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Attempts to deregulate some genetic modification (GM) methods in Australia.
Possible consequences.

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Background

The Australian government is trying to deregulate some new genetic modification (GM) techniques. While organisms made using these techniques will be able to be patented in the same way as genetically modified organisms (GMOs), the Australian government wishes to classify them as non-GMOs.

This document was written as a public service to highlight the implications of the proposed deregulation on health, the environment, farming systems, and trade. Deregulation could result in crises in each of these areas.

This document calls for these new GM techniques to be regulated and to be thoroughly assessed for any effects on health, the environment, farming systems and trade, using assessments that are based on evidence rather than assumptions.

SDN-1

The first technique being deregulated is called SDN-1 (site-directed nuclease-1). A process is used to create a “messy cut”[1] in the DNA of the organism so that the gene where the cut occurs no longer works. This “silences” the gene. The proposed deregulation means that anybody can use this method to make a GMO without needing approval first. This includes anyone who buys an easily-sourced kit over the internet for as little as $130, and makes them in their kitchen[2]. The resulting organism can be released into the environment without any environmental assessment. The organism can also enter your food supply without any safety assessment.

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for population health in Australia. It has written numerous submissions to the various reviews tasked with considering deregulating these new GM techniques, to oppose deregulation (for example, see reference number 2). The PHAA said that these organisms cannot be considered to be safe for human health, for many reasons, including the following:

- There seems to be uncertainty and debate about how these new techniques actually work.
- These new techniques are in their infancy and are constantly changing as techniques evolve.
- These techniques might unintentionally interfere with the functioning of an organism’s genes.
- There is little experimental evidence to be found in the peer-reviewed scientific literature where the risks of these new techniques have actually been measured. Consequently, any decision that is made now that products of these new techniques are safe, must be based on opinion and assumption rather than evidence. Consequently, a decision about deregulation should be deferred until the risks have actually been measured.
- If some of these organisms are later found to be unsafe, then these organisms may cause a huge health and financial burden for Australia.
- Concerns were raised that the expertise of the Gene Technology Technical Advisory Committee (GTTAC) of the Australian government regulator (Office of Gene Technology Regulator; OGTR) is heavily weighted towards those who do genetic engineering (some of whom are likely to have strong vested financial interests in deregulating the technology), and very underweighted towards people with qualifications or expertise in public health.

Since then, numerous scientific papers have been published in peer-reviewed scientific journals showing that SDN-1 techniques are not as precise as previously thought and can have numerous “off target” effects on the engineered organism, such as affecting other genes in the organism.

From a variety of media releases and the peer-reviewed scientific literature[3], comes this list of GM organisms (GMOs) that could now be quickly released into the Australian environment and food supply as a result of the proposed deregulation:

- Crops, including maize, rice, wheat, soy and flax.
- Fruit, including strawberries, grapefruit, grapes and apples.
- Vegetables, including potatoes, cabbage, tomatoes and cucumber.
- Other plants such as ryegrass, sugar cane, alfalfa, tobacco, oilseeds (e.g. canola), spice plants, forest trees, mushrooms, and lower plants (e.g. moss).
- Animals such as fish, sheep, chickens, pigs, cows and goats.
- Micro-organisms such as yeast (e.g. used for making bread, beer and wine), bacteria (e.g. used to make yoghurt) and viruses.

There is therefore a significant number of GMOs, made using SDN-1 techniques, that could soon be introduced into the Australian food supply without any safety assessment, including for any allergic, toxic, reproductive or cancer-causing effects. There will be no labelling, either. So, you will be eating them whether you want to or not.

dsRNA

The second technique being deregulated uses dsRNA (double stranded ribonucleic acid) methods. Such dsRNAs can also be called small interfering RNAs, artificial microRNAs, short or long double-stranded RNAs, and short hairpin RNAs[4,5]. The aim is to put a small section of dsRNA into a plant or other organism by methods such as spraying, dipping, injecting, using a virus, or by eating something that contains the dsRNA[4,5]. This process can silence or activate genes.

One expected application is as an insecticide. That is, an insect eats a plant that either contains dsRNA or has been sprayed with it, the dsRNA survives digestion in the insect, travels into the tissues of the insect, and silences a gene in the insect, which kills the insect[6]. Alternatively, the insect itself can be sprayed with the dsRNA. We know that agricultural sprays can travel for kilometres and that dsRNA can persist for a long time in the environment. This means that there is ample opportunity for the dsRNA to enter soil or water and for other organisms to take it up. It also means that while an agricultural spray containing a chemical insecticide needs a safety assessment, an agricultural spray containing a dsRNA insecticide will probably not.

There is some evidence that dsRNAs produced by GM plants may survive digestion in people. The US Environmental Protection Agency’s (EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel recommends ongoing research and monitoring because it is uncertain that all dsRNA molecules created by genetic engineering would be safe to consume[7]. If such dsRNA molecules survive digestion in people, there is a risk that they could also change how those people's genes are expressed[6].

There is also evidence that the gene silencing may be inherited by the offspring of some organisms that eat the dsRNA[6,8,9]. Indeed, patents held by Monsanto (now Bayer) not only state that this occurs, but also claim the offspring as their patented property[8,9]. While changes to the actual base pairs that are the building blocks of genes will still require regulation[4,5], it is important to note that you can change how genes are regulated without changing the base pairs[6,8,9]. And you can further do that in a way that allows the changes to be inherited[6,8,9]. One such method is called methylation. And that method will be deregulated[4,5].

Furthermore, methods of delivering the dsRNA do not appear to be regulated, such as materials or methods to increase the stability of the dsRNA in the environment or to increase the ability of the dsRNA to penetrate cells[8].

A recent review of how various government regulators (including Australia's) assessed the risks of dsRNA technology, found that the safety of dsRNA molecules was usually not considered at all, and if it was considered, regulators simply assumed that any dsRNA molecules were safe, rather than requiring proof that they were safe[6]. The review's authors provided numerous scientific studies to show that such assumptions were incorrect and, based on the evidence uncovered, also provided a suitable safety assessment process for regulators to follow. Unfortunately, the proposed deregulation will enshrine such incorrect assumptions into law by seeking to deregulate such organisms, with the result that no environmental or safety assessment will occur before such organisms enter the Australian environment or the Australian food supply. Indeed, it appears that no government approval may be required at all.

Null segregants

The proposed deregulation also regards organisms as being non-GM if (1) they have gone through a genetic modification process but "no longer have the genetic modification or any traits that occurred because of gene technology" or (2) the organism in question has not inherited a transgenic gene from a parent[4,5]. The first assumes that the genetic modification process has caused no unintended or unexpected consequences in the organism, either at the intended site of the genetic modification or elsewhere in the organism. The second further assumes that any such changes have not been inherited. Because the first is not thoroughly checked when GMOs are made[10], such organisms should not be deregulated until thorough checking standards are established.

Implications for consumers

There is no consensus that organisms produced by these methods are safe for your health. Deregulating these new techniques and the organisms that are produced using them, means that the types of organisms described above can enter your food without any safety assessment, including for any allergic, toxic, reproductive or cancer-causing effects. There will be no labelling, either. So, you will be eating them whether you want to or not.

Farming implications

Deregulating these techniques and the GMOs they produce, means that the resulting organism can be planted without any requirement for farmers to be told that the crop was developed using such techniques, without any requirement to determine how easily the organism could spread from one farm to another, and without any need for segregation to keep the harvested GM crop separate from harvested non-GM crops. There will also be no requirement for any assessment for environmental harm before release. These matters can result in significant issues for Australian farmers.

Because the DNA and dsRNA sequences developed using these techniques will be patented, this means that wherever these sequences land, they "belong" to the patent-holder. For dsRNA, this means that the maker of the RNA could enforce their patent rights over an organism (e.g. a plant) that was exposed to the dsRNA, potentially including fields of conventional crops or trees that had been sprayed with the dsRNA, as well as the seeds produced from those plants[8]. That is, if a crop is sprayed with patented dsRNA, the patent can extend to the crop and the grain produced by the crop. If fruit trees or vines are sprayed with patented dsRNA, the patent could extend to the fruit or grapes produced, possibly for the life of the tree or vine. If forestry trees are sprayed, the patent could extend to the life of the trees and possibly the timber produced.

The patent-holder can then enforce their patent rights. In the USA and Canada, this has resulted in farmers who were contaminated with past versions of GM crops, being sued for growing GM crops without a licence. The situation in Australia is potentially worse, because Australia has signed the UPOV 91 International Treaty that has allowed an "end-point royalty" to be deducted in Australia for plant breeding, which makes it easier for farmers to be fined. Now, rather than only charging the farmer for plant breeding at the time that the seeds are bought, the farmer can also have a pre-set fee per tonne deducted from his or her harvested grain once it is delivered and sold. Under the Plant Breeders Right Law (PBR), this fee can be deducted in the same manner as the Grains Research and Development Levy.

How this works in practice for patented GM crops in Australia can be seen with GM canola grown in Western Australia. Essentially, each farmer delivering canola for sale needs to declare if their truck-load contains GM canola. A sample is then taken from each load of non-GM canola, before the load is poured into a "stack" of non-GM canola from other farmers. If periodic testing of the stack reveals the presence of GM canola, those farmers' samples can be tested. Under the end point royalty system, the patent owner, at their discretion, then has the legal right to deduct their GM user fee from any grain payment to a contaminated farmer, regardless of the level of contamination present. CBH can also deduct a significant fine from the farmer's grain payment for not declaring the presence of GM canola in the grain. The farmer may also be required to pay for any price penalty of the whole stack, if the stack is downgraded as a result of GM contamination. Note that this means that in Australia, Monsanto does not need to take farmers to court to sue them for using their patented GMOs without permission. Instead, Monsanto has the legal right to automatically deduct a user fee from farmers who return a positive test for Monsanto's GMO, even if the GMO is present through no fault of the farmer, and farmers who object would need to take legal action against Monsanto to try to recover their money.

For sprays containing dsRNA, this means that where a farmer's crop is affected by spray drift from a neighbour, if the spray contains a "normal" herbicide, then the farmer can take legal action against the neighbour to recover losses. However, if the spray contains patented dsRNA, the affected farmer may now be further harmed by being both fined and charged a user fee for having the dsRNA on their property without a licence.

If farmers start getting fined for contamination in their crops, and the end-point levy and fine are sufficiently high, it would likely act as a strong inducement for farmers to declare their grain as being GM if there is a risk of contamination, or to decide that growing the GM crop under licence is a legally safer and cheaper option than growing a non-GM variety and being fined for any contamination.

This means that in effect, GM crop companies can get financially rewarded for their contamination. It provides an incentive for contamination.

It should be noted that spread of the GMO onto the fields of an organic farmer could result in the farmer losing their organic status, and therefore much of their livelihood, as well as being charged a user fee and possibly fined as described above.

Trade implications

Deregulating these GM techniques means that there will be no assessment needed to determine how these GMOs could impact our export markets. They can be planted without any records being kept as to where they are planted and where they have spread. Based on the experience of other countries, our exports are expected to quickly become contaminated with the organism[11].

There are two risks to trade as a result. The first occurs if a contaminated export arrives at a country that has not approved that GMO. That situation can result in the import being refused, resulting in serious financial loss for Australia. For this to happen, the recipient country first needs to decide that the organism is a GMO and needs regulating. This is certainly happening. In 2018, the European Union Court of Justice ruled that new GM techniques posed similar risks to older GM techniques and should be similarly safety assessed[12], while "New Zealand has recently amended its legislation to clarify that techniques developed after 1998, including genome editing, are within the scope of regulation as GMOs" [13]. Other countries are likely to follow suit, particularly since these techniques are regarded as producing GMOs under definitions used by international entities such as Codex Alimentarius and the Cartagena Protocol.

The recipient country then also needs to be willing to reject the importation, even though it may cause tensions between it and the country that exported the shipment. Many countries, including the countries of the EU, have a zero tolerance for GMOs the country has not approved. There were 200 cases of trade disruption due to unapproved GMOs between 2002 and 2012 [14], resulting in profound economic, social and environmental consequences for some exporting countries, including the permanent loss of export markets[11]. Losses have been in the billions of dollars.

The second type of risk occurs where the export is contaminated with a GMO that is actually allowed into the food supply of the importing country, but the food is labelled as being a GMO in that country. Labelling allows consumers to decide whether they want to eat the GMO or not. Because consumers remain highly reluctant to eat GMOs, they tend to choose not to eat them. This means that food manufacturers in those countries tend to specify non-GM ingredients for their products. As a result, the GM crops that have been planted commercially so far, tend to be those that avoid a GM label in most countries because they enter the human food supply as refined products, such as oil, sugar and starch. Or they end up in animal feed. While the proposed deregulation will allow some varieties of GM fruit, vegetables, animals, wheat and rice to quickly enter the Australian food supply without a label, they are still likely to be labelled in other countries, leading to problems for Australia when it tries to export them.

While some supporters of deregulating these GMOs argue that Australia should not suffer any trade problems because there are currently no methods available to test for these organisms, Dr John Fagan, who established a major laboratory to test for GMOs in the USA has stated: "In practice they are not more difficult to test for than the old fashioned GMOs. Enough information will be available in the patents and applications for approvals so that with just a little bit of molecular biological detective work, tests can be designed. And because these are commercial products, as soon as they enter the market, it will be possible, in one way or another, to obtain a sample that can be used to verify the tests designed. This is exactly how labs have been developing GMO tests since 1996."[15]

An example of what could happen with this type of trade issue is given by GM wheat. Although varieties of GM wheat have been available for years, it has never been commercially grown anywhere in the world, and any escapes of GM wheat varieties from old trial sites are quickly eradicated[16]. This is because wheat is eaten by people on a daily basis, e.g. in bread, cakes and pasta, and is labelled in many countries. When Canadian farmers asked their markets whether they would accept GM wheat from Canada, they found that: "The international customers that buy 82% of Canada's wheat crop say that they will stop buying if Canada introduces GM wheat. These customers have been clear—they will stop buying all wheat from us—GM and non-GM alike. This market loss issue applies to all GM wheat, not just RR wheat."[17]. Any introduction of GM wheat into Australia therefore risks losing an industry, that is worth $7.1 billion per year (5-year average)[18].

It should be noted that under the current legal agreements that farmers have to sign to grow a GM crop, the farmer growing the crop takes on any liability for losses and absolves the patent-holder of any liability[19].

Furthermore, if the Commonwealth Government deregulates these techniques, and hence defines all organisms made using these techniques to be non-GM organisms, the definition may automatically become the definition for States and Territories of Australia. If it does, then States such as South Australia and Tasmania, which have a moratorium against growing GM crops commercially for financial reasons, may find that the wording in their existing moratorium legislation may be ineffective against preventing these new GM crops from being grown in their State.

Rye grass as an example

A variety of rye grass, developed using SDN-1 techniques, is one of the organisms that could be quickly introduced as a result of deregulation[1] and provides an example of what could happen with deregulation.

The rye grass has been designed for use on diary farms[1]. Given that Australia has an end-point royalty system for GM crops, this is likely to either result in an end-point royalty being levied on the farm itself, or on the milk or meat produced from the farm, or on whoever buys the milk or the meat. If a royalty is placed on the farm, how is the patent-holder going to determine if this ryegrass is growing on the farm? Do they intend to come onto properties to test for the presence of their rye grass? If a royalty is placed on the milk produced, do they intend to test the milk for GM rye grass residues in the milk? Note that in a study conducted on milk on supermarket shelves in Italy, researchers were able to determine which GM crops the cows had been eating by testing their milk[20]. A positive test for this rye grass variety in milk could result in a user fee being deducted from the dairy producer, processor or consumer.

Pollen from rye grass can travel for many kilometres. It is one of the major causes of allergic rhinitis (hay fever) in people[21]. Allergic rhinitis affects approx. 3.1 million people in Australia[22]. The cost of medications alone was $226.8 million in Australian in 2010 [22]. This cost did not include any loss of productivity due to symptoms, such as taking time off of work. Deregulation of SDN-1 techniques will mean that there is no requirement to test this GM ryegrass for its allergic potential, and hence whether it will make hay fever worse in Australia.

Because of the ease in which rye grass pollen can spread, it is expected that GM rye grass will quickly spread throughout Australia. Annual ryegrass is one of the most serious and costly weeds of cropping systems in southern Australia[21]. Herbicide resistance is now making rye grass even more difficult to control. Note that wherever a patented GM organism lands, it "belongs" to the patent-holder, and the person who has it on their land is expected to pay the licence fee required by the patent holder. This means that farmers may soon have to pay for having GM ryegrass weeds on their property.

Organic farmers would be expected to be hit the hardest if this rye grass is released. It is difficult enough to control rye grass using herbicides. Organic farmers cannot use such herbicides. Furthermore, finding GM rye grass in an organic crop, or a positive test for it in milk produced from an organic dairy, could see the farm or dairy not only being charged an end-point royalty, and possibly fined, but also result in the farm or dairy losing its organic status.

Because rye grass is not usually regarded as part of the human diet, it is unlikely that this GM rye grass will obtain approval to enter the food supply of other countries. Yet rye grass is a major contaminant of cropping land in Australia and hence rye grass seeds can become a contaminant of harvested crops. If a contaminated export arrives at a country that has not approved that GMO, the shipment would likely be rejected, resulting in profound economic and social consequences for Australia. Since rye grass cannot be controlled or recalled once it is released into the environment, it would become a permanent part of the Australian landscape. Consequently, any loss of export markets could be permanent.

Note that if SDN-1 techniques are deregulated in Australia as planned, none of these consequences will need to be investigated before this rye grass is released into the Australian environment.

Desired actions

These new GM techniques and the organisms that are produced as a result, need to be thoroughly assessed, using assessments that are based on evidence rather than assumptions. They need to be thoroughly assessed for any effects on health before they are released into the human food supply. They also need to be thoroughly assessed for any effects on the environment, farming systems and trade before they are released into the environment. They also need to be labelled to ensure that consumers, farmers and food producers can chose to avoid them if they wish.

For all the above reasons, my colleagues and I are asking for these proposed amendments to the legislation (Gene Technology Amendment (2019 Measures No. 1) Regulations 2019;12) to be blocked, and for these new techniques and the organisms that are produced using them, to be fully regulated as GMOs.

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