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**“TRACEABILITY AND DETECTION OF GENETICALLY MODIFIED
ORGANISMS IN THE LABELLING OF FOOD PRODUCTION CHAIN. UE
DIRECTIVES AND MOLECULAR APPROACHES“**

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ABSTRACT

The deliberate release of genetically modified organisms (GMOs) into the environment and the application of modern biotechnology to food and plants is currently the focus of intense public and political debate with particular reference to the long-term effects on the environment and also the issue of food safety.

This untenable situation has led to the completion by the European Union, in July 2003, of a new regulatory framework for GM products, centred on the requirements of traceability and labelling.

Concerning the traceability, products consisting of GMOs or containing GMOs, and food products obtained from GMOs, which have been authorised on the basis of the procedure under Directive 2001/18/EC or Regulation 1829/2003/EC, are, in addition to labelling requirements, subject to traceability requirements pursuant to Regulation 1830/2003/EC.

A targeted definition of traceability was provided by the International Organization for Standardization and supported by regulation 178/2002/EC, which defines Traceability as “the ability to trace and follow a food, feed, food producing animal or ingredients, through all stages of production and distribution”. Traceability facilitates the establishment of the identity, history and source of a product. In general, the following reasons for the establishment of a traceability system for GMOs can be identified:

- (1) to possibly withdraw products when a risk to human health or the environment is established;
- (2) to facilitate the identification and monitoring of unintended and long term effects on the environment as well as on human and animal health, where appropriate;
- 3) to assist the control of labelling.

For the labelling, the regulatory issues and the relative risk analysis were currently harmonised by Codex Alimentarius. The new labelling threshold has now been set to 0,9% for GMOs having

successfully passed all authorization stages including a full risk assessment and final approval by the respective national and European Food Safety Authority (EFSA). In addition to food, this labelling regulation also applies to animal feed, requiring labelling if GMO material is present above the threshold. The EU has set a 0,5% tolerance for all those GMOs, for which the risk assessment has been finalized, but final approval for authorization in Europe has not yet been granted. In addition, a zero tolerance has been adopted for GMOs for which the risk assessment is ongoing and those for which authorization is not applied for.

Under this regulatory framework the significance of adequate molecular methods becomes more and more apparent. During the last decade a considerable number of molecular methods have been developed and validated that enable the detection, identification and quantification of GMO impurities. Most of them rely on the PCR technology and can only detect one specific stretch of DNA. It can, however, be anticipated that in the near future the situation will become more complex. The number of GMO varieties, including 'stacked-gene' varieties, which will enter the European Market will increase and it is likely that these varieties will harbour more variable constructs. New tools will be necessary to keep up with these developments. One of the most promising techniques is micro array analysis. This technique enables the screening for a large number of different GMOs within a single experiment.

In this paper we will discuss about the EU legislation and we will stress the attention to the molecular techniques, either genomic and proteomic ones, indispensable for the GMOs detection.