**Senator BACK:** You will be aware of the dialogue that has been going on about the process for the ovine strain-specific footrot vaccines—the application for a minor use permit or the approval of an emergency permit, which I understand at the moment is being offered to this company, to expire at the end of a six-month period. Given the lateness of the hour, can you give the committee an idea of where you are in your consultations, deliberations or decision making with regard to this issue of the strain-specific footrot vaccine.

**Ms Arthy:** We have granted an emergency permit until the end of July. That is granted on the basis that the registered product is currently not available in Australia because of the BSE restrictions in the US. We have granted it on the grounds of animal welfare. That is the permit. We are also working with the applicant to encourage them to bring forward a registration application so that it can be registered, knowing that, should the BSE status of the US change, the registered product could theoretically come back into the market.

**Senator BACK:** It is now the end of February and I understand this six-month period is due to expire in July. Can you give the committee some encouragement—or the applicant some satisfaction—that if they accept the six-month permit that the whole exercise will not come to a halt in July 2015 in the sense that any product that they may then have in development and being tested presumably at the University of New South Wales, or wherever it is being tested, would not actually expire in July 2015.

**Ms Arthy:** It is a complicated question for one minute to 11, but I will do my best.

**Senator BACK:** Don't feel bound by the time.

**Ms Arthy:** We have said to the applicant that we will honour the order of any farmer that has already had their herd tested and placed an order by the end of July, so that means that if they have put their order in it can still be supplied after 30 July. We are also monitoring what is happening with a potential change of the review of the risk assessment of BSE in the US, because that is a defining factor for us in terms of 30 July. We have—and we are planning to talk with the applicant very shortly—an internal clock of, say, the end of March to have another review of this to see whether the permit needs to be extended. That would then be given another three—

**Senator BACK:** This is a product of the Coopers company, I think, that was suspended because of the BSE content being manufactured in America. Could that product not have been manufactured in a country other than America that does not have the BSE cloud hanging over its head?

**Ms Arthy:** That is beyond my area of expertise. I will check whether my colleague has the answer.

**Senator BACK:** I am just wondering why it is that if the vaccine is unavailable in Australia it has not been deregistered, for example, and the market now be made clear.

**Ms Arthy:** I see where you are going. It is a commercial decision for the company about where they manufacture. What we are required to do by our legislation is that if a chemical is available for sale in the country then it is safe to use it. The applicant has kept their registration alive, so it is a commercial decision on their part. There is actually no mechanism for us to deregister it—unless we went down the chemical review and found there were issues with the chemical product.

**Senator BACK:** You did mention that one of the opportunities would be, in addition to or perhaps instead of, a six-month emergency permit to apply for registration. This is by the other company that wishes to be involved in the development of the strain-specific vaccine. Should they go down that process and then find the Footvax eligible again in Australia—because OIE or someone decided that the United States is no longer a BSE risk—would that then place in jeopardy the application process by this newer and second company?

**Ms Arthy:** If the company that is developing the strain-specific vaccine wants to put in an application for registration, what we do with other companies is if it is a genuine application we will continue the permit until the application is resolved. That is what we are trying to work on, with the applicant, to get an application in. It does not mean there would be a hiatus from the time the permit ends and the application is resolved.

**Senator BACK:** By permit you mean this emergency permit.

**Ms Arthy:** The emergency permit, yes.

**Senator BACK:** So if they made an application for registration—indeed, if they do apply and you give them approval for the emergency permit—it would remain in place until such time as the registration for that new vaccine is determined.

**Ms Arthy:** That is generally the case. I am saying 'generally' because we need to see the quality of the application.

**Senator BACK:** I am sure you do. I would obviously be very interested in the outcome and I will learn that in due course, I would think. Thank you.

**CHAIR:** I thank sincerely the professional staff, the people up there who have closely listened to all this all day—and deleted all the swear words—the assistance of the secretariat and the patience of the witnesses. Good evening.