



The emerging international regulatory framework for biotechnology.

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Abstract: Debate about the potential risks of genetically modified organisms (GMOs) to the environment or human health spurred attention to biosafety. Biosafety is associated with the safe use of GMOs and, more generally, with the introduction of non-indigenous species into natural or managed ecosystems. Biosafety regulation--the policies and procedures adopted to ensure the environmentally safe application of modern biotechnology--has been extensively discussed at various national and international forums. Much of the discussion has focused on developing guidelines, appropriate legal frameworks and, at the international level, a legally binding international biosafety protocol--the Cartagena Protocol on Biosafety. The Protocol is one among various international instruments and treaties that regulate specific aspects relevant to agricultural biotechnology. The present article presents the main international instruments relevant to biosafety regulation, and their key provisions. While international agreements and standards provide important guidance, they leave significant room for interpretation, and flexibility for countries implementing them. Implementation of biosafety at the national level has proven to be a major challenge, particularly in developing countries, and consequently the actual functioning of the international regulatory framework for biotechnology is still in a state of flux.

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