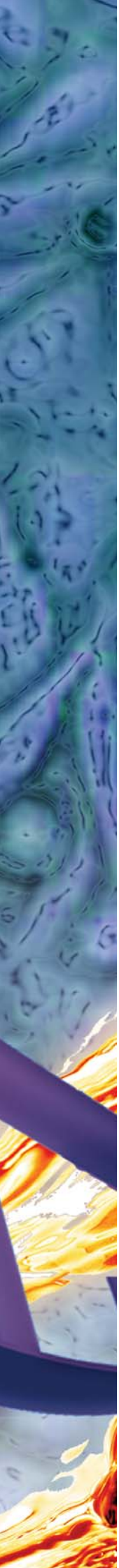

Depositing cell lines with ECACC

Dear Researcher,

The European Collection of Cell Cultures (ECACC) was founded in 1984 when it formed part of the Centre for Applied Microbiology and Research (CAMR) at Porton Down. Over the ensuing 20 years ECACC has developed into one of the largest collections of animal and human cell lines in the world, with more than 50,000 different cell lines in its cryostorage repository.

ECACC has always been, and remains a not-for-profit, strategic business unit operating within the public sector. In 2003 the parent organisation, CAMR, became a part of the newly formed Health Protection Agency, to which organisation ECACC now contributes.

The core business of ECACC is the storage, maintenance and distribution of authenticated animal and human cell lines. Though ECACC seeks to recover most of its costs through distribution fees, it receives additional support for infrastructure from the research councils, notably the MRC, and recently from the Wellcome Trust. This reflects the support that ECACC has always provided to a variety of UK research efforts such as the Human Genome Mapping Project.

ECACC does not own any of the cell lines in its collections. Rather, ECACC acts as the custodian for these cell lines in order that they can be made available for research purposes in a regulated and standardised form. Scientists who develop new cell lines are invited to deposit the cell lines with ECACC in order that:

1. The cell line is secured for the long term.
2. The cell line can be authenticated, characterised and catalogued.
3. The integrity of the cell line can be maintained and protected in a dedicated and highly regulated environment.
4. The cell line can be advertised and made available for research use worldwide.

ECACC makes no charge, to the Depositor, for this service and aims to recover its costs from distribution fees for the cell lines. ECACC's Information Pack on cell line deposition includes details of benefits and the contractual options that are available to the Depositor. Normally the income that can be realised from the sale of a cell line for research use is not sufficient to justify a full license agreement. However, our standard Deposit Agreement, provides that a license agreement may be introduced, at the request of the Depositor, if the value of the cell line proves to be unexpectedly high.

ECACC's promotion of a cell line will inevitably increase the use and awareness of the cell line and possibly attract commercial interest. In the event that ECACC is approached by a party that wishes to make commercial use of the cell line, such an expression of interest will be referred back to the Depositor. ECACC's support of a cell line generally increases its commercial value.

Further information about ECACC may be found on our website (ecacc.org.uk), or you may ask to speak to Dr Peter Thraves, who is responsible for ECACC's new cell accessioning programme, by telephoning + 44 (0)1980 612684 or by e-mail at: ecacc.technical@hpa.org.uk

Please contact us if you are interested in the possibility that ECACC might work for your cell lines.

Yours sincerely,

David Lewis PhD
Head of HPA Culture Collections

European Collection of Cell Cultures, Health Protection Agency, Centre for Emergency Preparedness and Response, Porton Down, Salisbury, Wiltshire, SP4 0JG, UK

Tel: 44 (0) 1980 612512 **Fax:** 44 (0) 1980 611315 **E-mail:** ecacc@hpa.org.uk **Web site:** www.ecacc.org.uk

Terms and Conditions of Supply

CELL LINES FROM ECACC'S GENERAL COLLECTION

FOR THE PURPOSES OF THESE TERMS AND CONDITIONS ECACC SHALL MEAN THE 'HEALTH PROTECTION AGENCY' ACTING THROUGH ITS OPERATING DIVISION 'THE EUROPEAN COLLECTION OF CELL CULTURES'.

1. The Recipient hereby confirms that he/she is authorised to receive, for and on behalf of his/her employer, the cell lines and that these terms and conditions shall be binding upon said employer.

2. The Recipient shall use the Cell Lines, and any progeny, derivatives or products thereof (collectively 'Derivatives') for research purposes only. Notwithstanding the foregoing, in no event shall the Cell Lines or Derivatives be directly or indirectly applied to human subjects.

3. Unless otherwise agreed by ECACC, the Cell Lines and Derivatives shall not be incorporated into any service or product for sale, or utilised in the commercial provision or production of any service or product for sale.

4. The Recipient shall not distribute the Cell Lines or Derivatives within their organisation unless the individuals receiving the same are bound by these terms and conditions. The employing organisation of the Recipient shall not distribute the Cell Lines or Derivatives to any affiliated or associated organisations without ECACC's prior written consent.

5. As between recipient and ECACC all rights of ownership over the Cell Lines and Derivatives and all intellectual property rights subsisting therein, shall rest in ECACC or third party depositor. No licence is granted to the recipient, except that specified in Clause 2.

6. ECACC shall have no liability to the Recipient in the event that the Cell Lines and/or Derivatives infringe any intellectual property right of a third party and all warranties relating thereto whether expressed or implied, by statute or at common law, are hereby excluded.

7. The Recipient shall indemnify ECACC, and the original depositors of the Cell Lines with ECACC, against all loss, actions, costs, claims, demands, expenses and liabilities which ECACC or the said depositors may incur, either at common law or by statute, in respect of death or personal injury or in respect of any loss or destruction of or damage to property (except to the extent that the foregoing is as a result of any negligence on the part of ECACC) which occurs in connection with the Recipient's use of the Cell Lines and/or Derivatives (or that of the Recipient's employer, where the Recipient is an individual).

8. The Recipient shall abide by all applicable governmental and regulatory regulations and guidelines when handling and using the Cell Lines and Derivatives, and shall ensure that he/she, and any colleagues and/or employees handling or using the same, is technically qualified to do so and are not under any restrictions in relation thereto.

9. The Recipient shall indemnify ECACC against any and all loss, actions, costs, claims, demands, expenses and liabilities incurred by ECACC and/or the aforesaid depositors, by reason of any breach of these terms and conditions.

10. In any publication making reference to the Cell Lines and/or Derivatives, due acknowledgement shall be given of the source of the Cell Lines (quoting ECACC's catalogue reference number) and that accurate reference is made to the work of the original depositor.

11. The above terms and conditions shall constitute a contract between ECACC and the Recipient made in England and governed by English law.

12. In addition to the above terms and conditions, ECACC may impose further terms and conditions upon the supply of a particular Cell Line. Should ECACC seek to do so, ECACC shall provide the Recipient with details of these additional terms and conditions either upon request for, or receipt of, an order from the Recipient. Such additional terms and conditions shall, upon acceptance by the Recipient, and in addition to those terms and conditions set out above, be deemed to be incorporated into the relevant supply contract.

Effective from 9 February 1998

ECACC use only

Accession No:

Depositors File:

Deposit Form - General Collection

Use this form for depositing cell lines into the ECACC General Collection

Please complete as fully as possible then e-mail or fax back to ECACC PRIOR to cell shipment.

Please post the original copy to ECACC.

Basic Information:

Cell Line Name . . . . . .

Depositor Name . . . . . .

Depositor Address . . . . . .

Telephone no. . . . . E-mail address . . . . . .

Depositor = Originator? Yes ☐ No ☐ If No, please give details of the Originator . . . . . .

. . . . . .

Species . . . . . .

Strain . . . . . .

Organ or Tissue . . . . . .

Cell Type . . . . . .

Morphology . . . . . .

Growth Characteristics . . . . . .

Growth Medium . . . . . .

. . . . . .

Subculture Routine: For Adherent Cells: Use split ratios of between 1: ☐ and 1: ☐

For Suspension Cells: Seed cells at densities between . . . . . cells/ml and . . . . . cells/ml

Saturation Density . . . . . Temp . . . . . °C . . . . . $\%CO_2$

Passage or Population Doubling Number of cells being shipped . . . . . .

Has the cell line been routinely cultured in the presence of antibiotics? Yes ☐ No ☐

Has the cell line been routinely tested for mycoplasma contamination? Yes ☐ No ☐ Test result: +ve ☐ -ve ☐

Mycoplasma eradicated? Yes ☐ No ☐ Give details of method used to eradicate mycoplasma: . . . . . .

. . . . . .

Additional Cell Line Information:

Have the cells been transformed? . . . . . ; Transforming agent if used . . . . . .

Are the Cells Tumourigenic? Yes ☐ No ☐ If Yes, to which species . . . . . .

Karyotype (if known) . . . . . Known Receptors . . . . . .

Characteristics of Interest . . . . . .

. . . . . .

Applications . . . . . .

. . . . . .

References Including any Patents Filed . . . . . .

I have been offered, and I have read, the full version ECACC Deposit Agreement. I understand that I/my organisation remains the Owner of the Cell Line. I hereby grant ECACC unrestricted rights to market and distribute the Cell Line on behalf of (name) . . . . . Signed . . . . . Date . . . . . .

European Collection of Cell Cultures, Health Protection Agency, Centre for Emergency Preparedness and Response, Porton Down, Salisbury, Wiltshire, SP4 0JG, UK

Tel: 44 (0) 1980 612512 Fax: 44 (0) 1980 611315 E-mail: ecacc@hpa.org.uk Website: www.ecacc.org.uk

ECACC use only

Accession No:

Depositors File:

Deposit Form - Hybridoma Collection

Use this form for depositing cell lines into the ECACC Hybridoma Collection.

Please complete as fully as possible then e-mail or fax back to ECACC PRIOR to cell shipment.

Please post the original copy to ECACC.

Basic Information:

Cell Line Name . . . . . .

Depositor Name . . . . . .

Depositor Address . . . . . .

Telephone no. . . . . E-mail address . . . . . .

Depositor = Originator? Yes ☐ No ☐ If No, please give details of the Originator . . . . . .

. . . . . .

Immunogen. . . . . .

Immunisation Protocol. . . . . .

Fusion Partner . . . . . .

Product Antibody (Specifically) . . . . . .

Antibody Subclass . . . . . .

Growth Medium . . . . . .

. . . . . .

Subculture Routine: For Suspension Cells: Seed cells at densities between . . . . . cells/ml and . . . . . cells/ml

Saturation Density . . . . . Temp . . . . . °C . . . . . $\%CO_2$

Passage or Population Doubling Number of cells being shipped . . . . . .

Has the cell line been routinely cultured in the presence of antibiotics? Yes ☐ No ☐

Has the cell line been routinely tested for mycoplasma contamination? Yes ☐ No ☐ Test result: +ve ☐ -ve ☐

Mycoplasma eradicated? Yes ☐ No ☐ Give details of method used to eradicate mycoplasma: . . . . . .

. . . . . .

Additional Cell Line Information:

Cross Reactants . . . . . .

Characterisation/ Screening Assay used . . . . . .

Recloned? Yes ☐ No ☐ Recloned (Date) ___ /___/___ Ab Production Tested (Date) ___ /___/___

Endogenous Viruses (if known) . . . . . .

Characteristics of Interest . . . . . .

Applications . . . . . .

References Including any Patents Filed. . . . . .

. . . . . .

Any Other Relevant Information . . . . . .

. . . . . .

I have been offered, and I have read, the full version ECACC Deposit Agreement. I understand that I/my organisation remains the Owner of the Cell Line. I hereby grant ECACC unrestricted rights to market and distribute the Cell Line on behalf of (name) . . . . . Signed . . . . . Date . . . . . .

Health Protection Agency

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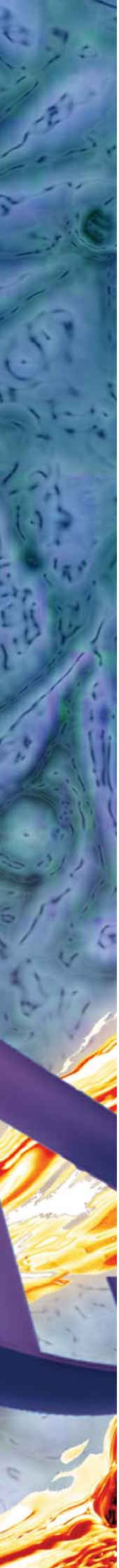

A Guide to Catalogue Deposits at ECACC

The aim of this guide is to provide answers to the most commonly asked questions but is not intended to replace the discussions with ECACC staff. Our goal is to maintain the quality of samples held in the ECACC collections so we can continue to provide authenticated cells lines and related information to the Scientific Community.

ECACC is based at the Health Protection Agency at Porton Down and is a not-for-profit strategic business unit. ECACC was originally founded in 1984 as a Cell Culture Collection to service the scientific research community. Today, the Culture Collection has expanded and diversified to become one of the premier collections in the world.

Our Collections are divided into a number of distinct categories:

The General Collection
This comprises of over 1000 cell lines originating from a variety of species from human and rodent to more exotic lines such as amphibians and insects.

The Hybridoma Collection
This is a collection of over 400 monoclonal antibody-secreting hybridomas.

The Human Genetic Cell Bank
This collection consists of 100,000 peripheral blood lymphocytes and EBV immortalised B-lymphoblastoid cell lines established from patients and their families with genetic and chromosomal abnormalities.

The HLA-Typed Cell Collection
This is a specialised collection of over 300 reference B-lymphoblastoid cell lines to be used in the investigation of the Human Leukocyte Antigen (HLA) system.

Commonly Asked Questions

Why Deposit Cells?
ECACC provides a long-term service role to the scientific community and has the expertise and facilities required to maintain and store important cultures. Batch quality control (QC) is carried out at ECACC, ensuring that the recipients of cell lines are provided with authentic material that is free from contamination.

Laboratories which do not have a service function can find handling requests for cell lines an administrative and time-consuming burden. Depositing cell lines with ECACC is free of charge, straight-forward and offers the benefits outlined in the following table.

Benefits of depositing your cell lines with ECACC	
Security and Storage	ECACC will expand, bank and characterise your cell line to ensure its integrity is maintained long-term. The banks will be stored in ECACC's state-of-the-art liquid nitrogen repository with its multiple levels of security and protection.
Authentication and Quality Control	The cell line will be unequivocally identified by DNA profiling and tested for microbial contamination, including mycoplasma.
Publication	All relevant data will be collated and published using ECACC's website and catalogues.
Promotion	The cell line(s), with associated data, will be promoted internationally so giving visibility to your research and ensuring recognition and full exploitation of the cell line.
Distribution	ECACC will distribute qualified stock in a controlled manner so relieving the depositor of this responsibility and protecting the integrity of the cell line.
Access	Depositors will be granted reasonable free access to their cell lines from ECACC stock.
Flexible Release Conditions	ECACC is very flexible in imposing release conditions on your cell line deposits should you wish to have more control on who receives your cell lines.

Who owns a deposited cell line?
The Depositor remains the owner of the cell line. ECACC serves in the role of custodian acting on behalf of the Depositor. This, together with a full definition of ECACC's undertakings to the Depositor, is described in the standard Deposit Agreement. This enables the Depositor to restrict access to the cell line if so desired, and to withdraw the cell line at any time.

What does it cost the Depositor?
There is no cost involved for the Depositor.

How will ECACC recover its costs?
ECACC recovers > 85% of its costs through distribution fees for the cell lines and related services. As a not-for-profit, public sector organisation the prices we charge are designed only to recover the costs of ECACC operations.

Do I need to sign a complicated Agreement?
ECACC offers a straight-forward Deposit Agreement that is intended to reassure and protect the Depositor. If a Depositor wishes to restrict access to named cell lines we recommend that this model is used. However, if a Depositor is happy to simply grant ECACC unrestricted rights to market a cell line it is sufficient only to sign a Deposit Form. The Depositor remains the owner in either case, and his/her basic rights are the same.

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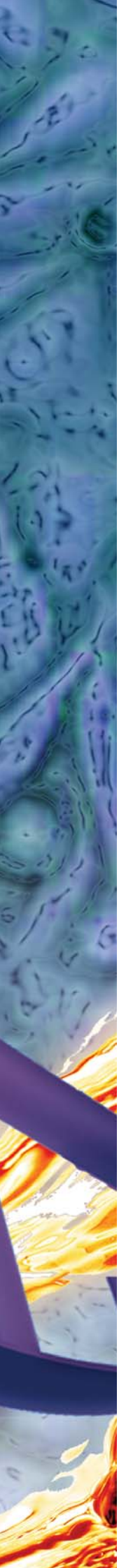

What does ECACC do with the cultures it receives?
A Master Cell Bank is generated which undergoes full quality control and authentication procedures. These include testing for mycoplasma by culture isolation, Hoechst DNA staining and PCR, together with culture testing for contaminant bacteria, yeast and fungi. Authentication procedures used include species verification by isoenzyme analysis and identity verification by DNA profiling.

ECACC routinely uses two different methods of DNA profiling. Classical DNA fingerprinting using multi-locus probes is carried out for non-human cell lines as the probes are able to cross hybridise with most common species. Human cell lines are analysed by PCR of short tandem repeat sequences within the chromosomal microsatellite DNA (STR-PCR). Ten different primer sets are used enabling a digital profile from 20 alleles to be generated which is stored on a database. Both methods enable ECACC to verify that the cell banks being distributed to customers are not cross-contaminated and are identical to the original stock received by ECACC from the original Depositor. ECACC is also able to confirm whether cells are free from contamination by HeLa; a well publicised problem in cell culture.

Whilst the cell line is undergoing the preliminary QC, a catalogue entry is made for the new cell line and forwarded to the depositor for approval. A growing culture from the Master Cell Bank can also be sent to the depositor if required. Once the Master Cell Bank passes QC tests and the depositor is satisfied with the catalogue entry, the cell line is added to ECACC's catalogue and made available to the scientific community.

How do I Access My Deposits?
The Depositor can have reasonable free access to his/her deposits whenever required, all we charge is a small fee to cover postage and packing.

How do I Deposit a Cell Line into the ECACC collection?
Just send us the following information for each cell culture to be deposited:

(a) A completed ECACC Deposit Form/Deposit Agreement

(b) A completed ECACC Biohazard Risk Assessment Form

(c) Any references or patent information associated with the development or use of the cell line

Following receipt of this information, ECACC will assess the Biohazard rating and status of the cell line.

Before we can receive or collect new deposits ECACC will notify you of acceptance of your cell line(s).

How do I get My Deposits to ECACC?
We strive to make the deposit of cell lines into the ECACC collections as easy as possible for you the Depositor. Once you are notified by ECACC of acceptance of a cell line we will work with you to arrange transfer of the cell line to ECACC. Within the UK it is likely that an ECACC scientist will visit to personally collect the cell line(s). Please read the following guidelines which outline the practicalities and documentation required:

1. Await confirmation of acceptance of your cell line(s). ECACC will then provide you with transportation instructions including information on how to package the cell line and the accompanying documentation required. We will also supply you with a box in which to package the cell line. Do not attempt to send cell lines prior to receipt of transportation instructions from ECACC. We will need to confirm the address where you would like the box sent to.

2. ECACC will assist with the documentation that should accompany the shipment by supplying templates and instructions on how to complete the documentation and where to affix this to the package. Documentation to be included in the shipment includes a Despatch Note, Commercial Invoice (outside of the European Union (EU)), Tray Plan (for frozen vials) and Material Safety Data Sheet (MSDS).

3. Please note that deposits which are, or contain, animal pathogens require an import licence into the EU. Please allow 8 weeks for this process, and submit information requested by ECACC for licence applications as quickly as possible.

4. For cell cultures classified as biosafety level 3 (ACDP 3) additional requirements must be met for transportation. Contact ECACC for advice.

5. Upon receipt of the cell culture(s), ECACC will contact you to acknowledge receipt of the cell line and provide a provisional reference number.

ECACC staff are here to ensure that the deposit of Cell Cultures in our Collection is a trouble-free experience. Please do not hesitate to contact ECACC if you have any further questions.

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WS2.ECACC/028/05

Biohazard Risk Assessment Form

To be completed prior to acceptance of a biological agent into an ECACC repository

For ECACC use only

Type of Deposit: . . . . . .

Accession Number. . . . . .

Depositor Code: . . . . . .

Activity Class: . . . . . .

Signed: . . . . . Date: . . . . . .

For Completion by Depositor

The Biological Agent is:

Animal Cell Virus ☐ Bacterium ☐ Yeast ☐ Plasmid ☐

Genetically Modified Yes ☐ No ☐ If yes. What Class . . . . . .

If you have answered Class 2 or above please forward to us any Risk Assessment you have carried out yourselves relating to this deposit.

Other (please define):. . . . . .

Species: . . . . . .

Strain: . . . . . .

Identification Code: . . . . . .

ACDP Hazard Group 1 ☐ 2 ☐ 3 ☐ 4 ☐ If USA deposit use SALS Category

Does this require a Specified Animal Pathogens Order Yes/No

If yes please refer to the DEFRA Web site for a licence application. www.defra.gov.uk

Brief description of deposit. If the agent is genetically modified (GM) include details of inserted gene, method/vehicle for insertion and any expression product.

. . . . . .

. . . . . .

. . . . . .

. . . . . .

. . . . . .

To be completed if the biological agent is genetically modified

ACDP Advisory Committee on Dangerous Pathogens

Hazard Group 1	A biological agent unlikely to cause human disease.
Hazard Group 2	A biological agent that can cause human disease and may be a hazard to employees, it is unlikely to spread to the community and there is usually effective prophylaxis and effective treatment available.
Hazard Group 3	A biological agent that can cause severe human disease and presents a serious hazard to employees. It may present a risk of spreading to the community, but there may be a prophylaxis or treatment available.
Hazard Group 4	A biological agent that causes severe human disease and is a serious hazard to employees. It is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

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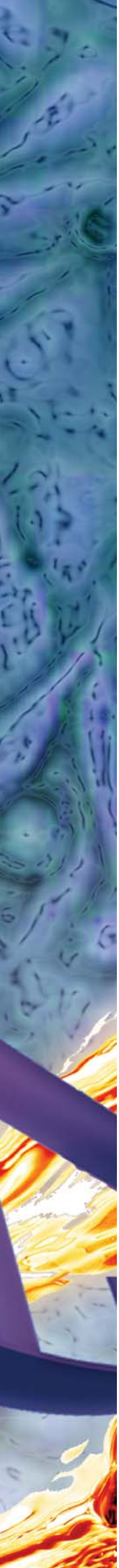

Biohazard Risk Assessment continued

ecacc European Collection of Cell Cultures

1.The host organism is ACDP Hazard Group 1 ☐ 2 ☐ 3 ☐ 4 ☐

2. Does the GM agent contain/produce a biologically active substance that could potentially cause harm to humans (e.g. toxin, cytokine, hormone, allergen, oncogene) Yes ☐ No ☐

3. What is the likelihood that the genetic modification can confer pathogenic traits in the host organism?

Negligible	Possible	Probably or Demonstrated

If "possible", "probably" or "demonstrated" please provide additional details:

. . . . . .

4. What is the potential for sequences within the GM agent being transferred to another related microorganism?

Negligible	Low	Medium	HIgh

If "medium" or "high" please provide additional details:

. . . . . .

5. In the light of your knowledge of this GM agent and its origination, what is your assessment of its potential to cause harm to human health in the event of exposure?

Negligible	Low	Medium	HIgh

If "medium" or "high" please provide additional details:

. . . . . .

Does this GM agent have the ability to survive, establish and disseminate in the environment? Yes ☐ No ☐

Form completed by:

Name: . . . . . .

Title: . . . . . .

Date: . . . . . .

Signature: . . . . . .

All details above are correct

ECACC may request further information in order to complete its risk assessment. To whom should such requests be addressed?

Name: . . . . . .

Fax: . . . . . .

E-mail: . . . . . .

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