

ADVISORY FORUM AND SCIENTIFIC COOPERATION UNIT

PRE-ACCESSION PROGRAMME
Parma, 15 May 2014
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Training Course on Risk Assessment in Genetically Modified Organisms and other Biotechnologies

**Venue: Ramada Plaza Antalya
Fevzi Cakmak Caddes
07100 Antalya
Turkey
17-19 June 2014**

Agenda

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Time		Activity	Tutor
From	To		
DAY 1 (17 May)			
9.00	9.30	<p>Welcome and introduction by the Turkish authorities and the EFSA Pre-Accession Coordinator followed by Ilona K. Sørensen</p> <p>Opening and welcome address. Overview of the training course activities: general and learning objectives, program and expectations for the course.</p>	
9.30	10.30	<p>Risk perception and introduction to toxicity risk assessment:</p> <p>Introduction to risk assessment risk analysis, including presentation of the three pillars of risk analysis: risk assessment, risk management and risk communication.</p> <p>Objectives of the session:</p> <p>The difference in risk perception among the public and risk assessors is illustrated. To understand the concepts of risk and hazard: acquire knowledge on the four basic steps of risk assessment: hazard identification, hazard characterization, exposure assessment and risk characterization.</p>	Max Hansen
10.30	11.00	<p>Risk management and risk communication</p> <p>Discussion on risk management and risk communication.</p> <p>Objectives of the session:</p> <p>To understand framework for the work on risk management and risk communication.</p>	Max Hansen
11.00	11.15	Coffee break	
11.15	11.45	<p>Overview and analysis of toxicity risk assessment procedures</p> <p>Review of single steps of a specific risk assessment illustrated by an example.</p> <p>Objectives of the session:</p> <p>To understand how the concepts in risk assessment is applied in practice.</p>	Max Hansen
11.45	12.15	<p>Introduction to GMO risk assessment</p> <p>Presentation of health risk assessment of GMO as held by EFSA (GMO Panel).</p> <p>Objectives of the session:</p> <p>To understand how GMO health risk assessment is carried out in the EU.</p>	Ilona K.Sørensen
12.15	13.00	<p>Casework</p> <p>Introduction to case work in GMO risk assessment.</p> <p>Objectives of the session:</p>	

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		To understand the process of risks assessment of GMO products based on a specific EFSA opinion.	
13.00	14.00	LUNCH	
14.00	15.00	Title of the Session: Legal Framework of the human health GMO risk assessment process.	Ilona K.Sørensen
		Content of the session: Presentation European legal framework concerning risk assessment of GMOs.	
		Objectives of the session: To understand basic legal framework and to be aware of the level of documentation necessary for the evaluation of the new gene products produced by the genetically modified organisms.	
15.00	15.45	Title of the Session: Stepwise understanding of the molecular aspects of the GMO risk assessment process.	Ilona K.Sørensen
		Content of the session: molecular assessment of GMO in in practice.	
		Objectives of the session: To understand the principles of the molecular risk assessment of the GMOs.	
15.45	16.00	Coffee break	
16.00	16.45	Title of the Session: Stepwise understanding of the molecular aspects of the GMO risk assessment process.	Ilona K.Sørensen
		Content of the session: molecular assessment of GMO in in practice.	
		Objectives of the session: To understand the principles of the molecular risk assessment of the GMOs.	
16.45	18.00	Title of the Session: Stepwise understanding of the toxicological aspects of the GMO risk assessment	Ilona K.Sørensen/ Max Hansen
		Content of the session: Introduction of the content of the different steps in the toxicity assessment.	
		Objectives of the session: To understand how different toxicity investigations can be used in the risk assessment.	
19.00	-	Welcome dinner	

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Time		Activity	Tutor
From	To		
DAY 1 (18 May)			
9.30	10.00	<p>Title of the session: Exposure assessment (concentration and consumption)</p> <p>Content of the session: A brief introduction to the methods and the uncertainties in the assessment of concentration of some substances in specific food items and the consumption of specific food items.</p> <p>Objectives of the session: Give participants an understanding of the strengths and limitations of exposure assessment.</p>	Max Hansen
10.00	10.45	<p>Title of the session: Casework</p> <p>Content of the session: Continuation of the case work on GMOs.</p>	Tutors of the day
10.45	11.00	Coffee break	
11.00	11.30	<p>Title of the Session: The rationale and methodology of environmental risk assessment ERA of GMOs</p> <p>Content of the session:</p> <ul style="list-style-type: none"> • Introduction to ERA • Lecture and group discussions <p>Objectives of the session: To increase the understanding of how the ERA is performed.</p>	Sylvie Mestdagh, EFSA
11.30	12.00	<p>Title of the session: Casework</p> <p>Objectives of the session: The case work on toxicity will be finalized and should include a critical review of the study report with focus on study design, performance and analysis.</p>	Tutors of the day
12.00	13.15	<p>Title of the Session: The two approaches of post market monitoring: case specific monitoring (of identified risks) and general surveillance (of unidentified risks)</p> <p>Content of the session: PP – presentation and lectures to describe the two approaches of post market monitoring:</p> <ul style="list-style-type: none"> • Case specific monitoring (of identified risks) 	Sylvie Mestdagh, EFSA

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		General surveillance (of unidentified risks)	
		Objectives of the session: To present to the participants the tools and strategies for monitoring surveillance of possible risks from GMOs.	
13.15	14.15	LUNCH	
14.15	15.15	Title of the of the session: Intended vs. unintended effects	Ilona K.Sørensen
		Content of the session: Scope and interplay between molecular characterization, compositional and agronomic characterizations in the identification of unintended effects of GM plants and products.	
		Objectives of the session: To make the participants to understand the assessment of the intended and unintended effects of GMO.	
15.15	16.15	Title of the of the session: Intended vs. unintended effects	Sylvie Mestdagh, EFSA
		Content of the session: Scope and interplay between molecular characterization, compositional agronomic and phenotypic characterizations in the identification of unintended environmental effects of GM plants and products.	
		Objectives of the session: To make the participants to understand the assessment of the intended and unintended effects of GMO.	
16.15	16.30	Coffee break	
16:30	17:30	Title of the Session: Post- market Environmental Monitoring continuation	Sylvie Mestdagh, EFSA

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Time		Activity	Tutor
DAY 1 (19 May)			
9.00	10.45	Title of the of the session: Case work and plenary presentation and discussion of the work performed in the groups of unintended effects of GM plants and products	Sylvie Mestdagh, EFSA
10.45	11.00	Coffee break	
11.00	12.30	Integrated GMO and chemical case work	Ilona K.Sørensen/ Max Hansen
12.30	13.00	Title of the of the session: Evaluation and closing remarks	Ilona K.Sørensen/ Max Hansen
13.00	14.00	LUNCH	