

Exam Date & Time: 20-Jul-2022 (10:00 AM - 01:00 PM)



## MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.

### REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS [PQA-MRA204T-S1]

Marks: 75

Duration: 180 mins.

#### SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

- 1) M/S AEN enterprises is a company involved in the following activities:  
 Rearing and milking of cows  
 Pasteurising, packing and selling milk.  
 Selling flavoured milk. (10)  
 Preparing and selling normal and fortified yoghurt.  
 Identify the activity/ies where NSF can be involved in certifying/consulting/training etc with the company
  
- 2) Define with at least one example each of the following: (10)
  - a. Nutraceuticals.
  - b. Dietary Supplement
  - c. Fortified Food.
  - d. Functional Food.
  - e. Medical Food
  
- 3) Mr. Abdul Khader, Mr. Jaleel and others are conducting a restaurant by name "Salwa Cafe" at Vazhuthacaud junction, Thiruvananthapuram. The allegation was that on 10.7.2012, the second accused prepared food article by name 'Shavarma', which was injurious to health and that was sold to several persons, who developed complications and that, around 10 persons were admitted in different hospitals in Thiruvananthapuram. It is alleged that a person by name Sachin Mathew Roy, aged 21 years, also purchased and consumed 'Shavarma' from the restaurant of the petitioners on 10.7.2012 and he developed serious gastro problem, which resulted in his death at Bangalore. It is further known that with regard to the death of Sachin Mathew Roy, Crime No.UDR/No.52/12 under section 174 of the Code of Criminal Procedure was registered in Kalasipalayam police station and it is being investigated. (10)  
 Based on the complaint received, Museum police has registered Crime No.732/2012 alleging offences under Sections 273, 328 and 34 of the Indian Penal Code and Food Safety and Standard Act, 2006.  
  
 On 12.7.2012 at about 8 p.m the Joint Food Safety Commissioner, Sri.K. Anil Kumar received a complaint over phone from Mr. Shobi Thilakan that he and his family were severely affected by food poisoning by consuming the 'Shavarma' in the evening on 10.7.2012 from the restaurant and they were undergoing treatment at PRS Hospital, Thiruvananthapuram. Based on the information, Food Safety Officer, Mobile Vigilance Squad, Thiruvananthapuram was entrusted to enquire the matter and report. By about 8 p.m on 12.7.2012 he met Sri.Shobi Thilakan and Dr. Rakesh

of Gastroenterology Department at the hospital, who was treating these patients and prepared statement. It is a clear case of food poisoning and Sri. Shobi Thilakan asserted that the 'Shavarma' he consumed was the reason for the food poisoning and explained the course of events as he purchased four 'shavarma' parcel by 8 p.m on 10.7.2012, went home and he and his wife and two children ate the same by 9 p.m. By early morning, all of them started vomiting and had Diarrhea etc. He had also informed that Aravind, aged 14, Muhammed Ammar, aged 8, Krishnanthampi and three other family members were also under treatment at the PRS Hospital due to consumption of 'Shavarma'. Out of them, Anand was in the IC Unit whose condition was critical. Food Safety Officer, Mobile Vigilance Squad, Thiruvananthapuram had conducted inspection in the premises of 'Salwa Cafe' at 9.30 p.m on 12.7.2012 and found that the hotel was running in unsanitary conditions and the proprietor failed to produce the PFA licence or Food Safety Standard Licence and medical fitness certificate of employees and hence ordered to close down the hotel under oral instruction from Commissioner of Food Safety.

Answer the following questions:

What should be the next action of food authority?

Are police justified and legally correct in registering the offence under Code of Criminal Procedure and FSSA?

Under which sections of FSS rules 2011 these offences can be registered against the hotel owners

- 4) Write a note on dietary supplement GMP under the following:
- i. Applicability.
  - ii. Standard operating procedures. (10)
  - iii. Master Manufacturing Record
  - iv. Personal and Plant
  - v. Manufacturing Control
- 5) List the functions of EFSA  
Compare between the GMP of food and pharmaceutical as per EU regulations (5+5 marks) (10)

## SECTION - B

**Answer all the questions.**

Answer the following (5 marks x 5 = 25 marks)

- 6) Write a note on nutraceuticals. (5)
- 7) Following evidence is available on vitamin D supplementation.  
A Cochrane systematic review assessed whether supplements with vitamin D alone or in combination with calcium and/or other vitamins and minerals given to pregnant women can safely improve maternal and neonatal outcomes. There was no evidence of an effect on either maternal pre-eclampsia in pregnant women receiving vitamin D plus calcium supplementation or on the risk of having a low birth weight infant (less than 2500 g) in pregnant women receiving vitamin D supplementation alone compared with pregnant women not receiving supplementation or receiving a placebo. Pregnant women who received vitamin D supplementation alone had significantly higher serum concentrations of 25-hydroxyvitamin D at term compared with those not receiving supplementation or placebo. Only one trial reported on side-effects, with the results indicating no difference in the prevalence of nephritic syndrome as a side-effect in pregnant women receiving vitamin D supplementation (5)

alone as compared with women not receiving supplementation or receiving a placebo. Thus currently there is insufficient evidence to directly assess the benefits or harms of vitamin D supplementation during pregnancy on maternal and infant health outcomes.

Based on this write the recommendations.

- 8) M/S AAK foods imports 1 million units of deep fried chips to India from Malaysia. After inspecting the consignment authorised officer informs the company that the label on the product is not as per the regulations. What are the options available to company as per Food Safety Standards (Import) order 2017? (5)
- 9) What are dietary supplements as per USFDA. (5)
- 10) LaJavaB Industries is engaged in preparing Indian Gooseberry (Amla) pulp. Is this manufacturer subjected to USGMP guidelines? Justify. (5)

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