Due to the potentially hazardous nature of industrial microbiology there are many directives and laws in place to ensure safe working practices.

On successful completion of this topic you will:
- understand current legislation relating to industrial microbiology (LO5).

To achieve a Pass in this unit you will need to show that you can:
- discuss the statutes that are relevant to industrial microbiology and their impact (5.1).
1 **EU directives**

European Union (EU) directives are legal acts provided for in the EU Treaty and published in the Official Journal of the EU, whereupon they enter into force. They set out certain minimum standards for health and safety of workers or consumers of products that must be achieved by every member state within a certain time frame, but they do not dictate how the standards are to be achieved. Member states are obliged to alter their own laws if necessary to make the EU directives law. Member states can establish higher levels of protection than those cited in the EU directives.

2 **Statutes relevant to industrial microbiology**

**EU Drinking Water Directive 98/83/EC**

This obliges member states to regularly monitor the quality relating to microorganisms, chemicals and compounds that produce odour, taste and affect the clarity of drinking water, to protect the health of consumers and to give them up to date information on its quality in relation to it being wholesome and clean.

The standards set by the EU are based on World Health Organization (WHO) guidelines for drinking water. There are 48 microbiological and chemical parameters that have to be tested and monitored regularly but water supplies serving fewer than 50 people may be exempt.

**Nitrates Directive 91/676/EEC**

This is part of the Water Framework Directive and its objective is to reduce water pollution by nitrate fertilisers used in farming. There are stages of implementation that involve identifying nitrate levels (which should be below 50 mg dm$^{-3}$) in water that may be used as sources of drinking water and identifying any water (fresh, estuarine or coastal) that is eutrophic; identifying areas of land that may drain into polluted water; and establishing an action programme – a good code of practice for farmers in relation to applying nitrate fertilisers and dealing with livestock manure.

Every four years member states must monitor and report on the nitrate concentration of drinking water supplies and also assess the effectiveness of their action programmes.

### Activity: When should fertilisers be applied?

Farmers are advised to:

- test the soil and ascertain its nitrate levels so that only as much nitrate fertiliser as is required is added
- not add fertiliser when it is raining
- only add fertiliser to fields that have crops growing
- make sure some winter crops are planted so soil is never bare
- leave an untreated strip around the edge of any field adjacent to a water course.

### Questions

1. Explain why fertiliser should not be added to soil when it is raining.
2. Explain why fertiliser should only be added to fields that have crops growing.

### Take it further

Research and find out:

1. How does digging up pastureland affect the nitrate content of nearby water courses?
2. How did the ‘Dig for Victory’ campaign of the Second World War affect the nitrate content of water courses in the UK and why is the effect still present today?
3. How are farmers expected to deal with their livestock slurry?
2.5: Current legislation relating to industrial microbiology

Activity: Analysing nitrate content of water

Nitrate levels in water greater than 4 mg dm⁻³ (4 parts per million [ppm]) can lead to eutrophication. In drinking water concentrations in excess of 10 mg dm⁻³ can lead to methaemoglobinia (blue baby syndrome) in infants but is harmless to adults; concentrations in excess of 50 mg dm⁻³ are deemed unsafe for adults and young livestock ruminants; concentrations in excess of 100 mg dm⁻³ are toxic to adult ruminants. Nitrate is colourless, tasteless and odourless.

- Use the test strips to find the nitrate levels in a range of water sources.
- Discuss the quality of these water sources.

Urban Waste Water Treatment Directive 98/15/EC

This is an amending act to enable member states to better interpret the Urban Waste Water Treatment Directive (UWWTD) of 1991 (91/271/EEC), which aims to protect the environment by directing how urban waste water is treated and discharged into the environment. The directive states the size in population equivalents (p.e.) of areas that should have collection and treatment systems for urban waste water and also requires that member states draw up and regularly update lists of areas that receive treated water, and send a copy of these published lists to the European Commission.

As different member states interpreted UWWTD 91/271/EEC differently, amendment 98/15/EC was introduced and specified that daily averages could be used for calculating total nitrogen concentration of water in conurbations of 10 000–100 000+ population equivalents.

Activity: Measuring BOD₅

Analyse samples of water to find the 5-day biochemical oxygen demand (BOD₅).

- Collect samples of water from different sources such as sewage outlets, fast flowing streams, ponds, bottled water and tap water (blank), in sterile 250 ml stoppered bottles.
- Use a dissolved oxygen probe to measure the dissolved oxygen content, in g dm⁻³, of each.
- Replace the stoppers and make sure they fit snugly.
- Wrap foil around the bottles to exclude light and prevent the growth of any photosynthetic algae. Place these in a cool box with ice blocks to transport them back to the lab.
- Incubate the samples at 20 °C for 5 days.
- Measure the dissolved oxygen again.
- Calculate the BOD₅, as follows:
  \[ \text{BOD}_5 = \text{change in dissolved oxygen of sample} - \text{change in dissolved oxygen in blank} \]
- Tabulate and comment on your results.

Genetic Manipulation Regulations 1989

Environmental regulation of biotechnology differs between member states of the EU. In the UK, under the Genetic Manipulation Regulations 1989, it is mandatory for any institution to give 30 days’ notice to the Health and Safety Executive of any intended genetic manipulation of cells or organisms or to give 90 days’ notice of intended release of GMOs (such as crop plants for field trials) into the environment. They must also submit a risk assessment. The Health and Safety Executive then consults with the Advisory Committee on Genetic Manipulation (ACGM), made up of scientific and medical experts, and employee representatives before responding.
Case study: Trials of genetically modified wheat

Aphid-resistant wheat has been developed at Rothamsted Research. DEFRA issued its consent for Rothamsted to carry out a trial of this wheat. The wheat has a gene inserted that produces aphid alarm pheromone and repels aphids.

Protesters planned to sabotage the trials but the trial, said to be of significant scientific and historical value, was protected by a High Court Injunction. The trials were protected by security cameras and anyone who breached the injunction faced a large fine or imprisonment. Protest groups say that the wheat is of no value in the UK but perhaps they forget that in other countries (or here in the future) such modified wheat may be important for food security and, as it reduces the need for chemical pesticides, benefits the environment in both the short and long term. In any case, we cannot know if these crops pose a threat if trials are not carried out. People were still allowed to register their protests but not to carry out criminal damage in the process.

Scientists value constructive debate on issues of genetically modified crop plants and have invited the protest group to take part, but to date this invitation has been declined. Huge amounts of chemical pesticides are used to control insects that are crop pests and ecologists want to know if there are less harmful ways of controlling such insects. Aphid-repellent wheat grows well in the lab, in the growth chamber and in the greenhouse so they need to know if it will grow in the field.

What many people do not realise is that crop plants are fairly fragile, which is why we do not get invasions of crop plants into uncultivated areas of land. GM crop plants are equally fragile so are unlikely to contaminate other plants. Ironically it is garden plants that pose a great threat to the environment, such as rhododendrons and Japanese knotweed, but no one goes to garden centres to protest about introduced plants and the ecological damage they do!

As well as Rothamsted, the John Innes Centre, the James Hutton Institute in Scotland and the Universities of Nottingham and Reading carry out cutting-edge research into GM crops.

Why is GM aphid-resistant wheat better for the environment than non-GM wheat?

Genetically Modified Organisms (Contained Use) Regulations 2000

This is the primary piece of legislation that applies to the use of genetically modified organisms (GMOs) and replaced the 1992 version. It has since also been amended in 2002, 2005 and 2010. These regulations are to provide human health and environmental protection from genetically modified microorganisms and plants and animals.

Anyone who wants to release a GMO has to obtain formal authorisation before so doing. Applications are scrutinised by independent scientists who consider potential allergenicity, toxicity and possibility of transfer of novel genes to other organisms. Government ministers in the UK are advised by ACRE – an independent Advisory Committee on Releases to the Environment.

The GMO (EU) Regulations provide a framework for all who work with such GMOs to carry out risk assessments, with regard to people and the environment, and put in place controls.

Biotechnology laboratories must classify their work according to the four levels of containment for microorganisms. They must notify the Health and Safety Executive before beginning any work with GMOs and notify activities with Class 2 (low risk) to Class 4 (high risk) microorganisms, and activities with GM plants and animals that are more hazardous to humans than their non-modified parental forms, to the Competent Authority and pay the required fees. Finally, they must contribute to the maintenance of a public register about GM premises and activities.
DEFRA (Department for Environment, Food and Rural Affairs) is responsible for any deliberate releases of GMOs into the environment. This can only happen if a science-based risk assessment shows that safety will not be compromised. The Food Standards Agency is the lead body for reporting on the safety of and applications to market GM food and feed.

**European Patent Convention (EPC) 1978**

Many techniques in biotechnology are new and can be patented. Many products such as genes and proteins, although natural, have only newly been isolated and purified so they can also be patented. Newly isolated strains of microorganisms and GMOs can be patented. The Patent Offices of Europe, Japan and US have a joint agreement on this.

The inventor must apply, using a patent agent and giving a clear title, for a patent for the process or product in his or her own country of residence and then in other countries. Each member state has its own patent laws but there is strong international cooperation. The EPC was held in 1973 and came into force in 1978. It established the EP Organisation and the EP Office (EPO) and a supporting Administrative Council.

Patents can be granted for any inventions in all fields of technology – this includes biotechnology such as GM plants where they show improved yield or resistance to pests, diseases or adverse conditions.

A biotechnology company may apply for a patent but other parties (competitors) may oppose the application. The EPO (European Patent Office) rules as to whether the EPC can grant the patent. See the Case study below for more information about working as a patent agent.

**Case study: Trainee patent agent with the British Technology Group**

Kofi Adeti has a degree in Microbiology and Biochemistry, a PhD in Microbiology, and works for the British Technology Group training as a patent agent. He is receiving specialised legal training so that he can talk to inventors and understand what they have done, while thinking like a lawyer and advising them about applying for a patent.

He will draft the patent specification and deal with the formal requirements of the Patent Office. Once a patent has been granted the patentee’s rights have to be enforced and the patent has to be maintained.

While training he works as assistant to a qualified patent agent and is supervised. He will have to pass very difficult examinations to become qualified as a UK patent agent and will also take a European examination to qualify as a European Patent Attorney. His work covers many areas such as vaccines, antibodies, antigens, cell lines, vectors, new pharmaceuticals and mechanical equipment such as milking machines. When qualified some of the work can be done on a freelance basis.
Checklist
In this topic you should now be familiar with the following ideas:
✓ EU directives set out minimum legal requirements for member states to follow
✓ the main statutes that are relevant to industrial microbiology and biotechnology are:
  • EU Drinking Water Directive 98/83/EC: Directs member states to provide clean, safe water for consumers and to check its safety by regular monitoring
  • Nitrates Directive 91/676/EC: This is concerned with monitoring nitrate levels in drinking water and with helping farmers to apply nitrate fertilisers in a way that is safe for the environment and for consumers
  • Urban Waste Water Treatment Directive 98/15/EC: This aims to protect the environment by directing how industrial and domestic waste water is discharged into the environment
  • Genetic Manipulation Regulations 1989: This requires institutions to give 30 days' notice of intended use of GMOs and 90 days' notice of intended release into the environment of GMOs, and to submit a risk assessment to the Health and Safety Executive
  • Genetically Modified Organisms (Contained Use) Regulations 2000: Replaces the previous 1992 regulations. It aims to provide human health and environmental protection from genetically modified micro and macroorganisms
  • European Patent Convention 1978: Decides whether a new biotechnology process or product can be granted a patent.

Further reading
www.environment-agency.gov.uk
www.cbi.eu/marketintel/EU-legislation-Microbiological-contamination-of-food/160071

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