

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Examinations 2016

Module Title: Regulation of Products for Human Consumption

Module Code: BIOL 7024

School: Biological Sciences

Programme Title: Bachelor of Science (Honours) in Nutrition and Health Science

Programme Code: SNHSC_8_Y3

External Examiner(s): Professor Aine McKillop

Internal Examiner(s): Ms Anna-Maria Keaveney

Instructions: Answer all questions

Duration: Examination period – 2 hr

Sitting: Semester 1

Requirements for this examination:

Answer any **four** questions

Note to Candidates: Please check the Programme Title and the Module Title to ensure that you have received the correct examination paper.
If in doubt please contact an Invigilator.

1. Discuss **two** of the following organisations in terms of their regulatory role
(25 marks)
 - a. Health Product Regulatory Authority
 - b. International Council on Harmonisation
 - c. Food Safety Authority of Ireland
 - d. International Organisation for Standardisation
2. Discuss the role of Quality Assurance, Good Manufacturing Practice and Quality Control in the production of Pharmaceutical products
(25 marks)
3. Discuss the requirements for making a nutritional labelling claim in terms of current EU legislation
(25 marks)
4. Discuss the four principles of biomedical ethics
(25 marks)
5. Compare and contrast US and EU regulatory requirements for a cosmetic product
(25 marks)