apropos

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Biotechnology und genetic engineering

Biotechnology is an industrial process involving the production or modification of chemical compounds using living organisms or parts thereof. It is a rapidly expanding area of science with numerous applications in

- medicine, drug manufacture
- conversion of raw materials
- food manufacture
- agricultural products
- auxiliary products for use in industry, and
- environmental protection.

Biotechnology is used in the production and conservation of foods and drinks such as bread, pickled cabbage, cheese, beer and wine, as well as in the production of medicines such as antibiotics, vitamins and blood products. However, the traditional products beer and wine continue to account for over 75 % of turnover in the biotechnology sector.

A sub-sector of biotechnology is genetic engineering. Founded on molecular biology, this work process enables genetic information to be transferred from one living organism to another and/or modified within a particular organism. This is possible because the blueprint for all the proteins of a cell - the genetic code - is universally applicable to all living creatures. This genetic information is stored in what is known as DNA (deoxyribonucleic acid).

Classical procedures and new applications in biotechnology

Biotechnological processes have been in use since ancient times. For instance, the observation that fruit juices with a high sugar content would produce an intoxicating effect when consumed after a time in storage led to what was probably the first biotechnological method of all: alcoholic fermentation. Today's methods of producing beer and wine differ from those of old only in respect of the technology used; the microbiological processes have remained the same. And the synthesising capabilities of micro-organisms have been used in the production of foods for thousands of years.

In the course of time, these procedures have been optimised in exhaustive trials with the aim of enhancing the traits, quality, cost effectiveness and reproducibility of a product.

Today's genetic engineering methods enable products and processes to be improved still further and, what is more, in a much shorter space of time than with conventional methods. Cloning the DNA of micro-organisms needed for a certain process enables them to be tuned to produce the desired product characteristics.

Conventional breeding methods and new approaches

Conventional methods of cross-breeding already involve crossing the genetic material of domestic animals and cultivated plants. As a rule, trial and error over many generations was required in order to arrive at the right combination of genes and thus the desired traits. Until recently, breeders were restricted to combining genes of closely related species which they selectively crossed to produce offspring exhibiting the all-important characteristics. Progress was slow on account of the long generation span, in particular in the case of the larger domestic animals.

Genetic-engineering methods pave the way to more rapid progress thanks to the options of

- extensions beyond the natural genetic boundaries of a particular species, and
- selectively modifying a genotype by synthesising genes or by translocating them to plant or animal cells.

Pharming

Genetic engineering enables the genes of one organism to be translocated to another. Hence, a gene taken from a human cell can function satisfactorily in the cells of a host animal, continuing to produce its respective protein there. Such a process might find practical application in the manufacture of therapeutic proteins, say in the milk of a "transgenic animal".

A well-known example here is the sheep Tracy, whose milk contains a human protein (alpha-1 proteinase inhibitor). Patients with a certain genetic defect rely on this protein to relieve the symptoms of the related illness (a serious lung-function impairment which leads to chronic damage of that organ). Previously, the substance had to be produced from donated blood and was not always available in large enough amounts. There was also a risk of infection through impurities. Producing the substance from animals has eliminated these two problems and cut costs in the process.

Research projects in agriculture; typical products

In the past, the finite set of genes available - especially in cultivated plants - limited the range of hybrids breeders were able to produce. Nowadays, the ability to synthesise new and to selectively translocate natural genes is opening new combination possibilities and accelerating success. Whereas conventional plant breeding involved working with the whole plant in tests in greenhouses or fields, the same experiments can now be performed in a test tube in a laboratory. And while 15 - 20 years would be required to produce and market a new variety using traditional methods, genetic engineering can do the job in half the time.

The goals of breeding include:

- creating strains that are resistant to bacteria, viruses, fungi and insects
- herbicide-tolerant plants
- increasing yield
- enhancing desirable traits (improvement in taste, longer life)
- creating plants with new or modified components
- producing superior proteins in transgenic plants

Examples:

- "Rape tuning":
  The oil from a new, genetically modified variety of rape is easier to process, containing a higher percentage of short-chain fatty acids.
- Potatoes:
  Potatoes in which post-germination is inhibited keep longer; better-quality starches.
- Apples:
  Greater resistance to insects
- Broccoli:
  Slower ripening process; vegetable keeps longer.
- Strawberries:
  Better resistance to frost
- Bananas, grain, corn, rape, soya beans, sugar beet:
  Enhanced resistance to herbicides and pests.
- Coffee:
  Better taste, less caffeine, higher yield.
- Grapes:
  New seedless varieties.

Examples of products already introduced to the market:

- The so-called "Flavr-Savr" tomato (USA)
  Ripening - and thus ageing - is blocked from a certain stage so that the fruit stays fresh for longer. This is achieved by reversing one of the fruit's own genes. Since these tomatoes do not have an extra gene, they cannot produce additional proteins.
- The enzyme Rennin as authorised for use in the manufacture of cheese (in the Netherlands, Italy and the United Kingdom):
  This enzyme is normally extracted from the stomachs of calves that are 10-14 days old. As well as being relatively expensive, this method is unable to guarantee any consistency between lots. When genetically engineered in bacteria or yeast cultures, the enzyme is cheaper and of a much more consistent quality.

Other examples:

- The enzyme Novamyl used in baking (Denmark)
- Special genetic yeast used in baking (Netherlands)
- Herbicide-resistant tobacco (France)
- Herbicide-resistant rape (Belgium)

Categories of genetically engineered food

Genetically engineered foods can be divided into five categories:

1. The food itself is genetically modified
   (e.g. the "Flavr-Savr" tomato)
2. The food consists of genetically modified organisms (GMOs)
   (e.g. ketchup made from "Flavr-Savr" tomatoes)
3. The food contains living GMOs
   (e.g. yoghurt made from genetically modified micro-organisms)
4. The food contains dead GMOs
   (e.g. bread made from genetically modified micro-organisms)
5. The food contains products made from GMOs
   (e.g. beer brewed using genetically modified yeast)

Since 15 May 1997, genetically modified foods of categories 1-3 have had to be labelled as such in accordance with the EU's "Novel Foods" Directive.
Genetically engineered products in categories 4 and 5 are not subject to obligatory labelling as their composition is indistinguishable from that of conventional products.

Positive and negative potential

There are positive and negative sides to genetic engineering. Beneficial aspects of this new technology include:

- Environment-friendly pest-control systems (increasing the resistance of plants; fewer pesticides required)
- Improves the resistance of plants to harmful environmental factors and diseases (greater yield; fewer phytopharmaceutical products required)
- Avoids over-fertilisation
- Reduces crop-loss due to pests
- Raises the quality and quantity of produce
- Enables animals to gain weight faster
- Animals less susceptible to disease
- Processes become more cost-effective
- Cost-effective production of consistent high-purity pharmaceutical substances in milk

Negative aspects include:

- Potential drop in the number of animal and plant species
- Risk of weeds becoming herbicide-resistant
- Risk of insect populations developing resistance to toxins
- Risk of previously unknown diseases
- Increased toxicity of genetically modified plants
- New, difficult-to-combat viruses or micro-organisms
- Spread of antibiotic-resistant viruses and micro-organisms

In listing the negative aspects, it should be remembered that most research goals can also be attained via conventional methods, albeit somewhat slower. The risks, then, are not specific to the genetic engineering method as such, but are inherent in the products or applications themselves.

Risks specific to genetic engineering

Genetic engineering is nothing more than a work process.
For this reason, it is important that risk assessment focuses on the potential dangers of the product in question, rather than the method - genetic or otherwise - used to manufacture it.

Experiments in genetic engineering carried out since 1972 have shown that the risk inherent in organisms containing nucleic acids recombined 'in vitro' (i.e. in a test tube or Petri dish) is no greater than the sum total of the risk potential already inherent in the genetic information present in the donor and recipient organisms.

Micro-organisms, in particular pathogens, must be handled with great care in order to prevent them from escaping into the environment and causing widespread infection. The biological safety philosophy in place today comprises an array of structural, technical and organisational safety and security measures based on the use of closed systems.

The aim of biological safety when working with pathogens or genetically modified organisms is to make products and work environments safe, while protecting the environment. In Germany, five directives regulate the implementation of the country's Genetic Engineering Act (GenTG). One such directive defines safety levels and prescribes safety precautions for work carried out in genetic engineering facilities.

In 1983, the World Health Organization (WHO) defined the following risk categories for work performed with various micro-organisms:

1. No human or environmental risk at all, e.g. vaccine strains (not involving pathogens)
2. Slight risk, e.g. the measles virus, Salmonella etc.
3. Moderate risk, e.g. HIV
4. High risk, e.g. smallpox virus

In Germany, as in other countries, over 85 % of all genetic-engineering projects are in the lowest category.

Tips for the underwriter

The risks involved in genetic engineering stem mainly from the respective field of application and the product manufactured, rather than from the technique per se. The same applies to the nature and scale of damage that may be caused.

Liability insurers may be confronted primarily with the following risks:

- Commercial TPL insurance

  The genetic engineering activities themselves may constitute a hazard to human health and the environment. The potential scale of the loss depends largely on the WHO risk category in question and on the state of the art. Loss scenarios might include the spread of disease or epidemics following the failure of safety systems in a genetics laboratory or production plant.

- Environmental impairment liability insurance

  Potential risks are the development of unexpected or unforeseeable resistant strains, or losses resulting from spreading monocultures caused, in turn, by a drop in the number of animal and plant species.

- Product liability

  The risk here is from harmful properties of a product that were not recognised prior to its release, or from the effects of unexpected or unforeseeable changes to a product. Underwriters would be advised to examine whether the product was adequately tested before its release.

  Property insurers too should take the genetic engineering factor into account when assessing a risk:

- Property insurance/Business interruption

  The potential scale of the immediate damage is not the only cause for concern in the field of genetic engineering. Failure of sophisticated plant and equipment can lead to a considerable loss of earnings. In addition, stringent official directives might well hinder the reconstruction of plant or delay the resumption of production. Sabotage of production facilities or destruction of crops by opponents of genetic engineering is also a possibility.

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