SCHEDULE 2

Information to be included in applications for consent to release or market organisms other than genetically modified higher plants

PART II

Information relating to the organisms

Characteristics of the genetically modified organisms in their final form

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

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

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

28. 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.

29. The activity of the gene product.

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

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

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

33. In relation to human health, animal health and plant health—

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

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

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

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

(i) diseases caused and mechanism 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) allergenicity, and

(x) availability of appropriate therapies.

(e) the other product hazards.

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to Genetically Modified Organisms (Deliberate Release) Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

– Blanket amendment words substituted by S.I. 2011/1043 art. 3-68-10