

## ANNEX II

### PART B

#### **Criteria establishing the safety of GMMs for human health and the environment**

#### **3. Specific criteria**

##### **3.1. Non-pathogenic**

The GMM should not be capable of causing disease or harm to a healthy human, plant or animal. Since pathogenicity includes both toxigenicity and allergenicity, the GMM should therefore be:

##### **3.1.1. Non-toxicogenic**

The GMM should not produce increased toxigenicity as a result of the genetic modification nor be noted for its toxigenic properties.

##### **3.1.2. Non-allergenic**

The GMM should not produce increased allergenicity as a result of the genetic modification nor be a noted allergen, having, for example, allergenicity comparable in particular with that of the micro-organisms identified in Directive 2000/54/EC.

##### **3.2. No harmful adventitious agents**

The GMM should not harbour known harmful adventitious agents such as other micro-organisms, active or latent, existing alongside or inside the GMM, that could cause harm to human health and the environment.

##### **3.3. Transfer of genetic material**

The modified genetic material must not give rise to harm if transferred; nor should it be self-transmissible or transferable at a frequency greater than other genes of the recipient or parental micro-organism.

##### **3.4. Safety for the environment in the event of a significant and unintended release**

GMMs must not produce adverse effects on the environment, immediate or delayed, should any incident involving a significant and unintended release occur.

GMMs that do not meet the above criteria may not be included in Part C.