Human Embryo

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[Training Material for Departmental Use]





Import

Human Embryo

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Note:

- 1. In this E-book, attempts have been made to explain *Compulsory Compliance Requirement for Import of Human Embryo*. It is expected that it will help departmental officers in their day to day work.
- 2. Though all efforts have been made to make this document error free, but it is possible that some errors might have crept into the document. If you notice any errors, the same may be brought to the notice to the NACEN, RTI, Kanpur on the Email address: rtinacenkanpur@yahoo.co.in. This may not be a perfect E-book. If you have any suggestion to improve this book, you are requested to forward the same to us.
- 3. If any officer is interested in preparing E-book on any topic relating to Customs, Central Excise or Service Tax, he may forward the E-book prepared by him to the Email addresses mentioned above. After necessary vetting, we will include the same in our E-book library for benefit of all Departmental officers.
- 4. The matter in this e-Book is based on variety of sources. The purpose of this e-Book is primarily education and training. It is not our intention to infringe any copyrights. However, if anybody has any issue with regard to any of the material used in this e-Book, the same may kindly be brought to my notice on the email address mentioned above.
- 5. If you feel that this e-book has really helped you in improving your knowledge or understanding of the subject matter, we request you to take few minutes out of your precious time and provide us your valuable feedback. Your feedback is important and will help us in improving our e-books.

Sd/-

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Compulsory Compliance Requirement for Import of Human Embryo

1. Introduction

- **1.1** Customs officers at border are required to implement or enforce provisions of several statutes passed by the Government of India. While they deal with import/export clearance of various commodities in their day to day work, the NACEN, Kanpur has attempted to prepare commodity-wise e-book laying down commodity specific compulsory compliance requirements (CCRs) to be enforced by the Customs Officers at the time of import and export. The e-book are aimed at enabling Customs officers to have all relevant legal provisions applicable to the commodity in question at one place so that they could enforce the relevant legal provisions without getting into research mode or to clear such goods out of sheer ignorance or lack of adequate knowledge.
- **1.2** It is expected that the commodity specific e-books will assist Customs officers in keeping pace with dynamic legal environment in our country and to effectively enforce relevant legal provisions at Border.
- **1.3** With increase in advancement in medical field, at times, Human embryos are increasing being imported into/exported out of India for infertility treatment or surrogacy. The Human Embryos are normally imported by Surrogacy Clinics/ART Clinics/ IVF Clinics /any Centre/Genetic Counseling Centers/other clinical establishment offering surrogacy services/Assisted Reproduction Services.

Classification of Human Embryo under Customs Tariff Act, 1975

1.4 Vide Circular No. 01/2014-Customs, dated 09.01.2014, the issue of classification under the Indian Tariff Act, 1975 was settled by the Central Board of Excise. The issue was examined by CBEC in consultation with Indian Council of Medical Research (ICMR) and it has been clarified that 'Human Embryo' is placed under the category of animal embryos and accordingly, 'human embryo' to be classified under CTH 0511 9999

Import Policy for import of Human Embryo under ITC (HS)

- 1.5 The Directorate General of Foreign Trade vide notification No. 52(RE-2013)/2009-2014 dated 2nd December, 2013 finalized Import Policy Norms for import of 'Human Embryos' and had put it into restricted category and the import was to be allowed subject to a NOC from ICMR.
- 1.6 The import policies for import of Human Embryo has been revised by the Directorate General of Foreign Trade vide notification number No. 25/2015-2020, dated 26.10.2015. Now, Import of Human Embryo has been put into "prohibited" category except for research purposes based on the guidelines of the Department of Health Research.

1.7 The important points to be kept in mind by the Customs Officer while dealing with import of Human Embryo:

ITC (HS): Prohibited except for research purposes based on the guidelines of the Department of Health Research HS Classification: 0511 9999

2. Guidelines for Import of Human Embryo [to be issued by the Department of Health Research]

- 2.1 The guidelines of Department of Health Research for import of human Embryo for research purpose are in the process of development and are likely to be issued shortly. However, the Department of Health Research has come out with the Instruction No. V.25011/119/2015-HR, dated 04.12.2015 on the issue of "commissioning of surrogacy" which *inter alia*, also explains the Government Policy towards import of Human Embryo.
- 2.2 This instruction may be downloaded from the website of the Department of Health Research under the following link:-

http://www.dhr.gov.in/latest%20Govt.%20instructions%20on%20ART %20Surrogacy%20Bill.pdf

3. Summary of Legal Provisions at a Glance

Important legal provisions relating to import of Human Embryo are summarized in the Table I below.

Table-1

Sr. No.	Notification/Circular/Instruction	Subject			
1.	CBEC Circular No. 01/2014-Customs, dated	HS Classification of			
	09.01.2014 Human Embryo				
2.	DGFT Notification No.25/2015-2020, dated26.10.	Policy for import of			
	2015	Human Embryo			
3.	Instruction No. V.25011/119/2015-HR, dated	Instruction regarding			
	04.11.2015 issued by Department of Health Research	Commissioning of			
	in the Ministry of Health and Family Welfare. Surrogacy.				

4. Text of relevant notifications/Circulars/Instructions

4.1 CBEC Circular No. 01/2014-Customs, dated 09.01.2014

Subject:- Classification of Human Embryo - regarding.

References have been received on issue of classification and importation of the 'Human Embryo' frozen in liquid nitrogen under the Customs Tariff Act, 1975. Doubts have been raised whether 'human embryo' is classifiable under heading 0511 or 3001.

- 2. The matter has been examined by the Board in consultation with Indian Council of Medical Research (ICMR). ICMR have clarified that **'Human Embryo'** is placed under the category of animal embryos. Accordingly 'human embryo' will be classified under CTH 0511 9999.
- 3. Import Policy Norms finalized by DGFT for 'Human Embryos' vide notification No. 52(RE-2013)/2009-2014 dated 2nd December, 2013 as **restricted** and the import will be allowed subject to a NOC from ICMR.
- 4. Pending cases may be finalized accordingly. Difficulty faced if any may be brought to the notice of the Board.

P.S: It may be noted that the DGFT notification No. 52 (RE-2013)/2009-2014, dated 02.12.2013, as mentioned in paragraph 3 above, is no longer relevant now in the light of new DGFT notification No. 25/2015-2020, dated 26.10.2015.

4.2 DGFT Notification No.25/2015-2020, dated 26.10.2015

Subject: Amendment in import policy of Human Embryo classified under Exim Code 0511 9999 of Chapter 05 of ITC (HS), 2012 – Schedule – 1 (Import Policy).

S.O. (E): In exercise of powers conferred by Section 3 of FT (D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby amends the import policy of 'Human Embryo' classified under Exim Code 0511 99 99 of Chapter 05 of ITC (HS), 2012 – Schedule – 1 (Import Policy).

2. Import policy of the item 'Human Embryo' classified under EXIM Code 0511 99 99 in Chapter 05 of ITC (HS), 2012 Schedule I (Import Policy) is revised from "free" subject to a 'No Objection Certificate' from Indian Council of Medical Research (ICMR)" to "Prohibited' except for research purposes based on the guidelines of the Department of Health Research. After revision, the import policy is as under:-

Human Embryo

Exim Code	Item Description	Policy Existing	Policy Conditions Revised Policy Condition
0511	Other	Free	Import of Human <mark>Import of Human</mark>
99 99			Embryo will be free Embryo is "Prohibited"
			subject to a 'No <mark>except for research</mark>
			Objection Certificate' purposes based on the
			from Indian Council of guidelines of the
			Medical Research Department of Health
			(ICMR) Research.

3. Effect of this Notification:

Import policy of the item 'Human Embryo' classified under EXIM Code 0511 99 99 has been changed from "free" subject to a 'No Objection Certificate' from Indian Council of Medical Research (ICMR)" to "Prohibited' except for research purposes based on the guidelines of the Department of Health Research.

5. Relevant Websites for reference and further research

- Website of Central Board of Excise and Customs (www.cbec.gov.in) for downloading the text of statutes, rules, notification and Circulars/instructions relating to Customs, Central Excise and Service tax.
- Website of Department of Health Research (<u>www.dhr.gov.in</u>)for downloading latest guidelines for import of Human Embryo.
- (iii) Website of Directorate General of Foreign Trade(www.dgft.gov.in) for obtaining latest information about Government Policy regarding import and export of various commodities.
- (iv) Website of NACEN, RTI, Kanpur (<u>www.nacenkanpur.gov.in</u>) for downloading free learning resources in the form of E-books on various topics of Customs, Central Excise and Service Tax.
