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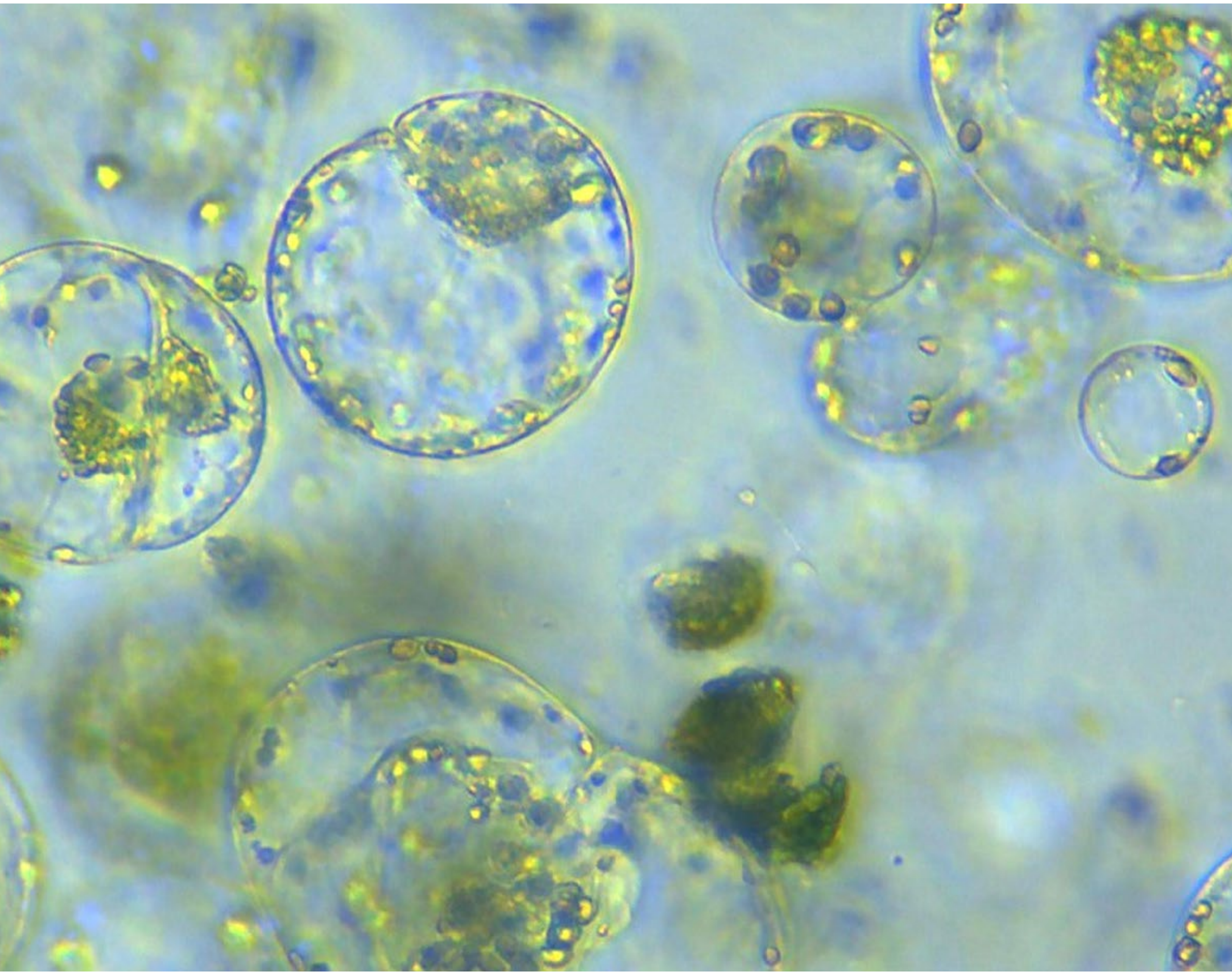

Agribusiness | Agrow

Game Changers: Gene-editing technologies and their applications 2020

Market Drivers, Trends and Restraints: Regulations, Patents and Competitive Environment; Company Profiles; Market Estimates and Forecasting

Please find the contents and sample pages below. If you have any questions, or would like to speak to a member of our team about this report please use our contact us page.

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Executive Summary

Chapter 1: Introduction

Gene-editing (also known as genome-editing or genome-engineering) is a set of novel techniques that are used for manipulating the genome of an organism at desired locations. The most popular gene-editing systems are meganucleases (MNs), zinc finger nucleases (ZFNs), transcription activator-like effector-based nucleases (TALENs), and the clustered regularly interspaced short palindromic repeats (CRISPR/Cas9). All of the mentioned above gene-editing systems exploit the natural gene repair mechanisms after double stranded DNA breaks caused by nucleases. In agriculture, these techniques are also becoming popularized as new plant breeding techniques.

To date, CRISPR is the most advanced gene-editing system, however, to overcome its limitations, scientists are trying to find out other alternatives to this system as well. Many CRISPR-Cas9 classes and variants are being researched and exploited for their applications in crop agriculture. CRISPR-Cas9 ortholog, CRISPR-CpfI, discovered by Feng Zhang group of the Broad Institute has various advantages over CRIPSPR-Cas9 system. The group has also discovered additional 53 class-II CRISPR-Cas candidates. Furthermore, UC Berkeley group has discovered CasX, CasY, HypaCas9 or GeoCas, a thermostable Cas9 systems. These new systems have simple structures, less off-target effects and higher homologous directed recombination frequency. Other Cas systems, namely spCas9-NG, xCas9, Cas13 and Cas14, are also being tested for their effectiveness in eukaryotic systems.

Chapter 2: Market drivers and restraints

The global population is estimated to reach 9.7 billion by 2050 and food production needs to be increased to feed the growing population. UN Food and Agriculture Organisation (FAO) estimates revealed a 70% increase in food production is required to maintain the current nutrition levels. As per the 2017 global report on food crises, hunger and malnutrition is rising and will continue to rise. One hundred and eight million individuals in 48 countries are at risk of severe food insecurity. Furthermore, climate change and a decrease in arable land in developed countries are also creating the need for development of climate resilient, disease resistant and high yielding crops. Rising food prices are also highlighting the need for such crops.

Owing to the above-mentioned factors, significant growth in the agriculture biotechnology sector is expected in the coming decade, which will be dominated by the gene-editing sector. Although transgenic crops are the most adopted agriculture technology with 191.7 million hectares of area covered under biotech crops in 2017, the technology is being criticized by the end consumers. Also, high costs and lengthy regulatory procedures are constraining the growth of this segment.

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The perception of gene-edited crops as natural products by many countries is making them an easy substitute for transgenic crops. USDA’s 2018 decision on not regulating the plants developed through traditional and new plant breeding techniques, if they are not plant pests or developed using plant pests, has opened the prospects of growth for gene-editing technology markets in the agriculture sector. Owing to the need for higher yields, federal governments all over the world are becoming more open to the adoption of gene-edited agricultural products. However, potential regulatory requirements, environmental and ethical concerns, and consumer acceptance might stall the growth of gene-edited crops in certain regions of the world.

Chapter 3: Market trends by crop

The potential benefits of gene-editing in crop agriculture can be broadly categorized as improved nutrition and greater productivity. The private sector is mainly focusing on improvement of maize, soybean, canola, cotton, rice, and wheat crops using gene-editing technologies. Among these crops, soybean is present in the product portfolio of ten out of twelve seed companies and breeding start-ups studied in this report. In 2018, Calyx released a gene-edited high oleic soybean “Calyno™” in the USA. In 2019, the same product was at pre-commercialization phase in Canadian market as well. Followed by soybean, maize is the second crop of importance with its place in the product pipeline of eight companies. Corteva Agriscience has developed waxy corn using gene-editing technology and is planning to commercialize the crop by 2020. Cibus, Calyxt, Yield10 bioscience, Precision biosciences, Pairwise Plants and Corteva Agriscience are investing in canola trait development using gene-editing technology. Currently, Cibus is the only company with commercial gene-edited canola traits.

Companies working on other crops are Pairwise Plants (fruits and vegetables), Arcadia Biosciences (hemp), Cibus (potato, peanut, flax and cassava), Benson Hill Biosystems (sorghum and barley), Calyxt (alfalfa), Tropic Biosciences (banana and coffee), Precision Biosciences (watermelon, stevia and chickpea), Inari Agriculture (tomato), and Bayer (strawberry).

Most of the gene-edited crops are at a developmental stage, except for Cibus’s SU canola™, Calyxt’s high oleic soybean and Arcadia’s GoodWheat™. Furthermore, gene-edited non-browning mushrooms and waxy corn are soon expected to hit the market.

Chapter 4: Regulatory status

Regulatory bodies all over the world are adapting, modifying or creating new regulations for gene-edited crops. With products available or at pre-commercialization stage many companies, namely Corteva Agriscience, Cibus, Calyxt, Arcadia Biosciences, Precision Biosciences and Yield10 bioscience are requesting formal opinions and approvals in different countries.

US authorities have supported gene-editing technology in agriculture by considering gene-editing technology as an extension of plant breeding techniques. However, the European Union decided to regulate the crops produced by using the technology under the existing GMO protocol.

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Argentina, Australia, Brazil, Canada, Colombia, the Dominican Republic, Guatemala, Honduras, Jordan, Paraguay, the United States, Uruguay, Vietnam and the Secretariat of the Economic Community of West African States announced their decision to support the agriculture innovation technologies at a World Trade Organization (WTO) meeting in Geneva, Switzerland in November 2018. These nations have identified gene-editing as non- transgenic plant breeding technology and have decided not to subject the crops developed through these technologies to GMO regulations. The WTO statement aims to create regulatory harmonization beyond North America to prevent regulatory asymmetries and trade disruption.

In a simplified statement, the regulatory framework for gene-edited crops is derived from existing novel trait and GMO definitions in most of the countries. While the USA, Canada and Argentina are using a product-based approach; the EU, Brazil, China, New Zealand and Australia laws are based on the process-based approach. This product vs. process approach has been a topic of debate ever since GM crops were introduced.

Currently, for gene-edited crops, three types of regulatory framework are being followed all over the world: 1. Similar to USA regulations; 2. iIdentical to the EU's regulatory structure and; 3. Somewhere in between the US and the EU's regulations.

Below is the description of regulatory decisions by countries on gene-edited crops:

Australia: Tools where proteins cut the DNA at a target location and allows DNA to repair naturally will be non-regulated. However, if a guide template is used to direct the repair process, the product will be regulated.

Argentina, Brazil, Canada, Chile, Colombia, United States: Non-transgenic GE crops are not GMO according to a WTO Statement.

Dominican Republic, Guatemala, Honduras, Jordan, Paraguay, Uruguay, Vietnam, Economic Community of West African States (ECOWAS): WTO Statement: - Gene-editing is considered as non-transgenic plant breeding technology and will not subject the crops developed through these technologies to GMO regulations.

Japan: Japan MHLW is not subjecting food and food additives derived through gene-editing technology to food safety regulations if the DNA double-strand break is induced by engineered restriction enzyme and following natural repair mechanism. In the presence of transgene, the technology will be considered recombinant DNA technology and hence there will be biosafety procedure.

Russia: Gene-editing technologies which do not necessarily insert foreign DNA are equivalent to conventional breeding methods.

The European Union: Using recombinant nucleases is considered GMO.

Belgium, Sweden, UK: Calling to update EU GMO laws / Gave permission for field trials before ECJ ruling.

Cyprus, Estonia, Finland, France, Germany, Greece, Netherlands, Italy, Portugal, Slovenia, Spain: Calling to update EU GMO laws.

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India: Regulatory guidelines for gene-edited crops are not yet published.

China: National Biosafety Committee is working on development of new guidelines.

Chapter 5: Patent landscape

The ownership of intellectual property of gene-editing technologies is divided among the public and private sectors. Patents belonging to MNs, ZFNs and TALENs are mostly owned by biotechnology firms. However, the public sector owns the rights over CRISPR-Cas9 IP. Most of the companies using gene-editing technologies have licensed their technologies from the public sector.

In the agriculture sector, the majority of the rights over ZFNs technology were provided by via the Chinese Academy of Agricultural Sciences to Dow Agrosciences, which further sub-licensed the technology to other firms. The University of Minnesota and Duke University have licensed TALENs and meganuclease based DNE™ technology to Calyxt and Precision Biosciences. Two Blades Foundation has provided rights over TALENs technology to Calyxt, Bayer, Monsanto and Corteva through Dow Agroscience.

In the gene-editing space, nearly all players have access to CRISPR-Cas9 IP. Currently, there is a patent dispute over CRISPR-Cas9 foundational IP between UC and Broad Group Institute. UC Berkeley had filed a patent interference application at USPTO's Patent Trial and Appeal Board (PTAB), following the award of a CRISPR-Cas9 US patent to the Broad Institute on April 2014. After reviewing the case, initially in February 2017, PTAB had stated that Broad's claims on CRISPR applications in eukaryotes did not interfere with the UC Berkeley team for the use of CRISPR-Cas9 in any environment. Later, in June 2019, USPTO renewed the dispute and declared an interference between 10 University of California patent applications and previously issued Broad Institute patents. The decision affects 13 of 15 Broad US patents, and mainly the first application that involves the use of CRISPR-Cas9 in eukaryotic systems.

Most of the larger agricultural companies including Bayer, Dow Dupont (Corteva Agriscience), Syngenta and BASF among others have licensed the basic CRISPR technology for research and commercial use from either of the groups, or from both groups and are further filing patent applications for technology applications in plant breeding.

As of 2019, among large agriculture biotechnology firms, Corteva Agriscience (previously, an agriculture division of Dow DuPont) is leading with around 65 patent applications in genome editing in agriculture at the WIPO. Dow DuPont has licensed the CRISPR-Cas9 technology through various licensing agreements from both Broad and UC groups, inorder to avoid any IP dispute in the future. Followed by Dow DuPont, Bayer (in collaboration with Monsanto) is the second largest with 30 applications. Syngenta has filed a total of 11 applications with the majority of them involving haploid induction editing (HI-Edit™) technology.

Start-ups and small breeding companies are extremely active in agriculture gene-editing space. As of 2019, Inari Agriculture is leading the patent application filings with 2400 traits patents in 75 patent families. Followed by Inari, Cibus has protected its technologies and traits by over 300 patents with patent applications across 16 patent families. Calyxt owns around 150 patents and has an additional 140 patent applicationspending

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worldwide. Calyxt has 17 patents issued in the USA with the remaining issued in key geographies outside the USA primarily Europe, Japan, and China. Furthermore, Caribou Biosciences and Benson Hill Biosystems have filed 125 and 80 patent applications, respectively. ERS Genomics has filed CRISPR/Cas9 a patent broadly throughout the world. 45 countries have granted patents between the years 2016-2019, including throughout the EU, Japan and in China. Yield10 Bioscience owns or held exclusive rights to 17 pending patent applications worldwide related to advanced technologies for increasing yield in crops. Agribody Technologies owns 16 US patents and has 5 pending US patent applications. The company is also filing patent applications on the use of genome editing in DHS genes.

Chapter 6: Competitive environment

The market for gene-edited agricultural products is very niche, as products have just started to enter the market space. In the coming decade the market will be highly competitive for seed, traits, food ingredients and technology platforms. Currently, trait development through gene-editing techniques is a highly competitive segment. The top five companies with the largest number of activities in the agriculture gene-editing space are Benson Hill Biosystem, Corteva Agriscience, Precision BioSciences, Arcadia Biosciences and BASF.

Patents, partnerships and in-licensing are the most prominent industry activities. ERS genomics has the greatest number of technology patents. Benson Hill Biosystems is involved in the largest number of partnerships in the industry for the development of improved plant traits.

Chapter 7: Company profiles

The principal industry players in the the agriculture gene-editing space consist of multinational seed giants, plant breeding and food ingredient start-ups/small companies, computational agriculture technology companies and gene-editing technology licensing companies.

Plant breeding and food ingredient start-ups/small companies form the largest segment with the presence of nine companies namely Arcadia Biosciences, Benson Hill Biosystems, Calyxt, Cibus, Inari Agriculture, Pairwise Plants, Precision Biosciences, Tropic Biosciences and Yield10 Bioscience.

Seed industry major players, Bayer, BASF, Corteva and Syngenta, constitute the second largest market segment, which is actively involved in technology licensing, funding and research collaborations. The third segment includes computational technology companies - Agribody Technologies, Amfora and Hudson River Biotechnology. The last segment is formed by Caribou Biosciences, ERS Genomics and Toolgen. These companies are earning their revenue mainly through out-licensing of their technologies.

Currently, companies involved in technology/trait licensing and computational technology have started earning revenue. A significant number of breeding start-ups are not generating any revenue and are developing their products through funding and collaborations. To date, none of the seed industry majors have commercialized any gene-edited product and are at the product development stage, except for Corteva, which is planning to release its gene-edited waxy corn during 2020. The only gene-editing companies which have started earning

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revenue through the sale of gene-edited products are Cibus and Calyxt. Arcadia is expecting to generate its revenue through sales of GoodWheat™ products in 2020.

Chapter 8: Market estimation and forecasting

The agricultural gene-editing technologies market was worth $321.89 million in 2019 and is expected to reach $1446.14 million by 2024, witnessing a CAGR of 35.05%.

The NAFTA region dominates the market with 78% of the global market share. With the presence of 12 gene-editing companies, the United States forms the hub for the agricultural gene-editing industry. APAC is the second largest market with 12% of the market share. LATAM and EMEA accounts for 6% and 4% of the market shares, respectively.

By product type, the agricultural gene-editing technology market could be segmented into seeds, food products and technology/trait licensing. In 2019, technology/trait licensing formed the largest segment with a size of $193.13 million. The segment is expected to witness a CAGR of 18.43% during the forecast period. The food products segment is the fastest growing and with the expected release of 13 new products between 2019-2024, the segment is projected to occupy 62% of the market share by 2024. The food products segment size will grow from $112.66 million in 2019 to $910.98 million in 2024. With 6% of total market share, seeds constitute the smallest market segment. The market for gene-edited seeds is expected to flourish in the USA and Canada and will witness a CAGR growth of 39.54% during the forecast period.

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Increased investment in agriculture technology is helping industry development and hence driving market growth. Below is the funding raised by gene-editing start-ups.

Table 3: Funding raised by gene-editing start-ups in $ million

Companies	Series A	Series B	Series C	Total
Benson Hills Biosystems	7.3	25	**60**	**92.3**
Pairwise Plants	25			25
Caribou Biosciences	11	30		41
Inari Agriculture	4.7	40	89	133.7
Tropical Biosciences	10			10

Source: IHS Markit Data

2.3.3. Investments in higher value niche crops and different traits

Gene-editing technologies, specifically CRISPR have been recognized as a breakthrough technology in agriculture. Various companies including start-ups and large seed companies are either licensing the technology from inventors or are developing their own technology. Many big seed companies namely BASF, Bayer CropScience, Syngenta, Corteva Agriscience are focussing on row crops, which is creating opportunities for start-ups to focus on high value, niche crops. Fruits, vegetables and nuts represent a large addressable market and have higher margins compared to row crops. Tropical Biosciences, the UK based start-up using gene-editing technology is focussing its research on optimizing banana and coffee crops with a global market size of $50 billion.

By 2025, key high value gene-edited crops expected onto the market include watermelon, strawberry, banana, coffee, hemp, stevia, alfalfa, flax, peanut, chickpea, cassava, camelina, potato and tomato.

Around the world, it is estimated that there are about 570 million farms with less than two hectares. These smallholder farms operate on 12% of the world's agricultural land and produce 80% of the food that is consumed in Asia and sub-Saharan Africa. Developing crops based on the needs of small-holder farmers can create tremendous opportunities for start-ups owing to less competition from seed giants. Gene-editing could become the technology of choice for the small holder for the following reasons:

1. Simple accessible format of technology, i.e. seed.
2. Traits developed using gene-editing technology are durable.
3. Gene-edited crop doesn't require any equipment or special training by smallholder farmers.
4. In most countries the process of gene-editing is considered as natural, as it doesn't involve transgene insertion, hence will have more public acceptance compared to transgenic crops.

Small-holder crops will enhance adoption of the technology and accelerate overall market growth.

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Table 4: Crop portfolio by company

Companies	Maize	Rice	Wheat	Soybean	Canola	Cotton	Fruits	Vegetables	Others
Pairwise Plants									
Yield10									
Arcadia Biosciences									
Cibus									
Benson Hill Biosystems									
Calyxt									
Tropic Biosciences									
Precision Biosciences									
Inari Agriculture									
Corteva									
Bayer									
Syngenta									

Source: IHS Markit Data

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3.3 Maize

Maize is an important crop globally and is used for animal feed and the production of starch, paper, packaging materials and others. The most common traits in GM maize are herbicide tolerance (HT) and insect resistance (IR). Insect resistant GM maize was first grown in the USA and Canada in 1996, and currently it is planted in 13

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Table 9: List of approved private sector applications by APHIS

S. N	Company	Year	Crop	Technology	Trait	Description
8	DuPont Pioneer	2016	Maize	CRISPER-Cas9	Improved processing attributes	Waxy corn with altered starch composition
9	Calyxt, Inc.	2016	Potato	TALEN	Improved processing attributes	PPO _ KO potato with improved processing characteristics
10	Simplot Plant Sciences	2016	Potato	TALEN	Consumer Trait	Low PPO5 potatoes with reduced black spot, a condition that is caused when potatoes are bruised or damaged
11	Donald Danforth Plant Science Center	2017	Setaria viridis	CRISPER-Cas9	Delayed Flowering	S. viridis line with a targeted mutation in the S. viridis homolog of the Z mays ID 1 gene resulting in a delayed flowering phenotype
12	Yield10 Bioscience	2017	Camelina sativa	CRISPER-Cas9	Not Disclosed	Camelina line developed using CRISPR/Cas9 gene editing technology resulting in the desired phenotype
13	Calyxt, Inc.	2017	Alfalfa	TALEN	Nutritional Quality /Consumer Trait	Alfalfa plants with improved nutritional quality, developed through targeted gene knockout
14	DuPont Pioneer	2018	Maize	CRISPER-Cas9	Disease Resistance	Corn product with improved resistance to Northern Leaf Blight (NLB) using alleles from corn

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Argentina was pioneer in publishing regulatory framework for new breeding technologies including genome-editing in 2015. In resolution No. 173/2015a, the Secretariat of Agriculture, Livestock and Fisheries outlines the procedure for a case-by-case assessment to determine whether a crop will be regulated as a GMO or not. Hence, the regulation for gene-edited crops in Argentina is similar to that of the USA and Canada, and gene-edited crops will not be subject to GMO regulation if no transgene is inserted.

4.4.2. Brazil

In Brazil, The National Biosafety Technical Commission (CTNBio) regulates biotechnology products under law No. 11,105 of March 24, 2005. In short Brazil's existing law for biotechnology products accommodates new plant breeding techniques under "mutagenesis techniques".

As per the Brazil's Normative resolution no. 16, of January 2018, plant breeding techniques can use molecular biology tools that can result in following:

- Precise edition of genomes, by the induction of specific mutations, generating or modifying wild and/or mutated alleles without the insertion of transgene(s)
- Genetic transformation and/or control of gene expression (activation/inactivation)
- Epigenetic regulation of gene expression by natural mechanisms with no genetic modification in the individual
- Genetic transformation and/or control of gene expression with genes of sexually compatible species
- Temporary and non-inheritable genetic transformation of cells and tissues
- Permanent or non-host infection of genetically modified viral elements
- The creation of alleles with autonomous inheritance, and recombination potential with the possibility of altering a whole population (gene drive)
- The construction of heterologous genes or new copies of homologous genes

Hence, if there is no insertion of transgene, gene-edited crop products with nucleotide deletions, substitutions and natural nucleotide insertions will be regulated on case-by-case basis.

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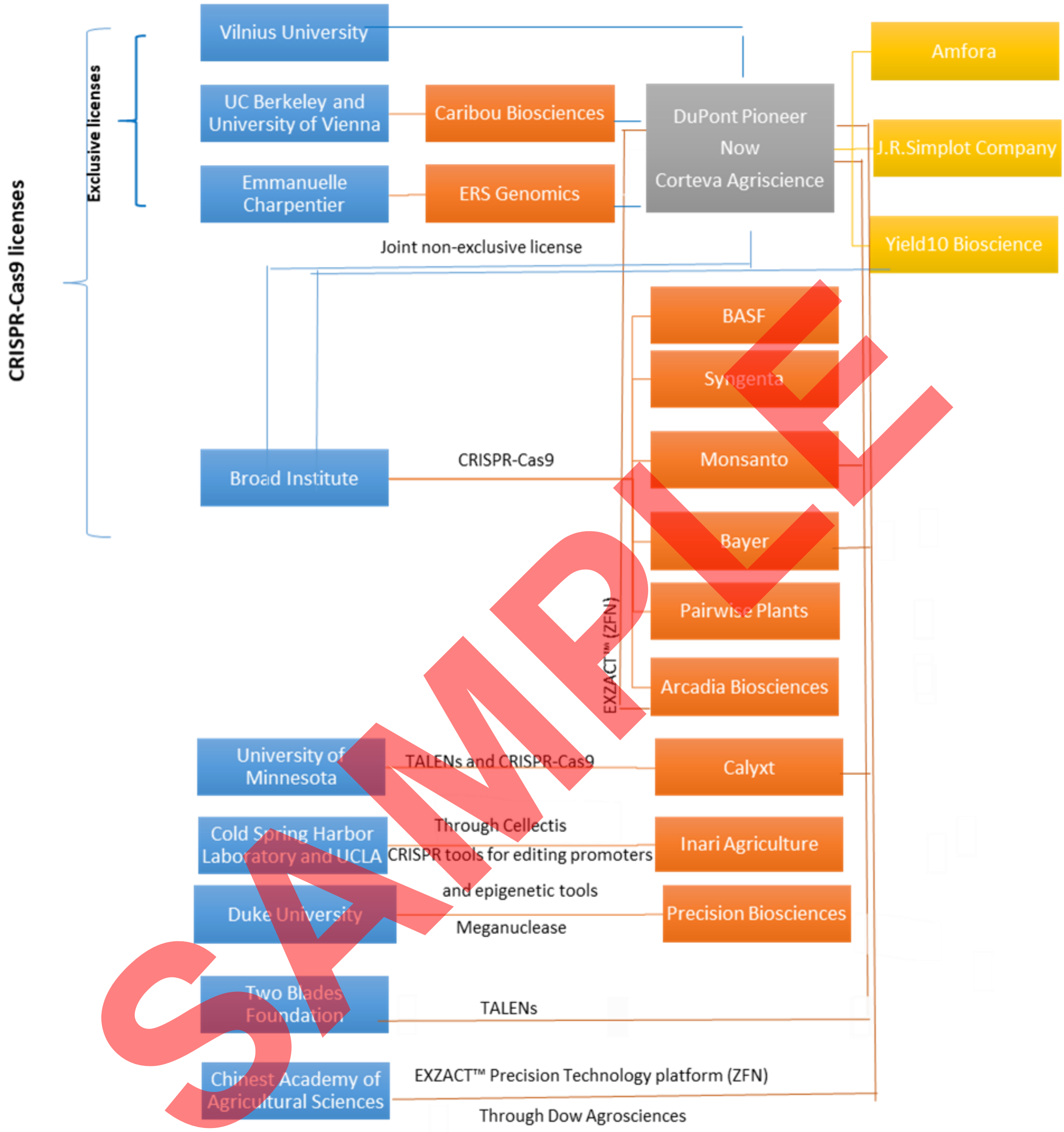
4.4.3. Others

Most of the other LATAM countries are adopting similar regulations. Chile signed a normative resolution in 2017 and will follow the same regulatory structure as that of Brazil. The Colombian government has also announced that it will not regulate gene-edited cacao.

4.5 EMEA

Plants having novel traits produced using radiation, chemical mutagens are not considered GMOs in European Union. In a debate on what could be considered a GMO in Europe, the Court of Justice of the European Union

Figure 16: Gene-editing technology licensing landscape in the agriculture industry



Source: IHS Markit

5.6 References & resources

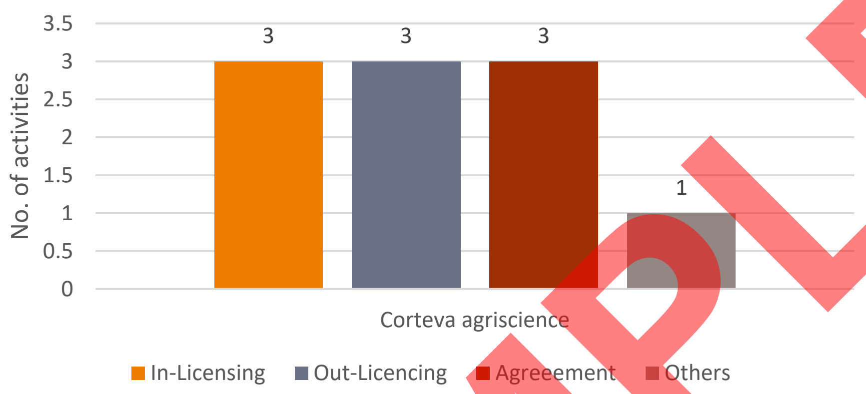
Broad Institute, Inc. v. Regents of the University of Cal., Patent Interference No. 106,048, 2017 WL 657415 (P.T.A.B. Feb. 15, 2017).

- May 2019, Benson Hill Biosystems entered into a partnership with RAPiD Genomics, a provider of genotyping and data analysis solutions for applications in the agriculture, forestry and livestock industries.

6.3.2. Corteva Agriscience

Corteva is the second most active company in the gene-editing space after Benson Hill Biosystems. Corteva was previously the agriculture division of DowDuPont and became an independent company in June 2019. The company is planning to commercialize its first CRISPR edited waxy corn by 2020.

Figure 19: Activities of Corteva Agriscience



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Corteva was very active in 2018, the principle activities for both 2018 and 2019 are covered below:

- April 2019, Corteva, Agriscience and the Broad Institute of MIT and Harvard signed a non-exclusive research and commercial licence agreement with Amfora, a biotechnology company. Through the agreement, Amfora will use intellectual property covering CRISPR-Cas9 and related gene-editing tools to develop crops with an increased protein content.

- October 2018, Corteva Agriscience and the International Rice Research Institute (IRRI) announced a multi-year framework agreement on collaborative rice research, deployment of new breeding technologies and development of breeding programs. The partnership will attempt to improve the genetic outcomes of breeding programs, encourage sustainable rice cultivation, and develop new rice varieties with higher yields and resilience against biotic and abiotic stresses.

- August 2018, Yield10 Bioscience signed a research licence agreement covering CRISPR-Cas9 genome-editing technology with the Broad Institute and Corteva Agriscience for the use of CRISPR-Cas9 genome-editing technology in crops.

- August 2018, Corteva Agriscience with the Broad Institute of MIT and Harvard and The J.R. Simplot Company announced a joint intellectual property licensing agreement for foundational CRISPR-Cas9 and related gene-editing tools.

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Chapter 7: Company profiles

7.1 Summary

The principal industry players in the agriculture gene-editing space comprise of multinational seed giants, plant breeding and food ingredient start-ups/small companies, computational agriculture technology companies and gene-editing technology licensing companies.

Plant breeding and food ingredient start-ups/small companies form the largest segment with the presence of nine companies namely Arcadia Biosciences, Benson Hill Biosystems, Calyxt, Cibus, Inari Agriculture, Pairwise Plants, Precision Biosciences, Tropic Biosciences and Yield10 Bioscience.

Seed industry major players, Bayer, BASF, Corteva and Syngenta constitute the second largest market segment, which is actively involved in technology licensing, funding and research collaborations. The third segment includes computational technology companies - Agribody Technologies, Amfora and Hudson River Biotechnology. The last segment is formed by Caribou Biosciences, ERS Genomics and Toolgen. These companies earn their revenue mainly through out- licensing of their technologies.

Recently, companies involved in technology/trait licensing and computational technology have started earning revenue. A significant number of breeding start-ups are not generating any revenue and are developing their products through various fundings and collaborations. To date, none of the seed industry major players have commercialized any gene-edited product and are at the product development stage, except for Corteva, which is planning to release its gene-edited waxy corn by 2020. The only gene-editing companies which have started earning revenue through the sale of gene-edited products are Cibus and Calyxt. Arcadia is expecting to generate its revenue through sales of GoodWheat™ products by the end of 2019.

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7.2 Introduction

This chapter will provide information on company finances or funding in the case of start-ups. Information on key developments, product pipelines, technology and business strategy will also be included in this chapter. Based on their activity and product type, companies are divided into the following four sections:

- Plant breeding and food ingredient start-ups/small companies
    - Arcadia Bioscience
    - Benson Hill Biosystems
    - Calyxt
    - Cibus

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3. **Lawsuit Settlement:**

   In May 2018, Bayer CropScience settled a lawsuit brought by Calyxt for an undisclosed amount. Bayer will destroy any technology, related product and confidential information covered by a 2013 license agreement and will permanently abandon patent applications that are based on or include data related to the covered technology. After this settlement Bayer and its subsidiaries have no access to Calyxt technology or intellectual property in future.

4. **Product deregulation:**

   Calyxt's high-fiber wheat and improved quality alfalfa products have been declared non-regulated articles in March 2018 and October 2017, respectively, under the Biotechnology Regulatory Services' "Am I Regulated?" process of the Animal and Plant Health Inspection Service (APHIS), USDA.

7.6 Cibus

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United States

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Email: info@cibus.com
Website: https://www.cibus.com

7.6.1. Introduction

Cibus is a leading advanced plant breeding company, which uses the latest gene-editing tools to improve various crop traits. Established in 2001, Cibus has a presence in North America and Europe, with offices in the US and the Netherlands.

Cibus uses its proprietary technology Trait Machine™ for the development of non-transgenic gene-edited crops. Trait Machine™ is a combination of a suite of technologies, with Rapid Trait Development System™ (RTDS™) as its main component. This utilizes gene-editing technologies, including CRISPR and TALENs to produce non-transgenic plant traits with the support of the Gene Repair Oligonucleotide (GRON) template. The technology has been successfully implemented in canola, rice and flax. Cibus' SU Canola™, which is tolerant to sulfonylurea herbicides, is currently being sold in the US market under the brand name Falco™ and has also received regulatory approvals in Canada. Cibus is currently working on the development of herbicide tolerant rice, late blight- resistant potatoes and glyphosate tolerant flax.

7.6.2. Technology

Cibus is using its Trait Machine™ technology for trait development. This technology is customizable at every step and can create stackable traits. The main component of this trait factory is RTDS™, which makes use of DNA-breaking nucleases that cut both strands of DNA at specific locations. Subsequent natural DNA repair of those segments leads to the production of non-transgenic plants. Cibus claims that RTDS™ does not include transgene addition and is more precise than either the CRISPR or TALENs system. Also, RTDS™ could be used to develop customized stacked traits.

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2. **Patent Grant:**

   In August 2019 the U.S. Patent and Trademark Office granted a patent to Yield10 covering the use of C4001 to improve productivity in crops. The grant relates to Yield10's U.S. patent application US15/897,958 titled "Transcriptional Regulation for Improved Plant Productivity." Also, the China National Intellectual Property Administration granted Yield10 a patent on C4001.

3. **Patent Grant:**

   In August 2019, the U.S. Patent and Trademark Office granted a patent to Yield10 covering the use of C3003. The U.S. patent 10,337,024 relates to, "Plants with enhanced photosynthesis and methods of manufacture thereof." Yield10 is the exclusive licensee of this intellectual property from the University of Massachusetts.

4. **Patent Application:**

   In June 2019, Yield10 filed a U.S. patent application covering new technology enabling low-cost production of PHA-based biomaterials in camelina, an oilseed crop. PHA-based biomaterials are of significant interest for their use in water treatment to remove nitrogen and phosphates, and as a biodegradable replacement for petroleum plastics in a range of applications. The new Yield10 patent application describes a discovery around maintaining the viability and vigor of camelina seed containing high levels of PHA biopolymer.

5. **Field Tests:**

   In 2018, Yield10's C3003 yield trait was tested for the first time in canola. The trait produced seed yield increases of up to 11% in the best lines of canola tested. There are plans to conduct further field tests for the C3004 yield trait in camelina and to evaluate the CRISPR-Cas9 genome-edited versions of C3007 in canola and C4004 in wheat and rice in 2019.

6. **Technology in-licensing:**

   In August 2018, Yield10 signed a non-exclusive research license for CRISPR-Cas9 gene-editing technology with DowDuPont's agricultural business, Corteva Agriscience, and the non-profit Broad Institute of MIT and Harvard.

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7.12 Bayer CropScience

Bayer AG
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Phone: +49-2173-380
Website: https://www.bayer.com

7.12.1. Introduction

Bayer AG is a healthcare and agriculture company with a 150-year history. The Bayer group constitutes 420 companies in 90 countries around the world. The Bayer group comprises pharmaceuticals, consumer health and crop science and animal health businesses.

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framework for gene-edited crops. They are expected to maintain the trade harmony; the region will set the similar regulatory structure. Hence, there are positive signs for market growth.

Furthermore, based on product type, the technology/licensing sector is the largest segment with 60% of the market share during 2019. Owing to a smaller number of commercialized products during 2019, food products account for 35% of the total market share. With the expected commercialization of thirteen new products between 2019-2024, the segment will witness the fastest CAGR of 62% during forecasted period. The gene-edited food products market size will grow from $112.66 million in 2019 to $910.98 million in 2024.

Figure 25: Expected gene-edited products commercialization by year

The market share of gene-edited foods will increase from 35% in 2019 to 62% in 2024. Cibus's SU Canola is the first commercialized gene-edited product. SU Canola^{TM} was initially released in United States during 2016 and the crop was grown mostly in North Dakota and Montana, and later the product was released onto the Canadian market during 2018. The second product that hit the United States market is Calyxt's "High oleic soybean meal and oil". Cibus made its first gene-edited products sale in the first quarter of 2019.

Gene-edited seeds form the smallest segment with a 5% market share. The segment is expected to grow with a CAGR of 39.54% during the forecast periodand will reach a value of $85.16 million. The NAFTA and LATAM regions will form the largest regions for the growth of the gene-editing seed sector.

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