

due to bruising. But at least three growers associations urged US and Canadian regulatory agencies to reject Okanagan's petitions for approval. Their objections were not made because of human health or safety concerns. In separate letters, the US Apple Association, the Northwest Horticultural Council and the BC Fruit Growers Association said GM apples may cause severe market disruptions, particularly in apple export markets averse to genetically modified organisms (GMOs). US Apple, however, changed its tune once USDA approval became imminent. "We are confident from the assurance we've received from Okanagan that they intend to stand by their pledge to clearly identify their apples in all marketing and packaging," enabling consumers to choose between GM and non-GM apples, says Wendy Brannen, director of consumer health and public relations at US Apple.

Okanagan's apples will not be labeled 'GM', but packaging will include the 'Arctic' name and logo. "It will be highly recognized as a GM product, given the amount of media attention we've had," says Carter at Okanagan. The company has not yet

decided whether the packaging will use other descriptive words, such as 'nonbrowning', which will partly depend on guidance from the US Food and Drug Administration, Carter says.

The GM apple may get caught up in the GMO labeling debate and used as an example, given its cachet as a family friendly, wholesome food, says Chris Schlect, president of the Northwest Horticultural Council in Yakima, Washington. "Apples are a symbolic product. It's a fruit that a mother gives to a child going to school," he says. "It's going to be used in the media and by Congress in issues over the national labeling initiative." Indeed, the Washington, DC-based Environmental Working Group put out a press release in February saying the approval of Arctic apples "underscores the need for a transparent and consistent national labeling standard."

Other consumer groups argued against the safety of Okanagan's apple. The Center for Food Safety (CFS) said USDA's environmental assessment was inadequate—a complaint the Center has made for nearly every biotech crop assessment USDA has conducted

in recent years. In its 61-page comment, the Center said that proper characterization of the PPO genes, their functions and the impacts of silencing them in the apple tree as a whole was not conducted. "I was floored by that," says Martha Crouch, former professor of biology at Indiana University in Bloomington and a consultant for CFS. "It seems like that would be the minimum you would want to know before you start an assessment." The Center noted that PPO genes have been shown in other plants to be associated with pathogen resistance, and that silencing them could lead to more susceptibility to disease and pests.

Okanagan says it conducted pest- and disease-resistance studies, and supplied the data to the USDA upon the agency's request. "We have not seen any difference in disease susceptibility or plant pest risk between Arctic and control apple fruit or trees," says Carter. "As summarized and analyzed in our petition document, we monitored all common orchard pests and diseases, including storage rot, over multiple years and multiple sites and saw no difference."

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## Around the world in a month



### NIGERIA

The Nigerian Senate adopts a key joint committee report establishing the National Biosafety Management Agency, which will regulate the safe use, handling and transport of genetically modified organisms and products in the country. Its sponsors had argued that the absence of a biosafety law has made it difficult for the agency to effectively perform its statutory functions and bring the benefits of the technology to Nigeria. A similar bill is being considered in the Nigerian House of Representatives.



### CHINA

China's State Council creates a \$6.5-billion venture capital fund to invest in startups in emerging industries, including biotech—the latest step in the government's two-year old strategy to let market forces eventually play a decisive role in China's economy. The funding will come from existing government capital designated for expansion of emerging industries as well as state corporations and private partners.



### URUGUAY

Uruguay's Parliament approves legislation to promote its biotech sector, including the formation of a capital fund for startups and a national register of biotech developments to help the disbursement of possible new tax benefits and incentives. The new law will allow greater private sector participation in the country's biotech R&D, innovation and tech transfer.



### TANZANIA

The government finalizes environmental regulations to allow biotech research. Earlier this year, President Jakaya Kikwete challenged Tanzanian scientists to establish the practicality of agbiotech research, eliminating obstacles such as a clause in the 2009 biosafety regulations sanctioning technology developers, financial backers and even sales outlets should anything go wrong in the development and use of agbiotech.



### BANGLADESH

Dhaka-based Incepta Pharmaceuticals is offering an unlicensed, generic version of Gilead's blockbuster hepatitis C drug Sovaldi (sofosbuvir) for \$10 a day, beating to market several Indian companies licensed by Gilead to produce the drug for 91 developing countries. Incepta is also in talks with the World Trade Organization to prequalify its version of Sovaldi as eligible for purchase by international aid agencies and countries. Gilead says it is "focused on enabling our 11 Indian generic partners to launch their authorized generic versions as soon as possible."