PRODUCT PROFILE

GM Waxy Corn Corteva

"CRISPR-waxy, in addition to delivering value to growers, is a product that should also help promote public and regulatory acceptance of CRISPR crops."

 N. Doane Chilcoat, Corteva Agriscience, March, 2020¹

Summary

The large seed and pesticide company Corteva Agriscience has clearance to introduce a genetically engineered (genetically modified or GM) corn (maize) produced through the genome editing (gene editing) technique called CRISPR, in Canada, Argentina, Brazil and Chile, and the company can also legally commercialize it in the US. The company refers to it as "CRISPR-Cas waxy corn" or "Next Gen waxy".

Waxy corn has a different starch profile from other corn. In Corteva's initial target markets of North America and Latin America, waxy corn is currently a minor crop used for food starch and some industrial products. However, waxy corn, also known as sticky or glutinous corn, is a major food crop in East and Southeast Asia, where it originates. This is the first GM waxy corn.

Corteva is using its GM waxy corn to test out the regulation of, and public response to, the new genetic engineering technique of CRISPR. Genome editing (gene editing) techniques such as CRISPR are a type of genetic engineering that results in the creation of genetically modified organisms (GMOs).

Name

Variety brand name unknown. Sold under the Pioneer brand.

No GM Event number known.

Corteva refers to it as "CRISPR-Cas waxy corn"² or "Next Gen waxy".³

Trait Promoted

Improved yield.

Market

The current stated target markets for Corteva's GM waxy corn are **North America and Latin America**⁴ where waxy corn is a minor crop used to produce speciality starch for some industrial uses such as adhesives (e.g. for bottle labels), as well as for thickening agents and carbohydrate supplements (e.g. corn starch) used in food product manufacturing.

- In the US, about a half-million acres of waxy corn are grown each year.⁵ This is less than 0.5% of US corn acres.⁶
- Corteva (Pioneer) also sells waxy corn in other countries including Argentina,⁷ Mexico⁸ and Australia.⁹

- Farmers typically grow waxy corn under "identity-preserved" systems where the waxy corn is kept separate from other corn varieties.¹⁰
- It is unclear when, or if, the company Corteva intends to commercialize its GM waxy corn. In April 2016, the company said it expected to sell to US farmers "within five years, pending field trials and regulatory reviews". 11 It launched a commercial pilot in 2019, 12 for a projected 2020 commercial launch.¹³

Company

Corteva:

- Spun off from DowDupont into an independent company in 2019.
- Formed in 2018 as an agricultural division of DowDuPont after the merger of the two large chemical companies Dow and DuPont, including DuPont Pioneer which was the leading supplier of waxy corn globally and the developer of this GM waxy corn.
- Second largest seed company: owns 19% of the global commercial seed market.14
- Fourth largest pesticide company: owns 11% of the global agrochemical market.

Regulation

Corteva's genetically engineered waxy corn has been cleared for release by government regulators in Canada without a risk assessment, could be released in the US without further assessment, and is a category of GMO (genetically modified organism) that is free from regulation in Argentina, Brazil and Chile:

- Canada: In February 2020, Health Canada determined that Corteva's GM waxy corn was "non-novel" and did not therefore need to undergo a government safety assessment: this product "is equivalent to varieties that have a history of safe use as food". 15 This decision was made public in September 2020.16
- **US**: In 2016, the US Department of Agriculture responded to a "Regulated Article Letter of Inquiry" from DuPont Pioneer (now Corteva) stating that the GM waxy corn does not need to be regulated.¹⁷ There is also a pre-market consultation process at the Food and Drug Administration that, while voluntary, Corteva is expected to engage in,¹⁸ but has not yet done so.¹⁹
- **Brazil:** In 2018, Brazil's national biosafety authority, CNTBio, ruled that Corteva's waxy corn was not a GMO and is not therefore be subject to the country's biosafety regulations for genetically modified crops.²⁰
- **Argentina & Chile:** Corteva says that, "Regulators in Argentina, Brazil, and Chile confirmed that if no DNA from another species is present in the plant, such plants will not be considered as GMO under their country's law" and therefore that the waxy corn will not need government regulation.²¹

From Health Canada's "List of non-novel determinations for food and food ingredients" 15

Date 1	Name of the food or food ingredient 🚹 👢	Description 🚹 🔱	Rationale for Non-Novel Determination (Refers to definition of a Novel Food as per Division B.28 of the FDR)
2020-02-25	Gene-edited corn for waxy trait	A type of corn with waxy or glutinous starch	Product is equivalent to varieties that have a history of safe use as food

Technology

Corteva used the genetic engineering technique of genome editing **CRISPR-Cas9**, classification SDN-1:²²

- CRISPR-Cas9 was used to knockout (inactivate) the waxy coding sequence:
 - ° Corn kernels normally contain 75% amylopectin and 25% amylose but the GM waxy corn kernels contain over 97% amylopectin, essentially eliminating amylose.
- This use of CRISPR-Cas9 in this case is classified as an SDN-1 technique because a pair of Site-Directed Nucleases (SDN) were used to cut DNA and trigger cell repair without the use of a repair mechanism.*

The genes for the genome editing components were inserted into the genome of the corn using the first-generation genetic engineering technique of particle bombardment. Most first-generation GM crops such as Roundup Ready soy and insect resistant Bt corn generally have one plasmid inserted. Corteva's GM waxy corn used six separate plasmids fired randomly at the corn's genome.

A total of six genetic sequences were inserted to introduce the deletion.²³ These packages (cassettes or plasmids) of DNA were inserted into cells using particle bombardment (a gene gun):

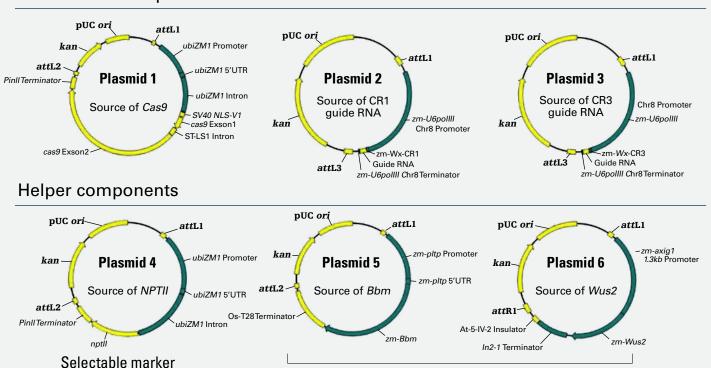
- Three genome editing plasmids:
 - 2 encoding for the CRISPR components (CR1 and CR3 guides)
 - o 1 encoding for the Caso DNA cutters
- Three "helper" plasmids:
 - 1 encoding resistance to the antibiotic neomycin to assist the selection of genetically engineered cells.
 - 2 encoding for corn morphogenic genes to increase the efficiency of the genetic engineering process.

The resulting transgenic plants were then crossed with a conventional hybrid to produce progeny that were screened to select those plants that did contain any **foreign DNA** remaining from the process of genetic engineering.

*For an introduction to CRISPR and SDN classifications see CBAN's report, page 4: www.cban.ca/GenomEditingReport

CRISPR-Cas components inserted into Corteva's waxy corn²³

CRISPR-Cas components



Morphogenic genes to facilitate plant transformation

Patents

- Corteva (DowDuPont) holds the most patents on CRISPR technology of any company or institution in the world,²⁴ in what it calls the "broadest CRISPR patent estate in the agriculture industry".²⁵
- There are several patents and licensing agreements that cover Corteva's GM waxy corn. This includes patents held by Corteva and licensing agreements with the Broad Institute of MIT and Harvard, the University of California, Berkeley, and Vilnius University, for different aspects of CRISPR-Cas9 technology.²⁶
- The primary licensing agreement involved in Corteva's development of CRISPR crops is an agreement with the Broad Institute that gives the company non-exclusive global rights to the institute's CRISPR-Cas9 technology for all agricultural uses and applications.²⁷
- The president and founding director of the Broad Institute is Eric Lander who was nominated in January 2021 to be US President Biden's Science Advisor and head of the White House Office of Science and Technology Policy.²⁸ Lander owns stock in Corteva, Dupont and Dow.²⁹

Why

Corteva has made it clear that they are using the GM waxy corn to test regulatory and public response to the genetic engineering technique of CRISPR (SDN-1).

Corteva calls this GM product, "Next-generation waxy corn – a flagship case of SDN-1/NHEJ genome editing via CRISPR/Cas9" and has presented the "Rationale: Familiar to market; identity preserved; technically simple, precedent-setting." ³¹

The waxy corn is the "first commercial agricultural product" Corteva has developed with CRISPR but "the technology has applicability for all Pioneer crops of interest."³² In 2017, the company said, "We think that CRISPR-Cas technology has an application in every crop that we work with"³³ and a 2018 presentation indicated Corteva's research and development in corn, canola, soy, rice, wheat and sunflower.³⁴

In the case of this GM waxy corn, Corteva says that the use of CRISPR afforded only slightly faster ("more than a year" faster) product development over using conventional breeding with marker assisted selection.³⁵

"CRISPR-waxy, in addition to delivering value to growers, is a product that should also help promote public and regulatory acceptance of CRISPR crops."

 N. Doane Chilcoat, Leader, Applied Science and Technology, Corteva, 2020³⁶

"Corteva Agriscience is a leader in the field of CRISPR for the development of agricultural products, specifically in row crops like corn, soybeans, sorghum and canola. We are committed to encouraging wide adoption of this technology in agriculture..."

Corteva, company website, 2021³⁷

"The starch isolated from waxy corn kernels has some unique applications in food and industry. It's a modest market but an ideal one for introducing a new variety. The genetics are very straightforward, and the supply chain isn't affected in any way. We can present our customers with an improved product—one that they're familiar and comfortable with. That's a nice starting point for an innovative technology; it lets us see how customers, regulators, and the public treat this kind of innovation."

 Corteva, sponsored article, 2017³⁸ [emphasis added]

"Starting with an identity-preserved product as our initial CRISPR-Cas offering allows us to lay a solid foundation for success of future larger volume products from this plant breeding innovation."

Dupont Pioneer, press release, 2016³⁹

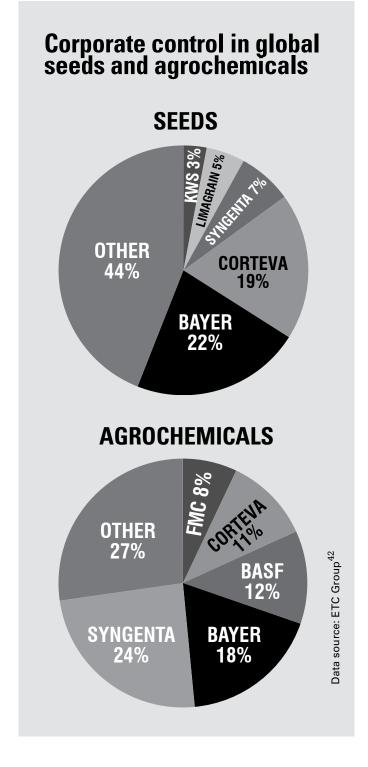
"The reason we are working on waxy corn is to have this conversation, because [we needed to come forward with something that had a long history of safe use as a trait, [that] has important industrial uses both in food [...], and in [other] industrial application, as well as ethanol. We needed to make something quick and have this conversation now, in order to get it out on the market...What I am hoping to convince you of today is that...we can get a product that will be accepted out there quickly, so that we can move the ball on the bigger goals that genome editing holds for us."

- Robert Meeley, Senior Research Scientist, Corteva 2018 [emphasis added]⁴⁰

"We are monitoring the development of the global regulatory policies for products of CRISPR-Cas technology and are in regular consultation with global regulatory bodies and government agencies."

- Neal Gutterson, Vice-President, Research and Development, Dupont Pioneer, 2017⁴¹

For discussion of genome editing please see "Genome Editing in Food and Farming: Risks and Unexpected Consequences," Canadian Biotechnology Action Network, 2020. www.cban.ca/GenomeEditingReport





The Canadian Biotechnology Action Network (CBAN) brings together 16 groups to research, monitor and raise awareness about issues relating to genetic engineering in food and farming. CBAN members include farmer associations, environmental and social justice organizations, and regional coalitions of grassroots groups. CBAN is a project of MakeWay's shared platform. www.cban.ca/gene-editing

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