1. The 738th Licensing Meeting of the Agency was held on 25 June 2013, in EPA Regional Inspectorate, Richview, Clonskeagh, Dublin 14.

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

In Attendance: Pat Higgins(SKM Enviros), Gary Grantham(SKM Enviros) – Agenda Item 2(i);
K Motherway & D Flynn – Agenda Item 2;
F Clinton(via Video Conference) – Agenda Items 3 & 4;
T McLoughlin(via Video Conference) & B Murray(via Video Conference) – Agenda Item 3;
AM Donlon(via Video Conference) – Agenda Item 4;
S McCarthy(via Video Conference) & D Flynn – Agenda Item 6(ii)
A Fanning(via Video Conference) & T Stafford(via Video Conference) – Agenda Item 7;
T O'Reilly acted as Minute Secretary.

4. **GMO Notificaion**
Clinical Trial using a genetically modified Organism

Applicant: **The Center for Cellular and Molecular Therapeutics at the Children's Hospital of Philadelphia**
5th Floor Colket Translational Research Building
3501 Civic Center Boulevard
Philadelphia PA 19104-4319
USA

Trial Location: **St James's Hospital**
James's Street
Dublin 8

GMO Reg No: **G0498-01**

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/13/01.

Bernie Murray gave a verbal presentation.

Inspector's Report
The Directors noted the Inspector's Report.

Recommended Consent
Cover Page
Amend the first page of the Consent to include the notifier's legal representative in the EU as follows;

GMO Notifier's Legal Representative in the EU: *Alan Boyd Consultants Ltd (UK)*
Electra House
Crewe Business Park
Crewe
CW1 6GL
United Kingdom

Reasons for the decision

Amend the first sentence as follows: 'The Agency is satisfied … … … of this consent, the *notifier* will ensure that all … … …human health and the environment.'

Condition

8.4 Insert new last sentence as follows; '*Where GMO contaminated material retained for further investigation becomes the subject of further investigation, the Agency shall be informed of the outcome of that investigation.'*

Following discussion, the Directors approved the recommendation to grant a consent, as modified, to a deliberate release into the environment of recombinant hybrid Adeno-Associated Virus(AAV) which has been engineered to express human coagulation factor IX (AAV8-hFIX19), for purposes other than for placing on the market to the Center for cellular and Molecular Therapeutics at the Children's Hospital of Philadelphia, 5th Floor Colket Translational Research Building, 3501 Civic Center Boulevard, Philadelphia PA 19104-4319 USA, at St James's Hospital, James's Street, Dublin 8, Register of Licence No G0498-01, subject to the conditions as set out in the Consent document.