

Total No. of Questions : 12]

SEAT No. :

**P1171**

**[4659] - 368**

[Total No. of Pages : 4

**B.E (Biotechnology)**

**B:IPR, BIOETHICS AND REGULATIONS  
(2008 Pattern) (Elective - IV ) (Semester - II)**

*Time : 3 Hours]*

*[Max. Marks : 100*

*Instructions to the candidates:*

- 1) *Solve Q-1 or Q-2, Q-3 or Q-4, Q-5 or Q-6, Q-7 or Q-8, Q9 or Q-10, Q-11 or Q-12.*
- 2) *Neat diagrams must be drawn wherever necessary.*
- 3) *Figures to the right indicate full marks.*
- 4) *Assume suitable data if necessary.*
- 5) *Answer to the two sections should be written in separate answer books.*

**SECTION - I**

**Q1)** Define ethics. What are the rights and responsibilities of researcher? Describe the functions of institutional ethics committee. **[18]**

OR

**Q2)** What is ICMR code? What does it consist of? Explain in short about 12 principles laid down under statement on general principles? **[18]**

**Q3)** What is bioethics? What are basic bioethics principles? Discuss any one in detail with one example. **[16]**

OR

**Q4)** Read the following case study and answer the questions. **[16]**

Confirmed fish kills in North Carolina were observed in 1994 in the Pamlico and Neuse Estuaries. Fish losses were reported to be in the millions. Reports of dead fish found floating in North Carolina tidal waters caused a great deal of concern. In the summer of 1997, thousands of fish were killed in the Pocomoke River on Maryland's Eastern Shore. Consequently, the public was

**P.T.O.**

banned from a five-mile stretch of the scenic waterway. Local watermen had begun reporting gaping red sores on fish almost a year previously but the fish kills and public ban brought this issue to national attention.

Research has shown that *Pfiesteriapiscicida*, a single-cell microorganism, is responsible for the fish kills in North Carolina, and is suspected to be the cause of fish kills in Maryland as well. *Pfiesteriapiscicida* has a complex life cycle that may include 24 flagellated, amoeboid, and encysted stages or forms. *Pfiesteria* may live for years in tiny, cyst-like shells buried in river bottom sediment, then hatch when conditions are right. Conditions supporting and / or encouraging *pfiesteria* are a combination of warm water temperatures (70F); increased levels of phosphorous, ammonium, and suspended solids; moderate to low salinity levels; and increased rainfall or runoff. When large numbers of fish swim into an area where *Pfiesteria* are present their excreta triggers encysted cells to emerge and become toxic. Other stages of *Pfiesteria* can also become toxic in the presence of fish excreta (amoeboid and flagellated cells). The small cells swim toward the fish prey and give off potent toxins which make the fish lethargic and often cause bleeding sores and hemorrhaging. Once fish are incapacitated, *Pfiesteria* feeds on the sloughed epidermal tissue, blood, and other substances that leak from the sores. When the fish are dead, flagellated stages transform to amoeboid stages and feed on the fish remains or, if conditions become unfavorable for the *Pfiesteria*, the *Pfiesteria* cells make protective outer coverings and sink to the bottom of the river as dormant cyst stages. All of these changes can take place in a matter of hours.

*Pfiesteria* outbreaks in North Carolina were shown to occur in waters that were heavily nutrient enriched. Possible sources of nutrients flowing into the water include sewage treatment plants, fertilizer runoff, chicken and hog manure, phosphate mines, and municipal wastewater treatment plants where effluents are rich in phosphorus and nitrogen.

The primary contributor to the problem in North Carolina, however, seems to be the state's large confinement hog-farming operations. After the outbreak in Maryland, a leading environmental group called for reforms in the handling of manure from the Eastern Shore's millions of chickens. Chicken waste is often applied to fields as fertilizer. Rain washes the nitrogen and other nutrients in the manure into the surrounding waters. The Pocomoke River, at its headwaters, drains the largest chicken -producing country in the nation. Maryland's Delmarva peninsula houses some 625 million chickens. Governor Glendening of Maryland has announced that farmers may soon be subject to regulations on animal waste disposal.

Maryland's top farm official has been quoted as saying that poultry farmers have been responsible in their handling of chicken waste. A spokesman for the poultry industry rejects the suggestion that chicken manure is responsible for the Pfiesteria outbreak, saying bird waste is well-managed. Farming advocates also note that if regulatory measures target only one possible source, the regulations might unfairly cause producers to go out business. Farmers work on small profit margins under current management practices.

Questions:

- a) Do you think that news reports, researchers, and politicians unfairly blame farmers without looking at other possible causes?
- b) If large poultry or hog operations are shown to be the primary cause of the pfiesteria outbreaks, should the producers be required to get rid of these animals? or reduce them to a certain number that will produce less waste?
- c) The chicken industry spokesman said that "bird waste is well-managed", implying that there is no cause for concern. Do you believe this statement? Can you think of assurances from another industry that were later proven false? How much of the public perception is formed by what we read and see and how much is formed by previous experiences?
- d) Should large, corporate, farms be allowed only in less populated states? Does a land owner have the right to use their land as they wish? Where should we set the boundaries between personal rights and the rights of society?

**Q5)** What do terms patent pending and patent applied for means? Can computer software and business methods be patented? What is the difference between non obviousness and inventive step? **[16]**

OR

**Q6)** What are the conditions for patentability? Describe any two conditions in detail. What are the different types of patents which are not patentable in India. **[16]**

## SECTION - II

**Q7)** Define copyright, trademark and domain name. Describe in detail about the requirements for registration for a trademark? [18]

OR

**Q8)** What is trade mark act 1999? What does trademark indicate? What does a trademark guarantees? What is the significance of trademark? [18]

**Q9)** Answer the following.

a) Draw a schematic showing the hierarchal structure in Indian biotechnology. [10]

b) Enlist any six functions of drugs controller general (India) DCGI [6]

OR

**Q10)** Describe the current good manufacturing practices for drugs. [16]

**Q11)** What is clinical research? What are the different types of clinical research? Describe the various phases in Clinical Research in detail. [16]

OR

**Q12)** What is quality assurance and quality control. What is the difference between QA and QC? Explain in detail about the steps involved in QC of any one biotech product assurance and quality control? [16]

