Europe angers US with strict GM labeling

European Union (EU) countries are to require all food and animal feed products linked in any way to transgenic crops to be clearly labeled as "genetically modified" (GM). Currently, only foods containing measurable amounts of genetically engineered DNA or resulting protein have to be given the GM label. But the new regime—agreed to in late November 2002 after lengthy negotiations between ministers of individual member states—extends labeling to end-products such as sugars and oils even when GM ingredients cannot be detected in them because they are physically and chemically identical to products derived from non-GM crops. Even meat suppliers who feed their animals with transgenic grain will have to GM-label their products .

Food items will be exempted only if they were derived from crop material of which less than 0.9% was genetically modified. Comprehensive tracing of GM corn shipments will be essential to verify this. The effect will be that North American manufacturers will soon find their corn- or soy-based foodstuffs—virtually all of which are GM-derived—tagged with what the National Grain and Feed Association (Washington, DC) has likened to a "skull and crossbones on the packet."

US farming interests are now expected to press the White House to launch an immediate protest to the World Trade Organization (WTO), with the aim of smashing European barriers to GM food imports. Europe's GM food moratorium is said to be costing US corn producers $250 million a year in lost sales.

The US industry is particularly worried by the effect of European policy on its customers in the developing world. In October, Zambia refused 63,000 tons of GM corn from the United States intended to help relieve the current famine in southern Africa. Its agriculture minister claimed that the corn could contaminate Zambia's agriculture, risking the loss of its cash-crop export markets in Europe. European politicians say Zambia's action is misguided. But it has alarmed US industry. In November, US farming corporations wrote to US trade representative Robert Zoellick demanding immediate WTO action against Europe because European policy "may be negatively affecting the attitudes and actions of other countries."

Europe has offered one concession to the US food industry: food containing GM ingredients that are believed to be safe but are not yet officially EU-approved will be allowed on the European market, provided the GM content is less than 0.5%.

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But a spokesperson for the US Biotechnology Industry Organization (BIO; Washington, DC) says the new labeling policy "represents an unacceptable technical trade barrier." BIO is urging European acceptance of the US Food and Drug Administration's (FDA; Rockville, MD) proposal that GM labeling is needed only where the genetic modification produces a "nutritional or compositional change" in the food.

EuropaBio, representing Europe's biotechnology industry, criticized the 0.9% threshold as "tough, perhaps impossible" for most crop producers. "In setting such a low level, ministers have simply ignored current labeling practices and other country threshold levels ranging from 1% to 5%", says EuropaBio spokesperson Simon Barber. "This places onerous burdens on the European Agro-Food industries and on national authorities who will have to enforce the law."

The EU Confederation of Food and Drink Industries (Brussels, Belgium) "strongly regretted" the decision and warned that the absence of reliable testing methods for GM ingredients "would lead to unfair competition and fraud."

The proposals now go back to the European Parliament for reconsideration. Meanwhile, the European Commission's research commissioner Philippe Busquin has announced that a new network of 45 GM laboratories is to be set up across Europe to help trace GM organisms in the food chain and enforce the new regulations.

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New products highlight ambiguity of orphan drug law

When researchers, clinicians, and the US Food and Drug Administration (FDA; Rockville, MD) gather later this month to review two new products to treat Fabry disease, a rare and deadly liposomal storage disorder, the discussion will center on important scientific issues—whether the drugs offer a hope of improvement to a patient population that currently has few options. But investors are paying as much attention to the legal drama surrounding the drugs, Genzyme General's (Cambridge, MA) Fabrazyme and Transkaryotic Therapies' (Cambridge, MA) Replagal.

Under FDA law, both products are considered "orphan drugs," entitled to seven years of market exclusivity if they win approval. But the same rules hold that the exclusivity is a winner-take-all proposition—once the FDA approves one orphan drug, it is barred from approving the same chemical entity for the same disorder from a different company unless that second drug is shown to be "clinically superior."

The problem, say lawyers, analysts, and agency watchers, is that the standards used to judge superiority are less than clear. Although no one is calling for a review of the original orphan drug law—which is celebrated by patient advocates and lawmakers for encouraging the development of therapeutics for rare diseases—the way the FDA applies the regulations leaves the agency with "a lot of wiggle room," according to Scott Gottlieb, an agency critic who works at the American Enterprise Institute (Washington, DC), a conservative think tank. "I'm as perplexed as anyone else. I don't think they have a solid interpretation of the rules."

The two products, which were both approved in Europe in March 2001, are nearly identical—both are versions of the protein agalsidase—and the companies and investors are now carefully examining the two-decade-old orphan drug law for superiority standards to see whether the differences in how the drugs actually work in the body are great enough for the FDA to justify approving both