

Extract from the Minutes of the 998th Licensing Meeting of the Agency was held on 13 March 2020, in EPA Headquarters, Johnstown Castle Estate, County Wexford

1. The 998th Licensing Meeting of the Agency was held on 13 March 2020, in EPA Headquarters, Johnstown Castle Estate, County Wexford.

Directors Present: L Burke (Chair);
G O’Leary, M Crowe, M Lehane (via Video Conference)
& T Ryan (via Video Conference).

4. **GMO Notification**

Deliberate release to administer a gene therapy treatment under a managed access programme – Reg. No. G0726-01

Notifier: **Wellcome-HRB Clinical Research Facility
St James’s Hospital
James’s Street
Dublin 8
and
Children’s Hospital Ireland
Temple Street
Rotunda
Dublin 1**

Trial Location: **Wellcome-HRB Clinical Research Facility
St James’s Hospital
James’s Street
Dublin 8**

GMO Reg Entry No: G0726-01

The Directors considered a recommendation from the Office of Environmental Sustainability that the Agency approve the recommended consent to conduct a deliberate release under Part II of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003. The following documentation was submitted: report of the Inspector dated 12 March 2020 and recommended consent for GMO Register No G0726-01; Summary Notification Information Format number B/IE/20/01.

Bernie Murray and Marie O’Connor gave verbal presentations.

Inspector’s Report

The Directors noted the Inspector’s report, detailing the background to the application and the reasons for the recommendation. The Directors also noted the Inspector’s assessment that the risk to human health and the environment from the deliberate release of this GMO is negligible. The Directors further noted the public consultations, the consultation with other regulatory bodies and Government Departments and the replies from members of the GMO Advisory Committee.

Recommended Decision

Reasons for the Decision

Amend the final sentence of the first paragraph to read as follows: ‘Furthermore, the Agency believes that, *subject to compliance with the conditions of this consent*, the risks

to human health and the environment from the deliberate release of these GMOs are negligible.'

Following discussion, the Directors approved the Consent with conditions, as modified, for deliberate release of a GMO into the environment for purposes other than for placing on the market to Wellcome-HRB Clinical Research Facility, St James's Hospital, James's Street, Dublin 8 and Children's Hospital Ireland, Temple Street, Rotunda, Dublin 1, GMO, Register Entry No. G0726-01.