Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Headquarters
PO Box 3000
Johnstown Castle Estate
County Wexford
Ireland

Consent for the Contained Use of Class 2 GMMs

GMO Register Number: G0163-02

GMO Notifier/User: SRCL Limited
Unit 1A Allied Industrial Estate
Kylemore Road
Dublin 10

Location of Contained Use: SRCL Limited
Unit 1A Allied Industrial Estate
Kylemore Road
Dublin 10

Consent Conditions for GMO Register Entry No. G0163-02

Consent to the Contained Use of Class 2 GMMs.

The EPA, in exercise of the powers conferred on it by the Genetically Modified Organisms (Contained Use) Regulations, 2001 to 2010 grants consent to:

SRCL Limited
Unit 1A Allied Industrial Estate
Kylemore Road
Dublin 10

for the contained use of Class 2 GMMs (as per GMO Register Entry Number G0163-02) in:

SRCL Limited
Unit 1A Allied Industrial Estate
Kylemore Road
Dublin 10

subject to eight conditions as set out in the conditions/annexes attached hereto.

REASONS FOR THE DECISION

The Agency is satisfied on the basis of the notification and supporting documentation received from the notifier, in respect of the contained use of Class 2 GMMs in accordance with Part II of the Regulations, that, subject to compliance with the conditions of this consent, the user will ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment. Furthermore, the Agency believes that the risk to human health and the environment from the use of this Class 2 GMM activity is low and that level 2 containment is appropriate.

In accordance with article 16(4) of GMO (Contained Use) Regulations, 2001 to 2010, '*...a consent granted for the first time use of a premises for a particular class of contained use shall be treated as a consent for the first time use of the premises for that class and for any lower class of contained use ....*' Therefore, this Class 2 GMM activity also covers Class 1 GMM activities.

CONSENT FOR

Consent is granted in accordance with Article 26 of the GMO (Contained Use) Regulations, 2001 to 2010, for the contained use of a Class 2 GMM activity.

SEALED by the Seal of the Agency on this, the 30th day of May 2024

PRESENT when the seal of the Agency was affixed hereto:

Anne Lucey

Anne Lucey, Authorised Person

INTERPRETATION

Accident

Any incident involving a significant and unintended release of a genetically modified micro-organism in the course of its contained use, which could present an immediate or delayed hazard to human health or the environment.

Agency

The Environmental Protection Agency (EPA).

Classification of Contained Use

The contained use shall be classified into one of the following classes:

Class 1 – Activities of no or negligible risk, that is to say activities for which level 1 containment, as set out in Table IA, Annex II, is appropriate to protect human health as well as the environment;

Class 2 – Activities of low risk, that is to say activities for which level 2 containment, as set out in Table IA, Annex II, is appropriate to protect human health as well as the environment;

Class 3 – Activities of moderate risk, that is to say activities for which level 3 containment, as set out in Table IA, Annex II, is appropriate to protect human health as well as the environment;

Class 4 – Activities of high risk, that is to say activities for which level 4 containment, as set out in Table IA, Annex II, is appropriate to protect human health as well as the environment.

Competent Authority

The Environmental Protection Agency is the Competent Authority for the purposes of the GMO (Contained Use) Regulations, 2001 to 2010.

Consent

Consent issued in accordance with Article 26 of the GMO (Contained Use) Regulations, 2001 to 2010.

Contained Use

"Contained use" means any activity in which organisms (including micro-organisms) are genetically modified or in which such organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which specific containment and other protective measures are used to limit their contact with the general public and the environment.

Containment Level	Containment level refers to the containment and control measures required to ensure safe containment of the GMM within the contained use facility: Level 1 containment - appropriate for Class 1 activities; Level 2 containment - appropriate for Class 2 activities; Level 3 containment - appropriate for Class 3 activities; Level 4 containment - appropriate for Class 4 activities.
CL1	Containment Level 1.
CL2	Containment Level 2.
Emergency Services	The fire, ambulance and Garda services in the geographical area where consent for the contained use activity of GMMs is granted.
First time use of a premises	The first time use of a premises means the first time use of a premises for an activity involving a contained use of a genetically modified micro-organism.
GMM	Genetically Modified Micro-organism means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination or by a combination of both.
GMO	Genetically Modified Organism means an organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination or by a combination of both. The term GMO encompasses GMMs, GM plants and GM animals.
GMO Register	A register of GMO users in Ireland, which is available for inspection at Agency Headquarters by any person during office hours. Each register entry provides details of the contained use activity.
GMP	Good Microbiological Practice.
GOSH	Good Occupational Safety and Hygiene.

Micro-organism	Micro-organism means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture.
Notification	A notification means the presentation of required information to the competent authority.
Notifier	Any legal or natural person who submits a notification to the Competent Authority under the GMO (Contained Use) Regulations, 2001 to 2010.
Obligation	A consent holder, or any other person carrying out an activity involving a contained use, shall ensure that all appropriate measures are taken to avoid adverse effects on human health or the environment.
Premises	Any facility, including a laboratory, in which an activity involving the contained use of a genetically modified micro-organism is carried out or where it is proposed to carry out such an activity or operation.
Regulations	GMO (Contained Use) Regulations, 2001 to 2010.
SOPs	Standard Operating Procedures.
User	Any legal or natural person responsible for a contained use, or for giving a notification of, or for meeting any other requirements in relation to, a proposed contained use.

CONDITIONS

CONDITION 1. SCOPE

1.1 These conditions are for the purposes of compliance with the Regulations. Nothing in these conditions shall be construed as negating the user's statutory obligations or requirements under any other enactments or regulations.

1.2 The authorisation hereby granted is for the contained use of a Class 2 GMM activity and any Class 1 GMM work.

1.3 No higher class of contained use activity (i.e. the contained use of Class 3 or Class 4 GMMs nor the contained use of GMOs) shall take place until such time as further consent is obtained under Article 19 or Article 36, respectively, of the GMO (Contained Use) Regulations, 2001 to 2010.

1.4 Only those GMMs detailed in GMO Register Entry Number G0163-02 shall be stored or handled at the location of the contained use.

1.5 The user is required to submit annual reports to the Agency as set out under Condition 5.

Reason: To clarify the scope of the requirement

CONDITION 2. AVOIDANCE OF ADVERSE EFFECTS ON HUMAN HEALTH AND THE ENVIRONMENT

2.1 In order to ensure the safety of personnel receiving and handling GM waste, the user shall draw up and implement SOPs on the following procedures:

(a) Training of staff;
(b) Safe packaging, receipt, inspection, storage and handling of GMM contaminated solid waste;
(c) Personal protective clothing and equipment;
(d) Measures for limiting access to the facility;
(e) Maintenance of records relating to training and accidents/incidents.

2.2 The user shall implement a staff training programme to provide for adequate training of all staff involved in the receipt, storage and handling of GMM waste in the following areas:

(a) Instruction and training in the safe handling, risks and procedures relating to Class 2 GMMs;
(b) Training in the SOPs set out under Condition 2.1 and the risk assessment conducted in respect of the Class 2 GMM activity.

2.3 The user or any other person involved in the receipt, inspection, storage and handling of GM waste shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment.

2.4 Only members of staff that have undergone training in accordance with Condition 2.2 shall be permitted to carry out the work described in GMO Register Number G0163-02.

2.5 The user shall only accept Class 2 GMM liquid and solid waste from EPA registered Class 2 GMM users.

2.6 Prior to GMM waste acceptance from new customers, the user shall verify that the customer is authorised under the conditions of their GMM consent to send waste off-site for treatment.

2.7 The labels on all GMM waste entering the plant shall be inspected to ensure it complies with the corresponding European Waste Catalogue (EWC) code and the description of the waste provided by the customer.

2.8 Any defective packaging noted during inspection shall be moved immediately to a secure bunded location and reported to management as an incident.

2.9 Verification of GMM waste incineration shall be sent to the customer for their records.

Reason: To avoid adverse effects on human health and the environment and to ensure a high level of safety

CONDITION 3. RISK MANAGEMENT AND CONTAINMENT MEASURES

3.1 The Risk Assessment and the containment measures applied shall be reviewed periodically by the user and shall be reviewed immediately if there is reason to consider that:

3.1.1 The containment measures applied are no longer adequate or the class assigned to the contained use is no longer correct; or,
3.1.2 In the light of new scientific or technical knowledge the assessment is no longer appropriate.

3.2 Where the user has reason to consider that containment measures applied to the contained use are no longer adequate or that a class assigned to a contained use is no longer correct or that the risk assessment carried out is no longer appropriate, the user shall:

3.2.1 Discontinue the contained use;
3.2.2 Carry out a review in accordance with Condition 3.1;
3.2.3 Immediately inform the Agency in writing of the review to be carried out in accordance with Condition 3.1;
3.2.4 Immediately on the conclusion of the review give the Agency a report on the outcome;
3.2.5 Obtain written consent from the Agency permitting the recommencement of the contained use activity.

3.3 Designated hand wash facilities shall be made available for personnel.

Reason: To ensure that containment measures are appropriate to the risk involved

CONDITION 4. NEW INFORMATION

4.1 Where the user becomes aware of new information which could have significant consequences for the risks posed by the contained use for human health or the environment, the user shall discontinue the contained use and, as soon as practicable, inform the Agency.

4.2 Prior to resuming the contained use, which was discontinued in accordance with Condition 4.1, the user shall:

(a) Review the Risk Assessment and the class and level of containment applied;
(b) Submit an amended notification to the Agency; and,
(c) Obtain written consent from the Agency permitting the recommencement of the contained use activity.

Reason: To minimise risks to human health and the environment and to inform the Agency of new information as required by the Regulations

CONDITION 5. RECORD KEEPING AND REPORTING

5.1 In the event that the GMM contained use activity ceases, the user shall notify the Agency of such in writing.

5.2 Records shall be maintained in respect of:

(a) Training records for members of staff associated with the GMM contained use activity, in accordance with Condition 2.2;
(b) All GMM related accidents/incidents;
(c) GMM customers (producers of GM waste) that have a contract with SRCL Ltd. for the acceptance and overseas incineration of GMM waste and their corresponding GMO Register Numbers;
(d) The measures taken to comply with Conditions 2.6 to 2.9;
(e) GM waste sent off site for inactivation and verification of inactivation.

These records shall be made available to the Agency on request. A report on these records shall be submitted and received by the Agency no later than 31st March of the year following the year being reported on.

Reason: To maintain written records and to comply with legislative requirements

CONDITION 6. WASTE INACTVIATION

6.1 Off-site Inactivation:

6.1.1 Waste material containing viable GMMs may be sent to an off-site inactivation facility agreed in advance with the Agency. The agreed facility shall be registered and regulated in accordance with the Regulations or Directive 2009/41/EC on the Contained Use of GMMs in another Member State.

6.1.2 Any waste sent off-site shall be sent in accordance with the provisions of the Waste Management (Shipments of Waste) Regulations, S.I. No. 419 of 2007.

Reason: To ensure inactivation of all waste material containing viable GMMs such that risks to human health and the environment are minimised

CONDITION 7. ESTABLISHMENT OF A BIOLOGICAL SAFETY COMMITTEE

7.1 A Biological Safety Committee (BSC) shall be established whose role it will be to review the risk assessments in respect regard to biological safety procedures.

Reason: To provide for a high level of safety and to comply with legislative requirements

CONDITION 8. ACCIDENT PROCEDURES

8.1 In the event of an accident involving the GMM and as defined by the glossary, the user shall immediately inform the Agency and shall provide:

8.1.1 Details of date and time of the accident and detailed information on the circumstances of the accident;

8.1.2 The identity of the GMM and the quantities involved;

8.1.3 Any information necessary to assess the effects of the accident on the health of the public or on the environment;

8.1.4 Full and detailed information on the action taken at the time of the accident and any ensuing actions;

8.1.5 Measures taken to avoid recurrence of the accident.

Reason: To ensure the notification of accidents involving GMMs

Sealed by the seal of the Agency on this, the 30th day of May 2024

PRESENT when the seal of the Agency was affixed hereto:

Anne Lucey

Anne Lucey, Authorised Person

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