

without testing, thereby treating them as if they were food additives that come under the generally recognized as safe (GRAS) categorical exemption. The FDA is using the GRAS exemption “to circumvent testing and to approve substances based largely on conjecture,” he says.

Here again, federal attorneys strenuously disagree. “Had Congress intended to establish a blanket requirement that substances derived through genetic engineering be subject to premarket approval, it readily could have done so...as it did with radiation,” they point out. “The definition [of food additive] is properly left to the expert agency... Based on its scientific assessment... the FDA concluded that there’s no scientific basis on which to distinguish foods derived through such technology from other foods.”

Some of the other arguments reflect each side’s vastly different interpretations of federal laws and procedures. For instance, the Alliance says that the FDA should have sought public comment on its policy, whereas federal attorneys say that such steps were unnecessary because the policy statement is “neither a rule nor a precedent but merely an announcement.” Moreover, that policy is “flexible and adaptable,” leaving agency officials free to apply more stringent safety standards as determined on a case-by-case basis. Taking their legal arguments one step further, federal attorneys add that “even if the policy statement were... characterized as a rule, it would still be exempt from notice and comment... because [it is] an interpretive rather than a substantive rule...”

In similar fashion, federal attorneys discount claims by the Alliance that the federal food policy violates or offends federal statutes protecting religious freedom. The Alliance demands that foods be labeled, thereby enabling consumers to determine whether genes derived from animals are present—arguing this information is helpful for consumers when they are abiding by certain religious dietary requirements or following a strict vegetarian diet.

Government attorneys say the FDA has no legal basis to require such labels. In this regard, the agency’s “failure to require something clearly cannot be construed as affirmatively placing an undue burden on a person’s religious beliefs.” In plainer terms, the FDA policy statement is “religion-neutral.” Moreover, the government attorneys point out that no products derived following an animal-to-plant gene transfer are yet being marketed, leaving open an opportunity for agency review when an actual case arises.

In the meantime, US attorneys say the FDA has sought to develop “a workable policy that would ensure the safety of the food supply and encourage innovation, without becoming unmanageable from a resource perspective.”

A judgment is expected before the end of the year.

Jeffrey L. Fox

Canadian farmers seek compensation for “genetic pollution”

Five years after genetically modified (GM) crops became available for use in Canada, the Canadian National Farmers Union (NFU; Saskatoon, Saskatchewan) is lobbying the Canadian federal government to legislate industry compensation for unintended genetic alteration of crops. NFU members, which include both organic farmers and those who grow GM crops, decry the “genetic pollution that has infringed on the livelihoods of farmers or the general public.”

The move follows the NFU’s annual meeting last December, in which a resolution was passed opposing the use of GM organisms. Agricultural biotechnology is a “gigantic experiment” says NFU spokesperson Stewart Wells. To Wells, an organic farmer from the province of Saskatchewan, it is the airborne contamination of his

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Organic and GM farmers claim that genetic pollution is infringing on their livelihoods.

canola with GM varieties of canola that is a problem.

Ann Clark, an agronomist at the University of Guelph in the province of Ontario, agrees. “Canola pollen can move up to 8 kilometers; [pollen from] corn and potatoes, about 1 kilometer,” says Clark, citing *New Scientist* (vol. 160, issue 2158, 1998) “Wind is only one of the ways pollen moves. Canola pollen, for example, is carried by pollinators.”

ANALYSIS

The Canadian government's national standards for organic agriculture, announced in April, prohibit the use of GM organisms but have yet to define a tolerance level for genetic pollution. Under the threat of airborne contamination, Wells and other organic farmers could lose their organic certification because it will be impossible to guarantee that their produce is free of genetically engineered traits. "If this continues, once wheat, barley, lentils, and other crops are genetically engineered, I won't have anything left to grow," he says.

Organic crop production represents a significant segment of the Canadian agri-food industry, approaching Canadian\$1 billion dollars (US\$0.68 billion) in sales annually. Sales are growing at 20% per year, according to the Canadian Organic Advisory Board. However, the nation's farmers have already lost markets for canola in Europe—from 83 tonnes in '94/95 to 20 tonnes in '97/98, according to Canola Council of Canada figures—some of which is attributed to uncertainty over whether the Canadian canola is genetically pure. "Exports are being vastly hurt right now," says Clark. Further losses in canola markets would be a blow to the Canadian economy; canola seed exports accounted for 22% of Canada's agrifood exports in 1997.

Moreover, farmers who cultivate GM varieties also claim to be affected by "genetic pollution." Tony Huethers, a canola farmer in the province of Alberta, planted several GM cultivars purchased from Monsanto (St. Louis, MO) in 1997. One

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field was sown with *Quest*, a Roundup (glyphosate)-resistant cultivar. Another field, 30 meters away across an intervening road, was sown with *Innovator*, a Liberty (glufosinate)-resistant cultivar, and *45A71*, a cultivar resistant to Pursuit (imazethapyr). The intervening distance between the fields exceeded the standard buffer zone of 6 meters. Two applications of Roundup herbicide last year to the field sown with *Innovator* and *45A71* killed all the weeds but revealed glyphosate-resistant

canola in the field sown with the other cultivars. The population was thickest near the road. Airborne dispersal of pollen from the glyphosate-resistant plants was suspected, given that the nearest source of natural pollination, a commercial bee hive, was 13 kilometers away.

Meanwhile, Percy Schmeiser, a Saskatchewan farmer who also grows GM crops, is being sued by Monsanto for possessing and growing Roundup-resistant canola without permission. Schmeiser contends that he inadvertently grew the crop, which he claims was spread to his fields via the wind or by pollinators such as bees.

Monsanto officials have not commented on the NFU action. However, speaking about the problems of contamination that the farmers in Saskatchewan have experienced, Aaron Mitchell, a Monsanto representative based in Saskatoon, says that "We always expected that a level of natural out-cross would occur within the species," and that "Farmers need to talk to their neighbors about the canola they grow."

The NFU anticipates a private members bill in the federal parliament when the current session resumes after a summer hiatus.

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