This is a general information note in relation to the making of representations to the EPA regarding a notification under Part II of the Genetically Modified Organisms (Deliberate Release) Regulations – S.I. No. 500 of 2003

1. The EPA has received a notification (G0726-01) on 25th February 2020 from The Clinical Research Facility at St James's Hospital, James's Street, Dublin 8, and Children's Health Ireland at Temple Street Hospital, Temple Street, Dublin 1, for the proposed deliberate release of a GMO into the environment for purposes other than placing on the market i.e. to administer a gene therapy product to paediatric patients under a managed access programme.

2. The notifier published a notice in The Irish Times on 27th February 2020 informing the public of the submission of this notification to the EPA and inviting any person or body to make representations on this notification in accordance with the requirements of Article 16(1) of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003.

3. Representations may be made by any person or body within a period of 28 days beginning on the day of publication of the notice. In this case, the notice was published on 27th February 2020, therefore the latest date for receipt of representations at the Headquarters of the Agency is **5 pm on 25th March 2020.**

4. Representations must be
   (a) made in writing
   (b) received by the EPA at the following address:

   The EPA
   P.O. Box 3000
   Johnstown Castle Estate
   Co Wexford.

   no later than 5 pm on 25th March 2020

   (c) accompanied by a fee of €10.
   Fees may be paid by cheque (made payable to the EPA) or by credit/debit card (please contact Agency HQ on 053 9160600). Payment will not be accepted at regional offices.

5. Representations which do not comply with the requirements set out in (4) above will be considered invalid and will be returned to the sender. The Agency will accept representations submitted by e-mail to licensing@epa.ie however, in keeping with point 4(b) above, the submission must be addressed to the EPA.

6. In the case of all valid representations received, the EPA will
   (a) acknowledge receipt of individual representations received, and
   (b) take them into consideration when making its decision.

The statutory requirements for making representations to the EPA are set out in Article 16, which is reproduced below for ease of reference.

Representations in respect of matters comprehended by this Part

16. (1) Any person or body may, within the period of 28 days beginning on the day of publication of a notice pursuant to article 15(1), make representations to the Agency in relation to the notification.

(2) Representations under sub-article (1) shall be—

(a) made in writing,

(b) addressed to the Agency at its headquarters,

(c) forwarded so as to reach the Agency within the period of 28 days beginning on the day of publication of the notice pursuant to article 15(1), and

(d) accompanied by the fee payable in accordance with article 48.

(3) Representations which do not comply with the requirements of sub-article (2) shall be invalid and shall be returned by the Agency to the sender, if known, together with any accompanying fee.

(4) Where the Agency receives representations in accordance with sub-articles (1) and (2), it shall—

(a) acknowledge receipt of the representations, and

(b) consider the representations in determining the notification.