

ANNEX I

1. For the purposes of Article 2(1) of this Directive the following general conditions shall apply:
 - the nature and objectives of the activities for which the material is to be introduced or moved shall have been examined by the responsible official body and found to comply with the concept of trial or scientific purposes and for work on varietal selections provided for under Directive 2000/29/EC,
 - the quarantine containment conditions of the premises and facilities at the site or sites at which the activities are to be undertaken shall have been inspected for compliance with the provisions laid down in point 2 and approved by the responsible official body,
 - the responsible official body shall limit the quantity of material to an amount that is adequate for the approved activities and in any case the amount shall not exceed quantities which have been determined having regard to available quarantine containment facilities,
 - the scientific and technical qualifications of the personnel by whom the activities are to be undertaken shall have been examined and approved by the responsible official body.
2. For the purposes of point 1, the quarantine containment conditions of the premises and facilities at the site or sites at which the activities are to be undertaken shall be sufficient to ensure a safe handling of the material such that any harmful organisms of concern are contained and the risk of spreading such harmful organisms eliminated. For each activity specified in the application, the risk of spread of the harmful organisms held under quarantine containment conditions shall be determined by the responsible official body, having regard to the type of material and the activity envisaged, and to the biology of the harmful organisms, the means of their dispersal, the interaction with the environment and other relevant factors relating to the risk posed by the material concerned. As a result of the assessment of the risk, the responsible official body shall consider and lay down as appropriate:
 - (a) the following quarantine measures concerning the premises, facilities and working procedures:
 - physical isolation from all other plant/harmful organism material, including consideration of control of vegetation in surrounding areas,
 - designation of a contact person responsible for the activities,
 - restricted access to the premises and facilities and to the surrounding area, as appropriate, to named personnel only,
 - appropriate identification of the premises and facilities indicating the type of activities and the personnel responsible,
 - maintenance of a register of the activities performed and a manual of operating procedures, including procedures in the event of escape of harmful organisms from containment,
 - appropriate security and alarm systems,
 - appropriate control measures to prevent the introduction into and the spread within the premises of harmful organisms,
 - controlled procedures for sampling and for transfer between premises and facilities, of the material,
 - controlled waste, soil and water disposal, as appropriate,

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- appropriate hygiene and disinfection procedures and facilities for personnel, structures and equipment,
 - appropriate measures and facilities for disposal of experimental material,
 - appropriate indexing (including testing) facilities and procedures; and
- (b) further quarantine measures according to the specific biology and epidemiology of the type of material involved and the activities approved:
- maintenance in facilities with separate chamber ‘double door’ access to personnel,
 - maintenance under negative air pressure,
 - maintenance in escape-proof containers with appropriate mesh size and other barriers e.g. water barrier for mites, closed soil containers for nematodes, electric insect traps,
 - maintenance in isolation from other harmful organisms and material, e.g. viruliferous plant food material, host material,
 - maintenance of material for breeding in breeding cages with manipulation devices,
 - no interbreeding of the harmful organisms with indigenous strains or species,
 - avoidance of continuous culture of the harmful organisms,
 - maintenance under conditions that strictly control the multiplication of the harmful organism, e.g. under an environmental regime such that diapause does not occur,
 - maintenance in such a way that no spread by propagules can occur, e.g. air streams should be avoided,
 - procedures to check the purity of cultures of the harmful organisms for freedom from parasites and other harmful organisms,
 - appropriate control programmes for the material to eliminate possible vectors,
 - for *in vitro* activities, handling of the material under sterile conditions: equipping the laboratory for the performance of aseptic procedures,
 - maintenance of harmful organisms spread by vectors under conditions such that there is no spread via the vector e.g. controlled mesh size, containment of soil,
 - seasonal isolation to ensure the activities are done during periods of low plant health risk.