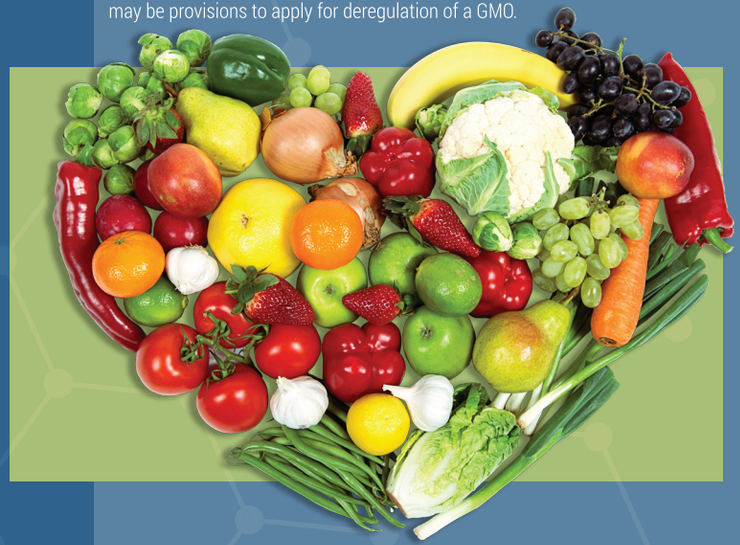
WHAT TYPES OF GMO USE REQUIRE AUTHORISATION?

The types of GMO applications that require authorisation may include: GMOs in facilities such as laboratories, glasshouses or animal facilities (contained use); field trials with limits and controls (confined use); commercial releases (placing on the market); import (including grain shipments intended for processing as food for people or feed for animals), and; export.

In most GMO regulatory systems, the lifetime of each authorisation is limited (e.g. between 5 - 10 years) with provisions for applications to vary, surrender or transfer an authorisation to account for changes in the circumstances occurring during authorisation period. If there are credible findings of adverse effects or breaches of conditions, there may be a need to repeal an authorisation and cease the associated activities. Most jurisdictions also make provisions for applications to protect certain information as confidential information. Finally, there may be provisions to apply for deregulation of a GMO.



WHICH COUNTRIES ARE USING GMOs?

Globally, regulatory authorities in over 40 countries have given approvals to use GMOs for different purposes (i.e. cultivation, food or feed). GM crops began being used commercially more than 20 years ago. Millions of farmers in 28 countries (USA, Brazil, Argentina, India, Canada, China, Paraguay, Pakistan, South Africa, Uruguay, Bolivia, Philippines, Australia, Burkina Faso, Myanmar, Mexico, Spain, Colombia, Sudan, Honduras, Chile, Portugal, Cuba, Czech Republic, Romania, Slovakia, Costa Rica and Bangladesh) grew 181.5 million hectares (448 million acres) of GM crops in 2014. Many of these countries and more carry out research on GMOs and the biotechnology development pipeline includes new crops and traits expected to be commercialised in the next 5 years. Some examples are vitamin A-enriched rice (Philippines) and late blight resistant potatoes (Bangladesh, Indonesia, and India). In Africa, biofortified bananas and pest resistant cowpea are also under development.

Many GM animals (mainly mice) are used in laboratories for medical research. Farm animals have been genetically modified to produce drugs in their milk or to try to improve meat quality and pets have been genetically engineered to make them glow (zebrafish; commercially available) or try to make them non-allergenic (cats). GM laboratory animals are widely used but most other GM animals are still at the research and development stage and have yet to be authorised for sale on the commercial market. The first GM animal likely to be marketed as food is a GM salmon, which is awaiting approval for human consumption in the USA.

Although no GM insects are currently commercially available, a number of different types are being developed and tested under strict regulatory oversight in efforts aimed to help reduce disease instances in humans and plants, e.g. malaria, yellow fever and dengue transmitted by mosquitoes, and plant diseases transmitted by pink bollworm, diamondback moth and Mediterranean fruit fly.

WHICH COUNTRIES BAN THE USE OF GMOs?

The situation with regard to national bans on the use of GMOs is ever-changing and complicated. For example, although the European Union has approved the seed of many GM crop varieties for use in animal feed, it has only approved two GM crops for cultivation: a GM maize which is resistant to a devastating pest, the European corn borer; and a potato that contains only one of the two starches traditionally found in potatoes (amylopectin) which is desired for industrial use such as paper-making. Eight EU member states (France, Germany, Poland, Italy, Luxemburg, Austria, Hungary and Greece) have banned an insect resistant maize variety citing environmental concerns. These are political bans that conflict with the scientific advice of the European Food Safety Authority (EFSA). Spain and Portugal continue to grow the insect resistant maize on a commercial scale. Germany, Sweden and the Czech Republic grow the amylopectin potato. Elsewhere, Algeria, Bolivia, Ecuador, Peru, Saudi Arabia and Thailand are amongst the number of countries that may allow GMO research and development (as well as, in some cases, GM food and feed import) but ban GM crop cultivation.

Many countries, including many in the Caribbean region, have not finalised laws and regulations regarding the use of GMOs, and as such, although there may be no national ban *per se*, any known GMO use would be, by default, unauthorised.

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GENERAL INFORMATION ON BIOSAFETY AND BIOTECHNOLOGY

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WHAT IS BIOTECHNOLOGY?

Biotechnology is a broad term that relates to using living organisms or their parts to carry out biological processes for use in industrial processes or services such as in agriculture, medicine and waste recycling. It includes using microorganisms to transform materials (e.g. fermentation in beer-making), different methods of propagation (plant tissue culture or grafting), and may also involve genetic alteration (through standard methods such as selective breeding).

WHAT IS MODERN BIOTECHNOLOGY?

Modern biotechnology means the application of: a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Recent advances in biotechnology provide ways of introducing very precise changes to genetic material - the sets of instructions in the cells of all living creatures - which can include genes, parts of genes, groups of genes and so on.

This allows scientists to transfer the properties "instructed" by a single gene from one organism to another. Using these new techniques, scientists can modify organisms by directly inserting or removing one or more genes so that an organism gains, loses or changes a specific characteristic or set of characteristics. For example, a variety of cotton has been genetically modified to resist pest damage by producing toxins that target certain insects. Modern biotechnology has a wide range of potential applications:

Research - Conducting basic research in biology and medicine with GM microorganisms, animals and plants,

Agriculture - Incorporating resistance to pests/diseases, incorporating herbicide tolerance, altering the timing and duration of flower production, or improving nutrition,

Therapeutic Goods - Modifying microorganisms to produce therapeutic products such as insulin and vaccines,

Medicine - Diagnosing and treating disease,

Industrial Uses - Producing enzymes to use in food processing, producing paper pulp and biological leaching of minerals,

Bioremediation - Using microorganisms or plants to decompose toxic substances and clean up industrial sites or environmental accidents.

WHAT IS A GENETICALLY MODIFIED ORGANISM?

The term genetically modified organism (GMO) means an organism in which the genetic material has been altered in a way that does not occur naturally through mating/fertilisation and/or natural recombination. GMOs may be plants, animals or microorganisms, such as bacteria, parasites and fungi.

WHAT IS BIOSAFETY?

Biosafety is used to describe efforts to reduce or eliminate the potential risks resulting from modern biotechnology and its products. It has similarly been defined as "the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms". Relevant scientific disciplines that underpin biosafety include: molecular biology, plant breeding, genetics, plant pathology, agronomy, weed science, entomology and ecology, amongst others.

HOW ARE GMOs REGULATED?

Regulation uses a legal framework to make decisions. In the case of regulating GMOs, decisions concern authorising activities with, or uses of, GMOs such that the health of people and the environment are protected. Where regulations exist, a set of regulations will control what people can do with GMOs, e.g. doing experiments, developing, breeding, growing, importing or transporting, in order to protect people and the environment by identifying and managing risks from GMOs. In such cases, GMOs cannot be put on the market or into the environment without approval. Every decision to authorise a GMO is based on a risk analysis; a reasoned, repeatable and transparent approach to identifying and managing risks. It is based on a well-established international approach and provides a rigorous, evidence-based framework for decisions made by each Regulatory Authority.




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