

Confidential Information - Contained Use

Procedure for submitting confidential information under the Contained Use Legislation

Relevant Legislation

1. Confidential information is dealt with under Article 9 of the GMO (Contained Use) Regulations 2001 to 2010

Procedure

2. A request for confidentiality must be made at the time of submission of the application.
3. Confidential information must be submitted in accordance with the requirements of Article 9 of the GMO (Contained use) Regulations 2001 to 2010
4. The application form ("Information to be submitted for a Class 1 / 2 or 3 GMM contained use notification under the GMO (Contained Use) Regulations, 2001 to 2010") contains a section querying the inclusion of confidential information in the notification, to which the Notifier must respond 'YES' or 'NO' as appropriate.
5. Where the Notifier has responded 'YES' indicating the inclusion of confidential information, the Notifier must provide 'verifiable justification' in support of their request for confidentiality.
6. Confidential information in respect of contained use 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.

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.

5. The Agency has 14 days within which to make a decision as to which information (if any) shall be treated as confidential.

6. The Agency shall not decide that any of the information set out under Article 9(4) of the GMO (Contained Use) Regulations 2001 to 2010 shall be confidential.
7. The Notifier will be informed of the Agency's decision in writing.
8. 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.
9. The confidential information will be held in a locked safe for safekeeping and returned to the Notifier once a decision on the application has been made by the Agency.