Mandatory Technical Requirements in Islamic Republic of IRAN

- **Mandatory Technical Requirements and complementary information related to technical measures issued by Iran national standard organization:**

- **Style manual for Exported Goods Conformity Assessment.**
http://isiri.gov.ir/Portal/file/?755366/Style-Manual-Exported-Goods-Conformity-Assessment-Methods.pdf

- **Style manual Issuing Ratification License for Type-Approval and COC of Imported Automobiles**
http://isiri.gov.ir/Portal/file/?755312/Style-ManualIssuing-Certificate-Of-Ratification-For-Type-Approval-and-COC-of-Imported-Automobiles.pdf

- **List of imported goods subject to technical regulations (mandatory requirements).**
http://isiri.gov.ir/Portal/file/?755310/List-Of-Imported-Commodities-Subject-To-Standard-Technical-Regulation.pdf

- **Imported Goods Conformity Assessment Method.**
http://isiri.gov.ir/Portal/file/?755306/Executive-Method-Imported-Goods-Conformity-Assessment-Methods.pdf

- List of authorized inspection companies for imported products.
http://isiri.gov.ir/Portal/file/?755307/List-Of-Inspection-Companies-Authorized-to-inspect-the-imported-commodities-from-the-Eurasian-Economic-Union-and-its-member-states-.pdf

- List of accredited technical inspection companies.
http://isiri.gov.ir/Portal/file/?755309/List-Of-Accredited-Technical-Inspection-Companies.pdf

- List of accredited laboratories.
http://isiri.gov.ir/Portal/file/?755308/List-Of-Accredited-Laboratories.pdf

Sanitary and Phytosanitary Measures in Islamic Republic of IRAN

- **Phytosanitary requirements for importing plants and plant products (Listed in Annex-1 to the Interim Agreement) to Iran issued by "Plant Production Organization." (ANNEX 1)**

- **Instructions and guidelines issued by "Ministry of Health and Medical Education" on:**

A) Sanitary and cosmetic products:

-Administrative instructions on examination of the Technical and sanitary Conditions for Overseas Cosmetic factories.
https://www.fda.gov.ir/OldFiles/e6d73f027053802f139b00225d7edfe3.doc

- Administrative instructions on health certificate for sanitary and cosmetic products. https://www.fda.gov.ir/OldFiles/13e1cd2de61f518121178f3969b82f27.pdf

- Instructions on examination of the scientific documents of sanitary and cosmetic products and the issuance of a health license.
https://www.fda.gov.ir/OldFiles/ed2c6e2755975d2e1abbd82e0375b23e.pdf

- Administrative instructions on examination of the Technical and sanitary Conditions for Overseas bulk Cosmetic factories and issuance of packing certificate.
https://www.fda.gov.ir/OldFiles/b47c6b9ea1a59e2499d5265e85ef6ecf.doc

B) Food and pharmaceutical products:

- Guidelines on registration of pharmaceutical products for imports. (ANNEX 2)

- Checklist for the examination of the technical and sanitary conditions of factories producing food / beverage/ raw materials / processes (for the issuance / reform / extend of the import license) (ANNEX 3)

- Administrative instructions on health licensing for import of raw materials, packaging items and processed foods and beverages
https://www.fda.gov.ir/getattachment/3d2e24d4-ee44-4b37-b963-922e2a2591a8/%D8%AF%D8%B3%D8%AA%D9%88%D8%B1%D8%A7%D9%84%D8%B9%D9%85%D9%84-%D8%A7%D8%AC%D8%B1%D8%A7%DB%8C%DB%8C-%D8%AB%D8%A8%D8%AA-%D9%85%D9%86%D8%A8%D8%B9-%D9%88-%D8%B5%D8%AF%D9%88%D8%B1-%D9%BE%D8%B1%D9%88%D8%A7%D9%86%D9%87-%D8%A8%D9%87%D8%AF%D8%A7%D8%B4%D8%AA%DB%8C-%D9%88

- Administrative instructions on examination of the Flavorings to issue a Health License for import.
https://www.fda.gov.ir/getattachment/15d58bd1-e1ba-4311-b0ed-2a4cb67178e2/%D8%AF%D8%B3%D8%AA%D9%88%D8%B1%D8%A7%D9%84%D8%B9%D9%85%D9%84-%D8%A7%D8%AC%D8%B1%D8%A7%DB%8C%DB%8C-%D9%86%D8%AD%D9%88%D9%87-%D8%A8%D8%B1%D8%B1%D8%B3%DB%8C-%D8%B7%D8%B9%D9%85-%D8%AF%D9%87%D9%86%D8%AF%D9%87-%D9%87%D8%A7-%D8%AC%D9%87%D8%AA

- Instructions on examination and verification of health certificate for imported food, beverages and raw materials.
https://www.fda.gov.ir/getattachment/28429321-6548-48ed-8af8-44323ff0c0e8/%D8%AF%D8%B3%D8%AA%D9%88%D8%B1%D8%A7%D9%84%D8%B9%D9%85%D9%84-%D9%86%D8%AD%D9%88%D9%87-%D8%A8%D8%B1%D8%B1%D8%B3%D9%8A-%D9%88-%D8%AA%D8%A7%D9%8A%D9%8A%D8%AF-%DA%AF%D9%88%D8%A7%D9%87%D9%8A-%D8%A8%D9%87%D8%AF%D8%A7%D8%B4%D8%AA-%D9%85%D8%AD%D8%B5%D9%88%D9%84%D8%A7%D8%AA

- **Requirements for importation of meat products issued by Iran Veterinary Organization:**

- Import Health Requirements for Fresh boneless Beef Meat from KAZAKHSTAN (ANNEX 4)

- Health Requirements for Importation of Chilled Ovine Meat from Kyrgyzstan into I.R.IRAN (ANNEX 5)

- Health Requirements for Importation of Chilled Ovine Meat from Russia to I.R.IRAN (ANNEX 6)

- Sheep Import Health Requirements for Slaughter into IRAN (ANNEX 7)

- Import Health Requirements for Fresh Frozen Ovine Meat from Kazakhstan into I.R.IRAN (ANNEX 8)

- Import Health Requirements for Fresh Frozen Boneless Beef meat from Kazakhstan into I.R.IRAN (ANNEX 9)

- Import Health Requirements for Fresh boneless Beef Meat from RUSSIA (ANNEX10)

- Import Health Requirements for Fresh Chilled Vacuum Boneless Beef Meat from Russia to I.R. Iran (ANNEX 11)

- Import Health Requirements for Vacuum Boneless Beef from Russia into I.R. Iran (ANNEX 12)

- Import Health Requirements for Frozen Boneless Beef Meat from Russia to I.R. Iran (ANNEX 13)

- Health Requirements for Importation of Fresh Frozen Ovine Meat from Russia INTO I.R.IRAN (ANNEX 14)

- Import Health Requirements for the importation of Frozen Deboned Venison from Russia into the I.R.IRAN (ANNEX 15)

- Health Requirements for Fresh Chilled Vacuum Packed Ovine Meat from Kazakhstan (ANNEX 16)

- Health Requirements for Import cattle intended for Promptly Slaughter into I.R. Iran (ANNEX 17)

- Health Requirements for Import Fresh Frozen Ovine Meat from KYRGYZSTAN INTO I.R.IRAN (ANNEX 18)

- Veterinary certificate for Domestic Bovine Animals intended for slaughter (for transit) (ANNEX 19)

ANNEX 1

Phytosanitary requirements for importing some plants and plant products to Islamic Republic of Iran

Following the previous negotiations and correspondence, we would like to inform you that for importing some consignments including green tea, tea bag and plywood to I. R. Iran it is not necessary to issue phytosanitary certificate.
Importing corn seed and barley seed to I.R. Iran are high risk and the import will be possible if the importer obtains the import permit (including the attached phytosanitary requirements) from NPPO, Iran and send it to export side to issue the phytosanitary certificate accordingly.

For importing some consignments as mentioned table 1, only issuing a phytosanitary certificate is necessary. For importing the others as mentioned table 2, please find the attachment on the relevant phytosanitary requirements. For all cases the import will be possible with mentioned requirements and inspection will be carried out by plant quarantine officials at the customs entry points.
All quarantine condition of importing plants and plant products to Iran is available on the internet:
http://ppo.ir/fa-IR/DouranPortal/4991/page

Table1: List of low risk consignments that a phytosanitary certificate is necessary

Row	Consignment	country
1	Split broad bean, Split bean, Split lentil, Split chick Pea, Split pea	All members of Eurasian Economic Union
2	Pinto bean grain	Kyrgyzstan, Armenia
3	Lentil grain	All members of Eurasian Economic Union
4	Kidney bean grain	Kyrgyzstan, Armenia
5	Corn grain	All members of Eurasian Economic Union
6	Semi milled rice	All members of Eurasian Economic Union
7	Buck wheat grain	All members of Eurasian Economic Union
8	Flax grain	All members of Eurasian Economic Union
9	Canola grain	All members of Eurasian Economic Union
10	Soybean meal	All members of Eurasian Economic Union
11	Cotton meal	Kazakhstan،Kyrgyzstan
12	Sun flower meal	All members of Eurasian Economic Union
13	Canola meal	All members of Eurasian Economic Union
14	Safflower meal	All members of Eurasian Economic Union
15	Thermo Wood	All members of Eurasian Economic Union
16	Mustard grain	All members of Eurasian Economic Union
17	Soybean grain	Armenia Belarus،Kyrgyzstan

Table 2: List of medium risk consignments that **the scientific name of pests, should be indicated in the phytosanitary certificate**

Row	Consignment	country
1	Pinto bean grain	Belarus Kazakhstan،Russia
2	Peas grain	Russia
3	Cotton	All members of Eurasian Economic Union
4	Soybean grain	Kazakhstan،Russia
5	Sun flower seed	All members of Eurasian Economic Union
6	Canola seed	All members of Eurasian Economic Union
7	Coco chips	All members of Eurasian Economic Union
8	Wood chips	All members of Eurasian Economic Union
9	Pinus Chips Bark	All members of Eurasian Economic Union

Phytosanitary requirements for importing Corn (*Zea mays*) seeds from Russia to I.R.Iran

1- Valid phytosanitary certificate from the country of origin, in which freeness of consignment from the following pests is indicated in the Additional Declarations:

Acanthospermum hispidum	*Ambrosia trifida*
Burkholderia andropogonis	*Cochliobolus carbonum*
Gloeocercospora sorghi	*Pseudomonas syringae* pv. *coronafaciens*

Note: The scientific name of the above mentioned pests should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.

2- Disinfection of the consignment with a suitable fungicide in Russia and indicating its particular features in the relevant phytosanitary certificate.
3- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.
4- Each part of consignment must be properly packed and labeled including the scientific name of plant (genus and species).
5- Delivering the import Permit, the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible.
6- If the consignment is of any infections which could be disinfected by quarantine officer expediency, the cost must be borne by the importer; otherwise it is destroyed or returned to the country of origin. If any quarantine pest is found, the consignment will be destroyed or returned.
7- The import permit can be used for one time.
8- It isn't permissible to change the entry custom without the prior permission of the NPPO, Iran.
9- Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original necessary documents in the entry border.
10- The validity period of import permit for consignment entry into one of the country's customs is for 6 months from the date of issuance.
11- The consignment must be exported directly from Russia to I.R.Iran and re-exporting via a third country is not authorized.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing Corn (*Zea mays*) seeds from the Armenia, Belarus, Kazakhstan and Kyrgyzstan to Iran

1- Valid phytosanitary certificate from the country of origin.

2- Disinfection of the consignment with a suitable fungicide in the country of origin and mentioning its particular features in the relevant phytosanitary certificate.
3- The consignment must be free of soil, crop residue, weed seeds, live insects and plant disease symptoms.
4- Each part of consignment must be properly packed and labeled including the scientific name of plant (genus and species).
5-Delivering the Import Permit, the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.
6- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.
7- The import permit can be used for one time.
8- It isn't permissible to change the entry custom without the prior permission of the NPPO, Iran.
9- Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original necessary documents in the entry border.
10- The validity period of import permit for consignment entry into one of the country's customs is for 6 months from the date of issuance.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing barley seed (*Hordeum vulgare*) from the Russia to Iran

1-Valid phytosanitary certificate from Russia in which the freeness of consignment from the following pests is indicated in the Additional Declarations:
Pseudomonas fuscovaginae *Mayetiola destructor*

Note: The scientific name of the above mentioned pest should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s

2- Disinfection of the consignment with a suitable fungicide in the country of origin and mentioning its particular features in the relevant phytosanitary certificate.

3- The consignment must be free of soil, crop residue, weed seeds, live insects and plant disease symptoms.

4- Each part of consignment must be properly packed and labeled including the scientific name of plant (genus and species).

5-Delivering the Import Permit, the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.

6- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.

7- The import permit can be used for one time.

8- It isn't permissible to change the entry custom without the prior permission of the NPPO, Iran.

9- Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original necessary documents in the entry border.

10- The validity period of import permit for consignment entry into one of the country's customs is for 6 months from the date of issuance.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing barley seed (*Hordeum vulgare*) from the Kazakhstan to Iran

1-Valid phytosanitary certificate from the country of origin in which the freeness of consignment from the following pest is indicated in the Additional Declarations:
Mayetiola destructor

Note: The scientific name of the above mentioned pest should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s

2- Disinfection of the consignment with a suitable fungicide in the country of origin and mentioning its particular features in the relevant phytosanitary certificate.

3- The consignment must be free of soil, crop residue, weed seeds, live insects and plant disease symptoms.

4- Each part of consignment must be properly packed and labeled including the scientific name of plant (genus and species).

5-Delivering the Import Permit, the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.

6- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.

7- The import permit can be used for one time.

8- It isn't permissible to change the entry custom without the prior permission of the NPPO, Iran.

9- Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original necessary documents in the entry border.

10- The validity period of import permit for consignment entry into one of the country's customs is for 6 months from the date of issuance.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing barley seed (*Hordeum vulgare*) from the Armenia, Belarus and Kyrgyzstan to Iran

1- Valid phytosanitary certificate from the country of origin.

2- Disinfection of the consignment with a suitable fungicide in the country of origin and mentioning its particular features in the relevant phytosanitary certificate.

3- The consignment must be free of soil, crop residue, weed seeds, live insects and plant disease symptoms.

4- Each part of consignment must be properly packed and labeled including the scientific name of plant (genus and species).

5-Delivering the Import Permit, the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.

6- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.

7- The import permit can be used for one time.

8- It isn't permissible to change the entry custom without the prior permission of the NPPO, Iran.

9- Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original necessary documents in the entry border.

10- The validity period of import permit for consignment entry into one of the country's customs is for 6 months from the date of issuance.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing rape (*Brassica napus* var.*napus*) seeds from all countries to I.R.Iran

1- Valid phytosanitary certificate from the country of origin, in which freeness of consignment from the following pests is indicated in the Additional Declarations:

Leptosphaeria maculans *Plasmodiophora brassica*

Note: The scientific name of the above mentioned pests should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.

2- Disinfection of the consignment with a suitable fungicide in the country of origin and indicating its particular features in the relevant phytosanitary certificate.
3- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.
4- Each part of consignment must be properly packed and labeled including the scientific name of plant (genus and species).
5- Delivering original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible.
6- If the consignment is of any infections which could be disinfected by quarantine officer expediency, the cost must be borne by the importer; otherwise it is destroyed or returned to the country of origin. If any quarantine pest is found, the consignment will be destroyed or returned.
7- Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original necessary documents in the entry border.
8- If the consignment is exported via a third country, a copy of phytosanitary certificate of the first exporter country (with all mentioned requirements) stamped by the second exporter country officials accompanied by the original Re-exporter certificate must be presented to quarantine officials at the point of entry and to the customs clearance office.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing sunflower (*Helianthus annus)* grain from Russia to Iran

1- Valid phytosanitary certificate from the country of origin, in which the freeness of consignment from the following pest is indicated in the Additional Declarations:

Diaporthe helianti

Note: The scientific name of the above mentioned pest should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.

2- Disinfection of the consignment with phosphine gas with 1.5 -2 g/m3 for at least one week at over 15˚C in the country of origin and mentioning its particular features in the relevant phytosanitary certificate.

3- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.

4- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible

5- As there are no possibility for disinfecting and completely controlling quarantine agents in our entry borders, if the consignment is found to be contaminated to quarantine harmful agents or the names of harmful agents which has emphasized in part one of this quarantine requirement, has not been mentioned in AD section (Additional Declaration) of phytosanitary certificate, the consignment will be returned or destroyed.

6- If the consignment is exported via a third country, a copy of phytosanitary certificate of the first exporter country (with all mentioned requirements) stamped by the second exporter country officials accompanied by the original Re-exporter certificate must be presented to quarantine officials at the point of entry and to the customs clearance office.

7- Passavant of consignment to domestic customs will be authorized only after investigation and confirmation of original copy of necessary documents in the entry border.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing sunflower (*Helianthus annus)* grain from Armenia, Belarus, Kazakhstan and Kyrgyzstan to Iran

1- Valid phytosanitary certificate from the country of origin.
2- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.
3- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible
4- As there are no possibility for disinfecting and completely controlling quarantine agents in our entry borders, if the consignment is found to be contaminated to quarantine harmful agents or the names of harmful agents which has emphasized in part one of this quarantine requirement, has not been mentioned in AD section (Additional Declaration) of phytosanitary certificate, the consignment will be returned or destroyed.
5- Passavant of consignment to domestic customs will be authorized only after investigation and confirmation of original copy of necessary documents in the entry border.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing Pea grain (*Pisum sativum*) from Russia to Iran

1-Valid phytosanitary certificate from Russia in which the freeness of consignment from the following pests is indicated in the Additional Declarations:
Pea early- browning virus
Pseudomonas savastanoi pv.*phaseolicola*
Pseudomonas syringae pv. *pisi*
Orobanche spp.

Note: The scientific name of the above mentioned pests should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.

2- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.

3- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.

4- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.

5 - Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.

6- If the consignment is exported via a third country, a copy of phytosanitary certificate of the first exporter country (with all mentioned requirements) stamped by the second exporter country officials accompanied by the original Re-exporter certificate must be presented to quarantine officials at the point of entry and to the customs clearance office.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing bean grain (*phaseolus vulgaris*) from Russia to Iran

1-Valid phytosanitary certificate from Russia in which the freeness of consignment from the following pests is indicated in the Additional Declarations:
Curtobacterium flaccumfaciens pv. *flaccumfaciens*
Pseudomonas savastanoi pv. *phaseolicola*
Xanthomonas axonopodis pv. *glycines*
Tomato black ring virus

Note: The scientific name of the above mentioned pests should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.

2- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.

3- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.

4- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.

5 - Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.

6- If the consignment is exported via a third country and the scientific name of the above mentioned pests are not indicated in the phytosanitary A.D of the country of origin, the Re-exporter country should do the laboratory tests and indicate the absence of the pests in the Re-export phytosanitary A.D and then stamp the tests documents and a copy of phytosanitary certificate of the country of origin by its own country officials and accompany them by the original Re-export phytosanitary certificate.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing bean grain (*phaseolus vulgaris*) from Kazakhstan to Iran

1-Valid phytosanitary certificate from Russia in which the freeness of consignment from the following pests is indicated in the Additional Declarations:
Xanthomonas axonopodis pv. *glycines*

Note: The scientific name of the above mentioned pest should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s

2- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.
3- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.
4- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.
5 - Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.
6- If the consignment is exported via a third country, a copy of phytosanitary certificate of the first exporter country (with all mentioned requirements) stamped by the second exporter country officials accompanied by the original Re-exporter certificate must be presented to quarantine officials at the point of entry and to the customs clearance office.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing bean grain (*phaseolus vulgaris*) from Belarus to Iran

1-Valid phytosanitary certificate from Russia in which the freeness of consignment from the following pests is indicated in the Additional Declarations:
Tomato black ring virus

Note: The scientific name of the above mentioned pests should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.

2- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.

3- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.

4- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.

5 - Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.

6- If the consignment is exported via a third country and the scientific name of the above mentioned pests are not indicated in the phytosanitary A.D of the country of origin, the Re-exporter country should do the laboratory tests and indicate the absence of the pests in the Re-export phytosanitary A.D and then stamp the tests documents and a copy of phytosanitary certificate of the country of origin by its own country officials and accompany them by the original Re-export phytosanitary certificate.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing soy bean grain (*Glycine max*) from Russia to Iran

1-Valid phytosanitary certificate from Russia in which the freeness of consignment from the following pests is indicated in the Additional Declarations:
Curtobacterium flaccumfaciens pv. *flaccumfaciens*
Pseudomonas savastanoi pv. *Phaseolicola*
Pseudomonas savastanoi pv. *glycines*
Xanthomonas axonopodis pv. *glycines*
Diaporthe phaseolorum var. *caulivora*

Note: The scientific name of the above mentioned pests should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.
2- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.
3- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.
4- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.
5 - Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.
6- If the consignment is exported via a third country and the scientific name of the above mentioned pests are not indicated in the phytosanitary A.D of the country of origin, the Re-exporter country should do the laboratory tests and indicate the absence of the pests in the Re-export phytosanitary A.D and then stamp the tests documents and a copy of phytosanitary certificate of the country of origin by its own country officials and accompany them by the original Re-export phytosanitary certificate.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing soy bean grain **(*Glycine max*) from Kazakhstan to Iran**

1-Valid phytosanitary certificate from the country of origin in which the freeness of consignment from the following pests is indicated in the Additional Declarations:
Pseudomonas savastanoi pv. *glycines*
Xanthomonas axonopodis pv. *glycines*

Note: The scientific name of the above mentioned pests should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.

2- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.

3- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.

4- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.

5 - Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.

6- If the consignment is exported via a third country and the scientific name of the above mentioned pests are not indicated in the phytosanitary A.D of the country of origin, the Re-exporter country should do the laboratory tests and indicate the absence of the pests in the Re-export phytosanitary A.D and then stamp the tests documents and a copy of phytosanitary certificate of the country of origin by its own country officials and accompany them by the original Re-export phytosanitary certificate.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing coco chips from all countries to Iran

1- Valid phytosanitary certificate from the country of origin.
2- Disinfection of the consignment in the country of origin with one of the following methods and mentioning its particular features in the relevant phytosanitary certificate:

A) Disinfection with Methyl- bromide at a concentration of at least 32 grams per cubic meter of gas, for at least 24 h at 20°C and above in condition NAP.
B) Disinfection with Phosphine at a concentration of 1-2 grams per cubic meter of gas consignment volume, at 15°C and above for at least 5 days

2- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.
3- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.
4- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.
5 - Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.
6- If the consignment is exported via a third country, a copy of phytosanitary certificate of the first exporter country (with all mentioned requirements) stamped by the second exporter country officials accompanied by the original Re-exporter certificate must be presented to quarantine officials at the point of entry and to the customs clearance office.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing pinus bark chips from all countries to Iran

1- Valid phytosanitary certificate from the country of origin.

2- Disinfection of the consignment in the country of origin with one of the following methods and mentioning its particular features in the relevant phytosanitary certificate:

A) Disinfection with Methyl- bromide at a concentration of at least 48 grams per cubic meter of gas, for at least 24 h at 21°C and above in condition NAP.

B) Disinfection with Heat Treatment (HT) at a temperature of at least 56°C for at least 30 minutes.

Note: when the temperature of central part the consignment reaches 56°C, the disinfection period is measured.

3- The maximum dimensions of the chips should be 25*75 milimeter.

4- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.

5- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.

6- If the consignment is found to be contaminated with any plant- damaging agents, which could be disinfected by quarantine officer expediency, disinfection will be carried out at the expense of the importer; otherwise it is destroyed or returned to the country of origin.

7 - Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.

8- If the consignment is exported via a third country, a copy of phytosanitary certificate of the first exporter country (with all mentioned requirements) stamped by the second exporter country officials accompanied by the original Re-exporter certificate must be presented to quarantine officials at the point of entry and to the customs clearance office.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing wood chips from all countries with the exception of those infected to *Bursaphelenchus spp*.

1-Valid phytosanitary certificate from the country of origin in which the freeness of consignment from the following pests is indicated in the Additional Declarations:

Monochamus spp.	*Bursaphelenchus* spp.
Cronartium quercuum	*Cryphonectria parasitica*
Ophiostoma spp.	*Phytophthora cinnamomi*
Ceratocystis spp.	*Gremmeniella abietina*
Lachnellula willkommii	*Ips* spp.
Dermea pini	*Anoplophora* spp.
Agrillus spp.	

Note: The scientific name of the above mentioned pests should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.

2- The maximum Diameter of the chips should be 30 millimeter and the dimensions should not be bigger than 80*30 millimeter.

3- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms.

4- Disinfection of the consignment in the country of origin with one of the following methods and mentioning its particular features in the relevant phytosanitary certificate:

A) Disinfection with Methyl- bromide at a concentration of at least 48 grams per cubic meter of gas, for at least 24 h at 21°C and above in condition NAP.
Note 1: It is necessary for every 5 degree reduction in temperature, 8 g of gas to be added to the initial dose.
Note 2: Disinfection at temperature less than 10°C is not acceptable.

B) Disinfection with Heat Treatment (HT) at a temperature of at least 70°C for at least 4 hours.
Note: when the temperature of central part the consignment reaches 70°C, the disinfection period is measured. The original thermograph print stamped by the quarantine officials should be submitted.

C) Disinfection with Phosphine at a concentration of 4-5 grams per cubic meter of consignment volume, at 15°C and above for at least 5-7 days.

5- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible for the consequences.

6- As there are no possibility for disinfecting and completely controlling quarantine agents in our entry borders, if the consignment is found to be contaminated to quarantine harmful agents or the names of harmful agents which has emphasized in part one of this quarantine requirement, has not been mentioned in AD section (Additional Declaration) of phytosanitary certificate, the consignment will be returned or destroyed.

7 - Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.

8- Importing wood chips from the countries infected to *Bursaphelenchus spp*. Including Portugal, China, Hong Kong, Taiwan, Japan, North Korea, Canada, Mexico and U.S.A is forbidden.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to import.

Phytosanitary requirements for importing raw cotton bales (*Gossypium hirsutum* from Armenia and Belarus to Iran

1- Valid phytosanitary certificate from the country of origin in which the freeness of consignment from the following pests is indicated in the Additional Declarations:

Pectinophora gossypiella *Pectinophora scutigera*
Helicoverpa zea *Earias fabia*
Anthonomus grandis *Glomerella gossypii*
Xanthomonas axonopodis pv. *Malvacearum*

Note: The scientific name of the above mentioned pests should be indicated in the phytosanitary certificate, otherwise; the documents are considered as incomplete. Moreover, any financial customs losses and non-delivery of the consignment due to the non-compliance are to be borne by the importer/s.

2- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms, Cotton seeds, seed barks and boll, and the cover should be safe and new.

3- Disinfection of the consignment **in the country of origin** with **Methyl-bromide** at a concentration of at least 40 grams per cubic meter of gas, for at least 24 h at 21°C and above in condition NAP.

Note 1: It is necessary for every 5 degree reduction in temperature, 8 g of gas to be added to the initial dose.

Note 2: Disinfection at temperature less than 10°C is not acceptable.

4- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible.

5- If the consignment is of any infections which could be disinfected by quarantine officer expediency, the cost must be borne by the importer; otherwise it is destroyed or returned to the country of origin. If any quarantine pest is found, the consignment will be destroyed or returned.

6- Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.

7- If the consignment is exported via a third country and the scientific name of the above mentioned pests are not indicated in the phytosanitary A.D of the country of origin, the Re-exporter country should do the laboratory tests and indicate the absence of the pests in the Re-export phytosanitary A.D and then stamp the tests documents and a copy of phytosanitary certificate of the country of origin by its own country officials and accompany them by the original Re-export phytosanitary certificate.

8- Re-exporting via a third country is authorized just with previous permission from NPPO of Iran.

Note:The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to importations.

Phytosanitary requirements for importing raw cotton bales (*Gossypium hirsutum* from Kyrgyzstan and Kazakhstan to Iran

1- Valid phytosanitary certificate from the country of origin.
2- Disinfection of the consignment in the country of origin with one of the following methods and mentioning its particular features in the relevant phytosanitary certificate:

   - Disinfection with Methyl- bromide at a concentration of at least 40 grams per cubic meter of gas, for at least 24 h at 21°C and above in NAP condition (**Disinfection at temperature less than 10°C is not acceptable).**
   - Disinfection with Phosphine at a concentration of 2 grams per cubic meter of gas consignment volume, at 15°C and above for one week.

3- The consignment must be free from soil, crop residue, weed seeds, live insects and plant disease symptoms, Cotton seeds, seed barks and boll, and the cover should be safe and new.
4- The limit for cotton seeds in the consignment is zero percent; otherwise the consignment cannot be released.
5- The consignment must be covered with safe and new coverage.
6- Re-exporting via a third country is authorized just with previous permission from NPPO of Iran.
7- Delivering the original phytosanitary certificate with mentioned requirements as well as other necessary documents to quarantine officers at the time of inspection of the consignment in destination border and customs clearance is mandatory. Otherwise, the importer will be found responsible.
8- If the consignment is of any infections which could be disinfected by quarantine officer expediency, the cost must be borne by the importer; otherwise it is destroyed or returned to the country of origin. If any quarantine pest is found, the consignment will be destroyed or returned.
9- Passavant of the consignment to domestic customs will be authorized only after investigation and confirmation of original of necessary documents in the entry border.

Note: The declared conditions have been issued as per contents of article 11 of plant protection act regarding plant quarantine issues and the importer is obliged to observe other rules and regulations related to importations.

ANNEX-2

GUIDELINES ON REGISTRATION OF PHARMACEUTICAL PRODUCTS FOR IMPORTS

IN THE ISLAMIC REPUBLIC OF IRAN

MINISTRY OF HEALTH AND MEDICAL EDUCATION

DEPUTY FOR FOOD AND DRUG

Division of Pharmaceutical and Narcotic Affairs

APRIL 2007

Contents

Regulations on Marketing Authorization of Pharmaceutical Products

According to article 14 of the Act on Medical Affairs, Pharmaceuticals and Foodstuff (passed in 1955 and amended in 1988), in the Islamic Republic of Iran the Ministry of Health and Medical Education (MOH) is the main body that, as the Iranian National Drug Regulatory Authority, regulates and implements the imports, registration, and customs release of any sort of pharmaceutical products.

As stated in the article 20 of the aforesaid Act, the MOH enforces standards and authorizes the manufactures and imports of pharmaceuticals and biological products. Imports of pharmaceuticals that are listed by the Iranian Drug Evaluation Committee Secretariat can be performed according to the following ten articles: (The aforesaid list is available at www.fdo.ir)

Article One) Registration Application:

1-1) Any legal entity that holds an exclusive agency of the Product License Holder (PLH) or its Marketing Authorization Holder (MAH), can apply for the registration and imports of the related pharmaceuticals at the Division of Pharmaceutical and Narcotic Affairs. The applicant shall present the followings for registration also:

1-1-1) The application form in appendix 1 filled out by the applicant

1-1-2) A photocopy of the exclusive letter of authorization endorsed by the Iranian Embassy in the country of origin.

1-1-3) A registration certificate issued by the Iranian Ministry of Commerce

1-2) In case the application is approved by the expert council, the applicant has to:

1-2-1) Introduce a qualified pharmacist as a responsible pharmacist (articles 10 and 11 of this material) to the Division of Pharmaceutical and Narcotic Affairs to follow up the registration and related affairs in that office.

1-2-2) The preliminary documents discussed in the sections 1-7 of article 2 have to be submitted to the Division of Pharmaceutical and Narcotic Affairs within 6 months of the approval. The application will be nullified, should the documents are not submitted within 6 months.

Article Two) Documents Required for Registration

The application for registration must be submitted on the company letterhead.
The following documents also must be attached:

2-1) A photocopy of the preliminary approval of the Division of Pharmaceutical and Narcotic Affairs

2-2) A photocopy of the responsible pharmacist's license

2-3) The original copy of the exclusive letter of authorization issued by the Product License Holder (PLH) or its Marketing Authorization Holder (MAH) endorsed by the Iranian Embassy in the country of origin. (a photocopy of the letter of authorization have to be included in the dossier of each product, the original exclusive agency letter also must be presented which will be returned upon verification)

The exclusive letter of authorization must be on the letterhead of the awarding company, sealed and signed by the director in charge, and it must include the followings, as a minimum:

A) Name and address of the Product License Holder (PLH) or Marketing Authorization Holder (MAH)
B) Name and address of the agent
C) The name of the product(s), pharmaceutical & dosage form
D) Date of issue of the letter of authorization
E) Validity date of agency
F) Authorities assigned to the agent
In case the agency is issued by a regional office, a photocopy of the letter of the parent company consisting of the authorities assigned to the regional office has to be submitted. The photocopy needs to be endorsed by the Iranian Embassy in the country of origin.

2-4) The original copy of the Certificate of a Pharmaceutical Product (CPP) that should conform to the format recommended by the World Health Organization (WHO) and shown in appendix 2, issued by the pharmaceutical competent authority of the country of origin or European Medicines Evaluation Agency (EMEA). The CPP needs to be endorsed by the Iranian Embassy in the country of origin along with the Summary of Product Characteristics (SPC).

2-5) The original copy of the GMP certificate for manufacturing and packaging site(s) issued by the pharmaceutical competent authority of the country of origin and endorsed by the Iranian Embassy in the country of origin. (This certificate is required only if in the CPP the GMP Standards of the manufacturing and packaging site(s) are not stated.)

2-6) The global registration status endorsed by the chamber of commerce and the Iranian Embassy in the country of origin.

NOTE:

The Medicine in question has to be registered and has consumption records in at least one country other than the manufacturing country. (Appendix 3)

2-7) Drug Importing Application Form (DIAF), Appendix 4, that has to be completed by the Product License Holder (PLH) or Marketing Authorization Holder (MAH).

Upon considering and approval of the above-mentioned documents, the applicant will be communicated to present the Dossier of the Medicine within 6 months to the Division of Pharmaceutical and Narcotic Affairs. Should the applicant fail do so, the registration will be considered null and void.

NOTE:

The presented Dossier will be considered according to the time table provided in Appendix 5.

The applicant shall dispatch the following documents to the Division of Pharmaceutical and Narcotic Affairs by an official letter:

2-8) A photocopy of the bank receipt for paying the registration fee according to the Iranian annual budget law. The receipt has to be endorsed by the financial office of the Deputy for Food and Drug.

2-9) The completed form for Registration of Medicines (Appendix 6)

2-10) The Dossier

The Dossier has to be typed and presented in English and it has to include the followings:

2-10-1) An official letter presented by the Product License Holder (PLH) or Marketing Authorization Holder (MAH) on introducing the qualified person who contributed to the Dossier including their name,

workplace address, telephone and fax numbers, E-mail address and their signature specimen

2-10-2) The Dossier should preferably be presented in CTD format (Common Technical Document), or else its contents should conform to the list set forth in Appendix 7.

2-10-3) Presenting the chromatograms and peaks (identification, analysis, impurities) of the active ingredients and finished product related to the batch number mentioned in the Dossier

2-10-4) In case the reference used in analysis of the active ingredients and finished product is not a valid pharmacopoeia, the In House method has to be presented along with the related documents of validation.

2-10-5) A sample of the Persian translation of the leaflet and printed matter on the outer packaging as stated in Appendix 8

The Dossier has to be thoroughly studied by the Responsible Pharmacist of the agency and presented to the Division of Pharmaceutical and Narcotic Affairs. The applicant will be notified of any sort of shortcomings upon reviewing the documents by the experts of the Division of Pharmaceutical and Narcotic Affairs. Then the responsible pharmacist has to remedy the shortcomings within six months. Obviously, this period will not be counted in the time schedule for registering the product. Should the applicant fail to complete the Dossier within this period, the registration procedure will be nullified and the applicant has to start the registration from scratch.

NOTE:

The applicant has to respond to the shortcomings thoroughly each time, otherwise reconsideration of the Dossier shall not be possible.

In case any sample of the product is required to be dispatched to the Division of Quality Control Laboratory of Deputy for Food and Drug, the matter shall be communicated to the applicant.
Two copies of the Dossier should be available in the archives of the applying company, and if required a copy shall be sent to the Division of Quality Control Laboratory of Deputy for Food and Drug.

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NOTE 1:

The registration of the medicine in question is possible only under the same name and the same manufacturing site as in the country of origin.

NOTE 2:

In case the name of the medicine to be registered in Iran is different from the name of the medicine in the country of origin and other consuming countries, the same has to be clearly indicated in the CPP. Also, the manufacturing company has to approve the identity of formulation, manufacturing methods and manufacturing site of the two different names.

NOTE 3:

As for the marketing authorization of biological medicines and controlled medicines, the related regulations have to be obliged as well as the regulations set forth in this guidelines.

NOTE 4:

The applicant will be held responsible for the contents of the Persian leaflet as for its conformity with the manufacturer's leaflet.

NOTE 5:

In case the Division of Pharmaceutical and Narcotic Affairs requires, a conformed copy of GMP approval of the manufacturing site(s) issued by the U.S. Food and Drug Administration (FDA), or European Medicines Evaluation Agency (EMEA), or Australia's Therapeutic Goods Administration (TGA), or World Health Organization (WHO) that is endorsed by the Iranian Embassy in the country of origin shall be presented.

NOTE 6:

If the Expert council requires, the Quality Control and Clinical Trial Section of the Division of Pharmaceutical and Narcotic Affairs shall present an approval of bioequivalency studies or clinical trial or Post Marketing Surveillance (PMS).

NOTE 7:

In case the Expert council requires a GMP audit to the manufacturing company, the same will be communicated to the applicant.

Article Three) Announcement of the Registration Number in Iran:

Upon evaluation of the aforesaid documents, the issue will be discussed in the expert council. Upon approval of the expert council, the medicinal product licence (Appendix 9) will be issued for the applicant and the registration number in Iran (IRC) will be announced.

Article Four) Pricing:

The applicant shall present the related pricing documents to the Pricing Committee of the Division of Pharmaceutical and Narcotic affairs.

NOTE 1:

The importer shall enter into a contract with a pharmaceutical distribution company.

NOTE 2:

The authorized agent shall approach the Division of Pharmaceutical and Narcotic Affairs to obtain the relevant regulations on promoting the pharmaceutical products and shall feel committed to these regulations.

NOTE 3:

As the Expert council urgently requires the need for reporting Adverse Drug Reactions (ADR),agencies are bound to report any sort of the Adverse Drug Reactions of their imported pharmaceutical products and the Periodic Safety Update Report(s) (PSUR) to the ADR Center of the Deputy for Food and Drug.

Article Five) Validity of the Marketing Authorization License:

The Marketing Authorization License will be valid for four years from the date of issue.
The agency has to submit the followings to the Division of Pharmaceutical and Narcotic Affairs to renew the license six months before the expiry date of the license:

5-1) The original copy of the exclusive letter of authorization as stated in part 2-3

5-2) Valid Representation Registration Certificate issued by the Iranian Ministry of Commerce
5-3) Certificate of a pharmaceutical Product (CPP) as stated in part 2-4
5-4) A photocopy of the Responsible Pharmacist's license
5-5) The bank receipt for license renewing fee
5-6) A photocopy of the existing Marketing Authorization License
5-7) An approval issued by the Product License Holder (PLH) or its Marketing Authorization Holder (MAH) on non-variation in the formulation, manufacturing methods and manufacturing site, and etc. of the medicine in question
5-8) A sample of the packaging (including the box, label, strip, cartridge or vial, carton labeling or shrink-wrap)
5-9) A specimen of the product
5-10) The latest approval of the Division of Quality Control Laboratory of Deputy for Food and Drug on the imported consignment of the medicine in question

Upon considering and approval of the above-mentioned documents, they will be referred to the expert council for renewing the license.
In case the registering company fails to meet the requirements of license renewing, it will lose marketing authorization.

Article Six) The Nullification of the Marketing Authorization License:

The Marketing Authorization License will be nullified in the following cases according to the decrees issued by the expert council:

6-1) The medicine in question is eliminated from the Iranian Drug List.
6-2) If proved that presented documents for registration are not genuine or are forged.

6-3) If proved that the pharmaceutical product has serious side effects and its consumption has been forbidden by the World Health Organization (WHO) or other national or international competent authorities.

6-4) If a competent national authority presents documentary evidence on the side effects of the registered brand

6-5) If proved that the manufacturer does not abide by the GMP standards or recurrently violates from the principles.

6-6) If the medicine fails to respond appropriately to the tests conducted by the Division of Quality Control Laboratory of Deputy for Food and Drug

In case the manufacture of the pharmaceutical product is terminated or its marketing authorization is suspended in the country of origin, the authorized agent in Iran shall immediately communicate the same to the Division of Pharmaceutical and Narcotic Affairs.

Article Seven) variations:

Any variations on agent, the manufacturer, the ownership of the manufacturer, the country of origin, the manufacturing and packaging site, and in the contents of the Dossier shall be officially announced by the Product License Holder (PLH) or Marketing Authorization Holder (MAH) and the same shall be communicated to the Division of Pharmaceutical and Narcotic Affairs by the importing company.
The documents required for any of the above-mentioned changes are as following that shall be officially presented to the Division of Pharmaceutical and Narcotic Affairs:

7-1) Agent change:
A) A letter from the Product License Holder (PLH) or its Marketing Authorization Holder (MAH) on nullifying

the previous agent endorsed by the Iranian Embassy in the country of origin.

B) A letter from the Product License Holder (PLH) or its Marketing Authorization Holder (MAH) on assigning the new agent endorsed by the Iranian Embassy in the country of origin as stated in part 2-3.

C) Registration Certificate issued by the Iranian Ministry of Commerce

Upon presenting the documents in part 7-1 the IRC of the registered medicine will be transferred to the new agent.

7-2) Changes in the name or address of the Product License Holder (PLH) or Marketing Authorization Holder (MAH):

New CPP shall be presented for any product as stated in part 2-4.

7-3) Changes in the ownership of the Product license Holder (PLH) or Marketing Authorization Holder (MAH):

A) A copy of the exclusive letter of authorization as stated in part 2-3

B) Representation Registration Certificate issued by the Iranian Ministry of Commerce

C) An official letter from the previous PLH/MAH on transfer of the ownership of the company to the new company endorsed by the Iranian embassy in the country of origin

D) Presenting a new CPP for any product as stated in part 2-4

7-4) Changes in the manufacturing and packaging site(s):

A) Presenting a new CPP for any product as stated in part 2-4

B) The original copy of the GMP certificate for the new manufacturing and packaging site(s)

C) The approval of the Division of Quality Control Laboratory of Deputy for Food and Drug on the new imported consignment of the medicine in question

D) An official letter presented by the Product License Holder (PLH) or its Marketing Authorization Holder (MAH) showing that the contents of the Dossier already submitted are fully obliged in the new manufacturing and packaging site(s).

7-5) Changes in the contents of the Dossier

Any changes in the contents of the Dossier (formulation, manufacturing methods, packaging, etc.) shall be officially and thoroughly communicated to the Division of Pharmaceutical and Narcotic Affairs. Approval and announce any changes after the issue of the IRC to the Product License Holder (PLH) or Marketing Authorization Holder (MAH) is permitted by the responsible pharmacist of the agency.

Article Eight) Proforma Invoice:

After registering the pharmaceutical product, the proforma invoice for imports will be admitted according to the following regulations:

8-1) Three copies of the proforma invoice shall be presented. The contents of the proforma invoice shall be confirmed (sealed and signed) by the responsible pharmacist.

8-2) The International Non-Proprietary Name (INN), Proprietary Name,

Pharmaceutical Form and Dosage stated in the proforma invoice shall be the same as in the Dossier.

8-3) Name and the address of the factory and the manufacturing country stated in the proforma invoice shall be the same as in the presented documents.

8-4) Type of packaging and pack size of the product stated in the proforma invoice shall be the same as in the Dossier.

8-5) The shelf life of the product shall be stated in the proforma invoice and it should have appropriate shelf life (at least 2/3 of the shelf life) at the time of delivery.

Article Nine) Invoice:

All the importing companies that abide by the following regulations can present a Commercial invoice to release their goods from the customs:
Obviously prior to the commercial invoice the proforma invoice and the order registration sheet of goods shall be admitted to the Division of Pharmaceutical and Narcotic Affairs. If goods are imported without foreign exchange transfer, the Division of Pharmaceutical and Narcotic Affairs shall be notified of the imports, otherwise, the importer will be held responsible.

9-1) Three copies of the invoice shall be presented. The contents of the invoice shall be confirmed (sealed and signed) by the responsible pharmacist.

9-2) Presenting the original copy of the applicant of the relevant proforma invoice

9-3) The commercial invoice has to refer to the number and the dated of the relevant proforma invoice

9-4) The International Non-Proprietary Name (INN), Proprietary Name,
Pharmaceutical Form and Dosage, pack size, name and the address of the factory and the manufacturing company stated in the invoice shall be the same as in the proforma invoice.

9-5) The batch number and the shelf life of the product shall be stated in the commercial invoice and it should have appropriate shelf life (at least 2/3 of the shelf life) at the time of delivery. Otherwise, a packing list that contains this information shall be presented. The presented packing list should bear the number and the dated of the relevant invoice.

9-6) Presenting the certificate of analysis that includes information on all delivered batches by the company in charge of releasing the goods.

The responsible pharmacist of the importing company has to keep the original copy of the certificate of analysis.

9-7) If the ingredients used in the formulation of the product, as stated in the Dossier, includes substances (such as lactose, magnesium stearate, gelatin, polysorbate 80, etc.) that require assurance of non-contamination to Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE), the responsible pharmacist shall complete and present the form for each commercial invoice of the goods.

Article Ten) Duties of the responsible pharmacist

10-1) Reviewing and approving the contents of all documents for marketing authorization based on the relevant regulations

10-2) Any change or amendment in the contents of documents for marketing authorization shall be followed by the responsible pharmacist and the same shall be reported to the Division of Pharmaceutical and Narcotic Affairs.

10-3) Presenting and approval of all certificates if required

10-4) Noting the responsible pharmacist's executive responsibilities in removing the imperfections, the responsible pharmacist shall take appropriate measures for improvements and inform the managing director and the Division of Pharmaceutical and Narcotic Affairs of the same with a scheduled plan.

10-5) Supervision over the procurement of the medicine to make sure that all contents of the Dossier, rules, bylaws, and the regulations of the Ministry of Health are being implemented.

NOTE:

Stating the IRC and the bar code on the secondary packaging of the medicine is mandatory and the same shall be supervised by the responsible pharmacist.

10-6) Other than Good Manufacturing Practice (GMP), the responsible pharmacist has to be fully familiar with the principles of Good Storage Practice (GSP), and Good Distribution Practice (GDP),for example:

- Being informed of the storage, shipment and packaging of the medicine based on the relevant regulations
- Supervision over the humidity and temperature of the warehouse
- Supervision over the security system of the warehouse
- Supervision over proper warehousing methods and training the warehouse personnel
- Supervision over delivering the imported consignments to the distribution companies based on the announced regulations
- Supervision over the recalled, refunded and faulty medicines and reporting the same to the Division of Pharmaceutical and Narcotic Affairs
- Storing samples of the imported medicines of each batch based on the relevant regulations
- Informing the medical health care professionals based on the relevant regulations and approving the promotions for obtaining permits
- Issuing the distribution permit for some pharmaceutical products based on the relevant regulations
- Other than the archives of the company, the responsible pharmacist is bound to keep the following documents:

A) Documents required to prove the relevant supervisions

B) Documents related to complaints, follow-ups, and assigning the affairs to the relevant departments, and outcomes of the measures taken

C) Current circular letters of the Ministry of Health and Medical Education

D) Statistics for imports and damages of each year

NOTE:

The responsible pharmacist is bound to present the sample(s) as well as the required documents to the Division of Quality Control Laboratory of Deputy for Food and Drug and Drug. The numbers of the medicines and the documents required is shown in the appendixes 10 and 11.

Appendix 1

Application Form for Registration of Imported Pharmaceutical Product

International Non-Proprietary Name (INN):
Proprietary Name :
Pharmaceutical Form & Dosage :
Packaging in Iran (Type of Packaging, the Number/Volume in Each Pack):
Pharmaceutical Group:
Name of Manufacturer(s);Country(ies):
Name of Product License Holder (PLH)/Marketing Authorization Holder (MAH):
Authorized Agent in Iran:
Name the Valid International Certificate(s) of the product, if any, (Such as U.S. FDA Certificate, EMEA Certificate, etc.):
List the country(ies) where the pharmaceutical product has been registered. In each case state the proprietary name used in that country.

Country	Proprietary Name

Appendix 2

World Health Organization

Model certificate of a pharmaceutical product

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Certificate of a pharmaceutical product[1]

This certificate conforms to the format recommended by the World Health Organization

No. of certificate

Exporting (certifying country):

Importing (requesting country):

1. Name and dosage form of the product:

1.1. Active ingredient(s)[2] and amount(s) per unit dose[3]:

For complete composition including excipients, see attached[4]:

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5] (yes/no)

1.3 Is this product actually on the market in the exporting country?

If the answer to 1.2. is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B[6]:

2.A.1. Number of product license[7] and date of issue:

2.A.2. Product license holder (name and address):

2.A.3. Status of product license holder[8]: (Key in appropriate category as defined in note 8)

2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is[9]:

2.A.4. Is a summary basis for approval appended?[10] (yes/no)

2.A.5. Is the attached, officially approved product information complete and consonent with the license?[11] (yes/no/not provided)

2.A.6. Applicant for certificate, if different from license holder (name and address)[12]:

2.B.1. Applicant for certificate (name and address):

2.B.2. Status of applicant: (Key in appropriate category as defined in footnote 8)

2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:[9]

2.B.3. Why is marketing authorization lacking? (not required/not requested/under consideration/refused)

2.B.4. Remarks[13]:

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable)[14]

If not or not applicable, proceed to question 4.

3.1. Periodicity of routine inspections (years):

3.2. Has the manufacture of this type of dosage form been inspected? (yes/no)

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15] (yes/no/not applicable)[14]

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16]: (yes/no)

If no, explain:

Address of certifying authority:

Telephone:

Fax:

Name of authorized person:

Signature

Stamp and date

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-license holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:

a. manufactures the dosage form;
b. packages and/or labels a dosage form manufactured by an independent company; or
c. is involved in none of the above.

9. This information can only be provided with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license has to be updated or it is no longer valid.

10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)

12. In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission has to be provided to the authority by the applicant.

13. Please indicate the reason that the applicant has provided for not requesting registration.

a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of origin;

b. the product has been reformulated with a view to improving its stability under tropical conditions;

c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;

d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;

e. any other reason, please specify.

14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

16. This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

Appendix 3

List of Countries in Which (Name of Drug with Strength and Pharmaceutical Form) is Registered :

We hereby confirm that, to the best of our knowledge, the following list is a true representation of the registration status of the preparation (Name of Drug).

Country	Trade Name	Registered Since	Registration No	Marketed Since

Name and Title of Responsible Official in the Company :

Signature of Responsible Official in the Company :

Date and Stamp :

Appendix 4
Drug Importing Application Form

1-<u>Drug information</u>

Product (Trade) name (as used in the country of origin) :	
Active substance(s) :	
Strength :	
Pharmaceutical form :	
Route of administration :	
Container, closure and administrative device (s) :	
Pack size and strengths used in the country of origin :	
Pack size for Iran :	
Shelf life period (In the country of origin):	
Shelf life period (In Iran):	
Shelf life (after reconstitution or dilution) :	
Shelf life (after first opening container) :	
Storage conditions :	

2-<u>Manufacturer</u>

Product license/ Marketing authorization holder (Name, address & country) :	
Number and date of the first marketing authorization / Renewal (In the country of origin):	
Number and date of the first marketing authorization (In the world) :	
Number of product license and date of issue**:**	
Manufacturer of finished product (Name, address & country):	

Responsibility	Name , Address & Country
Manufacturer(s) of the active substance(s):	
Manufacturer(s) of dosage form :	
Labeling :	
Primary packaging :	
Secondary packaging :	
Analytical testing :	
Batch release :	
Final release :	
Alternative manufacturing site/packaging site:	

3-<u>Authorized agent in Iran</u>

Name & address :	

4-<u>Qualitative and quantitative composition</u>

4-1- Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)

- List the active substance(s) separately from the excipient(s)

Name of the active substance(s)*	Quantity	Unit	Reference

Name of the excipient(s)*	Function	Quantity	Unit	Reference

Note: * the active substance should be declared by it's recommended INN, Accompanied by it's salt or hydrate relevant.

Details of any overages-these should not be included in the formulation columns but stated below :

- Active substance (s) :
- Excipient (s) :
- Incompatibilities of the excipients :

4-2-a- List of materials of animal and/or human origin contained or use in the manufacturing process of the medicinal product.

NONE	

Name	Function			Human	Animal (to be precised)	Animal origin Susceptible to TSE			
	AS	EX	R				Yes		NO
							Yes		NO
							Yes		NO
							Yes		NO
							Yes		NO

* AS = Active substance, EX = Excipient (including starting materials used in the manufacture of the active substance/excipeient) , R = Reagent/culture medium.

4-2-b- List of constituents from other origins
4-3- Coloring , flavoring and perfume compounds

4-4- A specimen of the lable and leaflet

5- Clinical particulars

5-1- Therapeutic indications

5-2- Pharmacodynamic properties

5-3- Pharmacokinetic properties

5-4- Contra – indications

5-5- Warnings and precautions

5-6- Interaction with other medicinal products and other forms of interaction

5-7- Use in pregnancy and lactation

5-8- Effects on ability to drive and use machines

5-9- Undesirable effects

5-10- Overdose

6- Names and titles of official signatories of registration dossier/Signature

- This is to certify that the information contained here in is true and correct.
- Name and title of responsible official in the company :
- Signature of responsible official in the company :
- Date and Stamp :
- Full address :

Appendix 5

Time Table for Evaluation of Dossier in the Division of Pharmaceutical and Narcotic Affairs

All Dossiers will be classified in one of the following four tracks (based on the time they are presented to the Division of Pharmaceutical and Narcotic Affairs):

A) Track one (Fast Track)…… …….…3-month period
B) Track two ……...…. .6-month period
C) Track three ……...12-month period
D) Track four ……24-month period

Note: The time needed for responding to deficiency letter will not be included the above-mentioned periods.

Track 1: (3-month period) Application for imports of pharmaceuticals that are neither domestically manufactured nor imported.

Track 2: (6-month period) Application for imports of pharmaceuticals that have one domestic manufacturer or one importer.

Track 3: (12-month period) Application for imports of pharmaceuticals that are not domestically manufactured but are imported by two or three importers.

Track 4: (24-month period) Other cases

Note 1: The Dossiers for herbal medicines and biological products are excepted from the above tracks.

Note 2: In case an applicant fails to complete a submitted Dossier within the stated period, the Dossier will be excluded for six months.

Appendix 6

Marketing Authorization Form and Dedicating an IRC for imports stored in the Data Bank of the Division of Pharmaceutical and Narcotic Affairs

The IRC is a common number for pharmaceutical products stored in the data bank of the Division of Pharmaceutical and Narcotic Affairs from which all information about the pharmaceutical product can be obtained. Therefore, it is necessary to get this Code and stating it on the secondary packaging of pharmaceuticals. To get this Code, the applicant shall submit the following form in print to the Division of Pharmaceutical and Narcotic Affairs. The artwork has to be attached to the form as well.

Drug Name:												
INN Name*:												

*As in the list of Iranian Drug Evaluation Committee Secretariat.

Dosage form:
Packaging form:
Route of Administration:
Packaging (Type of Packaging, Numbers in Each Pack, and material used):
Storage Condition:

EAN Number*:													

- European Article Number (EAN) is the number assigned by the manufacturing company or the authorized agency in Coding Center for Goods and Services. (Compatible with EAN13)

Importer Name:	Manufacturer Name:
Importer Tel:	Importer Fax:
Manufacturer Fax:	Manufacturer Email:
Manufacturer Address:	

Signed & Sealed

Appendix 7

Contents of Dossier

PART A: Administrative and Prescribing Information

A.1. Summary of Product Characteristics

A.2. Pharmacology and Toxicology Reports

A.3. Clinical Trials

A.4. Bioequivalency Study

A.5. Labeling
- A.5.1. Original Labeling
- A.5.2. Persian / English Labeling

A.6. Package Leaflet
- A.6.1. English Package Leaflet
- A.6.2. Persian Package Leaflet

A.7. Sample of Product

PART B : Drug Substance

B.1. Name and Site(s) of Manufacture

B.2. Specifications and Routine tests

B.3. Nomenclature and Description
- B.3.1. Condensed Formula

B.3.2. Chemical Abstracts Name
B.3.3. CAS Number
B.3.4. Non-proprietary Name (INN) and United States Adopted name (USAN)
B.3.5. Description
B.4. Method of Manufacture
B.4.1. Flow Chart of the Synthesis

B.5. Development Chemistry
B.5.1. Evidence of Structure
B.5.2. Physico-Chemical Characterization
B.5.3. Analytical Validation

B.6. Impurities
B.6.1. Organic Impurities (Related Substances)
B.6.2. Volatile Impurities (Residual Solvents)

B.7. Batch Analysis
B.7.1. Certificate Analysis and Batch Analysis
B.7.2. Reference Standard or Materials

B.8. Container Closure System

B.9. Stability Studies (According to ICH Requirements)

B.10. References

PART C : Drug Product

C.1. Manufacturer(s) Name and Address

C.2. Description and Composition of Drug Product
C.2.1. Composition
C.2.2. Pharmaceutical Development

C.3. Method of Preparation
C.3.1. Manufacturing Formula Standard
C.3.2. Manufacturing Process
C.3.3. Flow chart of Manufacturing Process
C.3.4. Equipments
C.3.5. Validation of the Manufacturing Process

C.4. In-process Controls

C.5. Re-process

C.6. Control of Starting Materials
C.6.1. Active Substance (s)
C.6.1.1. Active Substance(s) Described in a Pharmacopoeia
C.6.1.2. Active Substance(s) Not Described in a Pharmacopoeia
C.6.1.3. Scientific Data
C.6.1.3.1. Manufacturer
C.6.1.3.2. Certificate Analysis and Batch Analysis
C.6.1.3.3. Reference

C.6.2. Other Ingredients
C.6.2.1. Excipients Described in a Pharmacopoeia
C.6.2.2. Excipients Not Described in a Pharmacopoeia
C.6.2.3. Scientific Data
C.6.2.3.1. Manufacturer
C.6.2.3.2. Certificate and Batch Analysis

C.6.3. BSE / TSE Risk Clarification
C.6.4. Packaging Material
C.6.4.1.Specification and Routin Tests
C.6.4.1.1. Primary Packaging
C.6.4.1.2. Secondary Packaging

C.6.4.2. Scientific Data

C.6.4.2.1. Manufacturer

C.6.4.2.2. Batch Analysis

C.6.4.2.3. Compatibility

C.7. Control Tests on the Finished Medicinal Product

C.7.1. Release Specifications

C.7.2. Control Methods

C.7.2.1. Test Procedures for identification and Quantitative Determination of Active Substance(s)

C.7.2.2. Identification and Determination of Other Ingredients

C.7.2.3. Determination of Pharmaceutical-Technical Properties

C.7.3. Scientific Data

C.7.3.1. Validation of Analytical Methods

C.7.3.2. Certificate Analysis and Batch Analysis

C.8. Stability

C.8.1. Stability Tests on the Active Substance(s)

C.8.2. Stability Tests on the Finished Product

Note1:

Any typographical errors or corrections made in the Dossier including standard ranges and the dispatched results of the test shall not be acceptable.

Note 2:

Pharmacology and Toxicology Reports shall be available in the authorized agency, and they shall be presented to the Division of Pharmaceutical and Narcotic Affairs if necessary.

Note 3:

For items that are not the same as the origin brand, the Periodic Safety Update Report(s) (PSUR) shall be submitted to the ADR Center of the Deputy for Food and Drug.

Appendix 8

Regulations on Packaging of Pharmaceutical products

1) It is necessary to adhere to the relevant regulations on labeling and packaging of pharmaceutical products.
2) Printings on and in the package should be both in English and Persian.

Note:

The second language, other than Persian, used should be English.

2-1) If it is not possible to translate all material into Persian, the followings is the least that has to appear on outer packaging.

2-1-1) Pharmaceutical product name (both international non-proprietary and proprietary names) and pharmaceutical and dosage form

2-1-2) Direction for use (using the leaflet or printings on outer packaging)

2-1-3)Preferably stating the "SHOULD NOT BE USED DURING PREGNANCY" (for group-x pharmaceuticals)

2-1-4) Stating "KEEP OUT OF REACH OF CHILDREN"

2-1-5) Stating "SEE THE LEAFLET INSIDE"

2-1-6) Authorized agent name

2-1-7) Storage condition

2-1-8) Stating "REGISTRATION NUMBER IN IRAN" and bar code compatible with EAN13 on the outer packaging

In case a pharmaceutical product is imported without the outer packaging, it is necessary to state "REGISTRATION NUMBER IN IRAN" (IRC) on the immediate packaging.

2-2) The following information can be stated in English on the packaging of pharmaceuticals such as vials, ampoules, cartridges, blisters, and strips, and pharmaceuticals that are supplied with outer packaging:

2-2-1) Pharmaceutical product name (both international non-proprietary and proprietary names) and pharmaceutical and dosage form

2-2-2) The name of the Product license Holder (PLH) or Marketing Authorization Holder (MAH) and the country

2-2-3) Batch number of the manufacturer

2-2-4) Expiry date (MM/YY)

2-3) Contents on the carton or shrink-wrap shall be both in Persian and English.

The following information is the least to be printed on the carton or shrink-wrap:

2-3-1) Pharmaceutical product name (both international non-proprietary and proprietary names) and pharmaceutical and dosage form

2-3-2) Batch number of the manufacturer

2-3-3) Storage condition

2-3-4) The name of the Product license Holder (PLH) or Marketing Authorization Holder (MAH) and the country

2-3-5) Expiry date (MM/YY)

The importing company is allowed to translate the label and attach the translated material on the carton or the shrink-wrap.

3) The importing company is bound to supply the first consignment of pharmaceutical products along with appropriate Persian translation.

3-1) The patient information leaflet shall be presented in both Persian and English.

3-2) In case the pharmaceutical product includes two leaflets for the patient and the physician, the translation of the patient information leaflet is sufficient, but the physician leaflet in English shall be presented along with the product as well.

3-3) It is necessary to include name, address, telephone number, fax number, and E-mail address of the authorized agent in Iran in the leaflet.

3-4) A Persian translation of the patient information leaflet and the packaging shall be submitted.

3-5) The responsible pharmacist will be held responsible for any discrepancies between the contents of the patient information leaflet, packaging, carton, shrink-wrap and the original medicine.

4) The authorized agent in Iran is bound to present the registered pharmaceutical product with appropriate packaging and leaflet in Persian along with Registration code in Iran and bar code within a year from the approval of the Expert council.

Note 1:
The authorized agent in Iran can supply the medicine during the above-mentioned period in English and with Persian leaflet.

Note 2:
Other than the proprietary name the international non-proprietary name of the product shall be stated on the leaflet and packaging.

Appendix 9

Medicinal Product Licence For Imports

NO:
Date Of Issue(dd/mm/yy):

Name Of The Medicinal Product:
International Non-Proprietary Name:
Registration Number in Iran(IRC) :
Strength & Dosage Form:
Container, Closure & Any Administrative Device(s)/Pack Size:
Storage Conditions:
Shelf Life:
Name Of Manufacturer ;Country:
Name Of The Product Licence Holder/Marketing Authorisation Holder; Country:
Authorised Agent In Iran:
Importer:
Date Of Approval By The Expert Council:
Registration Fee Already Paid By The Authorised Agent In Iran.
This Licence Is Valid For 4 Years.
Director General For Pharmaceutical & Narcotic Affairs

Appendix 10

Requested quantities of the pharmaceuticals for submitting to the Division of Quality Control laboratory of Deputy for Food and Drug

No.	Pharmaceutical product	Quantity
1	Injection products with large volumes (serum, etc.)	20
2	Injection products with small volumes (1-2 cc)	100
3	Injection products with moderate volumes (5-10 cc)	100
4	Drops, ointments, and similar products(Sterile)	30
5	Oral solutions (syrups, suspensions)	20
6	Topical products (ointments, creams, sprays)	20
7	Shampoos	15
8	Tablets and capsules	200
9	Soaps	10
10	Suppositories	100
11	Vials for injection	30

The quantity of samples for anticancer medicines and chemotherapy is as following:

No.	Pharmaceutical product	Quantity
1	Vials and ampoules	Min. 30
2	Tablets and capsules	Min. 70
3	Topical products and liquids	Min. 10

For biological products, the Department for Biological Products of the Division of Pharmaceutical and Narcotic Affairs and the admitting section of the Division of Quality Control laboratory of Deputy for Food and Drug for vaccines and antisera shall recommend the required quantity.

Appendix 11

The documents required for dispatching the imported samples to the Quality Control Laboratories include:

- Complete documents for quality control including Certificate of Analysis, instructions (in case in-house method is used), along with validation method, peak, and the relevant calculations
- A valid packaged standard along with the relevant Certificate of Analysis

ANNEX-3

Department of Food and Beverage Affairs

Checklist for the examination of the technical and sanitary conditions of factories producing food / beverage raw materials / processes (for the issuance / reform / extend of the import license)

Requested profile:	**company name:**	**national ID:**	**phone number:** **Fax Number:**
Name of CEO:	**Mailing address:**		
☐ **Trading CO.** ☐**Manufacturing CO.**	**Technical Assistant name:** **license number:**		**Technical responsible phone number:**
Product specification	**Manufacture of Origin:**		**Country of Origin:**
	Interest company (if the source company is not the manufacturer):		
Groups of import products:		**Products Brands:**	

For issuing health license of processed material: Annexes 1-13 For issuing health license of raw materials: Annexes 1-9 and 12 For extend the issued health license of processed material: Annexes 1-11 and 14-18 For extend the issued health license of raw materials: Annexes 1-9 and 14-17	To increase processed food items: Attachment 1-11, 13, 18-19 To increase raw materials items: Attachment 1-8 and 19 To reform health license: Depend on type of correction, as amended according to the issuance In specific cases, please refer to Annexes 20 and 21.

Attachment Documentation ☐ **Issuing** ☐ **Extend** ☐ **Increase Items** ☐ **Reform**	Declare From Company		Secretariat Received Confirmation	Examination Verification By Experts And Explanations
1) official request letter of the company (Attachment No. 1)				
2) Company statute & the latest official newspaper ad.				
3)Confirmation of Technical responsible from TTAC System (Attachment No. 3)				
4) Product Details for requested items:				
4- 1) Name and percentage of ingredients, physical, chemical and microbiological characteristics and contaminants (Attachment No. 4- (a)				
4-2) Declaration of GM event for soybeans/corn, canola, cottonseed and their derivatives and starter (Attachment 4-B)				
5) Other required certificates according to the type of goods, such as the HALAL certification and etc. in accordance with the relevant provisions (Attachment No. 5)				
5- 1) RCMC product health certificate (for rice product)	Validity date:			
5- 2) Certificate of Trademark Registration for Rice Product and Brand Commitment (for Rice Product)	Validity date:			
5- 3) Tea Board certificate (for tea product)	Validity date:			
5-4) Valid organic certification for products with organic claims	Validity date:			
5-5) Gluten Free certificate or evidence for gluten-free claims				
5-6) HALAL certificate (for products of animal origin, such as enzymes and types of vinegar and fermented products) can be submitted for issuance health after receiving the technical committee vote				
6) safety and quality certificates issued by the CB to confirm the valid AB (Attachment 6)				
6- 1) GMP Certificate	Validity date:			
6-2) HACCP Certificate	Validity date:			
6- 3) ISO22000 certificate	Validity date:			
6- 4) FSSC22000 certificate	Validity date:			
6- 5) SQF certificate	Validity date:			
6-6) IFS FOOD certificate	Validity date:			
6-7) BRC FOOD certificate	Validity date:			
7) Free Sale for requested items according to the relevant instructions (Attachment No. 7)	Validity date:			

Attachment documents	Declare from company		Secretariat received confirmation	examination Verification by experts and explanations
8) For issuing health license: original Neglected Commitment of Imported Goods As described in the statement to extend or increase the license: (It is only necessary to re-send the manager if the manager changes.) (Attachment No. 8)				
9) For Processed Materials: exclusive contract representative of foreign manufacturing companies in accordance with the directive number 145818/675 dated 12/3/93 SH (Attachment No. 9) **For raw materials: Letter of Contract with a foreign company (Attachment No. 9)**	Validity date:			
10) Non-promotional commitment on unauthorized Persian language satellite networks (Attachment 10)				
11) General label design and labeling of the nutrition guide in accordance with (Attachment No. 11) the directive No. 5686/675 dated 25/1/ 94 SH				
12) PMF as described in the statement (Attachment No. 12)				
13) Letter of the GTIN and its relevant agreement (Attachment No. 13)				
14) The original health license (Attachment 14)				
15) Report on import performance (import volume, technology transfer evidence) (as required by the committee, such as manufacturer's letter, timetable, etc.) (Attachment No. 15)				
16) PMS Report, Includes Valid Test report (attachment 16)				
17) Documentation of the Recall process in Iran (Attachment No. 17)				
18) Sample of goods				
19) The legalized manufacturer's letter of manufacture of the requested product in the same registered production line or source for the increase of the pen or brand (Attachment No. 19)				
20) The communication letter between the manufacturer and the owner of the brand in the manufacturer's header (if the manufacturer and owner of the brand is not the same.(Appendix No. 20)				
21) A contract for the relationship between the Interest company and the manufacturer (if the supplier is not the manufacturer) (Appendix No. 21)	Validity date:			

Note 1: In the case of documents submitted under paragraphs 5, 6, 7 and 9, for obtaining a health certificate, it is necessary to be valid for a minimum of one year beyond the application; Otherwise, the validity of the health license will be the same as the minimum period of validity of the documents and will be conditional upon the provision of credible evidence.

Note 2: In order to facilitate the process and reduce the cost of applicants, in the cases necessary for legalization, such as Attachment 7 and 9, the process of studding of documents would start by giving a copy of the document to the food and beverage affairs, and in order to continue issuing health license after receiving the technical committee's vote and consent to the registration of the source and the product, the legalized original documents, along with a written letter on the letterhead of the applicant company, should be given to the food and beverage affairs.

Note 3: In order to facilitate the process, the required certificates, Radioactivity certificate for Russian, Ukraine and Japan products at the time of registration order and certificates for products of animal origin, including dioxin certificates, BSE, FMD, and for the milk powder, the melamine residue certificate, and the GMO free certificate for rice, are required at the time of release on the TTAC system.

All of the above is included in …. sheets with a soft copy of documents on a CD, including the folder of all attachments, respectively, delivered and approved by…… the company's managing director and ……. technical responsible, and committed to provide the original documents at each stage of the proceedings upon request by the food and beverage affairs.
It also accepts all legal responsibility for the authenticity and adequacy of the documents and legal consequences resulting from the provision of incomplete information and documents. In the event of a violation of the above provisions, that department, while closing the case, has the right to make any decision and deal with the company.

Manager's full name: **Date and signature:** **Stamp:**	**Technical responsible full name:** **Date and signature:** **Stamp:**

Iran Veterinary Organization
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Islamic Republic of Iran
Ministry of Jihad-e-Agriculture

ANNEX4

IR2016-2Import Health Requirements for Fresh boneless Beef Meat from KAZAKHSTAN(Last Updated 29/09/2018)

Scope:

This document serves to detail the minimum requirements for the production, preparation and packaging of fresh Boneless Beef Meat exported to I.R. of Iran. The related state competent authority of country of origin shall be responsible for ensuring that the requirements are to be met and assisting the representative(s) of Iran Veterinary Organization (IVO) for accomplishing the therein requirements.

GENERAL REQUIREMENTS:

1. Iran Veterinary Organization (IVO) is entitled to dispatch its own representative(s) to carryout supervision over ante-mortem, during slaughter and post-mortem inspections and final handling, including storage, loading and transport.
2. The slaughterhouse shall be an officially approved slaughterhouse (bearing an approval number is obligatory) already visited and approved by IVO representative(s) in terms of compliance with IVO regulations and standards including but not limited to geographical location & other epidemiological aspects ,construction plan ,facilities, equipments, maintenance, minimum required personnel expertise, auxiliary structures including but not limited to animal shed premise, water resources, waste disposal systems, cold stores and Quality Assurance Certificates .
3. Requirements of OIE Terrestrial Animal Health Code (Latest Edition) chapter on Bovine Spongiform Encephalopathy (BSE) shall be observed by related official competent authority, according to the latest OIE classification and approval of the origin country in terms of BSE risk status, and strictly conducted by official veterinarians in the slaughterhouse.
4. Requirements of OIE Terrestrial Animal Health Code (Latest Edition) chapter on Foot and Mouth Disease (FMD) shall be observed by related official competent authority, according to the latest FMD status of the origin country according to OIE reports or IVO representative(s) field investigations if required, and strictly conducted by official veterinarians in the slaughterhouse.
5. Iran Veterinary Organization (IVO) reserves the right to solicit any other documents, at its full discretion, based on the conducted library studies or report of the field visit conducted by IVO veterinary officers prior to issuing of Veterinary Import Permit (VIP).
6. The animals shall be originated from registered farms /areas officially registered with the state veterinary services of country of origin in which notifiable animal diseases have not been reported during last 6 months.
7. The origin of animal should not be from combining livestock and poultry/livestock and pig husbandry (namely the cattle, pig and poultry are rearing within a unit).

8. The animals shall be individually identified using ear tags and accompanied by official identification documents upon arrival at slaughterhouse.
9. The apparently healthy animals shall be subjected to veterinary examinations not more than 12 hours before slaughter and found eligible for slaughter and shall be male.
10. The Health certificate (OIE format or specimen already approved by IVO) shall be issued in English undersigned by official veterinarian complying with requirements stipulated in present IHR.
11. The shelf life of the fresh vacuum packed beef is 45 days at most. The slaughterhouse shall submit any and all documents approving the slaughterhouse claimed shelf life (less than above said shelf life) already validated and officially approved by the related competent authority in country of origin.

12. <u>The animals shall:</u>

- Not exceeding 30 (thirty) month of age for cattle (4 Permanent teeth at most)
- Were born and reared in country of origin.
- Were not fattened on foodstuffs contain animal derived proteins (official prohibition on feeding products containing mammalian derived ingredients to cattle shall be effective).
- Were not received hormonal growth promoters and withdrawal time for veterinary pharmaceuticals shall be observed.
- Get rest for at least 24 hours before slaughter.
- Be male.

12. <u>The carcasses shall:</u>

- Not injured, bruised or physiologically icteric.
- Were washed and cleaned with potable water.
- Were inspected and passed by official veterinarians.
- Were kept in chilling rooms at 0 to 4^{o} C for 24 to 72 hr.
- Were chilled to a core temperature of not more than 7 ^{o} C upon chilling room departure acquiring pH not more than 6 for beef.
- Deboning hall temperature not exceeds 10 ^{o} C.

13. <u>The meat shall</u>:

- Fit for human consumption.
- Free from contaminants
- Has no additional fat (maximum visible fat 7 PCT).
- Comply with following microbiological criteria(according to lab results)

Test	n	C	m	M
Total Count (CFU/g)	5	3	$1x10^5$	$1x10^6$
E. coli (CFU/g)	5	2	$5x10^1$	$5x10^2$
Salmonella spp.	5	0	0	Negative in 25 g
Clostridium Botilinum Toxin	5	0	0	Every & all testes packs

14. Packing and labeling

- Each and every cut weight shall not exceed 15 Kg.
- Modified Atmosphere Packaging (MAP) is not permitted and only simple vacuum practices are allowed.
- Each and every cut shall bear a separate label containing complete information
- The convenient carton net weight range shall be 20 to 25 kilograms.
- The quarter cut shall be performed through natural line along the grain.
- Color coding of the cartons must be as follow:
  1-Neck meat with yellow marking. 2- Forequarter meat with red marking.
  3-Hindquarter meat with black marking. 4-Striploin with green marking.
  5-Tenderloin with orange marking 6- Flank with Blue marking.
- The label shall state in Farsi and English posted over the carton and over cuts cover containing the following items:
  Type of cut , country of origin , name and address of importing company ,production date (slaughter date) , expire date (not more than 45 days for beef pending stored at zero degree Celsius under vacuum packed conditions) production date, slaughterhouse name & code , storage condition (Zero degree Celsius) ,VIP trace code and " produced under supervision of IVO representatives and slaughtered as per Islamic rites under supervision of religious representatives.
- The cartons shall be sea worthy made from food grade compatible materials.
- Tare weight of each empty carton should not be less than 1000 grams.

15. Storage

- The meat shall be stored at zero degree Celsius under vacuum packed conditions.

16. Slaughterhouse

- The slaughterhouse shall bear the EC approval number and entitled to export fresh vacuum packed beef/mutton meat to EU state members.
- The slaughterhouse shall submit any and all related documents describing the expiry date of fresh vacuum packed beef meat already approved and attested by related state competent authority of country of origin.

17. Transport

- The containers used to transport fresh vacuum packed beef meat shall be equipped with recording thermographs operating at least for 30 days upon start up.
- The Vacuum packed beef shall be reached into Iran Border Inspection Post (BIP) in Iranian port not later than 15 days after production date respectively with considering the maximum acceptable shelf life which subjected to variation pending confirmed and acceptable shelf life upon IVO officer scrutiny.
- The meat should be transported at zero to minus one degree Celsius under vacuum packed conditions.

19- Inspection at Border Inspection Post

Upon entry in to Iran custom, the consignment will be checked including but not limited to organoleptic and laboratory tests and the results shall comply with the IVO standards.

Iran Veterinary Organization Quarantine and Biosecurity office.

Iran Veterinary Organization
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Ministry of Jihad-e-Agriculture

ANNEX 5

IR2009-3/21.Health Requirements for Import CHILLED OVINE MEAT FROM Kyrgyzstan INTO I.R.IRAN(Updated 29.02.2016)

SCOPE

This document serves to detail requirements for the preparation in KYRGHYZISTAN of Chilled ovine/mutton meat for export to the Islamic Republic of Iran. The Veterinary Services of Kyrgyzstan shall be responsible for ensuring that the requirements of the export in relation to the preparation of meat subject to this agreement have been met and for assisting the representative of the Iran Veterinary Organization (IVO) for verifying that the requirements of this agreement have been met.

A. GENERAL REQUIREMENTS:

1. Iran Veterinary Organization (IVO) is entitled to dispatch its own representative to carry out ante-mortem, during slaughter and post-mortem inspection and final handling, including storage and loading.
2. The meat has been derived from healthy male sheep not exceeding 18 months of age,namely all sheep showing as 2-tooth one rising 4-tooth, in other hands 2 central incisors 6 milk teeth up to 2 middle incisors 4 milk tooth.
    - Were born and reared in the country of origin.
    - Came from herds officially registered with the administrative Veterinary of country of Origin.
    - Came from ovine herds in which OIE notifieable disease, not registered during 12 month ago.
    - Were not fattened on foodstuffs which included animal derived proteins (mammalian MBM).
    - Were kept for six months prior to export in an establishment where no case of rabies was reported for at least 12 months prior to slaughter.
3. In the country of origin or zone, surveillance and monitoring system established as referred to Article 14.9 (especially article 14.9.2) OIE international Health Code (2009).
4. The animals have been slaughtered in approved slaughterhouse situated in the quarantine area of free zone and found to be healthy before and after slaughter approved by IVO representative/s.
5. The meat was produced under conditions which fully comply with Iran national standard No 9717, European Union standards and Codex alimentarius and SPS agreements.
6. Subject to ante and post mortem inspection by the official veterinary service of the country of origin and IVO representative/s and were found to be free of clinical signs of any contagious and infectious diseases(Scrapie,PPR,Bluetongue,anthrax,ovine brucellosis,rabies).

7. Establishments which supply meat for export to the Islamic Republic of Iran should be approved by IVO representative before starting of the slaughtering and situated in the free zone.
8. Kyrgyzstan state veterinarians in each export slaughterhouse should monitor and observe inspection and production requirements in co-operation with the IVO representative.
9. The sheep must not be derived out of regions approved by IVO representative in terms of animal health.
10. Only animals which the IVO representative will have determined and adequately will have rested shall be presented for ante-mortem inspection.
11. Carcasses sent to the detain rout with major defects cannot be exported to the Islamic Republic of Iran.
12. In case of any clinical signs of obseved Echinococosis/Hydatidosis in any organs, the cacass should be condemned.

B. SPECIFIC CONDITIONS:

1. The meat in this consignment
   - Is fit for human consumption.
   - Is free of contamination by excrement and blood clots, especially in the neck and intercostals muscles of the ribs.
   - With normal odor
   - Shows no evidence of pathogenic agent(bacterium, fungus, parasite)

Product	Test	No. of samples (n)	c	m	M
Fresh Chilled Sheep Meat	Total count (CFU/g)	5	3	5×10^4	5×10^5
	Salmonella spp. (CFU/25g)	5	0	Negative	-
	E.Coli count (CFU/g)	5	2	5×10^1	5×10^2

2. **The carcasses of the animals from which the meat to be exported to the Islamic Republic of Iran were derived from;**

- Not injured, bruised or physiologically icteric(yellow) carcasses which;
  - are washed and cleaned completely with fresh water
  - produced from animal examined by an official veterinary service of country of origin and IVO representative/s before, during and after slaughtering and found to be fit for human consumption and which also controlled during processing and final handling.
  - derived from sheep which have not been treated with hormonal growth promotores and were not fattened on food stuffs which included animal proteins before slaughter.
- Should be kept in the chilling store from at least 24 to maximum 72 hours. The temperature of the chilling store must be kept between 0-4 ºC and humidity not less than 90% thereby the temperature of deepest part of the most masculine part of carcass should not exceed than 7 ºC.
- PH of the meat should be less than 6.3 after chilling room.
- The meat must not undergone any preserving process.
- All carcasses should be stamped by IVO representative.
- The transportation vehicle shall be approved by IVO representative. Bearing smooth, non corrosive(resistant against disinfectants) and washable surfaces, thermograph , carcasses enabling air circulation between carcasses is obligatory.
- other relevant requirements according to IVO rules and regulations should be fulfilled and IVO circulars in relation to principles of cleansing and disinfecting cold store govern this clause.

3. **Chilling conditions:**
   - All obvious lymphatic glands and nervous tissues were removed.
   - Carcasses should be kept at chilling room for 24 to 72 hours before going to cutting room. the temperature of chilling room must be between +0 to +4 degree centigrade and the deep bone temperature should be reached to +7 degree, and humidity not less than 85% and PH of the meat should be less than 6.4 after chilling room.
4. **Packing:**Carcasses should be wrapped in polythene and stockinet before being transported to the chillers.

One paper identification sheet (Lable) stating in Farsi and English should be printed indicating the following information :

the name of consignment,Halal Sign , the type of use , the country of origin , the name and adre address of importing company/or ordered by , that the production has been done under supervision of IVO representatives and the slaughtering has been done as per Islamic rites under supervision of IRAN religious representatives , the production date (date of slaughtering) , the expire date (72 hours after production date), the name of the slaughterhouse and sanitary code , keeping condition (keep at: 0-4°C) ,Trace Code

The labels must be sticked or printed over each wrapping of the carcasses The label or identification paper contents and format Should be confirmed by IVO.

5. **Storage:**

The shelf life of fresh chilled ovine carcass is 72 hours after exit carcasses from chilling room pending keeping in 0 to 4 degree Celsius under 85 to 90% humidity.

The maximum duration from slaughter to export shipment must be not more than 24 hours .

6. **Transportation**

The conveyances used to transport meat entered for export to the Islamic Republic of Iran are fitted with intended refrigeration equipment and recording thermographs.

The transportation vehicle shall be approved by IVO representative. Bearing smooth, non corrosive(resistant against disinfectants) and washable surfaces, thermograph enabling air circulation between carcasses is obligatory.

other relevant requirements according to IVO rules and regulations should be fulfilled and IVO circulars in relation to principles of cleansing and disinfecting cold store govern this clause

C. VETERINARY CERTIFICATE

The Kyrgyzstan veterinary officer will issue, in respect of each consignment of Fresh ovine carcasses a Veterinary Health certificate for export to the Islamic Republic of Iran produced in compliance with this agreement .The certificate shall be countersigned by IVO representative too.

The certificate will be endorsed:

1-The territory described above – mentioned has not occurred anthrax for 6 months.

2-The meat described above is obtained from ovine animal:

2-1 Which have remained in the territory as described under for at least 3 months before being slaughtered.

2-2 Which come from holdings in which there has been not detected outbreak of FMD in the previous 30 days, and the holding located in area around which within a radius of 10 Km there has been no case of FMD disease for last 30 days.

2-3 which undergone a quarantine period of 21 days befor transport to slaughterhouse, in an appropriate quarantine station, under supervision of representatives of IVO.

2-4 Which have been transported from the quarantine station to the approved slaughterhouse concerned without contact with animals which do not comply with the conditions required for export of their meat to I.R.Iran , and , if conveyed in a means of transport , that the latter has been cleaned & disinfected before loading .

2-5Which have passed the ant-mortem health inspection at the slaughterhouse with Iranian official veterinarian(s) during the 24 hours before slaughter and , in particular have shown no evidence of FMD , anthrax & sudden deaths and other contagious diseases at sole discretion of IVO representative.

2-6 Which have not come from a holding which for health reasons is subject to prohibition as a result of an outbreak of ovine or caprine brucellosis during the previous six weeks .

3-The meat is completely salmonella free.

4-The meat is fit for human consumption.

6- The radiometric test results & data from the consignments (at least 7 sample) should be lesser than 10 Bq/kg.

7- Were not fattened on foodstuffs which included animal derived proteins (mammalian MBM).

8- The meat derived from sheep which have not been treated with hormonal growth promotores and were not fattened on food stuffs which included animal proteins before slaughter

D-SANITARY CONTROLS AT ARRIVAL I.R.IRAN BORDER:

1-All consignments should be in accompany with original Veterinary Health Certificate signed and sealed by competent state authority official countersigned by IVO representative contains all requirements stipulated above mentioned.

2-All consignment shall be examined against organoleptical criteria including but not limited to appearance, odor and temperature (not exceed 7ºC at the deepest part of the muscles) and PH (min 5.4 –Max 6.3).

3-The installed thermographs shall be checked and inside information shall be controlled.

4-The Iran Veterinary Organization reserve the right to not issue the clearance from custom for those consignments that found not in compliance of provision of present document.

Iran Veterinary Organization Quarantine and Biosecurity office.

29/02/2016-Meat@ivo.ir

Iran Veterinary Organization
I.V.O

Islamic Republic of Iran
Ministry of Jihad-e-Agriculture

ANNEX 6

IR2016-1.Health Requirements for Import Chilled Ovine Meat from Russia to I.R.IRAN (Last Update29.02.2016)

Scope

This document serves to detail the requirements for import of Chilled Ovine meat from Russia to the Islamic Republic of Iran. The Veterinary Service of Russia shall be responsible for ensuring that the requirements of the import are fully been met and collaborate with the representatives of the Iran Veterinary Organization (IVO) to verify that the requirements of this document have been regarded.

A. General Requirements:

1. Iran Veterinary Organization (IVO) is entitled to dispatch its own representative to carry out ante-mortem, during slaughter and post-mortem inspection, handling, storage and loading.
2. The meat has been derived from healthy male sheep not exceeding 18 months of age.
3. Animals are born and reared in the country of origin.
4. Animal came from herds officially registered by the administrative Veterinary of country of Origin.
5. Animals came from ovine herds in which OIE notifiable diseases not registered during 12 month ago.
6. Animals are not fattened on foodstuffs containing ruminant's derived proteins (MBM).
7. Animals shall not show any clinical sign of any contagious or infectious diseases at ante – mortem inspection prior to slaughtering.
8. Animals shall be derived from Zone/Area considered as free from FMD by OIE.
9. In the country of origin or zone, surveillance and monitoring system for OIE notifiable diseases shall be established.
10. Animals shall be slaughtered in approved slaughterhouse situated in FMD free zone /area and found to be healthy before and after slaughter.
11. The meat shall be produced under conditions fully comply with international standards.
12. Establishments which supply Ovine meat for export to the Islamic Republic of Iran shall be approved by IVO representative before starting of the slaughtering and shall be situated in the free zone.
13. Russia State Veterinarians shall monitor and observe meat inspection and production processes in co-operation with the IVO representatives.
14. The sheep shall not be derived out of regions not approved by IVO representatives in terms of animal health.
15. Carcasses detained with any defects or organic changes cannot be exported to the I.R. of Iran.
16. In case of presence of any signs of Echinococosis/Hydatidosis in any organ, the carcass shall be condemned.
17.None of the animals shall be positive in Radionuclide test with Rapid radionuclide detectors (RRD)(more than 10 Bq/g consider as positive).
18.Animals which are intended to be slaughtered for I.R.Iran Shall be male and less than 18 months of age
19. Animals shall get rest for at least 24 hours before slaughter.

B. Specific Conditions:

Ovine Carcasses which is intended to be exported to I.R.Iran:
1. Shall be fit for human consumption.
2. Shall be free of contamination by excrement and blood clots, especially in the neck and intercostals muscles of the ribs.
3. Shall have normal odor.
4. Shows no evidence of pathologic changes due to bacteria, fungus and parasites
5. All visible lymphatic glands and nervous tissues shall be removed.
6. Not injured, bruised or physiologically icteric (yellow)
7. Are washed and cleaned completely with potable fresh water.
8. Derived from sheep which are not treated with hormonal growth promoters and are not fattened on food stuffs which contained ruminant proteins (MBM).
9. Shall be kept in the chilling room for 24 to 72 hours. The temperature of the chilling room must be kept between 0-4 ºC
10.The temperature of deepest part of the most masculine part of carcass should not exceed than 7 ºC before leaving chilling room.
11. PH of the meat shall be less than 6.2 before leaving chilling room.
12. The meat must not undergo any preserving process.
13. All carcasses shall be stamped by IVO representative.
14. Microbial and toxicological test of carcasses shall be put in place randomly in the country of origin and results shall be sent to IVO for further verification. Obviously the carcasses will be tested at the time of entry to the customs of I.R.Iran regarding the mentioned tests.
15.chilling room humidity shall be 85 percent.

C. Packing:
1. Carcasses should be wrapped in polythene and stockinet before being transported to the chillers.
2. Carcasses should be labeled by a Farsi and English label indicating the following criteria:
- Name of consignment.
- Halal Sign
- Type of use
- Country of origin
- Name and address of importing company
- Production date (date of slaughtering and packaging)
- Expiration date (72 hours after production date)
- Name of the slaughterhouse and sanitary code
- Storage condition (kept at: 0-4 ºC)
- Trace Code
- Deboning and repacking is extremely prohibited in destination.

D. Storage:

-The shelf life of fresh chilled ovine carcasses is 72 hours after leaving the chilling room.

- 2 Thermographs shall be installed in each container.

E. Transportation

- Russia

* Airplane or Vehicle transportation is allowed depending on the distance to Destination (borders of Islamic Republic of Iran).

F. Veterinary Certificate

The Russia veterinary officer will issue, for each consignment of Fresh ovine Carcasses, a Veterinary Health certificate for export to the Islamic Republic of Iran produced in compliance with this document.

D-Control at Borders:

1- At the borders, sampling will be done for controlling the compatibility of residues of drugs, heavy metals, anti-inflammatory drugs, (MRL) … in the case of incompatibility with the national and international standards , importation will be stopped from mentioned country.
2-All consignments shall go under biosecurity and biosafety control in accordance with original VHIP issued for nominated company.

Iran Veterinary Organization Quarantine and Biosecurity office.

29/02/2016-Meat@ivo.ir

ANNEX 7

IR2018-1/05. Sheep Import Health Requirements for Slaughter into IRAN

The governmental Veterinary Service of country of Origin must certify that the animals identified for export to Iran comply with the following requirements :

1.The identified sheep for export to Iran should be born and reared in the country of origin .

2.On the day of shipment the animals should show no clinical signs of contagious OIE listed diseases .

3.The use of mammalian MBM is forbidden for feeding ruminants , and this measure is effective .

4.On the day f shipment the exported animals should show no clinical signs of FMD , PPR, bluetongue , anthrax and were in an establishment in which no case of anthrax were officially declared for the twenty days preceding export and or had been vaccinated with an officially controlled vaccine at least twenty days but not more than six months prior to export .

5.The exported animals were kept for six months prior to export in an establishment where no case of Rabies was reported for at least 12 months prior to export .

6.showed no clinical sign of caprine and ovine brucellosis on the day of shipment ;

7.come from a sheep where no case of brucellosis has occurred during the 42 days prior to shimpment .

8.in the country or zone in order to scrapie:

a. a surveillance and monitoring system as referred to in Article 2.4.8.2 of OIE code is in place .
b. affected sheep are slaughtered and completely destroyed ;
c. the sheep selected for export showed no clinical sign of scrapie on the day of shipment .

9.showed no clinical sign of FMD on the day of shipment .

1. were kept in the establishment of origin since birth or

d. for the past 30 days , if a stamping-out policy is in force in the exporting country or
e. for the past 3 months , if a stamping – out policy is not in force in the exporting country .

and that FMD has not occurred within a 10-kilometre radius of the establishment of origin for the relevant period as defined in points a) and b) above ; and were not exposed to any source of FMD infection during their transportation from the quarantine station to the place of shipment .

10.showed no clinical sign of PPR on the day of shipment :

1. were kept since birth , or for the past 30 days , in an establishment where no case of PPR was officially reported during that period , and that the establishment was not situated in a PPR infected zone ; and / or
2. were kept in a quarantine station for the 30 days prior to shipment ;
3. have not been vaccinated against PPR ; or
4. were vaccinated against PPR ;
   f. not less than 15 days and not more than 4 months prior to shipment in the case of animals for breeding or rearing ; or
   g. not less than 15 days and not more than 12 months prior to shipment in the case of animals for slaughter .

11. were protected from culicoides attack for at least 100 days prior to shipment , or

1. were protected from Culicoides attack for at least 30 days prior to shipment , and were subjected during that period to a serological test to detect antibody to the BTV group shuch as the BT competition ELISA or the BT AGID test . with negative results on two occasions , with an interval of not less than 7 days between each test , the first test being carried out at least 21 days after introduction into the quarantine station , or
2. were protected from culicoides attack for at least 14 days prior to shipment , and were subjectedduring that period to a BTV isolation test or polymerase chain reaction test with negative results , on blood samples taken on two occasions , with an interval of not less than 7 days between each test . the first test being carried out at least 7 days after introduction into the quarantine station ; AND
3. were protected from Culicoides attack during transportation to the place of shipment .

12.showed no clinical sign of sheep pox on the day of shipment ;

1. were kept since birth , or for the past 21 days , in an establishment where no case of sheep pox pox was officially reported during that period , and that the establishment was not situated in a sheep pox pox infected zone ; or
2. were kept in a quarantine station for the 21 days prior to shipment ;
3. have not been vaccinated against sheep pox pox ; or
4. were vaccinated using a vaccine complying with the standards described in the Terrestrial Manual not less than 15 days and not more than 4 months prior to shipment (the nature of the vaccine used , whether inactivated or modified live virus, and the virus types and strains included in the vaccine shall also be stated in the certificate) .

13. showed no clinical sign of anthrax on the day of shipment ;

1. were kept for the 20 days prior to shipment in an establishment where no case of anthrax was officially declared during that period ; or
2. were vaccinated , not less than 20 days and not more than 6 months prior to shipment .

14. showed no clinical sign of Rabies on the day of shipment ;

1. were kept for the 6 months prior to shipment in an establishment where separation where separation from wild and feral animals was maintained and where no case of rabies was reported for at least 12 months prior to shipment .

15. immediately prior to loading , the animals to be exported have been inspected , on the premises of origin , by an official Veterinarians After inspection for wounds with myasis of new world old world screwworm , any infested animal has been rejected for export ;

1. immediately prior to entering the quarantine pens in the exporting country ;
    h. each animal has been thoroughly examined for infested wounds , under the direct supervision of an Official Veterinarian , and that no infestation has been found in any animal ; and

    i. any wounds have been traded prophylactic ally with an officially approved oily larvicide's at he recommended dose ; and

j. all animals have been dipped , sprayed , or otherwise treated immediately after inspection , with a product officially approved by the importing and exporting countries for the control of external parasite new world or old world screwworm , under the supervision of an Official Veterinarian and in conformity with the manufacturer's recommendations;

2. at the end of the quarantine and immediately prior to shipment for export :
    a. all animals have been re-examined for the presence of infestation and all animals have been found free of infestation ;
    b. all wounds have been prophylactic ally treated with an approved oily larvicide's under the supervision of an official veterinarian .
    c. all animals have been prophylactic ally treated again by dappling or spraying as in point 2) above .

16. pre-export quarantine measures :
    k. the animals selected for export were isolated in the establishment of origin for a minimum 21 days .
    l. The pre-export quarantine period must be under observaition of IVO'S Representative .

Iran Veterinary Organization
I.V.O

Islamic Republic of Iran
Ministry of Jihad-e-Agriculture

ANNEX 8

IR2017-05/02Health Requirements for Import FRESH FROZEN OVINE MEAT FROM Kazakhstan INTO I.R.IRAN(Last Update 28.05.2017)

SCOPE

This document serves to detail requirements for the preparation of frozen ovine/mutton meat in Kazakhstan for export to the Islamic Republic of Iran. The Veterinary Services of Kazakhstan shall be responsible for ensuring that the requirements of the export in relation to the preparation of meat subject to this agreement have been met and for assisting the representative of the Iran Veterinary Organization (IVO) for verifying that the requirements of this agreement have been met.

A. GENERAL REQUIREMENTS:

1. Iran Veterinary Organization (IVO) is entitled to dispatch its own representative to carry out ante-mortem, during slaughter and post-mortem inspection and final handling, including storage and loading.
2. The country of origin is free from FMD, or the animals has been derived from a free a zone that is free from FMD according to the provisions of chapter 8.8 of the Terrestrial Edition 2015, (one zone consisting of the regions of Akmola, Aktobe, Atyrau, West Kazakhstan, Karaganda, Kostanay, Mangystau, Pavlodar and North Kazakhstan, as designated by the Delegate of Kazakhstan in a document addressed to the Director General in August 2014 - FMD free zone where vaccination is not practicised.)
3. The meat has been derived from healthy male sheep not exceeding 18 months of age.
    - Were born and reared in the country of origin.
    - Came from herds officially registered with the administrative Veterinary of country of Origin.
    - Came from ovine herds in which OIE notifieable disease, not registered during 12 month ago.
    - Were not fattened on foodstuffs which included animal derived proteins (mammalian MBM).
    - Were kept for six months prior to export in an establishment where no case of rabies was reported for at least 12 months prior to slaughter.
4. In the country of origin or zone, surveillance and monitoring system established as referred to Article 14.9 (especially article 14.9.2) OIE international Health Code (2015).
5. The animals have been slaughtered in approved slaughterhouse located in the quarantine area of free zone and found to be healthy before and after slaughter approved by IVO representative/s.
6. The meat was produced under conditions which fully comply with Iran national standard No 4277, European Union standards and Codex alimentarius and SPS agreements.

7. The animals were subjected to ante and post mortem inspection by the official veterinary service of the country of origin and IVO representative/s and were found to be free of clinical signs of any contagious and infectious diseases(Scrapie, PPR, anthrax,ovine brucellosis,rabies).
8. Establishments which supply meat for export to the Islamic Republic of Iran should be approved by IVO representative before start of the slaughtering and situated in the free zone.
9. Kazakhstan state veterinarians in each export slaughterhouse should monitor and observe inspection and production requirements in co-operation with the IVO representative.
10. The sheep must not be derived out of regions approved by IVO representative in terms of animal health.
11. Only animals which the IVO officer has determined and adequately rested shall be presented for ante-mortem inspection.
12. Carcasses sent to the detain rail with major defects cannot be exported to the Islamic Republic of Iran.
13. Considering of anthrax ,all contexts of OIE Terrestrial Animal Health Code -2016 Article 8.1.4 should be fully respected by Kazakhestan Veterinary Services.

B. SPECIFIC CONDITIONS:

1. The meat in this consignment
- Is fit for human consumption.
- Is free of contamination by excrement and blood clots, especially in the neck and intercostals muscles of the ribs.
- With normal odor , without burn freezing
- Shows no evidence of pathogenic agent(bacterium, fungus, parasite)

Product	Test	No. of samples (n)	c	m	M
Fresh/FROZEN OVINE MEAT	Total count (CFU/g)	5	3	1×10^5	1×10^6
	Salmonella spp. (CFU/25g)	5	0	Negative	-
	E.Coli count (CFU/g)	5	2	5×10^1	5×10^2

2. The carcasses of the animals from which the meat to be exported to the Islamic Republic of Iran were derived from;

- Not injured, bruised or physiolocally icteric (yellow) carcasses which;
  - are washed and cleaned completely with fresh water.
  - The meat produced from animal examined by an official veterinary service of country of origin and IVO representative/s before, during and after slaughtering and found to be fit for human consumption and which also controlled during processing and final handling.

- must be derived from sheep which have not been treated with hormonal growth promotores before slaughter.
- not undergo any preserving process.

- All carcasses should be stamped by IVO representative.

3. Chilling and cutting conditions:

- Cutting of the carcasses must be accordance with Iran National Standard No 4276.
- The temperature of cutting room must be maintained at or below +10 degree centigrade.
- All obvious lymphatic glands and nervous tissues were removed.
- Carcasses should be kept at chilling room for 24 to 72 hours before going to cutting room. the temperature of chilling room must be between +0 to +4 centigrade degree and the deep bone temperature should be reached to +7 centigrade degree, and humidity not less than 90% and PH of the meat should be less than 6 after chilling room.
- The cuts accordance with Iran National Standard No 4276 should not weighted more than 2 kilogram and found in full compliance with IVO circulars.

4. Packing:

- Packing and labeling must be accordance with Iran National Standard No 4275.The color of lables should be as below:

-Leg (silverside, Rump, Knuckle, Topside): Black
-Hind Shank: Black
-Sir loin (short loin): Green
-Flank/ Flap: Blue
-Forequarter: Red
-Fore Shank: Red
-Breast: Red
-Neck: Yellow

- Different cuts can not be mixed in the same carton.
- The weight and the specifications of all empty cartons should be the same.
- Tare weight of each empty carton should not be more than 1000 grams.
- The cartons should be moisture proof and made from strong tissue material in order to prevent tearing during loading, stow aging and discharging.
    - Each cuts must hold a label and The same label identification sheet stating in Farsi and English should be attached on cartons and must indicate the following information :
    - The name and place of production(name and address , sanitary code of slaughterhouse), the date of production(date of slaughtering) , the type of cuts , and that the slaughtering has been done as per Islamic rites the labels must be put inside between two polyethylene bags, over each wrapping of the cuts and both end-side of each carton from outside .

- . The label or paper identification sheet contents and format should already confirmed by IVO.

5. **FREEZING AND STORAGE:**

- All products should be frozen in freezing tunnel with minus 35 to 45 degree centigrade within 24 to 48 hours; the temperature of meat in deepest part after freezing should be -18 degree C, at the time of going to the cold store.
- The meat shall be kept in cold storage with not warmer than minus 18 degrees C. The meat should be transferred to the final loading point with temperature of -18C.
- The maximum duration from slaughter to export shipment shall not be more than 60 days. If not so, the IVO's representative/s should give a special authorization for embarkation.

6. Transportation:

The conveyances used to transport meat entered for export to the Islamic Republic of Iran are fitted with intended refrigeration equipment and recording thermographs.

C. VETERINARY CERTIFICATE

The Kazakhstan veterinary officer will issue, in respect of each consignment of frozen ovine carcasses a Veterinary Health certificate for export to the Islamic Republic of Iran produced in compliance with this agreement .The certificate shall be countersigned by IVO representative too. Health attestations in the certificate will be endorsed:

1-The territory described above has been free for 6 months from anthrax.

2-The meat described above is obtained from ovine animal:

2-1 Which have remained in the territory as described under for at least 3 months before being slaughtered.

2-2 Which have been transported from the holdings of origin to the approved slaughterhouse concerned without contact with animals which do not comply with the conditions required for export of their meat to I.R.Iran , and , if conveyed in a means of transport , that the latter has been cleaned & disinfected before loading .

2-3 Which have passed the ant-mortem health inspection at the slaughterhouse with Iranian official veterinarian(s) during the 24 hours before slaughter and , in particular have shown no evidence of diseases & sudden deaths and other contagious diseases at sole discretion of IVO representative.

2-4 Which have not come from a holding which for health reasons is subject to prohibition as a result of an outbreak of ovine or caprine brucellosis within the recent 3 months.

3-The meat is completely salmonella free.

4-The meat is fit for human consumption.

D-SANITARY CONTROLS AT ARRIVAL I.R.IRAN BORDER:

1-All consignments should be in accompany with original Veterinary Health Certificate signed and sealed by competent state authority official countersigned by IVO representative contains all requirements stipulated above mentioned.
2-Upon entry in to ports of Iran, the consignment will be checked and the samples will be test organoleptically, microbiologically and chemically and results must fulfill Iran veterinary organization rules, Iran National Standard and EU legislation.
3-The installed thermographs shall be checked and inside information shall be controlled.
4-The Iran Veterinary Organization reserve the right to not issue the clearance from custom for those consignments that found not in compliance of provision of present document.

Iran Veterinary Organization Quarantine and Biosecurity office.

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Ministry of Jihad-e-Agriculture

ANNEX 9

IR2016-3Import Health Requirements For Fresh Frozen Boneless Beef Meat From KAZAKHSTAN To I.R. Iran(Last Updated 29/09/2018)

SCOPE

This document serves to detail the minimum requirements for the production, preparation and transportation frozen bonelss beef meat exported to I.R. of Iran. The relevant competent authority of country of origin shall be responsible for ensuring that the requirements are to be met and assisting the representative(s) of Iran Veterinary Organization (IVO) for accomplishing the therein requirements.

1 General Requirements:

1.1 Iran Veterinary Organization (IVO) is entitled to dispatch its own representative(s) to carryout supervision over ante-mortem, during slaughter, post-mortem inspections, chilling hall, deboning hall& freezing hall, as well as final handling, including storage, loading and transport.

1.2 Requirements of OIE Terrestrial Animal Health Code (Latest Edition namely, 2015) chapters on OIE _ Bovine Listed Diseases shall be observed by related official competent authority, according to the latest OIE classification and approval of the origin country in terms of Bovine diseases status, and strictly conducted by official veterinarians in the slaughterhouse.

1.3 Iran Veterinary Organization (IVO) reserves the right to solicit any other documents, at its full discretion, based on the conducted desk studies or report of the field visit conducted by IVO veterinary officers prior to issuing of Veterinary Import Permit (VIP).

1.4 The animals shall be originated from registered farms / areas officially registered with the state veterinary services of country of origin in which notifiable animal diseases have not been reported during last 6 months.

1.5 The animals shall be individually identified using ear tags and accompanied by official identification documents upon arrival at slaughterhouse (In accordance with OIE Terrestrial Animal Health Code_ 2015/ Chapters 4.1 &4.2).

1.6 The apparently healthy animals shall be subjected to veterinary examinations not more than 24 hours before slaughter and found eligible for slaughter.

1.7 The Health certificate (specimen already approved by IVO) shall be issued in English undersigned by official veterinarian complying with requirements stipulated in present IHR.

1.8 The animals shall be oriented from **establishments** that shall be free from anthrax, brucellosis, tuberculosis .

I .Regarding BSE ,in the country of origin:

1- The feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced.

2- Cattle selected for slaughter shall be eligible & qualified as follows:

a) Are identified by a permanent identification system in such a way as to demonstrate that they are **not** exposed cattle *which has been feed with meat-and-bone meal and greaves derived from ruminants;*

b) Were born at least 2 years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants was effectively enforced.

c) passed ante- and post-mortem inspections.

d) were not subjected a stunning process prior to slaughter,such as injecting air or gas into cranial cavity or to a pithing.

The meat was produced and handeled in a manner which ensures that such products do not contain & are not contaminated with The tissues listed in points 1 & 3 Article 11.4.14 , namely tonsils, distal ileum, brains,eyes, spinal cords, skull, vertebral column and adjacent tissues.

II. Regarding FMD:

1. It must be in accordance with OIE Terrestrial Animal Health Code_ 2015 article 8.8.8.
2. Showed no clinical sign of FMD on the day of shipment.
3. Were kept in the establishment of origin since birth or

a-For the past **30 days** , if a stamping-out policy is in force in the exporting country **or**

b-For the past **3 months**, if a stamping – out policy is not in force in the exporting country.

4. FMD has not occurred within a 10-kilometre radius of the establishment of origin for the relevant period as defined in points a) and b) above; and were not exposed to any source of FMD infection during their transportation from the quarantine station to the place of shipment.

2 <u>The animals characterizations:</u>

2.1 Not exceeding 30 (thirty) months of age.
2.2 Be born and reared in country of origin.
2.3 Not be fattened on foodstuffs contain animal derived proteins (official prohibition on feeding products containing mammalian derived ingredients to cattle shall be effective).
2.4 Not be received hormonal growth promoters and withdrawal time for veterinary pharmaceuticals shall be observed.
2.5 Two annexed tables are demonstrated in the pages 7 & 8 of this IHR for the Maximum Residues Limits whose shall be regarded for heavy metals, pesticides and veterinary pharmaceuticals within the beef which will have been exported from Russia to Iran.
2.6 Be male
2.7 Get rest for at least 24 hours before slaughter.

3 The carcasses shall:

3.1 Not be injured, bruised or physiologically icteric.

3.2 Be washed and cleaned with potable water.

3.3 Be inspected and passed by official veterinarians.

3.4 Be kept in chilling rooms at 0 to 4° C for 24 to 72 hr.

3.5 Be chilled to a core temperature of not more than 7° C upon chilling room departure acquiring pH not more than 6.

3.6 The beef shall produce under condition which fully complies with Codex Alimentarius and SPS Agreements.

4 The meat shall be:

4.1 Fit for human consumption.

4.2 Free from contaminants

4.3 Has no additional fat (maximum visible fat 7 PCT).

4.4 The radionuclide shall be less than 10 Becquerel per kg.

4.5 Comply with following microbiological criteria (according to lab results):

Test	n	C	m	M
Total Count (CFU/g)	5	3	1×10^{5}	1×10^{6}
E. coli (CFU/g)	5	2	5×10^{1}	5×10^{2}
Salmonella spp.	5	0	0	Negative in 25 g

1 Packing and labeling

1.1 Each and every cut shall weight 1-3 kg ± 15 % (if another is not requested by importer in accordance with the item stock numbers).

1.2 Each and every cut shall bear a separate label containing complete information.

1.3 The convenient carton net weight range shall be 20 to 25 kilograms.

1.4 The quarter cut shall be performed through natural line along the grain.

1.5 Color coding of the cartons must be as follows:

1-	Forequarter meat with red marking.
2-	Hindquarter meat with black marking.
3-	Flank meat with blue marking.
4-	Toside meat with grey marking.
5-	Neck meat with yellow marking.
6-	Striploin with green marking.
7-	Tenderloin with orange marking.

1.6 The label shall state in Farsi and English posted over the cartons and over the cuts containing the following items:

Type of cut, country of origin, name and address of importing company, production date slaughter date, expire date (not more than one year pending storage at minus 18 degree Celsius) under supervision of IVO reps and slaughtered as per Islamic rites under supervision of religious reps".

1.7 The cartons shall be export worthy made from food grade compatible materials.

1.8 Tare weight of each empty carton shall not be less than 1000 grams.

6 Deboning, chilling & cutting conditions:

6.1 The temperature of deboning hall and cutting room must be maintained at approximately +10 degrees centigrade.

6.2 All obvious lymph & hem lymph glands, nodes and nervous tissues shall be removed as far as possible.

6.3 Carcasses shall be kept at chilling room for 24 to 72 hours before going to deboning hall. The temperature of chilling must be between minus 1 up to minus 4 degrees of centigrade as well deep bone temperature shall be reached up to the minus 7 degrees of centigrade at the time of deboning.

6.4 Deboning hall shall be equipped with deboning and cutting sanitary tools & equipments. As well as the temperature of deboning hall must not to be warmer minus 10 degrees of centigrade.

7- **Freezing & Storage:**

6.5 All products shall be frozen within freezing tunnel with the minus 35 up to 45 degrees of centigrade within 24 to 48 hours, the temperature of meat in deepest part; post freezing shall be the minus 18 degrees of centigrade at the time of transporting to the cold store.

6.6 The meat shall be kept in cold storage with circumstances with not warmer than minus 18 degrees of centigrade. As well as the meat shall be transferred to the final loading point with not warmer than minus 18 degrees of centigrade.

6.7 The maximum duration from slaughter to export for any shipment shall be not more than 60 days. If not so, the IVO reprehensive(s) shall give a special authorization for embarkation of vessel.

8-Slaughterhouse:

8.1 The slaughterhouse shall bear the certain approval certificates such as HACCP or any relevant ISOs as well as shall be an officially approved slaughterhouse by competent veterinary authority of Russia government and the abattoir may be visited and approved by IVO representative(s) in terms of compliance with IVO regulations and standards including but not limited to geographical location & other epidemiological aspects, construction plan, facilities, equipment, maintenance, minimum required personnel expertise, auxiliary structures including but not limited to animal shed premise, water resources, waste disposal systems, cold stores and Quality Assurance Certificates.

8.2 The slaughterhouse shall submit any and all related documents describing the expiry date of frozen beef meat already approved and attested by related state competent authority of Russia.

9 Transport:

9.2 The containers used to transport beef meat shall be equipped with recording thermographs operating at least for 40 days upon start up.

9.3 The beef shall be reached into Iran Border Inspection Post (BIP) in Iranian port at least 60 days after production date with considering the maximum acceptable shelf life which subjected to variation pending confirmed and acceptable shelf life upon IVO officer scrutiny.

10 Inspection at Border Inspection Post:

Upon entry into ports of Iran, the consignment will be checked and the samples will be taken randomly from the containers, indeed not embareced for the all for organoleptical and microbiological testes and the results shall comply with the IVO & OIE standards.

Iran Veterinary Organization Quarantine and Biosecurity office.

ANNEX 10

Import Health Requirements for Fresh boneless Beef Meat from RUSSIA(Last Updated 29/08/2018)

This document serves to detail the minimum requirements for the production, preparation and packaging of fresh Boneless Beef Meat exported to I.R. of Iran. The related state competent authority of country of origin shall be responsible for ensuring that the requirements are to be met and assisting the representative(s) of Iran Veterinary Organization (IVO) for accomplishing the therein requirements.

GENERAL REQUIREMENTS:

1. Iran Veterinary Organization (IVO) is entitled to dispatch its own representative(s) to carryout supervision over ante-mortem, during slaughter and post-mortem inspections and final handling, including storage, loading and transport.
2. The slaughterhouse shall be an officially approved slaughterhouse (bearing an approval number is obligatory) already visited and approved by IVO representative(s) in terms of compliance with IVO regulations and standards including but not limited to geographical location & other epidemiological aspects ,construction plan ,facilities, equipments, maintenance, minimum required personnel expertise, auxiliary structures including but not limited to animal shed premise, water resources, waste disposal systems, cold stores and Quality Assurance Certificates .
3. Requirements of OIE Terrestrial Animal Health Code (Latest Edition) chapter on Bovine Spongiform Encephalopathy (BSE) shall be observed by related official competent authority, according to the latest OIE classification and approval of the origin country in terms of BSE risk status, and strictly conducted by official veterinarians in the slaughterhouse.
4. Requirements of OIE Terrestrial Animal Health Code (Latest Edition) chapter on Foot and Mouth Disease (FMD) shall be observed by related official competent authority, according to the latest FMD status of the origin country according to OIE reports or IVO representative(s) field investigations if required, and strictly conducted by official veterinarians in the slaughterhouse.
5. Iran Veterinary Organization (IVO) reserves the right to solicit any other documents, at its full discretion, based on the conducted library studies or report of the field visit conducted by IVO veterinary officers prior to issuing of Veterinary Import Permit (VIP).

6. The animals shall be originated from registered farms /areas officially registered with the state veterinary services of country of origin in which notifiable animal diseases have not been reported during last 6 months.
7. The origin of animal should not be from combining livestock and poultry/livestock and pig husbandry (namely the cattle, pig and poultry are rearing within a unit).
8. The animals shall be individually identified using ear tags and accompanied by official identification documents upon arrival at slaughterhouse.
9. The apparently healthy animals shall be subjected to veterinary examinations not more than 12 hours before slaughter and found eligible for slaughter and shall be male.
10. The Health certificate (OIE format or specimen already approved by IVO) shall be issued in English undersigned by official veterinarian complying with requirements stipulated in present IHR.
11. The shelf life of the fresh vacuum packed beef is 45 days at most. The slaughterhouse shall submit any and all documents approving the slaughterhouse claimed shelf life (less than above said shelf life) already validated and officially approved by the related competent authority in country of origin.

12. <u>The animals shall:</u>

- Not exceeding 30 (thirty) month of age for cattle (4 Permanent teeth at most)
- Were born and reared in country of origin.
- Were not fattened on foodstuffs contain animal derived proteins (official prohibition on feeding products containing mammalian derived ingredients to cattle shall be effective).
- Were not received hormonal growth promoters and withdrawal time for veterinary pharmaceuticals shall be observed.
- Get rest for at least 24 hours before slaughter.
- Be male.

12. <u>The carcasses shall:</u>

- Not injured, bruised or physiologically icteric.
- Were washed and cleaned with potable water.
- Were inspected and passed by official veterinarians.
- Were kept in chilling rooms at 0 to 4^{o} C for 24 to 72 hr.
- Were chilled to a core temperature of not more than 7 ^{o} C upon chilling room departure acquiring pH not more than 6 for beef.
- Deboning hall temperature not exceeds 10 ^{o} C.

13. The meat shall:

- Fit for human consumption.
- Free from contaminants
- Has no additional fat (maximum visible fat 7 PCT).
- Comply with following microbiological criteria(according to lab results)

Test	n	C	m	M
Total Count (CFU/g)	5	3	$1x10^5$	$1x10^6$
E. coli (CFU/g)	5	2	$5x10^1$	$5x10^2$
Salmonella spp.	5	0	0	Negative in 25 g
Clostridium Botilinum Toxin	5	0	0	Every & all testes packs

14. Packing and labeling

- Each and every cut weight shall not exceed 15 Kg.
- Modified Atmosphere Packaging (MAP) is not permitted and only simple vacuum practices are allowed.
- Each and every cut shall bear a separate label containing complete information
- The convenient carton net weight range shall be 20 to 25 kilograms.
- The quarter cut shall be performed through natural line along the grain.
- Color coding of the cartons must be as follow:
  1-Neck meat with yellow marking. 2- Forequarter meat with red marking.
  3-Hindquarter meat with black marking. 4-Striploin with green marking.
  5-Tenderloin with orange marking 6- Flank with Blue marking.
- The label shall state in Farsi and English posted over the carton and over cuts cover containing the following items:
  Type of cut , country of origin , name and address of importing company ,production date (slaughter date) , expire date (not more than 45 days for beef pending stored at zero

degree Celsius under vacuum packed conditions) production date, slaughterhouse name & code , storage condition (Zero degree Celsius) ,VIP trace code and " produced under supervision of IVO representatives and slaughtered as per Islamic rites under supervision of religious representatives.

- The cartons shall be sea worthy made from food grade compatible materials.
- Tare weight of each empty carton should not be less than 1000 grams.

15. Storage

- The meat shall be stored at zero degree Celsius under vacuum packed conditions.

16. Slaughterhouse

- The slaughterhouse shall bear the EC approval number and entitled to export fresh vacuum packed beef/mutton meat to EU state members.
- The slaughterhouse shall submit any and all related documents describing the expiry date of fresh vacuum packed beef meat already approved and attested by related state competent authority of country of origin.

17. Transport

- The containers used to transport fresh vacuum packed beef meat shall be equipped with recording thermographs operating at least for 30 days upon start up.
- The Vacuum packed beef shall be reached into Iran Border Inspection Post (BIP) in Iranian port not later than 15 days after production date respectively with considering the maximum acceptable shelf life which subjected to variation pending confirmed and acceptable shelf life upon IVO officer scrutiny.
- The meat should be transported at zero to minus one degree Celsius under vacuum packed conditions.

19- Inspection at Border Inspection Post

Upon entry in to Iran custom, the consignment will be checked including but not limited to organoleptic and laboratory tests and the results shall comply with the IVO standards.

ANNEX 11

IR2018-8/39 Import Health Requirements for *Fresh* Chilled VacuumBoneless Beef Meat From Russia To I.R. Iran*(Last Update 18/08/2018)*

SCOPE

This document serves to detail the minimum requirements for the production, preparation and transportation the vacuum beef meat exported to I.R. of Iran, in accordance with the authenticated veterinary certificates. The relevant competent authority of country of origin shall be responsible for ensuring that the requirements are to be met and assisting the representative(s) of Iran Veterinary Organization (IVO) for accomplishing the therein requirements.

1 General Requirements:

1.1 Iran Veterinary Organization (IVO) is entitled to dispatch its own representative(s) to carryout supervision over ante-mortem, during slaughter, post-mortem inspections, chilling hall, deboning hall, as well as final handling, including storage, loading and transport.

1.2 Requirements of OIE Terrestrial Animal Health Code, Volume II, Recommendations applicable to OIE Listed diseases and other diseases of importance to international trade (Latest Edition namely, 2016) on OIE _ Bovine Listed Diseases shall be observed by related official competent authority, according to the latest OIE classification and approval of the origin country in terms of Bovine diseases status, and strictly conducted by official veterinarians in the slaughterhouse.

1.3 Iran Veterinary Organization (IVO) reserves the right to solicit any other documents, at its full discretion, based on the conducted library studies or report of the field visit conducted by IVO veterinary officers prior to issuing of Veterinary Import Permit (VIP).

1.4 The animals shall be originated from registered farms / areas officially registered with the state veterinary services of country of origin in which notifiable animal diseases have not been reported during last 6 months.

1.5 The animals shall be individually identified using ear tags and accompanied by official identification documents upon arrival at slaughterhouse (In accordance with OIE Terrestrial Animal Health Code_ 2016/ Chapters 4.1 &4.2).

1.6 The apparently healthy animals shall be subjected to veterinary examinations not more than 24 hours before slaughter and found eligible for slaughter.

1.7 The Health certificate (specimen already approved by IVO) shall be issued in English undersigned by official veterinarian complying with requirements stipulated in present IHR.

1.8 The animals shall be oriented from establishments that shall be free from anthrax, brucellosis, tuberculosis and bluetongue.

I .Regarding BSE ,in the country of origin:

1. The feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced.

2. Cattle selected for slaughter shall be eligible & qualified as follows:

a) Are identified by a permanent identification system in such a way as to demonstrate that they are **not** exposed cattle *which has been feed with meat-and-bone meal and greaves derived from* ruminants.

b) Complied with Article 11.4.2 of OIE Code /2016 in which the ban on the feeding of ruminants with meat and bone meat meals & greavs derived from ruminants was effectively enforced.

c) passed ante- and post-mortem inspections.

d) were not subjected a stunning process prior to slaughter,such as injecting air or gas into cranial cavity or to a pithing process.

The meat was produced and handeled in a manner which ensures that such products do not contain & are not contaminated with :

The tissues listed in points 1 & 3 Article 11.4.14 , namely tonsils, distal ileum, brains,eyes, spinal cords, skull, vertebral column and adjacent tissues.

II. Regarding FMD:

1. It must be in accordance with OIE Terrestrial Animal Health Code_ 2015 article 8.8.8.

2. Showed no clinical sign of FMD on the day of shipment.

3. Were kept in the establishment of origin since birth or

   a. For the past **30 days** , if a stamping-out policy is in force in the exporting country **or**

   b. For the past **3 months**, if a stamping – out policy is not in force in the exporting country.

4. FMD has not occurred within a 10-kilometre radius of the establishment of origin for the relevant period as defined in points a) and b) above; and were not exposed to any source of FMD infection during their transportation to the place of slaughter house.

2 <u>The animals characterizations:</u>

2.1 Not exceeding 30 (thirty) months of age.

2.2 Be born and reared in country of origin.

2.3 Not be fattened on foodstuffs contain animal derived proteins (official prohibition on feeding products containing mammalian derived ingredients to cattle shall be effective).

2.4 Not be received hormonal growth promoters and withdrawal time for veterinary pharmaceuticals shall be observed.

2.5 Two annexed tables are demonstrated in the pages 6 & 7 of this IHR for the Maximum Residues Limits whose shall be regarded for heavy metals, pesticides and veterinary pharmaceuticals within the beef which will have been exported from Russia to Iran. The executive and feasible approaches could be random sampling with agreement between IVO and exporting veterinary services.

2.6 Be male

2.7 Get rest for at least 12- 24 hours before slaughter.

3 The carcasses shall:

3.1 Not be injured, bruised or physiologically icteric.

3.2 Be washed and cleaned with potable water.

3.3 Be inspected and passed by official veterinarians.

3.4 Be kept in chilling rooms at 0 to 4° C for 24 to 72 hr.

3.5 Be chilled to a core temperature of not more than 7° C upon chilling room departure acquiring pH not more than 6.

3.6 The beef shall produce under condition which fully complies with Codex Alimentarius and SPS Agreements.

4 The meat shall be:

4.1 Fit for human consumption.

4.2 Free from contaminants.

4.3 Has no additional fat, maximum visible fat 7 PCT, (if another is not requested by importer in accordance with the item stock numbers).

4.4 The radionuclide shall be less than 10 Becquerel per kg.

4.5 Comply with following microbiological criteria (according to lab results):

Test	n	C	m	M
Total Count (CFU/g)	5	3	1×10^5	1×10^6
E. coli (CFU/g)	5	3	5×10^1	5×10^2
Salmonella spp.	5	0	0	Negative in 25 g
Closteridum botilinum toxin	5	0	0	Every &all testes

5 Packing and labeling

The label shall state in Farsi and English posted over the cartons and over the cuts containing The following items: type of cut, country of origin, name and address of importing company, Production date (slaughter date), expire date. As well as, the slaughtering has been done as per Islamic rites. The label must be put out side over each wrapping of the cuts & each carton from outside.

5.1 The cartons shall be export worthy made from food grade compatible materials.

5.2 Tare weight of each empty carton shall not be less than 1000 grams.

5.3 The format of label should be confirmed by IVO.

6 Deboning, chilling & cutting conditions:

6.1 The temperature of deboning hall and cutting room must be maintained at approximately +10 degrees centigrade.

6.2 All obvious lymph & hem lymph glands, nodes and nervous tissues shall be removed as far as possible.

6.3 Carcasses shall be kept at chilling room for 24 to 72 hours before going to deboning hall. The temperature of chilling must be between minus 1 up to minus 4 degrees of centigrade as well deep bone temperature shall be reached up to the minus 7 degrees of centigrade at the time of deboning.

7 Slaughterhouse:

8.1 The slaughterhouse shall bear the certain approval certificates such as HACCP or any relevant ISOs as well as shall be an officially approved slaughterhouse by competent veterinary authority of Russia government and the abattoir will have been visited and approved by IVO representative(s) in terms of compliance with IVO regulations and standards including but not limited to geographical location & other epidemiological aspects, construction plan, facilities, equipment, maintenance, minimum required personnel expertise, auxiliary structures including but not limited to animal shed premise, water resources, waste disposal systems, cold stores and Quality Assurance Certificates.

8.2 The slaughterhouse shall submit any and all related documents describing the expiry date of fresh beef meat already approved and attested by related state competent authority of Russia.

9 Condition for vacuum chilled bovine cuts parts transportation:

9.1 Any kind of transportation vehicle (i.e. land or air transport) shall be approved by IVO representative. Bearing smooth, non-corrosive (resistant against disinfectants) and washable surfaces, fitted with refrigeration equipment and recording thermographs enabling air circulation between carcasses is obligatory.

9.2 During all stages of transportation, the temperature shall not exceed 4 degree Celsius.

9.3 The refrigerated vehicles cooling system shall be turned on 1 to 2 hours before Transferring meat consignments from chilling room to vehicle & the temperature inside it must be equivalent and analogous with the carcasses which will be exited from chilling room.

9.4 If the air transport method is considered the vacuum beef shall be transported to the airport at the earliest convenient time upon vehicle embark with the minimum possibility delay in departure

Inspection at Border Inspection Post:

Upon entry into ports of Iran, the consignment will be checked and the samples will be taken randomly from the containers, indeed not embareced for the all for thermograph checking , documents controling as well organoleptical and microbiological testes and the results shall comply with the IVO & OIE standards.

Annex I- Maximum Residues Limits (MRL) for Antibacterials , Pesticide, Heavy Metals in Red Meat

MRL (PPb)	Name of Residue	Group of Residues
200	Tetracycline	Antibacterials
600	Streptomycin	
50	Penicillin G	
100	Kanamycin	
100	Enrofloxacine	
600	Dihydrostreptomycin	
100	Gentamicin	
50	Amoxycillin	
50	Ampicillin	
100	Lincomycin	
100	Erythromycin	
100	Tilmicosin	
100	Tylosin	
500	Neomycin	
*1	Furazolidone	
*0.3	Chloramphenicol	
100	Sulfonamides	Sulfonamides
1	Dexamethasone	Steroids
100	Albendazole	Anthelmintics

Iran Veterinary Organization (I.V.O)
S. J. Asadabadi St., Valiasr Ave., Tehran-Iran
P.O.Box: 14155-6349 ; Postal Code: 1431683765
Tel: (+9821) 88958046 - 88957007
Fax: (+9821) 88957252 - 88962392
www.ivo.ir int.affairs@ivo.ir

Annex II- Maximum Residues Level(MRL) of Antibacterials , Pesticide, Heavy Metals in Red Meat

MRL (PPb)	Residues	Group
200	Heptachlor	Organochlorinc Pesticide
50	Diazinon	Organophosphat Pesticide
200	Malathion	
20	Cyhalothrin	Carbamates and other Synthetic Pyrethroid
50	Cypermethrin	
30	Deltamethrin	
100	Lead	Heavy Metal
50	Cadmium	
10	Mercury compound	

The residues (namely antibiotics,pestisides, heavy meatals and hormones) and radionucleotids plan documents & test results shall be send for IVO on annual basis but IVO reserves the right for random sampling and tests.

Natural and synthetic hormones , promoters are prohibited

Chloramphenicol & Nitroforans and forazolidon are prohibited

Iran Veterinary Organization Quarantine and Biosecurity office.

ANNEX 12

IR2016-3-8:Import Health Requirements for Vacuum Boneless Beef

from Russia into I.R. Iran

SCOPE

This document serves to detail the minimum requirements for the preparation of Vacuum Boneless Beef intended to be exported to I.R. of Iran. The related state competent authority of country of origin shall be responsible for ensuring that the requirements (Russian Veterrinary Department) are met and assisting the representative(s) of Iran Veterinary Organization (IVO) for accomplishing the therein requirements.

1 General Requirements:

1.1 - Iran Veterinary Organization (IVO) is entitled to dispatch its own representative(s) to carryout supervision over ante-mortem, during slaughter and post-mortem inspections and final handling, including storage, loading and transport.

1.2 - The slaughterhouse shall be an officially approved slaughterhouse (bearing an European approval number is obligatory) already visited and approved by IVO representative(s) in terms of compliance with IVO regulations and standards including but not limited to geographical location & other epidemiological aspects, construction plan, facilities, equipment, maintenance, minimum required personnel expertise, auxiliary structures including but not limited to animal shed premise, water resources, waste disposal systems, cold stores and Quality Assurance Certificates.

1.3 - Requirements of OIE Terrestrial Animal Health Code (Latest Edition) chapter on Bovine Spongiform Encephalopathy (BSE) shall be observed by related official competent authority, according to the latest OIE classification and approval of the origin country in terms of BSE risk status, and strictly conducted by official veterinarians in the slaughterhouse.

1.4 - Iran Veterinary Organization (IVO) reserves the right to solicit any other documents, at its full discretion, based on the conducted library studies or report of the field visit conducted by IVO veterinary officers prior to issuing of Veterinary Import Permit (VIP).

1.5 - The animals shall be originated from registered farms / areas officially registered with the state veterinary services of country of origin in which notifiable animal diseases have not been reported during last 6 months.

1.6 - The animals shall be individually identified using ear tags and accompanied by official identification documents upon arrival at slaughterhouse.

1.7 - The apparently healthy animals shall be subjected to veterinary examinations not more than 12

1.8 hours before slaughter and found eligible for slaughter.

1.9 - The Health certificate (OIE format or specimen already approved by IVO) shall be issued in English undersigned by official veterinarian complying with requirements stipulated in present IHR.

1.10- The shelf life of the fresh vacuum packed beef is the responsibilities of manufacturing company in exporting country as well as the requests of purchasing company in importing country

1.11- The animals shall be oriented from area that is free from anthrax, brucellosis, tuberculosis and milestone food-borne diseases.

2 <u>The animals shall:</u>

2.1 - Not exceeding 30 (thirty) month of age (6 Permanent teeth at most).
2.2 - Be born and reared in country of origin.
2.3- Not be fattened on foodstuffs contain animal derived proteins (official prohibition on feeding products containing mammalian derived ingredients to cattle shall be effective).
2.4- Not be received hormonal growth promoters and withdrawal time for veterinary pharmaceuticals shall be observed.
2.5- Get rest for 12 -24 hours before slaughter, in order to fulfill rigor mortis and glycogenesis phenomenon.
2.6- Be male.

3 <u>The carcasses shall:</u>

3.1- Not be injured, bruised or physiologically icteric.
3.2 - Be washed and cleaned with potable water.
3.3 - Be inspected and passed by official veterinarians.
3.4- Be kept in chilling rooms at 0 to 4° C for 24 to 72 hr.
3.5- Be chilled to a core temperature of not more than 7° C upon chilling room departure acquiring pH not more than 5.8.
3.6- Be handled in a Deboning hall temperature not exceeding 10° C.
3.7- The MRL of pharmaceutical agents and heavy metal shall be in accordance with the enclosed Annexes which are manifested in the end of this IHR.
3.8 - The radionuclide within the beef shall be lesser than 10 Bq per gram meat.
3.9- All obvious lymphatic glands & nodes, nervous tissues shall be removed and cleaned from the meat as far as possible, as well the meat cuts shall not be contaminated with specified risk materials.

4 The meat shall be:

4.1- Fit for human consumption.
4.2- Free from contaminants.
4.3- Has no additional fat (maximum visible fat 7 PCT).
4.4- Comply with following microbiological criteria (according to lab results):

Test	n	C	m	M
Total Count (CFU/g)	5	3	1×10^5	1×10^6
E. coli (CFU/g)	5	2	5×10^1	5×10^2
Salmonella spp.	5	0	0	Negative in 25 g
Clostridium Botilinum Toxin	5	0	0	Every & all testes

- heavy metals, drug and radionuclide's residue shall comply with attached Annex-1.

Packing & Labeling

- One paper identification sheet (Label) stating in Farsi and English should be printed indicating the following information:
- The name and place of production(name and address , sanitary code of slaughterhouse), the date of production , the type of cuts ,trace Code and that the slaughtering has been done as per Islamic rites the labels must be put outside over each wrapping of the cuts and both end-side of each carton from outside .
- The label or paper identification sheet contents and format should already confirmed by IVO.
- Modified Atmosphere Packing (MAP) is not permitted and only simple vacuum practices are allowed.
- The cartons shall be export worthy made from food grade compatible materials. Tare weight of each

– empty carton should not be less than 1000 grams.

The labels must be pasted up or printed over each wrapping of the cuts parts. The label or identification paper contents and format should be confirmed by IVO.

Condition for vaccum chilled bovine cuts parts transportation:

- The chilled bovine meat shall mainly be transported by truck.
- During all stages of transportation, the temperature shall not exceed 4 degrees Celsius.
- The refrigerated vehicles cooling system shall be turned on 1 to 2 hours before transferring meat consignments from chilling room to vehicle showing almost similar temperature with the carcass exiting from chilling room.
- The vacuum beef shall be transported to the airport at the earliest convenient time upon vehicle embark with the minimum possibility of carcass detention due to departure delay.

(i) -The conveyances used to transport meat entered for export to the Islamic Republic of Iran are fitted with intended refrigeration equipment and recording thermographs.

(ii) -The transportation vehicle shall be approved by IVO representative. Bearing smooth, non corrosive (resistant against disinfectants) and washable surfaces, other relevant requirements according to IVO rules and regulations should be fulfilled and IVO circulars in relation to principles of cleansing and disinfecting cold store govern this clause

SANITARY CONTROLS AT ARRIVAL I.R.IRAN BORDER:

1-All consignments should be in accompany with original Veterinary Health Certificate signed and sealed by competent state authority official countersigned by IVO representative contains all requirements stipulated above mentioned.

2-All consignment shall be examined against organoleptically criteria including but not limited to appearance, odor and temperature (not exceed 7ºC at the deepest part of the muscles) and PH 5.4 up to 5.8.

3-The installed thermographs shall be checked and inside information shall be controlled.

4-The Iran Veterinary Organization reserve the right to not issue the clearance from custom for those consignments that found not in compliance of provision of present document.

Iran Veterinary Organization
I.V.O

Islamic Republic of Iran
Ministry of Jihad-e-Agriculture

Ref:

Date:

All stages of meat production, from start to end, shall comply with related EU directives and National Iran Standard No.3228 unless otherwise explicitly stipulated in present document.

Iran Veterinary Organization

Qarantine and Biosecurity Office

Iran Veterinary Organization (I.V.O)
S. J. Asadabadi St., Valiasr Ave., Tehran-Iran
P.O.Box: 14155-6349 ; Postal Code: 1431683765
Tel: (+9821) 88958046 - 88957007
Fax: (+9821) 88957252 - 88962392
www.ivo.ir int.affairs@ivo.ir

Iran Veterinary Organization
I.V.O

Islamic Republic of Iran
Ministry of Jihad-e-Agriculture

ANNEX 13

IR/29/02/2016-95/45/23339Import Health Requirements for Frozen Boneless Beef Meat from RussiaTo I.R. Iran(Last Update27.02.2017)

SCOPE:

This document serves to detail the minimum requirements for the production, preparation and transportation frozen beef meat exported to I.R. of Iran. The relevant competent authority of country of origin shall be responsible for ensuring that the requirements are to be met and assisting the representative(s) of Iran Veterinary Organization (IVO) for accomplishing the therein requirements.

General Requirements:

a. Iran Veterinary Organization (IVO) is entitled to dispatch its own representative(s) to carryout supervision over ante-mortem, during slaughter, post-mortem inspections, chilling hall, deboning hall& freezing hall, as well as final handling, including storage, loading and transport.

b. Requirements of OIE Terrestrial Animal Health Code (Latest Edition naemely, 2015) chapters on OIE _ Bovine Listed Diseases shall be observed by related official competent authority, according to the latest OIE classification and approval of the origin country in terms of Bovine diseases status, and strictly conducted by official veterinarians in the slaughterhouse.

c. Iran Veterinary Organization (IVO) reserves the right to solicit any other documents, at its full discretion, based on the conducted library studies or report of the field visit conducted by IVO veterinary officers prior to issuing of Veterinary Import Permit (VIP).

d. The animals shall be originated from registered farms / areas officially registered with the state veterinary services of country of origin in which notifiable animal diseases have not been reported during last 6 months.

e. The animals shall be individually identified using ear tags and accompanied by official identification documents upon arrival at slaughterhouse (In accordance with OIE Terrestrial Animal Health Code_ 2015/ Chapters 4.1 &4.2).

f. The apparently healthy animals shall be subjected to veterinary examinations not more than 24 hours before slaughter and found eligible for slaughter.

g. The Veterinary Health certificate (specimen already approved by IVO) shall be issued in English undersigned by official veterinarian complying with requirements stipulated in present IHR.

h. The animals shall be oriented from zone that shall be free from anthrax, brucellosis, tuberculosis and bluetongue.

i. Regarding BSE ,in the country of origin:

I- The feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced.

2- Cattle selected for slaughter shall be eligible & qualified as follows:

i. Are identified by a permanent identification system in such a way as to demonstrate that they are not exposed cattle which has been feed with meat-and-bone meal and greaves derived from ruminants;

ii. Were born at least 2 years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants was effectively enforced.

iii. passed ante- and post-mortem inspections.
iv. were not subjected a stunning process prior to slaughter,such as injecting air or gas into cranial cavity or to a pithing process.
v. The meat was produced and handeled in a manner which ensures that such products do not contain & are not contaminated with :
vi. The tissues listed in points 1 & 3 Article 11.4.14 , namely tonsils, distal ileum, brains,eyes, spinal cords, skull, vertebral column and adjacent tissues.

j. Regarding FMD:

1- It must be in accordance with OIE Terrestrial Animal Health Code_ 2015 article 8.8.8.

i. 2. Show no clinical sign of FMD on the day of shipment.
ii. 3. Were kept in the establishment of origin since birth or
iii. For the past 30 days , if a stamping-out policy is in force in the exporting country or
iv. For the past 3 months, if a stamping – out policy is not in force in the exporting country.
v. 4. FMD has not occurred within a 10-kilometre radius of the establishment of origin for the relevant period as defined in points a) and b) above; and were not exposed to any source of FMD infection during their transportation to the place of slaughter house.

The animals characterizations:

a. Not exceeding 30 (thirty) months of age.
b. Be born and reared in country of origin.
c. Not be fattened on foodstuffs contain animal derived proteins (official prohibition on feeding products containing mammalian derived ingredients to cattle shall be effective).
d. Not be received hormonal growth promoters and withdrawal time for veterinary pharmaceuticals shall be observed.
e. Two annexed tables are demonstrated in the pages 7 & 8 of this IHR for the Maximum Residues Limits whose shall be regarded for heavy metals, pesticides and veterinary pharmaceuticals within the beef which will have been exported from Russia to Iran. The executive and feasible approaches could be random sampling with agreement Between IVO and Exporting veterinary services
f. Be male
g. Get rest for at least 24 hours before slaughter

The carcasses shall:

a. Not be injured, bruised or physiologically icteric.
b. Be washed and cleaned with potable water.
c. Be inspected and passed by official veterinarians.
d. Be kept in chilling rooms at 0 to 4° C for 24 to 72 hr.
e. Be chilled to a core temperature of not more than 7° C upon chilling room departure acquiring pH not more than 6.
f. The beef shall produce under condition which fully complies with Codex Alimentarius and SPS Agreements.

The meat shall be:

a. Fit for human consumption.
b. Free from contaminants
c. Has no additional fat (maximum visible fat 7 PCT).

d. The radionuclide shall be less than 10 Becquerel per kg.

e. Comply with following microbiological criteria (according to lab results):

Test	n	C	m	M
Total Count (CFU/g)	5	3	1×105	1×106
E. coli (CFU/g)	5	2	5×101	5×102
Salmonella spp.	5	0	0	Negative in 25 g

Packing and labeling:

a. Each and every cut shall weight 1-3 kg ± 15 %.

b. Each and every cut shall bear a separate label containing complete information.

c. The convenient carton net weight range shall be 20 to 25 kilograms.

d. The quarter cut shall be performed through natural line along the grain.

e. Color coding of the cartons must be as follows:

f. The label shall state in Farsi and English posted over the cartons and over the cuts containing the following items:

1-	Forequarter meat with red marking.
2-	Hindquarter meat with black marking.
3-	Flank meat with blue marking
4-	Topside meat with grey marking
5-	Neck meat with yellow marking
6-	striploin with green marking
7-	Tenderloin with orange marking

g. Type of cut, country of origin, name and address of importing company, production date (slaughter date), expire date (not more than 10 weeks pending stored at zero degree Celsius under vacuum packed conditions) production date, slaughterhouse,
name & code, storage condition (Zero degree Celsius), VIP trace code and stating “produced under supervision of IVO reps and slaughtered as per Islamic rites under supervision of religious reps”.

h. The cartons shall be export worthy made from food grade compatible materials.

i. Tare weight of each empty carton shall not be less than 1000 grams.

Deboning, chilling & cutting conditions:

a. The temperature of deboning hall and cutting room must be maintained at approximately +10 degrees centigrade.

b. All obvious lymph & hem lymph glands, nodes and nervous tissues shall be removed as far as possible.

c. Carcasses shall be kept at chilling room for 24 to 72 hours before going to deboning hall. The temperature of chilling must be between minus 1 up to minus 4 degrees of centigrade as well deep bone temperature shall be reached up to the minus 7 degrees of centigrade at the time of deboning.

d. Deboning hall shall be equipped with deboning and cutting sanitary tools & equipments. As well as the temperature of deboning hall must not to be warmer minus 10 degrees of centigrade.

Freezing & Storage:

a. All products shall be frozen within freezing tunnel with the minus 35 up to 45 degrees of centigrade within 24 to 48 hours, the temperature of meat in deepest part; post freezing shall be the minus 18 degrees of centigrade at the time of transporting to the cold store.

b. The meat shall be kept in cold storage with circumstances with not warmer than minus 18 degrees of centigrade. As well as the meat shall be transferred to the final loading point with not warmer than minus 18 degrees of centigrade.

c. The maximum duration from slaughter to export for any shipment shall be not more than 60 days. If not so, the IVO reprehensive(s) shall give a special authorization for embarkation of vessel.

d. Slaughterhouse:

I. The slaughterhouse shall bear the certain approval certificates such as HACCP or any relevant ISOs as well as shall be an officially approved slaughterhouse by competent veterinary authority of Russia government and the abattoir will have been visited and approved by IVO representative(s) in terms of compliance with IVO regulations and standards including but not limited to geographical location & other epidemiological aspects, construction plan, facilities, equipment, maintenance, minimum required personnel expertise, auxiliary structures including but not limited to animal shed premise, water resources, waste disposal systems, cold stores and Quality Assurance Certificates.

II. The slaughterhouse shall submit any and all related documents describing the expiry date of fresh beef meat already approved and attested by related state competent authority of Russia.

Transport:

a. The containers used to transport beef meat shall be equipped with recording thermographs operating at least for 40 days upon start up.

b. The beef shall be reached into Iran Border Inspection Post (BIP) in Iranian port at least 60 days after production date with considering the maximum acceptable shelf life which subjected to variation pending confirmed and acceptable shelf life upon IVO officer scrutiny.

Inspection at Border Inspection Post:

a. Upon entry into ports of Iran, the consignment will be checked and the samples will be taken for organoleptical and microbiological testes and the results shall comply with the IVO & OIE standards.

Iran Veterinary Organization Quarantine and Biosecurity office.

27/02/2017-Meat@ivo.ir

Iran Veterinary Organization
I.V.O

Islamic Republic of Iran
Ministry of Jihad-e-Agriculture

ANNEX 14

IR2017-05/02Health Requirements for Import FRESH FROZEN OVINE MEAT FROM Russia INTO I.R.IRAN(Last Update 29.02.2018)

SCOPE

This document serves to detail requirements for the preparation of frozen ovine/mutton meat in Russia for export to the Islamic Republic of Iran. The Veterinary Services of Russia shall be responsible for ensuring that the requirements of the export in relation to the preparation of meat subject to this agreement have been met and for assisting the representative of the Iran Veterinary Organization (IVO) for verifying that the requirements of this agreement have been met.

A. GENERAL REQUIREMENTS:

1. Iran Veterinary Organization (IVO) is entitled to dispatch its own representative to carry out ante-mortem, during slaughter and post-mortem inspection and final handling, including storage and loading.
2. The meat has been derived from healthy male sheep not exceeding 18 months of age.
   - Were born and reared in the country of origin.
   - Came from herds officially registered with the administrative Veterinary of country of Origin.
   - Came from ovine herds in which OIE notifieable disease, not registered during 12 month ago.
   - Were not fattened on foodstuffs which included animal derived proteins (mammalian MBM).
   - Were kept for six months prior to export in an establishment where no case of rabies was reported for at least 12 months prior to slaughter.
3. In the country of origin or zone, surveillance and monitoring system established as referred to Article 14.9 (especially article 14.9.2) OIE international Health Code (2015).
4. The animals have been slaughtered in approved slaughterhouse located in the quarantine area of free zone and found to be healthy before and after slaughter approved by IVO representative/s.
5. The meat was produced under conditions which fully comply with Iran national standard No 4277, European Union standards and Codex alimentarius and SPS agreements.
6. The animals were subjected to ante and post mortem inspection by the official veterinary service of the country of origin and IVO representative/s and were found to be free of clinical signs of any contagious and infectious diseases(Scrapie, PPR, anthrax,ovine brucellosis,rabies).
7. Establishments which supply meat for export to the Islamic Republic of Iran should be approved by IVO representative before start of the slaughtering and situated in the free zone.
8. Russia state veterinarians in each export slaughterhouse should monitor and observe inspection and production requirements in co-operation with the IVO representative.

9. The sheep must not be derived out of regions approved by IVO representative in terms of animal health.
10. Only animals which the IVO officer has determined and adequately rested shall be presented for ante-mortem inspection.
11. Carcasses sent to the detain rail with major defects cannot be exported to the Islamic Republic of Iran.
12. Considering of anthrax ,all contexts of OIE Terrestrial Animal Health Code -2016 Article 8.1.4 should be fully respected by Russia Veterinary Services.

B. SPECIFIC CONDITIONS:

1. The meat in this consignment
- Is fit for human consumption.
- Is free of contamination by excrement and blood clots, especially in the neck and intercostals muscles of the ribs.
- With normal odor , without burn freezing
- Shows no evidence of pathogenic agent(bacterium, fungus, parasite)

Product	Test	No. of samples (n)	c	m	M
Fresh/FROZEN OVINE MEAT	Total count (CFU/g)	5	3	1×10^5	1×10^6
	Salmonella spp. (CFU/25g)	5	0	Negative	-
	E.Coli count (CFU/g)	5	2	5×10^1	5×10^2

2. The carcasses of the animals from which the meat to be exported to the Islamic Republic of Iran were derived from;

- Not injured, bruised or physiolocally icteric (yellow) carcasses which;
  - are washed and cleaned completely with fresh water.
  - The meat produced from animal examined by an official veterinary service of country of origin and IVO representative/s before, during and after slaughtering and found to be fit for human consumption and which also controlled during processing and final handling.
  - must be derived from sheep which have not been treated with hormonal growth promotores before slaughter.
  - not undergo any preserving process.
- All carcasses should be stamped by IVO representative.

3. Chilling and cutting conditions:

- Cutting of the carcasses must be accordance with Iran National Standard No 4276.
- The temperature of cutting room must be maintained at or below +10 degree centigrade.

- All obvious lymphatic glands and nervous tissues were removed.
- Carcasses should be kept at chilling room for 24 to 72 hours before going to cutting room. the temperature of chilling room must be between +0 to +4 centigrade degree and the deep bone temperature should be reached to +7 centigrade degree, and humidity not less than 90% and PH of the meat should be less than 6 after chilling room.
- The cuts accordance with Iran National Standard No 4276 should not weighted more than 2 kilogram and found in full compliance with IVO circulars.

4. Packing:

- Packing and labeling must be accordance with Iran National Standard No 4275.The color of lables should be as below:

-Leg (silverside, Rump, Knuckle, Topside): Black
-Hind Shank: Black
-Sir loin (short loin): Green
-Flank/ Flap: Blue
-Forequarter: Red
-Fore Shank: Red
-Breast: Red
-Neck: Yellow

- Different cuts can not be mixed in the same carton.
- The weight and the specifications of all empty cartons should be the same.
- Tare weight of each empty carton should not be more than 1000 grams.
- The cartons should be moisture proof and made from strong tissue material in order to prevent tearing during loading, stow aging and discharging.
    - Each cuts must hold a label and The same label identification sheet stating in Farsi and English should be attached on cartons and must indicate the following information :
    - The name and place of production(name and address , sanitary code of slaughterhouse), the date of production(date of slaughtering) , the type of cuts , and that the slaughtering has been done as per Islamic rites the labels must be put inside between two polyethylene bags, over each wrapping of the cuts and both end-side of each carton from outside .
    - . The label or paper identification sheet contents and format should already confirmed by IVO.

5. **FREEZING AND STORAGE:**

- All products should be frozen in freezing tunnel with minus 35 to 45 degree centigrade within 24 to 48 hours; the temperature of meat in deepest part after freezing should be -18 degree C, at the time of going to the cold store.

- The meat shall be kept in cold storage with not warmer than minus 18 degrees C. The meat should be transferred to the final loading point with temperature of -18C.
- The maximum duration from slaughter to export shipment shall not be more than 60 days. If not so, the IVO's representative/s should give a special authorization for embarkation.

6. Transportation:

The conveyances used to transport meat entered for export to the Islamic Republic of Iran are fitted with intended refrigeration equipment and recording thermographs.

C. VETERINARY CERTIFICATE

The Russia veterinary officer will issue, in respect of each consignment of frozen ovine carcasses a Veterinary Health certificate for export to the Islamic Republic of Iran produced in compliance with this agreement .The certificate shall be countersigned by IVO representative too.

Health attestations in the certificate will be endorsed:

1-The territory described above has been free for 6 months from anthrax.

2-The meat described above is obtained from ovine animal:

2-1 Which have remained in the territory as described under for at least 3 months before being slaughtered.

2-2 Which have been transported from the holdings of origin to the approved slaughterhouse concerned without contact with animals which do not comply with the conditions required for export of their meat to I.R.Iran , and , if conveyed in a means of transport , that the latter has been cleaned & disinfected before loading .

2-3 Which have passed the ant-mortem health inspection at the slaughterhouse with Iranian official veterinarian(s) during the 24 hours before slaughter and , in particular have shown no evidence of diseases & sudden deaths and other contagious diseases at sole discretion of IVO representative.

2-4 Which have not come from a holding which for health reasons is subject to prohibition as a result of an outbreak of ovine or caprine brucellosis within the recent 3 months.

3-The meat is completely salmonella free.

4-The meat is fit for human consumption.

D-SANITARY CONTROLS AT ARRIVAL I.R.IRAN BORDER:

1-All consignments should be in accompany with original Veterinary Health Certificate signed and sealed by competent state authority official countersigned by IVO representative contains all requirements stipulated above mentioned.

2-Upon entry in to ports of Iran, the consignment will be checked and the samples will be test organoleptically, microbiologically and chemically and results must fulfill Iran veterinary organization rules, Iran National Standard and EU legislation.

3-The installed thermographs shall be checked and inside information shall be controlled.

4-The Iran Veterinary Organization reserve the right to not issue the clearance from custom for those consignments that found not in compliance of provision of present document.

Iran Veterinary Organization Quarantine and Biosecurity office.

ANNEX 15

IMPORT HEALTH REQUIREMENTS FOR THE IMPORTATION OF Frozen Deboned VENISON from Russia INTO THE I.R.IRAN(updated 22/12/2016)

SCOPE

This document serves to detail the minimum requirements for the production, preparation and transportation the venison exported to I.R. of Iran, in accordance with the authenticated veterinary certificates. The relevant competent authority of country of origin shall be responsible for ensuring that the requirements are to be met and assisting the representative(s) of Iran Veterinary Organization (IVO) for accomplishing the therein requirements.

General Requirements:

1) A health certificate in English signed by a full-time authorized veterinary official of the government of the exporting country stating:-

1.1 Iran Veterinary Organization (IVO) is entitled to dispatch its own representative(s) to carryout supervision over ante-mortem, during slaughter, post-mortem inspections, chilling hall, deboning hall, as well as final handling, including storage, loading and transport.

1.2) type of portions and package of the venison/venison products,

1.4) number of pieces or package and net weight,

1.5) names and addresses and registered number of the approved manufacturer

1.6) names and addresses of the exporter and the consignee,

1.7) dates of slaughter, manufacture, packaging and export,

1.9) certification of condition items (2) to (8).

1.10 The products originate from a government licensed establishment that processes animals For human consumption and operates under Government Veterinary Supervision.

2) The products shall be identifiable as originating from Russia

3) The country of origin is free form Contagious Bovine Pleuropneumonia.

4)The products shall be commercially packed in the original unopened packaging. Full containers of meat shall be sealed.

5)Documentation shall be in English, but labeling should

6) The country/region/zone of origin has been free from Foot-and-Mouth Disease (FMD) and officially approved by the Office International des Epizooties (OIE), for at least 3 (three) years prior to export.

7) The deer which come to the abattoirs must come from an area in which animals diseases are under control. They must be healthy, free from signs of any infectious and contagious diseases

including ectoparasitism.

8) The deer which come to the abattoirs must come from farms where no clinical signs or other evidence of Clostridial disease, Yersiniosis, Mucosal Disease, Johne's Disease, Bluetongue, Vesicular Stomatitis, Leptospirosis, Malignant Catarrhal Fever, Brucellosis and Tuberculosis has occurred during the past 12 (twelve) months prior to slaughter.
9) The venison have been processed in a designated establishment, approved for export to Thailand, in a sanitary manner under the supervision of a full-time veterinary official appointed by the government of the exporting country. Every precaution has been taken to prevent any contamination during the manufacturing, packaging, storage and until the time of export.
10) The venison do not contain preservatives, additives or any substances posing a harmful risk to human health.
11) The venison has been sampled to tests for food microorganisms as well as drug and pesticide residues according to the Codex Alimentarius and considered to be fit for human consumption.
12) The vehicles and containers used for transporting the meat should be thoroughly cleaned and disinfected immediately prior to export.
13) The venison shall bear a health mark or meat inspection legend in any form of a label, seal or stamp for recognition that the venison itself has been produced in accordance with standards which are acceptable to Thailand.
14) The venison shall not be transshipped at any intermediate port.
15) The venison is subjected to inspection/detention for laboratory testing upon arrival in Iran. The owner/importer shall be fully charged for incurred expenses.

16) Failure to follow the import procedures may result in returning the venison to the country of origin or destroying without compensation.
17) Foot and mouth disease and rinderpest have not occurred in the zone during the Previous 12 months.
18)Chronic wasting disease (CWD) of elk and deer has never occurred in the zone. The Russia Veterinary Authority should present all the surveillance and monitoring , particularly negative tonsil test for CWD.
19) Chronic Wasting Disease (CWD), TB and Brucellosis monitoring accreditations as positive, proactive marketing tools for promoting their products.
20) Considering of anthrax due to particular circumstances (climate changes in sub-polar area)all the contexts of the OIE/ Terrestrial Animal Health Code 2016 Article 8.1.14 must be exactly respected as following:
Veterinary Authorities of *importing countries* should require the presentation of an *international*

Iran Veterinary Organization (I.V.O)
S. J. Asadabadi St., Valiasr Ave., Tehran-Iran
P.O.Box: 14155-6349 ; Postal Code: 1431683765
Tel: (+9821) 88958046 - 88957007
Fax: (+9821) 88957252 - 88962392
www.ivo.ir int.affairs@ivo.ir

veterinary certificate attesting that the products originate from *animals* that:

1. have shown no sign of anthrax during ante- and post-mortem inspections; and
2. were not vaccinated against anthrax using live vaccine during the 14 days prior to *slaughter* or a longer period depending on the manufacturer's recommendations; and
3. come from *establishments* that are not placed under movement restrictions for the control of anthrax and where there has been no *case* of anthrax during the 20 days prior to *slaughter*

21) The products were derived from animals which passed veterinary ante-mortem and postmortem
Inspection

SPECIFIC CONDITIONS

1. The meat in this consignment

- Is fit for human consumption.
- Is free of contamination by excrement and blood clots, especially in the neck and intercostal muscles of the ribs.
- With normal odor, without burn freezing.
- Shows no evidence of pathogenic agent (bacterium, fungus, and parasite).

Test	n	C	m	M
Total Count (CFU/g)	5	3	1×10^5	1×10^6
E. coli (CFU/g)	5	2	5×10^1	5×10^2
Salmonella spp.	5	0	0	Negative in 25 g

2. The carcasses of the animals from which the venison to be exported to the Islamic Republic of Iran were derived from;

- Not injured, bruised or physiologically icteric (yellow) carcasses which;

i. Are washed and cleaned completely with fresh water.
ii. Were kept in chilling rooms which were maintained at temperatures of between 0 and 4 degree centigrade for a period of between 24 and 72 hours.
iii. Chilled to a core temperature not higher than 7 degree centigrade and the pH must be 5.5 to 5.7 at the time of removal from the chilling rooms.(measured approximately 24 hours post slaughter (so called ultimate pH)

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iv. Produced from animal examined by an official veterinary inspectorof veterinary service of

country of origin and IVO representative/s before, during and after slaughtering, and found to be fit for human consumption and which also controlled during processing and final handling.

Deboning, chilling, and cutting conditions

- The temperature of deboning hall/ cutting room must be maintained at or below +10 degree centigrade.
- All obvious lymphatic glands and nervous tissues were removed.

Carcasses should be kept at chilling room for 24 to 72 hours before going to deboning hall. The temperature of chilling must be between +0 to +4 degree C and the deep bone temperature should be reached to +7 degree C at the time of deboning and PH of the meat must be 5.5 up to 5.7 after chilling room.

- Deboning hall should have sanitary equipment of deboning and cutting the meat and temperature of deboning hall must not be warmer than +10 degrees Centigrade.

N.B: The cuts should not weigh more than 3 kilogram (±20%) and found in full compliance with IVO circulars.

4. Packing

- The net weight range of each carton should be 20 kilograms.
- Packing of one quarter and fraction cut by its natural veins in order to use whole capacity of a carton is allowed.
- Different cuts cannot be mixed in the same carton.
- Color coding of the cartons must be as follow:
- Neck meat with yellow marking.
- Forequarter meat with red marking.
- Hindquarter meat with black marking.
- Topside with grey marking.
- Striploin with green marking.
- Tenderloin with orange marking.
- When needed to complete the weight of the boxes with fractions of the respective forequarters. The cuts should be done by the natural inter muscular spaces.

- Each cut must hold a label and the same label identification sheet stating in Farsi and English should be attached on cartons and must indicate the following information:

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www.ivo.ir int.affairs@ivo.ir

- The type of cut , the name of consignment , the type of use , the country of origin , the name and address of importing company/or ordered by , that the production has been done

under supervision of IVO representatives and the slaughtering has been done as per Islamic rites under supervision of IRAN religious representatives , the production date (date of slaughtering) , the expire date (one year after production date), the name of the slaughterhouse and sanitary code, keeping condition (keep at: -18°C), and the labels must be put inside between two polyethylene bags,over each wrapping of the cuts and both end-side of each carton from outside .

- The cartons will be subject with four straps without over weights of any class in the boxes and a correct accommodation of the meat inside the box is needed to provide a perfect shut of the latter.
- The weight and the specifications of all empty cartons should be the same.
- The cartons for our purpose should be moisture proof and made from strong tissue material in order to prevent tearing during loading, stow aging and discharging.
- Tare weight of each empty carton should not be less than 1000 grams.

FREEZNING AND STORAGE:

- All products should be frozen in freezing tunnel with minus 35 to 45 degrees of centigrade within 24 to 48 hours, the temperature of meat in deepest part after freezing should be minus 18 degree of C at the time of going to the cold store.
- The meat shall be kept in cold storage with not warmer than minus 18 degrees of centigrade. The meat should be transferred to the final loading point with temperature of minus 18 degrees of C and lower.
- The maximum duration from slaughter to export shipment shall be not more than 60 days. If not so, the IVO representative/s should give a special authorization for embarkation.

Transportation:

The vehicles and containers used for transporting the meat should be thoroughly cleaned and disinfected immediately prior to export. As well as the conveyances used to transport beef entered for export to the Islamic Republic of Iran are fitted with intended refrigeration equipment and recording thermographs.

Iran Veterinary Organization Quarantine and Biosecurity office.

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ANNEX 16

IR2009-3/07-1R. Health Requirements For Fresh Chilled Vacuum Packed Ovine Meat From Kazakhstan (last Update*22.02.2019*)

SCOPE:

This document serves to detail requirements for the preparation of fresh chilled vaccumed ovine meat in Kazakhstan for export to the Islamic Republic of Iran. The Veterinary Services of Kazakhstan shall be responsible for ensuring that the requirements of the export in relation to the preparation of ovine meat subject to this IHR have been met and for assisting the representative(s) of the Iran Veterinary Organization (IVO) verifying that the requirements of this IHR have been fulfilled.

A. GENERAL REQUIREMENTS:

1. Iran Veterinary Organization (IVO) is entitled to dispatch it's own representative(s) to carry out ante-mortem, during slaughter and post-mortem inspection and including but not limited to storage and loading.
2. The country of origin is free from FMD (even with vaccination), or the animals have been derived from a zone that is free from FMD according to Article 8.5.11. OIE International Terrestrial Animals Health Code. (2008)
3. The meat has been derived exclusively from healthy ovine not exceeding than 18 months of age which
   - Were born and reared in the country of origin.
   - Came from flocks officially registered with the administrative Veterinary of country of origin.
   - Came from flocks in which OIE notifiable diseases have not registered during last 12 months.
   - Were not fattened on foodstuff which included animal derived proteins (mammalian MBM).
   - Were kept for six months prior to export date in an establishment where no case of rabies was reported for at least 12 months prior to slaughter.
4. In the country of origin or zone, a surveillance and monitoring system established as referred to Article 14.9 (especially article 14.9.2) OIE international Health Code (2008)
5. The animals have been slaughtered in approved slaughterhouse situated in the quarantine area of free zone and found to be healthy before and after slaughter approved by IVO representative/s.

6. The meat was produced under conditions which fully comply with provisions Iran national

7. standard No: 4277 and Codex alimentarius and SPS.
8. Subject to ante, during and post mortem inspection by the official veterinary service of the country of origin and IVO representative(s) the animals were found to be free of clinical signs of any contagious and infectious diseases (including Scrapie, PPR, Bluetongue, anthrax, ovine

9. brucellosis, rabies, etc).
10. Approved meat establishments which supply meat for export to the Islamic Republic of Iran should be approved by IVO representative before start of the slaughtering and situated in the free zone.
11. Kazakhstan state official veterinarians in export slaughterhouse should monitor and observe inspection and production requirements in co-operation with the IVO representative.
12. The sheep must be derived out of regions approved by IVO representative in terms of animal health status.
13. Only animals which the IVO officer has specified and adequately rested shall be presented for ante-mortem inspection.
14. Carcasses sent to the detain rail with major defects cannot be exported to the Islamic Republic of Iran.

B. SPECIFIC CONDITIONS:

1. The meat in this consignment

- Is fit for human consumption.
- Is free of contamination by excrement and blood clots, especially in the neck and intercostals muscles of the ribs.
- With normal odor and normal appearance.

Product	Test	No.of samples (n)	c	m	M
Fresh Chilled Vacuum Packed Ovine Meat	**Total count (CFU/g)**	**5**	**3**	**1×10^5**	**1×10^6**
	Salmonella spp. (CFU/25g)	**5**	**0**	**Negative**	**-**
	E.Coli count (CFU/g)	**5**	**2**	**5×10^1**	**5×10^2**
	Clostridium Botilinum Toxin	**5**	**0**	**0**	**Every & all testes**

- Shows no evidence of pathogenic agents(bacterium, fungus, parasite)

2. The carcasses of the animals from which the meat to be exported to the Islamic Republic of Iran were derived from:
   - Not injured, bruised or physiolocally icteric (yellow) carcasses.
   - Is washed and cleaned completely with fresh water.
   - The meat produced from animal examined by an official veterinary service of country of origin and IVO representative/s before, during and after slaughtering and found to be fit for

   - human consumption and which also controlled during .
   - processing and final handling.
   - The meat must be derived from sheep which have not been treated with hormonal growth promotores before slaughter.
   - The meat must not undergo any preserving process.
   - All approved carcasses should be stamped by IVO representative.
   - The shelf life of vacuumed fresh chilled ovine meat is 30 days after exit carcasses from chilling room pending keeping in 0 to 4 degree Celsius under 85 to 90% humidity.

3. Chilling and cutting conditions:
   - Cutting of the carcasses must be accordance with Iran National Standard No 4276.
   - The temperature of cutting room must be maintained at or below +10 degree Celsius
   - All obvious lymphatic glands and nervous tissues were removed.
   - Carcasses should be kept at chilling room for 24 to 72 hours before going to cutting room. the temperature of chilling room must be between +0 to +4 degree Celsius and the deep bone temperature should be reached to +7 degree, and humidity not less than 85% and PH of the meat should be less than 6.2 after chilling room.
   - The cuts in accordance with Iran National Standard No 4276 should not weighted more than 2 kilogram and found in full compliance with IVO circulars.
4. Packing:
   - Packing and labeling must be carried out in accordance with Iran National Standard No 4275.
   - Different cuts can not be mixed in the same carton.
   - The weight and the specifications of all empty cartons should be the same.
   - Tare weight of each empty carton should not be more than 1000 grams.
   - The cartons should be moisture proof and made from strong tissue material in order to prevent tearing during loading, stowaging and discharging.

- Each cuts must hold a label and The same label identification sheet stating in Farsi and English should be attached on cartons and must indicate the following information :
- The name and place of production(name and address , sanitary code of slaughterhouse), the date of production(date of slaughtering) , the type of cuts , and that the slaughtering has been done as per Islamic rites the labels must be put inside between two polyethylene bags, over each wrapping of the cuts and both end-side of each carton from outside .

- The label contents and format should had been already confirmed by IVO before printing and applying.

5. Transportation:

The transportation vehicle shall be approved by IVO representative. Bearing smooth, non corrosive (resistant against disinfectants) and washable surfaces, thermograph and enabling air circulation between packages is obligatory. Other relevant requirements according to IVO rules and regulations Should be fulfilled and IVO circulars in relation to principles of Cleansing and disinfecting cold store govern this clause.

C. VETERINARY CERTIFICATE

The Kazakhstan veterinary officer will issue, in respect of each consignment of fresh vaccumed ovine carcasses a Veterinary Health certificate for export to the Islamic Republic of Iran produced in compliance with this IHR .The certificate shall be countersigned and sealed by IVO representative too.

The certificate shall attested:

1-The territory described above-mentioned has been free for 12 months from FMD.

2-The territory described above – mentioned has not occurred anthrax for 6 months.

3-The meat described above is obtained from ovine animal:

3-1 Which have remained in the given territory as described under for at least 3 months before being slaughtered.

3-2 Which come from holdings in which there has been no outbreak of FMD in the last 30 days, and around which within a radius of 10 Km there has been no positive case of FMD disease for last 30 days.

3-3 Which have been transported from the holdings of origin to the approved slaughterhouse concerned without contact with animals which do not comply with the conditions required for export of their meat to I.R.Iran , and , if conveyed in a means of transport , that the latter has been cleaned & disinfected before loading .

3-4 Which have passed the ante-mortem health inspection at the slaughterhouse with Iranian official veterinarian(s) during the 24 hours before slaughter and , in particular have shown no evidence of FMD , anthrax & sudden deaths and other contagious diseases at sole discretion of IVO representative.

3-5 Which have not come from a holding which for health reasons is subject to prohibition as a result of an outbreak of ovine or caprine brucellosis during the previous six weeks .

4-The meat is completely salmonella free.
5-The meat is fit for human consumption.
D-SANITARY CONTROLS AT ARRIVAL I.R.IRAN BORDER:
1-All consignments should be in accompany with original Veterinary Health Certificate signed and sealed by competent state authority official countersigned by IVO representative contains all requirements stipulated above mentioned.
2-Upon entry in to ports of Iran, the consignment will be checked and the samples will be test organoleptically, results must fulfill Iran veterinary organization rules, Iran National Standard and EU legislation.
3-The installed thermographs shall be checked and inside information shall be controlled.
4-The Iran Veterinary Organization reserve the right to not issue the clearance from custom for those consignments that found not in compliance of provision of present document.

Iran Veterinary Organization Quarantine and Biosecurity office.

ANNEX 17

Health Requirements for Import cattle intended for Promptly Slaughter into I.R. Iran/September 2017

In accordance with *OIE_Terrestrial Animal Health Code, animal for slaughter means an animal intended for slaughter within a short time, under the control of the relevant veterinary authority. Thus the period between unloading from the vessel up to slaughter time must be at least 7 days.*

1-Public Health Attestation

GENERAL PRINCIPLES

1.1.The origin of animals should be from approved holdings by Competent Veterinary Authority and IVO experts, in accordance with purports of CHAPTERs 4.1.& 4.2 / OIE-Terrestrial Animal Health Code(2017) namely, General principles on identification and traceability of live animals and design and implementation of identification systems to achieve animal traceability ,accordingly animal Identification and registration. **The system for the identification and registration of individual bovine animals includes the following elements**:

- double ear tags for each animal with an individual number
- Maintaining a register on each holding (farm, market, etc.)
- bovine-passports
- a computerized database at national level with a future voluntary interoperability of bovine databases

(EC 911/2004)

1.2. come from holdings which have been free from any official prohibition on health grounds, , for the last 30 days in the case of anthrax, for the last six months in the case of rabies, free from brucellosis and have not been in contact with animals from holdings which did not satisfy these conditions; ;

1.3. Have not received

- Any stilbene or thyrostatic substances,

- oestrogenic, androgenic, gestagenic or ß-agonist substances (particularly ractopamine) for purposes other than therapeutic or zootechnic treatment (as defined in Directive 96/22/EC).

1.4. Have been exported from the country recognized as having a negligible or controlled BSE risk status in accordance with Chapter 11.4. of the Terrestrial Code of OIE:

a) *Were born and continuously reared in a country described in box I.7.*

1.4.1. The *exporting country has an effective and permanent surveillance and monitoring program against BSE within the framework laid down in Regulation (EC) No 999/2001.*

1.4.2. *The animals to be exported are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and this permanent identification system demonstrate that they are not exposed bovine animals as described in Chapter C, part I, point (4) (b) (iv) and part II, point (4) (b) (iv) of Annex II of Regulation (EC) No 999/2001***.**

1.5. *The animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively* ***Health Status of Exporting Country***

1.6. They come from the country or zone with code
1.7. Which, at the date of issuing this certificate:

1.7.1. has been from zones free FMD either with or without vaccination at least 12 months free for Rinderpest, Rift valley fever, contagious bovine Pleuropneumonia, lumpy skin disease and epizootic hemorrhagic disease, and from vesicular stomatitis

1.7.2. B) is free from Bluetongue disease for 24 months according to the Chapter 8.3.3 of Terrestrial Animal Code of OIE.

1.7.3. All the animals should be FMD vaccinated. The serotypes and strains of vaccine will be declared subsequently by IVO to Competent veterinary authority.

1.7.4. at the end of the quarantine and immediately prior to shipment for transport from quarantine to sea port :

a. all animals have been re-examined for the presence of infestation and all animals have been found free of infestation ;

b. All wounds have been prophylactic ally treated with an approved oily larvicide's under the supervision of an official veterinarian.

c. All animals have been prophylactic ally treated again by dappling or spraying.

1.7.5. at the end of the quarantine and immediately prior to shipment for transport from quarantine to sea port :

1.7.6. a. all animals have been re-examined for the presence of infestation and all animals have been found free of infestation ;

1.7.7. b. All wounds have been prophylactic ally treated with an approved oily larvicide's under the supervision of an official veterinarian.

1.7.8. c. All animals have been prophylactically treated again by dappling or spraying within the officially authorized assembly center, under supervision of official veterinarians from Veterinary authority of country of origin and Iranian veterinary authorities coincidently.

They did not come in contact with other cloven-hoofed animals not complying with the health requirements as described in this certificate

.2- *Sanitary measures in export quarantine in Country of Origin*

2.1. First of the entire quarantine establishment must be approved by SIF and subsequently with IVO representative(s)

Immediately prior to entering the quarantine station:

a. each animal has been thoroughly examined for infested wounds, under the direct supervision of an Official Veterinarian, and that no infestation has been found in any animal; and

b. any wounds have been traded prophylactic ally with an officially approved oily larvicide's at he recommended dose; and

c. all animals have been dipped or/and pouring-on or/and sprayed or/and otherwise treated immediately after inspection , with a product officially approved by the importing and exporting countries for the control of new world or old world screwworm , under the supervision of an Official Veterinarian and in conformity with the manufacturer's recommendations;

2.2. Prior to being presented for entry to the quarantine establishment, all bovines for immediate slaughter for export must be individually identified with a 'blue metal' ear tag issued by SIF as official identification. The tag number should be recorded in appropriate export documentation in such a manner that this identification could later be used to trace that animal back to the farm where it originated. In addition to the 'blue metal' tag, other forms of identification tags may be present on the animals such as microchips which could be implanted beneath the cattle skin (hypodermis) in the neck area.

2.3. The duration of quarantine will be at least 14 days.

2.4. The chronological quarantine management should be all-in /all-out manner namely, as early as entry of each consignment the quarantine should be sealed by supervision of Veterinary authority of country of origin and IVO representative for 14 days. Accordingly, no animal should enter quarantine establishment during this period.

2.5. 5% of each consignment should be tested the buffered brucella antigen tests or CF for brucellosis and the results should be negative even for a case (the samples ought to be selected randomly). In zones where RB51 vaccination is practiced, I-ELISA may help in differentiating antibodies due to vaccination from those due to infection, in accordance with chapter 2.1.4 OIE-Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2017.

2.6. The tuberculin test is the standard caudal fold injection with a reading of results at 72 hours as "No Reaction" even for a case, so 5% of each consignment should be tested (the samples ought to be selected randomly).

2.7. The animals for export are free of ectoparasites and have been dipped for ticks within 7 to 12 days of the date before the end of quarantine.

2.8. In the column "**age**", record the actual birth date of each animal the year of birth is sufficient as long as it is not November 2016(maximum two year old) in accordance with dental formulation.

3- *Animal transport attestation*

3.1 *Considering of road transport within* country of origin *from quarantine establishment to marine port and subsequently sea transport from* country of origin *port to Chabahar port in the Iran, the context of chapter 7.3 /OIE_Terrestrial Animal Health Code for transport of animals by land and chapter 7.2 /OIE_Terrestrial Animal Health Code for transport of animals by sea must be strictly regarded.*

3.2. the undersigned official veterinarian, hereby certify, that the animals described above have been treated before and at the time of loading in accordance with the relevant provisions of Regulation (EC) No 1/2005 in particular as regards watering and feeding, and they are fit for the intended transport.

3.3.The animals were protected from Culicoides attacks at all times when transiting through an infected zone for Bluetongue disease (the context of article 8.3.13 of OIE_Terrestrial Animal Health Code 2017 for transport of animals, protecting animals from culicoides attacks, during transportation

3.4.Any transport vehicles or containers from quarantine establishment in which they were loaded were cleaned and disinfected before loading with an officially authorized disinfectant.

3.5They were examined by an Iranian official veterinarian within 24 hours of loading and showed no clinical sign of disease.

3.6. On the day of shipment the animals should show no clinical signs of OIE listed diseases. (Either at end of quarantine period and embarking animals from quarantine pens to sea port and on the day of embarking to ocean cruise particular for transport live cattle which the specifications should be in accordance with *chapter 7.2 /OIE_Terrestrial Animal Health Code for transport of animals by sea.*

3..7 Iran Veterinary Organization (IVO) is entitled to dispatch its own representative(s) to carryout supervision over selection the animals, monitoring of quarantine, control health documents and endorsing them & land loading, ships loading and period sea transportation.

I. R. Iran Veterinary Organization

ANNEX 18

IR2010-3/41-R/5.Health Requirements for Import Fresh Frozen Ovine Meat From KYRGYZSTAN INTO I.R.IRAN(Last Update22/12/2017)

SCOPE

This document serves to detail requirements for the preparation of frozen ovine/mutton meat in Kyrgyzstan for export to the Islamic Republic of Iran. The Veterinary Services of Kyrgyzstan shall be responsible for ensuring that the requirements of the export in relation to the preparation of meat subject to this agreement have been met and for assisting the representative of the Iran Veterinary Organization (IVO) for verifying that the requirements of this agreement have been met.

A. GENERAL REQUIREMENTS:

1. Iran Veterinary Organization (IVO) is entitled to dispatch its own representative to carry out ante-mortem, during slaughter and post-mortem inspection and final handling, including storage and loading.
2. The country of origin is free from FMD (even with vaccination), or the animals has been derived from a free a zone that is free from FMD according to Article 8.5.11. OIE International Terrestrial Animals Health Code(2009).
3. The meat has been derived from healthy male sheep not exceeding 18 months of age.
   - Were born and reared in the country of origin.
   - Came from herds officially registered with the administrative Veterinary of country of Origin.
   - Came from ovine herds in which OIE notifieable disease, not registered during 12 month ago.
   - Were not fattened on foodstuffs which included animal derived proteins (mammalian MBM).
   - Were kept for six months prior to export in an establishment where no case of rabies was reported for at least 12 months prior to slaughter.
4. In the country of origin or zone, surveillance and monitoring system established as referred to Article 14.9 (especially article 14.9.2) OIE international Health Code (2009).
5. The animals have been slaughtered in approved slaughterhouse located in the quarantine area of free zone and found to be healthy before and after slaughter approved by IVO representative/s.
6. The meat was produced under conditions which fully comply with Iran national standard No 4277, European Union standards and Codex alimentarius and SPS agreements.
7. The animals were subjected to ante and post mortem inspection by the official veterinary service
8. of

9. the country of origin and IVO representative/s and were found to be free of clinical signs of any contagious and infectious diseases(Scrapie, PPR, Bluetongue, anthrax,ovine brucellosis,rabies).
10. Establishments which supply meat for export to the Islamic Republic of Iran should be approved by IVO representative before start of the slaughtering and situated in the free zone.
11. Kyrgyzstan state veterinarians in each export slaughterhouse should monitor and observe inspection and production requirements in co-operation with the IVO representative.
12. The sheep must not be derived out of regions approved by IVO representative in terms of animal health.
13. Only animals which the IVO officer has determined and adequately rested shall be presented for ante-mortem inspection.
14. Carcasses sent to the detain rail with major defects cannot be exported to the Islamic Republic of Iran.

B. SPECIFIC CONDITIONS:

1. The meat in this consignment

- Is fit for human consumption.
- Is free of contamination by excrement and blood clots, especially in the neck and intercostals muscles of the ribs.
- With normal odor , without burn freezing
- Shows no evidence of pathogenic agent(bacterium, fungus, parasite)

Product	Test	No. of samples (n)	c	m	M
Fresh/FROZEN OVINE MEAT	Total count (CFU/g)	5	3	1×10^5	1×10^6
	Salmonella spp. (CFU/25g)	5	0	Negative	-
	E.Coli count (CFU/g)	5	2	5×10^1	5×10^2

2. The carcasses of the animals from which the meat to be exported to the Islamic Republic of Iran were derived from;

- Not injured, bruised or physiolocally icteric (yellow) carcasses which;
  - are washed and cleaned completely with fresh water.
  - The meat produced from animal examined by an official veterinary service

- of country of origin and IVO representative/s before, during and after slaughtering and found to be fit for human consumption and which also controlled during processing and final handling.
- must be derived from sheep which have not been treated with hormonal growth promotores before slaughter.
- not undergo any preserving process.

- All carcasses should be stamped by IVO representative.

3. Chilling and cutting conditions:

- Cutting of the carcasses must be accordance with Iran National Standard No 4276.
- The temperature of cutting room must be maintained at or below +10 degree centigrade.
- All obvious lymphatic glands and nervous tissues were removed.
- Carcasses should be kept at chilling room for 24 to 72 hours before going to cutting room. the temperature of chilling room must be between +0 to +4 centigrade degree and the deep bone temperature should be reached to +7 centigrade degree, and humidity not less than 90% and PH of the meat should be less than 6.2 after chilling room.
- The cuts accordance with Iran National Standard No 4276 should not weighted more than 2 kilogram and found in full compliance with IVO circulars.

4. Packing:

- Packing and labeling must be accordance with Iran National Standard No 4275.The color of lables should be as below:
  -Leg (silverside, Rump, Knuckle, Topside): Black
  -Hind Shank: Black
  -Sir loin (short loin): Green
  -Flank/ Flap: Blue
  -Forequarter: Red
  -Fore Shank: Red
  -Breast: Red
  -Neck: Yellow
- Different cuts can not be mixed in the same carton.
- The weight and the specifications of all empty cartons should be the same.
- Tare weight of each empty carton should not be more than 1000 grams.
- The cartons should be moisture proof and made from strong tissue material in order to prevent tearing during loading, stow aging and discharging.
  - Each cuts must hold a label and The same label identification sheet stating in

- Farsi and English should be attached on cartons and must indicate the following information :
- The name and place of production(name and address , sanitary code of slaughterhouse), the date of production(date of slaughtering) , the type of cuts , and that the slaughtering has been done as per Islamic rites the labels must be put inside between two polyethylene bags, over each wrapping of the cuts and both end-side of each carton from outside .
- . The label or paper identification sheet contents and format should already confirmed by IVO.

5. **FREEZING AND STORAGE:**

- All products should be frozen in freezing tunnel with minus 35 to 45 degree centigrade within 24 to 48 hours; the temperature of meat in deepest part after freezing should be -18 degree C, at the time of going to the cold store.
- The meat shall be kept in cold storage with not warmer than minus 18 degrees C. The meat should be transferred to the final loading point with temperature of -18C.
- The maximum duration from slaughter to export shipment shall not be more than 60 days. If not so, the IVO's representative/s should give a special authorization for embarkation.

6. Transportation:

The conveyances used to transport meat entered for export to the Islamic Republic of Iran are fitted with intended refrigeration equipment and recording thermographs.

C. VETERINARY CERTIFICATE

The Kyrgyzstan veterinary officer will issue, in respect of each consignment of frozen ovine carcasses a Veterinary Health certificate for export to the Islamic Republic of Iran produced in compliance with this agreement .The certificate shall be countersigned by IVO representative too.

Health attestations in the certificate will be endorsed:

1-The territory described above has been free for 12 months from FMD.

2-The territory described above has been free for 6 months from anthrax.

3-The meat described above is obtained from ovine animal:

3-1 Which have remained in the territory as described under for at least 3 months before being slaughtered.

3-2 Which come from holdings in which there has been no outbreak of FMD in the

previous 30 days, and around which within a radius of 10 Km there has been no case of FMD disease for last 30 days.

3-3 Which have been transported from the holdings of origin to the approved slaughterhouse concerned without contact with animals which do not comply with the conditions required for export of their meat to I.R.Iran , and , if conveyed in a means of transport , that the latter has been cleaned & disinfected before loading .

3-4 Which have passed the ant-mortem health inspection at the slaughterhouse with Iranian official veterinarian(s) during the 24 hours before slaughter and , in particular have shown no evidence of FMD , anthrax & sudden deaths and other contagious diseases at sole discretion of IVO representative.

3-5 Which have not come from a holding which for health reasons is subject to prohibition as a result of an outbreak of ovine or caprine brucellosis during the previous six weeks .

4-The meat is completely salmonella free.

5-The meat is fit for human consumption.

D-SANITARY CONTROLS AT ARRIVAL I.R.IRAN BORDER:

1-All consignments should be in accompany with original Veterinary Health Certificate signed and sealed by competent state authority official countersigned by IVO representative contains all requirements stipulated above mentioned.

2-Upon entry in to ports of Iran, the consignment will be checked and the samples will be test organoleptically, microbiologically and chemically and results must fulfill Iran veterinary organization rules, Iran National Standard and EU legislation.

3-The installed thermographs shall be checked and inside information shall be controlled.

4-The Iran Veterinary Organization reserve the right to not issue the clearance from custom for those consignments that found not in compliance of provision of present document.

Iran Veterinary Organization Quarantine and Biosecurity office.

ANNEX 19

VETERINARY CERTIFICATE FOR DOMESTIC BOVINE ANIMALS INTENDED FOR SLAUGHTER FROM ..... TO ..... TRANSIT THROUGH THE ISLAMIC REPUBLIC OF IRAN/ARMENIA

ВЕТЕРИНАРНЫЙ СЕРТИФИКАТ ДЛЯ ДОМАШНЕГО КРУПНОГО РОГАТОГО СКОТА ПРЕДНАЗНАЧЕННЫХ ДЛЯ УБОЯ ИЗ ..... В ..... ДЛЯ ТРАНЗИТА ЧЕРЕЗ ИСЛАМСКУЮ РЕСПУБЛИКУ ИРАН / АРМЕНИЯ

Part I: Details of dispatched consignment / Часть I: Информация об отправленном грузе

1.1. Central Competent Athority: Центральный компетентный орган:		1.2. Certificate reference number: Регистрационный номер сертификата	
1.3. Local Competent Authority: Местный компетентный орган:		1.5. Consignee : Грузополучатель Name/Имя: Address/Адрес: Tel.No./Тел.:	
1.4. Consignor: Грузоотправитель Name/Имя: Address/Адрес: Tel.No./Тел.:			
1.6. Country of origin/ Страна происхождения: ISO Code/Код ISO:	1.7. Region of origin/ Регион происхождения: Code/Код:	1.8. Country of destination/Страна назначения: ISO code/Код ISO:	1.9. Region of destination/Регион назначения: Code/Код:
1.10. Place of origin/ Место происхождения:			
Name/ Имя: Name/ Имя: Name/ Имя:	Approval number/Номер разрешения: Approval number/Номер разрешения: Approval number/Номер разрешения:	Address/Адрес: Address/ Адрес: Address/Адрес:	
1.11. Place of loading /Место погрузки: Address /Адрес: Approval number/Номер разрешения:		1.12. Date of departure / Дата отправления: Time of departure /Время отправления:	
1.13. Means of transport / Транспортное средство: Aeroplane/Самолет: ☐ Ship/ Судно: ☐ Railway wago / Ж/Д вагон: ☐ Road vehicle / Дорожное транспортное средство : ☐ Other /Другое : ☐ Identification / Идентификация: ☐ Documentary references / Ссылки на документы:		1.14. Entry point in/Пункт въезда..... : 1.15. Commodity code (HS code)): Код товара (Код HS): 1.16. Quantity/Количество:	

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1.17. Description of commodity/Описание товара:

1.18. Commodities certified for / Товары сертифицированы для:

Slaughter/ Убой ☒

1.19. For Transit through / Для транзита через .....

1.20. Identification of the commodities/
Идентификация товаров:

Species (Scientific name) Виды (Научное название)	Breed / Порода	Identification system/ Система Идентификации	Identification number/ Идентификационный номер	Age/ Возраст	Sex/ Пол

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...lic Health Attestation/ Официальное свидетельство о здоровье:

Part II: Certification

I, the undersigned official veterinarian, hereby certify, that the animals described in this certificate / Я, нижеподписавшийся государственный ветеринар, настоящим подтверждаю, что животные, описанные в этом сертификате:

1. The animals shall be quarantined for 21 days in the country of origin under supervision of official veterinarian in the country of origin/ 1. Животные должны быть помещены в карантин на 21 день в стране происхождения под наблюдением государственного ветеринарна в стране происхождения.
2. A competent veterinarian and custom officer shall accompany consignment in order to prevent any change of animals/ Государственный ветеринар и таможенный служащий должны сопровождать груз для предотвращения любой смены животных.
3. The animals and accompained documents are checked at BIP / Животные и сопроводительные документы проверены в ПКП.

II.1.1 The animals come from holdings which have been free from any official prohibiton on health grounds, for the last 42 days in the case of brucellosis, for the last 30 days in the case of anthrax, for the last six months in the case of rabies, and have not been in contact with animals from holdings which did not satisfy these conditions/Животные прибыли из хозяйств, которые были свободны от каких-либо официальных ограничений/запретов по состоянию здоровья, в течение последних 42 дней от бруцеллеза, в течение последних 30 дней от сибирской язвы, в течение последних шести месяцев от бешенства, и не были в контакте с животными из хозяйств, которые не удовлетворяют этим условиям;

II.1.2 have not received/ они не получили

- any stilbene or thyrostatic substances / какие-либо стильбен или тиреостатические вещества
- oestrogenic, androgenic, gestagenic or B-ngonist substances for purposes other than therapeutic or zootechnic treatment (as defined in Directive 96/22/EC)/ эстрогенные, андрогенные, гестагенные или бета-агонистические вещества для нетерапевтических целей или зоотехнического лечения (как определено в Директиве 96/22 / ЕС)

II.1.3. have been exported from the country recognized as having a negligible or controlled BSE risk status in accordance with Chapter 11.4. of the Terrestrial Code of OIE/ Они были экспортированы из страны, имеющей незначительный или контролируемый статус риска губкообразной энцефалопатии крупного рогатого скота(ГЭКРС) в соответствии с главой 11.4. кодекс здоровья наземных животных МЭБ;

and/ ... were born and continuously reared in a country described in box I.6 / и / а) родились и постоянно выращены в стране, описанной в разделе I.6

II.1.4. The exporting country has an effective and permanent surveillance and monitoring programme against BSE within the framework laid down in Regulation (EC) No 999/2001 / Страна-экспортер имеет эффективную и постоянную программу наблюдения и мониторинга за губкообразной энцефалопатии крупного рогатого скота(ГЭКРС) в рамках, установленных в Регламенте (ЕС) № 999/2001.

II.1.5. The animals to be exported are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and this permanent identification system demonstrate that they are not exposed bovine animals as described in Chapter C, part I, point(4) (b) (iv) and part II, point (4)(b)(iv) of Annex II of Regulation (EC) No 999/2001 / Экспортируемые животные идентифицируются с помощью постоянной системы идентификации, позволяющей отследить их обратно до преграды и стады происхождения, и эта постоянная система идентификации демонстрирует, что они не подвергаются воздействию крупного рогатого скота, как описано в главе C, часть I, пункт (4) (b) (iv) и часть II, пункт (4) (b) (iv) Приложения II к Регламенту (ЕС) № 999/2001;

II.1.6. The animals were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced / Животные родились после того, как был введен запрет на кормление жвачных животных мясокостной мукой и кормами, полученными из жвачных животных.

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II.2 *Health Status of Exporting Country / Эпизоотическое ситуация экспортирующей страны:*

a) has been free for 24 months from foot-and-mouth,disease for 12 months from rinderpest, rift valley fever, contagious bovine pleuropneumonia, lumpy skin disease and epizootic haemorrhagic disease, and for 6 months from vesicular stomatitis and / а) был свободен в течение 24 месяцев от ящура, болезни в течение 12 месяцев от чумы крупного рогатого скота, Лихорадка Рифт-Валли контагиозной плевропневмонии крупного рогатого скота, узелковый дерматит КРС и эпизоотической геморрагической болезни, и в течение 6 месяцев от везикулярного стоматита и

b) .....(country/ region)(2) is free from Bluetongue disease for 24 months according to the Chapter 8.3.3 of Terrestrial Animal Code of OIE/ ..... / б) ..... (страна / регион) (2) в течение 24 месяцев свободна от болезни Блютонга в соответствии с главой 8.3.3 кодекс здоровья наземных животных МЭБ /

II.2.2. *Each animal to be exported has been born and raised in the territory described under point II.2.1. since birth and without contact with imported cloven-hoofed animals for the last 30 days/ Каждое экспортируемое животное было рождено и выращено на территории, описанной в пункте II.2.1. с рождения и без контакта с импортными парнокопытными в течение последних 30 дней;*

II.2.3. They have remained since birth or at least 60 days before dispatch in the vector-protected holding(s) described under box reference I.10; there has been no case / outbreak of the diseases referred to in point III.1.(a) and(b) within this period / Они оставались с рождения или, по крайней мере, за 60 дней до отправки в защищенном от векторов холдинге (ах), описанном в графе I.10; в течение этого периода не было ни одного случая / вспышки заболеваний, упомянутых в пункте III.1. (a) и (b);

II.2.4. *They are not animals to be killed under a national programme for the eradication of disease nor have they been vaccinated against the diseases referred to in point II.2.1(a)/ II.2.4. Они не являются животными, подлежащими убою в рамках национальной программы по искоренению болезней, и не были вакцинированы против болезней, указанных в пункте II.2.1 (a);*

II.2.5. *They come from herds / Они приходят из стады*

a. *included in an official system for the control of enzootic bovine leukosis and/ (a) включены в официальную систему контроля энзоотического лейкоза крупного рогатого скота и*
b. *they are not restricted under the national legislation regarding eradication of tuberculosis and brucellosis, and / (б) они не ограничены национальным законодательством в отношении борьбы с туберкулезом и бруцеллезом, и*
c. *recognised as officially tuberculosis free (3), / (c) признан официально свободным от туберкулеза*

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II.2.6. They have not been vaccinated against brucellosis and they
(2) either / (2) ya [come from herds which are recognised as officially brucellosis free:] (3)
(2) or / (2) ya da [are castrated males of any age:]
Они не были вакцинированы против бруцеллеза, и они
(2) либо / (2) ya [происходят из стад, которые официально признаны свободными от бруцеллеза:] (3)
(2) или / (2) я да [кастрированные самцов любого возраста:

II.2.7. Each animal which was selected to transit through Armenia/Iran has been marked individually.(4) /Каждое животное, которое было отобрано для транзита через Армению / Иран, было маркировано индивидуально.

II.2.8. They are / were(2) dispatched from their holding(s) of origin, without passing through any market (2)/Они были (2) отправлены из своего (их) холдинга (ов) происхождения, без прохождения через какой-либо рынок (2)

(a) They did not come in contact with other cloven-hoofed animals not complying with the health requirements as described in this certificate and / (a) они не вступали в контакт с другими парнокопытными животными, не отвечающими требованиям здоровья, как описано в этом сертификате, и

(b) They were not any place where, or around which within 30 km radius, during 40 days prior to dispatch there has been a case / outbreak of any of the diseases referred to in point II.2.1.; / они не находились в каком-либо месте, где или вокруг которого в радиусе 30 км, в течение 40 дней до отправки имел место случай / вспышка любого из заболеваний, указанных в пункте II.2.1 .;

II.2.9. Any transport vehicles or containers in wich they were loaded were cleaned and disinfected before loading with an officially authorised disinfectant/ Все транспортные средства или контейнеры, в которые они были загружены, были очищены и продезинфицированы перед загрузкой официально разрешенным дезинфицирующим средством;

II.2.10. They were examined by an official veterinarian within 24 hours of loading and showed no clinical sign of disease/Они были осмотрены официальным ветеринарным врачам в течение 24 часов после загрузки и не показали никаких клинических признаков заболевания,

II.2.11. They have been loaded for transit through Armenia/Iran on .... (dd/mm/yyyy) in the means of transport described under box reference
I.13. above that were cleaned and disinfected before loading with an officially authorised disinfectant and so constructed that faeces, urine, litter, or fodder could not flow or fall out of the vehicle or container during transportation.
Они были загружены для транзита через Армению / Иран на .... (дд / мм / гггг) в транспортных средствах описано под графом I.13. выше, которые были очищены и продезинфицированы перед загрузкой официально разрешенным дезинфицирующим средством и сконструированы таким образом, чтобы фекалии, моча, мусор или корм не могли стекать или выпадать из транспортного средства или контейнера во время транспортировки.

II.3. Animal transport attestation/ Информация о транспорта животных:

I, the undersigned official veterinarian, hereby certify, that the animals described above have been treated before and at the time of loading in accordance with the relevant provisions of Regulation (EC) No 1/2005 in particular as regards watering and feeding, and they are fit for the intended transport./Я, нижеподписавшийся государственный ветеринар, настоящим подтверждаю, что животные, описанные выше, были обработаны до и во время погрузки в соответствии с соответствующими положениями Регламента (ЕС) № 1/2005, в частности, что касается поения и кормления, и что они пригодны для предполагаемого транспорта.

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Part I.:
Box reference I.6.: provide the ISO code of the exporting country
Box reference I.11.: the assembly centre, if any, must fulfil the conditions for its approval, as laid down in Part 5 of Annex 1 to Regulation (EU) No 206/2010 (SANCO/4787/2009)
Box reference I.13.: registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) is to be provided. In case of unloading and reloading, the consignor must inform the entry point into Iran/Armenia.
Box reference I.20.: identification system: the animals must bear:
an individual number which permits tracing of their premises of origin. Specify the identification system (such as tag, tattoos,

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brand, chip, transponder.)
an eartag that includes the ISO of the exporting country. The individual number must permit tracing of their premises of ori
Box reference I.20.: Age: Date of birth (dd/mm/yyyy)
Box reference I.20: Sex (M=male, F=female, C=castrated)

Часть I:
- Графа I.6 .: укажите код ISO страны-экспортера.
- Графа I.11 .: центр сбора животных, если таковой предусмотрен, должен соответствовать условиям для его утверждения, изложенным в части 5 Приложения 1 к Регламенту (ЕС) № 206/2010 (SANCO / 4787/2009)
- Графа I.13 .: необходимо указать регистрационный номер (железнодорожные вагоны или контейнеры и грузовики), номер рейса (воздушное судно) или название (судно). В случае разгрузки и перегрузки грузоотправитель должен проинформировать пункт въезда в Иран / Армению.
- Графа I.20 .: Идентификационная система: У животных должны быть:
- индивидуальный номер, который позволяет отследить хозяйство происхождения. Указать систему идентификации (например, бурка, татуировки, клеймо, чип, транспондер)
- ушная бирка с указанием ISO кода страны экспортера. Индивидуальный номер должен позволять отслеживать отследить хозяйство происхождения.
- Графа I.20 .: Возраст: Дата рождения (дд / мм / гггг)
- Графа I.20: Пол (M = мужской, F = женский, C = кастрированный)

Part II/ Часть II

(1) Insert the ISO code of the country/ (1) Указать код ISO страны.

(2) Delete as appropriate/ (2) Ненужное вычеркнуть.

(3) Officially tuberculosis, brucellosis free regions and herds as laid down in Annex A to Directive 64/432/EEC/ (3) Официально регионы и стада, свободные от туберкулеза, бруцеллеза, как указано в Приложении А к Директиве 64/432 / ЕЕС

(4) Such as tattoo, ear-tag etc./ (4) такие как татуировка, ушная бирка и т. д.

(5) The color of the seal and the signature must be different from the color of printing of the certificate/ (5) Цвет печати и подписи должен отличаться от цвета печати сертификата.

Official veterinarian / Официальный ветеринар

Name (in capital letters)/ Имя (заглавными буквами): Qualification and title/ Квалификация и заголовок

Signature (5) / Подпись

Stamp(5)/ Штамп

Date: / Дата:

Dr Ebrahim Molayemi Certified English Translator to The Judiciary of Iran Licensed

فتوکپی برابر اصل است
CERTIFY TO BE A TRUE COPY OF ORIGINAL

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Certified to be a true and correct copy of the original and agrees therewith in every respect.

12 DEC 2019