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 **NORTON ROSE FULBRIGHT**

# Cultivate

Food and agribusiness newsletter

Issue 15 | April 2018

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in precision agriculture

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# Cultivate

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

## Cultivate

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## Editorial

Technological innovation continues to play a pivotal role in reshaping all parts of the food and agribusiness value chain – from the land we use for production, to the food processing methods and safety measures. In this issue of *Cultivate* we focus on how these new technologies are permitting us to increase food production in sustainable ways and what some of the emerging legal considerations are, including examining intellectual property protection challenges.

We explore a breakthrough development by a Dutch company permitting production on saline lands previously thought to be too inhospitable to grow food, genomic innovation in livestock breeding in Australia and Canada leading to economic benefits in the billions of dollars and the use of artificial intelligence to detect diseases in crops.

One of the challenges of rapid deployment of technology in agriculture is legislators and the regulators are struggling to keep pace. On the regulatory side, we share a proposal from a Dutch academic for reforms of the EU common agricultural policy, recent guidance relating to the food safety regulations in the United States and lessons learned from the tobacco sector as Canada adopts a new regulatory regime for cannabis.

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## Calendar

### April

New York, USA, April 23–25, 2018  
Global AgInvesting 2018

### May

Toronto, Canada, May 10, 2018  
Agri Tech Venture Forum

### Bangkok, Thailand, May 29–June 02, 2018

World of Food Safety Conference

### June

Melbourne, Australia, June 20, 2018  
4th Annual Agri Investor Australia Forum

### Nairobi, Kenya, June 20–22, 2018

AgriTech Africa 2018

### July

### Rome, Italy, July 16–18, 2018

3rd International Conference  
on Food & Beverage Packaging

# Intellectual property issues – big data, robotics and automation in precision agriculture

By David Wilson

**Agriculture has always embraced new technologies but the pace of change is now rapidly increasing as robots, drones, automation, artificial intelligence and digitization are increasingly taken up in agribusiness.**

Not long ago, it would have been inconceivable that technology would permit the level of automation that is progressively being introduced in agricultural production and the degree of precision agriculture that this affords. Never have farmers had so much powerful information available to inform better decisions about their livelihood and the ability to bring such precise analysis to the business of agriculture.

Technological development is already beyond the initial stage of simply sending up a drone to take some aerial photography and moving toward far more sophisticated collection of data and analysis. Sensors attached to drones or robotic vehicles can be used for crop imagery, pinpointing irrigation leaks, identifying locations of pest infestation, taking soil surveys. Data is sent back to the farmer in real-time, with predictive analysis giving insight, whether in relation to potential crop yield or a problem in the making. This offers a perspective not previously available, possibly allowing access to remote and/or dangerous locations.

After predictive algorithms calculate just where to plant, robotics and autonomous vehicles will automate formerly manual processes – planting or sowing the seed and then later

harvesting the crop. Automated irrigation delivers just the right amount of water in just the right places. Drones can apply pesticides, collect samples, and deliver tools and equipment. Driverless trucks might one day then transport the produce to market.

These technologies are being layered upon one another to create ever-increasing efficiencies and competitive gains. However, it's not only about the bottom line. New technology is making workplaces safer, with devices able to access otherwise inaccessible or dangerous areas, reduce workers' fatigue, and help lower the risk of incidents.

This article discusses intellectual property issues arising in automation and “big data” from an Australian legal perspective, but its themes will be relevant to agribusiness in other jurisdictions too.

## **Can automation be protected by intellectual property?**

All this technology means that more than ever, farmers will now be in contact with intellectual property, whether their own or belonging to others. This is different to older technologies, when purchasing a piece

of equipment did not come with the regular firmware updates. Farmers now need to take on digital devices with more awareness of licensing limitations around permitted uses, and freedom to operate requirements. Can the technology be used without transgressing someone else's intellectual property rights?

Patents protect inventions. Automating a formerly manual process may not however, meet the threshold requirement of being a “manner of manufacture”, or recognized patentable subject matter. In this regard, the Full Federal Court of Australia considered the question of patentability of automated processes in 2015. In *Commissioner of Patents v RPL Central Pty Ltd*<sup>1</sup>, the claimed invention was a computer used to assess the qualifications of applicants for a vocational training course. The Court distinguished between using a computer to merely carry out a scheme or plan in which the computer only acts as an intermediary (not patentable), and applying the use of the computer in a way that improves its functionality or solves a technical problem beyond the computer's normal use (might be patentable). The Court held that:

“Putting a business method or scheme into a computer is not patentable unless there is an invention in the way in which the computer carries out the scheme or method.”

On the other hand, individual components of technology that have

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<sup>1</sup> [2015] FCAFC 177.



specialized functions are more likely to be patentable. The sensor on the drone and what it is capable of monitoring and recording is more likely to be the subject of someone's intellectual property than automation itself. The firmware that drives this equipment is likely the subject of copyright. As with the introduction or development of any new technology, care should be taken to undertake corresponding "freedom to operate" checks to ensure that its use does not encroach upon third parties' rights and any licensing requirements are satisfied.

The increased computerization of devices and systems even raises the prospect of whether owners of goods have the "right to repair" their own property without obtaining intellectual property licenses from manufacturers. This issue has largely emerged as a consumer issue in the automotive sector, but there is a prospect that it will expand to other industries as use of computerized devices expands.

### Who owns the data?

All these devices generate a significant volume of data and information – which is exactly the point. The more information generated, the better, more varied and commercially insightful the predictive analysis.

Who "owns" all this data that will be generated? Is it the owner of the device the operator (if that person is not the owner) or the manufacturer which has programmed the device to collect and store the data?

As the analytics become more and more sophisticated, and the level of predictive analysis more specialized, it is increasingly likely that, compared to a farmer sending up a drone to take some aerial images, third party service providers will be engaged to operate the drone, collect data and provide analytics. This data can be aggregated, creating broader commercial value.

As third parties provide these services, the question of data ownership becomes more commercially important. Service providers want to commercialize their data. Farmers want access to information about their own property.

Therefore, the automation of such information gathering presents great commercial opportunities and potential value. However, there is presently a real risk that output such as images and data does not attract protection under Australian copyright law if there was no human input in its creation. This may affect the ability to protect or to commercialize that data and information.

While copyright protects compilations of data as a form of "literary work" and photographs as "artistic works" under the Australian Copyright Act, copyright does not subsist in "authorless works" that are created without the input of a human "author". This situation may arise where a computerized device is autonomously capturing images or data without human input. This outcome is potentially different in some other common law jurisdictions, for example the United Kingdom,



where the “author” of a computer generated work is the person “who made arrangements for the creation of the work”. (In cases where a human author has some involvement in the creation of the work, assessing whether copyright subsists will be a matter of assessing whether the degree of human involvement is enough to constitute authorship of the work.)

Additionally, a compilation of data or information must have been arranged with at least a basic level of skill and care in the selection and arrangement of the data. Therefore, without some degree of arrangement and selection of the data by a person, the collection of raw data is not likely to be the subject of copyright ownership.

The Copyright Act does not grant copyright ownership merely to the person (or corporation) whose camera was used, or who owned the vehicle with the camera on board. Therefore, works created automatically by a computer (in this case, a drone or robotic sensor) with no human input will not meet the test and will find themselves with no copyright owner.

Another form of copyright recognized by the Copyright Act is a “cinematograph film” (quite an antiquated term when applied to data streaming of visual images), which will subsist only after “the things necessary for the production of the first copy of the film has been undertaken”. This is inconsistent with a continuous live data stream, so therefore, there may not be ownership of copyright in the video being streamed.

Further, although often regarded in a proprietary sense, Australian law does not recognize data or information itself as a form of stand-alone property that can be owned, or bought and sold. Rather, any rights subsist in the ability to protect confidentiality over the

information by enforcing its secrecy, whether by contractual relationships or general obligations that arise in equity. Still applicable to data today, as long ago as 1943<sup>2</sup>, in a case about whether the acquisition of information about aircraft designs was taxable property, the Australian High Court said:

“Knowledge is valuable, but knowledge is neither real nor personal property. A man with a richly stored mind is not for that reason a man of property.”

Each case is to be assessed its own circumstances, but if the person collecting the data guards its security and prevents it reaching the public domain, it may have the necessary quality of confidence to qualify as confidential information. That might shut out farmers from “owning” data about their own properties, if that data has been collected by a third party.

In light of the above, the advent of “big data” has brought some significant challenges to the way intellectual property law conceives and deals with data. With automation, “big data” is less of a purely intellectual property issue about “ownership”, and more of an issue about granting access to data and records held by someone else.

In the consumer world, there have been calls by individuals for rights to access “their own” information, and legislated Data Access Rights are being contemplated or introduced. However, if limited to individual consumers, this still leaves farmers or agribusinesses locked out from access to data about their land, their crops or their produce, where that data is collected and stored by a third party. This can be resolved by contracting with service providers, although if data is in the public domain or not the subject of copyright, there

may not be any legally recognized subject matter to sell.

To the extent that copyright does subsist in any content captured using autonomous technology, consideration needs to be given to ownership of the copyright. As noted above, it is increasingly common for third party service providers to operate drones and other vehicles on behalf of a principal. In such circumstances, unless the service agreement provides otherwise, the default legal position in Australia is that copyright is not owned by the person commissioning the service provider, but rather remains owned by the creator of the work. This is commonly overlooked and misunderstood, and can lead to disputes about who owns – and therefore has the right to control or commercialize – said work.

## Conclusion

Automation technologies and big data bring new challenges under intellectual property law, particularly concerning the ownership of content created by automated processes. However together with bringing precise analysis and control of their crops, and therefore competitive edges and greater efficiencies, agribusinesses will find that there are distinct advantages in also understanding the intellectual property that they use.

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David Wilson is special counsel in our Perth office.

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<sup>2</sup> *Federal Commission of Taxation v United Aircraft Corporation* (1943) 68 CLR 525 at 534, per Latham CJ

# Genomic innovation in livestock breeding – what is your intellectual property strategy?

By Helen Macpherson and Dan Hays

Huge advances are being made in the livestock breeding and production sector as a result of the leaps and bounds being made in the field of genomics. Innovation in the genomics field is enabling stakeholders in the livestock breeding sector to more precisely and quickly breed (and also genetically engineer) animals with desired characteristics in relation to traits such as mature weight, growth rate, carcass quality, calving ease and milk yield and composition. These advances parallel what is happening in the human medical field in areas such as precision medicine.

In the livestock breeding sector, we have seen the sector move from traditional breeding programs using progeny testing to determine the estimated breeding values to genomic selection and gene editing. These advances mean that breeding programs which previously took a number of years to yield results have been transformed by these new technologies resulting in increased and more rapid returns in the livestock sector. For example, Meat & Livestock Australia estimates that its sheep and beef genetics and genomics program has resulted in economic benefits to the value of A\$2.88 billion for the Australian sheep meat industry and A\$2.3 billion for the southern beef industry between 2001/2002 and 2011/2012.

Genomic innovation in the livestock sector is being conducted both separately and collaboratively by private companies engaged in the livestock breeding sector, livestock industry associations, universities, private research institutes

and government agencies. An example of the collaborative approach is Livestock Gentec, based at the University of Alberta, Canada. The stated aim of Livestock Gentec is to bring the commercial benefits of genomics to the Canadian livestock industry. We at Norton Rose Fulbright have a particular interest in Livestock Gentec as one of Livestock Gentec's current research programs is exploring the different applications of genomics in particular in relation to issues such as the management of in-breeding through genomic mate allocation, using a breed of cows, the Hays Converter, the founding herd having been gifted to the University of Alberta by former Canadian Senator and current Norton Rose Fulbright Canada lawyer, Dan Hays.

## Your intellectual property strategy – three key issues

What is abundantly clear is that players in the livestock breeding sector are making significant investments in genomic innovation with the aim of reaping even larger returns from their breeding programs. So, how are stakeholders protecting their investment in genomic innovation? What legal issues do you need to be alive to? Here we focus on how intellectual property (IP) can be and is being used to protect stakeholders' investments and also achieve a return on these investments. We do this by considering the following three inter-related and key issues we believe you need to be alive to when considering how to implement an IP strategy

- What aspects of your breeding program should you seek to cover in your IP strategy?
- What form of IP should be deployed in relation to each component of the breeding program as well as the breeding program as a whole?
- Who will own or hold the IP?

But above all, we urge you to think globally when developing your IP strategy. And, by that we mean to develop an IP strategy that will protect your genomic innovation in all your major markets.

### What aspects of your breeding program should you seek to protect through IP?

A breeding program can be broken down into a number of components. These components include the methods and processes utilized in the program, the genomic material produced or applied in the program and the progeny resulting from the program.

It is important to consider what will be your IP strategy for each of these components, both individually and holistically. Developing an IP strategy for each component as well as the program as whole will ensure that your IP provides you with the maximum protection as well as placing you in the best position possible to monetize and so gain a return on your investment in your breeding program.

The question of what aspects of your breeding program you should seek to cover in your IP strategy cannot be considered in a vacuum. It must be considered in the context of whether, and if so, how, IP can be used to protect each of these components and also be used to generate revenue.

### What form of IP should be deployed in relation to each component of the breeding program as well as the breeding program as a whole?

This leads us to the second question of what form of IP should be deployed in relation to each component of the breeding program as well as the breeding program as a whole. IP comes in a number of different forms, including patents, confidential information and copyright, each with their pros and cons. For example, using a confidential information strategy means you seek to protect your genomic innovation through keeping it “secret”. However, using a confidential information strategy does

not prevent someone else from later and independently developing the same genomic innovation. On the other hand, a patenting strategy gives you a statutory monopoly over your genomic innovation for the patent term. So you can then rely on your patent rights to prevent others using the genomic innovation the subject of your patent.

A foundation consideration here is which forms of IP are available to you, and this may differ from country to country – so think globally. For example, the position on the patentability of biological materials and methods utilizing these materials differs from country to country, so it is vital that you are alive to this issue.

In Australia, the High Court (which is the equivalent of the US Supreme Court) has ruled that genes per se are not patentable in the Australian *Myriad* case ([2015] HCA 35). The *Myriad* litigation played out globally. In Australia, the High Court was asked to consider whether claims directed to the isolated nucleic acid sequences coding for the BRCA1 mutant polypeptide were patentable. The High Court unanimously held that such claims were not patentable. The High Court found that, despite the formulation of the claimed invention as a class of product, in substance the claims were to information embodied in arrangements of nucleotides. The information was not made by human action, it was discerned. An “invention” as recognized by the Australian Patents Act is something which involves “making”. It must be brought about by human action. The requirement in each claim that the sequence in the isolate bear specified mutations or polymorphisms was a characteristic of the human being from whom the nucleic acid was isolated. According to the High Court, it had nothing to do with the person who isolated the nucleic acid bearing the mutant sequence.

The High Court, however, left open the question of whether other types of genomic inventions, such as methods which use or apply genomic material, are patentable. This question has very recently been answered in the livestock breeding context in the Australian Federal Court decision of *Meat & Livestock Australia Limited v Cargill* [2018] FCA 51. Here, the Court held patent claims directed to a specified method of identifying a bovine trait from a nucleic acid sample are patentable.

The Australian position on the patentability of biological materials and methods utilizing these materials is in contrast to the US position on these issues. In the field of human medical diagnostics, US Courts have considered the patentability of biological materials and methods utilizing these materials in a series of cases including *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), *Association for Molecular Pathology v Myriad Genetics, Inc.*, 133 S.Ct. 2107, (2013) and *Ariosa Diagnostics, Inc. v Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). The net outcome of these cases is that in the US both biological materials as well as methods utilising biological materials or biological markers are not patentable.

### Who will own the IP?

As we have already mentioned, genomic innovation in the livestock sector is being conducted both separately and collaboratively by private companies engaged in the livestock breeding sector, livestock industry associations, universities, private research institutes and government agencies.

So, who will own the IP? It is important to get this right from the outset, so that it is clear who owns the IP in





the genomic innovation, and most importantly who has the right to use and financially benefit from the use of that IP.

The recent US case of *North American Deer Registry Inc v DNA Solutions Inc* (No. 4:2017cv00062 – Document 43 (E.D. Tex. 2017)) illustrates clearly the value in genomic innovation and the critical importance of who owns the IP in the information which forms the basis of that genomic innovation, and so has the right to use that information for financial benefit. In this case, the Court noted that “[t]he deer breeding industry is a potentially lucrative industry with single straws of buck semen selling for US\$5,000 to US\$20,000 on average, and ranging all the way up to US\$1 million to purchase the entire buck”.

The case involved the North American Deer Registry (NADR) which had hired DNA Solutions Inc (DNAS) to host its registry. Under the contract

- DNAS processed deer genetic information, performed matching services, and hosted a database for NADR’s information.
- NADR retained ownership of all biological materials, genetic information, genotype analysis data,

membership directory, and any other information provided by NADR.

- DNAS retained ownership of any code it created because of running the registry.
- DNAS agreed to preserve the confidentiality of NADR’s information and to return this information on termination of the contract.

Following termination of the contract, however, DNAS advertised that it had a database of over 230,000 deer genetic profiles and could offer comparisons and lineages for particular types of deer in North America. DNAS argued that it was permitted to use this information as it owned the database. The Court, however, disagreed, finding that the definition of NADR Information in the contract meant that DNAS was not allowed to keep any of the DNA-related information that had been presented to the Court. The Court further found that NADR’s member list, deer genetic information and deer lineages were its trade secrets, and that NADR had taken significant steps to keep its biological materials, genetic information, genotype analysis data and membership directory secret. These steps were “memorialized” in their successive contracts with DNAS.

NADR was therefore able to obtain a preliminary injunction to prevent DNAS misusing the confidential information obtained by DNAS pursuant to their contract with NADR, pending the outcome of a final arbitration between the parties.

## Conclusion

Stakeholders in the livestock breeding sector are using, and should be using, IP to protect and generate revenue from their investment in genomic innovation. This article has considered three issues which need to be at the forefront of your thinking when planning your IP strategy. In doing so, you will be able to maximize the protection afforded by your IP strategy as well as the revenue that can be generated.

*The authors would like to acknowledge the invaluable contribution of Anthony Brzoska, Norton Rose Fulbright Australia clerk, who conducted background research on the science underlying the legal issues discussed in this article.*

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Helen Macpherson is special counsel in our Sydney office and Dan Hays is senior partner in our Calgary office.

# Artificial intelligence and the future of agriculture

By Maya Medeiros

Artificial intelligence (AI) is pushing innovation in new ways and accelerating with advancements in computing power, data and algorithms. AI tools are being used in previously unachievable ways to improve the entire food supply chain. This will become even more important as the world's growing population creates an increasing demand for agricultural production.

## What is AI?

AI is a field of computer science that includes machine learning, natural language/speech processing, expert systems, robotics and machine vision. It enables computers to perform tasks traditionally completed by humans by automating decision making, learning and recognition. In some instances, human subject matter experts provide feedback on results as part of training or testing process and in turn machine learning dynamically updates programming code to improve the algorithms. The methodology used by AI can be represented by various graph and network structures. For example, an artificial neural network or neural net is a system designed to process information by simulating the framework of biological brains to automate tasks.

## How can AI apply to agriculture?

AI tools can augment human capabilities to improve agriculture productivity including crop monitoring, robotics and prediction analytics. In the future, we may eat food that has been planted,

watered, monitored, picked, sorted and delivered without human intervention.

Machine vision can recognize crop diseases and pest damage. For example, an AI tool created for farmers can automatically detect diseases in cassava plants with 98 percent accuracy<sup>1</sup>. The neural network that powers this AI tool runs entirely on a smart-phone, without the need for expensive processing resources, making it more accessible to farmers. The tool was built using an open source machine learning library. An AI technique called transfer learning enables a neural network trained to recognize one type of object to learn to recognize other objects with less training data. In this case, transfer learning enabled the AI tool to learn to detect cassava leaf ailments using a small number of high quality leaf images which is important as high quality leaf images may not be abundant. As globalization accelerates, the spread of pests and pathogens making it increasingly important to

have tools that can quickly detect disease to contain the problem.

Traditional fruit picking requires precision typically only capable by human hands and eyes which is why most fruit today is hand-picked. This is changing. A robotics company has developed an automated apple picker, to identify an apple, tell if it is ripe and then use a vacuum system to pick the apple without damage. This requires sensors and cameras to collect data to provide automated decision-making in real time to actuate robotic components. Systems are also being developed for other fruit such as oranges and strawberries.

Self-driving vehicles are not limited to streets. There are already self-driving tractors that can automatically navigate a farm on private land without the need for equipment makers to consider complex traffic and regulatory rules. A human driver can teach the farm layout to the tractor system and then take their hands off the steering wheel. There are also self-driving lawn mowers and automated weed whackers. The self-driving vehicles have data collection devices to capture navigation routes along with sensor data relating to internal components and the external environment.

Farming drones collect images and other statistics which an AI tool combines with imagery data, weather, soil, and expert plant pathology to deliver a visual farm dashboard with analytic overlays. Data from different systems can be uploaded to servers

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<sup>1</sup> Using Transfer Learning for Image-Based Cassava Disease Detection, Amanda Ramcharan, Kelsea Baranowski, Peter McCloskey, Babuali Ahmed, James Legg, David Hughes, *Frontiers in Plant Science* 2017 vol. 8 p. 1852.

for fleet management and precision agriculture services.

AI tools can generate farming forecasts and drive operational decision making. For example, an AI product accurately predicted corn and soybean yields by processing satellite and plant images using a combination of machine learning, meteorological and reported agriculture data. Initial testing of the system was done against years of historical data. The “real world” prediction data shows the estimates shifting over time which highlights the importance of constantly collecting new data and refining the algorithms.

## What are some legal considerations?

### Intellectual property

Developers of a new AI agriculture tool should consider the following

- An intellectual property (IP) strategy that layers IP rights to protect different aspects of the innovation.
- Contributors to the technology should be identified and tracked.
- Ownership and confidentiality should clearly be set out in a written agreement.
- Companies should have policies for developers incorporating third-party IP, even if inadvertently, as it may impact ownership of the technology and freedom to operate.
- Employees or a contracted developer, for example, may incorporate third-party source code without authorization, which may impact ownership and could create inadvertent liability of infringement of other’s IP rights.

- Contractual terms with end users and third parties should clearly specify permitted use and ownership for collected data.

Copyright is an important IP asset for AI as it protects any new original works which can cover computer program code, application programming interfaces, compilations of data and graphics. This protects the technology product (code) from unauthorized use and reproduction. Digital locks on products and services can protect the code and data. Circumvention of digital locks is an offence in some jurisdictions.

AI systems can also generate new works protectable by copyright, such as creating new artwork or music. However, most copyright statutes do not yet clearly define who owns machine-generated works. It is currently a point of contention in respect of some such works whether the work is generated by a machine, and or the role played by the humans in creation of the work. To this end, agreements should attempt to clarify ownership when possible. Further, an AI system may act or operate autonomously in a manner that infringes third-party IP rights. If existing laws do not extend liability to a machine, then a related stakeholder (such as the owner, developer, operator or another supply chain participant) may be responsible.

A trade mark may consist of a combination of letters, words, sounds or designs that distinguishes one company’s goods or services from those of others in the marketplace. A strong brand helps companies differentiate AI products and services from competitors and establish a strong reputation in the market. Algorithmic accuracy can help a company develop goodwill for its brand. AI companies are often stewards of important data assets and documentation should consider

these as valuable assets and document and register marks when possible. A reputable brand may be of paramount importance to customers.

An AI tool can be a “black box” device embedded within a finished product offered by a third party. This can make it difficult for the end customer to recognize the brand of the company supplying the “black box”. A co-branding agreement can provide for use of the mark associated with the “black box” on the finished product offered by the third party. This can help the “black box” provider become recognizable by the end consumer.

Patents provide an exclusive right to make, use and sell his or her invention, which may help companies, obtain or maintain market share, and protect research and development investments. In contrast with trade secrets, granted patents may be enforced against third parties that make, use or sell the claimed invention, despite independent development. Patents may also be used defensively as a negotiation tool and patent publications can be cited against subsequently filed applications to prevent grant which can protect freedom to operate.

AI involves software which is increasingly difficult to patent and there is no clear delineation of what is patentable and what is not patentable. Highlighting salient technical features such as technical advantages and practical implementation details can increase the likelihood of success during patent examination. The description should highlight physical form factors and discernible effects generated by the AI innovation, such as moving a physical machine to pick up an object. Given the quickly evolving AI market, obtaining early priority dates is important in view of the “first to file” nature of the patent system.

A company making, using or selling AI tools should also consider its freedom to operate to avoid encroaching on existing IP. A landscape assessment and competitor monitoring are helpful to mitigate risk. In the AI context, the legislative protection has not yet advanced as quickly as the technology, which makes early and ongoing IP portfolio management of particular importance. A company may then better control the use of its IP rights, including permitted use under licensing and collaborative arrangements.

### Privacy and data protection

AI tools can collect a large amount of data about farm operations for direct delivery to a server managed by the equipment maker. A farmer might not even have access to their own data due to technology protection measures by the equipment maker. Although agricultural information alone might not be considered to be personal data, a large amount of it in combination with different data sources might make it possible to identify an individual and breach data privacy laws. Privacy laws vary from country to country making it complex for both the equipment maker and farmer to navigate.

New data privacy laws, such as the EU General Data Protection Regulation (GDPR), are beginning to deal with AI explicitly. Under such privacy laws, key issues include whether all personal

information used by an AI system has been collected with the data subject's valid consent and such consent covers all purposes for which the AI uses the information.

AI tools are susceptible to hacking which can create both economic loss and physical damage. As a result of such incidents, businesses will need to ensure that all appropriate steps are implemented to guard against such risks and mitigate any breaches, in accordance with applicable legal requirements and industry practices.

### Supply chain liability

A self-driving tractor might crash into a neighboring farm, damaging property and injuring people. Who might potentially be liable for the harm caused? The current legal system would not confer separate legal personality on AI tools. Different AI supply chain participants might potentially be attributed with liability. Example participants include: the commissioner of the AI system or the person paying for its design; the designer of the system; the person who prepared the technical and functional specifications; the programmer; the licensor or distributor; the integrator or installer; the trainer or tester; the owner of the system; and the operator of the system.

Contractually, those in the supply chain may need to address more complex liability allocations than would be the case in a traditional supply arrangement. The autonomous nature of AI has the potential to shift that liability up the supply chain. The dynamic nature of AI makes it difficult to foresee how the software could evolve which may create unintended consequences.

### Conclusion

Autonomous farm machines and sensors will continue to crop up on farms and agriculture data will continue to grow in quantity and scope, making farming processes increasingly data-driven and data-enabled using AI tools. Responsible development and deployment of AI tools requires careful navigation of the complex legal risks. This is particularly complex given the autonomous nature of the tools, the changing nature of the AI system by machine learning and novel uses cases. Businesses should create a defensible process for the use of AI and consult with experts.

Please visit our site [www.aitech.law](http://www.aitech.law) for a detailed review of the legal and ethical implications of AI.

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Maya Medeiros is a partner in our Vancouver office.



# A proposal to reform EU common agriculture policy

By Paul Vine

An interview with Kai Purnhagen, lawyer and associate professor at Wageningen University, the Netherlands.

The EU common agricultural policy (CAP) is a system of subsidies paid to EU farmers. Its main purposes are to guarantee minimum levels of production so that Europeans have enough food to eat and to ensure a fair standard of living for those dependent on agriculture. In his interview, Paul Vine, a partner in the Norton Rose Fulbright Amsterdam office talks to Kai Purnhagen about his proposal for the wholesale reform of the EU CAP and a blue print for adopting the principles-based approach to CAP.

## Last year you published an interesting proposal for the wholesale reform of the EU Common Agricultural Policy (CAP). Can you tell us more?

Yes, it was called “Principles-based regulation – blueprint for a ‘New Approach’ for the internal agricultural market”.

In short, Perter Feindt, Professor of Strategic Communication, and I argue that the current CAP system suffers from complexity, inefficiency and ineffectiveness; that the normal discussions that attempt to address regulation, bureaucracy and divergence of national interests are not sufficient in themselves to materially improve the system; but that switching CAP to

a principles-based system may provide the answer.

## It is easy to criticize CAP but surely complexity and some inefficiencies are to be expected in a policy area responsible for 40 percent of the EU’s budget?

Of course such a large undertaking will involve a certain amount of complexity.

However, you must remember that CAP’s scope has grown significantly from its original post-war goal of ensuring food security for Europe.

Now CAP sits within an complex and overlapping policy and legal framework which includes “cross-compliance” (i.e. specific legal requirements to comply with environmental, public and animal health standards and – since the 2013 Ciolos reform – further “greening” standards); general EU law principles (e.g. to provide a high level of environmental and consumer protection under Art 37/38 of the Charter of Fundamental Rights and Art 114(3) of the TFEU); and, through the effect of trade and other market mechanisms, the requirements of comparable systems globally.

The resulting complexity, high administrative costs and the general orientation “more towards compliance than performance” has been criticized by the EU’s own auditors, the European Court of Auditors.

## You see a potential solution by analogy with the development of EU product safety legislation. Can you explain?

Yes, for more than 30 years, EU product safety legislation was structured as classical regulation – certain products and industries had specific prescriptions. For many products, mandatory, detailed and European-wide guidelines were introduced that covered the whole lifecycle.

But these standards almost by definition could never be truly comprehensive, were too static and did not take into account the different requirements of consumers and entrepreneurs in various member states. Overall, they grew into an almost unmanageable entanglement of rules.

Then in 1973, the Low Voltage Directive introduced the so-called “new approach”. Its design was unique and highly controversial at the time. It prescribed only the general and abstract goal of achieving “consumer safety” but left the concrete details and implementation to private standards organizations.

<sup>1</sup> IEA, Renewables 2017.

<sup>2</sup> HM Government, The Clean Growth Strategy.



Legally only the goal of consumer safety was binding. Producers could choose to comply with the standards organizations or, provided that they could still ensure consumer safety, develop their own.

Today, we call this principles-based regulation.

### **So how could product safety principles transfer to CAP?**

If you see CAP primarily as a policy which is concerned with agricultural products and production, then a reform of CAP parallels the “new approach” to create a European framework for high quality farm products.

### **Your paper includes a blue print for adopting the principles-based approach to CAP. Can you summarize that?**

Our proposal has three parts – a legally binding framework regulation, minimum legal requirements plus voluntary modular add-on standards, and a possible link to agricultural payments.

The starting point would be an EU regulation which would govern the general principles applicable to any activity as a farmer in the EU. Farmers would have to comply with

the principles or otherwise lose their market concession. The framework would also set out the institutional framework for monitoring compliance.

The second part would lay down the minimum legal rules that must be followed. These would be abstract, minimum objectives analogous to “achieve consumer safety” in a product safety context.

Sitting alongside the legal rules would be two groups of voluntary, modular standards made available to all farms. The first group of voluntary standards would help farms achieve the minimum legal requirements – compliance with voluntary standards would create the presumption that legal standards were also met. This is key, as the burden of proof is then with the claimant (e.g. the regulatory authority or consumer). The second set of standards, also voluntary, would cover farms that wished to go beyond the minimum – for example, develop organic farming, nature conservation, or animal welfare – and would allow them to use the corresponding quality labelling.

In all cases, farmers could develop their own methods to satisfy the minimum legal rules. However, in any dispute (e.g. product safety issues or environmental claims), the burden of proof will be on the farmer to show that they satisfied the legal rules.

The third limb of our proposal links farm payments to the standards above. With minimum standards, CAP would pay farmers additional costs for meeting CAP/EU requirements above world market standards. In respect of the second, higher quality standards, the basic mechanism could be similar to the current arrangements for organic farming, where certified farms that meet legal requirements receive specific premia.

### **Will take up of these ideas in CAP by the EU be likely?**

At EU level CAP reform discussion currently take place in different circles. Peter’s and my approach belongs to the circle discussed mainly in the ZaNexus project, funded by and discussed at the German government level. Our ideas were well-received in Germany. Currently we are working on a follow-up project where we refine these ideas and work on more concrete implementation solutions. Whether our ideas will also reach policy level in the EU, we do not know. We are, of course, lobbying for our ideas through our channels and hope that the German government will implement them at an EU level.

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Paul Vine is a partner in our Amsterdam office.

# Regenerative agriculture

## How this innovative approach to farm land management can drive long-term economic and ecological benefits.

By John Moutsopoulos

An interview with Tony Lovell, CEO & Founder, SLM Partners

SLM Partners is a professional agricultural asset management business with offices in London, New York and Australia. SLM Partners acquires and manages rural assets (including farm, forestry land and operating assets) on behalf of global institutional investors. In his interview, John Moutsopoulos, a partner in the Norton Rose Fulbright Sydney office talks to Tony Lovell about the science and innovation needed to produce long-term capital and sustainable benefits.

### To start with the basics, for those who have not heard about you before, what does SLM Partners do in the agribusiness sector?

SLM Partners is an asset management business that acquires and manages rural land on behalf of institutional investors. Our mission is to use investment capital to scale up regenerative and ecological farming and forestry systems that deliver both financial returns and environmental benefits.

Our first fund, the SLM Australia Livestock Fund, was established in 2012. We have acquired more than one million acres of land in southern Queensland and northern New South Wales for grass-fed cattle production. Our second fund, the SLM Silva Fund, invests in sustainable forestry in Ireland, with the European Investment Bank as anchor investor. We are also developing a new investment strategy for organic farming in the USA.

### How long have you been involved with SLM Partners?

I have been involved from the very beginning. I am one of the founders of SLM which began its life in 2009 in Australia. There was not anything like SLM in the agribusiness space, so we built it from scratch.

SLM Partners brings together investment professionals and experts in sustainable land management under one roof. One of the other co-founders, Paul McMahon, worked as an investment manager at Climate Change Capital in London and before that as a management consultant at McKinsey & Company. He has also done advisory work with the Prince of Wales's charities and the UN Food & Agriculture Organisation on sustainable agriculture and published a book on the global food system.

### What drives your commitment to agribusiness?

My great grandparents were some of the first settlers in the Tara district of Queensland which is located 300km West of Brisbane and known for its wheat, beef and wool commodities, so agriculture is in my blood. I have a passion for good farming, grazing in particular. It is my belief that you can make good money from doing the right thing and our goal is a simple one – to profitably leave our land in better condition every year.

Institutional investors bring a few key things to this – capital and patience being the main ones. Making changes on the land costs money and can take time. Those investors who understand just what agriculture actually is, and who are prepared to build a portfolio based on that understanding, will reap the rewards over time.

### So what is the SLM Partners investment mandate and are there any other investment managers with a similar mandate?

We invest in land management systems that deliver market-rate financial returns for institutional investors, while also building healthy soils, enhancing biodiversity and having a positive impact on climate change. Investors gain exposure to a real asset – farmland or forestland – that is uncorrelated with major asset classes and provides a natural inflation hedge. They can also benefit from income derived from the production of food or other natural commodities.

We have seen increasing interest among institutional investors in farmland and timberland over the last decade but most investment managers focus on conventional agriculture and forestry. SLM Partners is distinctive in its strong ecological focus, its global reach and its involvement in day-to-day land management and is one of a handful of ecological focused farm managers.

## What about impact investors. Is your mandate relevant to them?

Every investment makes an impact – positive or negative. Any institutional investor with an environmental, social and governance (ESG) mandate must give serious thought to investing in ecological farming. There need not be a choice between good returns or doing the right thing. Ecological farming produces measurable and positive environmental impacts together with solid and truly sustainable financial returns. Investing in ecological farming is investing in rebuilding a nation's soils – which must surely meet any ESG mandate.

## What is regenerative, ecological farming and how is it different to conventional farming?

Regenerative, ecological farming focuses on building healthy soil and harnessing the biological processes that sustain life. It minimizes reliance on inputs, especially those linked to fossil fuels, such as synthetic fertilisers and pesticides. It generates measurable ecological and climate change benefits, especially by storing carbon, while increasing resilience to climate extremes. In contrast, conventional farming often degrades soils and relies on chemistry to sustain yields. Intensive, conventional farming systems are unsustainable as they tend to pollute water, destroy biodiversity and produce large amounts of greenhouse gases.

SLM Partners' belief is that regenerative, ecological farming can deliver superior risk-adjusted economic returns for investors by delivering higher yields, lowering operating costs and/or opening up higher value markets (such as organic or grass-fed). They are, however, usually more knowledge intensive and require a high level of farming skill.

For example, in Australia we are regenerating extensive pastoral land by introducing a form of cattle management known as holistic planned grazing. This involves dividing land up into smaller paddocks, grouping animals in larger herds, and moving animals regularly according to a plan.

## So is regenerative, ecological farming a recent innovation?

We have seen a number of revolutions in agriculture over the past 200 years. First was the mechanical revolution, allowing farmers to manage larger areas. Then came the chemical revolution, when pesticides, synthetic fertilisers and new seeds delivered higher yields. However, this was often at the expense of soil degradation and other environmental damage and the profits did not always go to the farmers, but rather to the companies manufacturing the seeds and agro-chemicals.

Now we are on the brink of a biological and ecological revolution, as we harness our new understanding of natural processes to design a food system fit for the twenty-first century. The cutting edge science in agriculture today is not in chemistry but in biology. We are only beginning to understand soil microbiology, species interactions and ecosystem functioning.

For example, glomalin, a glycoprotein that plays a crucial role in binding soil particles together and creating soil fertility, was only discovered for the first time by an American scientist in 1996. Thanks to DNA sequencing, scientists have recently discovered the diversity of bacteria, viruses and fungi that live in and around plant roots in the soil. Studies show that one gram of healthy soil can contain up to one billion bacterial cells and 100,000 fungi. The important role of these microbes in agricultural production is now being understood and acted on.

## Can you tell us a bit more about the reasons why ecological farming can produce sustainable superior returns?

Firstly, ecological farming can produce higher yields per unit of external and artificial inputs. These external and artificial inputs are usually expensive, intrusive, addictive, and often harmful. Too often, we see higher prices for agricultural commodities being quickly absorbed by rapidly rising input costs. By minimising the use of these inputs, we can significantly lower operating costs.

Secondly, ecological farming builds natural capital, the true foundation of any investment in agriculture. Industrial agriculture is somewhat like a mining operation, extracting in a few short years the fertility that nature has taken millennia to build. Fortunately, once we start to work with nature we can rebuild the health, fertility and productivity of our land asset.

Lastly, ecological farming rebuilds soil health and brings resilience back into the ecosystem. Farming means dealing with the vagaries of the weather, and a strong, living, fertile soil within a healthy diverse ecosystem is a resilient system. Over time, this resilience will allow for more consistent and predictable production of both crops and livestock.

By farming ecologically, we can access the growing markets for chemical free, organic, nutrient dense food and fibre that is produced in a genuinely sustainable and positive way. Combine the upside benefits of this higher price potential with the downside protection of low inputs and resilience, ecological farming can produce higher margins per unit of production. High prices alone do not guarantee high returns to investors; strong margins are the best indicator of good long-term returns.

Farming ecologically also means that we are able to access the new and developing markets for ecosystem services, such as carbon offsets. These ecosystem services are produced as a natural “by-product” of our management, and so represent strong upside built on the foundation of a profitable farming operation.

### **What do you see as the most significant hurdle to the widespread adoption of regenerative farming practices in Australia and overseas?**

There can be a need for investment in new systems, and in some cases there may be a lag of a few years before the full benefits appear in the form of dollars. This can be challenging for farmers who are living from month to month – but it is also why patient investment capital can play a role. However, perhaps the biggest barrier is mindset, as regenerative farming can fly in the face of well-established practices. Change happens slowly in agriculture.

### **What are your views on how countries can prepare for long-term food security?**

There is plenty of food in the world, but it is not always of high quality, leading to poor diets and illness or affordable to the poorest members of society. It is also often produced in an unsustainable way. Our view is that we need to shift towards farming systems that deliver nutritious, healthy food, while preserving natural capital. In the long-term, agriculture can play an important role in combating climate change by acting as a carbon sink. Farmers will increasingly be rewarded not only for the food they produce but for the carbon they store in and on the ground.

We are starting to see this in Australia with the Government’s Emissions Reduction Fund, which is having a significant impact on land management in certain regions. We are participants in this scheme via our Australian cattle fund and will be supplying more than two million tonnes of verified carbon credits because of our land management approach.

### **What else can we learn from the Australian agribusiness sector?**

We are faced with a growing world population, many of whom are also benefiting from growing real incomes. Much of this growth is happening almost on Australia’s doorstep, in the countries to the north of us. As incomes increase, one of the first lifestyle changes they make is to improve their diet. They look for better quality food, and increase their consumption of protein. This protein comes usually from meat and dairy and Australia is well positioned to supply their needs. However, with any rapidly growing market we often see the entry of unscrupulous operators. The spate of food scandals in some Asian markets is testament to this. Australia’s well-deserved reputation as a clean, green supplier means we are well placed to be the go-to source of high quality and safe food and fibre for the burgeoning Asian middle classes. Producing this food and fibre using ecological farming strengthens our position.

In many parts of the world, land and water resources are under severe pressure. Soil erosion and degradation, dead zones in the Gulf of Mexico, encroachment from urban development onto some of the most productive land, all these mean that we have less land each year to grow our food and fibre on. At a time when we need to not only maintain levels of production, but increase them. These forces all bode well for the value of Australian rural

land, with solid steady increases likely over the next decades.

### **You clearly have a strong interest in the science behind agriculture and how this drives sustainable practices. There has been promising research and technology development in the sector. What do you think are some of the key changes the agribusiness sector will see in the next three years?”**

I think the most exciting recent developments are a return to basics. Agriculture is based on biology, and we are refreshing and renewing our connection with and understanding of how nature functions.

The work on glomalin and mycorrhizal fungi in soils, advances in composting techniques and the extraction and application of biologically enhanced “fertilisers”, the growing acceptance of the massive benefits of good grazing management on soil health, water retention, and carbon stocks, are just a few of these.

The growing awareness by consumers of the importance of food quality to our health is leading to a growing demand for nutrient dense food, produced in ways that heal rather than hurt. The importance of our gut micro-biome to human health, plus the impact food plays on this, will only drive this demand ever more strongly over the next decade.

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John Moutsopoulos is a partner in our Sydney office.

# Cannabis: learnings from the Tobacco Act

By Gregory B. Bordan, Arad Mojtahedi, and Sara Zborovski

**The Canadian government is getting set to legalize recreational cannabis through the introduction of the proposed Cannabis Act later this year.**

In anticipation of legalization, industry players are starting to make plans for advertising. Not surprisingly given that one key objective of the Cannabis Act is to protect Canadians from enticements to use cannabis, the Cannabis Act contains prohibitions on promoting cannabis. Many of these mirror prohibitions are found in the federal Tobacco Act.

## What's prohibited

At a high level, the proposed Cannabis Act adopts the same approach to restricting promotion as the Tobacco Act, banning *all* promotion of cannabis and cannabis accessories except as specifically authorized. This means that all promotion is prohibited unless it falls within a category which is specifically authorized in the Cannabis Act.

Both statutes include essentially the same broad definition of “promotion” and both contain similar authorizations.

For greater certainty, both statutes also set out, non-exhaustively, specific types of promotion that are prohibited. For example, both statutes prohibit testimonials or depicting any person, character or animal, real or fictional, in advertising.

Both Acts also prohibit promotion that could be appealing to young persons and what the Tobacco Act calls “lifestyle advertising,” meaning presenting a product or its brand elements “in a manner that associates it or its brand element with, or evokes a positive or negative emotion about or image of, a way of life such as one that includes glamour, recreation, excitement, vitality, risk or daring.”

These provisions have been interpreted in the context of the Tobacco Act, most notably by the Supreme Court of Canada in a 2007 judgment.

The Supreme Court of Canada read down the prohibition against advertising that is “appealing to young persons,” construing it as applying only to advertising that “could be particularly attractive and of interest to young persons, as distinguished from the general population” (emphasis added). Therefore, an advertisement is not prohibited merely because it is of general interest, appealing to young people just as it appeals to older people. The prohibition targets advertising that is particularly attractive to, i.e. intended to be appealing to, young persons as opposed to the general population.

With regard to lifestyle advertising, the Supreme Court attempted to strike a balance between the prohibited advertising and “true information and brand-preference advertising,” which is permitted. The court considered that the prohibition is intended to prevent the use of emotions and images that may induce people to start to use or increase their use of tobacco. According to the Supreme Court, “even advertising that does not appear on its face to connect a lifestyle with a tobacco product is prohibited if it subliminally connects a tobacco product with a lifestyle.”

## What's permitted

In terms of what's allowed, the Cannabis Act, like the Tobacco Act, authorizes only very limited promotion. The most significant authorization is for “informational promotion” and “brand-preference promotion,” both narrowly defined in the Cannabis Act. However, even such promotion is allowed only in communications addressed and sent to adults identified by name, or in places where young persons are not permitted by law, or when communicated by means of a telecommunication where reasonable means have been taken to ensure it cannot be accessed by young persons. These rules may be further refined by future regulations.





The rules on promotion are complex and open to significant interpretation. We expect the innovative cannabis producers will likely test the boundaries on what is authorized promotion under the Cannabis Act and that Health Canada, and eventually our courts, will have to grapple with interpreting and applying these prohibitions. Although it is reasonable to assume the interpretations of the Tobacco Act will also apply to the Cannabis Act given the strong similarity between the two, the

products present different risks and have different social histories. It will be interesting to see whether this leads to a divergence in the approach to interpreting and applying them. In the interim, while the industry and public wait for Health Canada and eventually the courts to provide guidance on what is allowed and what is not, it will not be surprising if we find some producers aggressively promoting their products in the hope of establishing effective brand awareness and public profiles before the regulator steps in.

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# Saline lands – Salt Farm Texel

By Saskia Blokland

## Interview with Adriaan Verbeek, managing director and Arjen de Vos, director of R&D of Salt Farm Texel

With the world population expected to reach nine billion before 2050, agricultural production has to increase by 70 percent. At the same time, less fresh water will become available for agriculture so the challenge is to produce more food with less water. While everybody is focussing on fresh water for agricultural production, Salt Farm Texel has a different perspective. Worldwide about one billion hectares of land is salt affected and this number increases by three hectares every minute. In addition, the amount of brackish water is equal to the amount of fresh water. Up until now, these saline resources of the world have not been recognized as a way to increase agricultural production.

Now, Salt Farm Texel is demonstrating the possible ways these resources can be useful by means of cultivating salt tolerant crops. Salt Farm Texel specializes in evaluating the salt tolerance of conventional crops, performing large-scale screening of possible salt tolerant cultivars, and developing saline agricultural practices. They work together with NGOs, investors, breeders and farmers across the world.

In an interview with Adriaan Verbeek and Arjen de Vos, we explore what makes Salt Farm Texel so unique in combatting the issues surrounding

salinization, i.e. the decrease in fresh water available for agriculture and the increase in saline affected soil – particularly in dry areas around the globe.

### What causes salinization?

Salinization can occur naturally or arise through mismanagement in irrigation. It exists around coastal areas or where the sea has retreated over a period of time, leaving salt affected soil. Dry regions are impacted the most as there is less water available to flush the soil causing salt build up. Soil salinization can also occur naturally when the ground water level rises, caused by changes in vegetation (e.g. the clearing of deeper rooted vegetation). The ground water – which is already salt affected – will come to the surface and affect the soil in the area.

Another cause of salinization is mismanagement in irrigation. When farmers start irrigating land with salt water the soil becomes increasingly damaged over time. This can be prevented, or slowed down, by flushing the soil with additional water. Often, however, water is already scarce in the area and as a result the soil will not be adequately flushed.

We have found the areas which are the most affected are Egypt, Bangladesh, Pakistan and parts of Africa due to their climate.

### How did Salt Farm Texel start?

Mark van Rijsselberghe founded the company; however, it was not until 2006 that matters really progressed when Arjen de Vos joined as a full time member of the team. Arjen first got involved in 2005 when he started his PhD on the topic of saline agriculture for the VU University in Amsterdam and after finishing his project stayed with Salt Farm Texel. We started to put our research into practice with Robin Konijn leading as CFO, who is also a co-shareholder with Mark.

### What makes Salt Farm Texel so unique?

Governments and NGOs primarily focus on how to turn salt water into fresh water. That will not, however, be enough to deal with this ever growing threat as so much fresh water has already turned into salt water and the process cannot be reversed. Salt Farm Texel is taking on this challenge from a different angle; rather than trying to put a hold to the salinization or reverse it, it looks at ways to grow vegetables using saline water and soil.

Using saline resources is a much more effective way to deal with this issue as there is simply not enough fresh water and what is there, is being lost at a rapid rate. We need to find ways to use saline resources and become less dependent on fresh water.

There are other institutions that are looking at similar solutions to us, but these tend to be more scientifically focused. We focus on practical solutions instead. It is great to see crops growing on soil that was previously unused or could only be used during the rainy season. We work together with local farmers who can pass on the knowledge.

### How do you operate?

In Texel we have our open air lab. Here we can test over 50 crops and 800 varieties thereof for salt tolerance and have done so over the last few years. The lab is a highly controlled environment and we can recreate local field conditions and apply the results directly to the relevant fields.

When we initially start a project we visit the area, collect the data and measure the levels and types of salinization. We have been working on projects in Bangladesh, Pakistan and Ghana.

In the past we have relied on data provided to use through other sources but discovered that often the data is not reliable or does not have the level of detail needed. Precise testing is required to achieve reliable and therefore usable data. After data collection and having measured levels and types of salinization, we return to Texel for testing. We perform large scale screening to identify the most tolerant varieties of (for instance) cabbage. We screen about 100 different varieties to identify the ten most tolerant. Of

these ten varieties we determine the exact level of salt tolerance, using levels of salinization that exist in the affected area. On the test field we measure the salt tolerance of the crop and their yield. We use these results as a reference for the crop performance on other locations to determine the yield potential in order to identify any potential yield gap. Certain crops are more tolerant than others, for example lettuce is more tolerant than strawberry. A crop often used in farming which is relatively salt tolerant is beets. We not only test the different types of crop but also experiment with fertilization and other variables.

### How do you re-create the affected area of e.g. Ghana, on Texel in the Netherlands? Are weather conditions affecting the experiment?

You may think that because it rains much more in the Netherlands than in Ghana the tests are distorted but the rain is nowhere near enough to dilute the irrigation water. For the test we irrigate a lot with saline water.

We also apply floating farming. This is a closed system of floating panels, with no evaporation. This method can be implemented in the various different types of circumstances, from saline clay to desert. This method is not suitable for all crops but can, for example, be applied to lettuce. Floating farming is not only good for testing but is a very efficient way of farming, requiring almost 75 percent less fertilization than traditional farming and it is the most water efficient way of growing crops.

We have developed growth models that we try to standardize to ensure we apply reliable methods in practice.

### How do you get the farmers to give up their usual ways of farming?

We usually contact the farmers through NGOs, but often the NGOs approach us for help and together we prepare a project plan.

Farmers in an affected area have usually farmed in a certain way for generations. Due to salinization, however, the yield has diminished and farmers will no longer farm during the dry season as they believe it is simply not possible. We have asked them to try different crops and use different methods but often it requires a lead farmer who is open to a new challenge to start the trend. Only when that farmer succeeds will others then follow the example.

We do not only come into the area to test and find the appropriate crop, we train the farmers so that over time they can continue farming without our involvement or assistance and can train other farmers in the area.

### You work with NGOs and the farmers locally. Are there any other parties you work with?

Yes, we have started to work with the breeders, however they are not currently focused on the issue of salinization as it has not been brought to their attention. Potato breeders, in particular, have started to work on potato varieties that have an increased salt tolerance.

### What is your view on knowledge sharing?

Salt Farm Texel consists of two entities. We have Salt Farm Texel B.V., a commercial organization and a Foundation which operates on an open





source basis, sharing its knowledge publicly. The Foundation is funded through subsidiaries and donations.

### **What is your goal?**

Our goal is to help the smallholder farmers who need our help the most. These farmers have to grow their crops on salt affected soil and can no longer produce enough food to feed their families. The threat of migration is imminent. By helping these farmers grow different varieties of crop we aim to prevent migration and other associated problems. We see ourselves as a social impact company.

According to the FAO about 80 percent of the farmers are jointly responsible for about 30–40 percent of the total production of crops. Our methods will not only help tackle the salinization problem but also generally improve the yield of the crop in those areas.

### **Do you feel you can make a difference whilst only helping small scale farmers?**

As a social impact company, helping only smallholder farmers is part of our philosophy. There is of course only so much we can do. The way we operate requires a lot of attention and time from our people “on the ground”. This sets our limits in terms of the scale of our operations. We train the farmers

locally to take over our role once we have completed our initial work but as we have already been in the area for several months we usually go back to offer support. Technology does help us to monitor from a distance.

We believe the awareness of issues surrounding salinization is slowly changing including the approach to solving it. Many NGOs, governments and commercial parties globally are starting to focus on searching for saline tolerant crops rather than trying to only bring a stop to the salinization of soil and water.

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Saskia Blokland is a partner in our Amsterdam office.

## Food safety

### FDA releases 2017 enforcement statistics and recall draft guidance

By Cori Goldberg and Krishna Kavi

On January 17, 2018, the US Food and Drug Administration (FDA) released its 2017 enforcement statistics. Overall, the statistics showed that there were no food importation debarment enforcement actions in the past year. Notably, there were 15,318 warning letters issued, 9,199 products recalled, and 2,945 recall events. There were 12 injunctions, 5 drug product debarments, and 3 seizures.

#### Warning letters

The 15,318 warning letters issued in 2017 were a slight increase from 2016 when 14,590 letters were issued. Although the total number of warning letters in 2017 was a significant increase since 2012, when 4,882 warning letters were issued by the FDA. Out of the total warning letters in 2017, the majority of the warning letters were issued by the Center for Tobacco Products (CTP), which issued 14,875 letters. This is a very high number considering the CTP's regulations are fairly recent. However this number seems to be on trend as 14,032 letters were issued by CTP in 2016. Notably, there was a marked decrease in the warning letters issued by FDA's Center for Devices and Radiological Health (CDRH), which sent 42 warnings in 2017, close to half of the 85 warning letters that CDRH sent in 2016.

Some trends observed with the FDA warning letters include the Center for Drug Evaluation and Research (CDER) issuing warnings for data integrity deviations and problems related to the relationship and duties divided between sponsors and contract manufacturing organizations. Another trend with FDA

warning letters has been for firms failing to test for product contamination. For example, one firm faced a warning letter for failing to test if diethylene glycol (DEG) or ethylene glycol (EG) was present in its products, when such ingredients had led to lethal poisoning incidents globally. The CTP warning letters largely involved "sales to minors" violations.

#### Recalls

The FDA recalled 9,199 products in 2017, which was a slight increase from the prior year when 8,305 products were recalled. Out of the total 9,199 FDA recalls in 2017, Center for Food Safety and Applied Nutrition (CFSAN) had the most total product recalls with 3,609 products. Food recalls also increased from almost 700 recall events in 2016 to almost 800 recall events in 2017.

The most recall events came from the CDRH, which had 1,068 recall events across Class I, II, and III devices. Specifically, the most recall events initiated by CDRH were for Class II devices, which had 977 total recall events.

Relatedly, the FDA issued draft guidance on January 18, 2017 regarding recalls. The draft guidance aims to improve the recall process and ensure that consumers are better protected by the industry providing more timely and comprehensive information on recalled products. Specifically, the FDA answered the question as to when a firm should issue public warnings and stated that public warnings should be issued when there is an urgent situation where a product being recalled presents a serious

hazard to health and where it would be difficult to use other means to prevent the use of a recalled product. For example, a public warning may likely be needed when a recalled product has already been widely distributed. Additionally, the agency clarified who can issue a public warning- the FDA may prepare and issue public warnings on its own in certain circumstances, such as when the public needs an immediate warning concerning a product and the firm has not issued a public warning or the warning is deficient. The FDA typically will work with the recalling firm to get accurate facts for its public warning.

Moreover, the agency explained that public warnings should not contain certain information such as information that takes away from the true purpose or substance of the warning. Additionally, the FDA stated that warnings that are brief and succinct are better at informing consumers. Also, firms should not use the warning to promote the qualities of the product being recalled or other products sold by the firm. Phrases that can be interpreted as minimizing the hazard, such as "an abundance of caution," should not be used, especially when illnesses and injuries have actually resulted from the product.

The FDA will accept public comments on the draft guidance until March 20, 2018. The Health Law Pulse will continue to monitor the draft guidance and FDA enforcement actions in 2018.

Cori Goldberg is a partner and Krishna Kavi is a senior associate in our New York office.



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## Food safety

# Bakery receives warning letter for listing “love” as an ingredient

By Benjamin Wallfisch

The US Food and Drug Administration does not have much of a sense of humor when it comes to the mandatory ingredient list on packaged food products. Last month, the FDA issued a Warning Letter to the Nashoba Brook Bakery in Concord, Massachusetts, for, among other violations, listing “love” as an ingredient in its granola and whole wheat bread, in violation of 21 C.F.R. § 101.4(a)(1), which requires the label or labelling of a food to display a list of ingredients, “listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel.” According to the FDA:

“‘Love’ is not a common or usual name of an ingredient, and is considered to be intervening material because it is not part of the common or usual name of the ingredient.”

Accordingly, it concluded that the products were misbranded under 21 U.S.C. § 343(i)(2), which sets forth the ingredient listing requirement.

It does not appear, however, that the FDA targeted this bakery solely for its creative labelling: an FDA inspection earlier this year found numerous serious violations of the Current Good Manufacturing Practice regulations, including failure to clean and sanitize equipment, staff wearing jewelry while working in direct contact with food,

and “[o]ne approximately one inch long crawling insect underneath exposed ready-to-eat foods in the pastry area,” as well as other labelling violations. After being issued a listing of the FDA’s inspectional observations (FDA Form 483), the bakery provided no formal response to the FDA, triggering the Warning Letter.

This case serves as a warning that food companies should avoid creative license with ingredient lists, even when the reasonable consumer would clearly not expect the “ingredient”—in this case, love—to be in the product.

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## Food safety

### FDA relaxes FSMA enforcement

By Cori Goldberg and Krishna Kavi

On January 5, 2018, the US Food and Drug Administration (FDA) released guidance entitled Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry. The guidance states that the FDA will exercise enforcement discretion for certain parts of the Food Safety Modernization Act (FSMA) rules. Essentially, the agency does not intend to enforce certain provisions in four regulations implementing FSMA. This agency action is not shocking given how the Trump Administration has been rolling back Obama-era rules and regulations and since FDA Commissioner Scott Gottlieb has not been focusing his efforts on FSMA implementation; his priority list has instead focused on things like the opioid crisis, drug pricing, mobile medical application development, and streamlining clinical trials.

Specifically, the enforcement discretion covers certain entities or activities covered by the Hazard Analysis, and Risk-Based Preventive Controls (HARPC) for Human and Animal food rules (Preventive Controls (PC) for Human Food and Animal Food), Current Good Manufacturing Practice (CGMP), the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule (Produce Safety rule) and the Foreign Supplier Verification Program (FSVP) rule.

Importers of food contact substances who had to comply with the FSVP regulations will be subject to the agency's new discretionary enforcement. The agency stated in the guidance that due

to the nature of food contact substances, the existing regulatory framework for these substances, and the FDA's strong premarket review and oversight of food contact substances already, "it is appropriate to consider the exercise of [FDA] enforcement discretion to not require importers of food contact substances to meet FSVP requirements." Specifically, the agency reasoned that by its very definition, food contact substances were not intended to have a technical effect in food.

The FDA has clarified in its guidance that regardless of its enforcement discretion, the prohibitions against the introduction or delivery for introduction into interstate commerce of adulterated food (under section 301(a) of the Federal Food Drug & Cosmetic Act (21 USC 331(a)) still applies to food contact substances. Further, the agency has left open the possibility that it may consider reversing course on its discretionary enforcement, if, for example, it receives new information regarding food safety concerns.

Further, the guidance aims to change how the FSMA rules would apply to entities that conduct farm-related activities but are not farms. Farms are exempt from the PC and CGMP requirements, while produce farms are typically covered by the Produce Safety rule, unless an exemption applies. The guidance applies to certain facilities conducting farm-related activities and establishments that fall outside of the current "farm" definition, since these entities typically are subject to the PC and CGMP requirements. The agency intends to initiate a rulemaking that could change the way the requirements in the PC rules

apply to these facilities that conduct farm-related activities, and in the interim, the agency intends to exercise enforcement discretion for the requirements in the PC rules for these specific entities and activities. Notably, the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce would still apply to these entities and activities.

Additionally, the FDA intends to use its enforcement discretion with written assurance, or "customer assurance," requirements for manufacturers, processors, importers, and farmers under the PC, FSVP, and Produce Safety rules. However, during this enforcement policy period, these groups must still disclose to their customers that the relevant hazards have not been controlled. Additionally, those customers (or other customers thereafter) will still have to comply with all other applicable requirements in federal, state, or local laws.

Moreover, the guidance explains that the agency has become aware of industry concerns about how the PC requirements apply to "certain activities performed on human food by-products for use as animal food before they are stored or transported and which do not affect their safety profile." To address these concerns, the agency has stated that it intends to exercise enforcement discretion for the following activities:

Drying/dehydrating, evaporating, pressing, chopping and similar activities to reduce weight, bulk, or volume and/or mixing, centrifuging, and similar activities to combine ingredients or separate components (e.g., water and solids).

Notably, this enforcement discretion does not apply when these activities are performed with the aim of significantly minimizing or preventing altogether animal food hazards, or when these activities introduce animal food hazards. Additionally, the statutory prohibition against the introduction or delivery for introduction of adulterated food into interstate commerce will still apply.

FDA Commissioner Scott Gottlieb also released a statement on January 4, 2018 explaining that the agency

values the feedback it has received on the new FSMA rules from farmers, manufacturers, and other stakeholders regarding the challenges that they have faced while trying to implement the new rules. The agency is trying to fix these remaining issues through rulemaking and other means; however, the agency acknowledged that such changes would take a long time. Thus, the agency released this guidance outlining the key FSMA areas where it seeks to exercise enforcement discretion in an effort to assist these stakeholders, while

the agency tries to make long term, permanent fixes to the rules.

Facilities should determine if they are impacted by the FDA's new discretionary enforcement and modify their FSMA preparations and processes accordingly. The Health Law Pulse will continue to monitor FSMA updates.

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## Food safety

### FDA commissioner discusses key policy goals for 2018

By Krishna Kavi

On December 14, 2017, the Commissioner of the US Food and Drug Administration (FDA), Dr. Scott Gottlieb, posted Looking ahead: Some of FDA's major policy goals for 2018 on FDA's blog, FDA Voice, and discussed FDA's policy agenda published on the Unified Agenda of Federal Regulatory and Deregulatory Actions (Unified Agenda), which provides the public with insight into regulations under development or review throughout the federal government. In the Unified Agenda, FDA outlines some of its efforts to modernize its approach and improve its efficiency, while protecting and promoting the public health and upholding FDA's "gold standard" for regulatory decision-making. Gottlieb discussed the FDA's contributions to the Fall 2017 Unified Agenda, which address a number of areas of policymaking underway at the agency, and are directly aligned with the FDA's major priorities

- Addressing the nicotine addiction crisis: the FDA is issuing Advance Notices of Proposed Rulemaking regarding their pursuit of targeted reduction of nicotine levels in combustible cigarettes to reduce their addictive value, the regulation of flavors in tobacco products to limit their appeal to youth while considering the potential role that some flavors may play in helping users transition away from combustible products, and how the FDA might define and regulate "premium cigars," taking into consideration the health effects of these products and their patterns of use.
- Amending standards for drug compounding and tracking: the FDA will issue several regulations on drug compounding to help ensure

that outsourcing facilities clearly understand which drugs they may compound and allow these firms to adopt more efficient, streamlined manufacturing standards, while ensuring safety and quality. Also, the FDA is pursuing a proposed rule to establish national standards for the licensing of prescription drug wholesale distributors and third-party logistics providers, as part of track-and-trace requirements to allow for the effective and efficient distribution of prescription drugs throughout the US.

- Continuing FSMA efforts: the FDA intends to propose a rule on lab accreditation, which will establish a program to accredit labs to do food safety testing and to require that these accredited labs be used in certain situations. Additionally, it is committed to pursuing a rulemaking that will clarify registration requirements for food facilities to better align how facilities and farms that perform similar activities are treated under the preventive controls rules and the produce safety rule. These efforts further the goals established by the Food Safety Modernization Act and its implementing rules.
- Empowering consumers: the FDA will include rulemaking that proposes a new type of patient medication document to help ensure that patients have access to clear, concise, and useful written information about their prescription drugs or biologics, delivered in a consistent and easily understood format, each time they receive a medication from the pharmacy. The FDA is also considering innovative actions to allow some drugs that would otherwise require

a prescription to be marketed without a prescription, through the use of innovative technologies and other conditions, that will ensure appropriate self-selection and/or appropriate actual use of the non-prescription drug product by consumers.

- Modernizing standards: the FDA is working to ensure that its standards and regulations reflect "the latest science and have not become outdated, obsolete or otherwise not applicable to the current environment." With this initiative, the FDA will update its requirements for accepting foreign clinical data used to bring new medical devices to market, reducing the burden on industry; propose a rule to modernize mammography quality standards by recognizing advances in technology and help to ensure women get the most relevant, up-to-date information about their breast density (now recognized as a risk factor for breast cancer); propose a new framework allowing FDA and product developers to take greater advantage of the efficiency of electronic, rather than paper, submissions for devices and veterinary drugs; and propose to remove an outdated inspection provision for biologics and outdated drug sterilization requirements, which will eliminate barriers to the use of certain sterilization techniques.

Gottlieb stressed that just because a previously identified regulation does not appear on this Unified Agenda submission does not necessarily mean the agency does not consider it a priority or will not continue to consider it moving forward. Over the next year, the FDA will address many additional priority areas,

including efforts to reduce the cost of drugs by encouraging competition, spur innovation across medical products, give consumers access to clear and consistent nutrition information, create greater regulatory efficiencies in bringing products to market, and put a dent in the country's opioid addiction crisis. The Health Law Pulse will continue to monitor for additional information about the many initiatives identified in the Fall 2017 Unified Agenda.

Special thanks to Robert Kantrowitz\* for his assistance in drafting this post.

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