

Event

Policymakers are being asked to take ethics into account as an integral part of the regulatory regimes that apply to biotechnology innovations in agriculture. While some countries like Norway have formalized this recommendation, there is no consensus regarding the role for ethics in regulatory systems.¹

Significance

Many countries including Canada and the United States have regulatory regimes that include a science-based process to approve novel products. If ethics were to influence, or become an integral part of this process, it would change the conditions under which novel products are developed.

Analysis

Commentators have put forward various proposals for the integration of ethics. The proposals critique the existing regulatory model, which is embodied in science-based risk assessment. The proposals are presented as reforms of this dominant model. Some aim to recognize the role of ethics as an integral part of the actual approval process, while others would like to see a wide-range of non-scientific issues (e.g. economic, trade, etc.) included in the regulatory scope.

Science-based risk assessment is inextricably linked with normative judgments, as opposed to purely empirical, or scientific findings. The inseparability of ethics from risk assessment only becomes problematic when the interdependence of scientific and ethical features cannot be examined for lack of transparency. Thus, one purpose of integrating ethics into regulation is to acknowledge the role that ethical norms and values already play in the approval process, by making sure that any inherent value judgment is dealt with explicitly and appropriately. According to its proponents, such formal recognition would promote transparent and open discussion on the acceptability of risk as well as critical review of all normative issues involved in science-based risk assessment.

Another objective of integrating ethics relates to the enforcement of ethical standards. Many commentators deplore the fact that science-based regulation is only concerned with a narrow set of technical or scientific issues. Therefore, they propose to alter the standard regulatory functions, that is, protection of human health and environment, to safeguard socially shared values and societal structures. Following this view, both science and ethics are deemed as necessary components of satisfactory regulatory regimes. Since the existing science-based model is limited in its ability to anticipate and control the full range of “non-scientific” risks and issues such as socioeconomic impact, fairness and social justice, the current model should be amended to offer formal and explicit treatment of these concerns.

Conclusion

The integration of ethics aims to reform the regulation of novel products. To do so, it first seeks to raise transparency by causing to be explicit – and thus accountable – the value judgments that are inherent to science-based risk assessment. Second, it intends to broaden existing regulatory requirements by introducing ethical standards as approval criteria. Concrete means to achieve these objectives (e.g. ethics committees, risk assessment policy, prohibitions) remain to be developed before they can be presented as a credible alternative to current regulatory models. Ultimately, the integration of ethics proposes to crystallize different social priorities or ideals and to grant more influence to ethical experts within the regulatory process. Despite being presented as a technical and organizational issue, the integration of ethics is therefore, first and foremost, a political issue.

¹ Lord F. and L. Létourneau. 2010. Making sense of demands for the integration of ethics into the regulation of GMOs. In C.M.R. Casabona, L. Escajedo San Epifano and A.E. Cirion (eds), *Global Food Security: Ethical and Legal Challenges*, Wageningen: WAP, pp. 281-86.