



# SLOVENSKI STANDARD

## SIST EN 13441:2002

01-september-2002

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### Biotehnologija - Raziskovalni, razvojni in analitski laboratoriji - Navodilo za zadrževanje gensko spremenjenih rastlin

Biotechnology - Laboratories for research, development and analysis - Guidance on containment of genetically modified plants

Biotechnik - Laboratorien für Forschung, Entwicklung und Analyse - Leitfaden für die Einschließung von gentechnisch veränderten Pflanzen

Biotechnologie - Laboratoires de recherche, développement et analyse - Guide pour le confinement des plantes génétiquement modifiées

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07.080      Biologija. Botanika. Zoologija    Biology. Botany. Zoology

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EUROPEAN STANDARD

EN 13441

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2001

ICS 07.080

English version

## Biotechnology - Laboratories for research, development and analysis - Guidance on containment of genetically modified plants

Biotechnologie - Laboratoires de recherche, développement et analyse - Guide pour le confinement des plantes génétiquement modifiées

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This European Standard was approved by CEN on 29 September 2001.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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## Foreword

This European Standard has been prepared by Technical Committee CEN/TC 233 "Biotechnology", the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2002, and conflicting national standards shall be withdrawn at the latest by May 2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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## Introduction

The measures described in this European Standard are designed to contain genetically modified plants, where this is required. Genetically modified plants include those in which the introduced genetic material is derived from another plant or from a non-plant source, for example a virus or other microorganism. Containment of genetically modified microorganisms, the subject of Directive 98/81/EC (including 90/219/EEC) [1] and/or genetically modified small animals associated with plants is not included in this standard; their containment may require different measures from those mentioned here.

The containment principles described apply both to greenhouses, including growth tunnels, and to the more complex containment facilities required when greenhouses do not provide the degree of containment required.

Risk analysis is required to determine any hazard and its magnitude as well as the containment measures needed to minimize the risk.

The selection of containment measures for plants classified in a given group requires identification of the means including work practices, by which particular plants may be dispersed in the relevant situation. Containment measures used for one species may be irrelevant to another, which is dispersed by different mechanisms. Containment measures are therefore selected for the particular situation.

In many cases, containment by biological rather than structural means will be appropriate. The use of male sterile plants and maternally inherited genetic modifications are examples of potential biological containment measures.

Users of this European Standard may be involved with hazards associated with materials, operations and equipment. This European Standard does not address all off these safety problems. It is the responsibility of the user of this European Standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations for the proposed work.

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## 1 Scope

This European Standard gives biological, physical and procedural containment measures for work with genetically modified plants including plants where the transferred genetic material is derived from a non-plant source. It defines measures to minimize hazards identified by risk analysis.

Containment may be provided in a greenhouse or in a growthroom, laboratory or other containment facility.

Containment of genetically modified microorganisms and/or small animals associated with plants is not included in this standard. Containment of microorganisms in laboratories is covered in EN 12128.

## 2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 12128, *Biotechnology — Laboratories for research, development and analysis — Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements.*

EN 12741, *Biotechnology — Laboratories for research, development and analysis — Guidance for biotechnology laboratory operations.*

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## 3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

### 3.1

#### biological containment

use of plants which are unable to remain viable in natural environmental conditions in the area of the containment facility, or which lack reproductive mechanisms required for dispersal

### 3.2

#### genetically modified plant

plant in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination

NOTE Within the terms of this definition, genetic modification occurs at least by the use of the techniques listed in Directive 98/81/EC, Annex 1 Part A ([1]).

### 3.3

#### greenhouse

structure with a wall, a roof and a floor designed and used principally for growing plants in a controlled and protected environment [Directive 98/81/EC]

NOTE An alternative definition in prEN 13031-1 dealing with structural aspects of greenhouses is: a structure used for the cultivation and/or protection of plants and crops which promotes solar radiation transmission under controlled conditions to improve the growing environment, and which is of a size that enables people to work within it [prEN 13031-1].

### 3.4

#### hazard

intrinsic potential property or ability of something (e.g. any agent, equipment, material or process) to cause harm [EN 1620]

NOTE Harm is an injury or damage to health of people and/or the environment.

### 3.5

#### physical containment

system for confining a microorganism and/or organism or other entity within a defined space [EN 1620]

**EN 13441:2001 (E)****3.6****risk**

probability of occurrence of a hazard causing harm and the degree of severity of the harm

**4 Risk assessment**

The analysis of risk should take account of the influence of regional, climatic and other environmental conditions which can also determine whether containment is required. The hazards present, and thus the need for and the nature of containment measures, should be assessed on a case by case basis, for each environmental situation.

For genetically modified plants, the potential hazards are as follows:

- a) that they may be able to cause harm to people by virtue of toxigenic or allergenic properties; and/or
- b) may become established in the environment and cause changes in ecosystems;
- c) may express other unwanted traits.

Control of hazard requires that the means by which the genetically modified plants are dispersed is identified and appropriate steps taken to prevent dispersion.

The containment measures appropriate for work with genetically modified plants are determined by the risk assessment of the proposed work, carried out in accordance with European and national regulations.

**5 Containment measures**

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**5.1 General**

Containment, when required, will be achieved by taking appropriate steps to prevent dispersal by the process relevant to a particular plant and/or by particular work practices.

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**5.2 Use of conventional greenhouses**

Where the hazard is assessed as minimal, a greenhouse designed to provide protection for the plants is acceptable for the cultivation of genetically modified plants. Such basic level structures include growth tunnels.

NOTE Requirements for commercial greenhouses are given in prEN 13031-1[3].

**5.3 Additional containment measures****5.3.1 General**

When containment is required, conventional greenhouses or plant tunnels are inherently unsuitable without application of additional features to control the dispersion of genetically modified material as pollen, seed, fruit and/or vegetative tissues. Where containment is needed, it may be achieved by physical containment measures, biological containment and appropriate work practices, either alone or in combination.

A non-exhaustive list of containment measures which will reduce dispersion is given in 5.3.2 to 5.3.4. Appropriate measures of containment should be selected from these and from other relevant and validated procedures not listed.

**5.3.2 Dispersal by pollen**

Dispersal by pollen may be controlled by one or more of the following means:

- a) covering flowers with fabric bags which will retain pollen;
- b) fitting pollen retaining filters over all openings; due attention should be paid to sealing places where pipes and other structures pass through walls;



- c) using male sterile plants or plants subjected to other sterilization procedures;
- d) ensuring that experimental plant flower only when susceptible plants in the environment are not in flower;
- e) removing susceptible plants from the immediate environment;
- f) preventing ingress and exit of birds and pollinating animals by fitting appropriate barriers to all openable windows and other openings;
- g) controlling access to the building;

NOTE Care should be taken that any access control measures do not conflict with other safety regulations, such as escape from fire.

- h) using reduced pressure to ensure inward air flow;
- i) sterilizing or, when appropriate, inactivating plant dispersing material in run-off water.

### 5.3.3 Dispersal as fruit and seeds

Dispersal as fruit and seeds may be controlled by one or more of the following means:

- a) preventing entry and exit of birds and other animals by fitting appropriate barriers to all openable windows and other openings;
- b) filtering run-off water;
- c) sterilizing or, when appropriate, inactivating plant dispersing material in run-off water;
- d) sealing places where pipes and other structures pass through walls;
- e) sterilizing or, as appropriate, steaming plant dispersing material leaving the greenhouse;

NOTE If an autoclave is used, it should be of suitable performance class as defined in EN 12347.

- f) using sexually sterile plants;
- g) controlling window opening;
- h) using solid, non-penetrable floor;
- i) controlling access to the greenhouse.

NOTE Care should be taken that any access control measures do not conflict with other safety regulations, such as escape from fire.

### 5.3.4 Dispersal by vegetative means

Dispersal by vegetative means may be controlled by one or more of the following means:

- a) constructing a wall around the facility below ground to a depth sufficient to prevent dispersion;
- b) transferring material from genetically modified plants to other facilities only when using closed robust containers;
- c) sterilizing or as appropriate, inactivating plant dispersing material in material leaving the greenhouse;

NOTE If an autoclave is used, it should be of suitable performance class as defined in EN 12347.

- d) fumigating the building after use;
- e) filtering run-off water;
- f) sterilizing or as appropriate, inactivating plant dispersing material in run-off water;