

ANNEX III A

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS II. INFORMATION RELATING TO THE GMO

- A. Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):
1. scientific name,
 2. taxonomy,
 3. other names (usual name, strain name, etc.),
 4. phenotypic and genetic markers,
 5. degree of relatedness between donor and recipient or between parental organisms,
 6. description of identification and detection techniques,
 7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques,
 8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts,
 9. organisms with which transfer of genetic material is known to occur under natural conditions,
 10. verification of the genetic stability of the organisms and factors affecting it,
 11. pathological, ecological and physiological traits:
 - (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;
 - (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;
 - (c) information on survival, including seasonability and the ability to form survival structures;
 - (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). 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: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.
 12. Nature of indigenous vectors:
 - (a) sequence;
 - (b) frequency of mobilisation;

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- (c) specificity;
 - (d) presence of genes which confer resistance.
13. History of previous genetic modifications.
- B. Characteristics of the vector
- 1. nature and source of the vector,
 - 2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO,
 - 3. frequency of mobilisation of inserted vector and/or genetic transfer capabilities and methods of determination,
 - 4. information on the degree to which the vector is limited to the DNA required to perform the intended function.
- C. Characteristics of the modified organism
- 1. Information relating to the genetic modification:
 - (a) methods used for the modification;
 - (b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
 - (c) description of the insert and/or vector construction;
 - (d) 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;
 - (e) methods and criteria used for selection;
 - (f) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.
 - 2. Information on the final GMO:
 - (a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
 - (b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
 - (c) stability of the organism in terms of genetic traits;
 - (d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;
 - (e) activity of the expressed protein(s);
 - (f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

- (g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
- (h) history of previous releases or uses of the GMO;
- (i) considerations for human health and animal health, as well as plant health:
 - (i) toxic or allergenic effects of the GMOs and/or their metabolic products;
 - (ii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
 - (iii) capacity for colonisation;
 - (iv) if the organism is pathogenic to humans who are immunocompetent:
 - diseases caused and mechanism of pathogenicity including invasiveness and virulence,
 - communicability,
 - infective dose,
 - host range, possibility of alteration,
 - possibility of survival outside of human host,
 - presence of vectors or means of dissemination,
 - biological stability,
 - antibiotic resistance patterns,
 - allergenicity,
 - availability of appropriate therapies;
- (v) other product hazards.