## Course Specifications

Valid as from the academic year 2016-2017

### Quality Management and Risk Analysis (I001750)

#### Course Size

<table>
<thead>
<tr>
<th>Credits</th>
<th>Study time</th>
<th>Contact hrs</th>
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<tbody>
<tr>
<td>5.0</td>
<td>125 h</td>
<td>60.0 h</td>
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</tbody>
</table>

#### Course Offerings and Teaching Methods in Academic Year 2017-2018

- **A (semester 2)**
  - Guided self-study: 2.5 h
  - Microteaching: 5.0 h
  - Group work: 10.0 h
  - Seminar: coached exercises: 15.0 h
  - Lecture: 17.5 h
  - Seminar: practical PC room classes: 5.0 h
  - Lecture: plenary exercises: 5.0 h

#### Lecturers in Academic Year 2017-2018

- Jacxsens, Liesbeth (LA07, lecturer-in-charge)

#### Offered in the Following Programmes in 2017-2018

<table>
<thead>
<tr>
<th>Programme</th>
<th>Credits</th>
<th>Offering</th>
</tr>
</thead>
<tbody>
<tr>
<td>Master of Science in Bioscience Engineering: Chemistry and Bioprocess Technology</td>
<td>5</td>
<td>A</td>
</tr>
<tr>
<td>Master of Science in Bioscience Engineering: Agricultural Sciences</td>
<td>5</td>
<td>A</td>
</tr>
<tr>
<td>Master of Science in Bioscience Engineering: Food Science and Nutrition</td>
<td>5</td>
<td>A</td>
</tr>
<tr>
<td>Exchange Programme in Bioscience Engineering: Agricultural Sciences (master's level)</td>
<td>5</td>
<td>A</td>
</tr>
<tr>
<td>Exchange Programme in Bioscience Engineering: Cell and Gene Biotechnology (master's level)</td>
<td>5</td>
<td>A</td>
</tr>
<tr>
<td>Exchange Programme in Bioscience Engineering: Chemistry and Bioprocess Technology (master's level)</td>
<td>5</td>
<td>A</td>
</tr>
<tr>
<td>Exchange Programme in Bioscience Engineering: Food Science and Nutrition (master's level)</td>
<td>5</td>
<td>A</td>
</tr>
</tbody>
</table>

#### Teaching Languages

English

#### Keywords

- Quality management systems, quality assurance, quality control, risk assessment, risk analysis, introduction to REACH, traceability, integrated quality management, document management, sampling techniques, measurement and control techniques

#### Position of the Course

A general introduction to implementation of quality systems in agricultural and food production units. The principles of quality management, quality assurance and quality control given apply specifically to production systems and units important for bio-engineers.

#### Contents

1. **Common part (week 1 until 6)**

1.1. **Theory**

A. General introduction:

(Approved)
Definitions of quality and quality management systems are discussed. Focus is made on the quality of biological systems in the agri-food chain. An overview of the evolution of quality and quality management systems is given and illustrated.

B. Overview of quality assurance standards
In this lecture quality assurance standards applied in the agri-food chain and against which certification is possible (e.g. ISO, HACCP, Good Manufacturing practices (GMP), PRP, BRC, IFS, GlobalGAP). Focus is made on the integration of the different standards towards a company specific quality management system. Principles of 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 is illustrated.

D. Risk analysis:
The principles of risk analysis are explained namely, risk assessment, risk management and risk communication, according to the Codex Alimentarius principles. Risk analysis on international level is discussed and the link to typical risk profiles. Diverse aspects of risk analysis are illustrated with examples in the agri-food chain.

E. Risk evaluation of chemical compounds - introduction to REACH
The introduction of an evaluation system for chemicals in EU REACH (Registration, Evaluation and Authorisation of Chemicals) imposes an important shift in the management and evaluation of chemicals. This introduction to REACH will discuss:
- fundamental aspect (risk, safety, environmental constraints, human health aspects, sustainability, etc)
- description of the models and methodology for calculation of exposure, effects evaluation and risk analysis

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
- quality from the perspective of the producer (company) : Statistical Proces Control (SPC), batch versus continuous sampling, Shewart chart, CONSUM charts
- quality from the perspective of the consumer : quantification of uncertainty and quality, OC-curves
Theory and PC exercises.

C. Document management
Explanation of writing and managing procedures, instructions and registration forms in a quality management system. Illustration via a guest lecture from a company active in the agri-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 chose two modules according to their interest, one from group A and one from group B. For students from the MSc in Bioscience Engineering: Food Science and Nutrition or MSc in Nutrition and Rural Development or MSc in Food technology, it is obligatory to select module 2 and module 3.

o group A:
  * risk analysis in the agri-food chain (module 3);
  * quality management system in the primary production (farm level)(module 4)
  * REACH : implementation, modelling and case studies (module 5)

o group B:
  * quality management system in a laboratory (module 1);
  * quality management system in the food industry (module 2);
  * quality- and risk perception of consumers (module 6);

• 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 chemical laboratory investigating food products. An audit will also be performed as case study.

• Module 2 : Quality management in the food industry:
Exercises and case studies on the introduction of Good Manufacturing Practices

(Approved)
Access to this course unit via a credit contract is determined after successful competences assessment. This course unit cannot be taken via an exam contract. Guided self-study, group work, lecture, microteaching, lecture: plenary exercises, seminar: coached exercises, seminar: practical PC room classes.

(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 illustrated a food safety management system in practice.

• Module 3 : Risk analysis in the agro and food industry :
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 trained 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 (farm 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 :REACH:
Implementation of REACH, models behind REACH and case studies of REACH and toxicological implications on environment or humans are trained. In an illustrative way, implementation projects (RIPs) are discussed. A software tool for risk evaluation of chemicals is evaluated (EUSES). Students prepare an exercise as case study and present their work.

• Module 6 : Quality and risk perception by the consumer :
Preferences of consumers are evaluated in the last years of quantity to quality. The importance of healthy diet and the relation between food and human health are reasons for the shift on consumer behavior and consumption patterns. Case studies are worked out around these principles and evolutions.

Initial competences
- Profound knowledge of the structure, organisation and typical processes applied in the agri-food chain.
- 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 steps in risk analysis in agri-food chain (REACH and food safety), 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).

(Approved)
Learning materials and price

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

References


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

day-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

evaluation 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 exits out of open questions in closed book formula
The examen practicum exits 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.