



MEMO

TO: Directors
FROM: Bernie Murray
cc: Frank Clinton
Tom McLoughlin
DATE: 6 June 2013

SUBJECT: Request to amend consent conditions for Notification No. B/IE/12/02 (G0493-01) in respect of the deliberate release of a GM vaccine Equilis RhodE (for the treatment of *Rhodococcus equi* in foals) into the environment for purposes other than for placing on the market (veterinary trial).

Background:

The Agency issued a consent to Intervet International B.V., the Netherlands, to carry out a veterinary trial involving the administration of a genetically modified (GM) vaccine to foals on the 10th April 2013. Under the EPA consent, the trial is subject to strict conditions.

On 30th May 2013, the notifier informed the Agency of a change occurring within the release site of Belmont Stud Farm, the site of the proposed veterinary trial, which would impact on condition 6.8 of the abovementioned consent.

Consent condition 6.8 states

"No horses (other than those in the ownership of Belmont Stud Farm) shall be allowed into the release site until such time as all trial foals have been moved from the release site".

In accordance with article 21 of the GMO (Deliberate Release) Regulations, S.I. No. 500 of 2003 and condition 4 of the aforementioned consent conditions, the notifier is required to inform the Agency of new information that becomes available or any unintended change to the deliberate release which could have consequences for risks to human health or the environment. In addition, the notifier is required to inform the Agency of the measures taken or that they propose to take in relation to the matters concerned.

Unintended change

Prior to May 2013, Belmont Stud Farm was one of two stud farms in Ireland which held the Agency for frozen semen artificial insemination (AI) of mares in Ireland for one stallion. As of May 2013, the other stud farm (located in Co Kilkenny) ceased conducting frozen semen AI making Belmont Stud Farm the sole provider of frozen semen. According to the notifier the number of mares using this service is expected to be very small (minimum 8; maximum 25) and AI with this stallion's semen will be availed of by home mares as well as visiting or external mares.

This means that external mares (not in the ownership of Belmont Stud Farm) visiting the stud farm for purposes of AI must use the stocks room (i.e. a crush, photo attached) and scanning equipment, both of which must also be used for vaccination of the foals during the course of the veterinary trial. The admission of external mares to the release site while

presenting negligible risk, would contravene Condition 6.8.

Condition 6.8 was introduced in order to minimise traffic (both equine and human) into and from the release site.

The current situation is that the stocks room will be used by:

- home mares accompanied by their foals for AI of the mare and/or vaccination of the foal¹;
- visiting mares for AI.

The notifier has proposed that the stocks room be decontaminated in accordance with condition 8 following its use for each of the following:

- AI of home or visiting mares;
- vaccination of foals with GM vaccine.

There is no provision in the legislation for a technical amendment of the consent conditions. However, the Agency issued amended conditions pertaining to a GM sugar beet field trial in March 1999.

Recommendation:

Having evaluated the information and the procedures proposed, I am satisfied that there is no increase in risk to human health or the environment and recommend the following:

- Delete condition 6.8 since external mares will henceforth be permitted to enter the site;
- Amend condition 8.4 as follows;
The stable floors within the release site shall be cleaned and treated with disinfectant each time bedding is removed or changed. **The stocks room wherein vaccination / scanning will be performed shall be cleaned and treated with disinfectant following vaccination of foals with GM vaccine².**

I propose that the modified consent conditions be issued separately and that the notifier be instructed to retain the modified conditions with the original consent conditions granted by the EPA on 10/4/2013.



Signed: _____
Bernie Murray, Inspector

¹ The gestation period for a mare is 11 months, therefore a mare can be in heat within 1 month of having foaled and can undergo AI while the foal is still with the mare.

² Red text = new text



Stocks room, internal size approximately 14 ft x 12 ft with concrete flooring.