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Name of the author	Position	Date of the Report
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Day 1 :

Title of the presentation:	EU food legislation and food safety principles
Code:	D1-3
Time:	16:00 – 16:30
Description (talk about yourself at the third person) Dr. Koëter explained in this presentation the essential aspects of the EU Food Legislation with Regulation 178/2002 as the umbrella regulation supplemented by a plethora of related and complementary pieces of food legislation, including legislation about official controls to ensure the compliance with Reg. 178/2002 (Reg.882/2004), Reg. 1107/2009 and Reg.396/2005 on pesticides and MRLs. Dr.Koëter also addressed in more detail legislative aspects related to: food additives, nutrition and health claims, compliance controls and on human health and environmental safety of food and feed. Special attention was paid to the separation of scientific assessment and risk management decisions. Herman Koëter also explained that full transparency is essential for the effective and appreciative functioning of EFSA and the Commission.	

Title of the presentation:	EU risk analysis system
Code:	D1-4
Time:	16:30– 17:15
Description (talk about yourself at the third person) Dr Koëter described the components of any risk analysis system (risk assessment, risk management and risk communication). He addressed and described the main three political EU institutions: the European Parliament, the Council of the EU and the European Commission and their respective roles in risk analysis. Furthermore he explained the role of the European (executive) Agencies (in particular EFSA) and the Member States in risk analysis and the interaction between all. In addition, reference was made to the RASFF. Emphasis of Dr Koëter's lecture was on the respective responsibilities of each body mentioned, their respective interests (scientific, economic, social, cultural and political) and the efficiency of cooperation.	

Questions Day 1: There were no questions asked by the audience on either lecture. However, at the end of both lectures Dr Koëter presented a series of 5 questions to the audience, providing a multiple choice of responses as follows (responses by raising hands, hence percentages are estimates):

D 1-3: Question 1:	What triggered the establishment of EFSA?
D1-3: Answer 1:	a) The need to harmonise food safety assessment in the EU (approximately 30%) b) The BSE crisis (correct answer) (approximately 60%) c) The wish to avoid food import from outside the EU (approximately 10%)
D1-3: Question 2:	The EU food regulation addresses three main aspects which are?
D1-3: Answer 2:	a) The food law, establishment of EFSA and the RASFF (correct answer)

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	(approximately 80%) b) The establishment of EFSA, rules on the import of food and the RASFF (approximately 20%) c) The food law, establishment of EFSA and the Food and Veterinary Office (FVO) (1 person)
D1-3: Question 3:	What is the difference between an EU Directive and an EU Regulation?
D1-3: Answer 3:	a) A Directive is adopted by the Commission and a Regulation by the Parliament (approximately 10%) b) A Regulation is immediately enforceable as law in all Member states and a Directive requires an initiative without dictating how to achieve this (correct answer) (approximately 70%) c) A regulation is legally binding and a Directive is not (approximately 20%)
D1-3: Question 4:	What are the biggest food related health concerns?
D1-3: Answer 4:	a) The contamination of food with very toxic chemicals b) Microbiological contamination of food c) The overconsumption of 2 specific food additives (sugar and salt) (correct answer) (approximately 100%)
D1-3: Question 5:	Who is responsible for the management of the RASFF?
D1-3: Answer 5:	a) EFSA and the food authorities in all Member States (approximately 60%) b) It is a joint responsibility of the European Commission and EFSA (approximately 10%) c) The European Commission is responsible (correct answer) (approximately 30%)
D1-4: Question 1:	What is the difference between risk assessment and risk analysis?
D1-4: Answer 1:	a) risk assessment and risk analysis are synonyms (1 or 2 persons) b) risk assessment is the first element of analysis (correct answer) (approximately 70%) c) risk assessment is the 2nd step of risk analysis, following hazard assessment (approximately 30%)
D1-4: Question 2:	Most of EFSA's opinions are drafted by its scientific staff and endorsed by external experts: true or false
D1-4: Answer 2:	a) true: only the scientific staff of EFSA is fully independent (approximately 10%) b) not true; only the panel of external experts is fully independent (approximately 10%) c) not true; the panel of external experts is fully responsible for the EFSA opinion and is supported by EFSA staff (correct answer) (approximately 80%)
D1-4: Question 3:	What is the role of the EU ECDC?
D1-4: Answer 3:	a) the ECDC provides input to the zoonosis report of EFSA (approximately 40%) b) there is no working relationship because ECDC deals with human diseases and EFSA with animal diseases (none) c) the ECDC and EFSA work together on all food borne diseases involving zoonotic organisms (correct answer) (approximately 60%)
D1-4: Question 4:	What is the most visible proof of EFSA's independence?
D1-4: Answer 4:	a) it publishes and communicates its scientific opinions independently from the EC, the EP and the EU Council (correct answer) (approximately 40%) b) its isolated seat in Parma, Italy, far from the EU institutions in Brussels (1 or 2 persons) c) it reports to its management board which is independent from the EC, the EP and the EU Council (approximately 60%)
D1-4: Question 5:	Does an EFSA opinion overrule a national opinion?
D1-4: Answer 5:	a) no, an EFSA opinion is an opinion of experts from all over the EU whereas a national opinion is developed by experts from the respective Member State (correct answer) (approximately 40%)

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	b) no, Member State opinions have legal power over EFSA opinions (approximately 20%) c) yes, EFSA opinions overrule national opinions because they are developed by independent experts from many EU Member States (approximately 40%)

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Day 2 :

Title of the presentation:	Introduction to risk assessment
Code:	D2-1
Time:	09:00 – 09:45
Description (talk about yourself at the third person) Dr Herman Koëter started the lecture with an explanation of the basic difference between hazard and risk and after that addressed hazard assessment and characterisation involving hazard identification and dose response relationships. In addition to human health effects, also environmental hazard assessment will be detailed. Next, he explained qualitive and quantitative exposure scenario's (with emphasis on the need for food consumption data collection efforts) emphasizing the diversity of consumption patters across the EU and across subsets of consumers (e.g., pregnant women, elderly people). After that Dr Koëter explained the 3rd element of risk assessment: risk characterisation. He then addressed practical application of the risk assessment outcomes such as acceptable daily intake (ADI), tolerable weekly intake (TWI) and food standards.	

Title of the presentation:	EU approach to food risk assessment
Code:	D2- 3
Time:	11:00 – 11:30
Description (talk about yourself at the third person) Dr Koëter started this lecture with a detailed description of the organisational structure of EFSA from its establishment in 2002 and how it evolved over time. He clarified the complementary roles of the respective external experts and EFSA scientific staff. Furthermore, Dr Koëter addressed in detail the selection of members of the (currently) 10 scientific expert Panels, task forces and working groups and the differences between these groups. Moreover, he explained responsibilities, declarations of interest, the concept of 'terms of reference',safeguarding the scientific quality and scientific output communication. Finally, Herman Koëter explained the role and input from Member States' experts, in particular via the Advisory Forum.	

Questions Day 2: (Questions from the audience)

D2-3, Question 1:	Are all GMO's banned in the EU?
D2-3, Answer 1:	No, there are no GMO's evaluated by EFSA the outcome of which indicated an unacceptable risk for human consumption. Also with respect to environmental safety, no GMO evaluated by EFSA showed an appreciable level of concern.
D2-3, Question 2:	How were (are) the expert panel members selected?
D2-3, Answer 2:	Calls for experts are widely and timely distributed to national authorities, government organisations, scientific societies and universities and sometimes published in scientific journals. Next, EFSA applies 2 sets of selection criteria: eligibility criteria (including the absence of a criminal record, inadequate education, private sector affiliation) and selection criteria (including experience, expertise, scientific recognition, international experience). Selected candidate experts are shared with the National food safety authorities for advice (confidential) and the draft final list is proposed to the EFSA Management Board for final approval.
D2-3, Question 3:	Can experts from countries outside the EU apply for panel membership?
D2-3, Answer 3:	Yes, anybody can apply but priority is given to EU experts. Only when a certain

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	expertise is not offered or available from EU Member States or EEA countries, experts from other countries are considered. This does not happen frequently but an example has been a US expert on BSE.
D2-3, Question 4:	How does EFSA deal with complicated substances?
D2-3, Answer 4:	(Following confirmation of what was meant), emerging difficult substances or developments are initially addressed by EFSA's Scientific Committee. An example of this is nanotechnology. EFSA initially addressed this as a self-task about the possible need of specific risk assessment approaches, soon after the Commission also started activities (stakeholder consultation) and formally requested EFSA to develop scientific guidance.
D2-5, Question 5:	Has EFSA set any priority for the assessment of the health risks of trans-fatty acids in food?
D2-5, Answer 5:	Trans-fatty acids were addressed by EFSA in 2004 and are currently not considered a priority merging risk.

Questions Day 2: (Questions posed by the tutor)

At the end of both lectures Dr Koëter presented a series of 5 questions to the audience, providing a multiple choice of responses as follows (voting was recorded electronically):

D2-1: Question 1:	What is the difference between risk assessment and risk analysis?
D2-1: Answer 1:	a) risk assessment and risk analysis mean the same b) risk assessment is part of risk analysis (correct answer) c) risk analysis is part of risk assessment
D2-1: Question 2:	Are animals always involved in the risk assessment of a food additive?
D2-1: Answer 2:	a) yes, because toxicological testing is always carried out in animals and safety cannot be assessed without toxicity testing b) no, there are alternative methods such as in vitro testing and computational approaches for some of the endpoints (correct answer)
D2-1: Question 3:	Do we have reliable European data on food consumption?
D2-1: Answer 3:	a) not yet, harmonisation across the Member States takes time (correct answer) b) yes, food consumption data from different Member States can be pooled and provide reliable information
D2-1: Question 4:	What stands for NOAEL?
D2-1: Answer 4:	a) not observable adverse effect level b) not observed as effect level c) no observed adverse effect level
D2-1: Question 5:	What is the main reason why TTC is such an important concept?
D2-1: Answer 5:	a) because it saves an enormous amount of animals (partly correct answer) b) because it saves an enormous amount of time (correct answer) c) because it saves an enormous amount of money (partly correct answer)
D2-3: Question 1:	How many EFSA Panels are assigned to carry out scientific evaluations of dossiers as dictated by EU legislation?
D2-3: Answer 1:	a) 6 (correct answer, namely ANS, CEF, FEEDAP, GMO, NDA, PPR). (72%) b) 4 (0%) c) 10 (28%)
D2-3: Question 2:	What is the current size each panel should strive for?
D2-3: Answer 2:	a) 20 (2%) b) 11 (0%) c) 21 (correct answer) (86%) d) Variable (12%)
D2-3: Question 3:	What are the kinds of potential interests that are considered to be reported?
D2-3: Answer 3:	a) financial, intellectual and perceived (correct answer) (65%)

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	b) financial, intellectual and interest related to the product being evaluated (15%) c) financial, intellectual and the expert's affiliation (20%)
D2-3: Question 4:	What are "terms of reference"?
D2-3: Answer 4:	a) conditions enabling scientists to do the scientific work requested (22%) b) information about the background and reasons for the request to do the scientific work (19%) c) detailed description and clarification of the request to do the work (correct answer) (59%)
D2-3: Question 5:	Why is communication of EFSA's Opinions very important?
D2-3: Answer 5:	a) for full transparency of the separation between risk assessment and risk management (correct answer) (29%) b) in order to provide clear and unbiased information to the European consumer (53%) c) for full transparency and visibility of EFSA (18%)

Day 3 :

Title of the presentation:	Context of EU legislation on pesticides residues, residues of veterinary medicinal products and environmental contaminants
Code:	D3- 1
Time:	09:00 – 09:30
Description (talk about yourself at the third person) Dr Koëter started explaining the fundamental aspects of maximum residue levels (MRLs) being on the one hand the most effective use of the pesticide of veterinary medicine and on the other the lowest achievable level of the pesticide or veterinary medicine in the food treated. Next he explained the differences between pesticide MRL's and MRL's for residues of veterinary medicines: e.g., the consideration of the acute reference dose (ARfD) for pesticide MRLs and the roles of the European Medicine Agency (EMA), the European Food Safety Authority EFSA) and the European Commission (EC) in the process of proposing and setting EU MRLs for pesticides and veterinary drug residues. Furthermore, Dr Koëter explained the sensitivities in the process of converting national pesticide MRLs for food products into EU MRLs. He also paid attention to the implementation of Reg. 396/2005, replacing a series of older directives. Finally Dr Koëter addressed the EFSA and EC approaches for maximum tolerable levels of chemical contaminants in food, taking into account the ALARA concept (as low as reasonably achievable).	

Questions Day 3: (Questions from the audience)

D3-6: Question 1:	Rare earth chemicals are considered a food health risk in China. Please explain on what grounds?
D3-6: Answer 1:	Rare earth chemicals appear to be used in China in fertilizers and, consequently, may end up in vegetables and potential exposure could be considerable.
D3-6: Question 2:	Are toxicity data available for rare earth chemicals?
D3-6: Answer 2:	The Chinese expert was not aware of any toxicological data for rare earth chemicals.

Questions Day 3: (Questions posed by the tutor)

At the end of the lecture Dr Koëter presented a series of 4 questions to the audience, providing a multiple choice of responses as follows responses were recorded electronically):

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D3-1: Question 1:	What are the basic elements for consideration for the MRL for pesticides?
D3-1: Answer 1:	a) the upper level of safety and the estimated level of exposure b) the upper level of safety and the lowest acceptable level of efficacy (correct answer) c) the highest level of efficacy and the estimated level of exposure
D3-1: Question 2:	What was the major hurdle in the process of EU pesticide MRL development?
D3-1: Answer 2:	a) the difference in climate and geographical conditions between EU Member States b) the lack of expertise to define MRL's in severl Member States c) economic influence in the process of setting national MRL's (correct answer)
D3-1: Question 3:	What was the most relevant incentive to the development of Reg.(EC) 396/2005?
D3-1: Answer 3:	a) high and consistent level of consumer protection across the EU (correct answer) b) fair and level playing field for the agro sector across the EU c) to improve community trade through harmonised MRL's
D3-1: Question 4:	What is the biggest risk of relatively high levels of veterinary medicinal product residues in animal products?
D3-1: Answer 4:	a) risk of toxic effects in consumers of contaminated animal products b) risk of antimicrobial resistance in animals, environmental species and humans (correct answer)

Session	
Summary of site visits/discussions and conclusions	

Day 4 : *<make a summary of 7-8 lines of your presentation(s)/one frame by presentation>*

Session	
Summary of site visits/discussions and conclusions	

Question Day 4: *<list questions asked by participants in your field of expertise>*

Question 1:	
Answer 1:	

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Question 2:	
Answer 2:	

Day 5 : *<make a summary of 7-8 lines of your presentation(s)/one frame by presentation>*

Session	
Summary of site visits/discussions and conclusions	

Question Day 5: *<list questions asked by participants in your field of expertise>*

Question 1:	
Answer 1:	
Question 2:	
Answer 2:	