# STANDING COMMITTEE ON
# UNIFORM LEGISLATION AND STATUTES REVIEW

## GENE TECHNOLOGY (WESTERN AUSTRALIA) BILL 2014

**TRANSCRIPT OF EVIDENCE**
**TAKEN AT PERTH**
**MONDAY, 1 DECEMBER 2014**

**Members**

**Hon Kate Doust (Chair)**
**Hon Brian Ellis (Deputy Chair)**
**Hon Mark Lewis**
**Hon Amber-Jade Sanderson**

**Hearing commenced at 12.20 pm**

**Ms KATHERINE SMART**
**Policy and Legal Coordinator, Project Manager, GM Policy and Regulation, Department of Agriculture and Food, examined:**

**Ms CATHARINE ASHFORTH**
**Principal Legal Officer, Manager, Legal and Commercial, Department of Agriculture and Food, examined:**

**The CHAIR**: Thank you for coming along early, my name is Kate Doust and I am the Chair of the Standing Committee on Uniform Legislation and Statutes Review. I will just do the introductions and then we will kick things off, if that is all right. This is Hon Brian Ellis, Hon Amber-Jade Sanderson, Hon Mark Lewis and Alex Hickman our research officer. Thank you very much for coming in today. This is our first day of looking at two particular bills, and today you are the first witnesses for the gene technology bill. We just want to get a briefing rather than have a structured hearing because we are going to treat it as though we do not know anything about this legislation and we hope that you can give us—I hate to use the words "the dummies guide", if you like—to what is involved with this. We are not looking at the policy of this bill; we are looking at the mechanics of it and how it interacts with the state versus federal government and those sorts of things. That is probably what we are looking to frame our discussion around today. You would have received some questions from the committee office last week just to give you a bit of an idea about some of the things that we are interested in. There may be other things that we have missed that you might want to provide information on. Because it is not a structured hearing today, we are not going to ask you to swear an oath or affirmation. Do you want to start off providing a statement about what the bill is about, or take us through that and then perhaps we can go through the questions, or do you want to just start with the questions? I am quite happy to leave that up to you.

**Ms Smart**: I am happy to give an outline of the purpose and what this is aiming to achieve. In 2001, the states and territories signed the Gene Technology Agreement committing to have a consistent national approach to the regulation of gene technology and to make sure the state and territory legislation was consistent with the commonwealth legislation on the subject. The commonwealth Gene Technology Act 2000 basically requires you to obtain a licence before you deal with a genetically modified organism. The definition of "dealing" is very broad. It is making, manufacturing, using, breeding, propagating, transporting and disposing—it is a very broad definition. Essentially, with a number of exceptions to that, you will need a licence before you can deal with a GM organism. The exemptions are things which have been declared an exempt dealing, which are things which are very well understood and pose a very low risk—things like creating a cDNA library, for instance. Things which have been classified as a notifiable low-risk dealing, you do not need a licence for. These are again very low risk and very well understood. Provided that an institutional biosafety committee has approved what you are planning on doing, you do not need a licence.

Things which have been listed on the GMO register: these are things which might have previously had a licence but the Office of the Gene Technology Regulator has decided that a licence really is not required for dealing with these in the future. At the moment, the only thing on the GMO register are the purple carnations. These are carnations which were genetically modified to have particular lilac and mauve petal shades. Emergency dealing determinations are another category where you do not have to go through the full licencing process if you can demonstrate that there is an emergency

need for this technology and the commonwealth minister has signed off after an abbreviated assessment process. The final category is—no, that is it, sorry. I did them in a slightly different order.

With the exception of those few categories, basically, any other dealing with a GMO requires a licence under the federal commonwealth act. The commonwealth act also establishes the Office of the Gene Technology Regulator, which administers the act. It sets out the assessment process for obtaining a licence, the consultation process, it sets out requirements for the public record and what information has to be made publicly available, so it is a fairly broad ranging act. In 2006, WA introduced the WA Gene Technology Act, which was at the time consistent with the commonwealth act. It was, I suppose—Katy can correct me—sort of like a copy-and-paste-type approach to the commonwealth act at the time. However, over time, the commonwealth act has been amended. The commonwealth act was amended in 2007. The commonwealth Gene Technology Regulations which sit under the act had been amended in 2006, 2007, 2009 and 2011, and the WA legislation simply has not kept pace. There was an independent review in 2011, which found that our act was not consistent with the commonwealth act. There were a number of options identified for how to remedy that, and the one that was pursued was a new act which simply applied the law of the commonwealth as a law of the state, which is what this bill is doing, so that every time the commonwealth act changes, rather than us having to amend our act, those changes will come in automatically. I suppose that is a kind of overview of what this is about.

**The CHAIR**: Have you got anything else you would like to add to that?

**Ms Ashforth**: No, not to that overview.

**The CHAIR**: We might just start to go through those questions, if that is okay?

You may have covered some of these matters in your opening remarks. The first question we have is: please describe how the regulation of genetically modified organisms—GMOs—is currently undertaken of individuals and organisations in WA under the Gene Technology Act 2006?

**Ms Smart**: Details of all applications are actually publicly available on the Office of the Gene Technology Regulator website. At the moment, we are not aware of any applications being rejected because the applicant is covered by the inconsistent WA act rather than by the commonwealth act. To date, as far as I am aware, the applicants have been covered by the commonwealth act.

**The CHAIR**: What changes will occur regarding the regulation of GMOs in WA by the passing of the bill?

**Ms Smart**: There will not be changes to the actual system of regulation, but it will rectify gaps in the coverage. It will make sure that everything is consistent. For example, a certain type of dealing might be classed as a notifiable low-risk dealing under the WA regulations but be classed differently under the commonwealth regulations, so it will make sure that all that is consistent and it will bring the WA act up to date with the changes to the commonwealth act that were passed in 2007.

**The CHAIR**: If those inconsistencies exist now, has it been an issue for people operating with GMOs?

**Ms Smart**: As I say, we are not aware of any applicants being rejected because they are applying under the inconsistent WA act. As far as I am aware, all the applicants who currently have got licences have applied to the OGTR and have done so under the commonwealth act.

**The CHAIR**: Is there any way that we can find out how many people currently have licences?

**Ms Smart**: It is publicly available information. The website is: www.ogtr.gov.au. All notifiable low-risk dealings or dealings not involving release and dealings involving release are listed there by applicant.

[12.30 pm]

**Hon BRIAN ELLIS**: I will follow up for clarification. You were saying that since 2011, we have found that we were not consistent with the commonwealth act. I thought every time there was a change in the commonwealth act, we changed our act to keep pace, but you are saying that has not been the case?

**Ms Smart**: That has not happened, no.

**Hon BRIAN ELLIS**: So we are three years behind?

**Ms Smart**: The last changes to the commonwealth act were in 2007.

**Hon BRIAN ELLIS**: So more than three years?

**Ms Smart**: The last changes to the commonwealth regulations were in 2011.

**The CHAIR**: That leads us to the next question. We would like if you could perhaps set out the differences between the Gene Technology 2000, the commonwealth act, and the WA Gene Technology Act 2006. So, if there are clear differences, if you are able to articulate those for us.

**Ms Smart**: As I say, because the WA act has not been changed since it was originally brought in in 2006 and because the commonwealth act was amended in 2007, all of the amendments that were in the 2007 amendment to the commonwealth act are not in the WA act. We have the explanatory memorandum for the commonwealth changes, if that would be of use.

**The CHAIR**: I think so.

**Ms Smart**: Essentially, the 2007 amendment to the commonwealth act set out the emergency dealing determination provisions, which are the provisions where, if there is an emergency, you do not have to go through the full licence assessment process; the commonwealth minister can have an abridged process.

**The CHAIR**: Can you explain to us what that actually means?

**Ms Smart**: The emergency dealing determination allows for an expedited approval of a GMO for release, recognising that there are situations in which you might need more rapid adoption; for example, there was the equine horse flu vaccine a couple of years ago, which was a GM vaccine. Generally, the process to get a licence under the normal rules takes 255 working days for a commercial release. Obviously, in the case of a vaccine that was not going to work. So, the process for an emergency dealing determination to be made is that the commonwealth minister has to be satisfied that there is an imminent threat, that the GMO proposed is likely to prevent that threat and that any risks associated with that can be managed. He has to take advice from the commonwealth Chief Medical Officer, Chief Veterinary Officer or Chief Plant Protection Officer, as appropriate, and also has to speak to the states and territories about it as well. So there is still a fairly stringent regulatory process to go through, but it is just a more abridged version than its standard commercial licensing process. That was introduced in the 2007 amendments to the commonwealth act. It also made some clarification and operational sorts of amendments as well, which are not in the WA act. On page 1 of the explanatory memorandum is a list of dot points, towards the bottom of that page, which is a further summary of what those changes are.

**Hon MARK LEWIS**: Katherine, a bit of potted history between the Gene Technology Act and the Genetically Modified Crops Free Areas Act—what is the difference?

**Ms Smart**: The Gene Technology Act is about protecting the safety and health of people in the environment by regulating dealings with GM organisms and making sure any risks can be appropriately managed. The GM Crops Free Areas Act is state legislation based on marketing purposes, so that is after something has been approved and been granted a commercial release by the Office of the Gene Technology Regulator, it still cannot be grown in WA unless there is an exemption order in place.

**Ms Ashforth**: That is because there has been an order made under the act designating the whole of WA as an area in which GM crops cannot be grown. So, it is not the act itself that prevents that.

**Hon MARK LEWIS**: That is under the GM tech area?

**Ms Ashforth**: Under the GM Crops Free Areas Act, there was an order made some years ago.

**Hon MARK LEWIS**: It is not under the gene tech act 2006?

**Ms Ashforth**: No.

**The CHAIR**: It is a separate piece of legislation. That is the one where they refer to the gatekeeper principle, is it not?

**Ms Smart**: I am not sure, sorry.

**The CHAIR**: The next area, moving on, is looking at section 14 of the commonwealth act. We just want to know if you can explain the effect of a wind-back notice issued under section 14 of the commonwealth act?

**Ms Ashforth**: A wind-back notice will have effect to wind back the reach of the commonwealth act in areas that both it and the state could apply or might apply or there is some doubt as to which one, so when there is a wind-back notice in place the state act will apply. It is really just a clarity thing.

**The CHAIR**: Can you give us an example of where that might happen?

**Ms Ashforth**: An example of when a wind-back notice has been used?

**The CHAIR**: Yes, that would be helpful:

**Ms Ashforth**: I know that they are in place in the other states that have had their acts declared to be corresponding, but I cannot think of any examples where they have actually worked in those states.

**The CHAIR**: Okay. Is there any intention to give a wind-back notice to the commonwealth minister under section 14 of the commonwealth act following the passing of that bill?

**Ms Ashforth**: Yes, there would be.

**The CHAIR**: If so, which state agency will take on the role of the regulator in respect to individuals or organisations covered by the bill?

**Ms Ashforth**: No state agency will take on the role of the regulator. The regulator keeps all those functions, even when acting, technically, under the state act.

**The CHAIR**: Will there be somebody in the Department of Agriculture and Food who is a point of contact and liaison person to the regulator here in Western Australia?

**Ms Smart**: Yes, we already have that. When licences are received by the regulator, they are distributed to authorised agencies for comment and input, and the department of agriculture is already on that list, so we are contacted when there is a licence. There is also the gene technology interdepartmental committee, which is broader; it covers representatives not just from agriculture but also health, and that also provides feedback on licence applications as appropriate. That will be one point as well, because the Gene Technology Act does not just apply to agriculture, it is all dealings with GMOs, whether that is the medical–pharmaceutical research phase, and not just ag.

**The CHAIR**: That is something people do not always think about; is it not? I think most people would connect it directly to agriculture rather than other areas.

**Ms Smart**: There are things—for instance, like insulin is a GMO and has been for many years.

**The CHAIR**: Is it intended, following the passing of the bill, to modify the application of the commonwealth act by regulations pursuant to clause 7 of the bill?

**Ms Ashforth**: No, it is not; in fact, it is the intention to keep it as consistent as possible—completely consistent for as long as possible.

**The CHAIR**: So no modifications at all are planned?

**Ms Ashforth**: No.

**The CHAIR**: Is the reference to regulations in clause 7 of the bill intended to mean regulations made by the Governor pursuant to clause 21(1)?

**Ms Ashforth**: Yes.

**The CHAIR**: Can you explain the effect of clause (2) of the bill, which reads —

> Those Commonwealth gene technology laws so apply as if they extended to matters in relation to which the State may make laws —
>
> (a) whether or not the Commonwealth may make laws in relation to those matters; and
>
> (b) even though the Commonwealth gene technology laws provide that they apply only to specified matters with respect to which the Commonwealth may make laws.

**Hon MARK LEWIS**: Chair, just for Hansard's benefit that is clause 6(2).

**The CHAIR**: Yes, I did say that.

**Hon MARK LEWIS**: You said (2)—sorry, I only heard (2).

**The CHAIR**: I think Hansard has got that now.

**Ms Ashforth**: The commonwealth laws applying as commonwealth laws are limited by the commonwealth constitutional powers, so clause 6(2) wants to make it clear that when those commonwealth laws are applying as applied laws, that is as laws of the state, then they apply according to the state's legislative powers regardless of whether or not the commonwealth would have constitutional reach in the particular case or not.

**The CHAIR**: The follow-up to that would be: does it mean that the commonwealth gene technology laws will apply to sole traders and other state-based organisations over which the commonwealth does not traditionally have power under the Australian Constitution?

[12.40 pm]

**Ms Ashforth**: It does not. It just means that the laws will apply as laws of the state to those people or organisations.

**The CHAIR**: Can you explain the effect of clause 15(4) of the bill, which states —

> A provision of a Commonwealth administrative law applying because of this section that purports to confer jurisdiction on a federal court is taken not to have that effect.

**Ms Ashforth**: That makes it clear that the state law cannot confer powers on a federal court because the state does not have that power. It has been clearly recognised by the High Court.

**The CHAIR**: The final question that we have on that paper is: regarding the tabling of amendments to the commonwealth gene technology laws in the Parliament pursuant to clause 20 of the bill, please enlarge upon what is stated in the explanatory memorandum, which states —

> The Bill includes a provision (clause 20) requiring tabling in Parliament of any changes to the applied Commonwealth legislation. This will ensure the Parliament is kept fully informed and can take any legislative action as it sees fit.

Can you explain how this process differs from the existing arrangement whereby WA is required to pass corresponding legislation before any amendments to the commonwealth act can apply in terms of the ability of WA to take legislative action?

**Ms Ashforth**: Any changes to the commonwealth act now, as we have said has been the problem in WA, have to be specifically enacted by the state Parliament. If the new bill is enacted, the changes to the commonwealth laws will be automatically applied but the state Parliament retains the power

it has always had, which is not affected at all by either of the bills to make any laws it chooses and to amend or repeal any laws that it has adopted or applied. But the tabling just is designed to ensure that none of those changes slip past without the attention of Parliament being brought to them so that they have an opportunity to specifically consider whether they might object to them.

**The CHAIR**: Would any future changes where the state Parliament is notified be treated in the same way as we are dealing with this bill as uniform changes and we would go through a similar process to what we are currently doing with the bill or is it simply a noting of the changes?

**Ms Ashforth**: Yes, it is tabling those changes.

**The CHAIR**: What happens in the case where the Western Australian Parliament decides that it does not agree with the changes that the commonwealth has made in relation to gene technology?

**Ms Ashforth**: It would have to introduce legislation to dis-apply them, if you like.

**Ms Smart**: I might be able to add at that point that before the commonwealth legislation is changed, there is an extensive consultation process, which includes what was formerly called the Gene Technology Ministerial Council, but is now the Legislative and Governance Forum on Gene Technology. The WA representative on that is Ken Baston and sitting below that is the Gene Technology Standing Committee, which provides high-level advice. Our director general, Rob Delane, is a member of that committee. Any changes to the commonwealth act go through the Gene Technology Standing Committee and the legislative and governance forum before the commonwealth act is changed. WA would be aware of any changes and would have the opportunity to comment and raise any concerns during that process.

**Hon MARK LEWIS**: That is the executive arm of government. Can we just play this out a bit? The notice comes in and sits in both houses. Where would that come into the process? Would it come in as a regulation?

**The CHAIR**: Probably as a message, I would imagine.

**Hon BRIAN ELLIS**: I am not sure either. This bill is putting us under the commonwealth act. If we do not agree with something that is put into that act, how do we stop it? I am not sure how that process would happen either.

**Ms Ashforth**: The Parliament would need to introduce a bill making the changes that are required. Parliamentary Counsel could draft anything.

**The CHAIR**: The minister of the day would have to take the step to introduce legislation once they were notified of the changes. If they were not satisfied, they would have to go through normal processes to introduce a new bill—a state bill—to change it in some way.

**Ms Smart**: Or to exclude those changes.

**Hon MARK LEWIS**: I was picking up something before that though. It comes into the upper house. How does the notice sit in Parliament?

**Ms Ashforth**: It is required to be tabled in both houses.

**The CHAIR**: It may come in with a ministerial statement and a document to be tabled by the minister.

**Hon MARK LEWIS**: That is when we get to hear about it and then we can say, "Hang on, we have some issues around that. We need to send that off to uniform leg."

**The CHAIR**: No, you will not have that option. It is commonwealth legislation. They are just telling us it has been done. It is out of our hands as a state Parliament. They are simply telling us what they have done. The only recourse for change is to introduce a totally separate piece of state legislation to try to remedy whatever we did not like.

**Hon MARK LEWIS**: There is no disallowance process?

**The CHAIR**: No, not under these arrangements. That is why when we did that other piece of legislation earlier this year, we worked really hard to make sure we had that part 6 in so that the minister could still maintain the state's engagement and rights, not that you have to worry about that. It is an interesting position. This has been a fairly contentious issue for quite a period of time in the gene technology space. It is an interesting way of managing it, I suppose, for the state. Is it the case in every other state where they have just simply adopted the commonwealth legislation?

**Ms Smart**: This is the approach that has been taken in New South Wales, Tasmania and the Northern Territory—to adopt the commonwealth law as the law of the state.

**The CHAIR**: What do they do in the other states? Is it Victoria and South Australia?

**Ms Smart**: In Victoria, South Australia and Queensland, they maintain their own legislation consistently.

**The CHAIR**: Are you able to explain to us why they did that?

**Ms Smart**: No, I am sorry.

**The CHAIR**: That is okay.

**Hon BRIAN ELLIS**: If this bill is passed, we come under the commonwealth act. This brings us up to speed with any changes in the future. Does it bring us up to speed with changes that should have been done since 2006 or 2007?

**Ms Smart**: Yes, it will apply the commonwealth gene technology laws comprising both the act and the regulations as they are today and as they change from time to time. We will immediately jump into consistency.

**Hon BRIAN ELLIS**: The same process would apply, as we just spoke about, if some of those changes since 2007 disagreed with by our minister, then you would have to go through the process we just spoke about.

**Ms Ashforth**: Except that I do not think he would have introduced this bill if he had any qualms.

**Hon BRIAN ELLIS**: I accept that. I do not know how many changes have been done since 2007 compared to the commonwealth act. It would be interesting to see how that could play out.

**Ms Smart**: The commonwealth act has only been amended the once since the introduction, in 2007. The commonwealth gene technology regulations have been amended numerous times.

**Ms Ashforth**: Our act was only passed in 2006. I think it commenced operations sometime in 2007. After having first been introduced, I think in 2001, it took an awful long time to get through.

**The CHAIR**: There is a fairly substantial parliamentary inquiry into that.

**Hon MARK LEWIS**: The explanatory memorandum states —

> The bill includes a provision (clause 20) requiring tabling in Parliament of any changes …

You are saying that the minister will bring in an amendment to the bill in Parliament to reflect the changes.

[12.50 pm]

**Ms Ashforth**: No; there is no need. They automatically apply under this act. That is purely and simply to make sure that Parliament is given notice of them.

**Hon MARK LEWIS**: So we might need to find out what that tabling process is.

**The CHAIR**: It is reading out a statement and saying, "I table information about changes to the act." I think it is as simple as that.

**Hon MARK LEWIS**: That is it, and the minister pops up —

**The CHAIR**: At the start of the day

**Hon MARK LEWIS**: — and says that.

**The CHAIR**: We probably have not had to deal with something like this on our committee for a while.

We probably do not have any further questions today because we are just starting out on this process and I think we are reporting on this bill back to the Parliament in late February next year. So there may be an opportunity, once we have been through submissions and are part way through the process, for us to call you back in just to clarify a few things for us or just to make sure that we have got things right in our own space about what is happening with this. We certainly thank you for coming in today. That has been very useful for us to start the ball rolling. Hansard has been recording the hearing today and you will get a copy of the transcript. If you read it and if there are any corrections that you need to make, do so. You cannot change the language or the context or anything, but if there are any corrections that you need to change, do so and return it as quickly as you can. In that way, we can actually go back over it and it helps us with our work on the bill.

We will certainly come back to you at some point. It may be that we need clarification on points from time to time, so we may send you an email or a letter or ask you to come back in again on a different date if that is okay.

**Ms Ashforth**: Certainly.

**The CHAIR**: Thank you very much for that. That certainly was very informative and I think it has given us a few things to think about as we work through this bill. We certainly appreciate your time.

**Hearing concluded at 12.52 pm**