

MINISTRY OF ENVIRONMENT AND FORESTS

NOTIFICATION

New Delhi, the 20th September, 2006

G.S.R. 616(E).— Whereas the Ministry of Environment and Forests has notified the rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms / Genetically Engineered Organisms or Cells, Rules 1989 hereinafter referred to as Rules vide No. GSR 1037 (E) dated 5th December 1989, --

And whereas rule 20 of the rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms / Genetically Engineered Organisms or Cells, Rules 1989 empowers the Ministry of Environment and Forests to exempt an occupier handling a particular microorganism/genetically engineered organism from the application of the provisions of Rules 7 to 11 (both inclusive).

Now, therefore, in pursuance of rule 20 of the rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms / Genetically Engineered Organisms or Cells, Rules 1989, the Central Government hereby considers it necessary that the manufacturer and/or importer of recombinant pharmaceuticals falling in the following categories may be exempted from the provisions of rules 7 to 10 (both inclusive) of the above said Rules with effect from the date of publication of this notification in the official gazette.

- (a) Indigenous product development, manufacture and marketing of pharmaceutical products derived from organisms falling under Risk Group I and Group II as specified in the Recombinant DNA Safety Guidelines, 1990.
- (b) Import and marketing of products derived from Living Modified Organisms (*LMOs*) as Drugs and Pharmaceuticals in bulk and/or finished formulations where the end product being imported is not a Living Modified Organisms.

[F. No. 12/7/2004-CS]

DESH DEEPAK VERMA, Jt. Secy.

Note:— the principal rules were published in the Gazette of India vide number GSR 1037 (E) dated 5.12.1989, which came into force vide notification SO 677 (E) DATED 13TH September 1993 and amended vide notification GSR 493 (E) Dated 14th July 2005.