

*Extract from the Minutes of the 728th Licensing Meeting of the Environmental Protection Agency, held on 9 April 2013
at EPA Headquarters, Johnstown Castle Estate, Co. Wexford.*

1. The 728th Licensing Meeting of the Agency was held on 9 April 2013, in EPA Headquarters, Johnstown Castle Estate, Co. Wexford.

Directors Present: L Burke (Chair).
D Lynott; G O'Leary; M Crowe & M Ó Cinnéide

4. **GMO**

(i) *Veterinary Trial using a genetically modified vaccine*

Applicant: Merck Sharp & Dohme acting on behalf of Intervet International B.V.
Wim de Körverstraat,
35 NL – 5831 AN Boxmeer
The Netherlands

Location: Belmont Stud
Belmont
County Offaly

GMO Reg No: G0493-01

The Directors considered a recommendation from the Office of Climate, Licensing, Research and Resource Use that the Agency approve the recommended Consent to conduct a veterinary trial under Part II of the GMO (Deliberate Release) Regulations. The following documentation was submitted: Inspector's Report and Recommended Consent for notification number B/IE/12/02. Bernie Murray gave a verbal presentation.

Inspector's Report

The Directors noted the Inspector's Report.

Recommended Consent

The Directors agreed that the Notifier's address on the front page and the second page of the Consent should be amended to include '*The Netherlands*', the country in which the notifier is located.

Interpretation

Release Site Amend the definition and insert new last sentence as follows; '*(Townland Code: S14901; Townland Name Bellmount or Lisderg).*'

Condition

3.3 Amend the first sentence of the condition as follows; 'The notifier, *subject to the agreement of the Agency*, shall employ i.e. the Principal Investigator (PI).'

3.4 Amend the condition as follows; 'The *notifier through the PI* shall assigned tasks shall be.'

- 3.5 Amend the second sentence of the condition as follows; 'The notifier through the PI or a control.'
- 5.1 Insert new condition as follows; 'All foals shall be held within the release site for at least two weeks after last vaccination.'
- 5.1 & 5.2 Renumber existing conditions 5.1 and 5.2 as 5.2 and 5.3 respectively.
- 6.1 Amend the first sentence of the condition as follows; 'The notifier through the PI shall during the veterinary trial.'
- 6.5 Amend condition as follows; 'The notifier through the PI shall advise all staff that persons have serious consequences, should not enter the release site vacated the release site and the release site has been decontaminated as outlined under Condition 8.'
- 7.2 Amend condition as follows; 'The notifier through the PI shall inform for each of 2013, 2014, 2015 and 2016.'
- 7.3 Amend the first sentence of the condition as follows; 'The notifier through the PI shall part in the trial.'
- 7.4 Amend condition as follows; 'While recognising, the notifier through the PI been administered.'
- 7.5 Amend the condition as follows; 'The notifier through the PI each vaccine administration.'
- 7.7 Amend the condition as follows; 'In addition to the records the notifier through the PI the following:'
- 7.7.2 Amend the condition as follows; 'The movement of GM waste by SRCL Ltd. (GMO Register No. G0163-01), or other conditions 8.1 to 8.5 inclusive;'
- 7.7.3 Amend the second sentence of the condition as follows; 'These entries shall be co-signed by the notifier through the PI and the veterinary trial staff member;'
- 7.12 Amend the condition as follows; 'The Agency shall taken by the notifier through the PI further to the animal's death.'
- 8.1 Amend condition as follows; 'Contaminated disposables, from Belmont Stud Farm by SRCL Ltd. (GMO Register No. G0163-01, or other means prior to disposal.'
- 8.2.1 Amend the condition as follows; 'collected in double Farm by SRCL Ltd., (GMO Register No. G0163-01), or other prior to disposal, or'
- 8.3 Amend the condition as follows; 'Straw, litter, bedding removed by SRCL Ltd., (GMO Register No. G0163-01), or Belmont Stud Farm.'
- 8.5 Amend the condition as follows; 'Each year, following completion from Belmont Stud Farm by SRCL Ltd. (GMO Register No. G0163-01), or another registered means prior to disposal.'

Condition Reason

Conditions 6 Reason

Amend Reason as follows; 'To comply with the *GMO (Deliberate Release) Regulations S.I. No 500 of 2003* and to avoid adverse effects on human health and the environment.'

Condition 8 Reason

Insert new Reason as follows; 'To ensure inactivation of all waste material containing viable GMMs such that risks to human health and the environment are minimised.'

Condition 9 Reason

Insert new Reason as follows; *'To provide for adequate financing for the performance of site inspections.'*

Following discussion, the Directors approved the recommendation to grant a consent, as modified, to a deliberate release of GM vaccine Equilis RhodE (for the treatment of Rhodococcus equi in foals) into the environment for purposes other than for placing on the market to Intervet International B.V., Wim de Körverstraat, 35 NL – 5831 AN Boxmeer, The Netherlands, at Belmont Stud, Belmont, County Offaly, Register of Licence No G0493-01, subject to the conditions as set out in the Consent document.

