

Opinion of the Scientific Committee on Plants on three guidance documents on genetically modified micro-organisms (opinion expressed by the SCP on 24 September 1999)

TERMS OF REFERENCE

The Commission requested the Scientific Committee on Plants to review the following three draft opinions in connection with the implementation of Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

1. Criteria for establishing whether a genetically modified micro-organism (GMM) is safe for human health and the environment and would be suitable for inclusion into Annex IIC of Directive 90/219/EEC ¹
2. Guidance on the criteria to be investigated to determine whether a genetically modified micro-organism is suitable for inclusion in Annex IIC ²
3. Draft Guidance for risk assessment outlined in Annex III of the proposed amendment to directive 90/219/EEC on the contained use of genetically modified micro-organisms COM(95) 640 ³

BACKGROUND

The Commission gave an undertaking to the Council, during the adoption of Council Directive 98/81/EC on the contained use of genetically modified micro-organisms, to produce criteria to complete Annex IIB to allow the inscription of GMMs in Annex IIC before 5 December 2000. These criteria were to be proposed by the Commission and adopted by the Council acting by a qualified majority. A further commitment was made to produce guidance for the principles of risk assessment set out in Annex III for completion no later 5 June 2000. This guidance would be adopted by a regulatory committee on the basis of a proposal from the Commission, set up under Article 21 of the Directive. The above mentioned three documents have been developed by the Commission services with the assistance of national experts nominated by the Member States competent authorities appointed under Directive 90/219/EEC.

OPINION OF THE COMMITTEE

The Scientific Committee on Plants decided that it would be appropriate to address the request for opinion as follows:

- 1) To formulate an overall scientific opinion on the key elements and principles on the criteria for establishing whether a GMM is safe for human health and the environment and would be suitable for inclusion into Annex IIC of Directive 90/219/EEC.
- 2) To produce a modified version of the three documents.

Key elements and principles associated with the safety of GMMs for human health and environment

1) The verification and authentication of a micro-organism is extremely important for establishing whether a GMM is safe for human health and the environment. There are several ways to classify a micro-organism. These consist of a number of classical (morphological, nutritional, biochemical) methods that can be validated further by modern molecular techniques. Information on these methods and on the micro-organisms can be obtained from a large number of handbooks and established culture collections.

The Committee recommends that the paragraph on strain verification/authentication be modified to include a broad, general description of the methodologies for classification, in order not to exclude important taxonomical methods. Moreover, it is suggested to refer to appropriate culture collection organisations for further sources of information.

2) It is extremely difficult to establish the safety of a micro-organism with absolute certainty. In practice, it may be possible to obtain a documented history of safe use. Such a documented history of safe use will only be acceptable as evidence of safety if the GMM has not only been used under highly controlled conditions to guarantee its safe use. Against this background, the Committee recommends that a history of safe use should be accepted as establishing safety, if the non-modified host has been used over a long period of time with a good safety record, for instance, as a food ingredient. Moreover, the inserted gene must have an established safety record.

3) The Committee endorsed the view that increasing the genetic stability of a GMM over the unmodified micro-organism should not lead to harm per se in the environment. Against this background, if it is known that the GMM is not harmful, increased genetic stability should not be a problem.

4) To establish the (non) pathogenicity of a micro-organism a clear definition of health is a prerequisite. In the opinion of the Committee, health in this context implies a human, animal or plant which is not compromised towards invasion and subsequent establishment of micro-organisms, normally considered non-pathogenic.

5) Many food grade starter cultures that have been in use for a long time in fermented products and that are not necessarily laboratory adopted strains can be considered safe. In addition, certain non-pathogenic wild type micro-organisms can be considered as safe on account of their history of safe use.

6) Increasingly, additional information is becoming available on the transfer of genetic material in the environment and on the effects of non-specific absorption on the transfer of genetic material. New approaches are emerging to establish the growth rate of micro-organisms in the environment (soil as well as animal gut) and new data becoming available should be taken into consideration when considering the fate and effect of GMMs.

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¹ Document XI/366/97-Rev. 4

² Document XI/367/97-Rev. 4

³ Document XI/368/97-Rev. 4