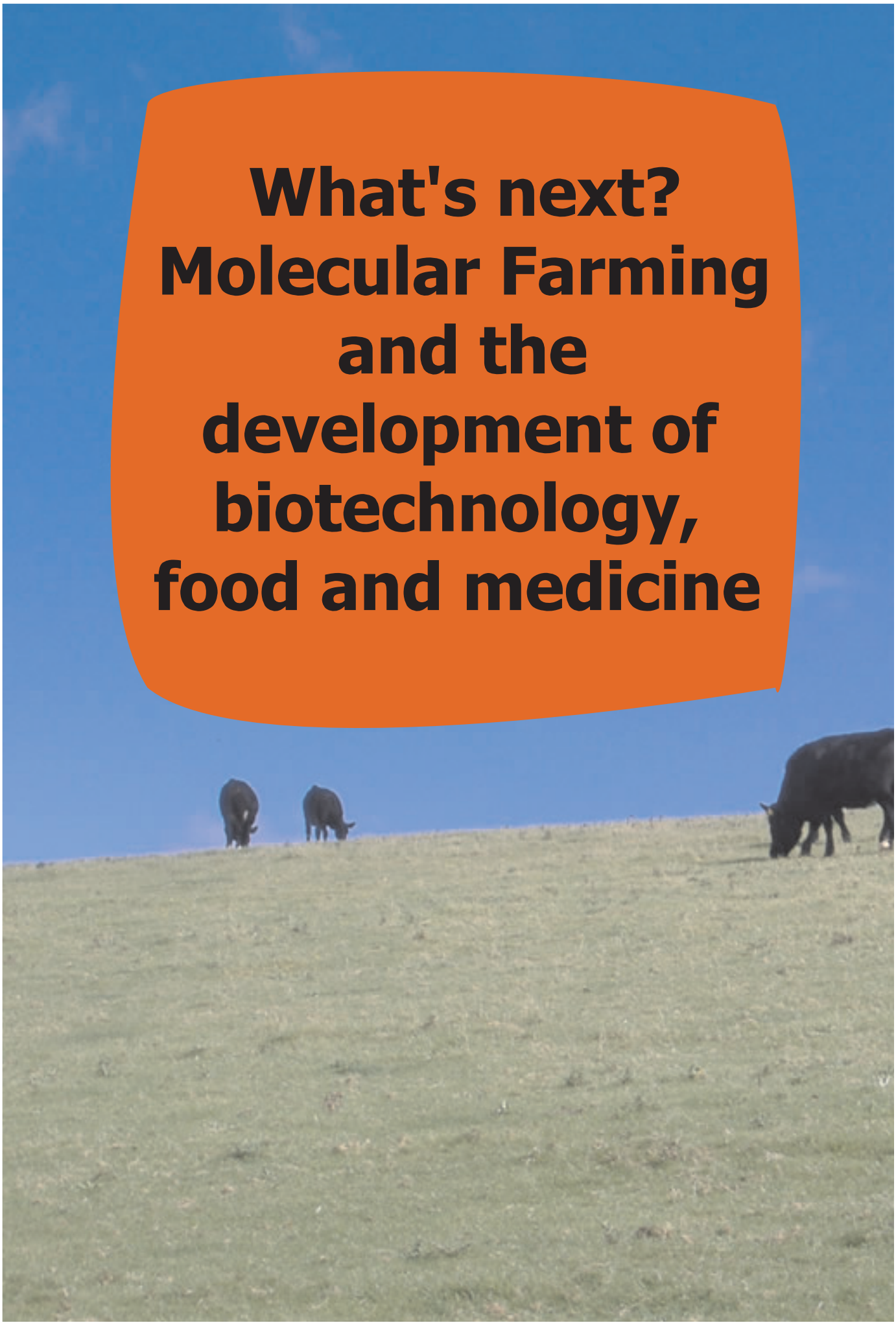

What's next?
Molecular Farming
and the
development of
biotechnology,
food and medicine

What is this booklet for?

In the next meeting of the group, we will be discussing one possible future development in the way we produce medicines. This has the potential to change the way governments, companies and the public think about medicine and food.

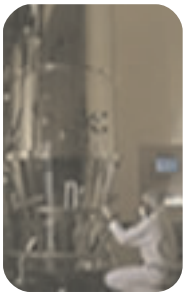
This booklet provides some information about molecular farming, or plant-made pharmaceuticals. It is provided because many people have previously not heard of molecular farming.

You are not expected to be an expert in this area to contribute to the discussion group. I am much more interested in your views and perspective than in your knowledge of the topic.

What is molecular farming?

Molecular farming is the production of pharmaceuticals (drugs) in genetically modified plants. These include vaccines, drugs such as human growth hormone and antibodies used in cancer diagnosis and treatment.

As yet, no human medicines produced in plants are on the market, however a pig vaccine manufactured by Dow Agroscience was approved in the US in February 2006 and researchers anticipate that human drugs will follow.



What are the benefits?

In producing drugs it is important to find a method that is acceptable, environmentally safe and cost-effective.

Plant made pharmaceuticals may be cheaper and safer than other production methods. Current methods are expensive with some antibodies costing more than £500 per gram. Plant made pharmaceuticals may cost a tenth of this and be much quicker to produce.

Drugs can be extracted from plants using methods similar to those used in food processing. If demand for a pharmaceutical goes up, it should be simple to plant more crops.

What are the problems?

One concern is that it is possible that these plants may introduce drugs into the food system.

There are a number of small differences between proteins produced in plants and animals. This could mean that plant made pharmaceutical proteins cause an allergic reaction in humans.

Environmental problems may include the spread of the gene to other plants, or unintended effects of the inserted gene. As these proteins are intended to be used as medicines in humans, it may be that they also have effects in animals that might eat the plants.

Who is doing it?

Both medicine and agriculture are dominated by a number of very large companies. In agriculture, these include Monsanto, Dow and Syngenta. In medicine, these are the large pharmaceutical companies such as GlaxoSmithKline or Pfizer. Some, such as Bayer, have operations in both areas.

Most research in molecular farming is happening in small companies and university laboratories. Most of this is in the USA. In 2004 the EU gave €12 million to fund the 'Pharma-Planta' research consortium of university laboratories and small companies.

What crops are being used?

The most important crops currently used in molecular farming research are tobacco and maize (corn). Other plants being used include potatoes, tomatoes, barley, rice, duckweed and moss.

Maize (corn) has many advantages for pharmaceutical production. It is cheap and well known. There is also a well developed infrastructure for production and processing. As a food crop, it can be eaten and so is safe.

The main problem with maize is that its pollen can easily be spread by wind. It couldn't be grown in areas where maize is planted for food unless it was contained within a greenhouse. Alternatively it could be grown in areas not traditionally used for maize growing, or isolated areas such as islands.

There is lots of experience with genetically modified tobacco. It provides high yields of plants and produces lots of seeds. There is a large industry already based on processing tobacco. Tobacco is not used for food or animal feed so it is unlikely that it would contaminate either the human or animal food chain.

The disadvantages of tobacco are that many varieties produce high levels of toxic chemicals. Tobacco also contains substances which might interfere with processing it into drugs.

How are these plants contained?

There are two ways of containing the crops. The first involves using either plants which are self-pollinating and less likely to spread or by using sterile plants which do not produce pollen. Unusual varieties can also be used to check that the crop does not spread.

The second form of containment is physical, and involves isolating the crops to reduce the likelihood of pollen spreading, or using greenhouses.

How is it controlled?

At the moment, no GM plants can be grown outdoors in the EU, including the UK, without a licence. No drug can be released without going through a trial process which often takes several years. To be planted in the EU, GM crops producing pharmaceuticals would have to go through both of these approval processes. At the moment however, there are no specific guidelines for governments on how to deal with pharmaceuticals produced in GM crops.

What kind of things are being produced?

Rabies antibodies

Rabies is a disease which kills 50,000 people around the world each year. Although a vaccine is available, in many parts of the world it is impractical and expensive.

Genetically modified tobacco plants are being used to produce rabies antibodies. If you are infected, the disease is fatal unless a course of post-exposure vaccination and 2 weeks of antibody treatment is administered. The least expensive treatments, which are still used extensively, are prepared from animal brain and are potentially hazardous.

Trials of the modified tobacco are taking place in greenhouses in the EU, including Kent.

HIV microbicides

At the end of 2003, the World Health Organization (WHO) estimated that 40 million people worldwide were infected with HIV.

Researchers are producing anti-HIV antibodies in genetically modified maize crops. These crops will be planted in South Africa, and it is hoped a plant-produced microbicidal cream for topical application will be ready for clinical trials by 2009.

In the absence of a vaccine , microbicides inactivate or neutralise HIV to prevent sexual transmission. They need to be used regularly, therefore they need to be produced cheaply and in large quantities. Production on a large scale is not currently possible with existing technologies using mammalian cell cultures or bacteria.

Gastric lipase in maize

A lack of gastric lipase is involved in causing a condition known as exocrine pancreatic insufficiency. Most patients need to be treated with up to twenty tablets per day. The current supply of gastric lipase is from pigs, but a French company, Meristem, is carrying out clinical trials with a version produced in corn grown in France.

The disease mainly affects patients who have cystic fibrosis or who suffer from pancreatic disease and who do not produce enough enzymes for digestion.

This is thought to be one of the products closest to getting approval for medical use.

Thank you for reading this booklet

If you have any questions about the research before the next meeting, please contact me, either at 07870699208 or by email at r.milne@ucl.ac.uk

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