Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

PART A

GENERAL PROVISIONS

Article 2

Definitions

For the purposes of this Directive:

(1) 'organism' means any biological entity capable of replication or of transferring genetic material;

(2) 'genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

Within the terms of this definition:

(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;

(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification;

(3) 'deliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment;

(4) 'placing on the market' means making available to third parties, whether in return for payment or free of charge;

The following operations shall not be regarded as placing on the market:

— making available genetically modified microorganisms for activities regulated under Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms[(1)] including culture collections,

— making available GMOs other than microorganisms referred to in the first indent, to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment, the measures should be based on the same principles of containment as laid down in Directive 90/219/EEC,

— making available GMOs to be used exclusively for deliberate releases complying with the requirements laid down in part B of this Directive;

(5) 'notification'	means the submission of the information required under this Directive to the competent authority of a Member State;
(6) 'notifier'	means the person submitting the notification;
(7) 'product'	means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market;
(8) 'environmental risk assessment'	means the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Annex II.

(**1**) OJ L 117, 8.5.1990, p. 1. Directive as amended by Directive 98/81/EC (OJ L 330 5.12.1998, p. 13).