

# **TECHNICAL DOCUMENTATION**

## **1. INTRODUCTION**

**2. A COPY OF THE WRITTEN CONSENT OR CONSENTS OF THE COMPETENT AUTHORITIES TO THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF THE GENETICALLY MODIFIED ORGANISMS FOR RESEARCH AND DEVELOPMENT PURPOSES WHERE PROVIDED FOR BY PART B OF DIRECTIVE 2001/18/EC**

**3. THE COMPLETE TECHNICAL DOSSIER SUPPLYING THE INFORMATION REQUESTED IN ANNEX IIA OF DIRECTIVE 2001/18/EC, INCLUDING THE RESULTS OF INVESTIGATIONS PERFORMED FOR THE PURPOSES OF RESEARCH AND DEVELOPMENT**

### **I. General Information**

A. Name and address of the notifier

### **II. Information Relating to the GMO**

A. Characteristic of the recipient or (where appropriate) parental organism

B. Characteristics of the vectors

C. Characteristics of the modified organism

### **III. Information Relating to the Conditions of Release and the Receiving Environment**

A. Information on the release

### **IV. Information Relating to the Interaction between the GMOs and the Environment**

A. Characteristics affecting survival, multiplication and dissemination

B. Interactions with the environment

### **V. Information on Monitoring, Control, Waste Treatment and Emergency Response Plans**

A. Monitoring techniques

B. Control of the release

C. Waste treatment

D. Emergency response plans

#### **4. THE COMPLETE TECHNICAL DOSSIER SUPPLYING THE INFORMATION REQUESTED IN ANNEX III OF DIRECTIVE 2001/18/EC, INCLUDING THE RESULTS OF ANY INVESTIGATIONS PERFORMED FOR THE PURPOSES OF RESEARCH AND DEVELOPMENT**

##### **A. The Following Information Shall Be Provided**

1. Name of the product and names of the GMOs contained therein
2. Name of the manufacturer or distributor and his address in the community
3. Specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited
4. Type of expected use: industry, skilled trades, consumer use by public at large etc

##### **B. The Following Information Shall Be Provided Where Relevant**

1. Measures to take in case of unintended release or misuse
2. Specific instructions or recommendations for storage and handling
3. Estimated production in and/or imports to the Community
4. Proposed packaging.
5. Proposed labelling.

#### **5. THE ENVIRONMENTAL RISK ASSESSMENT RESULTING FROM THE INFORMATION PROVIDED UNDER POINTS III.E.1 TO III.E.4 ABOVE**

##### **5.1 Summary**

##### **5.2 Assessment of the risk to humans**

- 5.2.1 Hazard identification
- 5.2.2 Assessment of the degree of exposure and the likelihood of each hazard occurring
- 5.2.3 Assessment of level of risk
- 5.2.4 Consequences of a hazard occurring
- 5.2.5 Assessment of the overall risk of harm to humans

### **5.3 Assessment of the risks to the environment**

5.3.1 Hazard identification

5.3.2 Assessment of likelihood

5.3.3 Assessment of level of risk

5.3.4 Assessment of the consequence

5.3.5 Assessment of the overall risk of harm to the environment

### **5.4 Assessment of the overall risk**

### **5.5 Control Measures**

## **6. CONCLUSION**