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NORTON ROSE FULBRIGHT

Cultivate

Food and agribusiness newsletter

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Cultivate

Cultivate delivers market insight into the global food and agribusiness sector. It is published four times a year by Norton Rose Fulbright and is available online and in print.

Cultivate Published by Norton Rose Fulbright – July 2017 – Issue 13 Editors – Kathy Krug and Shane Bilardi Deputy editor – Cynthia Lareine

Editorial

In this thirteenth edition of *Cultivate*, we focus on the innovative technology that is helping to change the food and agribusiness sector. Like almost every other industry, the food and agribusiness sector is seeing increasing change and disruption driven by new technology and the new businesses that this technological change creates. In this edition, we have a profile on the introduction of cellular agriculture and analysis on how agritech is a necessity for the UK to remain a leader in the industry. Given the importance of technological change to the sector, we will continue to focus on these issues for upcoming editions of *Cultivate*.

We also review three major cases that have turned the European Commission's spotlight on the agricultural sector. These cases are likely to guide the Commission's review of mergers in key parts of the agricultural sector for years to come. Other highlights in this edition include the impact of EU trade agreements on the agricultural sector and the latest news in food safety for a number of jurisdictions.

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Calendar

September

Johannesburg, South Africa, September 7 2017 Urban Agri Summit 2017

October

Kigali, Rwanda, October 4-5 2017 Poultry Africa 2017

Cape Town, South Africa, October 8-11 2017 3rd International Conference on Global Food Security

Chicago, USA, October 11-12 2017 Agri Investor Chicago Forum 2017

Paris, France, October 23-25 2017 19th International Conference on Food Processing & Technology

November

Peterborough, East of England, November 7 2017 AIC's Agribusiness 2018 Conference

Athens, Greece, November 13-14 2017 7th European Food Safety & Standards Conference

Dubai, UAE, November 27-28 2017 8th International Conference on Food Safety, Quality & Policy

Cellular agriculture – an introduction

Sasha Mandy and Érika Bergeron-Drolet

If you could eat a hamburger made entirely from cultured cow tissue, would you do it? Would your answer change if you knew that the burger you were eating did not come from a slaughtered cow, and required much fewer resources to produce compared to a conventional hamburger? A handful of start-ups and a couple of non-profits are betting that you, and many people like you, will still bite into that burger.

The emerging field of cellular agriculture is the latest frontier in agri-technology. According to New Harvest, a non-profit helping to advance research in this area, cellular agriculture is "the production of agricultural products from cell cultures". These agricultural products are not limited to the beef burger mentioned above, or even to beef. There are start-ups currently working on making animal-free milk, egg whites, leather, and most ambitiously, various types of meat. While the companies focusing on meat are forecasting five to ten years before products are available to the average consumer, you may not have to wait as long to access some other products. Perfect Day, a start-up based in San Francisco, is hoping to launch their animal-free milk this year, and Modern Meadow, a Brooklyn-based business, is aiming to roll out leather samples for partners in 2017 as well.

The hotbeds of innovation in this field are found on both coasts of the US, the Netherlands, and in Israel. Significant capital is required for these companies to scale-up to a size that will allow mass production of their "cell ag" products. They have been successful in attracting initial rounds of venture capital. Modern Meadow, for example, raised US\$40 million in 2016 from very seasoned investors including the investment arm of billionaire Li Ka-shing and Singapore's sovereign wealth fund, to scale up their production of leather.

Cellular agriculture should not be confused with another frontier of agritech – plant-based meats. Plant-based meats aim to reproduce the taste and texture of conventional meat. These plant proteins aspire to more than your garden-variety veggie burger. They aim to replicate the experience of eating meat, from the sizzle of a patty on the grill to the smell of it wafting through the air. Beyond Meat, which produces a variety of plant-based meats, has achieved significant success with its Beyond Burger, dubbed the "burger that bleeds" because of the presence of a red beet extract. The plant-based Impossible Burger is also receiving rave reviews, and is being served currently at select restaurants in some US cities.

Plant-based and "clean" meat are therefore products whose time has come, or will shortly. Their presence is signalling a shift in how conventional meat producers, retailers, and customers view their sources of protein. Many in the conventional meat industry are watching for signs that they should consider diversifying their product offerings to shift from being purveyors of slaughtered meat to being purveyors of protein regardless of its origin.

This recognition of future growth opportunities may have been behind some of the recent investments by "Big Meat". Tyson Foods, a major producer of different meats, bought a five per cent stake in Beyond Meat, the makers of the plant-based Beyond Burger. On this side of the border, earlier this year Maple Leaf Foods bought Lightlife Foods, a leading manufacturer and brand of refrigerated plant-based protein foods in the US, for US\$140 million.

Legal issues to watch for

Any new emerging technology should consider the landscape in which it operates, and consider the legal issues raised by the branding, sale, or manufacture of its products.

For companies that are active in this space, or intend to be soon, they should consider two legal issues in particular: intellectual property (IP) rights, and regulatory requirements.

Companies should make sure that the products they sell, or the methods used to make them, do not infringe the IP rights of existing rights holders. These risks can be mitigated with proper clearance searches and opinions to ensure that the manufacture, sale,



or use of these innovative products will not result in a cease-and-desist letter or a lawsuit. Knowing the patent landscape in their industry can help these companies navigate the patent minefield and emerge unscathed.

Companies should also consider how they will differentiate their products from similar products in the marketplace. Branding is key to this effort, and consideration should be given to securing trademarks and domain names that are unique and distinctive of their products. More specifically, companies should avoid using trademarks that incorporate terms that have a defined meaning under food laws and regulations (unless the product actually corresponds to that definition) as the marks could be considered false, misleading or deceptive.

On the regulatory front, different countries offer different, and sometimes conflicting, regulatory regimes. The Good Food Institute, a clean meat non-profit based in the US, is working hard to document the regulatory requirements in different countries. Norton Rose Fulbright is helping them in their efforts, and we invite you to contact us if you seek regulatory approval for your product.

Companies involved in cellular agriculture are likely to bump into a number of regulatory challenges before being able to bring their products to market, as current laws and regulations were obviously not drafted with this industry in mind. For example, in Canada, all applicable definitions of "meat" and "meat products" refer to animal slaughter, which is not contemplated as part of the clean meat production process. Therefore, clean meat producers or retailers may not be able to label their products as "meat" or "meat products". They could technically be said to fall within the definition of "simulated meat products", an expression traditionally used to designate plant-based meat substitutes, which covers food products that do not contain "meat products" but that have the appearance of meat products. However, this characterization is far from ideal from a marketing standpoint and could generate confusion amongst consumers since clean meat contains real animal cells.

Food products derived from cellular agriculture will likely have to be approved by regulatory authorities as "novel foods" in at least some jurisdictions before they can reach consumers. Novel food applications are usually supported by extensive scientific data pertaining to various aspects of the food including nutritional composition, toxicology and allergenicity. In whatever form, the path to market for "cell ag" products is likely to require amendments to current laws and regulations, consultation and collaboration with regulatory authorities and solid scientific data to dissipate any safety concerns.

The legal barriers to market will crystallize as companies start offering their products to the average consumer. We will continue to follow developments in this field to keep you in the loop. As summer approaches, consider throwing a plant-based burger on the BBQ to get a taste of the future.

Sasha Mandy is a lawyer and patent agent and Érika Bergeron-Drolet is an associate in our Montréal office.

Agricultural technology: Can the UK continue to be a leader in the field post Brexit?

Victoria Scopes

It is widely accepted that current farming methods are not sufficient to feed the world's growing population and that investment in new agricultural technologies will be necessary if we are going to find a way to feed the world's estimated nine billion people by 2050.

The UK has been a world leader in the agricultural and agricultural technology sectors: from the agricultural revolution to recent use of DNA marker-assisted breeding to create a new variety of disease-resistant pearl millet, which has improved the lives of millions of people in India. The UK government's, published in 2013, explicitly acknowledged agricultural technology as a distinct sector and that the UK should be at the forefront of revolutionizing food production to address growing populations and dwindling resources, both on a national and global scale. The 2013 strategy paper set out some central factors necessary for an environment in which both public and private entities can confidently invest in research and development: a stable regulatory environment, especially given the long-lead time between initiating research and development and bringing a product to market; and regulation that is not overly burdensome and which does not stifle innovation. Following the uncertainty caused by the Brexit decision, it may be some time before the UK has a stable and certain regulatory environment or the confidence to invest heavily in new technology when farmers face the withdrawal of European Union (EU) subsidies. It has,

however, been suggested that post-Brexit there may be changes intended to support not only the UK's farmers but also the agricultural technology sector; a subsidy system and decreased regulation designed to encourage innovation.

Subsidizing innovation

In a speech to the National Farmers' Union (NFU) in February 2017, Andrea Leadsom (the then Secretary of State for Environment, Food and Rural Affairs) said of Brexit that, "I want to use this opportunity to allow innovation to flourish - not just for the sake of productivity, but also as a means of improving the landscape around us." Development and increased use of technology in farming were key messages in Leadsom's address to the NFU and the suggestion was that post-Brexit agricultural subsidies should be designed to offer a greater reward for innovation. Amending EU agricultural subsidies (the Common Agricultural Policy) to support innovation is something that is being considered at an EU-level, but it may be that the UK is better placed to encourage increased use of technology in the agricultural sector as there are not the same concerns about its

potential impact on employment as in other EU countries. Indeed, one of the key concerns in the UK post-Brexit is conversely whether there will be sufficient numbers of agricultural workers if post-Brexit immigration controls prevent seasonal workers from coming to work in the UK. EU migrants represent 120,000 of 400,000 workers in the UK food-processing industry, and horticultural and fruit farmers rely on about 75,000 seasonal workers from the EU each year. But while Leadsom, in her address to the NFU conference. suggested that new technologies should have a role in replacing traditional labor, the level of technology required to replace low skilled migrant workers with UK high-tech workers is likely to be years in the making.

De-regulation

Much has been said about the opportunity to decrease regulation in a post-Brexit UK and Leadsom in her address to the Oxford Farming Conference in January 2017 said that "as we prepare to leave the EU, I will be looking at scrapping the rules that hold us back and focusing instead on what works best for the UK." The EU's application of the precautionary



principle has been subject to criticism; the precautionary principle places the burden on the inventor or innovator to disprove any risk even, as its critics would say, in circumstances in which there is no scientific consensus around potential harm. To some, this is stifling potential innovation; to others it is a common sense reaction to the unknown effects of new technology. The UK government has confirmed that as part of preparations for Brexit it is reviewing regulations surrounding genetically modified (GM) organisms and it is possible that GM crops could be licenced for commercial growth in the UK post-

Brexit. Genetic modification is not the only area in which the UK has opposed EU regulation and disagreements have ranged from restrictions on the use of certain pesticides such as neonicotinoids and glyphosates to animal cloning for food production. George Eustice (the Minister of State for Agriculture), in a written answer to the Houses of Parliament in October 2016, stated that regulation should be "science-based and proportionate" which may imply a move away from the EU's precautionary principle. However, suggesting that the UK can successfully market controversial technologies such as GM products simply by changing

national regulation is to over-simplify the case. For example, the economics of developing GM seeds on a commercialscale which are not currently marketable in Europe (especially if the GM seeds are developed specifically for Western European climates or to be resistant to geographically-specific diseases) are questionable. Although the restricted licencing of GM crops grown in the EU limits the market for GM seeds (only one type of GM crop is currently grown commercially in the EU), the EU does import GM products. But any export of products to the EU will depend on the trade arrangements reached post-Brexit; arrangements

which may be more difficult where UK regulations are no longer equivalent. However, the UK is a net importer of agri-food goods and the government's White Paper on leaving the EU is optimistic that the UK and the EU have a mutual interest in ensuring continued high levels of market access in the agrifood sector in the future.

If there is to be a broad domestic market for GM products, or indeed other food developed and produced using new and unfamiliar technologies, it is not just regulations but also minds that need to be changed. Leadsom has already been accused of environmental irresponsibility by the Green Party following her statement that the "three crop rule" (the EU regulation requiring certain larger farms to grow at least three crops) should be scrapped after Brexit. Suggestions of commercial production of GM crops or deregulation of certain pesticides will undoubtedly cause a strong adverse reaction amongst a vocal minority; it is less clear how the majority of the UK public would react. Following the Brexit decision, it is notable that GM crop developers Monsanto and Syngenta seem to be stepping up a public relations campaign designed to change minds in favour of GM technology. Monsanto is reportedly preparing to work with UK scientists and Vance Crowe, recently appointed "Director of Millennial Engagement" at Monsanto, has been in the UK giving a series of talks promoting GM crops to the UK public. Syngenta has partnered with the Evening Standard for a series of food debates, including on the role of technology in food production. In a recent interview, Syngenta warned that either consumers will have to accept innovation or face higher prices and supply shortages.

Research funding

The UK government has put significant amounts of public money into agrifood research and development, as has the private sector. The most recently available data (published by the UK government in 2016) is from 2012-3 and shows UK government investment in agri-tech research and development of about £320 million and UK private investment of around £500 million in those years. But UK research and development has also benefitted hugely from EU investment and Horizon 2020 (which replaced FP7 in 2014 and is the biggest ever EU research and innovation programme) has a budget of nearly €80 billion spread over seven years (2014 to 2020), with €4.1 billion for food, agricultural and bio-economy. The UK is a net recipient of EU research funding, ranking second in numbers of participants and funding. Not only are UK entities involved in Horizon 2020 projects which are meant to continue post-Brexit but whether UK entities will be able to participate in any future EU research funding is currently uncertain. Just one example of a Horizon 2020 project with UK involvement and interest is research into the prevention, detection and control of xylella fastidiosa, a bacterium which has caused severe damage to olive crops in Europe. The UK is expected to be hit particularly hard by an olive oil shortage in 2017 (caused largely by poor weather in Spain and xylella fastidiosa in Italy), with the price of olive oil rising by up to a third. Russell IPM Limited (a leading UK manufacturer of innovative biorational products, including insect pheromonebased monitoring and control systems), the Natural Environment Research Council and the University of Salford are all receiving EU funding to

participate in this multidisciplinary research programme. The UK is expected to guarantee funds for research bids made directly to the EU until 2020 (including Horizon 2020), but the future of research funding beyond 2020 is less certain. What is certain is that the UK's continued participation in research projects both within Europe and globally is essential, wherever the funding is obtained.

Looking forward

The UK is experiencing a period of increased regulatory and financial uncertainty for farmers, agri-tech companies and investors alike in the run-up to Brexit. There are no clear and easy answers and it appears likely that wide-reaching change will have to be faced, whether it is to agricultural subsidies, regulation of controversial technologies or the basis and funding of research and scientific collaboration. However, the ultimate reward could be subsidies that reward innovation, a regulatory environment which protects the public and the environment in a manner that is proportionate and science-based, and on-going collaboration both with the EU and globally permitting the UK to continue to play a leading role in addressing world food sufficiency concerns.

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The agricultural sector in the EU merger review spotlight

Jay Modrall

Three recent mega-deals – the merger of Dow and DuPont, ChemChina's acquisition of Syngenta, and the merger of Bayer and Monsanto – as well as a less publicised transaction involving Bunge and Cargill – have turned the European Commission's spotlight on the agricultural sector. Two of the three mega-mergers, Dow/DuPont and ChemChina/Syngenta, were approved with extensive remedies.¹ Part of the remedy, FMC Corporation's purchase of pesticide and agrochemical businesses divested by DuPont, raised significant issues in its own right and will lead to another extensive Commission merger decision, likely later this summer.² By contrast, the Bunge/ Cargill transaction was approved without remedies after a thorough but relatively quick review.³ The third industry megamerger, Bayer/Monsanto, was notified recently⁴ after extended pre-notification discussions.

These cases are likely to guide the Commission's review of mergers in major parts of the agricultural sector for years to come. Although the full decision in Dow/DuPont has not yet been published, and Bayer/Monsanto and FMC/DuPont divestment business are still under review, it is already possible to draw some useful inferences about the Commission's current approach to strategic mergers in the agricultural sector. These cases reflect the Commission's focus on innovation, the possible need for an up-front buyer for divested businesses, and

- 2 See http://ec.europa.eu/competition/elojade/isef/case_ details.cfm?proc_code=2_M_8435.
- 3 See the Commission's decision at http://ec.europa.eu/ competition/mergers/cases/decisions/m8199_596_7.pdf.
- 4 See http://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=2_M_8084.

the treatment of competition between patented and generic products in the agricultural sector.

Background

Agriculture is a large sector comprising many different businesses, ranging from the seed business, to crop protection (e.g. pesticides), to various forms of processing to distribution at multiple levels of the value chain. When examining a merger, the Commission takes a case-by-case approach and tends to define narrow markets based on whether the products in question are interchangeable or substitutable by the consumer in view of the products' characteristics, prices and intended uses. For example, the pesticides sector has been subdivided into herbicides, insecticides and fungicides and subdivided yet again

based on more narrow use cases (e.g. separate markets for cereal herbicides, soybean herbicides and rice herbicides).

The Commission's approach to market definition in a particular case is often critical to its analysis of any substantive issues. Generally speaking, when the Commission defines markets narrowly, fewer products are likely to be considered overlapping, but when products do overlap, the parties are likely to have higher combined market shares, and the Commission is more likely to raise concerns. The Commission also examines the parties' pipelines and the effects of combining broad portfolios of products, in particular where the merging parties offer a wider range of products than their competitors. It is relatively rare for these aspects to become a focus of concern, however, because any anti-competitive effects are likely to be more speculative than the effects of combining existing products. Also rarely, the Commission may be concerned about a transaction's effect on innovation in general.⁵

Where the Commission has serious doubts about the effects of a notified transaction on competition, the parties may try to address these doubts by offering remedies. While the most suitable remedy varies depending on the nature of the concern, the Commission generally prefers a divestiture of all of the overlapping products of one of the parties,

¹ The Commission's press release in the Dow/DuPont case can be found at http://europa.eu/rapid/pressrelease_IP-17-772_en.htm, while the Commission's decision in ChemChina/Syngenta can be found at http:// ec.europa.eu/competition/mergers/cases/decisions/ m7962_4097_3.pdf

⁵ Guidelines on the assessment of horizontal mergers under Council Regulation (EC) No. 139/2004 of 5 May 2004 on the Control of Concentrations Between Undertakings, paras. 20(b) and 38, 2004 0.J. (C 31) 7, 9.

potentially with other assets needed to make the divested business viable. Where divestiture remedies are required, the Commission normally allows merging parties a reasonable period after closing to complete the divestiture. In rare cases, typically where it has doubts about the merging parties' ability to find a suitable buyer, the Commission can require that merging parties not complete their deal until they have entered into a binding sales agreement with an approved purchaser (a socalled "up-front buyer" remedy).

The Commission's approach in the recent agricultural transactions has confirmed its traditional narrow approach to market definition. On the other hand, the Commission has taken innovative approaches to other issues, including innovation competition and remedies. Each of these cases is summarized briefly below.

Dow/DuPont

US-based chemical companies Dow and DuPont notified their proposed merger to the Commission on June 22, 2016. The deal would create the largest integrated crop protection and seeds company in the world and a leading integrated producer of certain petrochemical products (i.e. polyolefins and monomers) used in packaging and adhesive applications.

The Commission found that the merged entity would have held very high market shares for a number of pesticides, with few other competitors remaining. Its concerns related to certain selective herbicides for cereals, oilseed rape, sunflower, rice and pasture, in the case of herbicides; products controlling chewing and sucking insects in fruits and vegetables and some other crops, in the case of insecticides; and rice blast fungicides. The Commission also found that the merger would significantly reduce the number of competitors for certain acid co-polymer products from four to three and strengthen DuPont's dominant position in the ionomer market.

From an upstream market perspective, the Commission was concerned that Dow and DuPont were competing head-to-head in a number of important pesticide innovation areas. The Commission found evidence that the merged entity would have lower incentives and a lower ability to innovate than they would have had separately, and that the merged entity would decrease its investment on developing innovative products. It also found that, after the merger, only three global integrated players would remain to compete with the merged entity in an industry with very high barriers to entry. The Commission's concerns about innovation competition are familiar from its approach to recent mega-mergers in other sectors, such as GE/Alstom and Halliburton/Baker Hughes, but Dow/DuPont is the first agricultural merger to raise such issues.

The Commission approved the merger on March 27, 2017, slightly more than 15 months after the deal was announced. The Commission required the divestiture of most of DuPont's pesticide business, relevant assets in its petrochemical business and almost its entire R&D capabilities. Unusually, the Commission insisted on an up-front buyer remedy. DuPont promptly reported that it is selling its crop protection business and R&D capabilities to FMC Corporation, a US-based chemical manufacturing company,⁶ suggesting that DuPont started negotiating in parallel with the Commission's review. FMC notified its acquisition of pesticide and other agrochemical products from DuPont on June 8. That transaction raised antitrust issues of its own, leading to the submission of commitments on July 6, 2017, reflecting the complexity

6 See http://investors.dupont.com/investor-relations/ investor-news/investor-news-details/2017/DuPont-Announces-Agreement-with-FMC/default.aspx. involved in obtaining antitrust clearances in major strategic mergers.

ChemChina/Syngenta

On September 23, 2016, ChemChina notified to the Commission its proposed acquisition of the Swiss-based global seeds and crop protection company Syngenta. ChemChina is a Chinese state-owned company, active in Europe through its subsidiary Adama Agricultural Solutions, an Israeli company primarily active in the manufacturing and distribution of offpatent formulated crop protection and pest control products and the largest producer of generic crop protection products in the world.

The Commission approved the acquisition on April 5, 2017, about 14 months after ChemChina's offer was announced. The Commission took a typically narrow approach to market definition. The Commission regarded each raw material and active ingredient as a separate market, with broad geographic markets (global or EEA-wide). The Commission divided herbicides between non-selective herbicides and selective herbicides by crop; insecticides based on the relevant crop and application segment and again based on the type of insect targeted; fungicides based on application segment, crop and disease level; and plant growth regulators between insecticides, fungicides and by crop. The Commission defined the geographic markets for these products as national in view of the regulatory barriers.

Following this narrow approach to market definition, the Commission identified 462 markets in which the parties competed and had combined shares over 20 per cent, making them so-called "affected markets" requiring further investigation. The Commission applied two filters to identify markets where concerns were unlikely to arise, one based on market concentration as measured by the Hirschmann-Herfindahl index, and a second where the parties' combined market shares were below 30 per cent and at least three significant alternative competitors were present. The Commission was able to rule out issues in other markets based on individual assessments. It also ruled out concerns in merchant active ingredients, in view of the existence of spare capacity in the market and the presence of alternative suppliers, as well as vertical concerns arising from the combination of upstream and downstream activities from merchant active ingredients to downstream crop protection product markets.

The remaining concerns involved 115 markets covering seven crop categories. The Commission focused on these markets based on the parties' market shares, the closeness of competition between their products, the existence of pipeline products and the lack of generic competition (other than from Adama) in those markets. To address these issues, the parties agreed to divest a significant part of Adama's existing pesticide business, including 29 of its generic pesticides under development, its seed treatment business, its plant growth regulators business, all relevant assets underpinning its pesticide and plant growth regulators businesses and some of Syngenta's pesticides.

Although ChemChina agreed to significant divestitures to win approval, the Commission was relatively flexible in its requirements. The Commission did not require an up-front buyer for the divested business, suggesting that it was more confident a suitable buyer could be found than in it was in Dow/DuPont. The divestiture package consisted of a varied group of assets, contracts and personnel (including a mix of Adama and Syngenta assets), not a stand-alone business. The Commission raised no concerns about innovation competition and did not require divestiture of R&D capabilities. On the other hand, the fact that several of the divested products were pipeline products indicates that the Commission did not limit its scrutiny to overlaps in existing products.

Another noteworthy aspect of the case is the Commission's approach to competition between patented and generic products. The Commission found that Adama is a close competitor of Syngenta in many pesticide markets. The Commission considered Syngenta's branded products and Adama's generic products as part of the same markets. This approach is in line with the Commission's approach in the pharmaceutical sector, where it has held that originator drugs and generic copies belong to the same relevant product markets, as generics can effectively substitute originator drugs after patent expiry.7

Bayer/Monsanto

On September 14, 2016, Bayer and Monsanto announced that they had reached an agreement under which Bayer will acquire Monsanto in a US\$66 billion deal. The transaction was notified to the Commission on June 30, 2017, almost ten months after signing. The transaction reportedly raises overlap issues in a number of markets, including cotton seeds, vegetable seeds, herbicide-tolerant seeds, soybeans and canola, as well as possibly herbicides.⁸

While it is premature to say whether the Commission will raise concerns about the transaction, and if so in which markets, the parties are reportedly already in talks with possible buyers.⁹ This pro-active approach may reflect the parties' concern that the Commission may require an up-front buyer remedy to secure approval, or their hope that addressing key overlap markets early could help them avoid a lengthy "Phase II" investigation.

It is unclear whether the Commission will raise concerns about innovation competition in the Bayer/Monsanto review. The Commission did not list Monsanto as an important innovative pesticide producer in Dow/DuPont, but Monsanto was identified as a considerable and innovative competitor to Syngenta when Syngenta acquired Monsanto's sunflower seed business in 2010. Possibly to head off such a line of inquiry, Bayer and Monsanto have stressed their deep commitment to innovation, noting that the combined entity would have an annual R&D budget of approximately US\$2.5 billion.¹⁰

Bunge/European Oilseed Processing Facilities

Bunge notified its proposed acquisition of two Cargill oilseed processing facilities and dedicated bulk terminal assets on December 23, 2016, and the Commission cleared the transaction without remedies on February 6, 2017. Both parties sell and produce soybean meal, crude soybean oil and bulk refined soybean oil, primarily to animal feed, the food industry and biodiesel customers. The assets involved consisted of oilseed crushing and seed oil refining facilities in the Netherlands and facilities for oilseed crushing and storage in France. Both facilities can handle either soybeans or rapeseed.

The Commission updated its analysis of markets for oilseed products, focusing on soybean meal, crude soybean oil and refined soybean oil. The Commission's market investigation suggested that soybean meal should be

⁷ See e.g. Case COMP/M.6969 – Valeant Pharmaceuticals International/Bausch & Lomb Holdings (5 August 2013), para. 14; Case COMP/M.5778 – Novartis/Alcon (9 August 2010), para. 15.

⁸ See: https://www.ft.com/content/e76f4d8a-23f2-11e6 9d4d-c11776a5124d.
9 See: http://uk.reuters.com/article/us-monsanto-m-a-

⁹ See: http://uk.reuters.com/article/us-monsanto-m-abayer-idUKKBN16G1PB.

¹⁰ See: http://www.press.bayer.com/baynews/baynews. nsf/id/ADSF8F-Bayer-and-Monsanto-to-Create-a-Global-Leader-in-Agriculture.



viewed as a separate product market, rather than part of a broader market for non-grain feed ingredients. Similarly, the Commission's investigation suggested that crude soybean oil might be a separate market, rather than part of a broader market for crude vegetable oils, but the market test results were less clear regarding whether refined soybean oil could be considered part of a broader market for bulk refined seed oil. The Commission's market tests were also inconclusive regarding the definition of geographic markets, which could be local, national, regional or even EEA-wide.

Despite some locally high market shares (in particular for soybean meal in France and crude soybean oil in Portugal), the Commission found that the proposed acquisition did not raise serious competition concerns because of the presence of several alternative competitors, including importers, in the relevant markets. Although this case was much less complex than the three mega-mergers discussed above, and no remedies were required, the decision sheds light on the Commission's approach to market definition in relation to different types of oilseed products and reflects a pragmatic approach to competitive assessment

even in hypothetical markets with high combined shares.

Conclusion

Depending on the timing of the Bayer/ Monsanto review, the Commission seems set to adopt five detailed merger review decisions in the agricultural sector this year. Although the Dow/ DuPont decision has not so far been published and FMC/DuPont divestment business and Bayer/Monsanto are still under review, the Commission's approach to these cases has a number of lessons for agricultural companies considering entering into M&A activity.

First, obtaining EU approval for large, complex mergers requires significant time and planning; approval of the Dow/DuPont and ChemChina/Syngenta transactions each required well over a year. Bayer and Monsanto may be aiming to accelerate the process by negotiating divestitures in parallel with the notification process, but the process still seems likely to require a year or more. By contrast, smaller, narrowly focused transactions like Bunge/European Oilseed Processing Facilities can be approved much more quickly, but even in these cases the Commission's narrow approach to

market definition in the agricultural sector can be expected to trigger close scrutiny of any overlaps.

Second, as in other sectors, the Commission will closely scrutinize the impact of agricultural mergers on innovation competition. Since such effects are speculative by nature, this can be a difficult issue for merging parties to address. Depending on the results of its market investigations, the Commission may require divestiture not only of overlapping products, but also pipeline products and R&D capabilities.

Third, at least in large, complex transactions, the Commission may require divestitures to be negotiated with approved, up-front buyers, not in the normal post-closing process. Whether or not an up-front buyer is required, addressing overlaps that are expected to be problematic early in the process may help expedite approval. However, identifying the relevant businesses and negotiating a divestiture in parallel with the moving target of a Commission review can be challenging.

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Impact of Free Trade Agreements in the EU

Paul Vine

The EU has recently published a detailed review on the "Impacts of EU trade agreements on the agricultural sector." The paper is published, in the Commission's own words, against a background of rising protectionism within the EU and its main trading partners. Together with a detailed review of some of the EU's main free trade agreements (FTAs), the report aims to aid the debate on the pros and cons of trade liberalization.

This article discusses some of the key principles.

The first is that the Commission reiterates its strong pro-trade policy which is underpinned by the following economic reality. That the EU is the single largest exporter of agri-food products, with exports reaching €129 billion in 2015. This export performance has been driven by agricultural policies, technological advances and EU trade policies. In the next decade, the European Commission estimates that 90 per cent of additional food demand will be generated outside of the EU. The Commission therefore expects to continue its support for FTAs.

Against that background, whilst the report considers agri-trade broadly, it focuses on three, specific EU FTAs with Mexico (2000), Switzerland (2002 and 2005) and South Korea (2011). Mexico as one of the earlier, more basic FTAs focusing on tariff and quota reduction. Switzerland as the largest, neighboring trading partner for food and agri products. And South Korea as one of the most ambitious and far-ranging EU FTAs. The second message is that the FTAs have had a strong, positive effect on the EU's economy. The Commission estimates that these three FTAs alone have increased EU agri-food exports by more than €1 billion and supported at least 20,000 jobs in the agri food sector and around 8,000 jobs in related activities. The FTAs impacted mostly in the areas one would expect – tariff concessions; rules of origin; regulatory harmonization; import procedures; and dispute resolution.

However, whilst that overall result is in line with the EU's support for FTAs, the third key point is that there are limits to the effectiveness of FTAs in the broader economic, political and legal context.

Even in the comparatively simple area of tariff reduction, whilst the general picture is that the EU's FTAs have led to significant tariff reductions on a large percentage of product lines, two points stand out

• First, the trade weighted picture (i.e. considering tariff reductions

weighted for volume of imports and exports) is not so clear. In fact, trade-weighted tariffs for EU exports have not reduced line with the tradeweighted tariffs on EU imports. That is, in simple tariff numbers, these do not seem to be favorable FTAs for the EU.

• Secondly, growth in exports under the FTAs (apart from Switzerland) seems in large part to be in product lines that were already successful EU exports, rather than benefitting other product lines or sectors that were liberalized under the FTA.

In this second aspect, the Commission acknowledges that supply side, demand side and market-specific, socalled "bilateral", factors can have as much or more effect than the FTA itself. For example

- Supply how much competitive advantage does the FTA give EU exporters compared with other FTAs? How much knowledge do producers/exporters have about trade agreements? Where is their competitive advantage? Do they have access to efficient distribution channels? Are there high fixed costs to entry?
- Demand can I export a product to suit local consumer tastes? To what extent are consumers happy to substitute local products for imported ones?



• Bilateral factors – factors like language and culture that lead certain countries to trade more naturally with each other.

The report supplements these relatively intuitive observations with fairly rich data and case studies. For example, EU/Mexico agri trade has grown steadily throughout the period of the FTA but, outside of the high end market, French wine exporters, for example, have failed to grow market share. Part of the reason is bilateral factors – the common language and historical and cultural ties with Spain, Chile and Argentina aligns marketing and preferences more closely with Mexican consumers. The other is access to distribution channels. The French exporters are relatively small and fragmented compared with, for example, the large Australian exporters, so have not been able to market and distribute as effectively in Mexico.

The two lessons from the report overall are that first, whilst a lot of political attention and public opinion focuses on FTAs themselves, a large part of the equation lies outside of their terms. Secondly a number of these other factors can be supported by local policy and administration (e.g. education of exporters to improve awareness of FTAs and how best to take advantage of their terms; public support for co-ordinated marketing and distribution overseas).

The last point to note is that the Commission displays a realistic appreciation of the advantages and limitations of FTAs in posing the question: "The central question in this study is: do trade agreements create trade or is the EU just making agreements where trade is growing anyway?"

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New proposed Canadian food safety regulations

Sara Zborovski and Érika Bergeron-Drolet

The long-awaited Safe Food for Canadians Regulations (Regulations) have been pre-published in the Canada Gazette I. The public consultation on the proposed Regulations closed on April 21, 2017.

The proposed Regulations are made under the Safe Food for Canadians Act (the Act), which was adopted back in 2012 with a view to improving the safety of the Canadian food supply through establishing consistent, prevention-focused requirements for food that is imported or prepared for export or interprovincial trade.

The highly anticipated Regulations, which elaborate on the principles in the Act, result from significant consultation with stakeholders that began in 2013. Key objectives of the Regulations include prevention, enhanced market access for Canadian exporters and consolidation of 14 different, overlapping and at times inconsistent, food-based regulations to a single set of outcome-based requirements to improve consistency, enable innovation and flexibility and level the playing field across foods and between importers and Canadian producers.

The proposed Regulations include a number of new, and some not-sonew requirements around licensing, preventive controls, traceability, ministerial exemptions, packaging, labelling, recognition of foreign systems, inspection legends, seizure and detention, organic products and some commodity-specific requirements. The three key food safety elements are the following:

Licences

The Regulations would replace the current commodity-based licence regime by requiring licences based on activity, rather than commodity. Under the proposed Regulations, licences will be required for food importers, companies preparing food for export or for interprovincial trade, and for companies slaughtering food animals from which meat products for export or interprovincial trade may be derived. Licences are proposed to be valid for two years, for a fee of approximately C\$250 and will be subject to suspension in the event of non-compliance.

Traceability requirements

Traceability requires a company to be able to track the movement of food one step back (to the person who provided it) and one step forward (to the person to whom it is provided) throughout the entire supply chain, up to the point of retail sale. The Regulations apply the international standard for traceability established by Codex to anyone importing, exporting and interprovincially trading food, as well as to other persons holding a licence issued under the Act, and to growers and harvesters of fresh fruits or vegetables that are to be exported or traded interprovincially. Industry will be permitted to keep either electronic or paper records, as long as they can

be accessed and provided to Health Canada within 24 hours (or possibly less in the case of an imminent risk to human health). Records will have to be maintained for a minimum two years.

Preventive controls

The Regulations propose that food subject to the Regulations and all regulated activities be conducted in a manner consistent with internationally recognized good agricultural and manufacturing practices, i.e. GAPs, GMPs and HACCP. The proposed Regulations address certain key preventive control elements, including sanitation and pest control, transportation and equipment, storage, hygiene and complaints and recall. Most regulated parties will be required to develop and maintain a written preventive control plan (PCP) that demonstrates how to identify and eliminate (or reduce) hazards and risks related to food products. The PCP should be developed based on HACCP principles and should address the seven key elements of an HACCP plan.

The CFIA is proposing a phased approach for the coming into force of the proposed Regulations to account for different levels of industry-readiness and the concerns of small businesses. Additionally, it has promised support for industry in the form of guidance documents, continued communication and new compliance tools.

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Crop insurance: a gateway to success

Richard Watkins

Periods of drought have the ability to devastate crops. A lack of rainfall can leave subsistence farmers, who are reliant on a successful harvest, in desperate situations. Coupled with the uncertainty which climate change is now making a reality, there is an urgent need to consider how to increase the resilience of subsistence farmers.

A particular type of insurance – index based insurance – has evolved to address the needs of smallholders in regions most at risk from drought.

By offering the ability to protect investments against disaster, farmers may be encouraged to invest more in agricultural inputs and new farming technologies. The availability of insurance may also result in lenders becoming more willing to provide finance to farmers, with the risk of crop failure now further detached from the risk of default.

Index based insurance may pave the way for subsistence farmers, allowing them access to previously unavailable technologies to secure their development and escape the poverty traps which have so far hindered their growth.

Policy overview

Under traditional indemnity insurance, pay-outs are based on a client's loss. With index based insurance, pay-outs occur when an index falls below a predetermined threshold. By using rainfall as this index and setting an appropriate threshold, farmers can take out policies to insulate themselves against the effects of drought.

As the pay-out under index based insurance is determined by an objective

index, the need to verify losses through individual farm visits is eliminated. The requirement for verification of loss has previously limited the feasibility of traditional indemnity insurance.

The objective nature of the pay-out also means the policy is more resilient to moral hazard; with the pay-out no longer dependent on the crop, farmers remain incentivized to ensure its success in otherwise difficult conditions.

As the policy is determined by climate data only, there is no field loss adjustment. In theory, this should result in prompt policy pay-outs, allowing farmers to reinvest the proceeds into establishing next year's crop.

Policy limitations

Prior to implementing a policy, the climate data needs to be analyzed. A lack of reliable weather data in sub-Saharan regions may limit the ability of an insurer to set an appropriate threshold for an index based policy.

The issue of "basis risk" has also been identified as a particular limitation. This is the difference between the loss experienced by a policyholder and the insurance pay-out received. With an index based policy, a policyholder may receive a pay-out even though their crops have been successful. Conversely, and more concerning, it is possible for a policyholder to experience crop failure despite the threshold for pay-out not being exceeded.

Example: Ethiopian insurance

Following pilot studies, the government of Ethiopia introduced index based insurance with the aim of supporting the nation's smallholders. The policy was initially offered to around 200,000 farmers, however, this looks set to increase as awareness spreads.

In October 2015, farmers in four regions of Ethiopia received their first pay-out under the policy, to cover the loss of the previous years' harvest caused by an El Nino event.

Independent recommendations

Weather shocks can trap farmers in poverty, but the risk of these shocks also limits the willingness of farmers to invest in measures that might increase their productivity and improve their economic status. The International Finance Corporation found those insured under the Global Index Insurance Facility generated 16 per cent more in earnings and invested 19 per cent more in their farms when compared to uninsured neighbors.

Studies are showing that index based insurance is having a positive impact. Whilst not designed to protect against every peril, it is able to protect farmers where there is a well-defined environmental hazard.

Richard Watkins is an associate in our London office.

Can agriculture pull Nigeria out of recession?

Lisa Koch

After entering its first recession in 25 years, Nigeria is looking for ways to kick-start its economy in a world of lower oil prices.

The Nigerian economy contracted for the first time in 25 years when its GDP fell by 1.51 per cent in 2016. In a country where oil accounts for more than 95 per cent of exports and foreign exchange earnings, previous economic policies have left the country vulnerable and ill-prepared for the sharp and continuous decline in crude oil prices. Its agriculture sector, which accounted for 23.1 per cent of GDP in 2015, presents an opportunity for Nigeria to diversify its economy and rescue itself from economic recession, but only to the extent it can resolve the industry's current state of inefficiency and underperformance.

Nigeria's agriculture sector is dominated by smallholders and subsistence farmers. Data collected by the World Bank shows that in 2014 37.3 per cent of the country's total area was made up of arable land. Despite these demographics and despite agriculture employing 38 per cent of the working population, the country is unable to meet its domestic food requirements, according to the 2016 Agriculture Promotion Policy (the APP). The APP estimated shortages of approximately four million tonnes of rice, four million tonnes of wheat and 60 million chickens in 2016. Nigeria is the leading consumer and producer of rice in Africa vet it is also the second largest importer of rice in the world behind China. There is a clear opportunity for the country to bolster its domestic agriculture sector to improve growth, diversify the economy and achieve food security.

Fortunately, in the Economic Recovery and Growth Plan published in February 2017, the government made agriculture and food security a top priority and claimed that an expansion in agribusiness will lead to mass employment as a result of large domestic demand, the potential for import substitution and opportunities arising from increasing yields and raw material processing.

One group of people already benefitting from large domestic demand and import substitution is rice farmers in places like Tarasa and Sokoto. According to the National Bureau of Statistics, the prices for locallyproduced rice increased by 60 per cent across the country in 2016, which subsequently improved rice farmers' incomes and standards of living. Local farmers are not the only ones benefitting from the rising demand. In February 2017, Dangote Rice Ltd announced a pilot rice project involving 500 hectares of farmland in Sokoto with plans to expand the project to cover over 25,000 hectares cultivated by nearly 50,000 farmers. Similarly, Wacot Rice Ltd recently invested nearly US\$30 million to build the country's largest rice mill in Argungu, Kebbi State. Despite the government's optimism and increasing private investment, there are strong signals that the country cannot rely on agriculture alone to pull itself out of recession. The buoyant domestic rice market is primarily supported by foreign currency restrictions introduced in 2015 that are artificially increasing the price of imported rice. Even more concerning is Nigeria's infrastructure deficit and insufficient access to inputs. According to the APP, the infrastructure deficit adds an additional 50-100 per cent to the cost of local produce. The Growth Enhancement Scheme, an input subsidy programme introduced in 2012, has been characterized by late or non-delivery of inputs, substandard or counterfeit inputs and the exclusion of rightful beneficiaries.

Nigeria should continue to prioritize the development of its domestic agriculture industry as the demands of a growing population, rising prices and the prospect of increasing efficiencies are likely to attract further domestic and international investment in the industry.

Cultivate would like to thank Paolo Del Val, Trainee, for his contribution to this article.

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Food safety

Formula milk suppliers targeted by Singapore competition authority

Wilson Ang

On May 10, the Competition Commission of Singapore (CCS) published a market study report on formula milk supply to babies, infants and young children in Singapore. The CCS commenced its review of the formula milk market in October 2015 due to the sharp increase of formula milk prices in Singapore in recent years, a trend which had caused much concern amongst parents and couples seeking to start a family. The review was completed in December 2016.

The CCS reviewed the practices of six major formula milk manufacturers in Singapore. While the CCS concluded that the milk manufacturers had not engaged in any anticompetitive practices in the market, it highlighted several issues which had contributed to the sharp price increase of formula milk.

The CCS found that the increase in formula milk retail prices was mainly attributable to the increase in mark-up of wholesale prices over manufacturing costs of formula milk, including on raw materials, packaging and logistics. As local consumers' (parents') top three considerations in purchasing formula milk purchase are the brand name, nutrition and safety, formula milk manufacturers mainly compete on "premiumisation" - i.e. building a premium image for their formula milk products - through marketing activities and introducing new ingredients into the milk.

"Premiumisation" seeks to build up consumer brand loyalty, thereby strengthening consumer perceptions and entrenching their purchasing behavior. This strategy had a clear impact on the consumer market. The CCS found that consumers would generally only compare prices between two or three brands which met their requirements. Furthermore, the CCS noted that, in 2015, approximately 95 per cent of formula milk sales were premium and specialty milk with only around five per cent being standard (i.e. non-premium) milk. This gave major manufacturers the market power to increase the prices of formula milk.

To build a premium brand image, manufacturers invested heavily in marketing, research and development (with an increase of 42 per cent in total marketing expenditures between 2010 and 2014). The heavy cost of investment, coupled with strong consumer brand loyalty and customers' preference of "premium" brands, were factors that were likely to have driven wholesale prices to increase at a faster rate than manufacturing costs of formula milk.

The CCS also noted that formula milk manufacturers prioritize non-price items, including product quality and innovation, over price competition.

As 70 per cent of parents using formula milk in private hospitals do not switch to a different milk brand after leaving the hospital unless there is a medical need, manufacturers invest heavily in marketing activities to hospitals (such as sponsorships, providing funding or support for medical education, product brochures and samples, supplying "ready-to-feed" (RTF) milk, and monetary contributions to private hospitals) so as to gain a "first-mover" advantage by having their formula milk placed on the hospitals' milk rotation systems (whereby hospitals provide a "default" brand of formula milk to parents with no preference for a particular brand).

The CCS also found that many consumers do not have a sufficient understanding of the nutritional content of formula milk as well as the dietary requirements of babies, infants and young children. As such, many consumers wrongly believe that the more expensive or premium products are of higher quality. Some of the formula milk manufacturers therefore import their products from Europe, Australia and New Zealand so as to strengthen their products' premium image. In turn, retailers (including supermarkets and pharmacies) endeavour to stock milk products according to consumers' preferences and milk manufacturers' marketing plans.

These factors posed significant barriers to entry and expansion for the formula milk market, thereby limiting the extent to which (smaller) existing brands and new brands could compete. A new formula milk manufacturer would find it challenging to devote significant resources to marketing and promotional activities to convince consumers of its product's "premium" image within a short period of time. For instance, in 1998, an unbranded milk product from Italy failed to enter into the Singapore market due to consumers' preferences for known and expensive brands which were presumed to be of higher quality and reliability.

The CCS also noted that the presence of parallel imports in the Singapore formula milk market is negligible. This could be due to the strict product labelling and import documentation requirements which parallel importers would have to comply with. As a result, the local supply of formula milk is mainly obtained from authorised distributors and there is a lack of alternative sources of supply. This limits intra-brand price competition in the market. The CCS concluded that the significant barriers to entry and limited price competition provided the major formula milk manufacturers the power to raise prices.

The CCS provided the following three broad recommendations with a view to providing consumers with more choices, lowering entry barriers in the market and increasing competition between formula milk manufacturers

- Assisting consumers to understand the choices of formula milk in the market by educating them on the nutritional content of formula milk, babies', infants' and young children's nutritional requirements, allowing them to counter simple heuristics (such as "more expensive means better quality") and improving their awareness of the availability of different formula milk products at different prices, including milk of standard brands which typically cost less than half of the premium brands' prices and which also meet recognized safety standards and nutrient composition requirements.
- Encouraging intra-brand competition by reviewing parallel importation rules, subject to considerations of food safety and security, and inter-brand competition by encouraging the entry of new private labels into the market.

• Reducing barriers of entry and expansion for new and competing brands by reviewing formula milk manufacturers' sponsorship and milk rotation programmes provided to hospitals.

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Food safety

Latest US Executive Order shows support for agribusiness development and food safety

Cori Goldberg and Krishna Kavi

On April 25, 2017, President Trump issued the Presidential Executive Order on Promoting Agriculture and Rural Prosperity in America.

The Executive Order established the Interagency Task Force on Agriculture and Rural Prosperity that will identify legislative, regulatory, and policy changes to promote in rural American agriculture, such as economic development, job growth, and infrastructure improvement. The Task Force will be chaired by the Secretary of Agriculture.

The Executive Order directs the Task Force to report back to the President in 180 days recommending legislative, regulatory, or policy changes such as those that would

- Remove obstacles to economic prosperity and the quality of life in rural America.
- Progress innovation and technology for agricultural production and

long-standing, sustainable rural development.

- Bolster and expand educational advancement and opportunities for students in these rural communities.
- Strengthen the State, local, and tribal agencies that implement rural economic development and agricultural and environmental programs to better fit these programs to relevant region-based developments.
- Mandate that executive departments and agencies rely on leading science and methods available when reviewing or approving crop protection tools.
- Advance food safety and ensure that regulations and policies implementing Federal food safety laws are grounded in science.

The Executive Order also directs the Task Force to comply with earlier executive orders, such as the Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs, which states that "for every one new regulation issued, at least two prior regulations be identified for elimination." Industry predicts that the Task Force will focus on areas such as biotechnology, including pesticide approvals, and regulation regarding genetically modified organisms. While the details regarding the changes that the Task Force recommends to President Trump are still outstanding, the Health Law Pulse will follow these developments closely.

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