

Quality Management and Risk Analysis (I001750)

Course size (nominal values; actual values may depend on programme)
Credits 5.0 Study time 125 h Contact hrs 60.0 h

Course offerings and teaching methods in academic year 2018-2019

Offering	Language	Teaching Method	Hours	
A (semester 2)	English	seminar: practical PC room classes	5.0 h	
		microteaching	5.0 h	
		lecture: plenary exercises	5.0 h	
		group work	10.0 h	
		guided self-study	2.5 h	
		lecture	17.5 h	
		seminar: coached exercises	15.0 h	

Lecturers in academic year 2018-2019

Jacxsens, Liesbeth	LA23	lecturer-in-charge
De Schamphelaere, Karel	LA22	co-lecturer
Spanoghe, Pieter	LA21	co-lecturer
Uyttendaele, Mieke	LA23	co-lecturer
Van Labeke, Marie-Christine	LA21	co-lecturer

Offered in the following programmes in 2018-2019

Programme	crdts	offering
Master of Science in Bioscience Engineering: Chemistry and Bioprocess Technology	5	A
Master of Science in Bioscience Engineering: Agricultural Sciences	5	A
Master of Science in Bioscience Engineering: Food Science and Nutrition	5	A
Exchange Programme in Bioscience Engineering: Agricultural Sciences (master's level)	5	A
Exchange Programme in Bioscience Engineering: Cell and Gene Biotechnology (master's level)	5	A
Exchange Programme in Bioscience Engineering: Chemistry and Bioprocess Technology (master's level)	5	A
Exchange Programme in Bioscience Engineering: Food Science and Nutrition (master's level)	5	A

Teaching languages

English

Keywords

Quality : quality management systems, traceability, integrated quality management, document management, sampling techniques, measurement and control techniques,
Risk analysis : exposure assessment, risk assessment, risk analysis, human toxicology, introduction to REACH, ecotoxicology, agro-food chain

Position of the course

The objective of the course is to introduce the concepts of quality management and risk analysis, which are important topics in future careers of bioscience engineers in production companies or organisations in the agro-food chain.

A general introduction to quality management systems in primary production, food processing and (agro)-chemical production companies/organisations is given. The principles of quality management, quality assurance and quality control to production

systems and units are explained, important to govern quality and safety of produced products. This course broadens up the world of bioscience engineers to understand how a quality management system supports a production process. A general introduction to risk analysis and its compounds risk assessment, risk communication and risk management is also given. Focus is both on impact on human health (due to intake via food or direct contact with chemicals – human risk assessment) and impact on the environment (ecological risk assessment). The concepts of risk analysis and quality management are further technically explored and illustrated during the modules.

Contents

The first 6 weeks theoretical lectures are given on quality management and risk analysis, followed by 6 weeks of modules, where the more technical aspects of quality management and risk assessment are explored by the students. Practical illustrations are foreseen by invited guest speakers of companies or organisations.

1. Common part (week 1 until 6)

1.1. Theory

A. General introduction to quality and quality management

Definitions of quality and quality management systems are discussed. An overview of the evolution of quality and quality management systems is given and the building blocks of quality management system are explained.

B. Overview of relevant quality assurance standards

In this lecture, most common quality assurance standards applied in the agri-food chain and against which certification is possible (e.g. ISO 9000, BRC, IFS, GlobalGAP).

Focus is on the integration of the different standards towards a company specific quality management system. Principles of audit, certification and accreditation are discussed.

C. Traceability and integrated quality management

The principles of traceability and integrated quality management are explained and illustrated with case studies of invited companies in the agri-food chain. Principles, components and chain interactions are discussed. Based on case studies, important constraints or difficulties of implementation of traceability system are illustrated.

D. Introduction to risk analysis - human risk assessment

The principles of risk analysis are explained namely, risk assessment, risk management and risk communication. Focus will be on risks related to human health (e.g. via food intake or direct contact with chemicals) but also ecological risks (due to environmental pollution). Classification of risks into risk profiles are explained and also the more technical, probabilistic approaches in risk assessment.

E. Risk evaluation of chemical compounds - introduction to REACH

REACH (Registration, Evaluation, Authorisation and restriction of CHEMicals) stands for the harmonized risk assessment (human and environmental risk assessment) at European level of chemicals produced and imported in EU. REACH is currently the most important regulatory framework in the management and evaluation of chemicals. This introduction to REACH will discuss:

- fundamental aspects of REACH (human and environmental exposure, dose response curve, risk assessment, non-animal testing, QSAR, quality of studies and quality of data)
- description of the models and methodology, description of data requirements for human and environmental risk assessment, mitigation measures in case of risk occurrence.

F. Introduction to ecological risk assessment

Ecological risk assessment concerns evaluation of risks of chemicals to ecosystems (aquatic and terrestrial). First, the similarities and differences between approaches in ecological and human risk assessment are indicated. Various EU legislative and regulatory frameworks on ecological risks for different groups of chemicals are briefly introduced (industrial chemicals, priority substances, plant protection products, pharmaceuticals). Finally, different methods and approaches for estimating exposure (environmental concentrations) and effects on organisms and ecosystems (e.g., “no-effect” concentrations) are illustrated and brought together to assess ecological risks.

1.2. Exercises

A. Sampling techniques (generic principles on sampling plans are discussed i.e. variability and uncertainty, sample size, stratification, randomisation) : theory and PC exercises

B. Measurement and control techniques : theory and PC exercises.

- quality from the perspective of the producer (company) : Statistical Process Control (SPC), batch versus continuous sampling,
- quality from the perspective of the consumer : quantification of uncertainty and quality, OC-curves

C. Document management

Explanation of writing and managing procedures, instructions and registration forms in a quality management system. Illustration via a lecture from a company active in agri-

(Approved)

food chain explaining how documents are written, managed and a quality management system as a whole is organised.

2. Modules (week 7 until 12)

In the next weeks, students can choose two modules according to their interest, one from group A (related to risk assessment) and one from group B (related to quality management systems). For students from the MSc in Bioscience Engineering: Food Science and Nutrition it is obligatory to select module 2 and module 3.

Modules are under permanent evaluation.

o group A (modules in risk assessment)

* Risk assessment in the agri-food chain related to human health risks (via food intake) (module 3);

* Human exposure and risk assessment to chemicals (module 5);

* Ecological risk assessment in practice (module 6);

o group B (modules in quality management)

* Quality management system in a laboratory (module 1);

* Quality management system in the food industry (module 2);

* Quality management system in the primary production (agricultural level)(module 4)

• Module 1 : Quality management system in a laboratory:

Exercises and case studies on the implementation of a quality management system in a laboratory according to the ISO 17025 principles. A case study will be conducted by the students in a microbiological and/or chemical laboratory.

• Module 2 : Quality management in the food industry:

Exercises and case studies on the introduction of Good Manufacturing Practices (GMP), Pre Requisite Programs (PRP) and Hazard Analysis Critical Control Points (HACCP) in a food processing industry will be trained. Also exercises on the implementation of quality assurance standards, typical for the food industry are given (e.g. BRC, IFS). Case study on the elaboration of a company specific HACCP plan by small groups of students will be prepared, reported and presented. A company visit is foreseen to illustrate a food safety management system in practice.

• Module 3 : Risk assessment in the agri-food chain related to human health risks (via food intake):

Risk assessment calculations on microbiological and chemical hazards in foods are explained. Also exposure to pesticide residues via food or via application of pesticides is discussed. Application of typical software @risk to make probabilistic risk estimations on human exposure is taught to the students. Students will work out a case study and prepare a report and defend their work via a presentation.

• Module 4 : Quality management in primary production (agricultural level):

Exercises and case studies on the implementation of a quality management system at primary production (farm level) in the plant production or in the animal production are conducted. A farm visit is organised and an audit or inspection against a quality assurance standard is conducted, reported in small groups.

• Module 5 : Human exposure and risk assessment to chemicals:

Implementation of human exposure models such as consexpo, BROWSE,... to assess the risk of exposure to chemical contaminants. A case study of these models will be given in an introduction course. Students work out an exposure scenario around a biocide, they collect input data, evaluate data quality, prepare a human risk assessment and present their work. Different software tools for human risk evaluation of chemicals will be used in this case study.

• Module 6 : Ecological risk assessment in practice:

This module will start with a laboratory practical that includes a standard ecotoxicity test and a biodegradation test with a chemical substance. This will be followed by two PC-exercises in which the students will perform data treatment on the test results, and evaluate persistence, bioaccumulation, toxicity (PBT) and estimate environmental concentrations and ecological risks for this substance. Finally, the students will, in groups of 4-6, select an EU substance dossier that is under so-called "public consultation" and critically review it (including checking the calculations). The results of the critical review will be presented and discussed (and perhaps submitted as a public comment to the EU).

Initial competences

Profound knowledge of the structure, organisation and typical processes applied in the agri-food chain (processes, technologies)

Knowledge on biological and chemical reaction mechanisms

Quality Management and Risk Analysis builds on certain learning outcomes of course unit 'Modelling and Simulation of Biosystems'; or the learning outcomes have been achieved differently.

Final competences

- 1 Describe, distinguish and discuss the basic principles and properties of quality and quality management systems
- 2 Define, explain and judge the principles of traceability in the agri-food chain.
- 3 Give the step in risk analysis in agri-food chain (REACH and food safety and ecological risks), elucidate and assess.
- 4 Apply document management in a quality management system.
- 5 Apply and analyse statistical sampling plans and measure and control techniques in the frame of a quality management system.

Conditions for credit contract

Access to this course unit via a credit contract is determined after successful competences assessment

Conditions for exam contract

This course unit cannot be taken via an exam contract

Teaching methods

Guided self-study, group work, lecture, microteaching, lecture: plenary exercises, seminar: coached exercises, seminar: practical PC room classes

Extra information on the teaching methods

The first 6 weeks (common part theory and practicum) exists out of lectures, plenary exercises, PC exercises.

The last 6 weeks (modules) exists , depending on the module, out of : Seminar: coached exercises, Seminars: practical PC room classes, Group work and Micro teaching (presentation)

Learning materials and price

A syllabus and documents are available on Minerva Cost: 20 EUR

References

- Luning P.A., Marcelis W.J. 2009. Food Quality management. A techno-managerial approach. Wageningen Press. 323 p.
 Luning P.A., Devlieghere, F., Verhé, R.. 2006. Safety in the agri-food chain. Wageningen Press, 684
 Vose D. 2000. Risk analysis; a quantitative guide. Wiley.418 p.

Course content-related study coaching

For the theory as well as for the theoretical exercises, the student has the possibility to ask extra information or explanation to the lecturer during contact hours or e-mail. Several assistants are involved in the practical exercises and can be contacted for extra information. Slides of the lectures are available via Minerva.

Evaluation methods

end-of-term evaluation and continuous assessment

Examination methods in case of periodic evaluation during the first examination period

Written examination, open book examination

Examination methods in case of periodic evaluation during the second examination period

Written examination, open book examination

Examination methods in case of permanent evaluation

Assignment, report

Possibilities of retake in case of permanent evaluation

examination during the second examination period is possible

Extra information on the examination methods

PGE (for the content of the first 6 weeks (common part)):

The examen theory exists out of open questions in closed book formula

The examen practicum exists out of open questions in open book formula (all related documents and preparations can be used by the student)

The examens are only in written version.

NPGE (for the content of the last 6 weeks (modules)):

Dependent of the chosen module a workpiece is prepared or a report which is presented to the professor of the module.

Calculation of the examination mark

PGE Exam theory : 35%

PGE Exam practicum : 15%

NPGE module : 25%

NPGE module : 25%

Total : / 20

Students who eschew periodic and/or permanent evaluations for this course unit may be failed by the examiner.