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Acting Director-General

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Note to Mr. L. Romero Requena, Director-General,
Legal Service

Subject: **Legal status of new plant breeding techniques in the biotechnology field – definition of GMO**

I am writing to ask the opinion of the Legal Service on the conclusions reached by my Services on the definition of GMO under EU legislation. These conclusions are described in Annex I to this note.

The definition of genetically modified organism (GMO) is common to Directive 2001/18/EC and Regulation (EC) No 1829/2003. This definition, which was established in 1990 under Directive 90/220/EC and confirmed – with minor changes in 2001 when Directive 2001/18/EC, replacing Directive 90/220/EC, was adopted - was designed by defining the characteristics of the organism and taking into account the techniques used to obtain this organism which were available at the time. In Directive 2009/41/EC, the notion of genetically micro-organism (GMM) is largely inspired by this definition.

Since the adoption of Directive 2001/18/EC, a number of **new techniques** have been developed leading to organisms in which the genetic material is altered – definitively or transiently – compared to the initial organism, at a degree depending on the technique used. These techniques do not correspond to the techniques which are listed in the Directive as leading to the creation of a GMO. However, the Directive does not provide for a closed list of techniques.

In order to ensure that no GMO/GMM or GM food and feed are placed on the market without an authorisation required under the GMO legislation, it is therefore essential to clarify whether these **new techniques** lead to organisms which fall under the scope of GMO legislation.

This clarification is key for the companies which are developing these new techniques. Many of them (mostly universities or start-ups) have indicated that should their product be considered as falling under the GMO legislation, they would not apply for an authorisation, alleging costs in terms of process and image of their product).

In order to take account of the scientific and technical developments in the biotechnology field, upon request of the Member States, in 2007 the Commission set up an Expert Working Group to assess whether a number of new techniques could fall or not within the scope of the GMO legislation, focussing on plant breeding techniques. The Group

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also took account of the implications for microorganisms as defined in Directive 2009/41/EC. This group finalized its report in December 2011.

The following new techniques of genetic modification were assessed by the Experts[1].

- Oligonucleotide Directed Mutagenesis (ODM),
- Zinc Finger Nuclease Technology (=actually three techniques: ZFN-1, -2, -3),
- Cisgenesis and Intragenesis (=actually two different techniques),
- Grafting,
- Agro-infiltration (=actually two techniques, "senso stricto" and "floral dip"),
- RNA-dependent DNA methylation (RdDM),
- Reverse Breeding.

The Expert Working Group, which was made of scientists from the Member States, on some techniques reached conclusions, although not always unanimously, while on others it left questions open. Their final Report, which is hereby attached as Annex II, clearly indicated that the views expressed therein were those of the Expert Working Group and did not necessarily represent those of the EU institutions or the Competent Authorities. Following the publication of this Report, my Services undertook to deliver a systematic legal analysis to clarify whether each of the techniques that had been examined was considered as falling or not under the GMO legislation. In this context my Services reiterated that the Commission would not be bound by the conclusions of the Expert Working Group.

In the light of the above, I would be grateful to receive your opinion on the conclusions reached by my services on the definition of GMO under EU legislation which are described in Annex I to this note.

The clarifications will help us to take position on the individual status of the organisms produced by each of the above-mentioned techniques.

Ladislav Miko

Annex I: Legal interpretation
Annex II: Expert Group report

Copy: (SJ), Mr M. Flueh, , , , , , (SANTE).

[1] Synthetic genomics, a twelfth technique, was only dealt with marginally, no conclusions were reached and DG SANCO considers that further work is needed to identify what synthetic biology really comprises and will thus not take position on this last technique in this note.