bhutan Agro Industries Limited, Wangchutaba, Thimphu	FSL-TH/20/A028	Packaged drinking water and Juices	-do-
17	Laykha Dairy, Paro	FSL-PA/20/A031	Dairy Products	-do-
18	K P Milk Processing Unit, Thimphu	FSL-TH/20/A042	Dairy Products	-do-
19	Uhm-Chuna Natural Spring Water,Paro	FSL-PA/20/A043	Packaged Drinking Water	-do-

20	Ongmo's Product, Bumthang	FSL-B/20/A044	Cookies, Jam & Candy	-do-
21	Bhutan Herbal Tea, Bumthang	FSL-B/21/A045	Herbal Tea	-do-
22	Bhutan Mountain Coffee, Paro	FSL-PA/21/A046	Roasted Coffee	-do-
23	Bhutan Superfood and Herbs, Paro	FSL- PA/21/A053	Tea & Cereal Products	-do-
24	Jinlab Agro Products, Tsirang	FSL-TS/21/A055	Spices, Jam & Wine	-do-
25	Paro Gangtey Spring Water, Paro	FSL-PA/21/A057	Packaged Drinking Water	-do-
26	Bio Bhutan, Thimphu	FSL-TH/21/A061	Ginger, Turmeric and Mustard oil	-do-
27	Samcholing Zangja TshonglayDetshen, Trongsa	FSL-TR/21/A062	Green Tea	-do-
28	Crystal Moon Products, Gelephu	FSL-SG/22/A074	Fruits and Vegetable Pickle	-do-
29	Tashi Beverages, Chukha	FSL-C/22/A081	Coca cola, Water, Fanta, Sprit	-do-
30	Beekeper Cooperative of Bhutan, Bumthang	FSL-B/22/ A083	Honey Production and Packaging	-do-
31	MSPCL, Kawajangsa, Thimphu	FSL-TH/22/84	Herbal Tea	-do-
32	Kurje DrubChu, Bumthang	FSL-B/22/A085	Packaged Drinking Water	-do-

33	Druk Phendhay Silchu, Sarpang	FSL-SG/22/A092	Natural Mineral Water	-do-
34	Bhutan Organics, Thimphu	FSL-TH/23/A097	Tea and Sea buckthorn Juice	-do-
35	Yelha Cordyceps Products, Thimphu	FSL-TH/23/A100	Herbal Tea	-do-
36	Sherchok Women's Group, Gelephu	FSL-SG/23/A101	Spices and Condiments	-do-
37	Bhutan Brewery Pvt. Ltd, Chukha	FSL-C/23/A102	Beer	-do-
38	Serja breweries Private Limited, S/Jongkhar	FSL-SJ/23/A103	Beer	-do-
39	Bhutan Milk and Agro Pvt. Ltd., Chukha	FSL-C/24/A104	Fruit juice/drink Spring water Yogurt Flavored milk Yogurt drinks Orange & other fruit drinks	-do-
40	Druk Herbal Cordyceps (DHC) Production, Thimphu	FSL-TH/24/A114	Cordyceps Tea and Matsutake Tea.	-do-
41	Bhutan Naturals, Samdrup jongkhar	FSL-SJ/23/A094	Spices: Ginger	-do-
42	Rigsum Honey Cordyceps, Haa	FSL-H/22/A078	Cordyceps Artisan Infused Honey -do-	
43	Thugzom's Livelihood Agro, Haa	FSL-H/24/A107	Carrot, Apple & Ginger Candies	-do-

#### **Annexure-C**

#### (Name and Address of the Competent Authority)

# HEALTH CERTIFICATE FOR IMPORT OF FOOD PRODUCTS INTO INDIA INTENDED FOR HUMAN CONSUMPTION (EXCEPT MILK AND MILK PRODUCTS\*)

Health certificate No: Date of Issue:

Description of Consignment							
. Invoice No. and Date:			2. Quantity:				
3. Consignor / exporter							
Name:							
Address:							
4. Consignee /importer: Name:							
Address:							
5. Country of origin:							
6. Place of loading:							
7. Declared Port of Entry:							
8. Mode of Transport:							
<ul><li>9. Date of Export:</li><li>10. Conditions for transport /</li></ul>	storage: Frozen	/ (	hilled / Amh	ient /			
11. Identification of the produ	•					·	
multiple lines may be used for							
a) Description of the food	along with HS co	od	e:				
b) Name and address of N Establishment	Manufacturer /		Approval number of establishment				
c) Name of the Lo			rpe of ckaging	Number packages	of s	Net Weight	
d) Date of Manufacture or	0 0	Best before (if applicable)		Date of Expiry			

#### CERTIFICATION

The undersigned Authorized Official certifies that the food and agricultural/livestock products (which comes under the ambit of FSSAI) described herein have been produced in the facility complying with Sanitary and Hygienic requirements as specified in Schedule 4 of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and the products meet the food safety requirements as given below:

- a. Were manufactured at (an) establishment (s) that has / have been approved by the Competent Authority in the exporting country.
- b. Complies with the Product specific standards as specified under various Food Safety and Standards Regulations.
- c. Does not contain drug / antibiotics / mycotoxins / pesticides / heavy metal residues etc., above the limits prescribed by the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.
- d. Contains only those food additives as specified in Appendix 'A' of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 within the limits specified.
- e. Conforms to the microbiological requirements specified in Appendix 'B' of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.
- f. Regular inspection/ monitoring of checks in according with FSS Act, 2006, rules and regulations made thereunder and as per the criteria specified by FSSAI.
- g. Products exported to India conform to the requirements prescribed by FSSAI including any other regulatory requirements.

Inspection Date:	Official stamp:	Name and Signature of Authorized Official
Place of Issue:		

This certificate is valid for 45 days from the date of issue.

\*Note: This certificate will not be applicable for Milk and Milk Products to be exported to India.