Volume 5
Issue 3 *Summer 1999*

Article 2

August 2015

GMOs in Europe: A Genetically Modified Ordeal?

GianCarlo Moschini
Iowa State, moschini@iastate.edu

Jay Corrigan
Iowa State University, corrigan@iastate.edu

insure that no hormonal additive has been administered.

Another option would be to set standards limiting hormone residues in meat products to safe or precautionary levels and to impose a ban when the standards were violated. Such standards are already defined by an international institution, such as the Codex Commission, which is shielded from direct political influence. The latter instrument raises the issue of harmonization of standards. Some countries may not agree with international standards as was the case with the EU. Harmonization goes against the presumption of most economists that harmonization of standards among heterogeneous trade partners with different tastes is not optimal. Hence, in practice, finding acceptable standards may be difficult.

An important question induced by the hormone trade dispute is: How safe are growth hormones? Based on more than 30 years of hormone use in the United States, there is no evidence of hormone residues in meat exceeding recommended standards, or of adverse human health effects coming from this process attribute of beef. For most hormones, the absence of health consequences hinges on good veterinary and animal husbandry practices in hormone use. These good practices imply that hormone residues are minimal and correspond to naturally occurring hormone residues levels present in animal products. Hormones, both natural and synthetic, tend to have short half-lives, in the order of a few days. This means their concentration decreases by half within a few days and to nearly undetectable levels within a few weeks. Deviations from these good practices, such as overdose, late injection, or improper injection forms, can have adverse health consequences. Hormones do have health consequences and can be carcinogenic at high dosages. Hence, control and producer education on appropriate procedures appear to be essential components of a well-functioning system. ♦

GMOs in Europe: A Genetically Modified Ordeal?

by Giancarlo Moschini
moschini@iastate.edu
515-294-5761
Jay Corrigan
corrigan@iastate.edu
515-294-6740

One thing seems certain: we are now familiar with yet another acronym. GMO stands for genetically modified organism and designates a living entity (such as a bacterium, plant, or animal) whose genome has been modified by recombinant DNA technology. The ability to alter the genetic makeup of organisms directly by such methods (i.e., transgenic) constitutes the hallmark of modern biotechnology and has ushered in a new era in agricultural research.

The promises of biotechnology in agriculture have at last begun to be realized, and in recent years an increasing stream of transgenic plants have been approved and marketed mostly (but not only) in the United States. Two such crops now well known to midwestern farmers are Roundup Ready (RR) soybeans and Bt corn. For RR crops, the relevant genetic material comes from a particular strain of *Agrobacterium* that, once introduced into the plant, confers resistance to glyphosate herbicide. For Bt crops, the genetic material of interest comes from another bacterium, *Bacillus thuringiensis;* once inserted into maize, it confers to the plant the ability to kill the European corn borer.

Acceptance of GMOs

The GMOs, by and large, have been welcomed by U.S. agriculture and by a number of other countries (notably Canada and Argentina). These new crops were virtually unknown before 1996 but have experienced breathtaking adoption rates. For example, in 1999 more than 50 percent of the soybean crop grown in the United States is genetically modified (at least 40 percent of U.S. corn and about 40 percent of U.S. cotton are also transgenic). For the next crop year it is estimated that 100 percent of the soybeans grown in Argentina will be herbicide resistant. But GMOs have struck a different cord in Europe, where they have met with numerous obstacles from consumers, businesses, policymakers, and regulators.

Safe food is at issue. Transferring genetic material from one organism to a completely different one is perceived by some as unnatural, and it is feared that the presence of a foreign genetic code may induce the transformed organism to produce unwanted toxins and allergens. The absence of risk from eating such food, it is claimed, has not been adequately documented.

Continued on page 7

GMOs in Europe
Continued from page 3

The environment is another concern. It is feared that the herbicide- and insect-resistant traits of new crops may spread to other plants in the wild; that genetically modified plants may be deleterious to other species (as in the recent debate on whether or not Bt corn harms the larval stage of monarch butterflies); and that specific genetic sequences conferring antibiotic resistance, which are used as "markers" in the genetic engineering process, may unwittingly aid the development of antibiotic resistant germs that could eventually harm humans.

An array of related issues are championed by particular segments of the European public. Some, for instance, perceive the whole idea of transferring genetic material between different organisms as unethical. Others question whether private research and development activities in a rapidly consolidating biotechnology sector is concentrating too much power in the hands of a very few multinational companies.

GMO Regulation in Europe

The novelty of GMOs has required the introduction of specific regulations in most countries. The United States has chosen to rely heavily on existing regulatory tools, with limited specific adaptations that entail a role for three separate federal agencies that enjoy widespread public confidence (U.S. Department of Agriculture, Environmental Protection Agency, and Food and Drug Administration). The European Union (EU), with a unique institutional setting, has chosen to rely more on new legislation.

The EU is not a country; it is the collection of 15 (rather different) countries united in the pursuit (not yet fully realized) of political and economic union. Regulatory activities in the EU are seen as the domain of politicians as much as bureaucrats. Both European bureaucrats and politicians, it must be said, have a less-than-spotless record in such matters, as evidenced by the recent debacles associated with the British

Regulatory activities in the EU are seen as the domain of politicians as much as bureaucrats.

"mad cow" disease and this year's Belgian dioxin scare. As a consequence, European consumers have developed skepticism about what they are told is safe to eat, and policymakers have read into that a need for more action on the regulatory front. Be that as it may, the legislative underpinning of the EU regulation of GMOs has two pillars: the 1990 Directive on the deliberate release of GMOs into the environment (Directive 90/220/EEC), and the 1997 legislation concerning novel foods (Regulation 258/97/EC).

A Complicated Process

The 1990 Directive constitutes the backbone of EU legislation concerning GMOs. Its purpose is to protect human health and the environment when releasing GMOs or placing them on the market. While it was intended to work somewhat like the U.S. system, this legislation also reflects the peculiar institutional structure of the EU. The complex regulatory procedure starts by requiring anyone wishing to release or market a GMO to "notify" the competent authority of any one EU country by supplying a host of documentation (including a risk assessment). This country (the rapporteur) should provide an initial evaluation within 90 days.

If the rapporteur supports the GMO, the dossier is forwarded to the European Commission (effectively, the executive government of the EU), which, after considerations of its own, sends it to the competent authorities of each of the other EU countries. These countries have 60 days to evaluate and respond. If the Commission receives no objection, it informs the rapporteur country, which can then proceed by issuing the final written authorization.

If any one country objects, however, the matter must be resolved following a protocol specified in the Directive itself, which entails a role for the Commission, a role for a standing EU committee, and a role for the EU Council of Ministers (the chief EU decision body for legislative and political matters). Once a decision is made it is binding for all member countries. Still, under the authority of the Directive (article 16), individual countries can provisionally prohibit marketing of an approved GMO on their territory citing possible risk to human health and the environment.

Because the 1990 Directive did not apply to nonliving substances extracted from GMOs, the EU developed additional legislation to regulate food produced from GMOs. The 1997 Regulation identifies a "novel food" as one not previously consumed to a significant degree within the EU. Specifically, the 1997 Regulation applies to food containing or consisting of GMOs, and foods produced from but not containing GMOs. Because RR soybeans and Bt corn were already commercialized in the EU prior to the introduction of this Regulation (under the authority of the 1990 Directive), *ad hoc* legislation was required to extend the definition of "novel food" to products of these genetically modified crops as well (Regulation 1139/98).

The 1997 novel foods regulation establishes a mondatory EU-wide pre-market approval for all foods obtained from GMOs and it mandates "labeling" of novel foods and novel food ingredients. Specifically, consumers should be informed when a food contins GMOs. This lavelling feature is highly controver-

sial and sets EU regulation apart from that of the United States (where no mandatory labeling of foods obtained from GMOs exists).

An Ambiguous Process

While the EU regulatory structure for GMOs is ambitious in scope, it is fraught with ambiguities and loopholes. The timelines laid down in the Directive and the Regulation are often violated. Article 16 of the Directive has been abused by some countries to provide indefinite restrictions on EU-approved GMOs (Austria and Luxembourg). In certain instances, rapporteur countries have withheld issuing the final written authorization even after all approval hurdles had been cleared (France). As a result, only a handful of GMOs have so far been approved in the EU (they include Novartis' Bt corn, Monsanto's RR soybeans and Bt corn, and AgrEvo's LibertyLink corn, but exclude many other transformation events already approved and used in U.S. crop production).

With public concerns about GMOs munting, the system has effectively stalled. Indeed, no new GMO crop has been approved in the EU for more than ayear; and at their June 1999 meeting, the EU council of (Environmental) Ministers appeared to agree on continuing this *de facto* moratorium on new approvals.

The strict labeling requirements are also somewhat empty at present. For example, it ha yet not been decided what exactly it means for a food to be "free" of GMOs (i.e., critical threshold levels need to be agreed on), and testing methods to monitor a label's claims concerning GMOs have not been specified.

Efforts to integrate and streamline EU legislation on GMOs have been held back by the mass resignation of the Commission in March 1999. The new, recently appointed Commission, and they newly elected European Parliament (yet another EU institution, which shares legislative power with the Council), will have their hands full in sorting out the problems under the watchful eyes of a somewhat confused, but increasingly dissatisfied, public. Given the situation, little substantial progress may be expected in the near future. For example, in light of the current *de facto* moratorium on using the 1990 Directive, approval of new GMO crops may be delayed as far out as 2002.

Implications for U.S. Agriculture

In a world where talk of global markets is commonplace, it comes as no surprise that the European struggle to sort out its position on GMOs has implications for U.S. agriculture. Delay in approving new GMO crops in Europe means lower than expected revenue for U.S. life science multinationals that are at the forefront of new crop development. On the other hand, from the producer's point of view, this delay *per se* is penalizing EU farmers by hampering their competitive position (compared with U.S. and Argentine farmers).

. . . in light of the current de facto moratorium on using the 1999 Directive, approval of new GMO crops may be delayed as far out as 2002.

The EU labeling laws, however, may hold perhaps the most serious implications for U.S. agriculture. Some believe that food labeled as containing GMOs will be less appealing to European consumers, and in fact many EU retailers have undertaken to supply what consumers apparantly want: GMO-free food. Some food chaines and retailers have gone further by rpomising to shun foods and food ingredients containing GMOs. If these trends are sustained, they would create incentives to develop handling and processing systems characterized by "identity preservation."

This point was brought home suddenly a few months ago when major U.S. commodity handlers (including Archer Daniels Midland and Cargill) announced that they would not buy maize produced with GMO varieties not yet approved for importation in the EU. Keeping GMO crops and food separated from their traditional counterparts at every stage of the production and marketing chain will be a costly undertaking, which may eventually be reflected in a price "premium" for GMO-free commodities (or a "discount" for GMO commodities).

Given the trade implications of the EU regulation of GMOs, there is considerable concern in the United States, where the export sector is vital to the marketing of all major crops. Some U.S. officials are complaining loudly that the EU labeling law constitutes an inadmissible technical barrier to trade, and have threatened to take the matter up within the World Trade Organization. Whereas such an attitude is understandable, it oversimplifies the issues. It would appear that European consumers' concerns are genuine, and that the preoccupation of EU policymakers is to address those concerns (rather that to exploit them for protectionist purposes).

If a GMO trade war were to break out, it would dwarf the recent banana and beef-hormone confrontations between the EU and the United States. The June 1999 meeting of the G8 group of industrialized countries considered the matter, and bought some time by charging the Organization for Economic Cooperation and Development with providing advice on the global implications of GMO foods and crops. In the meantime, a serious campaign of scientifically based education aimed at consumers and the general public that emphasizes facts and eschews rhetoric is overdue on both sides of the Atlantic. ♦