IHS Markit® now a part of S&P Global

Crop Science Weekly Briefing

09 January 2024

Contacts

Sanjiv Rana
Editor-in-chief
Sanjiv.Rana@ihsmarkit.com

Robert Birkett
Specialist Reporter
Robert.Birkett@ihsmarkit.com

Akashpratim Mukhopadhyay
Specialist Reporter
Akashpratim.Mukhopa@ihsmarkit.com

Amritesh Malhan
Specialist Reporter
AmriteshSingh.Malhan@ihsmarkit.com

Contents

Top news topics and headlines of 2023

02 January 2024

A broad mix of topics comprised our most-read news articles during 2023. These included: regulatory moves within the EU; legal wrangles within the US, impacting Bayer as well as the EPA; developments involving glyphosate herbicide; global market developments; pipeline updates by major companies; and enhanced activity in biologicals. (Detailed analysis of each of these topics will be provided in forthcoming annual review articles to be published over the next two weeks).

Getty

Regulatory moves within the EU

Developments within the EU surrounding the proposal to halve pesticide use under the Farm to Fork targets as well as transforming the existing EU sustainable use of pesticides Directive (2009/128 – SUD) into a sustainable use Regulation (SUR) have generated high interest among our readers for the past couple of years. That trend continued in 2023 as the year saw a lot of wrangling and some surprising decisions on that front.

The impending deadline of glyphosate's EU approval, which would have run out on December 15, kept the topic high on readers' interest. In December, the approval was **extended** by 10 years.

Legal wrangles within the US

While legal cases continued being a headache for the EPA as well as for Bayer, those involving chlorpyrifos insecticide and glyphosate garnered the most interest.

In November, the US Court of Appeals for the Eighth Circuit **vacated** a 2021 order issued by the EPA to revoke all food tolerances for chlorpyrifos. That led to the EPA **outlining** plans to reinstate tolerances.

In the same month, a US appeals court **upheld** an injunction blocking the state of California from requiring businesses to warn consumers of the cancer risk from Bayer legacy business Monsanto's glyphosate-based Roundup. Bayer **considered** that an "important ruling" for its ongoing litigations over the product. The company had been beset with a losing streak through most of the second half of the year. Its belief seemed to hold ground as the streak was reversed in a **California trial** at the very end of the year.

Bayer restructuring

While Bayer's legal fortunes kept readers' interest high, the company's confirmation of its **plans** to cut management positions led to a lot of clicks. Amid investor dissatisfaction at the diminished market capital following the acquisition of Monsanto in 2016, group chief executive officer Bill Anderson admitted: "The status quo is simply not an option for Bayer."

Crop protection market development

The year proved to be a tough one for the industry, especially the second and third quarters of the year, with all major companies recording declines. Although articles about their financial results generated high interest, the most-read article turned out to be about the preliminary **analysis** of the global market published by S&P Global Commodity Insights' Crop Science team in November. That estimated a 1.8% decline overall in 2023.

Our exclusive **interview** with Brazilian crop protection industry trade association, the Sindiveg, was widely read. It talked about difficult market conditions prevailing in the biggest national market globally, especially de-stocking within the distribution chain.

The market in 2023 presented a very different picture to the conditions prevailing during the previous year. All top 20 companies in our **annual ranking** based on 2022 sales recorded increases, which was also among the top-read articles last year.

Company pipeline updates

Updates about company pipelines involving agrochemicals, biologicals, agbiotech as well as digital agriculture generated widespread interest. Among the most-read updates were the ones by **Bayer**, **BASF** and **Corteva Agriscience**.

Syngenta's IPO

Syngenta Group's progress on its initial public offering (IPO) remained among the highly-read stories. In May, the Group withdrew its application from the Science and Technology Innovation Board of the Shanghai Stock Exchange (STAR Market). It subsequently **applied** to list on the main board of the Chinese Shanghai Stock Exchange.

FMC's troubles

FMC spent the last few months of the year dealing with the negative sentiment created by a critical **report** by US short-seller firm Blue Orca Capital concerning the patent estate of the company's flagship diamide insecticide technology. The report alleged that FMC had not divulged to its investors a "string of stunning legal defeats around the globe" that facilitated the introduction of generic diamide offerings in the crucial markets of India and China by competitors. While FMC vigorously **defended** its growth plans, a **lawsuit** was filed against it, alleging that the business had failed to disclose crucial information, which led to shareholder losses in the aftermath of the report.

Biologicals

News about corporate activity surrounding biologicals, especially actions by **Syngenta**, **Corteva** and **Rovensa** to form specialist units led to a lot of interest. That was complemented by our round of interviews focusing on biologicals. The companies covered included **Bayer**, **Syngenta**, **BASF**, **FMC**, **Adama**, **Amvac**, **Valent BioSciences**, **STK**, **Botanical Solution** and **BioConsortia**.

How the top six CP companies fared in 2023

02 January 2024

The agrochemical industry faced tough market conditions in 2023 amid severe channel de-stocking on account of factors such as inflationary prices and concerns over supply security. Most major players reported a significant fall in revenues, with many businesses lowering their sales forecasts for the year.

Following the Covid-19 pandemic's impact on economies during the previous couple of years, geopolitical conflicts and

Getty

weather took over as two major factors that influenced global markets in 2023, according to a **preliminary analysis** by S&P Global Commodity Insights' Crop Science team.

Russia's invasion of Ukraine in 2022 resulted in energy and food security crises, most acutely across Europe, the Middle East and Africa. The team also cites the Israel-Gaza war having some if, as yet, a not as severe impact on global agricultural markets. Meanwhile, extreme weather events last year included wildfires in southern Europe, Hawaii and Canada; flooding in Brazil, China, India and Libya; and heatwaves in South-East Asia, China, much of Europe and the US state of California.

Syngenta

The Syngenta Group started off 2023 with 3.4% growth in revenues to around $9,200 million in the **first quarter**. However, combined revenues had fallen 9% to $8,300 million by the **following quarter** and slid by 13% to some $6,800 million in the **third quarter**. Meanwhile, the Syngenta Group subsidiary, Syngenta Crop Protection, recorded a fall of 4.6% in crop protection sales to $8,000 million in the **first half** of 2023.

The company agreed a slew of important deals last year. Early in 2023, Syngenta's Indian subsidiary, Syngenta India, partnered with agricultural drone company **IoTechWorld Avigation** for drone spraying services. This was followed by Syngenta Crop Protection agreeing a deal with Belgian biologicals company **Aphea.Bio** for the introduction of the latter's biostimulant, Activ (Stenotrophomonas rhizophila), across Europe.

In March, Syngenta's Japanese subsidiary, Syngenta Japan, sold assets related to the paddy rice fungicide, pyroquilon, to agrochemical business **Kyoyu Agri**. The same month Syngenta and Israeli chemicals business **ICL** agreed a collaboration for the turf market.

Halfway through the year, Syngenta Seeds and US synthetic biology company **Ginkgo Bioworks** agreed a research partnership focused on screening a targeted genetic library for novel trait discovery. Soon afterwards, Syngenta Crop Protection sealed a deal with UK agricultural biologicals company **Unium Bioscience** to distribute products based on the latter's biostimulant, Nuello In. Syngenta Crop Protection also joined hands with **FMC** in May to commercialize tetflupyrolimet-based herbicides in various Asian markets for use on rice.

The company signed two key deals in November, starting with a **partnership** with US seed technology business InnerPlant and US farm equipment manufacturer John Deere to develop an integrated solution to combat fungal pathogens affecting soybeans. Shortly afterwards, Syngenta Group and UK agricultural equipment manufacturer **CNH Industrial** agreed to integrate Syngenta's digital Cropwise platform with CNH's farm equipment brands, Case IH and New Holland Agriculture.

On the legal side, Syngenta **urged** a US federal court to dismiss an anti-competition **lawsuit** filed by the country's competition authority, the Federal Trade Commission (FTC), and a dozen of its states. The business refuted allegations that it used loyalty programs to bar competitors from selling cheaper generic products to US farmers. In December, Syngenta reached a **settlement** in a lawsuit that it had filed against a farmer in the US for alleged breach of the company's intellectual property rights involving its conventional disease-resistant and drought tolerant hybrid wheat variety, AgriPro SY Monument.

Bayer

Bayer's Crop Science division's crop protection sales fell by 14.4% to €3,980 million ($4,259 million at the average rate for the quarter) in the **first quarter** of 2023. The figure includes sales of herbicides, fungicides and insecticides, as well as revenues under "other" business, which is dominated by seed treatments but includes sales of oilseed rape and cotton seed products.

In the **second quarter**, the division reported that sales dropped by a third (33.1%) to €2,914 million ($3,176 million), wiping out the stellar gains of the same period the year before. This was followed by the business recording a 15.7% drop in crop protection sales to €2,700 million ($2,971 million) in its **third quarter**. Bayer anticipates a 5% decline in sales for the financial year citing a fall in glyphosate prices as the major driver.

Moving to key deals, Bayer agreed a new collaboration with US biotechnology business **Oerth Bio** in January to advance the latter's Protac (proteolysis targeting chimera) protein degrading technology. Shortly afterwards, the division agreed a deal to become the exclusive distributor of select pheromone-based biological crop protection products from French semiochemical company **M2i**.

The business agreed a partnership to develop biological crop protection and biostimulant products with Spanish biologicals company **Kimitec** in late January. This was followed by a partnership with US information technology business **Tavant** to focus on introducing innovative digital solutions. Bayer also forged a strategic partnership with US agribusiness **Cargill** in India with an eye on offering digital agriculture solutions to the nation's smallholder farmers.

In the second half of the year, the company agreed a five-year deal with US plant gene editing business **Pairwise** focused on developing gene edited short-stature corn (maize). Bayer also collaborated with US digital agriculture business **Arable** to improve its seed traits through application of the latter's technology.

In December, Bayer signed three crucial agreements. They included: Bayer's digital agriculture business, The Climate Corporation, forming a global partnership with Switzerland-based agricultural technology company **XFarm Technologies** for the former's FieldView platform; a commercial licensing deal with Canadian agricultural biotechnology business **MustGrow Biologics** involving Bayer's mustard-based biopesticide technology in its Europe, Middle East and Africa region; and a collaboration with French artificial intelligence (AI) enabled drug designer **Iktos** to expand the use of AI in the discovery and development of sustainable crop protection products.

Meanwhile, there were multiple developments in the lawsuits filed against the company for failing to warn users of the alleged carcinogenic effects of Bayer's legacy business Monsanto's glyphosate-based herbicide, Roundup. Most recently, the business won a **trial** in the US state of California, reversing a five-trial **losing streak** that saw the company being directed to pay well over $1.5 billion in cumulative damages to a string of litigants.

In **November**, Bayer called the **verdict** from a US appeals court upholding an injunction blocking the state of California from requiring businesses to warn consumers of the cancer risk from Roundup an "important ruling" for ongoing litigations over the product. A more in-depth analysis of the court cases will be published in the coming days.

Other legal proceedings included the Brazilian Supreme Court **ordering** the division to return millions in royalties paid by soybean growers to Monsanto for use of its genetically modified Intacta RR2 Pro (MON87701xMON89788) soybeans. Monsanto also reached a **settlement** with the US state of Pennsylvania after the latter dragged it to court over alleged environmental harm caused by its use of polychlorinated biphenyls (PCBs).

BASF

BASF's Agricultural Solutions division posted a 14.5% increase in sales to €3,891 million ($4,210.1 million) for its **first quarter** and attributed the gains to an increase in prices and a marginal improvement in volumes. The business includes crop protection as well as seed and trait products. However, revenues fell by **9.3%** to €2,231

million ($2,429.9 million) and by **18.6%** to €1,744 million ($1,918.8 million), respectively, in the following two quarters.

In terms of deals and collaborations agreed in 2023, BASF sold its Caldwell, Idaho-based seed coating facility to US private equity and holdings firm **Tide Rock** in March. Two months later, BASF entered a partnership with US sustainable agriculture business **Regrow Ag** for its integrated digital platform, Xarvio Digital Farming Solutions.

BASF Digital Farming and German technology provider Bosch's joint venture, One Smart Spray's, precision sprayer technology was integrated within UK-based **CNH Industrial**'s agricultural brand product portfolios in May. **Later** in the year, BASF Digital Farming expanded its digital connectivity options for farmers by integrating Xarvio Field Manager digital farming platform into CNH's global operating platform.

In the second half of last year, BASF agreed a joint distribution deal with French biological crop protection company **Vivagro** for the sweet orange oil-based fungicide/insecticide/acaricide, Essen'ciel, in Italy and Spain. The business further agreed a collaboration with Spanish digital agriculture business **Vegga** to incorporate its agricultural decision support system, Agrogenio, into the latter's precision agriculture platform. Meanwhile in Germany, BASF partnered with Hamburg-based chemical company **Helm** to link up their digital agriculture platforms for the 2023/24 planting season in the nation.

Corteva Agriscience

Corteva Agriscience witnessed a similar trend as peer companies, with modest growth in the **first quarter** followed by a sudden decline in sales. The business' crop protection sales rose by 5.4% to $2,189 million in the first quarter. The increase was driven by a rise in prices and a boost from an improved product mix.

However, sales plunged 22.7% to $1,781 million in the **second quarter**, wiping out all the gains made in the corresponding three-month period last year. In the **third quarter**, revenues fell by 10.6% to $1,712 million. The decline would have been greater but for a 7% boost from its biologicals acquisitions, says Corteva.

In October, the company **issued** a profit warning and downward guidance for its full-year sales. Corteva is expecting 2023 sales in the range of $17 billion and $17.3 billion. It cites concerns in Brazil for its bleaker outlook, including "lower-than-expected corn planted area, ongoing headwinds in crop chemicals, delayed farmer purchases on plantings and crop protection applications, as well as elevated levels of generic products".

Corteva started off the year with the **takeover** of Spanish biological crop protection supplier Symborg, as well as US biostimulants business Stoller in March. Shortly afterwards, the company sold its global glyphosate herbicide business to US agrochemical and specialty chemicals business **Albaugh**.

Corteva also forged a **partnership** with US agricultural commodities shipping company Bunge and Chevron Corporation business Chevron USA also in March. Later that month, the business signed an alliance with US biotechnology business **PacBio** for the development of new workflows for plant and microbial genome sequencing.

In July, Corteva agreed a deal to gain exclusive rights to develop and commercialize lead biofungicide candidates of Israeli plant biotechnology company Evogene's agricultural biologicals subsidiary, **Lavie Bio**. The collaboration was followed by an exclusive distribution deal with Argentine soybean development consortium **Bioceres** to advance the availability of biological solutions in Europe.

Corteva agreed a strategic collaboration with UK-based gene-editing start-up, **Tropic Bioscience**, for developing non-transgenic disease-resistance traits in corn (maize) and soybeans in the last leg of 2023. The

company also sealed a supply collaboration with US molecular diagnostics business **Alveo** to expand the latter's offering of molecular sensing and disease diagnostics technology.

On the legal side, Corteva joined Syngenta in **urging** a US federal court to dismiss an anti-competition lawsuit filed by the FTC and a dozen states. In September, the business filed a **lawsuit** against US seed technology company Inari and its Belgian business, Inari Agriculture, for breach of its intellectual property rights.

UPL

The UPL Group recorded a 17.2% decline in revenues to INR 89,630 million ($1,090.6 million) for its **first quarter** in 2023. This was followed by an 18.7% drop in revenues to INR 101,700 million ($1,235 million) for its **second quarter**. For both periods, all constituent entities of UPL apart from its seeds business, Advanta Enterprises, witnessed an erosion in revenues.

The company anticipated a gradual normalization of inventory levels shoring up its global crop protection activities in the forthcoming quarters, adding that the situation had "largely normalized" in Europe, Asia and Latin America markets barring Brazil, where the scenario was improving in tandem with North American markets.

Moving to key deals, UPL's India-based agriculture connectivity subsidiary, Nurture.Farm, partnered with a **rice research station** in February with an eye on evaluating improved cultivation practices of paddy rice farming. The same month, the company expanded an existing distribution deal focusing on the US with biopesticide company **AgBiTech**.

In May, UPL forged a partnership with US soil analytics company **Biome Makers** to utilize the latter's soil functional analysis technology, BeCrop Test, in a series of global trials. This was followed by the company collaborating with US agriculture venture capital company **Radicle Growth** for an investment challenge involving start-ups working on biological crop protection solutions.

In the second half of the year, UPL partnered with the US University of Arkansas' System Division of Agriculture (**UADA**) with an eye on gaining exclusive access to the latter's filed patents covering the "novel" use of the herbicide safener, fenclorim.

The business also agreed to collaborate with Brazilian agricultural research corporation **Embrapa**'s Embrapa Territorial division on the development of metrics and sustainability indicators for coffee production in Brazil. Through its legacy business, Arysta LifeScience, UPL sealed a sales deal with Japanese agrochemicals business **Phytochrome** for the latter's range of biostimulant products in Japan.

FMC

FMC recorded a marginal dip (-0.5%) in agrochemical sales to $1,344 million during its **first quarter**, while sales were up 4% organically. However, the period was followed by an over 30% slide in sales to $1,015 million and a 28.7% decline to $981.9 million, respectively, during the **second quarter** and the **third quarter**.

In **October**, FMC cut its full-year and fourth quarter forecasts. The lower end of its fourth-quarter estimates was slashed from some $1,650 million to $1,139 million, a drop of some 30%. At the top end of the estimates, the company forecasted final quarter business of around $1,379 million, down from some $1,770 million. FMC also anticipates a near 23% drop in annual sales to $4,480 million at the lower end of its estimates. The top end of the forecast is of $4,720 million.

The business agreed deals in multiple regions in 2023. Early in the year, FMC joined hands with **Syngenta Crop Protection** to commercialize tetflupyrolimet-based herbicides in various Asian markets for use on rice. In Ukraine, the company's subsidiary, FMC Ukraine, signed a memorandum of co-operation (**MoC**) with the nation's Ministry for Development of Economy and Trade. Furthermore, FMC agreed a deal with Brazilian seed company **Girassol Agricola** to supply cotton seed treated with its products in the country.

The company also outlined a new strategic **growth plan** and long-term financial goals for the next 10 years until 2033. By 2033, FMC aims to rake in approximately $2 billion through its Plant Health business, and another $2 billion from four new ais in its pipeline, adding that pheromone-based solutions would play a "significant" role in fulfilling the target. The business intends to generate over 35% of its revenues from these two segments from their present share of less than 10%.

In terms of judicial updates, FMC was granted a **preliminary injunction** by a Mexican court against Chinese company Shandong Weifang Rainbow Chemical over the latter's alleged patent infringement in seeking registrations for its chlorantraniliprole (trade-marked a Rynaxypyr)-based insecticides.

In November, a **lawsuit** was filed against FMC alleging that it failed to disclose crucial information leading up to the publication earlier in 2023 of a scathing **report** by US short-seller firm Blue Orca Capital concerning the patent estate of the company's flagship diamide insecticide technology. FMC has dismissed the report as "misleading and factually inaccurate", stressing that it has "always been clear and transparent about its diamide growth strategy". The business maintains that it has "consistently disclosed material developments in diamide litigation in SEC (the US Securities and Exchange Commission) filings".

Deals/M&A round-up 2023: Busy year for biologicals and dig ag

03 January 2024

The global crop protection sector in 2023 was marked by players reworking their strategies to gain competitive advantage and market share. That took the shape of collaborative deals and acquisitions, which permeated across business lines including synthetic and biological crop protection, digital and precision agriculture, as well as regenerative farming.

Getty Images

Several factors influenced this trajectory. While major businesses went on to acquire smaller rivals to consolidate their position and gain access to novel technologies, start-ups agreed to deals and takeovers with an eye on navigating complex regulatory landscapes, as well as to unlock capital and resources, and benefit from established go-to-market strategies.

Additionally, favourable regulatory outlooks across geographies, government initiatives to spur the adoption of advanced technologies, and expansion into newer markets shaped how companies traversed the deals landscape last year.

Of the **hundreds** of mergers and acquisitions as well as partnerships covered by *Crop Science Market Reporting* in 2023, the big six crop protection players – BASF, Bayer's Crop Science division, Corteva, FMC, Syngenta and UPL – accounted for several big-ticket deals. A comprehensive round-up of that can be read **here**. However, a wider look at the industry's dynamics from last year reveals an intriguing landscape, one that is teeming with

newer companies that have fragmented a sector long regarded as the stronghold of established incumbent players.

While 2023 was largely characterized by a funding winter for several industries, the crop protection sector emerged as the preferred investment destination for institutional investors and venture capitalists alike. It exhibited resilience even as economies tried to reverse a Covid-19-induced downturn and struggled to adapt to volatile geopolitical situations. On the other hand, concerns over food security escalated over the past two years amid armed conflicts in different regions, while perceptible changes in weather and strained agricultural production deepened the sense of foreboding and led to a renewed focus on sustainability.

These circumstances largely set the backdrop against which the crop protection sector functioned in 2023, while industry-specific woes, such as mounting channel inventory on account of weakened demand, over-production, and supply chain issues posed additional hurdles.

Biologicals

While established crop protection businesses drew investments during the year – often from private entities, and sometimes from state-run bodies to run pilot projects – a significant bulk of investor wealth in 2023 was earmarked for smaller rivals. Firms focusing on biological crop protection were among the winners, with billions being channelled into that industry for research and development initiatives.

The shift was prompted by rising resistance issues involving synthetic pesticides, strong push from environmentalist groups to outlaw certain widely used active ingredients to safeguard human health and the environment, and the phase-out of some such ais across various jurisdictions, most importantly in the EU. While generally negative consumer perception of chemical ais influenced the move, protracted legal tussles involving some commonly used pesticides, and various governments calling for wider adoption of biologicals further directed investor corpus towards the sector.

Biostimulants lead the way

Biostimulants emerged as a burgeoning product line in 2023, with algae- and sea-weed-based solutions generating special interest among larger players. Early in the year, Japanese company Mitsui & Co agreed to **acquire a stake** in Irish biostimulants manufacturer C&B Agri (Donegal), which specializes in producing biostimulants derived from seaweeds, as well as amino acids of marine origin. The acquisition followed the latter designing a product based on the seaweed, *Ascophylum nodosum*, with Mitsui highlighting the investment as its maiden capital infusion into the sector.

In fact, the growing relevance of biostimulants led Syngenta Group to form a **new business unit**, Syngenta Biologicals, through the consolidation of its in-house biologicals business with Valagro, a company that it acquired **in 2020**. The newly established business specializes in the development of a seaweed-based biostimulant, as well as a biofungicide, Taegro (*Bacillus subtilis var amyloliquefaciens* strain FZB24).

Peer firm Corteva seized the opportunity as well, **launching** its biologicals business, Corteva Biologicals, in December.

Furthermore, the year saw $45 million **flowing into** US agricultural biotechnology business NewLeaf Symbiotics to advance the firm's pink-pigmented facultative methylotroph (PPFM) technology that focuses on biostimulants and biopesticides. US agrochemical company American Vanguard's (Los Angeles, California) subsidiary, Amvac Chemical (Newport Beach, California), is utilizing the technology through a **deal** with NewLeaf, and has introduced a bioinsecticide, BioWake Prime, for the control of corn rootworms (*Diabrotica*

virgifera). Towards the end of the year, Amvac went on to extend the collaboration to include geographies such as Argentina, Brazil, China and Ukraine.

On the other hand, bioherbicides, a relatively unexplored segment, saw a surge in interest, with authorities in the US **extending grants** to a start-up, Harpe Bioherbicide Solutions (Research Triangle Park, North Carolina), for advanced research in biological control of herbicide-resistant weeds. The business went on to **draw** nearly $11 million in investments during the year from a consortium of investors led by Decatur, Illinois-based US agricultural processor Archer Daniels Midland (ADM), highlighting that efforts are to be directed to transform its non-selective bioherbicide concepts into "commercial ready" stages.

Focus on peptides

Peptide-based crop protection technologies captured investors' attention as well, figuring in pesticide strategies more often than in previous years. One of the frontrunners, the US-based, UK-listed bioproducts company, Plant Health Care (PHC – Raleigh, North Carolina), signed a commercialization and **distribution agreement** involving its foliar biofungicide, Obrona, in the US, with Walnut Creek, California-based US agrochemical distributor Wilbur-Ellis. The product leverages PHC's PHC279 peptide and forms a part of the company's PREtec peptide portfolio.

Additionally, PHC **set afoot plans** to raise up to £2.8 million ($3.5 million at the current rate) to advance its technology pipeline. Funds were also infused into another UK company, Solasta Bio. It **secured** £4 million ($5 million) from a consortium of investors for the development of bioinsecticides based on insect neuropeptides that regulate the pests' essential physiological functions.

The promising intellectual property (IP) pipeline of a relatively smaller number of start-ups working on peptides spurred consolidation. In the US, life sciences venture capital company Flagship Pioneering's (Cambridge, Massachusetts) agricultural biotechnology subsidiary, Invaio Sciences, **acquired** St Louis, Missouri-based US crop protection business Peptyde Bio. The takeover is expected to facilitate Invaio Sciences' access to Peptyde Bio's "established platform" and IP portfolio, besides enabling it to leverage the latter's lead peptide candidates to design and discover peptides for crop protection applications.

Moreover, peptide-based crop protection piqued the interest of agricultural regulatory bodies in the US. Over $3 million from authorities in the state of California went to **seven projects** focusing on sustainable pest management solutions, including those that leverage peptides for the suppression of Pierce's disease (*Xylella fastidiosa*) on grapevines, and citrus greening disease or Huanglongbing (HLB – *Candidatus liberibacter asiaticus*) in citrus crops.

On the other hand, **federal funding** was granted to a team led by US synthetic biology business Ginkgo Bioworks (Boston, Massachusetts) to develop algal pest-specific antimicrobial peptides (AMPs) to enhance the "tolerance of the algae and their protective microbiome to AMP treatment". AMPs are short chains of amino acids exhibiting antimicrobial activity, with the company rating them as a "more environmentally friendly alternative" to synthetic pesticides.

The EPA went so far as to grant **tolerance exemptions** for pesticide residues to the peptide, flg22-*Bt*, on all food commodities when the ai is used as a plant growth regulator (PGR), and inducer of local and systemic resistance in accordance with label directions and GAP. The regulatory decision went in favour of Elemental Enzymes, a US company functioning out of St Louis, Missouri.

Multitude of deals

As well as expanding their biological portfolios, major crop protection players undertook a host of deals with smaller rivals, besides acquiring businesses with promising technologies. Most of these transactions were reported from Europe and the US, with Corteva and Bayer emerging as two of the most prolific investors. Here, again, biologicals reined over the conventional crop protection segment.

In 2023, **Corteva Agriscience** completed the takeover of Spanish biological crop protection supplier Symborg, as well as US biostimulants business Stoller. Additionally, the business agreed a deal to gain **exclusive rights** to develop and commercialize lead biofungicide candidates of Israeli plant biotechnology company Evogene's agricultural biologicals subsidiary, Lavie Bio.

As for Bayer, the company agreed to become the **exclusive distributor** of select pheromone-based biological crop protection products from French semiochemical company M2i, besides joining hands with Spanish biologicals company Kimitec to **develop** biopesticides and biostimulants. The company intends to leverage artificial intelligence (AI) to accelerate the development of solutions as part of the latter partnership.

Belgian biological pest control company **Biobest**, on the other hand, completed its acquisition of US biopesticide business BioWorks, besides **picking up** an 85% stake in Brazilian company Biotrop Soluções Biológica.

The deals space saw participation from Japanese businesses such as Mitsui & Co, with its subsidiary, **Certis Belchim**, partnering with Italian multi-sector biologicals company Clever BioScience for the development of biopesticides. In another development, a joint **distribution agreement** was signed between BASF and French biological crop protection company Vivagro for the sweet orange oil-based fungicide/insecticide/acaricide, Essen'ciel, in Italy and Spain.

In fact, the already diversified biologicals industry in Europe expanded even further with Syngenta Crop Protection partnering with two Belgian biological companies during the year. These included a deal with **Aphea.Bio** for the introduction of the latter's biostimulant, Activ (*Stenotrophomonas rhizophila*), across multiple countries in the region over the next five years. The other one was with **Biotalys**, and involves research, development and commercialization of new biocontrol solutions to manage pests in a broad variety of crops.

Dutch bioproducts company Koppert Biological Systems was active as well, **acquiring** a Swedish peer business, and creating a **strategic alliance** with Indian company PI Industries.

In **Brazil**, Koppert's subsidiary in that nation agreed a partnership with application equipment provider Orion Tecnologia e Sistemas covering in-furrow application of biological products on grain crops.

In addition to these deals and numerous others, the year saw UPL and US agriculture venture capital company Radicle Growth (San Diego, California) collaborating for an **investment challenge** involving start-ups working on biological crop protection solutions. The initiative, dubbed "The Radicle Natural Plant Protection (NPP) Challenge by UPL", will see the partners invest a shade over $1.7 million in entities focusing on protecting crops from biotic stresses such as bacteria, fungi, nematodes, insects, arachnids and weeds. Decisions for the funding are to be made in March this year.

Conventional crop protection

Deals and acquisitions in the conventional crop protection industry paled in comparison to their biological counterparts. The year was marked by a mixed bag of partnerships involving major players, as well as a few

instances of production and IP assets changing hands. However, conventional crop protection flourished as a whole, with established as well as smaller players vying to expand their footprints.

Bayer inked a number of deals during the year. In India, it **collaborated** with agrochemical company Crystal Crop Protection to roll out two paddy rice insecticides, Curbix Pro and Kollar (both ethiprole + imidacloprid), while in France, its Lyon-based residue analysis laboratory was acquired by US contract research organization SynTech Research. Bayer also agreed to **transfer** its crop protection production plant in Valencia to Spanish agrochemical company Industrias Químicas del Vallés.

Syngenta was party to numerous deals during the year, with one of them seeing the company **partner** with FMC to commercialize tetflupyrolimet-based herbicides in various Asian markets for use on rice. The ai was discovered and developed by the latter business with support from Syngenta. In India, the company collaborated with agrochemical firm Best Agrolife to **market** the herbicide, Movondo (pyroxasulfone 85% WG), in the country.

Additionally, Syngenta agreed a key deal in Japan, where domestic agrochemical business **Kyoyu Agri** agreed to take over its assets related to the paddy rice fungicide, pyroquilon.

Major developments took place at Corteva as well, with the business **deciding** to sell its global glyphosate herbicide business to US agrochemical and specialty chemicals business Albaugh (Ankeny, Iowa). The transaction involved intangible assets, including trade names, registrations, regulatory data, formulations, patents and know-how. The deal followed Albaugh's takeover of Corteva's European glyphosate operations, and encompasses all markets, barring Argentina.

Smaller players such as Canadian agrochemical formulation company **Vive Crop Protection** (Mississauga, Ontario) and US agricultural products business **Indigo Ag** (Boston, Massachusetts) raised funds, while yet others **expanded** their research capabilities.

Digital agriculture

Drones

Drones emerged as one of the most prominent segments within the digital agriculture industry, with a significant number of collaborations being reported from India, where agricultural use of the technology took off in 2022 following the government **approving** an interim two-year approval for drone-based spraying of almost all pesticides registered in the country.

Investments into the Indian agricultural drone ecosystem saw a number of domestic players generate millions in investment. Chennai-based drone manufacturer Garuda Aerospace raised **$22 million** and **$3 million**, respectively, through two separate funding exercises, besides **partnering** with Rallis India for a pilot project on drone-based spraying. The year was also marked by Indian crop protection and fertilizer company Coromandel International (Secunderabad) gradually **expanding** its shareholding in a domestic drone start-up, and subsequently picking up a **majority stake** in the firm to capitalize on an exponentially spreading national market.

Among global companies, Syngenta subsidiary, Syngenta India, **joined hands** with Indian agricultural drone company IoTechWorld Avigation for spraying services.

The number of developments outside India were relatively less. Chinese precision and digital agriculture company **XAG** and Thai agricultural business Chia Tai's agritech subsidiary, FarmInno, launched agricultural

drones in Thailand, while some $20 million **flowed into** US drone-based crop protection company Guardian Agriculture.

Cross-border collaborations were **forged** between US crop intelligence provider Intelinair (Indianapolis, Indiana) and Swedish business Solvi to expand the former's drone-based AGMRI crop intelligence platform. French agricultural image analysis business Hiphen (Avignon), on the other hand, **acquired** US agriculture technology company SlantRange (San Diego, California), which specializes in drone-based phenotyping.

Platform integrations

The usage of data platforms for the analysis of agronomic data became mainstream in 2023. Cross-platform compatibility and the ability to share data between platforms of partnering service/equipment providers spurred collaborations. Major digital agriculture players proceeded to integrate and connect their offerings with an eye on achieving inter-operability, besides improving efficiency, and driving up yields.

In the EU, BASF **agreed** to integrate its agricultural decision support system, Agrogenio, with Spanish digital agriculture business Vegga's precision agriculture platform. UK-based agricultural equipment manufacturer CNH Industrial (Basildon), on the other hand, partnered with BASF Digital Farming and German technology provider Bosch's joint venture, One Smart Spray, to **integrate** the latter's precision sprayer technology of the same name within its agricultural product portfolio.

Additionally, **BASF** and German chemical company Helm decided to link their digital agriculture platforms for the 2023/24 planting season in Germany, while CNH went on to **acquire** a French digital agriculture start-up, Augmenta. CNH also **partnered** with the Syngenta Group to integrate the latter's digital Cropwise platform with two of its farm equipment brands.

Bayer took part in similar exercises as well. The company's digital agriculture business, Climate Corporation, **decided** to integrate its digital platform, FieldView, with **acquired** Canadian Digital Agriculture business Combyne Ag's crop marketing management tool, Combyne. It also **integrated** FieldView with Canadian digital agriculture business AgExpert's farm management software, AgExpert Field (AEF).

Robotics

The increased adoption of robotic solutions in matured markets such as the US stood out as a noticeable trend during the year, and companies raised large amounts of capital to develop the niche sector. Among other businesses, Seattle, Washington-based US robotics firm Carbon Robotics **raised** $30 million, besides adding **new features** to its laser-based weeding robots.

In fact, the demand for robotic agricultural solutions in the US prompted Brazilian digital agriculture supplier Solinftec to expand its robotics **manufacturing capacity** in the former country, while a German and a US entity forged a deal to **develop** AI-driven robots to eliminate weeds. Additionally, US agricultural technology start-up Aigen (Seattle, Washington) **unveiled** a weeding robot powered by solar and wind energy. The business **raised** $12 million in funding during the year.

Many governments also infused capital into the agricultural robotics sector. Authorities in the UK, for instance, **awarded** over £3.8 million ($4.8 million at the current rate) to a domestic company to accelerate the delivery of robotic crop harvesting systems for the horticulture industry, besides **investing** £12.5 million ($15.4 million) in 19 projects to develop agricultural automation and robotic technologies. The disbursement expanded the UK government's fiscal contribution to the segment since 2021 to £120 million ($147.6 million).

Regenerative agriculture

Mounting concerns over climate change and efforts to reduce greenhouse gas (GHG) emissions from agricultural operations translated into several key deals being forged in 2023. Many companies and institutes took part in furthering this collaborative approach, including, but not limited to Bayer, BASF, soft drinks manufacturer PepsiCo, retail giant Walmart, and US farm trade platform and digital agriculture company Farmers Business Network (FBN – San Francisco, California.

The US and Canada were at the forefront of such partnerships. An alliance between **PepsiCo and Walmart** proposed to infuse up to $120 million for the development of regenerative agriculture in the two countries, while the former **infused** $216 million into three long-term, strategic partnerships focusing on the adoption of regenerative agriculture practices across the US.

Programs by other companies **expanded** during the year as the concept made inroads into markets such as India. The country saw Bayer **rolling out** its direct-seed rice (DSR) as part of the firm's regenerative agriculture initiative.

Furthermore, a partnership was **signed** between the India-based research center, International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), and UK-based biotechnology research business Eagle Genomics (Cambridge). The deal involves ICRISAT sharing datasets with the latter with an eye on driving regenerative agriculture targets and developing new approaches to sequester carbon.

Regenerative agriculture as a practice gained ground in Europe, with several businesses collaborating in various capacities to expand its scope and implementation. UPL **set afoot** an agricultural decarbonization program in France as part of a Europe-wide initiative with three distributors, while Syngenta **unveiled** a suite of products including seeds, crop protection solutions, biostimulants and digital agriculture offerings in Portugal.

In 2023, digital agriculture came to be increasingly linked with regenerative approaches, and work was undertaken to deliver related product suites for mainstream use. Some $28 million was **raised** by US soil data measurement and mapping business EarthOptics (Arlington, Virginia), while the company also **collaborated** with a peer to offer a "research-grade" product leveraging sensor data and AI for soil carbon measurement.

Moreover, concept such as regenerative agriculture and carbon farming received global exposure through the recently concluded UN Climate Change Conference of the Parties (COP28), which saw relevant authorities brainstorm climate change and allied issues. The UN Framework Convention on Climate Change (UNFCCC) **partnered** with technology giant Microsoft during the event to design an AI-based platform to monitor emissions from industries including agriculture.

Annual review 2023: Many new ais unveiled

03 January 2024

The year 2023 saw the first global approval or introduction in key markets of many new active ingredients from the pipelines of some leading companies. Information about ais to be launched during the coming years was also revealed when they were assigned ISO names.

BASF marked the first global launch of its insecticide, Efficon (dimpropyridaz – trade-marked as Axalion), in **Australia**. Dimpropyridaz is the sole representative of a unique class of

Getty

chemistry with a novel mode of action that stops piercing and sucking insect pests from feeding. BASF says that it anticipates approvals and launches in Asia, Europe, and South America over the coming years. The ai also received approval from the **Brazilian** national health surveillance agency, the Anvisa. But assessments from the other two competent authorities, the environmental agency, the Ibama, covering environmental fate, and the Ministry of Agriculture on agronomic aspects, remained pending before full registration could be granted.

Corteva Agriscience introduced its picolinamide fungicide, florylpicoxamid (trade-marked as Adavelt), in **three countries** – Canada, Australia and South Korea – marking the global debut of the ai. Corteva claims that florylpicoxamid features a "novel target site of action" with no cross-resistance to other modes of action, adding that it is characterized by preventative as well as curative properties, and can be used in IPM programs as a resistance management tool. The business highlights that the new ai has been built on the discovery of its first picolinamide ai, fenpicoxamid (trade-marked as Inatreq). The ai also received approval from **Brazil**'s Anvisa, but full authorization would require the assent of the Ministry of Agriculture and the Ibama. An application to register florylpicoxamid in **the US** is pending with the country's EPA.

Corteva also received **US registration** for its nematicide, fluazaindolizine (trade-marked as Reklemel). Fluazaindolizine was first approved in 2021 in **Australia**, and soon after in **Canada**, India and Mexico. The first product based on the ai, Salibro, was launched in **Mexico** in October.

Syngenta Crop Protection received approval **in Brazil** for its insecticide, isocycloseram (trade-marked as Plinazolin) and four **products** based on it. The company also launched two products based on the ai **in India**. Isocycloseram received its first global approval in **Argentina** in late 2021. It was approved in **Australia** in 2022.

Japanese company **Nihon Nohyaku**'s Indian subsidiary, Nichino India, received **registration** for a benzpyrimoxan-based insecticide for use on rice. The company says that benzpyrimoxan is "highly effective" against planthoppers (*Nilaparvata lugens*). Nihon Nohyaku received its first global approval for benzpyrimoxan in **Japan** in 2020.

New ISO names

The ISO Technical Committee on Common Names for Pesticides approved eight new ai names during the year. Those includes five herbicides, one insecticide, one insecticide/acaricide, and one acaricide.

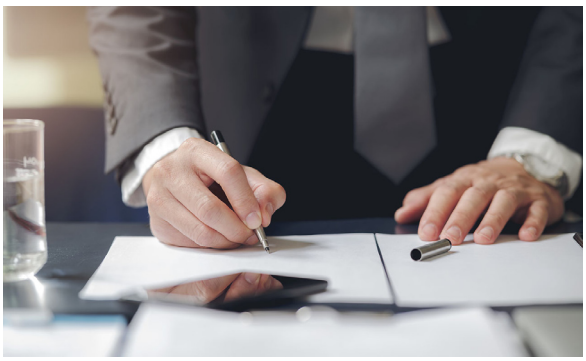
The herbicides were: **Corteva Agriscience**'s picolonic acid herbicide, indolauxipyr; **Bayer's Crop Science division**'s isoxazole herbicide, icafolin; Syngenta Crop Protection's triketone herbicide, metproxybicyclone; Chinese company **Liaoning Cynda**'s benzoylpyrazole herbicide, pyraquinate; and Chinese company **Liaoning Cynda**'s herbicide, feproxydim (trade-marked as Mabaike).

The other ais included: **Bayer**'s insecticide/acaricide, sulfiflumin; Indian business **PI Industries**' (Udaipur) insecticide, pioxaniliprole; and Chinese company **Jiangsu Yangnong Chemical**'s acaricide, bisulflufen.

NthAm review 2023: Year defined by policy rejig and litigations

08 January 2024

The crop protection regulatory regimes in North America, including those of the US and Canada, were marked by a host of legislative as well as judicial developments in 2023. Authorities in the former geography focused on enhancing the implementation of human and environmental safety guidelines in the wake of a string of lawsuits involving the US EPA and major crop protection businesses, while updates from Canada, often marred by regulatory delays, included revised guidance on the nation's biotechnology laws, and the issuance of a five-year pesticide review workplan.



Getty Images

Efforts to overhaul the crop protection policy frameworks in these countries coincided with similar undertakings by peers across the globe. The US EPA, in particular, made a noticeable shift in prioritizing the registration of low-risk pesticides, including biologicals, besides increasing its engagement with public as well as government stakeholders to eliminate chances of regulatory oversight and probable litigations. Legislative developments were also focused on biotechnology initiatives, including those dealing with new breeding techniques (NBTs).

Canadian authorities, on the other hand, grappled with a resource crunch amid "significant" workload involving post-market review programs for pesticide active ingredients. That translated into delayed regulatory action and mounting backlogs as the nation's Pesticide Management Regulatory Agency (PMRA) tried to deliver re-evaluation decisions dictated by the legislative requirement to assess pesticide registrations every 15 years.

US legislative developments

Biotechnology

Authorities in the US relaxed regulations related to NBTs in 2023, enabling the industry to undertake developmental projects and build genetic pipelines by leveraging provisions under the country's **national biotechnology initiative**. The project sought to improve the transparency and efficiency of regulatory processes for products derived using biotechnology, besides implementing measures to facilitate easier navigation of the nation's gene editing framework.

The **widened biotechnology rules** cover loss of function modifications, polyploid plants, as well as multiple and successive edits. The USDA expects the relaxed framework to afford the deregulation of certain plants with loss of function mutations in the same gene across all chromosomes, "regardless of how the mutation is generated".

Additionally, the year saw relevant government bodies being **tasked with identifying** areas of ambiguity, gaps, or uncertainties in the country's **2017 update** to its co-ordinated framework for the regulation of biotechnology, as well as policy changes made pursuant to Executive Order 13874 of 2019. The latter seeks to modernize the region's regulatory framework for agricultural biotechnology products.

The US EPA also notified the availability of **resources** to aid biotechnology developers in exercising the "full benefits" of its relaxed rules that exempt certain plant-incorporated protectants (PIPs) created using genetic engineering from registration requirements under the US Federal Insecticides, Fungicides and Rodenticides Act (FIFRA). The PIPs Exemption Final Rule was communicated **in May**, with the guidelines becoming effective from July 31.

Focus on biologicals

Factors such as rising resistance issues involving synthetic pesticides, a strong push from environmentalist groups to outlaw certain widely used ais to safeguard human health and the environment, and increasing regulatory scrutiny over such ais across various jurisdictions prompted the EPA to prioritize the adoption of biological crop protection approaches. Moreover, protracted legal tussles involving some commonly used conventional pesticides further necessitated the move.

The year saw the Agency **granting** registration to Medford, Massachusetts-based US biotechnology business GreenLight Bioscience's double-stranded RNA (dsRNA)-based bioinsecticide ai, ledprona, for three years. The development aligned with the pesticide watchdog's **proposal** to that effect from October, making the ai the first of its kind with a derived sprayable solution that can be commercially used to treat plants.

The EPA anticipates novel pesticide technologies such as ledprona fostering the development of alternatives to synthetic crop protection offerings that may pose increased risks, besides having reduced efficacy on account of resistance issues.

In fact, in April, the USDA's Animal and Plant Health Inspection Service (APHIS) came up with **draft guidelines** focusing on information requirements and the process for submitting permit applications involving genetically modified micro-organisms used for crop protection purposes. The draft proposed that developers acquire a permit for regulated activities involving GM microbial species that meet the definition of plant pests as per the country's revised biotechnology regulations under title 7 of the Code of Federal Regulations, part 340 (7 CFR part 340).

The APHIS highlighted that such organisms should not be plants, but those that that have received DNA from a plant pest, and that the pests are either "capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease".

As for exemptions, the Service emphasized that permits would not be required for the import or inter-state movement of "disarmed" GM Agrobacterium spp as long as they are moved as a secure shipment, the modified genetic material is stably integrated into the genome, and the modified material does not include the complete infectious genome of a plant pest.

Additionally, the draft proposed to relax permit requirements for the movement of GM micro-organism derived products that are registered with the EPA as microbial pesticides, so long as such organisms are not classified as plant pests under US biotechnology regulations.

Endocrine screening

In 2023, the EPA developed a **strategic plan** to implement its "Endocrine Disruptor Screening Program" (EDSP) with an eye on evaluating the potential effects of pesticides on the endocrine system in humans. The EDSP is likely to be initiated with some 400 conventional pesticide ais that are undergoing registration reviews or are in the process of being registered for the first time.

The EDSP was established in 1996 following an amendment to the US Federal Food, Drug, and Cosmetic Act (FFDCA) to study how pesticides could affect the human endocrine system. Its implementation, however, had been plagued by delays, primarily stemming from the **lack of scientific methods** to test "thousands" of chemicals promptly and cost-effectively for their endocrine-disrupting effects.

The latest development followed a report from the EPA's Office of the Inspector General in 2021 concluding that the Agency had made "limited progress" in implementing the EDSP and recommending that it develop a strategic plan to kickstart the project. Besides putting the EDSP into effect, the EPA anticipates the plan and its supporting documents furthering its assessment of pesticides' effects on the endocrine system through evaluations under FIFRA.

New York's neonic law

Furthermore, the state of New York's "Birds and Bees Protection Act" was **ratified** as a law towards the end of the year. It seeks to protect birds and pollinators from risks posed by five neonicotinoid insecticides – clothianidin, imidacloprid, thiamethoxam, dinotefuran and acetamiprid. The development made it the first law of its kind to be formalized by a US state, and followed the Act gaining legislative **approval** earlier in the year.

While the newly ratified law prohibits the sale, distribution and purchase of corn (maize), soybean and wheat seeds treated with clothianidin, imidacloprid, thiamethoxam, dinotefuran and acetamiprid from January 1, 2027, it sets a July 1, 2025, cut-off date for ceasing the use of imidacloprid, thiamethoxam and acetamiprid for treating outdoor ornamental plants and turf, except when they are used for the production of agricultural commodities.

The treatment of outdoor ornamental plants and turf with clothianidin and dinotefuran, however, must cease immediately, unless relevant authorities issue a written order seeking their use for addressing an "environmental emergency".

Notably, the aforementioned ais are undergoing registration reviews by the EPA, which is mandated by the FIFRA to review each registered pesticide every 15 years to determine whether they continue to meet standards of registration by not posing harm to human health or the environment.

In May, the Agency **updated** its final biological evaluations (BEs) covering three of the ais – **clothianidin**, **imidacloprid** and **thiamethoxam**. The exercise focused on their "likely to adversely affect" (LAA) determinations involving species listed under the nation's Endangered Species Act (ESA).

The new analyses have been added to the insecticides' final BEs **released** in June 2022.

Vulnerable species pilot

The year also saw the EPA come up with an update to its vulnerable species pilot (VSP) program as part of the implementation of a **workplan** that seeks to safeguard species listed under the ESA from pesticide-related harm. The development followed the release of a draft white paper on the VSP earlier during the year, identifying 27 federally threatened species, and suggesting measures to mitigate harms caused to them by pesticides.

The revised VSP contained an endangered species range map highlighting areas that are vital for the conservation of a species, besides clarifying the scope of the initiative for non-agricultural uses. Additionally, the update considered potential exemptions to the proposed mitigations, besides looking into requirements for other measures, as well as revising some of the recommended approaches.

Adversities in the US

US regulatory watchdogs, including the EPA and the USDA, as well as companies operating in the nation came under legal scrutiny in 2024, with the year being marked by some consequential court judgements.

Chlorpyrifos

Among the most significant was the US Court of Appeals for the Eighth Circuit **vacating** a 2021 order issued by the EPA to **revoke** all food tolerances for the organophosphate insecticide, chlorpyrifos, alongside the latter's **rejection** of objections against its decision. The development followed several US farm organizations **dragging** the Agency to court over its mandate, which was issued subsequent to an **order** from the US Court of Appeals for the Ninth Circuit to bar use of chlorpyrifos on food crops or modify food tolerances for the insecticide to comply with federal food safety law.

Environmentalists and advocacy groups had exerted pressure on the EPA **since 2007** to revoke the ai's food tolerances citing evidence of neuro-developmental harms, and arguing that its cumulative exposures violated safety standards set by the US Federal Food, Drug and Cosmetic Act (FDCA).

Backing its move to nullify the EPA's mandate, the Court highlighted that the regulator's 2022 order denying objections to its decision was issued as the pesticide watchdog was "unable to conclude that the high-benefit agricultural uses [of chlorpyrifos] were safe". It added that the Agency had uncovered 11 such uses just months before it had to pull the plug on the ai's uses on food crops.

Subsequently, the EPA came out with plans to **reinstate** the tolerances of chlorpyrifos, and a notification to that effect is expected to be published upon the issuance of the Eighth Circuit's mandate. However, the USDA's role in the initial 2021 decision drew scrutiny, and an investigative panel of the US House of Representatives (lower house of the nation's Congress), House Committee on Oversight and Accountability, has **initiated a probe** into the matter.

Notably, US farmers use an estimated 5 million lbs (2,268 metric tons) of chlorpyrifos on more than 50 crops, including soybeans, alfalfa, almonds, apples, citrus fruits, corn (maize) and strawberries. The insecticide has been in use in the country since 1965.

Streptomycin

Another unfavourable ruling saw the US Court of Appeals for the Ninth Circuit **tossing out** the EPA's **2021 decision** to allow use of the anti-biotic, streptomycin, on citrus groves in the state of Florida. It concluded that the Agency had not fully considered the ai's potential harm to pollinators and had failed to comply with the ESA while delivering its mandate.

Backed by the powerful citrus industry in the state, the amended registrations allowed growers to annually spray some 650,000 lb (294,835 kg) of streptomycin on citrus trees across the state until January 2028.

As a result of the Court's decision, the registration was sent back to the EPA for reconsideration, with the development marking a win for environmentalists and farmworker advocates who **sued the regulator** in 2022 to block the use of streptomycin on citrus crops to tackle citrus greening disease or Huanglongbing (HLB – *Candidatus liberibacter asiaticus*) and citrus canker (*Xanthomonus citri*).

Streptomycin has been used commercially since the 1950s to control bacterial plant diseases and it is the ai in pesticide products licensed for use on an array of crops, including apples, pears, celery, peppers, potatoes and tomatoes. The Agency's move to amend its registration was dictated by the widespread prevalence of HLB, which has plagued citrus cultivation in Florida for more than a decade and cost the industry some $3 billion in lost revenues. Citrus production in the state is estimated to have plunged more than 70% from 20 years ago.

ESA settlement

In 2023, the US District Court for the Northern District of California approved a **settlement** that required the EPA to overhaul its regulation of pesticides to better protect endangered species as part of its obligations under the ESA. The settlement mandates the Agency to transition from a chemical-by-chemical, species-by-species approach to meeting its ESA requirements and develop a strategy for herbicides by May 30, 2024, and for insecticides by March 31, 2025.

Moreover, the EPA must create similar strategies for rodenticides and fungicides, besides finalizing a plan to protect over two-dozen species considered highly vulnerable to pesticide harm. It must also finish ESA reviews for four rodenticides by 2024 and eight organophosphate insecticides by 2027.

The agreement settled a lawsuit brought by the US non-profit Center for Biological Diversity (CBD) and the Pesticide Action Network (PAN) that targeted the EPA's alleged failure to comply with the ESA when it made registration decisions for some 382 pesticide ais. First filed in 2011 in the same California court, the so-called "pesticide mega-suit" is the largest ever ESA case against the EPA. The complaint was ultimately pared down to 35 ais covering more than 1,000 pesticide products containing one or more of these ais.

However, the recent court ruling could result in increased restrictions on widely used crop protection products.

Bayer's Roundup predicament

There were multiple developments involving the lawsuits filed against Bayer for failing to warn users of the alleged cancer risks from its legacy business Monsanto's glyphosate-based herbicide, Roundup. Most recently, the company won a **trial** in the US state of California, reversing a five-trial **losing streak** that saw it being directed to pay well over $1.5 billion in cumulative damages to a string of litigants.

However, in what could benefit Bayer's arguments in several ongoing cases of a similar nature, a **verdict** from a US appeals court upheld an injunction blocking the state of California from requiring businesses to warn consumers of the cancer risk from glyphosate. The ai has been a part of the state's Proposition 65 list of chemicals known to cause cancer since 2017.

Notably, Monsanto has faced thousands of lawsuits since the International Agency for Research on Cancer (IARC) classified glyphosate as a "probable human carcinogen" **in 2015**. Bayer disputes the classification, noting that the EPA and other international regulators have found that the ai does not pose a cancer risk. Additionally, it has contended that state-based, failure-to-warn claims were pre-empted by the FIFRA, and that adding a cancer warning to glyphosate would be misleading and illegal as the Act denies that the derived products cause cancer.

Bayer's **first major defeat** involving such cases came in 2018, and the $289 million award from the verdict was **subsequently reduced** to $39 million. Notwithstanding the spate of defeats, the prevalent reversal of legal fortunes has prompted the company to downgrade its anticipated losses. It has already spent some $11 billion to settle more than 100,000 glyphosate cases and has since **set aside** some $4.5 billion to contest tens of thousands of unresolved claims.

The business maintains that some 113,000 of the approximately 165,000 claims in the ongoing Roundup litigations have been resolved.

PCB-related damages

Monsanto, on the other hand, **reached a settlement** with the US state of Pennsylvania after the latter dragged it to court over alleged environmental harm caused by its use of polychlorinated biphenyls (PCBs). The company is to pay the state $100 million in restitution for the purported contamination of 1,300 miles (2,092 km) of streams and 3,600 acres (1,457 ha) of lakes over a span of five decades.

The lawsuit, filed in 2020, claimed that Monsanto's use of PCBs contaminated fish in Pennsylvania's waterways, besides causing other environmental harm. While Monsanto asserted that it had "never manufactured or disposed of PCBs in Pennsylvania's environment", the firm agreed to resolve the claims without admitting liability or wrongdoing on its part.

Other corporate disputes

Litigations also brewed between companies and regulators over a variety of issues. For instance, Syngenta Crop Protection and Corteva Agriscience **urged** a US federal court to dismiss an anti-competition **lawsuit** filed by the country's competition authority, the Federal Trade Commission (FTC), and a dozen states. Both businesses refuted allegations of using loyalty programs to bar competitors from selling cheaper generic products to US farmers.

Meanwhile, Corteva Agriscience filed a lawsuit against US seed technology company Inari (Cambridge, Massachusetts) and its Belgian business, Inari Agriculture, for alleged breach of its intellectual property rights. Corteva **accused** Inari of theft of proprietary technology, claiming that the latter used a third-party agent to obtain protected Corteva "biotech" seeds, "illegally" exported the seeds out of the US, "made slight" genetic modifications of the traits, and sought US patents for those modified traits.

Furthermore, an investor **dragged** FMC to court alleging that the business had failed to disclose crucial information leading up to the publication earlier in the year of a **scathing report** by US short-seller firm Blue Orca Capital concerning the patent estate of the company's flagship diamide insecticide technology.

The class action lawsuit filed with the US District Court for the Eastern District of Pennsylvania held FMC liable for wiping out $630 million in shareholder assets in the immediate aftermath of the short-seller report going public. It named FMC's president and CEO, Mark Douglas, and CFO, Andrew Sandifer, as defendants in the case.

FMC, however, asserted that "the claims in the complaint are without merit", adding that the company will "vigorously defend itself".

Canada's NBT guidance

During the year, Canadian authorities came up with an updated guidance for **Part V** of the nation's Seeds Regulations, making the legal framework more conducive to the introduction of food crops derived through NBTs such as gene-editing. The revised guidelines followed reforms to Canada's Novel Food **Regulations** in July 2022.

The guidance responded to the requirement for enhanced lucidity surrounding regulations involving gene-edited plants, highlighting that any plant that releases seeds into the environment would be subject to pre-market clearance only when: the plant contains foreign DNA; the plant has a new commercially viable herbicide tolerance trait; or the plant is of a new crop species or is intended for new uses in Canada.

Additionally, the guidance established a three-pronged approach to support the release of gene-edited food products in the country. It includes the formation of a "Government-Industry Steering Committee on Plant Breeding Innovations Transparency" with an eye on facilitating discussions as such products are introduced in

the nation's market. Another measure is to expand the Canadian seed variety transparency database for more clarity surrounding individual seed varieties, while yet another involves the database being placed under federal watch to ensure its "completeness and robustness".

Furthermore, the rules mandate that plant breeders continue to be deemed responsible for notifying the Canadian Food Inspection Agency (CFIA) of all "novel" plants, with the country defining such plants as those that have "no history of safe use as a food source in Canada, [been] manufactured by new processes applied to plant materials, or produced by plants that have been genetically modified by a variety of techniques".

Review workplan

Amid criticisms over delayed regulatory response, the PMRA published a pesticide re-evaluation and special review **workplan** outlining its objectives until March 31, 2028. It contains the proposed and final pesticide review decisions published since April 2023, besides all open re-evaluations and special reviews, as well as new re-evaluations expected to be initiated within the five-year period.

Rating its workload involving post-market review programs for pesticide ais as "significant", the Agency highlighted that the period from April 1, 2022 to March 31, 2023 saw it dedicating resources to prioritize the re-evaluations of ais registered before 1995. The regulator also observed that its ongoing efforts to streamline the re-evaluation processes for lower priority ais have resulted in the completion of assessments involving the majority of such ais.

However, the PMRA stated that the work associated with the reviews of older pesticides had affected the re-evaluations of several "higher priority" ais, observing that its activities were also impacted by other pressing obligations, including responding to ongoing and increasing litigation, notices of objection, and the scientific complexity associated with certain pesticide reviews. The Agency noted that the number of re-evaluation initiations dictated by the 15-year legislative requirement to assess pesticides continued to be high with an increasing backlog.

To address the situation, the PMRA is looking to develop "a continuous oversight and a proportional effort approach" for pesticide evaluations under a "transformation agenda". In its **workplan from 2022**, the Agency communicated its intention to collaborate with stakeholders to develop a proportional risk-based transformation agenda, which it had intended to implement across the regulatory lifecycle of pesticides over the next several years.

Europe review 2023: SUR and glyphosate dominated news

08 January 2024

News emanating from the EU focused on several areas, but from the beginning of 2023 the spotlight would remain on two topics that have held center stage in agrochemical-related discussions within the EU for the last couple of years. Those were: the European Commission's proposals to halve pesticide use while also transforming the existing EU sustainable use of pesticides Directive (2009/128 – SUD) into a sustainable use Regulation (SUR); and the impending deadline of glyphosate herbicide's approval, which was to have ended on December 15.

Getty

The use-reduction proposals with legally binding targets were initially laid out in **June 2022** as part of the EU's Farm to Fork strategy. They sought to set clear objectives and enforceable rules to halve the use and risk of chemical pesticides and reduce the use of more hazardous pesticides by 2030. But the proposals soon began hitting **roadblocks** when member states stated asking for an impact assessment on potential consequences on food security, especially in light of the Russian invasion of Ukraine.

In July, a parliamentary vote on the proposed SUR was **delayed** until autumn. In **October**, the European Parliament's agriculture and rural development committee (AGRI) proposed amendments seeking to water down the SUR's goals. It called on the Committee on the environment, public health and food safety (ENVI), as the body responsible to take its suggestions into account, including smaller and more protracted reductions in agrochemical use than those previously proposed.

Subsequently, the ENVI adopted its position. It stated that the EU must reduce the use and risk of chemical plant protection products (PPPs) by at least 50% and the use of "more hazardous products" by 65%, compared with the 2013-2017 average. The Commission's initial proposals were for a 50% target for both based on the 2015-2017 average. The AGRI proposal sought a far less ambitious reduction that would have seen 30% cuts by 2035 against a 2011-2013 baseline of pesticide usage.

But in a stunning development in **November**, MEPs voted to reject the proposals. At first reading, the proposals were rejected by 299 votes to 207, with 121 abstentions. That left it to the EU Council of Ministers, which could determine whether the proposals are definitively rejected or returned to Parliament for a second reading.

In **December**, the Council of Ministers revealed that they were looking to pursue the proposals to halve the use and risk of pesticides by 2030 despite the rejection vote. But EU Commissioner Stella Kyriakides conceded that the vote had created difficulties in the decision-making process.

The two likely options are either the intervention of the EU executive in withdrawing its own proposal or a decision by the EU Ministers to continue working on the file regardless of the outcome of the Parliament's vote, which could result in a second reading in Parliament.

New goals will be likely watered down from those previous ones. A compromise position on use targets would likely include mandatory 50% reduction goals at EU level, but stopping short of national targets. "This means that we no longer talk about national reduction targets, but quantitative objectives, targets, measures and timetables that are national in nature and contribute to the reduction in the use of plant protection products," stated Spanish Agriculture Minister Luis Planas Puchades. Spain held the Presidency of the EU Council from July 1 to December 31.

Glyphosate

In **July**, the European Food Safety Authority's (EFSA) published its report on the safety assessment of the active ingredient. The review covered the impact of glyphosate on the health of humans, animals and the environment and did not identify any critical areas of concern. The delay in the EFSA's report, which was supposed to have been published in 2022, was the reason a one-year **extension** was given to glyphosate's original five-year approval expiring on December 15, 2022.

Following the EFSA's green light, the European Commission in September **recommended** that EU member states approve a 10-year authorization renewal for the herbicide. Giving its reasoning for a 10-year approval rather than the typical 15 or the previous only five-year re-authorization, the Commission pointed out that glyphosate had been subject to two comprehensive assessments since 2012. Neither of them had identified

concerns indicating that the approval criteria were not fulfilled. But it also noted that research on glyphosate had intensified in recent years and new insights on the herbicide's potential impact on human health and environment might arise. "In order to balance those considerations, it is appropriate to provide for a renewal of the approval of glyphosate for a period of 10 years," the Commission explained.

But member states, as usual, remained split on the issue and were unable to arrive at a consensus. In a vote in **October**, they failed to arrive at a qualified majority on the Commission's proposals. While a majority (18 out of 27) voted in favour, three (Austria, Croatia and Luxembourg) voted against while six states abstained. A qualified majority requires that at least 55% of the member states (15 of the 27) representing a minimum 65% of the bloc's population vote for or against the proposal.

Following that, the Commission referred the matter to the Appeal Committee, which voted in **November**. That vote also remained inconclusive, with 17 member states voting in favour. Germany and France were member states that abstained in both votes. That left the matter in the hands of the Commission, and it went ahead with the 10-year renewal. In line with Comitology rules, in the absence of a qualified majority in the Appeal Committee, the Commission was legally obliged to adopt the renewal decision before the expiry of the current approval, it clarified. The decision came in the form of EU **Regulation 2023/2660**. The new authorization is valid until December 15, 2033.

Member state bans

Luxembourg has been the only EU member state to unilaterally ban glyphosate. That action came into effect in 2021. But in **April** 2023, the Administrative Court in Luxembourg upheld a previous ruling by an administrative tribunal annulling the government's decision to withdraw the approvals for eight crop protection products containing glyphosate. Luxembourg's Ministry of Agriculture subsequently reinstated the product approvals.

Germany had intended to ban glyphosate by the end of 2023. But following the EU extension in December, the federal office of consumer protection and food safety, the BVL, **extended** the national approval of glyphosate-based products by a year until December 15, 2024. The Federal Ministry of Food and Agriculture, the BMEL, issued a six-month order last month in the official gazette to **maintain** use restrictions on the herbicide running from December 31, 2023.

New genomic techniques (NGTs)

The idea of NGTs and new breeding techniques (NBTs) as being an integral part of the EU's stress for greater sustainability in agriculture has been taking shape for a few years. The idea received further impetus in February last year, when the Court of Justice of the European Union (CJEU) softened its stance, **ruling** that plants produced through in vitro use of mutagenesis could be excluded from the scope of EU GMO registration Directive (2001/18), provided they have conventionally been used in a number of in vivo applications and have a long safety record with regard to those applications. That ruling removed a hurdle created earlier by the same Court's opinion in 2018 that new mutagenesis techniques should be regulated as GMOs.

In **July**, the Commission came up with a bold legislative proposal for the regulation of plants obtained by certain NGTs and their use in food and feed. The focus of the proposal were plants produced by targeted mutagenesis and cisgenesis (including intragenesis), products containing or consisting of these plants, and food and feed containing, consisting or produced from these plants. The proposal established two categories of plants obtained by NGTs – those comparable to naturally occurring or conventional plants, and those with more complex modifications. Both categories will be subject to different requirements to reach the market taking into account their different characteristics and risk profiles.

The Commission pointed out that the proposal aimed to: give incentives to steer the development of plants towards more sustainability; ensure transparency about all NGT plants on the EU market (for instance, through labelling of seeds); and offer robust monitoring of economic, environmental and social impacts of NGT products.

To become law, the Regulation must be adopted by EU member states in the Council and the European Parliament, following the ordinary legislative procedure. Once approved, it would modify EU Regulation 2017/625 on official controls to ensure the application of food and feed law, rules on animal health and welfare, plant health and crop protection products.

UK Precision Breeding Bill

In **March**, the Genetic Technology (Precision Breeding) Bill introduced by the UK's government in 2022 became a law following royal assent. The development established a simpler legal framework for plants and animals derived using precision breeding technologies such as gene editing and NBTs, separating them from regulations involving the environmental release and marketing of genetically modified organisms. It covers only England, and not the devolved administrations of Northern Ireland, Scotland and Wales.

It marked a shift from the earlier stance that classified plants developed using NBTs as GMOs, granting the former a status similar to plants bred through conventional methods. The new framework is in line with the government's view that where genetic alterations and combinations are of the type that are selected for traditional breeding, the environmental release of such plants should not be weighed against standards established for the environmental release of GMOs. It outlines fresh criteria to determine whether an organism is precision bred.

Neonicotinoids

Ever since all outdoor uses of the neonicotinoid insecticides, clothianidin, imidacloprid and thiamethoxam, were banned in the EU in **2018**, member states have been giving emergency derogations for their use to tackle severe pest problems that cannot be effectively dealt with by any other means. But at the beginning of 2023, the CJEU ruled that EU member states should not be permitted to grant emergency authorisations for banned pesticides including the three neonicotinoid insecticides. That Court ruling ended derogations of banned active ingredients under Article 53 of the agrochemical registration Regulation No 1107/2009.

The verdict followed a Belgian court agreeing to send five prejudicial questions to the CJEU to clarify the legal limits for the provisions for emergency authorisations. A **case** was brought before the Belgian Administrative Court by environmentalist groups seeking annulment of Belgium's **decision** in 2021 to allow emergency use of imidacloprid in seed treatments for sugar beet. They cited risks to bees as their motive.

Following the CJEU ruling, France **decided** not to grant a derogation for the sowing of sugar beet seeds treated with products containing imidacloprid and thiamethoxam for 2023. At least 11 member states have granted emergency authorisations since the 2018 EU ban. Those followed the struggles of European farmers to control yellowing virus damage in sugar beet crops since the neonicotinoid ban.

Digital agriculture

Although nothing substantive happened at the EU level, there were efforts at member state level to make investments into digital and precision agriculture.

The UK government **invested** £12.5 million ($15.4 million) in 19 projects to develop agricultural automation and robotic technologies. The fundings aimed to boost productivity, food security and sustainable farming practices. The disbursement brought the total government funding in the space to £120 million ($147.6

million) since 2021. Of that, over £3.8 million ($4.6 million) were **awarded** to accelerate the delivery of robotic crop systems for the horticulture industry. The funding was expected to aid in the creation of the world's first open development platform for robotic crop harvesting.

France declared its intention **to invest** €65 million ($69.5 million) over eight years to accelerate digital agriculture and agroecology in the nation. Its Priority Research Programme and Equipment (PEPR) to that effect is part of France's 2030 targets. The Ministry of Agriculture outlined four key initiatives: using technology to support changes in agricultural practices; utilising animal and plant genetic resources; developing new generations of agricultural equipment; and developing digital decision-making tools, especially ones based on artificial intelligence (AI). In October, the Ministry also **launched** the "Agricultural Robotics Grand Challenge" with an investment of €21 million ($22.2 million).

France Ecophyto

In May, France **kicked off** its Ecophyto 2030 initiative with an ecological planning project on crop protection products and the adaptation of crop protection techniques. The first Ecophyto plan was launched in 2008 with the aim of halving the use of pesticides by 2018. But in 2014, it was deemed a failure. In 2015, **Ecophyto II** was launched, pushing back the deadline to 2025. The plan was modified into a revised version, **Ecophyto II+**, in 2018.

The revised incarnation of the country's less successful Ecophyto initiatives aims to align the country's pesticide reduction regulations with that of the EU. That aim was a result of many cases in past years of the country imposing bans on certain active ingredients while they were still approved for use within the EU. In **2018**, a few days before the EU imposed a ban on three neonicotinoid insecticides, France put in place a ban on not just those three ais, but also on two others that were not part of the EU's ban. A more recent example is the country banning the herbicide, S-metolachlor, in **April 2023**, when the ai was still undergoing the EU renewal process. The EU finally decided **last week** to withdraw by April 23, 2024, all approvals for products containing the herbicide.

NBTs round-up 2023: Sector gains from regulatory overhauls

04 January 2024

Regulations concerning the use of new breeding techniques (NBTs) such as gene editing for agricultural crops gained further clarity in 2023, with Canada, the EU, and the US leading the way.

Getty Images

The year saw increased proliferation of crops derived through NBTs, aided by relaxed guidelines across various jurisdictions, as well as research dedicated to gene editing techniques including CRISPR-Cas9, transcription activator-like effector-nucleases (TALENs), and targeted mutagenesis and cisgenesis.

The sector benefited from a host of deals, as well as increased flow of investments. Research and development activities focused on imparting crops with traits such as disease resistance, stress tolerance, improved yield and elevated nutritional content, with an increasing number of field trials being initiated during the past 12 months.

US

Regulatory overhaul

Authorities in the US relaxed regulations related to NBTs in 2023, enabling the industry to undertake developmental projects and build genetic pipelines by leveraging provisions under the country's **national biotechnology initiative**. The project sought to improve the transparency and efficiency of regulatory processes for products derived using biotechnology, besides implementing measures to facilitate easier navigation of the nation's gene editing framework.

The **widened biotechnology rules** cover loss of function modifications, polyploid plants, as well as multiple and successive edits. The USDA expects the relaxed framework to afford the deregulation of certain plants with loss of function mutations in the same gene across all chromosomes, "regardless of how the mutation is generated".

Additionally, the eased guidelines apply to modifications without the insertion of exogenous DNA into diploid or autopolyploid plants with any combination of loss of function modifications in a single allele, or all of them within a single genetic locus. Provisions have also been made for allopolyploid plants with loss of function modifications in one or both alleles.

The year saw relevant government bodies being **tasked with identifying** areas of ambiguity, gaps, or uncertainties in the nation's **2017 update** to its co-ordinated framework for the regulation of biotechnology, as well as policy changes made pursuant to Executive Order 13874 of 2019. The latter seeks to modernize the region's regulatory framework for agricultural biotechnology products.

Decisions were also taken to expand the purview of the US agriculture regulator, USDA's, deregulation guidelines involving gene-edited crops. Authorities anticipate the measure enabling the Department's Animal and Plant Health Inspection Service (APHIS) to exempt plants with biotechnology-derived modifications from registration requirements, provided that the applications are backed by "scientific evidence" that such plants could be bred using conventional processes.

Licensing gathers pace

The eased laws were greeted by a flurry of regulatory status review (RSR) requests from various companies, with the USDA **deregulating** a multitude of gene-edited crops throughout the year. Moreover, the updated framework translated into a sizeable rise in the intellectual property (IP) portfolios of various entities, besides motivating businesses to forge partnerships. The USDA **claimed** that plant variety patents had doubled during the last decade, highlighting that the competitive environment was made more conducive through improved IP protection for new crop varieties.

Bayer's Crop Science division, for instance, agreed a **five-year deal** with US plant gene editing business Pairwise (Durham, North Carolina) to develop gene-edited short-stature corn (maize). The firms are to employ Pairwise's **Fulcrum** CRISPR technology platform to develop gene-edited versions of Bayer's Preceon Smart Corn System, including the short-stature corn. The partners anticipate the 30-40% shorter corn being sturdier and less likely to fall over or break due to extreme weather conditions such as strong winds or heavy rain.

US bioherbicide start-up Harpe Bioherbicide Solutions (Research Triangle Park, North Carolina) **executed** an IP licensing agreement with Corteva Agriscience and the Broad Institute of MIT and Harvard. That deal revolves around CRISPR-Cas9 and related gene editing tools aiding research and facilitating the development of Harpe's herbicide-tolerant crop systems.

Corteva, however, was embroiled in a **lawsuit**, having complained against US seed technology business Inari (Cambridge, Massachusetts) for allegedly infringing upon its IP rights. Inari was accused of using a third-party agent to obtain protected Corteva "biotech" seeds, and "illegally" exporting those seeds out of the country, besides making slight genetic modifications to the traits and seeking US patents. A writ petition on the matter was filed in the US District Court for the District of Delaware.

Developments also took place on the technology front. Corteva Agriscience and US biotechnology business PacBio (Menlo Park, California) **designed** new workflows for plant and microbial genome sequencing, with the latter anticipating the efforts driving the implementation of CRISPR-Cas9 and related gene-editing techniques. Moreover, Corteva signed an **agreement** with UK gene-editing business Tropic Bioscience to develop non-transgenic disease resistance traits in corn and soybeans using the former's proprietary Gene Editing Induced Gene Silencing (GEIGS) technology.

Licensing deals accounted for innovations such as TALENs as well, with US charitable group 2Blades Foundation (Evanston, Illinois) completing a non-exclusive **licensing agreement** involving the technology with Wilmington, Delaware-based US biotechnology business Napigen. 2Blades happens to hold exclusive rights for commercial applications of TALEN, and the licensing is expected to advance Napigen's efforts to edit plant organelles with an eye on enhancing crop productivity.

Furthermore, institutional investments flowed into the sector through the USDA, which **infused** over $25 million into 11 projects for the control of citrus greening disease or huanglongbing (HLB – *Candidatus liberibacter asiaticus*) through measures including the development of gene-edited HLB-resistant citrus hybrids.

Relaxed PIP guidelines

Aside from gene-edited crops, US regulators exhibited a **favourable outlook** towards plant-incorporated protectants (PIPs) created using genetic modification. The nation's EPA relaxed rules that exempt certain PIPs from registration requirements under the US Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), implementing a **final rule** that was communicated in May.

The EPA rated PIPs created through genetic modification as "virtually indistinguishable" from those derived using conventional breeding techniques, concluding that that they posed "no greater risk than PIPs created through conventional breeding that have been exempt [from registration requirements] since 2001".

Consequently, FIFRA registration and tolerance requirements under the US Federal Food, Drug, and Cosmetic Act (FFDCA) have been exempted for: PIPs that have been genetically modified to insert or modify a gene with the intent of matching a gene found in a sexually compatible plant; and "loss-of-function" PIPs in which such modification reduces or eliminates the activity of a gene, translating into the plant becoming resistant to pests.

However, the pesticide watchdog explained that the exemption applied not only to PIPs created through genetic modification but also included those that "could also have been created through conventional breeding".

The decision is likely to mitigate regulatory hurdles, besides driving down costs involved in commercializing certain PIPs. It is also expected to foster research and development in agricultural biotechnology, and benefit businesses designing PIPs for minor crops.

In December, the EPA **notified** the receipt of an application from Bayer to register the miRNA-derived PIP, GA20ox_SUP, for use as a plant growth regulator (PGR).

Canada

Updated regulations

Across the border in Canada, authorities came up with an **updated guidance** for Part V of the nation's Seeds Regulations, making the country's legal framework more lenient for the introduction of food crops derived using NBTs. The revised guidelines followed reforms to Canada's Novel Food Regulations in July 2022.

The rules highlighted that any plant that releases seeds into the environment would be subject to pre-market clearance only when: the plant contains foreign DNA; the plant has a new commercially viable herbicide tolerance trait; or the plant is of a new crop species or is intended for new uses in Canada.

Additionally, the government established a three-pronged approach to support the release of gene-edited food products in the country. It includes the formation of a "Government-Industry Steering Committee on Plant Breeding Innovations Transparency" to facilitate discussions as such products are introduced in the nation's market. Another measure is to expand the Canadian seed variety transparency database for more clarity surrounding individual seed varieties, while yet another will involve the database being placed under federal watch to ensure its "completeness and robustness".

The rules still mandate that plant breeders be deemed responsible for notifying the Canadian Food Inspection Agency (CFIA) of all "novel" plants, which the country defines as those plants that have "no history of safe use as a food source in Canada, manufactured by new processes applied to plant materials, or produced by plants that have been genetically modified by a variety of techniques".

However, Canada's reliance on the organic sector stood out despite the leeway granted to NBTs, and the government warming up to the idea of introducing gene-edited food crops. The revised guidelines continue to reserve organic certifications for conventional seeds, with the authorities stressing that retaining such mandates are necessary to draw investments, and to "protect the integrity of the organic sector".

Nevertheless, the updated guidance prompted additional research initiatives, and its notification was followed by the government-run National Research Council of Canada (NRC) reporting the **development** of over 7,000 canola lines through mutagenesis as part of a three-year collaboration with Corteva Agriscience. Over 50 canola varieties with increased protein, reduced fiber, and lower anti-nutritional content were selected for further analysis.

Proposals in the EU

In 2023, efforts were made by the EU to gradually adopt plants derived through new genomic techniques (NGTs) for use as food and feed.

The year was defined by the European Commission's bold **legislative proposal** for the regulation of plants produced by targeted mutagenesis and cisgenesis (including intragenesis), as well as products containing or consisting of these plants, and food and feed containing, consisting or produced from these plants. It sought to establish two categories of plants obtained by NGTs – those comparable to naturally occurring or conventional plants, and those with more complex modifications. Both categories would be subject to different requirements to reach the market on account of their different characteristics and risk profiles.

Category 1 NGT plants would include those that could also occur naturally or be derived through conventional breeding. They would be subject to a verification procedure, based on criteria set in the proposal. Plants that meet these criteria are to be treated as conventional plants, and they would be exempted from the requirements of EU GMO legislation under Directive (2001/18). Information on category 1 NGT plants is to be

provided through the labelling of seeds, in a public database, and through the relevant catalogues on plant varieties.

The proposal sought to place all other NGT plants under category 2, highlighting that the requirements of the GMO legislation would apply to them. They would be subject to risk assessment and authorization before being put onto the market. Furthermore, they would be traced and labelled as GMOs, with the possibility of a voluntary label to indicate the purpose of the genetic modification. The risk assessment, detection method, and monitoring requirements for these plants would be adapted to different risk profiles, and regulatory incentives would be available for NGT plants featuring traits that could contribute to sustainability goals.

To become law, the Regulation must be adopted by EU member states in the Council and the European Parliament, following the ordinary legislative procedure. Once approved, it would modify EU Regulation 2017/625 on official controls to ensure the application of food and feed law, as well as rules on animal health and welfare, plant health, and crop protection products.

Easing stance

The proposal came as a clear indication of the Commission's often repeated **conviction** that NGTs could contribute to the objectives of EU strategies, notably the European Green Deal and the Farm to Fork and Biodiversity strategies. The Commission points out that the proposal seeks to: give incentives to steer the development of plants towards more sustainability; ensure transparency about all NGT plants on the EU market (for instance, through labelling of seeds); and offer robust monitoring of economic, environmental and social impacts of NGT products.

In fact, the idea of NGTs as being an integral part of the EU's emphasis for greater sustainability in agriculture has been around for a few years. It gained ground after a controversial ruling by the Court of Justice of the European Union (CJEU) **in 2018** stated that all organisms produced through in vitro random mutagenesis be included within the EU GMO registration Directive (2001/18), and hence be regulated as GMOs.

Subsequently, in 2021, the Commission published **a study** that stressed the need for new legislation for plants produced using the aforementioned techniques. The following year, an EU **consultation** on the matter revealed that almost 80% of respondents felt that the bloc's legislations governing GM crops under EU GMO Directive (2001/18) were not adequate for plants obtained by targeted mutagenesis or cisgenesis.

But, in February 2023, the CJEU **softened its stance** when it ruled that plants produced through in vitro use of mutagenesis could be excluded from the scope of Directive (2001/18), provided they had conventionally been used in a number of in vivo applications and had a long safety record with regard to those applications.

In a factsheet published by the Commission, the benefits of plants produced using NGTs include: more resistance to pests, diseases, adverse environmental conditions, and to the effects of climate change; requirement of less natural resources, fertilizers and pesticides; improved nutrient content of food and feed; and reduced content of harmful substances such as toxins and allergens.

Among products being developed using NGTs were: potatoes producing substantially less acrylamide; tomatoes resistant to fungal pathogens; rice tolerant to drought and salt, and thus able to cope with stresses related to climate change; and wheat with increased protein content and grain size.

Mixed reactions

However, attempts to liberalize the EU's regulatory framework for NGTs drew **unfavourable opinions** from some EU members such as Germany, and the country voiced its opposition to the deregulation of plants

produced using targeted mutagenesis and cisgenesis. Austria is opposed to the move as well, with its Minister of Climate Action and Environment, Leonore Gewessler, questioning the scientific basis of the Commission's proposal to deregulate NGT-derived plants. Ms Gewessler's outlook was supported by Hungary and Cyprus.

The Swiss Advisory commission on agriculture (BEKO), on the other hand, feels that "special treatment" for the new technology was **justified**, including separation from regulations governing GM crops.

Status in the UK

The Genetic Technology (Precision Breeding) Bill **introduced** by the UK's government became a law in 2023 following its royal assent, marking a shift from the earlier stance that classified plants developed using NBTs as GM. The simpler framework exempts such plants from regulations involving the environmental release and marketing of GMOs. It covers only England, and not the devolved administrations of Northern Ireland, Scotland and Wales.

Notably, England's and the rest of the UK's monitoring of NBTs were governed by the CJEU's 2018 ruling mentioned earlier in this piece. The altered perspective gained ground with the UK leaving the jurisdiction of the ECJ post Brexit, and the UK Houses of Parliament **ratifying** draft regulations in March 2022 to simplify the approval process for research trials on plants derived through NBTs.

The newly introduced framework is in line with the government's view that where genetic alterations and combinations are of the type that are selected for traditional breeding, the environmental release of such plants should not be weighed against standards established for the environmental release of GMOs.

Additionally, it outlines fresh criteria to determine whether an organism is precision bred, classifying it as such only when: any feature of its genome results from the application of modern biotechnology; every feature of the genome that results from such application is stable; every feature of the genome that results from applying biotechnology could have resulted from traditional processes, whether or not in conjunction with selection techniques, alone, and; the genome does not contain any feature that results from the application of any artificial modification technique other than modern biotechnology.

India and China

Reports from India focused on various entities, public as well as private, leveraging the nation's relaxed gene editing **regulations**. The country exempts products derived through two gene editing techniques, site directed nuclease (SDN)-1 and SDN-2, from the purview of its regulations governing GMOs.

India is utilizing these technologies to breed new crop varieties and develop traits such as disease resistance and drought tolerance. The derived crops would be eligible to circumvent biosafety assessments undertaken by the nation's apex biotechnology regulatory body, the Genetic Engineering Appraisal Committee (GEAC).

The year also saw scientists **develop** a gene-edited mustard that is less pungent, besides being resistant to the fungal pathogen, *Sclerotinia sclerotiorum*, and pests including cutworms (*Spodoptera litura*). The development team claimed that the mustard variety was the first of its kind globally, highlighting that CRISPR-Cas9 technology was used to develop the crop with low glucosinolate content.

In neighbouring China, the Ministry of Agriculture and Rural Affairs issued "Regulations for the Review of Gene-Edited Plants for Agricultural Use (Trial)", clarifying the classification standards of gene-edited plants and simplifying the review rules. It enhanced operability under **guidelines** for field trials involving the safety evaluation of gene-edited plants, and is likely to accelerate their commercialization as opposed to GMO counterparts, which must undergo a prolonged five-step process to receive a biosafety certificate.

Subsequently, Chinese authorities **issued** a safety certificate to the nation's maiden gene-edited crop, a high-oleic acid soybean variety developed by Jinan-based Chinese biotechnology business Shandong Shunfeng Biotech, in May. The soybean was developed by altering two of its genes for increased production of oleic acids, with the company claiming that its soybeans contain around four times more oleic acid than conventional varieties of the crop. The five-year approval is valid until April 20, 2028.

Other jurisdictions

The Brazilian biosafety commission, the CTNBio, regulates gene-edited products on a case-by-case basis and **exempts** them from regulation when there is no insertion of transgenes. That mirrors the regime in Argentina.

In Africa, at least two countries – **Kenya** and **Nigeria** – have issued guidelines on gene editing. They seek to define which gene-edited organisms and/or derived products are to be regulated as GMOs, and which are to be treated as conventional varieties or breeds.

As for Australia and New Zealand, the Food Standards Australia New Zealand (FSANZ), in 2021, **proposed** changes to definitions for "food produced using gene technology" and "gene technology". It sought to distinguish between established GM food technologies, and food produced using NBTs. A public consultation on the matter generated over 1,700 comments, and a summary of stakeholder feedback was published in 2022. Further regulatory communication is expected this year.

Dig ag review 2023: Alliances fuel sectoral expansion

04 January 2024

The radical transformation of the digital agriculture industry set afoot at the beginning of the decade gathered pace in 2023. In Asia, the rate of implementation was more pronounced compared with matured markets across the EU, Latin America, and North America. Headway was made in Africa as well, where consorted efforts from national governments, corporate entities, and international organizations translated into substantial improvement of farming practices.

Getty Images

Innovations during the year were primarily focused on artificial intelligence (AI), machine learning and remote sensing. While drone-based offerings made inroads into burgeoning Asian markets including India, China, Thailand, and Vietnam, geographies such as Canada and the US moved towards the adoption of robotic solutions, besides offerings leveraging Internet of Things (IoT) and advanced sensors.

Deals galore

The expansion of the digital agriculture industry in 2023 was directly influenced by an increasing number of companies getting into partnerships or acquiring businesses to foray into the sector. *Crop Science Market Reporting* **recorded** nearly 100 such developments encompassing a myriad of technologies over the course of the year.

Major crop protection players with significant presence in the digital agriculture market accounted for the greatest number of deals in 2023. Bayer's Crop Science division was among the most prolific, forging deals in Asia, the EU and North America.

In Europe, Bayer's digital agriculture business, **FieldView**, signed an agreement with Milan-based Italian firm XFarm Technologies to operate in all the markets where either of the entities had presence. The company also **forayed** into the Middle East, where it allied with Canadian digital agriculture company Fermata to reduce pesticide usage in Israel though the use of AI. Additionally, Bayer acquired Canadian Digital Agriculture business **Combyne Ag** with an eye on accelerating the development of new grain marketing management solutions.

BASF Digital Farming and German technology provider Bosch **rebranded** their joint venture, Bosch BASF Smart Farming, as One Smart Spray. A cross-border deal saw the joint venture **collaborating** with US agricultural equipment manufacturer Agco (Duluth, Georgia) to develop and commercialize smart spraying equipment in the Americas and Europe. BASF also **agreed** to integrate its agricultural decision support system, Agrogenio, with Spanish business Vegga's precision agriculture platform.

UK-based agricultural equipment manufacturer CNH Industrial (Basildon) partnered with One Smart Spray to **integrate** the latter's precision sprayer technology of the same name within its agricultural product portfolios. CNH also went on to **acquire** a French digital agriculture start-up, Augmenta, besides **partnering** with the Syngenta Group to integrate the latter's digital Cropwise platform with two of its farm equipment brands.

Capital was infused into the digital agriculture sector by a number of national governments. This included authorities in the UK **awarding** over £3.8 million to a domestic company to accelerate the delivery of robotic crop harvesting systems for the horticulture industry.

Government-led investments were reported from several nations in the Horn of Africa region, where digital technologies were earlier deployed on a large scale by the UN FAO to track desert locust (*Schistocerca gregaria*) swarms. The immediate threat having subsided, such solutions underwent additional testing to mitigate potential pest attacks that could impact the region's key crops.

Private partnerships in Africa mostly focused on crop monitoring and risk assessment solutions. In Kenya, for instance, Fairgro Africa entered into an agreement with Indian agricultural technology provider **Arya.Ag** for crop monitoring through the latter's smartphone application. Similar collaborations involving other entities were set afoot in neighbouring countries as well.

Investments took place in the Oceania region. BASF's venture funding arm, **BASF Venture Capital**, infused capital into New Zealand-based agricultural automation company Autogrow's digital farming business, WayBeyond, while Australian precision agriculture business **Braiin** entered into a "business combination" agreement with US special purpose acquisition company Northern Revival Acquisition Corporation.

Besides these, a number of crop protection players leveraged digital technologies to undertake trials of their products. Among others, these included UPL, which forged a partnership with US soil analytics company Biome Makers (Sacramento, California) to utilize the latter's soil functional analysis technology, BeCrop Test, in a series of **global trials**.

Product introductions

As for the launch of new digital products and services, an especially large number were introduced into Latin American markets. While **Syngenta** brought a nematode diagnosis tool to Brazil, the nation's agricultural research corporation, **the Embrapa**, unveiled three digital tools for a variety of agricultural functions.

Growers in Brazil also gained from Adama's **introduction** of a farm management platform, alongside Syngenta's launch of offerings intended for the country's **sugar cane** growers. BASF marked its presence by **launching** its Xarvio Agro Experts digital agriculture service.

In Guatemala, US electric aircraft manufacturer Pyka forged a partnership with Guatemalan fruits producer Grupo Hame (Guatemala City) to **conduct trials**. The latter is to subsequently lease Pyka's "autonomous" agrochemical spraying aircraft, Pelican Spray, for use across its banana plantations.

Dutch bioproducts company Koppert Biological Systems (Berkel en Rodenrijs) contributed to the growing number of new digital solutions and services as well. It **unveiled** a digital assistant that is trained on large amounts of data, including product, biological and ecological information, to provide "around-the-clock" access to agricultural knowledge and support from Koppert experts.

Additionally, the year saw Bayer **facilitating** secure, compliant exchange of farm data between its digital farming platform, Climate FieldView, and original equipment manufacturers (OEMs) through industry platform Microsoft (MS) Azure Data Manager for Agriculture. The businesses are in a partnership to leverage Bayer's recently launched cloud-based solution, **AgPowered Services**.

Regional reviews

India

In India, the adoption and expansion of digital agriculture technologies was influenced by three factors – corporate tie-ups and investments, government schemes, and narrowing digital divide on account of a surge in smartphone ownership. The year was marked by major players committing to bullish investments in the nation's digital agriculture ecosystem. These businesses, alongside new entrants, introduced a plethora of offerings dedicated to precision farming, crop and soil health monitoring, crop risk assessment, and weather services.

Crop protection companies took an active interest in India's new digital agriculture framework and vied for a foothold of the largely untapped market. The contenders included domestic and international entities, with some pureplay agrochemical firms also entering the fray.

Among international businesses, Syngenta Group agrochemical business Adama initiated a **project** for drone-based crop protection early in the year, while Bayer and US agribusiness Cargill **partnered** to offer digital solutions to smallholder Indian farmers.

Domestic players attempted to step up their offerings through acquisitions and collaborations. Coromandel International **incorporated** a new subsidiary to design, develop and manufacture agricultural drones. Moreover, the company went on to **expand** its stake in an Indian drone business, and subsequently became its **majority** shareholder. Two other entities – drone manufacturer Garuda Aerospace (Chennai), and agrochemical company Rallis – **partnered** for drone-based spraying.

On the other hand, Syngenta **agreed a deal** with Indian agricultural drone business IoTechWorld Avigation (Gurugram) for a similar exercise, and FMC **kicked off** its drone spraying service in the country.

Furthermore, NASA went on to **collaborate** with an Israeli firm for agricultural remote sensing activities in India, while Canadian company Clean Seed Capital Group **signed an agreement** with Indian automotive company Mahindra & Mahindra (Mumbai) to introduce the former's Smart Seeder seeding technology in the latter's country.

Investments and outreach

Start-ups focusing on digital agriculture thrived, aided by a steady flow of investments. Garuda raised two tranches of capital amounting to **$22 million** and **$3 million**, respectively, while Bengaluru-based Indian agricultural intelligence provider CropIn **raked in** $14 million from a host of investors. Grants also went into developing **remote sensing** and **Earth imaging capabilities**.

During the year, several businesses reached out to India's farmer producer organizations (FPOs) for improved adoption of their digital platforms. That led to enhanced grower understanding of prevalent and emerging technologies, besides enabling the companies to test their offerings in field conditions through pilot projects.

Further sectoral impetus came in the form of crop-specific standard operating **procedures** (SOPs) for drone-based spraying issued by the nation's Ministry of Agriculture and Farmers' Welfare, and wider proliferation of the government's Kisan (farmer) Drone scheme, which extends financial assistance to growers for the purchase of agricultural drones.

China and the Asia Pacific

The regulatory tailwinds extended into China, where the government undertook initiatives to highlight the benefits of digital farm technologies. Major developments included the introduction of a national big data platform for the rice industry, and wider adoption of drones for farming activities.

Efforts were also undertaken to develop digital solutions for farming in hilly and mountainous regions.

Furthermore, China's "No. 1 Document", which highlights the government's goals for the nation's agriculture industry, provided a glimpse of the work being carried out to integrate satellite-based technologies into farm monitoring devices.

The expansion of drone usage in the country was led by Guangzhou-based Chinese digital and precision agriculture company XAG.

Other markets in Asia mostly saw advancements in terms of agricultural drone use. In **Thailand** and **Vietnam**, this was led by XAG through new launches, as well as the establishment of a co-operative to promote drone technology in the latter geography. Additionally, Norwegian plant nutrition business Yara (Oslo) **launched** its farm advisory platform, FarmCare, in Thailand.

One **partnership** was reported from Australia, where Canadian farm automation start-up Verge Ag and the Australian Grains Research and Development Corporation (GRDC) collaborated for a project to optimize on-farm operations for grain growers.

North America

US

Sectoral activities in the US revolved around accelerating innovation, with several start-ups coming into existence, and established players bolstering their portfolio of offerings through collaborations or takeovers. Technologies such as machine learning, AI and robotics gained traction, with the remote sensing and satellite sector flourishing on account of government initiatives, business consolidation and investments.

The usage of data platforms for the analysis of agronomic data became mainstream in 2023. Cross-platform compatibility and the ability to share data between platforms of partnering service/equipment providers

spurred collaborations. Major digital agriculture players proceeded to integrate and connect their offerings with an eye on achieving inter-operability. These included **Syngenta** and CNH Industrial, besides BASF Digital Farming, which **integrated** its Xarvio Field Manager system with CNH's global operating platform.

In Canada, digital agriculture supplier Farmers Edge (Winnipeg, Manitoba) **partnered** with US food and agriculture data infrastructure start-up Leaf Agriculture (Los Angeles, California) to leverage the latter's data platform.

Several other firms expanded their suite of offerings. These included **Bayer**, Minneapolis, Minnesota-based US data analytics company **Sentera**, and US digital agriculture company **Farmers Business Network** (FBN – San Carlos, California).

Fundings and alliances

Investments undertaken during the period focused on technologies across the board.

The increased adoption of robotic solutions stood out as a noticeable trend during the year, and companies raised millions to develop the niche sector. Seattle, Washington-based US robotics business Carbon Robotics **raised** $30 million, and also **added features** to its laser-based weeding robots. Several other companies also took to working on similar technologies.

In fact, the demand for robotic agricultural solutions in the US prompted Brazilian digital agriculture supplier Solinftec to expand its robotics **manufacturing capacity** in the former country, while a German and a US entity forged a deal to **develop** AI-driven robots to eliminate weeds. Furthermore, US agricultural technology start-up Aigen (Seattle, Washington) **unveiled** a weeding robot powered by solar and wind energy. The business also **raised** $12 million in funding during the year.

The US digital agriculture industry also went through consolidation, with start-ups being taken over by bigger rivals. Among many other acquisitions across the sector, Duluth, Georgia-based US agricultural equipment manufacturer Agco **agreed** to acquire a majority interest in Sunnyvale, California-based US positioning technology company Trimble's agricultural assets for $2 billion.

John Deere, on the other hand, **acquired** a US precision spraying equipment maker, while Canadian carbon mapping business Scope Carbon (Vancouver, British Columbia) **signed** a non-binding letter of intent to acquire US image-based crop data and analytics company Farm Flight (Tempe, Arizona).

Leveraging satellites

The satellite and remote sensing segment were led by NASA, and San Francisco, California-based US satellite technology business Planet. The latter launched as many as 36 satellites under its SuperDove constellation for measuring crop yields, among other purposes, besides **joining hands** with NASA's global food security and agriculture program, NASA Harvest, to support the parties' joint food security and agricultural monitoring solution. Satellite and remote sensing-based solutions for specific agronomic uses were leveraged by a host of other businesses as well.

In 2023, NASA partnered with **educational institutions** for the detection of crop ailments through remote sensing solutions, while the USDA focused on **studying** geospatial technology, besides **introducing** an agricultural tool based on its findings.

An interesting development came in the form of US seed technology business InnerPlant (Davis, California) **initiating** the building of a "first-of-a-kind" satellite-mounted device that detects signals from crops

engineered by the company to fluoresce in response to situations of stress including attacks from pathogens, or a lack of water and nutrients. The company went on to **secure** multiple approvals from the USDA's Animal and Plant Health Inspection Service (APHIS), besides **collaborating** with Syngenta and John Deere to develop an integrated solution to combat fungal pathogens affecting soybeans.

Canada

In Canada, global players expanded their portfolios for wider market penetration, while start-ups lined up a host of innovations.

One of the biggest acquisitions during the year was Bayer's purchase of Ottawa, Ontario-based Canadian digital agriculture business Combyne, and subsequently **integrating** the former's digital agriculture business Climate Corporation's digital platform, FieldView, with Combyne's crop marketing management tool.

A different deal saw Canadian digital agriculture business **AgExpert** (Toronto, Ontario) integrating its AgExpert Field (AEF) farm management software with Bayer's FieldView platform.

AI dominated digital agriculture offerings in Canada. Among other stakeholders, Toronto, Ontario-based Ukko Agri joined an alliance to design an AI-based in-field platform to predict and combat anthracnose (*Colletotrichum* spp) and ascochyta blight (*Ascochyta rabiei*) affecting the nation's lentils. Another Canadian business, Winnipeg, Manitoba-based agricultural risk management company Agi3 Risk, **introduced** an AI-derived crop insurance solution, AgriEnhance, to provide users with "real-time" insights with an eye on helping them address potential losses.

Other developments revolved around the placing of various solutions on the market by companies, as well as Farmers Edge **receiving** an offer from its majority shareholder to take the business private.

Digital/precision ag tracker

S&P Global Commodity Insights' *Crop Science Market Reporting* has unveiled an advanced **data tool** that tracks all business activities such as mergers and acquisitions, company deals, and investments, in the digital agriculture sector.

The tool is an expansion of our **combined** offering that covers business activity in crop protection, agricultural biotechnology, and digital agriculture. It contains two distinct trackers – one focused on **crop protection** and agricultural biotechnology, and the other covering **digital/precision agriculture**.

Glyphosate in legal and regulatory crosshairs during 2023

05 January 2024

The EU brought its protracted reassessment of glyphosate herbicide to a conclusion amid industry cheers when the European Commission **renewed its approval** for 10 years in December last year. The renewal commenced on December 16, when the previous approval of the active ingredient expired. The new authorization is valid until December 15, 2033.

Getty images

The tortuously long reassessment was merely the front runner in glyphosate news running on several tracks.

The Commission **went ahead** with its proposed ten-year approval after a vote by EU member states failed to reach a qualified majority in the autumn. It stressed that the herbicide had been subject to two comprehensive assessments since 2012, **neither of which** had identified concerns indicating that the approval criteria laid down in EU agrochemical Regulation 1107/2009 would not be fulfilled. The European Food Safety Authority (EFSA) defines a concern as critical when it affects all proposed uses of the ai under evaluation, such as pre-sowing uses, post-harvest uses, etc., thus preventing its approval or renewal.

Key member states provided some verbal opposition but abstained during voting, allowing the Commission to determine the herbicide's fate.

Four member states acted as rapporteur states in the reassessment, double the typical number. their assessments came along with the EFSA and European Chemicals Agency's (ECHA) with the latter arriving at its conclusion after a public consultation and expert hearing unanimously agreed that there was no evidence to classify glyphosate as a carcinogen.

The authorization is subject to certain new conditions and restrictions. They include a prohibition on the use of glyphosate as a pre-harvest use as a desiccant, and that member states: pay particular attention that sufficient data be provided on co-formulants contained therein; pay particular attention to the assessment of the risk to small herbivorous mammals, in particular for those uses where such risk was identified by the EFSA; and for non-agricultural applications, ensure that the use of products containing glyphosate be minimized or prohibited in sensitive areas such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds, and in the close vicinity of healthcare facilities.

The reassessment saga included the Commission extending the approval by a year in **late 2022** after the EFSA had failed to complete its reassessment in time. That followed a previous five-year extension rather than the typical 10.

European countries

Within European countries, the glyphosate controversy remained center stage. In May, a **French court** reportedly banned the sale of two glyphosate-based herbicides produced by Syngenta due to the lack of analysis on the ai's potential harm to some wildlife. The court said that the "precautionary principle" was not respected in the French authorities' evaluation procedure of the ai.

In January, the European Commission **approved France's** €215 million ($235 million at the current rate) aid scheme to help mitigate the economic consequences related to a planned phase out of glyphosate usage.

In April, the Administrative **Court in Luxembourg** upheld a previous ruling by an administrative tribunal annulling the national government's decision to withdraw the marketing authorizations for eight crop protection products containing glyphosate. Luxembourg's Ministry of Agriculture subsequently reinstated the product approvals.

Germany had intended to ban glyphosate by the end of the year. Following the EU extension in December, the federal office of consumer protection and food safety, the BVL, **extended** the national approval of glyphosate-based products by a year until December 15, 2024. The Federal Ministry of Food and Agriculture, the BMEL, issued a six-month order last month in the official gazette to **maintain use restrictions** on the herbicide running from December 31, 2023.

Mexico

Early in the year, **Mexico tempered** its 2020 decree to phase out the use of GM maize and glyphosate. A new decree was issued, setting the complete phase out of GM maize for most uses in food, and glyphosate use from March 31, 2024 – a two-month extension on the previous decree – and allowing certain continued uses of GM maize. In December 2020, Mexico issued a decree initiating a four-year phase-out of the uses of glyphosate and GM maize for human consumption and in feed. That would have ended uses by the end of January 2024.

The amended order brings the phase out deadline under three months away.

The new decree instructs federal agencies to: revoke any and refrain from granting authorizations and permits for the import, production, distribution and use of glyphosate. It orders that they undertake actions to establish "sustainable and culturally appropriate alternatives and practices, that maintain agricultural production and are safe for human health, the country's biocultural diversity and the environment, free from toxic substances that pose acute, chronic or sub-chronic hazards".

The decree also cautions that any implemented alternatives for the gradual replacement of glyphosate "must be able to maintain agricultural production and be safe for human health". It claims that to limit the potential impact from the gradual substitution of the agricultural uses of glyphosate, the Ministries of Agriculture and the Environment will promote "sustainable and culturally appropriate alternatives" to glyphosate including the use of other "health-safe" agrochemicals or biological products.

The decree immediately directed that federal agencies refrain from acquiring, using, distributing, promoting and importing glyphosate-based products, for any public programs or government activity.

Clashes with US

The policy softening followed clashes with United States-Mexico-Canada Agreement (USMCA – successor trade deal to NAFTA) trade partner the US and offers some compromise that national commentators suggested may aid Mexico in other trade areas.

The US launched a trade dispute with Mexico under USMCA initiating a dispute settlement panel. Canada joined the US in the dispute.

CropLife Latin America's president told Crop Science Market Reporting that the Mexican government had launched a WTO action likely as a counter action. The WTO action had a late September expiration date. He believes that the commitment from the Mexican government is political and expects the issue to be a major one at re-election for this year's presidential vote.

Behind the scenes discussions saw MPs delay ratification of the decree orders, pending a "third party" impact assessment that was presented in the second half of last year. This led to some disputes between national and state governments in Mexico on the issues, including glyphosate's phase out.

In May, the Mexican secretary of food self-sufficiency **denounced US demands** against the government's policy to phase out most GM corn uses and all glyphosate herbicide use. Sub-secretary Víctor Suárez Carrera said that the government would not submit itself to actions against the decree.

Also in the first half of the year, Mexico **sought to halve** imports quotas on glyphosate as part of the government's policy to phase out use of the ai. The government's science and technology counsel, the Conacyt, recommended competent authorities halve import quotas this year as it had done for the previous two years. For 2023, the counsel recommended quotas of 4,131,544 kg of formulated glyphosate herbicides and 314,308 kg of technical product. That was down from the near 8,300- metric ton quota for formulated product and a

little over 628,000 kg of technical product the previous year. The policy is part of the phase out of the herbicide. Reported glyphosate imports were dramatically down over the two previous years.

Bayer litigations

Bayer legacy business Monsanto has faced thousands of lawsuits since the International Agency for Research on Cancer (IARC) classified glyphosate as a "probable human carcinogen" in 2015.

The company's first major defeat involving such cases came in 2018. The $289 million award from the verdict was subsequently reduced to $39 million. Also, prior to last year, Bayer had failed in its attempt to get the US Supreme Court to rule that federal laws pre-empted state laws in their requirement to print warnings on its labels.

However, a reversal of legal fortunes in recent months led to the company downgrading its anticipated losses. Bayer had already spent some $11 billion to settle more than 100,000 glyphosate cases and since set aside some $4.5 billion to contest tens of thousands of unresolved claims.

Last year commenced with the US Missouri Supreme Court granting an **emergency writ** petition filed by Bayer lawyers, issuing a preliminary prohibition to halt a multi-plaintiff trial in St Louis, Missouri midway through jury selection. The case involved six plaintiffs from an original five cases combined under the name, Griswold. It was among a plethora surrounding legacy business Monsanto's glyphosate-based Roundup herbicide.

Such actions are exceedingly rare, Bayer legal counsel Bryan Cave Leighton Paisner's representatives told Crop Science Market Reporting. They claim that juries in the city of St Louis have issued "outsized verdicts" in multi-plaintiff product liability cases in recent years. Therefore, avoiding a multi-plaintiff trial in the city was a major victory for Bayer, it said.

A St Louis court judge granted the defendant's motion in October for a directed verdict at the close of plaintiff, Mark McCostlin's, evidence in Barbara Allegrezza et al vs Monsanto Company. Mr McCostlin was a plaintiff in the lawsuit. The directed verdict came as the **second of thousands** of Roundup lawsuits excluded from Multi District Litigation in St Louis County, Missouri.

As of **October 10 last year**, Monsanto had reached settlements or was close to settling in a substantial number of claims. Of the approximately 165,000 claims, some 113,000 had been settled or were not eligible for various reasons.

By September, the company was on a nine consecutive trial wins run. In the Peters case in Hawaii, which was scheduled for trial in October, the court granted summary judgement in favour of Monsanto, finding that the plaintiff's labelling and failure to warn claims on Roundup and PCBs were pre-empted. That court permitted the plaintiff to appeal, and the trial was indefinitely postponed.

Prop 65 win for glyphosate suppliers

In October, a divided federal appeals court ruled that the state of California **could not require** businesses to warn consumers about the potential dangers of glyphosate. The state lost the appeal to a legal reversal it suffered in 2020. California added the herbicide to its Proposition 65 list of cancer-causing chemicals in 2017, a move that relied on the IARC 2015 declaration.

Bayer considered the win upholding an injunction against the state an "**important ruling**" for ongoing litigations over the product. "Striking down compelled speech for Roundup warnings is also an important ruling for our personal injury litigation, which also focuses on the labels for these products," the company said.

Any potential further appeal by the state would require it to ask the Ninth Circuit to reconsider its ruling or appeal the ruling to the US Supreme Court. Any appeal to the Supreme Court would be discretionary, meaning that the Court does not have to take the case and, in fact, takes a very small percentage of the cases that petition for its review each year, the company cautions.

California officials have not yet responded to the ruling, but the dissenting view from US Circuit Judge Mary Schroeder could provide grounds for appeal.

In December, Bayer won a trial in California. That **reversed** a five-trial losing streak. The verdict was the company's 10th win in its last 15 cases. However, those recent losses saw the company being directed to pay over **$1.5 billion** in cumulative damages to a string of litigants. The company says that it is confident of at least drastically reducing those damages as it managed with its first loss in 2018.

Following the recent run of losses, Bayer shareholder Union Investment reportedly called on the company to engage with plaintiffs to settle more cases.

Bayer's shareholders in **Germany** and **the US** have filed to sue the company for allegedly "misleading them" about the quality of its due diligence prior to the 2018 takeover of Monsanto, and for damages due to the fall in share price thereafter. In the proceedings in the US, District Court for the Northern District of California certified a class action lawsuit in May 2023.

In June, Bayer **agreed to pay** the US state of New York $6.9 million to settle claims for allegedly misleading consumers about the safety of Monsanto's Roundup herbicide. New York Attorney General Letitia James began investigating Roundup claims in 2020 amid concerns that Bayer was violating a 1996 settlement between Monsanto and state officials over making unsubstantiated claims about the safety of the herbicide in advertising. Bayer said that the award neither showed that it admitted nor denied the allegations.

Prices

Bayer reported a 46% plunge in revenues on a currency and portfolio-adjusted basis for its herbicide business in the first half of 2023. It attributed the steep decline largely to lower volume business and prices for its glyphosate-based products. The decline stretched into the third quarter with substantial price falls for its glyphosate-based products.

Prices dropped in the first half to close to the cost of production, barely leaving any margins for producers by June. They rallied briefly in the third quarter but were still half of what they were in much of 2022.

Nufarm/IBI-Ag agree bioinsecticide development deal

03 January 2024

Nufarm has agreed a development deal with Israeli agricultural biotechnology business IBI-Ag (Ness Ziona). The collaboration provides Nufarm exclusive rights to develop and commercialize several bioinsecticide candidates discovered by IBI-Ag.

"This partnership signifies a significant milestone for IBI-Ag, as it not only showcases our remarkable technological advancements but also underlines the strength of our product-market alignment and our comprehensive go-to-market strategy," says IBI-Ag chief executive officer Arnon Heyman.

Nufarm's group executive of portfolio solutions Rico Toft Christensen, echoes the sentiment. "Innovation and technology are the cornerstones of our future, and we focus on partnerships and collaborations to ensure we can access innovative solutions for our customers," he adds.

Farmers Edge/LTIMindtree unveil Indian agtech facility

05 January 2024

Canadian digital agriculture supplier Farmers Edge (Winnipeg, Manitoba) and Indian digital solutions business LTIMindtree (Mumbai) have unveiled an innovation hub in the Indian city of Mumbai. The Farmers Edge Innovation Lab (FEIL) will focus on technologies such as remote sensing and agronomic modeling with an eye on analyzing weather patterns and their impact on crop production, besides delivering insights on soil health, and assisting growers in "optimizing" field processes.

Farmers Edge intends to leverage LTIMindtree's expertise in technologies including generative artificial intelligence (AI), Internet-of-Things (IoT), and drones, adding that FEIL's efforts will be directed towards the development of a "tailored setup" to achieve goals related to sustainability, yield enhancement, and economizing farm operations.

Rovensa Next launched in Turkey

08 January 2024

Portuguese company Rovensa (Lisbon) has launched its biological agricultural products unit, Rovensa Next, in Turkey. The move follows the unit launching various regional and national operations at trade fairs globally in **November** last year. Those included operations in North America, including the US and Mexico, further into South America at a fair in Colombia, in the Middle East and North Africa (MENA) region, and in South Africa.

Marketing and development manager for the MENA region, Hassan El Fakharany, highlights that Rovensa Next biosolutions can be integrated into sustainable agronomic programs in Turkey, offering "crucial support" in mitigating the impacts of climate change.

The launches followed **debuts** over the past year in Brazil, China, France, Italy, **Portugal and Spain**. Rovensa Next was launched as a new unit in February 2023, when it was formed **aggregating** Rovensa group companies.

CNH delists from European bourse

05 January 2024

UK agricultural equipment manufacturer CNH Industrial (Basildon) has completed the voluntary delisting of its shares from the Euronext Milan stock exchange. Post the decision, the company is solely listed on the New York Stock Exchange (NYSE).

CNH planned the move early last year following a "careful review" of relative trading volumes on the two exchanges, as well as the costs and administrative resources required to maintain the listings. It adds that concentrating trading in one market should allow for increased liquidity and investor focus.

The business reports that the majority of its stock trading has "progressively shifted" to the NYSE, indicating that CNH's business profile and investor base fit better with a single US listing. "The single listing on the NYSE is the latest step in our ongoing simplification journey, which accelerated in 2022 as we became an agriculture and construction equipment pureplay," says chief executive officer Scott Wine.

EarthOptics issues operational update

08 January 2024

US soil data measurement and mapping business EarthOptics (Arlington, Virginia) has posted an operational update, highlighting that it has "physically measured" 1 million acres (404,686 ha) of farmland and ranchland. The company claims to have measured and mapped land across four continents and 45 US states since 2021, adding that its pace of measurement stands at 10,000 physical soil samples per day, and the mapping of 100,000 acres (40,468 ha) each month.

EarthOptics points out that it has tallied 300,000 metric tons of sequestered carbon, underlining that it is "significantly advancing" regenerative agriculture practices through its soil data analysis platform, SoilMapper. It explains that the offering leverages ground truth soil samples to train its artificial intelligence (AI)-based system to read soil attributes such as nutrient levels, ground compaction, carbon content, and moisture.

The company **raised** $28 million in Series B funding early last year. In November, the firm forged a multi-year collaboration with Redwood City, California-based US soil analytics business Trace Genomics to offer growers a "research-grade" soil carbon measurement product, dubbed the C-mapper.

Glyphosate prices in China fall further in December

03 January 2024

China's ex-factory prices of the herbicide, glyphosate, fell to a low of about RMB 26,000 ($3,640) per metric ton by mid-December 2023, which is close to the lowest price of RMB 24,000 ($3,360) recorded in June last year. The fall has been attributed to increased stocks with producers amid depressed demand in November. As a result, producers in the provinces of Anhui, Sichuan, and Henan increased their factory maintenance periods in order to shore up prices, which were approaching the cost of production.

After experiencing the highs of 2022, which began with prices at a per metric ton high of RMB 75,000 ($10,500) in January and remained over RMB 60,000 ($8,400) until September, 2023 was a tough one for Chinese glyphosate manufacturers. After starting the year at a high of RMB 45,000 ($6,300) per metric ton in January, prices remained on a downward trend during the first half, hitting rock bottom in June. That was close to the cost of production, barely leaving any margins for producers.

Prices rebounded in July to around RMB 35,000 ($4,900), continuing the upwards trend in August, when they peaked at around RMB 38,000 ($5,320) per metric ton. The brief rally in prices was a result of a phased de-stocking, which occurred due to low production capacity utilization. That, and regained demand from South American markets drove production again, resulting in the consequent fall in prices, which went below RMB 30,000 ($4,200) in November.

In terms of raw material costs, prices of yellow phosphorus and glycine came under downwards pressure because of adequate supply and high inventories. Industry estimates put the production cost of glycine-based routes of manufacturing to be running at about RMB 25,300 ($3,542) per ton.

Exports

During the first 11 months of 2023, exports of non-halogenated organophosphate derivatives – the harmonized system code mainly indicating glyphosate – decreased by 24.7% compared with the same period in 2022.

EU decides not to renew S-metolachlor approval

05 January 2024

The European Commission has decided not to renew the approval of the herbicide, S-metolachlor. EU member states have been directed to withdraw authorizations for crop protection products containing the active ingredient by April 23, 2024. Any grace period granted by member states for use of existing stocks shall expire by July 23, 2024. In May 2023, the Commission **extended** the approval period of the ai to November 15, 2024.

In its assessment, the European Food Safety Authority (EFSA) identified several critical areas of concern involving the use of the ai. It concluded that there was a potential for S-metolachlor and its relevant herbicidally active metabolites to be present in groundwater above the parametric drinking water limit of 0.1 µg/L, based on monitoring data. Furthermore, the Authority found a high potential for groundwater exposure above the parametric drinking water limit of 0.1 µg/L for metabolites that were toxicologically relevant due to concerns or data gaps concerning genotoxicity and/or carcinogenicity.

In **April** 2023, France unilaterally decided to ban the use of the ai. Following that, the country sought to get the Commission to recommend a withdrawal at the EU level as well, "so as to ensure that the rules for the use of products based on S-metolachlor are the same for all EU farmers".

Brazil approves PHC's Teikko seed treatment

03 January 2024

Brazilian authorities have approved US-based, UK-listed bioproducts company Plant Health Care's (PHC – Raleigh, North Carolina) nematicide, Teikko (PHC68949). The product, based on the company's PREtec (plant elicitor response) peptide technology, has been approved as a seed treatment in time for commercial launch for the 2024/25 season. It is for the control of root-lesion nematodes (*Pratylenchus brachyurus*) on soybeans.

Chief executive officer at PHC Jeff Tweedy welcomes the approval. "Unlike Teikko, current soil fumigants and other chemical nematicides are known to have damaging off-target effects," he says. "We are excited about the developing plans to launch Teikko in 2024, with strong growth thereafter."

PHC says that Teikko brings benefits such as three-year shelf-life and no special requirements for storing, allowing flexibility of distribution to the farmers, low rates for easy industrial seed treatment, no interference or incompatibility with other traditional seed treatments, such as fungicides and insecticides, and reliable performance under different environmental conditions, such as drought or humidity.

In May, Brazilian authorities granted **first stage** regulatory approval to PHC68949 and approved the conditions for its use on soybeans. Additional crops and nematode species will be added to the Teikko product label, the company notes.

The company is in discussion with potential distributors for launch of Teikko during 2024.

Uruguay approves Corteva GM soybeans

02 January 2024

Uruguay's government has approved Corteva Agriscience's stacked insect-resistant and herbicide-tolerant DAS81419 soybeans. The national biosafety service through the biosafety cabinet has sanctioned the recommendation of the national biosafety body's risk management commission, the CGR. The commission **recommended approval** of the soybean technology earlier this year.

DAS81419 soybeans contain the Cry1Ac and Cry1F toxins for Lepidoptera control, as well as the pat gene for glufosinate herbicide tolerance.

The biosafety cabinet includes the Ministries of Agriculture, the Environment, Public Health, Energy, the Economy and of Foreign Affairs.

France extends Certiphyto certificate renewal deadline

08 January 2024

The French Ministry of Agriculture and Food Sovereignty has granted an extension for the renewal of Certiphyto certificates. The certification scheme was **launched** by the government in 2010 for consumers of crop protection products as part of Ecophyto 2018, the aim of which was to have reduced pesticide usage in the country by 2018.

The extension has been granted until December 31, 2027 for metropolitan areas. For overseas territories such as Martinique, French Guiana, Réunion, Mayotte, Guadeloupe and Saint-Martin, the extension has been granted until December 31, 2028. Meanwhile, farmers and other professionals renewing their Certiphyto certificates in 2024 and 2025 will be given priority to request strategic advice and provided the additional time, if necessary.

The certificate is required for the purchase and use of crop protection products in France. For its renewal, consumers are required to follow a "strategic advice" with a recognized adviser to build a crop protection strategy, explains the regulator, adding that the advice is required to renew the certificate.

However, the Ministry notes that deployment of counselling services has been slower than expected, making it difficult for some farmers to get appointments. The limited deployment is attributed to insufficient development of the advisory offer for farmers and low anticipation of the obligation, it adds.

As a result, France will be providing a provisional certificate – valid for one year instead of five, as is the case for regular renewals – to those who have not been able to obtain a strategic advice appointment prior to their application for renewal.

The computer systems for applying and processing applications will be updated over the current year to incorporate the new provisions, says the Ministry. Transitional arrangements for the renewal of the certificates are to be published on the regulator's website.

Syngenta launches Spirale fungicide in Ukraine

04 January 2024

Syngenta has launched the fungicide, Spirale (difenoconazole + fenpropidin), in Ukraine for sugar beet producers. The product is for the control of *Cercopsora* spp, *Ramularia* spp, *Phomopsis* spp and powdery mildew (*Erysiphaceae* spp), says the business.

Spirale provides "long-term effectiveness" against strobilurin-resistant races of *Cercopsora* spp, says the company. The two active ingredients inhibit sterol biosynthesis and are not cross resistant, explains Syngenta, adding that both belong to different fungicidal classes and inhibit different enzymes.

Difenoconazole acts slowly and over a long period, while fenpropidin provides "rapid therapeutic activity", says the business. "The combination of difenoconazole and fenpropidin makes it possible to increase the efficiency of penetration and absorption of both ais by the plant," it adds.

Customer Care
CustomerCare@ihsmarkit.com
Asia and the Pacific Rim
Japan: +81 3 6262 1887
Asia Pacific: +604 291 3600
Europe, Middle East, and Africa: +44 (0) 1344 328 300
Americas: +1 800 447 2273

now a part of

S&P Global