



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL  
ENVIRONMENT

Directorate B - Protecting the Natural Environment

Brussels,  
ENV B3/AA/ D(2008)

**WORKING GROUP ON THE ESTABLISHMENT OF A LIST OF TECHNIQUES  
FALLING UNDER THE SCOPE OF  
DIRECTIVE 2001/18/EC ON THE DELIBERATE RELEASE OF GENETICALLY MODIFIED  
ORGANISMS INTO THE ENVIRONMENT  
AND DIRECTIVE 90/219/EEC  
ON THE CONTAINED USE OF GENETICALLY MODIFIED MICRO-ORGANISMS**

**TERMS OF REFERENCE**

---

**1. INTRODUCTION**

At the meeting of the Competent Authorities under Directive 2001/18/EC<sup>1</sup> which was held on 16 April 2007, the Dutch delegation proposed that a Working Group (WG) be set up to address new techniques which are applied in plant breeding and modification of organisms in general. The background for this request is that Member States increasingly deal with questions from stakeholders whether newly applied techniques result in a genetically modified organism (GMO). These questions have led to different interpretations among Member States. In order to harmonize the approach of Member States in this issue, the Dutch delegation proposed that the WG address whether these (new) techniques lead to GMOs as defined under Directives 2001/18/EC and 90/219/EEC<sup>2</sup>. The proposal was welcomed by BE, DK, DE, SE, FI, FR, AT, MT, NO and SL.

**2. TERMS OF REFERENCE**

Directive 2001/18/EC and Directive 90/219/EEC provide for a general definition of a Genetically Modified Organism (GMO) and a Genetically Modified Micro-organism

---

<sup>1</sup> Directive 2001/18/EC<sup>1</sup> of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 17.4.2001, p. 1

<sup>2</sup> Directive 90/219/EEC, Council Directive of 23 April 1990 on the contained use of genetically modified micro-organisms

(GMM) respectively. These Directives include annexes which provide additional information regarding the techniques that result in genetic modification, that are not considered to result in genetic modification, or that result in genetic modification but yield organisms that are excluded from the scope of the Directives. The following parts of Directive 2001/18/EC and Directive 90/219/EEC as amended by Directive 98/81/EC<sup>3</sup> have to be taken into account:

- Definition of a GMO : "*genetically modified organism (GMO)*" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" (Directive 2001/18/EC Article 2)
- Definition of a GMM: "*genetically modified micro-organism (GMM)*" shall mean a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" (Directive 90/219/EEC, Article 2)
- List of the techniques leading to genetic modification (Annex I Part A of Directive 90/219/EEC and Annex IA, Part 1 of Directive 2001/18/EC)
- List of the techniques which are not considered to result in genetic modification (Annex I, Part B of Directive 90/219/EEC and Annex IA Part 2 of Directive 2001/18/EC)
- List of the techniques of genetic modification yielding organisms to be excluded from the Directives (Annex II Part A of Directive 90/219/EEC and Annex IB of Directive 2001/18/EC)
- The objective of the legislation is to protect human health and the environment (Directive 2001/18/EC, Article 1; Directive 90/219/EEC Article 1)

The techniques listed in the Annexes (Annex IA Part 1, Annex IA Part 2 and Annex IB of Directive 2001/18/EC and Annex I Part A, Annex I Part B and Annex II Part A of Directive 90/219/EEC) could be complemented with relevant new techniques, if that is considered necessary, and according to the appropriate procedures foreseen for a possible review of Directive 90/219/EEC and Directive 2001/18/EC.

As stipulated by Article 31(1) of Directive 2001/18/EC, Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release and placing on the market of GMOs. The establishment of a specialised WG focusing on techniques leading to genetic modification can serve the purpose of risk prevention in the sense of the above provision.

### **3. OBJECTIVE(S)**

The WG shall evaluate a list of new techniques for which it is unclear whether they result in genetic modification. These techniques will be discussed in the light of:

- the definition of a GMO/GMM;

---

<sup>3</sup> Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

- the techniques listed in the Annexes of the Directives; and,
- the most recent available scientific data.

The WG shall discuss the possible consequences on the list of the techniques presented in the aforementioned Annexes.

The WG should compare the definitions of GMM/GMO and the annexes in the two Directives and analyse potential discrepancies.

This work may represent the basis for future guidelines or new categorisation of techniques of genetic modification. The most appropriate means to present the findings of the WG will be discussed in the course of the meetings of the Competent Authorities under Directives 2001/18/EC and 90/219/EEC or in a joint meeting under both Directives.

The WG is an ongoing working group, which may be consulted in the light of new scientific information and methodological progress.

#### **4. APPROACH**

- The WG should include experts under Directive 90/219/EEC and Directive 2001/18/EC.
- A list of (new) techniques will be proposed and categorized as an initial working tool of the WG. In this context a priority list of techniques shall be established by the Member States. Priority will be given to techniques that are already in use or will become important in the near future.
- Techniques will be discussed by technical experts of each Member State in the light of the definitions (and Annexes) of the Directives in order to determine whether or not they would result in genetic modification in the context of the Directives and to what extent they can be compared to techniques already listed in the Annexes of the Directives
- The findings of the WG may be referred to EFSA for their opinion
- The terms "recombinant nucleic acid techniques" will be interpreted in the light of the aforementioned list of new techniques.
- The structure and substance of the work, as well as the prioritisation of the tasks assigned to the WG should be decided by the Commission in consultation with the Competent Authorities under Directive 2001/18/EC and Directive 90/219/EEC.
- The outcome of the WG will be presented to the meetings of the Competent Authorities of both Directives or to a joint meeting of the Competent Authorities under the two Directives. It shall be reviewed and updated in the light of new scientific information and methodological progress.

#### **5. SETTING UP OF THE WORKING GROUP**

The Competent Authorities were required to nominate national experts as members of the WG by 30 September 2008 at the latest.

The work of the WG will be carried out by WG meetings preceded and followed by work co-ordinated via e-mail.

Further information as regards the structure and the substance of the work progress will be provided on a regular basis to Member States.

## **6. PROPOSED WORK PLAN AND AGENDA**

During the first meeting of the New Techniques WG, the experts will compile and complement the list of techniques to be analysed. A starting point will be the list of techniques already provided by the Member States in 2007. A prioritisation of the tasks shall be defined. It is planned to work in sub-groups dealing with different categories of techniques, if suitable. Each sub-group will nominate a rapporteur. The outcome of the first meeting shall be submitted to and agreed by the Competent Authorities under Directive 2001/18/EC and Directive 90/219/EEC.

The sub-groups will work via e-mail co-ordination. The results will be presented at the subsequent meeting of the WG. It is planned to commence the activity of the group in December 2008. A document outlining the state of play of group's work will be presented to the Competent Authorities on a regular basis.