

No license needed to import & export biological samples from Aug 4, 2016

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Biotech companies, CROs, research centers and other can relax now. The government has allowed hassle-free import and export of various biological samples by removing the mandatory requirement of an export/import license for these samples.

This great step was notified by the Director General of Foreign Trade (DGFT) by Notification number 19/2015-2020 by DGFT director general, Mr Anup Wadhawan on 4th August 2016.

An ABLE team, led by Honorary Chairperson, Dr Kiran Mazumdar-Shaw, had worked tirelessly for the past three months with various government agencies to get these restrictions removed. Prior to this, companies, particularly those in the contract research sector, were forced to go through a licensing process that took almost 4-5 months of paper work to get or send out every human biological samples for research or commercial purposes.

Every such sample handling had to be authorized by the Indian Council of Medical Research (ICMR). The ICMR committee that approves such samples handling meets once in three months and hence the process used to take 4-5 months to get approval for each imported/exported sample, causing immense delays to CRO companies. This was because, there was strict deadlines of 3rd January, 20th April, 31st July and 31st October to submit applications to the ICMR committee prior to each meeting. And no mid-term applications were entertained.

With the new notification, amending the existing rules that made it mandatory to get import/export license, an organization has to only give a self-certification to the customs authority that they are /will follow all the applicable rules, regulations and procedures for safe transfer and disposal of the biological samples.

According to the DGFT notification, customs authorities at all exit and entry points have been informed about the revised guidelines related to the handling of biological samples. Appropriate changes in the relevant software on the Customs networks.

"The import of human biological samples by the Indian diagnostic laboratories/Indian Clinical Research Centers for lab analysis/ R&D testing or export of these material to foreign laboratories should be permitted by customs authorities at the port of entry/exit without prior approvals (Import license/export permit) from any other government agency, provided the concerned Indian company/agency submits an undertaking that they are following and will follow all the applicable rules, regulations and procedures for safe transfer and disposal of the biological samples being imported/exported as per the related norms/regulations set by WHO/DFT/SCOMET items in Export Policy of ITC (HS), 2012 schedule2 (export policy)/Ministry of Environment , Forests and Climate Change, Government of India, to the Customs authorities at the port of entry/exit along with details of such samples," says the DGFT notification.

Source: ABLE