



AGREEMENT
FOR
RECOGNITION OF OFFICIAL CONTROL EXERCISED BY BHUTAN FOOD
AND DRUG AUTHORITY (BFDA),
MINISTRY OF HEALTH,
ROYAL GOVERNMENT OF BHUTAN
BY
FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA (FSSAI),
MINISTRY OF HEALTH AND FAMILY WELFARE,
GOVERNMENT OF INDIA

6/

12

The Food Safety and Standards Authority of India (FSSAI), Ministry of Health and Family Welfare, Government of India, hereinafter referred to as **FSSAI** and The Bhutan Food and Drug Authority (BFDA), Ministry of Health (MoH), Royal Government of Bhutan, hereinafter referred to as **BFDA**, and are hereinafter jointly referred to as Parties and individually as Party;

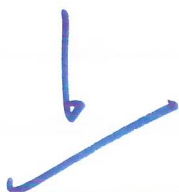
RECOGNIZING the official control exercised by BFDA on Food Business Operators (FBO's) as equivalent to FSSAI's requirement for export of food products to India;

ENSURING that food and agricultural/livestock products exported from Bhutan to India are safe, wholesome and meet FSSAI's requirements;

REDUCING duplication in the inspection of products notified under FSSAI's Import Inspection Scheme from time to time;

DESIRING to enhance the technical cooperation in the areas and activities that fall within the scope of their activities;

GUIDED by their wish to establish a workable mechanism between BFDA and FSSAI; to develop, cooperate and facilitate the trade; and



NOW THEREFORE, the Parties hereby agree to the following terms and conditions:

Article 1

SCOPE

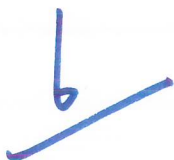
1. This Agreement covers all food and agricultural/livestock products which are under the ambit of FSSAI's Import Inspection Scheme, as amended from time to time and recognition of BFDA's export inspection and certification system by FSSAI in the widest sense possible, to facilitate trade on the basis of equal entitlement, mutual benefit and amicable cooperation.

Article 2

OPERATIONS UNDER THE AGREEMENT

BFDA:

2. The BFDA through its HQ at Thimphu, Bhutan with its designated field Offices, shall exercise official control by implementing Food Safety Management System (FSMS) based certification and regular monitoring, to ensure that the products exported to India conform to the requirements prescribed by FSSAI including any other applicable regulatory requirements.



3. The BFDA shall issue a Health Certificate as a proof of compliance with the requirements prescribed by FSSAI, while exporting the products to India.
4. The BFDA shall provide evidence of authenticity of certificates issued by BFDA field Office as and when requested by FSSAI.
5. The BFDA shall immediately take appropriate remedial action including legal action, where required, whenever any non-compliance is reported by FSSAI. The action taken by BFDA shall be shared with FSSAI.
6. The BFDA shall share with FSSAI the list of all Approved Food Processing establishments along with their scope, which are under their official control.
7. The BFDA shall share the specimen signatures of their officers who are authorised to sign export certificates/health certificates along with security features of Health Certificates, with FSSAI to identify/check counterfeit certificates.

FSSAI:

8. The FSSAI shall recognize the export inspection and certification system of BFDA, so that the Certificates issued by BFDA field Offices are accepted by the Indian Authorities at their border entry points as a proof of the commodity complying with the requirements prescribed by



FSSAI, including any other applicable regulatory requirement, so that the commodities are not subjected to routine inspection. The FSSAI may however, consider conducting random verification checks to ensure the continued compliance of products covered under this Agreement.

9. The FSSAI shall immediately notify BFDA whenever a consignment exported under BFDA's certification system is found not complying with FSSAI's requirements.
10. The FSSAI shall extend technical cooperation in terms of training and capacity building against its requirements, wherever requested by BFDA.

GENERAL:

11. Both BFDA and FSSAI shall cooperate with each other in taking required action in case of violation of any regulatory requirement in respect of the products covered under the Agreement. However, any legal action to be taken shall be governed as per the existing laws of the respective country.



Article 3

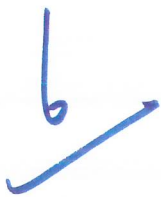
ASSESSMENT OF BFDA'S EXPORT CERTIFICATION SYSTEM

12. The FSSAI, if required may request BFDA for assessment of its export certification system in respect of product(s) covered under this Agreement. The dates and frequency of such assessments shall be mutually decided between the Parties. These assessments shall be conducted according to the requirements of FSSAI's Import Inspection Scheme. The BFDA shall take timely action on the agreed outcome of such assessments carried out.
13. During assessment of official control of BFDA, FSSAI shall also access the processing establishments on sample basis and testing laboratories.

Article 4

CRITERIA FOR CERTIFICATION

14. The BFDA shall issue health certificates only if its export certification system establishes that the product is complying with the requirements prescribed by FSSAI, including any other applicable regulatory requirements. The format of the Certificates to be issued shall be as agreed to by the FSSAI.

A handwritten signature in blue ink, consisting of a stylized 'b' followed by a diagonal stroke.A handwritten signature in blue ink, consisting of a stylized 'B' followed by a checkmark-like stroke.

Article 5

TRANSPARENCY, INFORMATION EXCHANGE AND COOPERATION

15. Both the Parties shall co-operate and communicate to the fullest practicable extent, their requirements as well as any changes in their requirements that may be relevant to the other Party and have an effect on the operation of this Agreement. This shall include, but not be limited to, legislations, regulations, policies, procedures and guidelines concerning enforcement and inspection.
16. Both Parties understand that any and all activities under this Agreement shall be subject to the availability of funds and resources and the laws governing the respective Party. Unless agreed otherwise, the travel, boarding and lodging costs of delegations to be exchanged shall be covered by the sending Party and the receiving Party shall provide the logistics support.

Article 6

CONFIDENTIALITY

17. Any information and correspondence under this Agreement shall be treated "confidential" by both Parties and utilized for the purpose of operation of this Agreement only. Such information and



correspondence shall not be shared with third parties without prior written permission of the concerned Party.

18. The confidentiality obligations imposed upon the Parties under this Agreement shall not apply to information which is:

- (a) already a part of the public domain, through no fault of the Parties;
- (b) in the possession of one of the Parties prior to the receipt of the information under this Agreement;
- (c) received by one of the Parties from a third party with a good legal title thereto; and
- (d) required by law or by a court order.

Article 7

LIABILITY

19. If a claim is filed by a person or organization against a Party to this Agreement, in connection with the activities of the other Party, the Party shall immediately inform the other Party of such claim and send without delay all the relevant information and documents. The Party shall not pay the plaintiff any money for claims filed without the consent of the other Party.



Article 8

VALIDITY OF THIS AGREEMENT

20. This Agreement is valid from the date of its signing for a period of 3 years and may be extended on mutual understanding for further 3 years. This Agreement may be terminated by either Party by giving three months' prior notice in writing. If during the period of the "notice", a specific assignment is being conducted under the Agreement, the assignment shall continue through its completion.

Article 9

REVIEW & MODIFICATION

21. This Agreement may be amended and supplemented as mutually consented to in writing by both the Parties for further bilateral cooperation. Such amendment shall come into force on such date as may be determined by the Parties.

Article 10

DISPUTE SETTLEMENT

22. Any dispute, controversy or claim, arising out from the implementation or interpretation of this Agreement shall be solved amicably through consultations, discussions and negotiations and failing which the



dispute shall be referred to and decided at the Government to Government level.

Article 11

OTHER AGREEMENTS

23. Nothing in this Agreement shall be interpreted to prejudice or modify any existing Understanding or Agreement to which the Royal Government of Bhutan and the Government of India are the parties.

Article 12

LANGUAGE

24. Any certificates, test reports, as well as all correspondences pursuant to this Agreement, shall be in English.

Article 13

NOTICES

25. Every notice, request or any other communication required or permitted to be given pursuant to this Agreement shall be in writing and addressed to:

**Bhutan Food and Drug
Authority (BFDA), MoH**

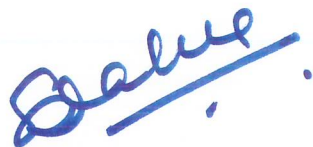
**Food Safety and Standards
Authority of India (FSSAI),
MoHFW**



IN THE WITNESSES THEREOF, the undersigned, duly authorized thereto have signed this Agreement on Twenty First day of March of the year Two Thousand Twenty Four at Thimphu, in two original copies in English and these two texts shall be equally authentic for interpretation.

For and on behalf of FSSAI,
Ministry of Health and Family
Welfare, Government of India

For and on behalf of BFDA, Ministry
of Health, Royal Government of
Bhutan



Mr. Sudhakar Dalela,
Ambassador of India to
Bhutan



Mr. Pemba Wangchuk,
Secretary, Ministry of
Health,
Royal Government of Bhutan