Coordinated Framework: Structure Needs An Overhaul

Sixteen years after the Coordinated Framework was put into effect, agricultural products thus far created through biotechnology appear safe to eat and have not caused environmental problems. However, the regulatory experiences with them highlight significant weaknesses and gaps in the regulatory structure that need to be fixed to keep that record intact, especially as genetic engineering (GE) moves into new areas, such as crops that produce pharmaceuticals and transgenic animals.

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The Framework was a creative attempt to regulate an emerging technology using existing laws, but it has relied on a patchwork of agencies regulating GE products under dubious legal authority with different standards and procedures. The system also lacks the transparency and public participation necessary to instill public confidence in the governmental review. It is clear that new legislation is needed to protect humans and the environment.

In the area of food safety, the Federal Food, Drug, and Cosmetic Act does not require premarket approval of certain GE foods. Currently, GE animals require premarket approval by FDA and pesticidal plants require premarket approval by EPA (including a food-safety analysis), yet nonpesticidal GE plants, such as herbicide-tolerant soybeans, are subject only to FDA's voluntary consultation process. That process, which the FDA itself says is "not a comprehensive scientific review of the data generated by the developer," culminates only in an agency statement that it has "no further questions . . . at this time." This is not exactly a finding that the food is safe.

Recently, the FDA proposed regulations mandating premarket notification by technology developers for GE crops, but the rule does not upgrade the nature of the scientific review nor does it result in a safety determination. Unless Congress amends the FFDCA to establish premarket approval with a thorough scientific assessment by FDA, the public will continue to have to rely on industry's food-safety determination.

The FFDCA also needs modernization to properly regulate GE animals. The FDA plans to regulate GE animals under its "new animal drug" authority (where the inserted gene and the expressed protein are "animal drugs"). That legal authority is sufficient to regulate GE animals, but those regulations do not allow public access to the application nor any opportunity for public input. Congress should amend FFDCA to make the GE animal approval process open and transparent or else establish a new approval process for those products, since gene insertions have little in common with ordinary "animal drugs."

The Coordinated Framework also fails to ensure that all products receive a thorough assessment before release into the environment. The USDA regulates GE crops under a questionable interpretation of the Plant Pest Act, which argues that GE crops are "potential" plant pests. It is difficult to make a convincing scientific argument, however, that GE corn or soybeans could become plant pests. Even under USDA's creative statutory interpretation, the regulations don't mandate review for some GE crops, such as products produced with a gene gun.

For GE crops captured by USDA regulations, its review does not always include a thorough environmental assessment. The USDA only conducts environmental assessments when a developer seeks to deregulate a product, which usually occurs with large-scale commercialization. Thorough environmental assessments are not conducted for hundreds of permitted releases, including crops producing pharmaceuticals. Also, where an environmental assessment is completed, it is unclear whether the USDA has authority to address environmental risks that fall outside its mandate to protect against plant pests.

The environmental assessment of GE animals is another area of weakness. The FDA conducts an environmental assessment when approving GE animals, but it may not be able to deny an application if environmental concerns are identified. In addition, the FFDCA's confidentiality provisions apply to environmental assessments, preventing a transparent and participatory review of environmental risks.

Finally, the Coordinated Framework fails to safeguard human health and the environment after products are approved. The FDA's authority to immediately take an animal drug off the market if it proves hazardous does not apply to environmental harms. Further, after GE crops are deregulated by USDA, there is no legal mechanism to require environmental monitoring or to address environmental problems that might arise.

For pesticidal plants, EPA has required post-registration environmental monitoring and conditional registrations, but the agency has not dedicated resources to enforcing conditions imposed with its registrations. Nothing shatters public confidence in a regulatory system more than when an agency approves products, but does not conduct follow-up compliance and enforcement activities.

The time is ripe to improve the regulation of agricultural biotechnology. With new legal authority and better regulations, a strong, but not stifling, system can be established that independently reviews and approves products that are safe for consumers and the environment. Such a system is essential if consumers are to have confidence in biotechnology.

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