Extract from the Minutes of the 779th Licensing Meeting of the Environmental Protection Agency, held on 8 July 2014 at EPA Headquarters, Johnstown Castle Estate, Co Wexford.

1. The 779th Licensing Meeting of the Agency was held on 8 July 2014, in EPA Headquarters, Johnstown Castle Estate, Co Wexford.

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

4. **GMO Notificaion**

Clinical Trial using a genetically modified Organism

Applicant:	**The GUIDE Department**
	Wellcome Trust/ Health Research Board Clinical Research Facility
Trial Location:	**St James's Hospital**
	James's Street
	Dublin 8
GMO Reg No:	**G0536-01**

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 clinical trial under Part II of the GMO (Deliberate Release) Regulations. The following documentation was submitted: Inspectors Report and Recommended Consent for notification number B/IE/14/01 & B/IE/14/02.

Bernie Murray gave a verbal presentation.

Inspector's Report

The Directors noted the Inspector's Report. The Directors noted a typographical error on the cover page of the Inspector's Report. It was noted that Additional Information submitted under Article 19 of S.I. 500 of 2003 was received on 23 May 2014 and not 2013 as stated in the document.

Recommended Consent

Reasons for the Decision

The Directors agreed to amend the last sentence in the first paragraph as follows; 'Furthermore, the Agency believes that the *risks* to human ... ... of these GMOs are negligible.'

Condition

5.1.2 Amend Condition as follows; 'the containment measures set out in table ... ... level 1 measures including 'optional' measures *15 and 17.*'

Annex I

Amend Row 3 Column 3 to read as follows;

Notifier/PI shall make available to clinical trial staff:

- *SOPs set out under condition 5.2.1 (condition 5.2.2 and 6.1)*
- *make SOP on worker protection measures (Condition 6.1) available to clinical trial staff*

Amend Row 4 Column 3 to read as follows;
PI
- *shall implement SOPs set out under condition 5.2.1*
- *Consent conditions issued by the EPA (condition 3.2.2)*

Following discussion, the Directors approved the recommendation to grant a consent, as modified, to conduct a clinical trial under Part B of the GMO (Deliberate Release) Regulations to assess the safety and immunogenicity of recombinant Hepatitis C vaccines in Hepatitis C unaffected, HIV-1 seropositive individuals at the Wellcome Trust-HRB Clinical Research Facility, St James's Hospital, Dublin 8, Register of Licence No G0536-01, subject to the conditions as set out in the Consent document.