Factsheet

GMO Regulation

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. These are sometimes also known as living modified organisms (LMOs), genetically engineered organisms (GEOs), genetically manipulated organisms, transgenic organisms, and biotech crops/-animals.

GENERALLY, HOW ARE GMOs REGULATED?

Regulation uses a legal framework to make decisions. In the case of regulating genetically modified organisms (GMOs), decisions concern the authorisation of activities with, or uses of, GMOs such that the health of people and the environment are protected. Where regulations exist, regulators are mandated to 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.

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.

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This material was produced with support from the United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF), under project GFL/2328-2716-4C20, "Regional Project for implementing National Biosafety Frameworks in the Caribbean Sub- region".