

## 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*

- 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.