Regulation of Crop Biotchnology in the European Union: 25 years of Lessons and Lament

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After 25 years of experience it is now evident that the EU's regulatory framework for crop/food biotechnology has not been fit for purpose and remains unsustainable given the rapid pace of advances in modern plant biotechnology. This paper examines the key drives that have led to the current issues and future problems faced by the EU's regulatory framework for crop biotechnology. As the current EU regulatory framework is triggered only if a plant has been developed via recombinant DNA technology it does not apply to other crop varieties that have been 'modified' by using traditional or next generation gene editing methods. As a result, the regulatoy framework is not in accordance with the 'precautionary principle', which is the EU's chosen basis for the regulation of crop biotechnology. In essence, the EU crop biotechnology regulatory fiasco has largely been a construct of past 'biopolitical' decisions to choose a process rather than a product-based approach to regulate new plants or foods, including GM crop varieties. A more appropriate regulatory framework, that would better reflect the idea of the precautionary principle, would focus on the traits expressed by a plant and also comparatively assess the plant's potential environmental and health risks against the benefits derived from the new crop. The EU's experience developing, implementing and evolving its reguatory framework for crop biotechnology offers important lessons for the governance of new and emerging technologies.

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