

GM RA Number

**SGUL RISK ASSESSMENT FOR GENETICALLY MODIFIED PLANTS**

This is SGUL’s Risk Assessment Form for Genetically Modified Plants ONLY. If you intend to use or create Plant-associated Genetically Modified Microorganism you should also complete a GMM RA form.

**1 – Title of the project.**

**2 – Characteristics of the GM plant(s):**

Unless you are making a request for non-disclosure in relation to intellectual property rights this section must be completed in detail, otherwise, you must include at least general characteristics of the GMO(s).

2.1 – **Species and variety of the parental organism**. (If biological containment will be used include details of the disabling mutation(s).)

**2.2 – Origin and function of the genetic material involved.** (Preferably a list of genes, gene families, or gene functions should be included. Genes must be identified in a way that an outside reviewer will have a general idea of their function. A three letter name may not be sufficient. When the function of the gene is unknown, providing the function of any know homologues may help.)

**Risk Assessment**

The Genetically Modified Organisms (Contained Use) Regulations 2014 and the Environmental Protection Act (EPA) 1990 require that suitable and sufficient assessment of the risks to human health and the environment be carried out for activities involving the genetic modification of organisms. The primary role of the risk assessment is to determine the appropriate control measures that are needed to afford maximum protection to both human health and the environment. This, in turn, will determine the notification requirements for the proposed work.

**3 – Hazards arising from the activity in relation to the environment**:

Note that it has been made clear by the SACGM that The Regulator will not accept simple statements such as ‘it is not anticipated’ without proper justification and supporting evidence.

**3.1 – Capacity of the GM plant to survive, become established and disseminate: (**This includes its ability to compete with or displace other plants.)

**3.2 – Hazards associated with the inserted genetic material:** (e.g. does the insert encodes a toxic product which could have adverse effects on animals, plants, or the soil’s ecology?)

**3.3 – Potential for transfer of genetic material between the GM plant and other organisms:** (This includes retrotransfer, lateral transfer, and sexual transmission.)

**4 – Hazards arising from the activity in relation to human health**: (You should focus on the effects of the modification rather than on the hazards posed by the parental organism itself, e.g. increased allergenic or toxic effects, potential to act as a novel reservoir for human disease, or adverse effects to humans caused by altered physical factors. It is particularly important to carefully assess the transfer of genes that are novel and not normally found in plants. Examples of such genes would include those encoding biologically active, pharmaceutical or industrial products. The inadvertent transfer of such genes to edible species might pose a particular risk.)

**5 –Risks associated with the activity (consequences and likelihood of the hazards listed above being realised.)**

**5.1 – Risks to the environment:**

**5.2 – Risks to human health:**

**Yes** [ ]

**No** [ ]

If the answer to this question is “Yes” this activity will have to be notified to the Health and Safety Executive.

**6 – Control Measures:** (There is no regulatory requirement to set a formal containment level (i.e. Containment Level 1, 2, 3 or 4) for work with GM plants. However, it may be helpful to set a containment level that is appropriate for the facility in which the work will be carried out. A guide on the control measures for each containment level is provided on the SACGM Compendium of Guidance† and Schedule 8 of Contained Use regulation 2014‡. Otherwise, list the control measures to be used).

NOTE: Containment measures are not only based on the use of physical barriers, but rely on rigorous procedural and management control as well as biological factors which limit the plant’s ability to survive and disseminate.

**Does the GM plant require containment measures above the containment level of the plant growing facility?**

**Yes** [ ]

**No** [ ]

**7 – Are all the non-GM risks in this activity adequately covered by up-to-date COSHH RAs or other risk assessment(s)?**

**Yes** [ ]

**No** [ ]

**8 – Describe the waste management measures that will be applied:** (Describe how SOLID and LIQUID waste material will be treated and disposed.)

**9 –Has the principal investigator notified this activity to the head of the relevant institute and received approval to carry out the work?**

**Yes** [ ]

**No** [ ]

Name of the head of the institute:

**10 – Name and email address of the Principal Investigator.** (All the communication regarding this GM activity will be via de PI named here.)

**11 –Name, email address, and level of competency of each worker involved in the activity (1 = fully competent, 2 = needs supervisor’s advice and approval before work, 3 = requires direct supervision)**

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| Name | Email address | Competency level |
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NOTES

† The SACGM Compendium of guidance Part 4: Genetic modification work that involves plants

(including plant-associated genetically modified microorganisms) page 69-72

‡ The Genetically Modified Organisms (Contained Use) Regulations 2014, Schedule 8, tables 1a and 1b.