

SPECIAL REPORT

Out of bounds

With the use of transgenic crops expanding around the globe, we need to decide what level of unapproved plants we are willing to accept in our diets. Zero is not an option, says Heidi Ledford.

Steve Linscombe still isn't quite sure how it happened. The director of the Louisiana State University AgCenter for Rice Research knows that he grew a few lines of transgenic rice in field trials between 2001 and 2003. He also knows that one of those lines, LLRICE601, was grown on less than one acre. What he is not clear on is how the line then wended its way into the food supply. That little mystery is now the subject of an official investigation and a class-action lawsuit.

When the escape was announced in August last year, LLRICE601 had not been approved for human consumption. The US Department of Agriculture (USDA) rushed to deregulate the crop, granting permission on 24 November for LLRICE601 to be grown without a permit. By then, Japan had already declared a month-long ban on all imports of US long-grain rice, and the European Union had started to require all US long-grain rice imports to be tested and certified at the expense of the exporters. Meanwhile, Bayer CropScience, the company that created the rice strain, put the blame squarely on farmers and an "act of God".

By that logic, this would not be the first time that a deity has aided and abetted the escape of a genetically engineered crop. On 21 December, Syngenta was fined \$1.5 million for allowing its unapproved pest-resistant Bt10 corn (maize) to mix into seed distributed for food. The past decade is smattered with examples of unapproved crops sneaking through containment barriers (see 'Some past escapes'). When they make it into the food supply — as with LLRICE601 and Bt10 — public outcry and financial losses follow. But amid the calls for tighter regulations, experts say one truth is being drowned out: no

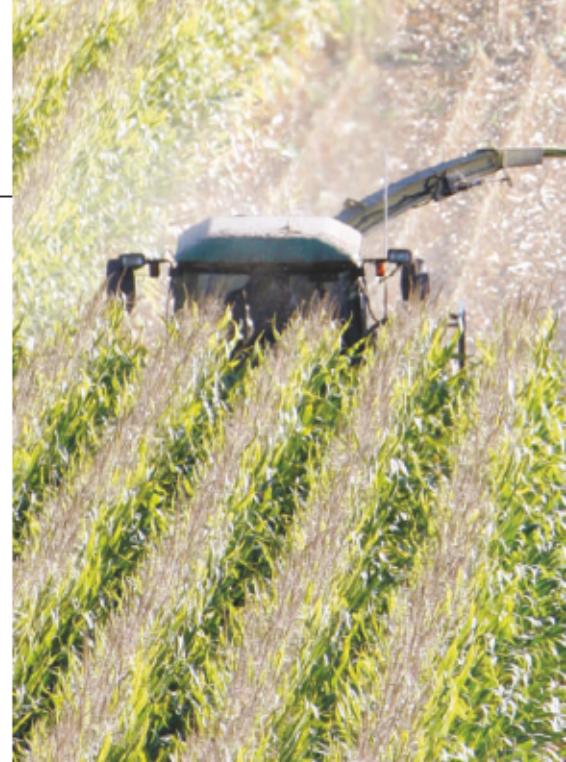
amount of regulation can guarantee that these crops will not escape and multiply.

Meanwhile, the stakes are getting higher. Since 1991, the USDA has approved nearly 400 field tests of crops that produce pharmaceutical and industrial compounds, leaving many concerned that future escapes could have severe consequences for human health. A close call came in 2002, when stalks of corn designed to produce a pig vaccine were found mixed with \$2.7-million worth of Nebraska soya beans destined for human consumption. Prodigene, the corn's maker, was fined \$250,000 and forced to buy and destroy the soya beans.

No guarantees

Although the use of transgenic crops is spreading around the globe, production is still concentrated in the United States, which grows more than half of the world's genetically engineered crops. There, they are monitored by three regulatory agencies: the USDA regulates field tests, the Environmental Protection Agency monitors crops genetically engineered to produce pesticides, and the Food and Drug Administration provides a voluntary 'consultation' on the safety of crops for human consumption. That voluntary consultation sets the United States apart from many other countries, including China and many European countries, which require crops to be evaluated for toxicity and allergenicity before being approved.

In the 20 years since the USDA started to regulate field tests, it has approved nearly 50,000 field sites. But an internal audit commissioned by the USDA inspector-general and released on 22 December 2005 was severely critical. The report admonished the agency for lacking basic



information about test sites, failing to inspect field tests sufficiently, and neglecting the fate of the crops after testing. USDA regulator Rebecca Besch says that a year on, many of the report's recommendations have been enacted. The agency now asks for detailed coordinates of field test sites, she says, and is revising its environmental standards.

Jeffrey Wolt, an agronomist at Iowa State University in Ames, commends the USDA for its efforts, but says that tougher regulations are no guarantee of confinement. "There has been this strong effort by regulators and industry to tighten this stuff up," he says. "But no matter how much you ratchet it down, the risk is not going to be absolute zero because that's a scientific impossibility."

Other scientists agree. Transgenic plants have many ways to escape. For plants pollinated by wind and insects, such as canola, pollen transfer is a constant threat. And although seed harvesting and processing equipment is designed to keep different varieties apart, there is no guarantee of success. "Just like anything, it is not 100%", says Linscombe. "You could have a seed that gets caught somewhere in a planter and later jars itself loose." And of course even if

SOME PAST ESCAPES

Limagrain Seed and Monsanto withdrew 60,000 bags of Canadian canola after finding that it was contaminated with unapproved herbicide-resistant seed.

Unapproved insect-resistant corn produced by Monsanto escaped its field trial site and released pollen to a commercial crop. The commercial corn was destroyed.

ProdiGene field-tested corn in 2001 that was engineered to produce a pharmaceutical. The next year, transgenic corn was found mixed with commercial corn that surrounded the site, and the crops were destroyed.

Transgenic contaminants of corn engineered to produce a pharmaceutical were harvested with commercial soya bean plants a year after they were field-tested by ProdiGene. Some 500,000 bushels of soya beans were destroyed.

Unexpected winds at a field-test site released herbicide-resistant, transgenic bentgrass produced by Scotts Company beyond its containment area.

1997

2001

2002

2002

2004

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Escape route: genetically modified corn can mix with other crops if not harvested properly.

only a few seeds make their way into breeding stock, their numbers can then multiply.

Meanwhile, says Michelle Marvier, an ecologist at Santa Clara University in California, the focus on designing effective biological containment has kept attention away from an even more slippery culprit: human error. "The reality is that humans are involved, and we inevitably make mistakes." She warns that any risk evaluation of a genetically engineered crop should consider that crop likely to escape.

Several countries have opted not to take that risk. After the news of LLRICE601 contamination, major exporters in Vietnam announced that they would not be growing any transgenic rice. And even some countries that grow genetically modified crops are cautious about the ones they will accept. Argentina, for example, the world's second largest producer, refuses to grow any genetically engineered crop that has not been approved for consumption in its major export markets, including the European Union. That policy is intended to prevent unintended mixing of crops from hurting Argentina's

robust agricultural export sector (although it hasn't protected neighbouring Brazil — which did not allow genetically engineered crops until last year — from repeated contamination from Argentina's transgenic stocks).

Harsh punishments

In the United States, the idea is that escape can be prevented if producers know that they will be punished if unapproved plant material is detected in the food supply. If a company is responsible for contamination, it typically has to remove the unapproved material at its own expense, and as an additional deterrent, deal with the flurry of negative press that undoubtedly follows. "It is really bad for the reputation of these firms and the technology itself," says Guillaume Gruere, an agricultural economist at the International Food Policy Research Institute in Washington DC. But he says that the regulatory agencies' zero-tolerance policy clashes with the inevitability of escape. "The problem is the threshold. If you want zero percent, it's going to be pretty much impossible."

And despite the negative press, US public opinion of genetically modified crops seems to have been changed little by the escapes so far, judging from the results of a survey done by the Pew Initiative on Food and Biotechnology last year. The number of Americans who approve of genetically modified food has hovered unchanged at around 26% for the past five years, whereas the number that explicitly disapproves has shrunk from 58% to 46%.

What about crops that produce pharmaceuticals and industrial compounds? In 2003, the USDA issued stricter guidelines for containment of these plants. Isolation distances from food crops were increased, and field test sites were to be inspected more frequently. And so far, no such strains have been deregulated, meaning that they must always be contained no matter how well they are tested.

But Margaret Mellon, director of the Union of

Concerned Scientists' Food and Environment programme, doubts that those regulations will be enough. Her organization has called for a ban on the outdoor production of pharmaceuticals in food crops, arguing that the amount of regulation needed to guarantee containment would be prohibitively expensive both to the government and to researchers. The union has gone through the USDA regulations and analysed points at which transgenic crops could still escape, such as machine cleaning and seed transport. "Regulations that are sufficiently stringent to plug all of those holes really are not feasible," says Mellon. "We see how much trouble the agency is having even with the current ones." Instead, she argues, production of pharmaceuticals or industrial compounds should take place only in non-food crops such as tobacco.

The problem is that such a ban would have a chilling effect on research, because the technology for creating and processing transgenic food crops is well understood and therefore much cheaper. At this stage, a US ban seems unlikely, and no other country has an official ban on

pharmaceutical-producing crops. In 2005, the Oregon Department of Agriculture convened a panel to evaluate the risks and potential economic benefits of growing animals and plants that produce pharmaceuticals in the state. The panel concluded last October that the benefits outweigh the risks.

Back in Louisiana, Linscombe plans to enact a few new regulations of his own. After his experience with LLRICE601, he says that he will be taking drastic measures to separate any experimental crops from his breeding stock, to at least minimize the chance of contamination. He is considering buying separate processing equipment for genetically modified crops. And he plans to greatly exceed the typical three-metre distance that is required between strains. "We have two farms that are located five miles apart," he says. "Any transgenic work in the future is going to be on one farm, and the breeding work on the other."

Nature reported that Syngenta had mistakenly produced and distributed a regulated, insect-resistant strain of genetically modified corn (434, 423; 2005). The Environmental Protection Agency and the USDA decided that the crop did not pose a risk to human health.

Greenpeace reported that it had found evidence of unapproved rice being sold illegally in China over the previous two years.

The USDA found that BASF had planted regulated genetically engineered corn outside the area specified by its permit.

Unapproved herbicide-resistant rice produced by Bayer CropScience was found in US rice sold for food. The USDA decided retrospectively that the crop did not pose a risk to human health.

Unapproved pest-resistant transgenic rice was found in European imports from China.

2005

2005

2006

2006

2006