

The Genetically Modified Organisms (Contained Use) Regulations 2014

Notification of Accidents Involving Genetically Modified Organisms (Regulation 22)

- Please provide the information relating to the accident (significant and unintended release) in as much detail as possible.
- Please note that information supplied in accident notifications is subject to the disclosure provisions set out in The Environmental Information Regulations 2004, regulation 12. Personal details are subject to the Data Protection Act. Information you do not wish to be disclosed should be provided in section 10.
- Please continue on separate sheets if required.
- Guidance on filling out this form is available at the end of this document.

For HSE use only

Date received by HSE

1. General data

Date of accident Time of accident

GM centre number

Name of organisation

Address of premises where contained use is carried out

Principal activity of installation

Classification of contained use (class 1, 2, 3 or 4 GMM or notifiable larger GMOs)

2. Type of accident

Please describe the type of accident, for example, mechanical failure of equipment (breakage/leakage etc), fire, explosion, failure in operation or equipment or standard procedures.

3. Organisms involved

Please provide details of the identity of the genetically modified organism(s) involved, including contained use notification numbers.

Approximate quantity of genetically modified organism(s) involved.

Form and/or concentration of organisms involved.

4. Description of the circumstances of the accident

Please describe how the accident is thought to have occurred.

5. Emergency plan

Was there an emergency plan drawn up in advance?

Yes No

If yes, please provide the name of the person who drew up the emergency plan in the box provided in Section 10 (Confidential information) of this form.

6. Emergency measures taken

Please describe action taken at the time of the incident and any action taken since.

(a) Inside the installation:

(b) Outside the installation:

7. Assumed or established cause(s) of accident

Please provide information on the causes of the accident and action taken to establish those causes. (If not known, the information should be supplied as soon as possible).

8. Nature and extent of exposure

Please provide information on the nature and extent of exposure.

(a) Inside the installation:

Please include information on:

- persons exposed to the genetically modified organism (any names of individuals should be given in Section 10)
- casualties
- damage to health
- material damage
- damage affecting the containment measures (equipment and facility)
- whether the danger to health is still present
- if the danger still exists, details should be provided.

8. Nature and extent of exposure (continued)

(b) Outside the installation/to the environment:

Please include information on:

- persons exposed to the accident (any names of individuals should be given in Section 10)
- casualties
- damage to health
- types of environments exposed (water, sewage systems, agricultural land, natural environments)
- material damage
- damage affecting the containment measures (equipment and facility)
- damage to the environment (immediate and possible long term effects)
- whether the danger is still present
- if the danger still exists, details should be provided.

Note: Information on damage to the environment need only be supplied for genetically modified micro-organisms

9. Member States already informed bilaterally of the accident

Please provide details of any European Economic Area states that have been informed of the accident.

Confidential Information

10. Non-disclosable information not supplied in 1-9

Please provide full details not provided in 1 - 9, and justification of the need to keep this information exempt from disclosure.

Name of person responsible for supervision and safety of GM contained use at the premises (as provided in premises notification or contained use notification forms).

Name of person who drew up the emergency plan

Name of person notifying the accident

Please send completed forms to:

The Notifications Officer
Health and Safety Executive
Building 5S2 Redgrave Court
Merton Road
Bootle
Merseyside
L20 7HS

Email address:

bioagents@hse.gsi.gov.uk

Please use this sheet for additional comments

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NOTES FOR GUIDANCE

Notifying accidents

1. Regulation 22 of the Genetically Modified Organisms (Contained Use) Regulations 2014, GMO(CU), place responsibility on centres to immediately notify the Competent Authority (CA) of accidents as defined in the regulations, involving genetically modified organisms. There may be situations where as well as notifying the Competent Authority under GMO(CU), HSE also requires notification under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR), for example, if a person were to require hospital treatment. This guidance aims to explain what should be considered to be an accident for the purposes of the GMO(CU) legislation and what information should be provided in the accident notification.

What is an accident?

2. Regulation 2(1) of GMO(CU) defines an accident as:

“... an incident involving a significant and unintended release of genetically modified organisms in the course of a contained use which presents an immediate or delayed hazard to human health or to the environment”.

3. Therefore, an accident is where a GMM is released in such a way that it poses an immediate or delayed risk to human health or the environment, or where a larger GMO is released in such a way that it poses an immediate or delayed risk to human health. Accidents which result in release of GMMs and larger GMOs from primary containment, but not the laboratory or building, may therefore constitute an accident, depending on the nature of the GMM or larger GMO.
4. Situations, which might constitute an accident, depending on the organisms involved, their mode of transmission and the nature of the accident, might include:
 - the spillage of any class 3 GMM outside of a microbiological safety cabinet (MSC) or other primary container;
 - a major spillage of a class 3 GMM within a MSC;
 - the spillage of any class 2 GMM outside of a MSC or other primary container, where it is thought likely that an individual or the environment could have been exposed during the spill or during decontamination;
 - the release or escape of a GMO, other than a GMM which could cause harm to human health, for example, by acting as a novel disease reservoir;
 - infection (classical) of a person with a (replication competent) GMM, as this constitutes a significant and unintended release.
5. Spillage or release of a class 1 GMM is unlikely to count as an accident as class 1 GMMs are unable to pose a risk to human health or the environment. If you are in any doubt as to whether you need to notify the CA, please contact the inspection team. Please note that any intention to release a GMO is subject to the Genetically Modified Organisms (Deliberate Release) Regulations 2002.

What information do you have to provide?

6. Regulation 22 of GMO(CU) states that ‘if an accident occurs, a person responsible for contained use must immediately inform the competent authority of the accident and must provide the following information:
 - the circumstances of the accident;
 - the identity and quantity of the genetically modified organisms concerned;
 - any information necessary to assess the effects of the accident on the health of the general population, and, in the case of a GMM, on the environment; and
 - any measures taken in response to the accident.

Who do you contact?

7. Accident notifications should be sent to:

The Notifications Officer
Health and Safety Executive
Room 5S2 Redgrave Court
Merton Road
Bootle
Merseyside
L20 7HS

Email Address: bioagents@hse.gsi.gov.uk

8. The Notifications Officer receives notifications on behalf of the CA. Details of the accident should be submitted using this form to ensure the CA receives all the relevant information regarding the accident. However, you are advised to inform HSE immediately of any incident by telephone in the first instance.

NOTES FOR GUIDANCE cont'd

What will the CA do with the information?

9. The Notification Officer will circulate the information provided to all members of the CA. However, regulation 27 also places duties on the CA where it is informed of an accident. These include:
- to ensure that any necessary measures are taken;
 - immediately inform those EEA States which could be affected by the accident;
 - collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit their effects;
 - send to the European Commission:
 - information on the circumstances of the accident; the identity and quantity of GMOs concerned and the measures taken in response to the accident;
 - information on the effectiveness of the measures taken in response to the accident; and
 - an analysis of the accident, including recommendations to limit its effect and to avoid similar accidents.
10. This means that HSE inspectors will need to investigate the accident to obtain all the information to make recommendations to avoid similar accidents and to share the lessons learnt with our European counterparts. HSE inspectors will therefore regard any attempt to avoid notification of an accident as a serious matter.

Information added to the public register

11. The CA are required to publish when an accident occurs at a premises on the public register. No detailed information about the accident is published, only the date of the accident at the premises concerned.

Non-disclosable information provided in an accident notification

12. Although the detailed information provided on the accident notification form is not placed on the public register, it is kept on HSE files and therefore will be made available to the public if requested. The Environmental Information Regulations 2004 (EIR 2004), regulation 12 sets out the disclosure provisions for information provided in an accident notification. These provisions are essentially the same as for other notified information and ensure that information can be made available to the public if requested, unless the CA agrees at the time of the request that the information should not be disclosed. However, you must provide full information to the CA to allow them to carry out their duties under regulation 27. If a request for information is received, the CA will decide whether the information provided in the accident notification should be exempt from disclosure on the grounds that it contains:
- information relating to matters affecting international relations, national defence or public security;
 - information relating to, or to anything which is or has been the subject matter of, any legal or other proceedings (whether actual or prospective);
 - information relating to the confidential deliberations of any relevant person or to the contents of any internal communications of a body corporate or other undertaking or organisation;
 - information relating to matters to which any commercial or industrial confidentiality attaches or affecting any intellectual property.
13. Full justification of the need to keep the information exempt from disclosure must be provided with any request for non-disclosure. If, on receipt of a request, the CA decides to release this information in accordance with the requirements of Freedom of Information Act 2000 and EIR 2004, it will inform the centre in writing before releasing the information. You are required to inform the CA of any changes in circumstances relating to the request for non-disclosure.
14. Please note that all personal information is confidential and provision is made for this on the form.