***Training course 5: Risk assessment in Genetically Modified Organisms and other biotechnologies***

The course in GMO risk assessment is aiming to present an up to date, objective overview over broad

and complex issues of risk assessment of genetically modified organisms used as food and feed. The

course will bring up to date overview over general concept of risk analysis and risk perception.

In order to introduce the participants to the differences between the definitions of risk and hazard

several adequate examples will be used covering broad spectrum of scientific issues related to the

theme of the course. With the definitions and tools used in the process of risk assessment in place the

general introduction to the GMO and other biotechnologies will follow up. This part of the course will

also be focusing on the up to date status of the European Regulation/ Guidelines and its requirements.

Learning objectives:

To make the participants understand an essential role of well and critically performed

molecular risk assessment of GMOs, which is the first step in total GMO analysis.

To assess the level of documentation necessary for the evaluation of the insertion and

expression of the new gene products in the genetically modified organism.

To introduce them to the new emerging molecular technologies and to describe their usefulness

and their perspectives in future risk assessments of the GMOs

At the end of the course, participants will be familiar with:

Molecular characterization of the GM product, taking into the account the characteristics of the

donor and recipient organism.

The compositional, nutritional and agronomic characteristics of the GM product

The potential toxicity and allergenicity of the GM product.

The potential environmental impact following deliberate release of the GMO.

The complexity level of the workshop will be adapted to the participants‟ experience in GMO

risk assessment which will be accessed beforehand.

There are however certain issues which need to be explained in depth and which are closely related to

above main points. Therefore the course will also cover:

An introduction to the basic principles of animal studies with the emphasis of the international

animal test guidance.

The use of appropriate statistical principles and methods for the comparative analysis of food

and feed and for the environmental risk assessment (ERA) of GMOs as well as a crucial subject:

Distinguishing between statistical significance and biological relevance in GMO risk assessment.

Dietary exposure assessment

Comprehensive understanding of the main models, algorithms and typical data requirements

for dietary exposure assessment to GMOs are presented. In order to give the participants.