Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

SCHEDULE 2

CRITERIA FOR THE CLASSIFICATION OF ORGANISMS

PART I

Criteria as applicable for classification of micro-organisms in Group I

Recipient or parental organism

- (a) (a) non-pathogenic;
- (b) no adventitious agents;
- (c) proven and extended history of safe use or built-in biological barriers, which, without interfering with optimal growth in the reactor or fermenter, confer limited survivability and replicability, without adverse consequences in the environment.

Vectors/Insert

- (a) (a) well characterised and free from known harmful sequences;
- (b) limited in size as much as possible to the genetic sequences required to perform the intended function;
- (c) should not increase the stability of the construct in the environment (unless that is a requirement of intended function);
- (d) should be poorly mobilisable;
- (e) should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drugs to control disease agents).

Genetically modified micro-organisms

- (a) (a) non-pathogenic;
- (b) as safe in the reactor or fermenter as recipient or parental organism, but with limited survivability and/or replicability without adverse consequences in the environment.

Other genetically modified micro-organisms that could be included in Group I if they meet the conditions in paragraph 3

- (a) those constructed entirely from a single prokaryotic recipient (including its indigenous plasmids and viruses) or from a single eukaryotic recipient (including its chloroplasts, mitochondria, plasmids, but excluding viruses);
- (b) those that consist entirely of genetic sequences from different species that exchange these sequences by known physiological processes.