

Brazil has adopted a technology-based approach to regulate GMOs. In 2005 a new biotechnology law created a centralized agency – the National Biosafety Technical Committee - to assess risks and to decide on a scientific basis if a GMO can be used in field (containment) experiments or commercially released. CTNBio decisions cannot be challenged by any other instance except the National Biosafety Council, composed of 11 State Ministers. Even the Council can only argue based on social or economic issues directly linked to the commercial use of the new GMO product.

The same law defines what is a GMO. As many other former legislations, the Brazilian law and decree regulate genetic engineering (GE) products, which should contain a transgenic DNA either in its genome or in extrachromosomal plasmid or organelle DNA. Although the GE definition is rather ample and encompasses most new techniques, the constraint imposed by the presence of a new transgenic DNA could exclude certain products from CTNBio's assessment, potentially creating a limbo for many new products.

However, there is consensus at CTNBio that every product derived from any new breeding (or gene) technology should be regulated and should be assessed before being released, even if it doesn't contain a "foreign" DNA. CTNBio can by law decide how to solve omissions and has acted accordingly in the assessment of genetically modified organisms that do not fit the strict letter of the law.

The present regulatory framework, being designed de novo to assess GMO risks, can conveniently handle crops, perennial trees, animals or microorganisms. Oxitec's RIDL *Aedes aegypti* was assessed without any major challenges and any other transgenic pest will most probably be assessed using essentially the same guidelines and procedure adopted before, which are in strict conformity to the Cartagena Protocol and hence accepted by all Parties.