

CS09:

Identification of cDNAs mapping to human chromosome 45q using recombinant E. coli plasmids

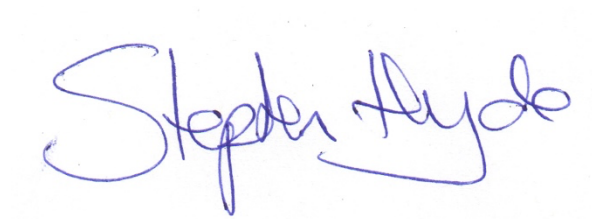
Reviewed: NDCLS DSAC Meeting 2025-10-29

Sample Review: samples confirmed destroyed.

Agreed Status: Retire

Action: Retain for reference in case future re-activation necessary

Contact NDCLS Biological Safety Officer for re-activation

A handwritten signature in blue ink that reads "Stephen Hyde". The signature is written in a cursive, flowing style. The first name "Stephen" is written in a larger, more prominent script, and the last name "Hyde" is written in a similar but slightly smaller script. The ink is a vibrant blue, and the signature is set against a plain white background.

NDCLS Biological Safety Office
2025-10-29

Review of risk assessment under the transitional arrangements of the Genetically Modified Organisms (Contained Use) Regulations 2000

Department:

NDCLS

Supervisor:

Dr Southwood

Ref. No:

CS9

Project Title:

Identification of cDNA's mapping to human chromosome 5q using recombinant E.coli plasmids

- ✓ The above risk assessment has been reviewed
- ✓ Appropriate containment measures have been selected as indicated on the attached table(s) and either
- ✓ (i) the original risk assessment remains valid
- or
- ... (ii) the following changes have been made to the risk assessment

Title Amended

Environmental risk re-evaluated.

Classification and assignment of final control measures

In the following complete the centre section in response to prompts in left column using guidance in right column

| Classification | Class | <i>GUIDANCE</i> The highest numbered column in which a control measure is required indicates the Class of the activity - circle class on table 1a |
|--|---------------------|---|
| Assign corresponding level of containment | I | |
| specify which, if any, of the optional control measures at this containment level are required | Containment Level I | |
| | NA | The class number indicates the minimum containment level required |
| specify any other control measures required | NA | The optional control measures are listed on the table as "may be required" |

Reviewed By:

Signature:

Steph Hys

Date:

12/4/2000

Review approved by Genetic Modification Safety Committee

Yes/No

Signature:

Date:

(Biological Safety Officer)

Table 1a: Containment Measures for Activities involving GMMs in Laboratories

Where a item is listed as "may be required" this indicates the item to be an option at that particular containment level and its requirement should be determined by the risk assessment for the particular activity concerned. Delete no or yes as indicated by risk assessment.

| Containment Measures | Containment Levels | | | |
|---|---------------------------------------|---------------------------------------|---------------------------------------|--|
| | 1 | 2 | 3 | 4 |
| Isolated laboratory suite | not required | not required | required | required |
| Laboratory sealable for fumigation | not required | not required | required | required |
| Surfaces impervious, resistant and easy to clean | required for bench | required for bench | required for bench and floor | required for bench, floor, ceiling and walls |
| Entry to lab via airlock | not required | not required | may be required no / yes | required |
| Negative pressure relative to the pressure of the immediate surroundings | not required | may be required no / yes | required | required |
| HEPA filtered extract and input air | not required | not required | required for extract | required for input and extract |
| Microbiological safety cabinet/enclosure | not required | may be required no / yes | required | required (class 3) |
| Autoclave | required on site | required in the building | required in the lab suite | required in lab (double ended) |
| Access restricted to authorised personnel | not required | required | required | required |
| Specified measures to control aerosol dissemination | not required | required so as to minimise | required so as to prevent | required so as to prevent |
| Shower | not required | not required | may be required no / yes | required |
| Protective clothing | suitable protective clothing required | suitable protective clothing required | suitable protective clothing required | complete change of clothing and footwear |
| Gloves | not required | may be required no / yes | required | required |
| Control of disease vectors (eg rodents, insects) which could disseminate GMMs | may be required no / yes | required | required | required |
| Specified disinfection procedures in place | may be required no / yes | required | required | required |
| Inactivation of GMMs in effluent from handwashing sinks, showers etc | not required | not required | may be required no / yes | required |
| Inactivation of GMMs in contaminated material and waste | required by validated means | required by validated means | required by validated means | required by validated means |
| Laboratory to contain its own equipment | not required | not required | required | required |
| An observation window or alternative so that occupants can be seen | may be required no / yes | may be required no / yes | required | required |
| Safe storage of GMMs | may be required no / yes | required | required | secure storage required |
| Written records of staff training | not required | may be required no / yes | required | required |

| | | | | |
|----------------|---------|---------|---------|---------|
| CLASSIFICATION | CLASS 1 | CLASS 2 | CLASS 3 | CLASS 4 |
|----------------|---------|---------|---------|---------|

Number 9

CS 9

RISK ASSESSMENT

Made under the

GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 1992

DEPARTMENT: University Department of Cellular Science

SUPERVISOR: Dr. J. Boultonwood

TITLE OF PROJECT: Identification of novel cDNAs
mapping to 5q. by isolation of recombinant E. coli
plasmids.
Identification of cDNAs mapping to human chromosome 5q using recombinant
E. coli plasmids.

Assessed By: Carrie Fidler

Signature: C Fidler

Date: 30/11/95

RISK ASSESSMENT APPROVED BY GENETIC
MODIFICATION SAFETY COMMITTEE:

☒ YES ☐ NO

Signature:

J. L. Corneil

Date: 18/1/96

PERMISSION GRANTED BY HEAD OF DEPARTMENT
FOR PROJECT TO BE UNDERTAKEN:

YES/ ☒ NO

Signature:

K. C. A.

Date: 6.1.96

| CHARACTERISTICS OF, AND HANDLING PRECAUTIONS FOR, RECIPIENT (HOST) AND DONOR ORGANISMS | | |
|---|---|---|
| | RECIPIENT | DONOR |
| What is the full name of the organism? (Include species, subspecies and strain as appropriate) | HB101 E. coli | Human |
| Is the organism wild type or disabled? [see Appendix 1 for list of known disabled organisms] | WILD TYPE / <u>DISABLED</u> | WILD TYPE / <u>DISABLED</u> |
| Is the organism pathogenic for man? | YES / <u>NO</u> | YES / <u>NO</u> |
| ACDP Hazard Group of organism: | <u>1</u> / 2 / 3 / 4 | <u>1</u> / 2 / 3 / 4 |
| Are there any other hazards of the organism or its products? If yes identify type: - toxic, allergenic, oncogenic, carcinogenic, other (specify) | YES / <u>NO</u> | YES / <u>NO</u> |
| Is the organism pathogenic for plants or animals? | YES / <u>NO</u> | YES / <u>NO</u> |
| Control measures: - Containment Level - additional precautions (circle) | <u>1</u> / 2 / 3 / 4 microbiological safety cabinet gloves avoid use of sharps other (specify) | <u>1</u> / 2 / 3 / 4 microbiological safety cabinet gloves avoid use of sharps other (specify) |

| DESCRIPTION OF THE GENETIC MODIFICATION | |
|--|---|
| Technique used to introduce the vector or insert into the organism: | Transformation |
| Nature and source of the vector: | psport |
| Function of the genetic modification and/or of the new nucleic acid: | To grow up vector containing insert of interest |

FOR GENETICALLY MODIFIED BACTERIA:

**ASSESSMENT OF RISK TO HUMAN HEALTH AND ASSIGNMENT OF
CONTAINMENT/ CONTROL MEASURES**

ASSIGNMENT TO CONTAINMENT:

[see Appendix 2 for guidance in assigning values]

Overall Value:

$$\frac{10^{-9}}{\text{Access}} \times \frac{10^{-9}}{\text{Expression}} \times \frac{10^{-9}}{\text{Damage}} = \frac{10^{-27}}{\text{ }}$$

CIRCLE OVERALL VALUE AND CORRESPONDING ACGM CONTAINMENT LEVEL BELOW

Overall Value: 10^{-15} or lower

10^{-12}

10^{-9}

greater than 10^{-9}

Containment Level:

①

2

3

* contact Safety Office

HEALTH CONSIDERATIONS:

How does the pathogenicity of the GMO compare to that of the donor and recipient

N/A.

GMO

less / equivalent / more

pathogenic than donor

GMO

less / equivalent / more

pathogenic than recipient

Are there are other hazards of the GMO or its products?

If yes identify:

- toxic, allergenic, oncogenic, carcinogenic, other (specify)

YES / **NO**

Are any additional precautions necessary?

If yes circle as appropriate:

YES / **NO**

microbiological safety cabinet

gloves

avoid use of sharps

other (specify)

After consideration of the actual procedures to be undertaken are the control measures assigned to protect human health adequate?

If no specify what additional measures are needed:

YES / NO

RISK ASSESSMENT FOR ENVIRONMENTAL PROTECTION

Do any of the following characteristics of the GMO result in a potential hazard to the environment

- capacity to survive, establish, disseminate and/or displace other organisms
- pathogenicity to animals or plants
- potential for transfer of genetic material between the GMO and other organisms
- products of gene expression (particularly if they are toxic)
- other negative effects on organisms
- phenotypic and genetic stability

YES / NO

YES / NO

YES / NO

YES / NO

YES / NO

YES / NO

YES

If NO hazards identified circle:

NO ENVIRONMENTAL HAZARDS IDENTIFIED - NO ADDITIONAL PRECAUTIONS NECESSARY

If hazards are identified then estimate:

LIKELIHOOD OF HAZARD(S) being manifested (taking containment into account)

HIGH / MEDIUM / LOW / NEGLIGIBLE

CONSEQUENCES OF HAZARDS being manifested

SEVERE / MEDIUM / LOW / NEGLIGIBLE

CIRCLE RISK IN MATRIX AS APPROPRIATE:

| CONSEQUENCE OF HAZARD | LIKELIHOOD OF HAZARD | | | |
|-----------------------|----------------------|------------------|------------------|------------------|
| | High | Medium | Low | Negligible |
| Severe | High | High | Medium | Effectively Zero |
| Medium | High | Medium | Medium/Low | Effectively Zero |
| Low | Medium/Low | Low | Low | Effectively Zero |
| Negligible | Effectively Zero | Effectively Zero | Effectively Zero | Effectively Zero |

If risks are low or effectively zero circle:

NO ADDITIONAL PRECAUTIONS NECESSARY TO PROTECT ENVIRONMENT OTHER THAN THOSE TO PROTECT HUMAN HEALTH

Otherwise specify additional control measures to reduce all risks to low/effectively zero:

CLASSIFICATION OF THE GENETICALLY MODIFIED ORGANISM

| | |
|--|--|
| <p>Is the final GMO pathogenic? For:</p> <ul style="list-style-type: none"> - humans - animals - plants <p>Does the insert code for any potentially pathogenic or harmful traits that will result in a pathogenic or harmful phenotype (to man or the environment) of the GMO?</p> <p>Have any antibiotic resistance markers been introduced which could compromise the treatment of any infection that may occur?</p> <p>If the answer to any of the above is YES circle:</p> | <p>YES / <u>NO</u></p> <p>YES / <u>NO</u></p> <p>YES / <u>NO</u></p> <p>YES / <u>NO</u></p> <p>YES / <u>NO</u></p> <p>Group 2</p> |
| <p>If all NO then:</p> <p>Does the genetically modified micro-organism meet the criteria for classification as Group 1 [see Appendix 3 for guidance]</p> <p>If YES circle:</p> <p>If NO circle:</p> | <p><u>YES</u> / NO</p> <p>Group 1</p> <p>Group 2</p> |

CLASSIFICATION OF ACTIVITY

| | |
|--|---|
| <p>TEST OF PURPOSE:</p> <p>Is the activity being undertaken for any one or more of the following purposes?</p> <ul style="list-style-type: none"> - teaching, research, development, non-industrial, non-commercial | <p><u>YES</u> / NO</p> |
| <p>TEST OF SCALE:</p> <p>Is the activity "small scale" i.e. is the culture contained and easily inactivated using standard laboratory techniques?</p> | <p><u>YES</u> / NO</p> |
| <p>If the answer to both of the above questions is yes circle:</p> <p>If answer to either is no circle:</p> | <p>Type A</p> <p>Type B</p> |