Food Registration Manual

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Contents

Illustrated and arranged by
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Business Development Manager

1- Introduction:

The Islamic Republic of Iran requires each importer of FMCG related products to register the brand, supplier and the manufacturer in the Ministry of Commerce (MOC) and Ministry of Health (MOH) of Iran prior to importing any products to the country.

The websites to the chamber of commerce and MoH are as follows:

Iran Chamber of commerce - https://iccima.ir/

Iran Ministry of Health - https://www.fda.gov.ir/

The first step in the registration process is to register the brand name of the parent company in the Ministry of Commerce of Iran. In order to do so, the agent of the parent company requires submitting a true copy of the "Exclusive Distributorship Agreement" between the two companies to the MOC. This document should be signed and approved by the Ministry of Commerce or Chamber of Commerce and the Embassy of Iran in the parent company's country of origin.

After registering the parent company's name and brand in MOC, the agent in Iran has to apply for registering the manufacturing plants of the products in Ministry of Health of Iran. MOH requires a list of documents that has to be given by the parent company and submitted by the agent in order to register the manufacturing plant prior to registration of the products.

Each product/raw material that is imported to Iran, requires an IRC Code (Iran Registration Code). This IRC code is a unique code for each and every product. In order to obtain the IRC Code, the agent has to register each product/raw material in MOH and the TTAC - Tracing, Tracking and Authentication Control System (www.ttac.ir).

The registration process is time consuming; it normally takes around 6 to 8 months (depending on the product) to register a manufacturer and its products in the MOC and MOH. Bear in mind that the mentioned time exceeds if the documentation submitted is in complete or have to be revised.

Note: Iran MOH has the right to audit the manufacturing plant before Issuing the IRC.

The current manual is published to help you grasp a better understanding towards the Iranian Ministry of Health registration procedures in detail. The forms and samples of such documents are put within the appendix as a reference for you.

This manual applies to all raw materials and packaging items subject to source and product registration used in food and beverage industries and processed products.

2- Definitions

Manufacturing plant

It is a place where the raw material or processed food and beverage products are manufactured, packed and registered in the country of origin. Which are independent legal entities.

Beneficiary company

Is a company that is not the manufacturer of the raw material nor in any part of the production procedure, but only in relation to the commercial operations of a raw material or premix or has intentions to become the brand owner in which must have a written document of communication with the manufacturer.

Raw material

The raw material refers to the basic material for processing products such as additives, which are approved to be used in manufacturing plants. The items below are also referred to as raw material:

- Packaging raw materials, including granules, papers, foils, envelopes & etc.,
- Agricultural raw materials such as rice, tea and legumes and grains
- All processed materials that enter the country in bulk

Processed product

A Processed product refers to a product that has entered the country as a final product and is directly distributed at the supply level.

Source registration

Source registration means confirming the technical and sanitary conditions of the production unit of the original/foreign manufacturer by the documents submitted to the Ministry of food and drug or the international inspections and audits certified by international regulations.

** For Foreign manufacturing companies that have a comprehensive quality and safety system for all their branches, in case one of their sources achieves quality and safety is approvals given by the General Administration; all other branches are considered to be approved.

Product registration

Product registration is a confirmation of the formulation, features and the safety of the product produced by a registered factory based on national/International standards or the rules and regulations of the General Administration.
Iran Food & Drug Administration (https://www.fda.gov.ir/)

3- Documentation required for the Issuance of import health permit

- A Completed checklist for the application for issuing the import health permit for raw materials and processed food and beverage products (form number F-FW25-001-3)
- A declaration letter
- A valid distribution agreement or contract between the two companies
- Food Safety and quality certificates such as ISO 22000, BRC (British Retail Consortium), IFS (International Featured Standard), HACCP
- Free Sale Certificate (FSC)
- The analysis sheet including the name and percentage of the ingredients of the requested products along with physical, chemical, and microbial specifications and pollutants (on the letterhead with the producer's stamp and signature)
- Notarized letter of commitment for the imported goods
- Persian label artwork containing the nutrition guide and ingredients in Persian on the label
- PMF (Plant and Product Master File) on the letterhead of the manufacturer and with its stamp and signature of the manufacturer
- All other approvals and certificates such as
    a. Health certificate

b. Genetically Modified Organism (GMO) for products like Soy, corn products, rapeseed, canola, cottonseed and their derivatives and starters
c. Organic certificates
d. Halal certificates
e. BSE, FMD, Dioxin, Melamine certificates

All must be approved by competent government authorities and attested by the Iranian embassy in the country of origin

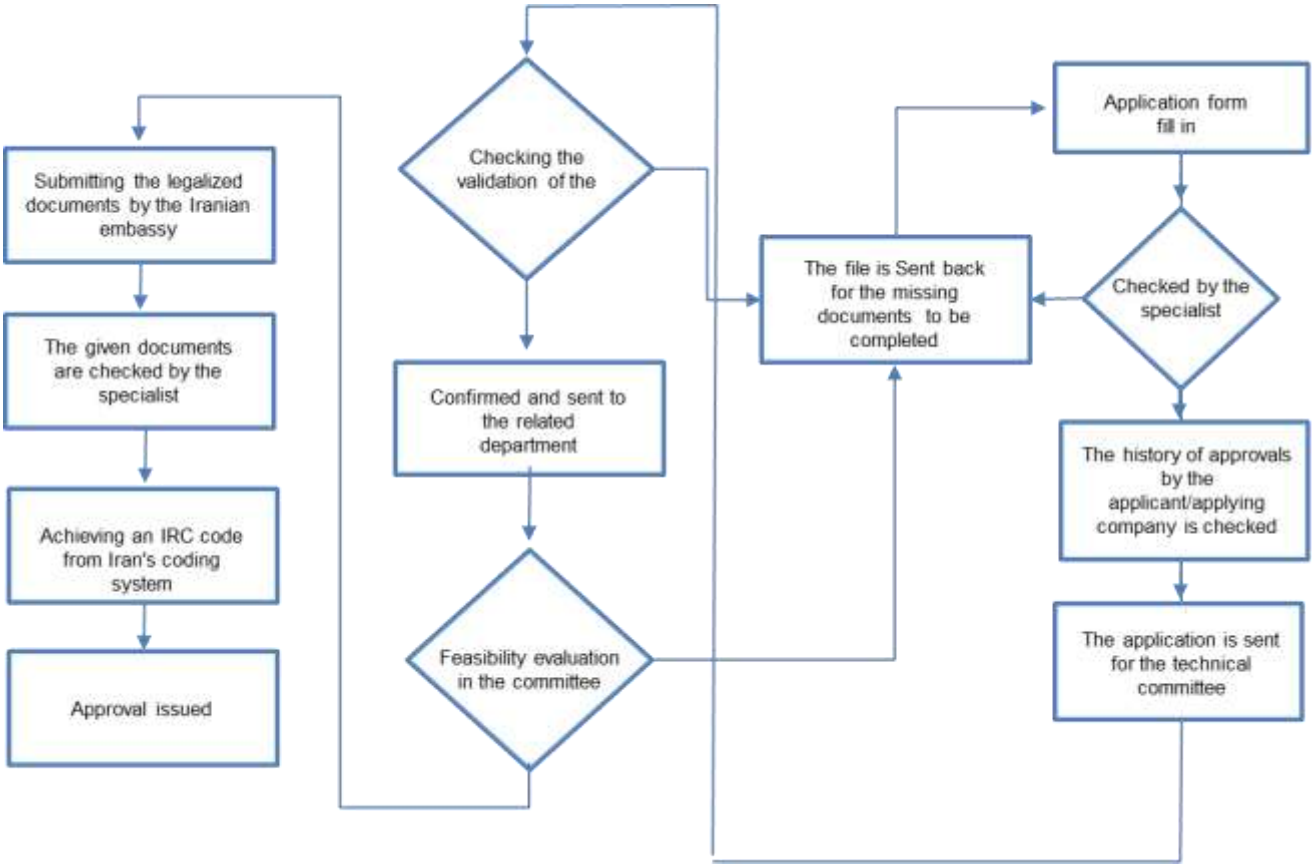
- The technical officer certificates and approvals
- The company statute and all its activities
- A letter stating that the new product with the requested brand name is produced in the same production line or registered source, confirmed by the competent authorities of the country of origin and attested by the Iranian embassy.

4- Requesting an IRC (Iran Registration Code)

IRC for the product, the code issued for the original product achieved by the coding system.

IRC for the derivatives of the main product achieved by TTAC (https://ttac.ir) system and by the technician.

IRC procedure in a view



Appendix 1- ISO 22000/ HACPP/ Halal certificates

ISO Certificate sample

Certificate

This is to Certify that

Your Organization Name

Site 1:Your Organization Complete Address with Pin Code

Site 2:Your Organization Complete Address with Pin Code

has been found in Compliance with requirements of

Food Safety Management Systems

ISO 22000:2005

for the following scope:

Your Organization Scope
(Manufacturing of ABX Products or
Providing Service of XYZ or
Trading of PQR Products).

Certificate No. : XXX/XXXXX/XXXX
Original Certificate Date : XX - XX - XXXX
Issue Date : XX - XX - XXXX
Expiry Date : XX - XX - XXXX

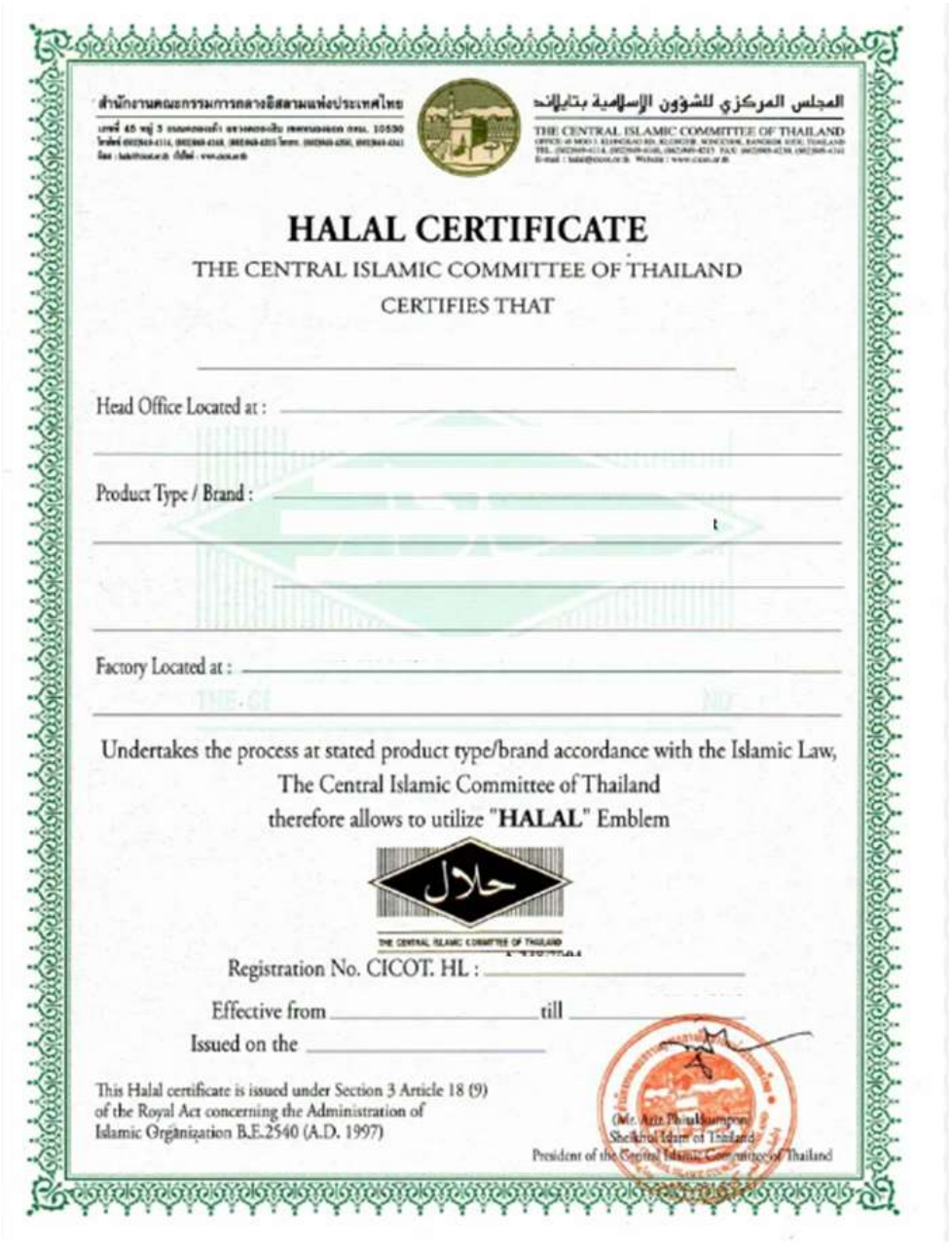
To check this certificate status visit:
"http://uasl.uk.com/certifiedorganization.html"

Authorised Signature
Quality Control Certification
UK Office: 1529, Chynoweth House,
Trevissome Park, Truro TR4BUN, Cornwall, UK
India Office: 2nd Floor, Ansari Market,
Karol Bagh, Delhi - 110 042, India

CERTIFIED

ISO 22000:2005

Halal Certificate sample



สำนักงานคณะกรรมการกลางอิสลามแห่งประเทศไทย

المجلس المركزي للشؤون الإسلامية بتايلاند

THE CENTRAL ISLAMIC COMMITTEE OF THAILAND

HALAL CERTIFICATE

THE CENTRAL ISLAMIC COMMITTEE OF THAILAND

CERTIFIES THAT

Head Office Located at :

Product Type / Brand :

Factory Located at :

Undertakes the process at stated product type/brand accordance with the Islamic Law,
The Central Islamic Committee of Thailand
therefore allows to utilize "**HALAL**" Emblem

حلال

THE CENTRAL ISLAMIC COMMITTEE OF THAILAND

Registration No. CICOT. HL :

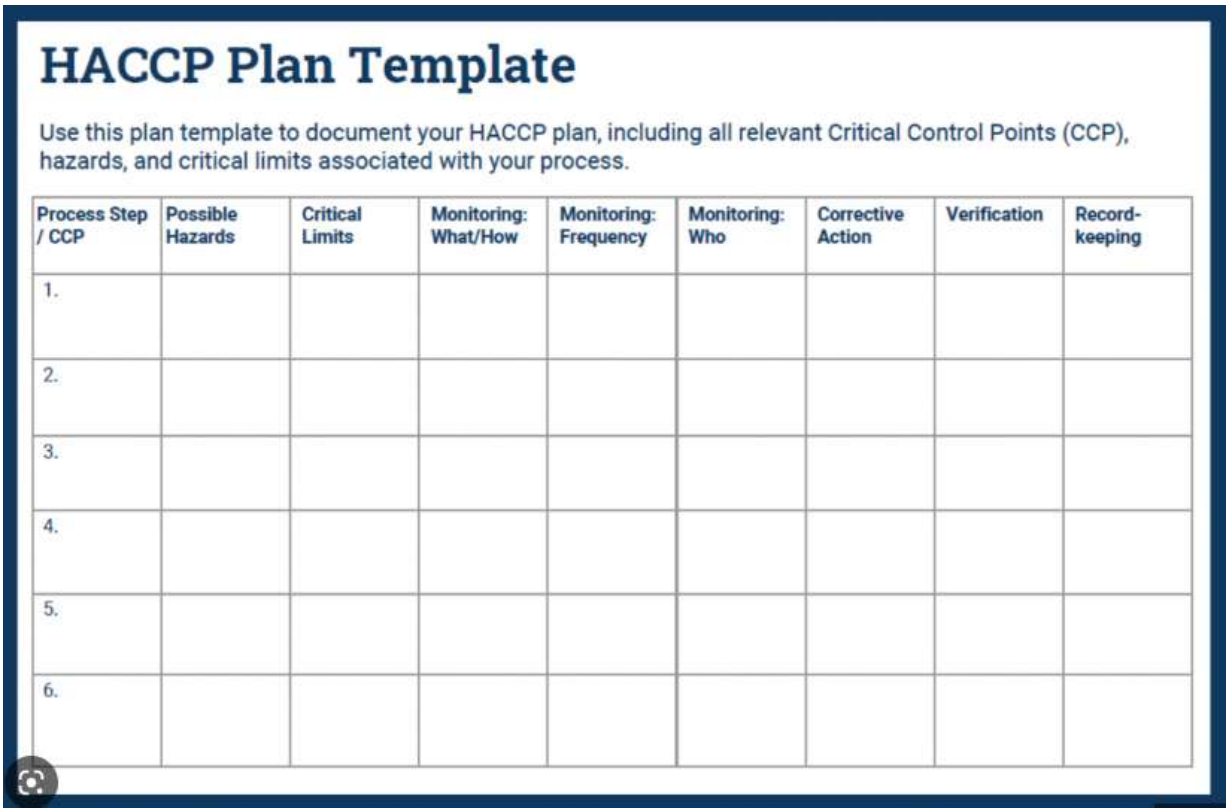
Effective from _____ till _____

Issued on the _____

This Halal certificate is issued under Section 3 Article 18 (9)
of the Royal Act concerning the Administration of
Islamic Organization B.E.2540 (A.D. 1997)

(Mr. Aziz Phitakthampoon)
Sheikhul Islam of Thailand
President of the Central Islamic Committee of Thailand

HACCP sample



HACCP Plan Template

Use this plan template to document your HACCP plan, including all relevant Critical Control Points (CCP), hazards, and critical limits associated with your process.

Process Step / CCP	Possible Hazards	Critical Limits	Monitoring: What/How	Monitoring: Frequency	Monitoring: Who	Corrective Action	Verification	Record-keeping
1.								
2.								
3.								
4.								
5.								
6.								

Appendix 2- Free Sale Certificate (FSC)

Date:

Name of Licensee: Name of Manufacturer:

Address: Address:

Tel: Tel:

Fax: Fax:

Website: Website:

Free Sales Certificate

This is to certify that the products of company *(Please name your company)*, under …… Brand *(Name your Brand)* are freely sold in large scale in …… *(Countries names)*, and are freely and in large scale exported to other countries.

Products: *(List your products in details; please insert a table for this part)*

..

..

Appendix 3- Certificate of Analysis (CoA)

Header:
Logo of the laboratory or company issuing the certificate (if applicable) Identification no. of the CoA

Name and address of the laboratory issuing the CoA: _____

Identification no. of the CoA: _____ Name, address and contact person representing the originator of the request for analysis: _____

Registration no. of the sample: __ Date received: _____ Quantity received: _____ Name of the product (International Nonproprietary Name (INN), brand name, etc.): _____

Dosage form, strength, package size (if applicable): _____ Type and material of the primary packaging: _____

Batch number: _____ Date of manufacture (if available): _____ Expiry date/retest date: _____ Name and address of the original manufacturer: _____

Phone: _____ Email: _____ Name and address of the repacker and/or trader (if applicable): _____

Phone: _____ Email: _____ Specifications for testing: _____

Test	Method reference[1]	Acceptance criteria	Result[2,3]	Compliance statement

Additional information, if requested by the customer:

Comments:

Conclusion on compliance of the sample with the specifications:

Name of the head of laboratory or person authorized to approve the certificate:

Phone: _____ Email: _____ Signature:
Date:

Appendix 4 – Health Certificate

Date:

Name of Importer:	**Name of Manufacturer:**
Address:	Address:
Tel:	Tel:
Fax:	Fax:
Website:	Website:

Health Certificate

Products: *(List your products in details; please insert a table for this part)*

..

..

..

We hereby certify that the above mentioned products of our company have been laboratory tested for quality and have been approved for human use.

Their ingredients are by no means harmful to the human health or environment. we hereby state that above mentioned products are free for sale without any limitation in the country of origin.

We hereby state that the quality of all products sold to our distributor in Iran will be guaranteed.

Quality and safety of all our products which will be sold to our representative company: ….. *(Distributor company name in BOLD)* in Iran for the next one year will be guaranteed from the date of issuing this certificate.

The manufacturing company confirms compliance with the EU Cosmetics Directive concerning 1, 4-dioxane in products containing ethoxylated surfactants.

We confirm that products are not infected by TSE and BSE. Their Ingredients do not have any human or swine source.

Signature

Appendix 5- Plant and Product Master File

Name:	
Address:	
Date of visit:	Date of last visit (if the site has been visited before by IR-IRAN FDA experts:
Scope of assessment:	
Name of assessors:	
Name and kind of products (Flow diagram of identified products must be attached):	
Number of branches with their addresses:	
List of countries that products are exported (documents must be attached if the products export to ENAJA countries):	
Type of packaging:	
Certificates & approval (copy of valid certifications must be attached):	
ISO9000 series ISO14000 ISO17025 HACCP system ISO22000:2005	IFS BRC CFS (Free sale) FDA Others

2. **Facility, including:**
   - Description of its size and nature of construction
   - Number of staff
   - Amount and type of products made
   - The company's quality policy
3. **The manufacturing facility:**
   - Floor plan, nature of construction, (i.e. type of building, is it open or closed construction, type of walls), air quality and type of air filtration system if relevant.
   - Method of cleaning relevant to the type of product, pest control program (if relevant).
   - Details of any other manufacturing activity carried out on site.
   - Good quality photographs can be used to illustrate features, when appropriate.
4. **Storage facilities:**
   - Brief description of the storage facility.
   - Procedures and facilities for quarantining incoming materials (both raw materials and finished product) until approving for release.
   - Procedures for quarantining and disposal of reject material.
   - QA procedures for releasing both raw materials and finished product from storage and quarantine.
5. **Sanitation:**
   - Description of cleaning and general hygiene procedures.
   - Evidence of documented cleaning procedures, e.g. a copy of an SOP for cleaning.
6. **Personnel issues:**
   - Qualifications/experience of production manager and QC manager
   - Staff training needs and what is done to address them.
   - Personal hygiene and PPE (Personal Protective Equipment) needs relative to needs of the product and

7. Process water:

- Quality required and steps taken to ensure that water quality meets those requirements.
- If the required standard is water drawn from the domestic water supply, then that should be stated in the specification for process water.
- Type of testing required if relevant, how often, evidence that it is done.
- Procedures for waste water filtration system

8. Equipment:

- Type of equipment used.
- What steps are taken to ensure that it is correctly installed, regularly calibrated, maintained and adequately cleaned.
- Details of cleaning procedures and checks carried out on cleaning procedures to ensure that they are adequate if different products are made in the same equipment.
- Details of procedures for making sure there is no cross contamination from other parts of the facility.

9. Specifications:

- Confirmation that written specifications for raw materials, intermediates and finished products as well as packaging materials exist (these should be consistent with registration specifications).
- Examples of specifications should be provided (e.g. for representative raw materials and final product).

7. Production procedures:

- Procedures for checking that raw materials meet specifications.
- Details of the production procedure; packaging and labeling procedures.
- Description of in-process quality checks (e.g. for unwanted micro-organisms such as yeasts, moulds and bacteria) and quality tests on the finished product.
- Documented release procedures to ensure that finished product is not released until results of all required tests are available and have been checked against release specifications.
- Description of batch records kept which cover the process from starting materials to finished products.
- If different products are made in the same equipment, procedures for ensuring there is no cross-contamination from the previous product of the product being made.
- Documented procedures for implementing PMS program

7. Quality control procedures:

- Evidence of quality control function that is related to production and marketing.
- Evidence that it is being implemented correctly.
- Documented change control procedures.
- Ability to conduct required quality control checks.

8. Brief description of recall procedures, complaints handling procedures and self-inspection procedures.

9. Documentation

All Procedures Must Be Documented And Signed By The Quality Control Manager.

Appendix 6- Declaration letter

Manufacturer Letterhead

Reference No.

Issuance Date:

To: Islamic Republic of Iran Ministry of Health and Commerce

Declaration Letter

We, (Manufacturer Name) having office at ....., Tel ....., Fax ....., Email: ....., registered No ….. , hereby confirm that (supplier name) is authorized to sell our Products to **Health Invest Tamin co. (HITCO)** represented by Mr. Ali Babaie as the CEO, having office at No 56, Alvand Street, Tehran, Iran, Postal Code: ……., Phone: +98 (21) ……. Fax: +98 (21) ……., Email: ……. , website: www.hitcoholding.com , Registration number: 342195 which is the **Exclusive Distributor** of our supplier for the following Products with the following brands in Iran territory.

Product name	**Brand name**	**Manufacturer name**

Dispute Resolution: Any difference, dispute, controversy and/or claim should be settled in accordance with the Arbitration Rules of the International Chamber of Commerce in Paris/ France

Termination: It will be after the expiry of LOA.

This agency agreement is valid for 5 years.

Sincerely yours,

Signature

Name

Title