Confidential Information – Deliberate Release

Procedure for submitting confidential information under Part B (field trials / clinical trials / veterinary trials) of the Deliberate Release legislation

Relevant Legislation

Confidential information is dealt with under Article 10 of the GMO (Deliberate Release) Regulations S.I. No 500 of 2003 (amended by the GMO (Deliberate Release) (Amendment) Regulations S.I. No 278 of 2021.

Procedure

1. A request for confidentiality must be made at the time of submission of the notification in the notification cover letter

2. The Notifier must provide verifiable justification in support of their request for confidentiality.

3. Confidential information in respect of deliberate release activities must be submitted in the following format.
   Two (2) copies of the notification text must be submitted as follows:

   (a) **Non-confidential information** – i.e. the full notification text with the confidential text deleted.
   The header on each page must be marked '**NON-CONFIDENTIAL**' so that it is immediately recognisable that this text is non-confidential.

   The deleted confidential text must be replaced with the wording **'INFORMATION DELETED FOR CONFIDENTIALITY PURPOSES.'**

   Non-confidential information will be made available on the Agency's website and to the Agency's GMO Advisory Committee where deemed necessary;

   (b) **Confidential information** – i.e. the full notification text inclusive of the confidential information.

   The header on each page must be marked '**CONFIDENTIAL**' so that it is immediately recognisable that this text is confidential.

   The confidential sections of the text must be in bold and italicised or coloured such that it stands out and is readily identifiable.

   Confidential information will only be viewed by Agency staff, by the Agency's GMO Advisory Committee and independent experts (where they have signed a confidentiality agreement) as deemed necessary by the Agency;

   (c) Details of any **annexes / supporting data** the Notifier wishes to keep confidential must be provided on a separate sheet and identified as confidential as per subpoint (b) above.

4. The confidential information must not be sent to the EPA by e-mail. Rather it must be sent by registered post or courier, as per the notifier's preference. It should be addressed to the GMO Inspector with whom the notifier is dealing. The notifier must inform the GMO Inspector and GMO administrative staff that the confidential information is in transit such that they may expect its receipt.

The Agency will consider the request and will decide which information will be considered confidential.

5. The Agency shall not decide that any of the information set out under Article 10(4) of the GMO (Deliberate Release) Regulations, S.I. No 500 of 2003, shall be confidential.

6. The Notifier will be informed of the Agency's decision in writing.

7. Further to a decision being made regarding the status of confidential information, the GMO Register will be completed within 14 days and forwarded to the Notifier for his/her agreement.

8. The Notifier must publish a notice in a newspaper informing members of the public about the proposed deliberate release within the same 14 day period.

9. The confidential information will be held in a locked safe for safekeeping and will be destroyed in-house once a decision on the notification has been made by the Agency..