SCHEDULE 1 Regulations 6 and 11

CONSENT TO RELEASE OR MARKET

PART I

GENERAL INFORMATION

1. The name and address of the applicant, and the name, qualifications and training of the responsible scientist and of every other person who will be responsible for planning and carrying out the release of the organisms, for carrying out the release and for the supervision, monitoring and safety of the release.

PART II

INFORMATION RELATING TO THE ORGANISMS

Characteristics of donor, parental and recipient organisms

2. Scientific name and taxonomy.

3. Usual strain, cultivar or other name.

4. Phenotypic and genetic markers.

5. The degree of relatedness between the donor and recipient organisms or between the parental organisms.

6. The description of identification and detection techniques.

7. The sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.

8. The description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, prey, parasites, competitors, symbionts and hosts.

9. The potential of the organisms for genetic transfer and exchange with other organisms.

10. Verification of the genetic stability of the organisms and factors affecting that stability.

11. The following pathological, ecological and physiological traits:

(a) the classification of hazard according to existing Communities rules concerning the protection of human health and the environment;

(b) the generation time in natural ecosystems, and sexual and asexual reproductive cycle;

(c) survivability, including seasonability and the ability to form survival structures, including seeds, spores and sclerotia;

(d) pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses), and ability to colonise other organisms;

(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;

(f) involvement in environmental processes, including primary production, nutrient turnover, decomposition of organic matter and respiration.

12. The sequence, frequency of mobilisation and specificity of indigenous vectors, and the presence in those vectors of genes which confer resistance to environmental stresses.

13. The history of genetic modification and of any application of additional techniques to the organism.

Characteristics of the vector

14. The nature and source of the vector.

15. The sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms and to make the introduced vector and insert function in those organisms.

16. The frequency of mobilisation, genetic transfer capabilities and/or methods of determina tion of the inserted vector.

17. The degree to which the vector is limited to the DNA required to perform the intended function.

Characteristics of the modified organisms

18. The methods used for the modification.

19. The methods used—

(a) to construct inserts and to introduce them into the recipient organism;

(b) to delete a sequence.

20. The description of any insert and/or vector construction.

21. The purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function.

22. The sequence, functional identity and location of the altered, inserted or deleted nucleic acid segments in question, and in particular any known harmful sequence.

Characteristics of the genetically modified organisms

23. The description of the genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

24. The structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organisms.

25. The stability of the organisms in terms of genetic traits.

26. The rate and level of expression of the new genetic material in the organisms, and the method and sensitivity of measurement of that rate and level.

27. The activity of the gene product.

28. The description of identification and detection techniques, including techniques for the identification and detection of the inserted sequence and vector.

29. The sensitivity, reliability (in quantitative terms), and specificity of detection and identification techniques.

30. The history of previous releases or uses of the organisms.

31. In relation to human health—

(a) the toxic or allergenic effects of the non-viable organisms and/or their metabolic products,

(b) the product hazards,

(c) the comparison of the organisms to the donor, recipient or (where appropriate) parental organisms regarding pathogenicity,

(d) the capacity of the organisms for colonisation, and

(e) if the organisms are pathogenic to humans who are immunocompetent—

(i) diseases caused and mechanisms of pathogenicity including invasiveness and virulence,

(ii) communicability,

(iii) infective dose,

(iv) host range and possibility of alteration,

(v) possibility of survival outside of human host,

(vi) presence of vectors or means of dissemination,

(vii) biological stability,

(viii) antibiotic-resistance patterns,

(ix) carcogenicity, and

(x) availability of appropriate therapies.

PART III

CONDITIONS OF RELEASE

The release

32. The description of the proposed deliberate release, including the purpose or purposes of the release and the foreseen products of the release.

33. The foreseen dates of the release and time planning of the experiment including frequency and duration of releases.

34. The preparation of the site before the release.

35. The size of the site.

36. The methods to be used for the release.

37. The quantity of organisms to be released.

38. The disturbance of the site, including the type and method of cultivation, and mining, irrigation, or other activities.

39. The worker protection measures taken during the release.

40. The post-release treatment of the site.

41. The techniques foreseen for elimination or inactivation of the organisms at the end of the experiment or other purpose of the release.

42. Information on results of previous releases of those organisms, or of organisms of the same type as those which are to be released, and in particular releases on a different scale or into different ecosystems.

The environment (both on the site and in the wider environment)

43. The geographical location and national grid reference of the site onto which the release will be made, or the foreseen areas of use of the product.

44. The physical or biological proximity of the site of the organisms to humans and other significant biota.

45. The proximity to significant biotopes or protected areas.

46. The size of the local human population.

47. The local economic activities which are based on the natural resources of the area.

48. The distance to the nearest drinking water supply zone and/or areas protected for environmental purposes.

49. The climatic characteristics of the region or regions likely to be affected.

50. The geographical, geological and pedological characteristics.

51. The flora and fauna, including crops, livestock and migratory species.

52. The description of the target and non-target ecosystems likely to be affected.

53. The comparison of the natural habitat of the recipient organisms with the proposed site or sites of release.

54. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

PART IV

THE ORGANISMS AND THE ENVIRONMENT

Characteristics affecting survival etc

55. The biological features which affect survival, multiplication and dispersal.

56. The known or predicted environmental conditions which may affect survival, multiplica tion and dissemination, including wind, water, soil, temperature and pH.

57. The sensitivity to specific agents.

Interactions with the environment

58. The predicted habitat of the organisms.

59. The studies on the behaviour and characteristics of the organisms and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms and greenhouses.

60. The capability of post-release transfer of genetic material—

(a) from the genetically modified organisms into organisms in affected ecosystems,

(b) from indigenous organisms to the genetically modified organisms.

61. The likelihood of post-release selection leading to the expression of unexpected or undesirable traits in the genetically modified organisms.

62. The measures employed to ensure and to verify genetic stability, the description of genetic traits which may prevent or minimise dispersal of genetic material, and methods to verify genetic stability.

63. The routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact and burrowing.

64. The description of ecosystems to which the organisms could be disseminated.

Potential environmental impact

65. The potential for excessive population increase of the organisms in the environment.

66. The competitive advantage of the organisms in relation to the unmodified recipient or parental organisms.

67. The identification and description of the target organisms.

68. The anticipated mechanism and result of interaction between the released organisms and the target organisms.

69. The identification and description of non-target organisms which may be affected.

70. The likelihood of post release shifts in biological interactions or in the host range.

71. The known or predicted effects on plants and animals and non-target organisms in the environment, impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

72. The known or predicted involvement of the organisms in biogeochemical processes.

73. Any other potentially significant interactions of the organisms with the environment.

PART V

MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY PLANS

Monitoring techniques

74. Methods for tracing the organisms, and for monitoring their effects.

75. Specificity (to identify the organisms, and to distinguish them from the donor, recipient or the parental organisms), sensitivity and reliability of the monitoring techniques.

76. Techniques for detecting transfer of the donated genetic material to other organisms.

77. Duration and frequency of the monitoring.

Control of the release

78. Methods and procedures to avoid and/or minimise the spread of the organisms beyond the site of release or the designated area for use.

79. Methods and procedures to protect the site from intrusion by unauthorised individuals.

80. Methods and procedures to prevent other organisms from entering the site.

Waste treatment

81. Type of waste generated

82. Expected amount of waste.

83. Possible risks.

84. Description of treatment envisaged.

Emergency response plans

85. Methods and procedures for controlling the organisms in case of unexpected spread.

86. Methods, such as eradication of the organisms, for decontamination of the areas affected.

87. Methods for disposal or sanitation of plants, animals, soils, and any other thing exposed during or after the spread.

88. Methods for the isolation of the area affected by the spread.

89. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

SCHEDULE 2

Regulation 11

CONSENT TO MARKET

PART I

GENERAL INFORMATION

1. The name of the product and the name of the genetically modified organisms in the product.

2. The name and address in the Community of the manufacturer or distributor of the product.

3. The specificity of the product and the exact conditions of use including, where appropriate, the type of environment and/or the geographical areas within the Community for which the product is suited.

4. The type of expected use of the product and the description of the persons who are expected to use the product.

PART II

ADDITIONAL RELEVANT INFORMATION

5. The measures to be taken in the event of the escape of the organisms in the product or misuse of the product.

6. Specific instructions or recommendations for storage and handling of the product.

7. The estimated level and amount of production of the product within the Community and the estimated level and amount of imports of the product into the Community.

8. Information regarding the proposed packaging for the product and its appropriateness so as to avoid the escape of genetically modified organisms during storage or at a later stage.

9. Information regarding proposed labelling including the proposals for stating, in full or summarised form, the information prescribed in paragraphs 1 to 3, 5 and 6 above.