16

TOWARDS A BIO-ECONOMY
Biotechnology research in the European Union

KEY THEMES

- The EU bio-economy.
- Stages of risk assessment.
- Safety and the precautionary principle.
- Horizon 2020: a budget for innovation.

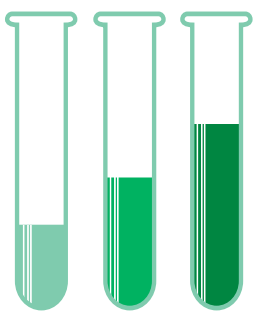
A bio-based economy

Over the past decade the concept of a bio-based economy has emerged. The term refers to an economy that links its industrial development with sustainability, and in an environmentally friendly, socially responsible manner.

The concept was introduced into the European Union (EU) in 2005 as the European Knowledge-Based Bio-Economy (KBBE), and with it came the determination to invest significantly in Europe's knowledge base in order to realise the potential of its most innovative technologies.

The EU's bio-economy sectors have an estimated annual turnover of € 2 trillion, accounting for more than 22 million jobs. Biotechnology is one of the key sectors, with a wide range of tools for using bioresources more efficiently, improving agricultural yields, saving energy and creating industrial processes that are friendly to the environment. The KBBE received support of just under € 2 billion for the period 2007–2013 to cover food and agriculture alongside biotechnology. The fact that these are grouped together underlines their interdependence.

Biotechnology is a key component of the new bio-economy, which seeks to enable sustainable and environmentally friendly industrial development.



The biotechnology part of KBBE includes:

- novel sources of biomass;
- marine and freshwater biotechnology;
- industrial biotechnology and biorefineries;
- environmental biotechnology for the clean-up of contaminated environments and the development of environmentally friendly industrial processes;
- new trends in biotechnologies (including bioinformatics, systems biology, synthetic biology and nanobiotechnologies).

Controversy, safety and risk assessment

As with all new technologies, the potential risks and benefits of biotechnology in general – and genetically modified organisms (GMOs) in particular – have to be identified and quantified. Safety has to be ensured before products containing GMOs (or where GMOs are used in a production process) can find their way to the consumer or the environment.

In Europe, GM research, development, release and commercialisation are still matters of some debate, so the challenge has been to produce legislation that reflects a broad range of public viewpoints. Such legislation has been in place since the early 1990s, having evolved and been updated over time. In general, the rules and procedures it defines comply with those of international bodies such as the World Trade Organization, the Cartagena Protocol on Biosafety and the Convention on Biological Diversity.

Potential risks must be weighed against benefits for any progress to be made with feeding the world.

Currently, the main legislation covering agriculture and food safety deals with the deliberate release of GMOs into the environment, GM food and feed, GM micro-organisms and the coexistence of GMOs and non-GMOs.

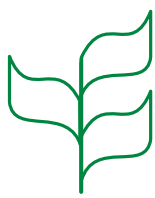
In investigating the biosafety of GMOs, three steps need to be followed: risk assessment, risk management and continuous monitoring.

Risk assessment and management

The overarching body responsible for scrutinising the risk of GM food and feed in Europe is the European Food Safety Authority (EFSA), which draws on highly qualified scientific experts from a number of European countries to conduct its assessments. The EFSA is committed to ensuring that panel members are truly independent.

Figure 16.1 outlines the different stages involved in assessing risk and managing it once a decision to authorise a given GMO has been taken. The assessment stage involves a good deal of formal and informal communication between the EFSA, the applicant and EU Member State authorities. This may be about specific concerns or calls for additional evidence, or it may simply be to clear up uncertainties or misunderstandings.

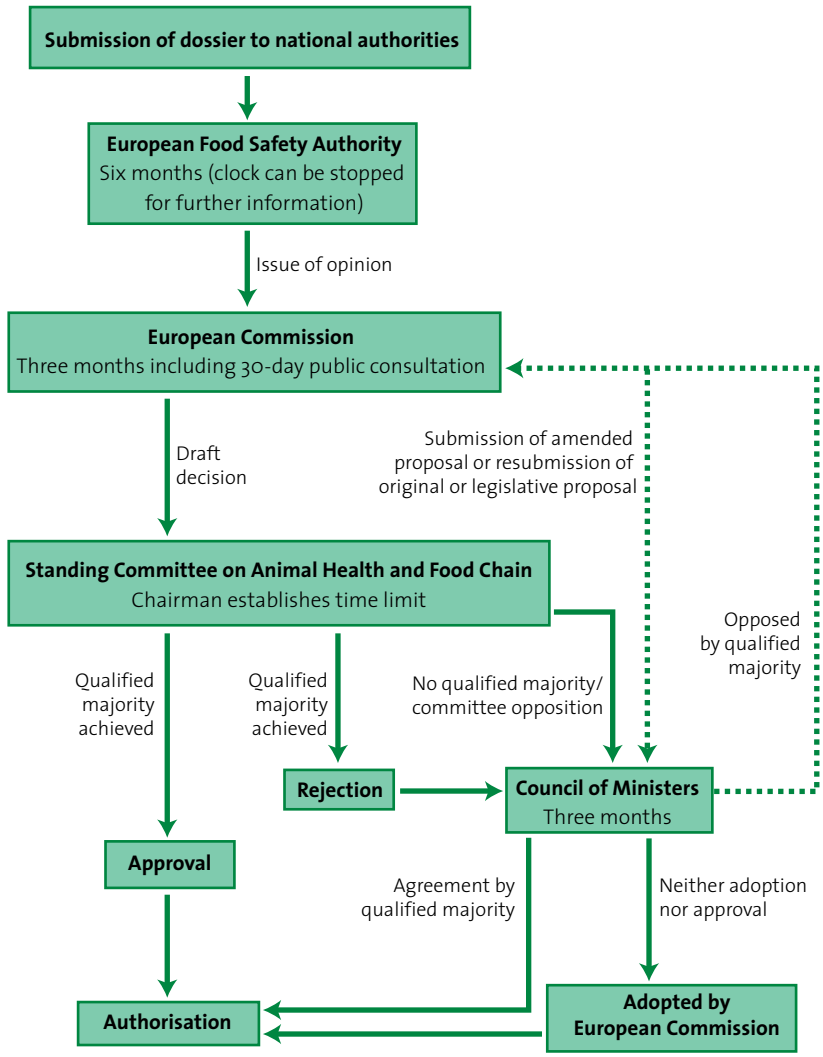
The United Nations Convention on Biological Diversity is one of several international bodies that help to define the rules and procedures of genetic research.



Once a GMO has been authorised following a favourable opinion from the EFSA, the European Commission submits a draft decision to Member States for their vote. To date, in almost all cases, no qualified majority for or against authorisation of a GMO has been obtained. There has been stalemate. The same has sometimes happened when draft decisions have been forwarded to the governing Council of Ministers. There, too, no majority has been reached over marketing GMOs.

Something comparable also happens when decisions have to be made on the cultivation of a GMO in the EU. Some Member States, unhappy about a novel

Figure 16.1 The authorisation process for genetically modified organisms in Europe



Source: Bennett and Jennings, 2013

organism being grown in their territory, invoke a safeguard clause in the legislation. For example, six states are currently using safeguard clauses to ban the cultivation of a genetically engineered variety of maize – MON810 – although other European countries, along with many more around the world, do grow this insect-resistant crop.

Monitoring

There is a legal requirement to monitor the potential effects of all GMOs grown or consumed within the EU. This takes place at every stage, from initial field trials to commercialisation.

Monitoring can be both general and specific:

- general surveillance is conducted to verify or refute the results of the initial risk assessment where no special monitoring requirements were requested;
- case-specific monitoring can include such actions as surveying the development of the resistance of insects to a pesticide produced by a GMO.

Both these are important tools for decision and policy makers who may need to adjust their positions according to results. If used constructively, they help close the gap between initial risk assessment and practical experience and, thereby, avoid forfeiting the benefits of new products or technologies unnecessarily.

Three decades of research on safety

The EU has undertaken research to evaluate the risks and benefits of GMOs to human, animal and environmental health. These studies were carried out on the basis of the precautionary principle, which can be summarised as "better safe than sorry". This means that, if a technology or novel crop has a suspected risk of causing harm then, in the absence of scientific evidence that it is harmful, the burden of proof that it is not falls on those supporting or endorsing it.

The EU is not alone in following this principle: other international organisations such as the Organisation for Economic Co-operation and Development (OECD) do too, not just in the interests of consumer safety but to harmonise their approach to risk assessment and to ease international trade in agricultural or industrial products.

In 2001, the European Commission published its first overview, *EC-Sponsored Research on Safety of Genetically Modified Organisms*, covering 15 years and 81 projects in more than 400 laboratories. Among the topics were horizontal gene transfer, GM plants in the environment, plant-microbe interactions, GM fish and food safety. A second volume followed in 2010, presenting the results of a further 50 projects involving 400 European research groups. In 2013, a thorough, systematic review of the scientific research conducted on GM crops in the past decade was completed.

Brian Robert Marshall/CC-BY-SA 2.0

Using a technique that turns plants into "vaccine factories", a co-funded EU/Russian research project has developed an exceptionally fast and effective way of creating vaccines to combat some of the most devastating infections affecting farm livestock, including foot and mouth disease.

What does this research tell us about the safety of GM products? The main conclusion to be drawn from the efforts of more than 130 investigations, covering a period of more than 25 years, and involving more than 500 independent research groups, is that modern biotechnology is inherently no more risky than conventional plant-breeding technologies. The research on biosafety came up with a large volume of scientific evidence for these results: data that fail to demonstrate any specific hazard linked to GM technology.

One other conclusion was that today's biotechnology research and applications are far more diverse than they were 25 years ago. This means, among other things, that biotechnology has strengthened its position at the core of Europe's knowledge-based bio-economy by being able to contribute even more towards meeting the challenges of sustainable food safety and security.

European biotechnology on the world stage

The EU has been keen to promote international cooperation in plant biotechnology, both between Member States and with countries outside the EU. A major tool for this is the Partnering Initiative, which foresees increasingly systematic cooperation in research and development programmes that tackle common challenges. To date, Europe has established Partnering Initiatives with India on biomass and biowastes, and with China on fibre crops and genetic crop improvement.

In addition, the European Commission is actively cooperating with industrialised countries including Australia, Canada, New Zealand and the USA on plant biotechnology, along with the so-called BRIC countries: Brazil, Russia, India and China.

The EU has been keen to promote international cooperation in plant biotechnology, both between Member States and with countries outside the EU.

Significant funding has been made available for cooperation with emerging countries in specific areas of research, such as plant vaccines in Russia and sweet sorghum and *Jatropha* (physic nut) in the tropics.

Horizon 2020

The EU's Horizon 2020 initiative will use a budget of € 80 billion during 2014–2020 to drive research and innovation across its Member States, embracing science, industrial innovation, and the major concerns shared by all Europeans such as climate change, food safety and security, an ageing population and so on. With biotechnology explicitly identified as the engine of the bio-economy, the use of new genetic methods and techniques will figure prominently in this wide-ranging, cross-cutting initiative to develop industry and agriculture across Europe.