South Australia

Gene Technology Regulations 2002

under the *Gene Technology Act 2001*

Contents

Part 1—Preliminary

1—Short title

(1) These regulations may be cited as the *Gene Technology Regulations 2002*.

(2) These regulations may also be referred to as the *Gene Technology Regulations*.

2—Commencement

These regulations will come into operation when the *Gene Technology Act 2001* comes into operation.

3—Definitions

In these regulations—

Act means the *Gene Technology Act 2001*;

advice to proceed, being an instrument so named issued by the Genetic Manipulation Advisory Committee, has the same meaning as in section 190(3) of the Commonwealth Act;

animal includes every kind of organism in the animal kingdom, including non-vertebrates but not including human beings;

Commonwealth Regulations means the *Gene Technology Regulations 2001* of the Commonwealth;

expert adviser means—

(a) in Part 4, an expert adviser appointed under section 102(1) of the Commonwealth Act; and

(b) in Part 6, an expert adviser appointed under section 113(1) of the Commonwealth Act;

Genetic Manipulation Advisory Committee means the Committee of that name administered by the Minister for Health and Aged Care of the Commonwealth;

physical containment level, followed by a numeral, is a specified containment level under guidelines made by the Regulator, under section 90 of the Act, for the certification of facilities.

3A—Numbering

(1) In order to maintain consistent numbering between these regulations and the Commonwealth Regulations—

(a) if the Commonwealth Regulations contain a regulation that is not required in these regulations, the provision number and heading to the regulation appearing in the Commonwealth Regulations are included in these regulations despite the omission of the body of the regulation; and

(b) if these regulations contain a regulation that is not included in the Commonwealth Regulations, the regulation is numbered so as to maintain consistency in numbering between regulations common to both regulations.

(2) A provision number and heading referred to in subregulation (1)(a) form part of these regulations.

Notes—

1 A note appears under each heading of a kind referred to in subregulation (1)(a) describing the omitted regulation of the Commonwealth Regulations.

2 A note appears under each regulation of a kind referred to in subregulation (1)(b) highlighting the non-appearance of an equivalent regulation in the Commonwealth Regulations.

3 This regulation does not appear in the Commonwealth Regulations.

3B—Notes

Notes do not form part of these regulations.

Note—

This regulation does not appear in the Commonwealth Regulations.

Part 2—Interpretation and general operation

4—Techniques not constituting gene technology

For the purposes of paragraph (c) in the definition of ***gene technology*** in section 10 of the Act, gene technology does not include somatic cell nuclear transfer if the transfer does not involve genetically modified material.

5—Organisms that are not genetically modified organisms

For the purposes of paragraph (e) in the definition of ***genetically modified organism*** in section 10 of the Act, an organism listed in Schedule 1 is not a genetically modified organism.

Part 3—Dealings with GMOs

Division 1—Licensing system

6—Dealings exempt from licensing

(1) For the purposes of section 32(3) of the Act, a dealing, in relation to a GMO, is an exempt dealing if—

(a) it is a dealing of a kind referred to in Part 1 of Schedule 2; and

(b) it does not involve a genetic modification other than a modification described in Part 1 of Schedule 2; and

(c) it is conducted in accordance with Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology) for physical containment Level 1; and

(d) it does not involve an intentional release of the GMO into the environment.

(2) For the avoidance of doubt, exemption under subregulation (1) does not apply to a dealing that does not comply with subregulation (1), whether or not that dealing is related to a dealing that does so comply.

Notes—

1 A dealing affected by this regulation could be any of the forms of dealing mentioned in the definition of ***deal with*** in section 10(1) of the Act.

2 Exemption from provisions of the Act does not preclude the application of other Commonwealth and State laws.

3 ***Intentional release of the GMO into the environment*** is defined in section 11 of the Act.

7—Application for licence—prescribed information

(1) For the purposes of section 40(2)(a) of the Act, the following information must be contained in an application for a licence:

(a) for an application to which Division 3 of Part 5 of the Act applies, the information specified in Part 1 of Schedule 4;

(b) for an application to which Division 4 of Part 5 of the Act applies, the information specified in Part 2 of Schedule 4.

(2) In preparing that information, an applicant must take account of risks that the proposed dealing, or dealings, with a GMO may incur in relation to the health and safety of people and the environment.

(3) The information to be given in the application must be—

(a) as comprehensive as existing scientific knowledge, when the application is made, permits; and

(b) supported by whatever relevant data and references are available to the applicant.

(4) To the extent that compliance with subregulation (3)(b) does not provide relevant data and references, the applicant must include in the application—

(a) a statement that specified information is incomplete or unavailable, as the case may be; and

(b) an indication of the significance of the incomplete or unavailable information to the evaluation of the possible risks of the proposal in relation to the health and safety of people and the environment; and

(c) a summary of known existing scientific evidence relevant to such evaluation; and

(d) applying that summary, an evaluation of the possible risks based on theoretical approaches, and research methods, that are generally accepted in the scientific community.

Notes—

1 Additional information, specified in writing by the Regulator, may also be required.

2 At the commencement of the regulations, there is no fee payable for an application for a GMO licence.

8—Time limit for deciding an application

(1) For the purposes of section 43(3) of the Act, the period within which the Regulator must issue, or refuse to issue, a licence is—

(a) in relation to an application to which Division 3 of Part 5 of the Act applies, 90 days after the day the application is received by the Regulator; or

(b) in relation to an application to which Division 4 of Part 5 of the Act applies, 170 days after the day the application is received by the Regulator.

(2) For the purpose of determining the end of a period mentioned in subregulation (1), the following days are not counted:

(a) a Saturday, a Sunday or a public holiday in the Australian Capital Territory;

(b) a day on which the Regulator cannot proceed with the decision-making process, or a related function, because the Regulator is awaiting information that the applicant has been requested, in writing, to give;

(c) if, in relation to the application, the Regulator publishes notice of a public hearing under section 53 of the Act, a day in the period that—

(i) begins on the day of publication; and

(ii) ends on the day when the public hearing ends;

(d) a day on which the Regulator cannot proceed with the decision-making process, or a related function, because—

(i) the applicant has requested, under section 184 of the Act, that information given in relation to the application be declared confidential commercial information for the purposes of the Act; and

(ii) the Regulator is—

(A) considering the application; or

(B) waiting until any review rights under section 181 or 183 of the Act, in relation to the application, are exhausted;

(e) if, in relation to the application, the Regulator requests the Gene Technology Ethics Committee to provide advice on an ethical issue, a day in the period that—

(i) begins on the day the request is made; and

(ii) subject to subregulation (3), ends on the day when the advice is given or, if the advice is not given within the period, if any, specified under subregulation (3), on the last day of that period.

(3) The Regulator, when seeking advice under section 50(3) or 52(3) of the Act, or from the Gene Technology Ethics Committee, may specify a reasonable period within which the advice must be received, and, if the advice is not received within that period, must proceed without regard to that advice.

9—Prescribed authorities

For the purposes of sections 50(3)(c) and 52(3)(c) of the Act, the following Commonwealth authorities and agencies are prescribed:

(a) Australia New Zealand Food Authority;

(b) Australian Quarantine and Inspection Service;

(c) National Health and Medical Research Council;

(d) National Industrial Chemical Notification and Assessment Scheme, National Occupational Health and Safety Commission;

(e) National Registration Authority for Agricultural and Veterinary Chemicals;

(f) Therapeutic Goods Administration, Department of Health and Aged Care of the Commonwealth.

10—Risk assessment—matters to be taken into account

(1) For the purposes of sections 51(1)(g) and 51(2)(g) of the Act, other matters to be taken into account in relation to dealings proposed to be authorised by a licence include—

(a) any previous assessment, in Australia or overseas, in relation to allowing or approving dealings with the GMO; and

(b) the potential of the GMO concerned to—

(i) be harmful to other organisms; and

(ii) adversely affect any ecosystems; and

(iii) transfer genetic material to another organism; and

(iv) spread, or persist, in the environment; and

(v) have, in comparison to related organisms, selective advantage in the environment; and

(vi) be toxic, allergenic or pathogenic to other organisms.

(2) In taking into account a risk mentioned in section 51(1) of the Act, or a potential capacity mentioned in subregulation (1), the Regulator must consider both the short term and the long term.

11—Prescribed conditions of licence

Note—

At the commencement of these regulations, no conditions are prescribed under section 61(b) of the Act.

Division 2—Notifiable low risk dealings

12—Notifiable low risk dealings

(1) For the purposes of section 74(1) of the Act, a dealing with a GMO is a notifiable low risk dealing if—

(a) it is a dealing of a kind mentioned in Part 1 of Schedule 3 (other than a dealing also mentioned in Part 2 of Schedule 3); and

(b) it does not involve an intentional release of the GMO into the environment.

(2) For the avoidance of doubt, subregulation (1) does not apply to a dealing that does not comply with subregulation (1), whether or not that dealing is related to a dealing that does so comply.

Notes—

1 A dealing affected by this regulation could be any of the forms of dealing mentioned in the definition of ***deal with*** in section 10(1) of the Act.

2 ***Intentional release of the GMO into the environment*** is defined in section 11 of the Act.

13—Requirements in relation to notifiable low risk dealings

(1) A person must not undertake a notifiable low risk dealing unless—

(a) the proposed dealing has been assessed, by an Institutional Biosafety Committee, to be a dealing of a kind mentioned in Part 1 of Schedule 3; and

(b) within 14 days after completion of the assessment, the Committee has notified the Regulator, by giving the Regulator, in relation to the proposed notifiable low risk dealing, the information specified in Part 3 of Schedule 3; and

(c) the person, and the project supervisor for the proposed dealing, have received written notice from the Committee that paragraph (b) has been complied with.

(2) A notifiable low risk dealing, when undertaken, must comply with the following requirements:

(a) the dealing must be conducted in a facility that—

(i) is certified by the Regulator to—

(A) at least physical containment level 2; or

(B) any other containment level that the Regulator considers suitable for conducting the dealing; and

(ii) is of appropriate design for the kind of dealing being undertaken;

(b) the conduct of the dealing must be properly supervised, and a record of details of the dealing kept;

(c) if the dealing involves human pathogens, it must be conducted only in accordance with the recommendations for vaccination given in Australian Standard AS/NZS 2243.3:1995(Safety in laboratories: microbiology);

(d) to the extent that the dealing involves transporting a GMO, the transporting must be conducted in accordance with any relevant guidelines, as in force from time to time, issued by the Regulator.

(3) For the purposes of subregulation (1)(a), a proposed dealing is taken to be assessed if the assessment applies to—

(a) in relation to the dealing, the particular GMO concerned, or a class of GMOs that includes that GMO; or

(b) in relation to the particular GMO, or class of GMOs, a class of dealings that includes that dealing.

(4) From the commencement of these Regulations, until two years after the commencement, a person who complies with subregulation (2) may undertake a notifiable low risk dealing although any, or all, of the provisions of subregulation (1) have not been complied with if there is in force a notice issued by, or on behalf of, the Genetic Manipulation Advisory Committee declaring that the dealing is a notifiable low risk dealing.

Division 3—Certification and accreditation

14—Regulator to decide certification application within 90 days

Note—

The Commonwealth Regulations provide the period within which the Regulator must consider and decide an application for certification of a facility.

15—Application for certification—failure to provide section 85 information

If an applicant for certification fails to provide information required under section 85(1) of the Act within the period specified in a notice given under section 85(2) of the Act, and gives no reasonable explanation for the failure, the Regulator may refuse to certify the facility that is the subject of the application.

Note—

A refusal to certify a facility is a reviewable decision (see Division 2 of Part 12 of the Act).

16—Regulator to decide accreditation application within 90 days

Note—

The Commonwealth Regulations provide the period within which the Regulator must consider and decide an application for accreditation of an organisation.

17—Application for accreditation—failure to provide section 93 information

If an applicant for accreditation fails to provide information required under section 93(1) of the Act within the period specified in a notice given under section 93(2) of the Act, and gives no reasonable explanation for the failure, the Regulator may refuse to accredit the organisation that is the subject of the application.

Note—

A refusal to accredit an organisation is a reviewable decision (see Division 2 of Part 12 of the Act).

Part 4—Gene Technology Technical Advisory Committee

Division 1—Conditions of appointment

18—GTTAC members and advisers—term of appointment

Note—

Regulation 18 of the Commonwealth Regulations provides for the term of appointment of members of the Gene Technology Technical Advisory Committee and expert advisers to the GTTAC.

19—GTTAC members and advisers—resignation

Note—

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20—GTTAC members—disclosure of interests

Note—

Regulation 20 of the Commonwealth Regulations sets out when and how members of the Gene Technology Technical Advisory Committee must disclose any interests of a kind likely to be considered at a meeting of the GTTAC.

21—GTTAC members and advisers—termination of appointment

Note—

Regulation 21 of the Commonwealth Regulations sets out the circumstances of terminating the appointment of members of the Gene Technology Technical Advisory Committee and expert advisers to the GTTAC.

22—GTTAC members—leave of absence

Note—

Regulation 22 of the Commonwealth Regulations provides when the Chairperson and members of the Gene Technology Technical Advisory Committee may be granted leave.

23—Expert advisers—disclosure of interests

Note—

Regulation 23 of the Commonwealth Regulations sets out when and how expert advisers to the Gene Technology Technical Advisory Committee must disclose any interests of a kind likely to be considered at a meeting of the GTTAC.

Division 2—Committee procedures

24—Committee procedures generally

Note—

Regulation 24 of the Commonwealth Regulations provides that the Gene Technology Technical Advisory Committee must perform its functions as informally as the Commonwealth Regulations allow and how the GTTAC may obtain information.

25—Committee meetings

Note—

Regulation 25 of the Commonwealth Regulations provides when the Gene Technology Technical Advisory Committee may have meetings and provides that in certain circumstances meetings may be by videoconference or teleconference.

26—Presiding member

Note—

Regulation 26 of the Commonwealth Regulations provides that the Chairperson of the Gene Technology Technical Advisory Committee presides at its meetings and who presides in the Chairperson's absence.

27—Quorum

Note—

Regulation 27 of the Commonwealth Regulations provides that half the members of the Gene Technology Technical Advisory Committee comprises the GTTAC's quorum.

28—Voting

Note—

Regulation 28 of the Commonwealth Regulations provides that decisions of the Gene Technology Technical Advisory Committee must be made by a majority of members present and voting and that the Chairperson has a deliberative and casting vote.

29—Records and Reports

Note—

Regulation 29 of the Commonwealth Regulations provides that records must be kept of the Gene Technology Technical Advisory Committee's proceedings and when reports must be prepared.

Division 3—Subcommittees

30—Operation of subcommittees

Note—

Regulation 30 of the Commonwealth Regulations states that regulations 24, 25, 26 and 28 of those regulations apply to a subcommittee established under section 105(1) of the Commonwealth Act.

Part 5—Gene Technology Community Consultative Committee

31—GTCCC—conditions of appointment

Note—

Regulation 31 of the Commonwealth Regulations provides that Division 1 of Part 4 of the Commonwealth Regulations applies to the conditions of appointment of members of the Gene Technology Community Consultative Committee.

32—GTCCC—Consultative Committee procedures

Note—

Regulation 32 of the Commonwealth Regulations provides that Division 2 of Part 4 of the Commonwealth Regulations applies to the procedures of the Gene Technology Community Consultative Committee.

33—GTCCC—operation of subcommittees

Note—

Regulation 33 of the Commonwealth Regulations provides that regulations 24, 25, 26 and 28 of the Commonwealth Regulations apply to a subcommittee established under section 110A(1) of the Commonwealth Act.

Part 6—Gene Technology Ethics Committee

34—GTEC—Conditions of appointment

Note—

Regulation 34 of the Commonwealth Regulations provides that Division 1 of Part 4 of the Commonwealth Regulations applies to the conditions of appointment of members of and advisers to the Gene Technology Ethics Committee.

35—GTEC—Committee procedures

Note—

Regulation 35 of the Commonwealth Regulations provides that Division 2 of Part 4 of the Commonwealth Regulations applies to the procedures of the Gene Technology Ethics Committee.

36—GTEC—operation of subcommittees

Note—

Regulation 36 of the Commonwealth Regulations provides that regulations 24, 25, 26 and 28 of the Commonwealth Regulations apply to a subcommittee established under section 116(1) of the Commonwealth Act.

Part 7—Miscellaneous

37—Reviewable State decisions

Note—

The scheme for reviewable State decisions under the Commonwealth Act does not apply under the South Australian legislation.

38—Review of decisions

Note—

Regulation 38 of the Commonwealth Regulations provides that a person whose interests are affected by a decision in relation to the termination of the appointment of a member to a committee under those regulations may apply to the Administrative Appeals Tribunal for review of the decision.

39—Record of GMO and GM Product Dealings

(1) For the purposes of section 138(2) of the Act, the following particulars are prescribed in relation to a notifiable low risk dealing that is notified to the Regulator:

(a) the name of the organisation proposing to undertake the notified dealing;

(b) in terms of Part 1 of Schedule 3, the kind of notifiable low risk dealing proposed;

(c) the identifying name given to the proposed undertaking by the organisation;

(d) the date of the notification.

(2) For the purposes of section 138(3) of the Act, the following particulars are prescribed in relation to a GM product mentioned in a designated notification:

(a) the name of the organisation producing the GM product;

(b) a description of the GM product, with reference to—

(i) the ***applicable Act***, being the *Agricultural and Veterinary Chemicals (South Australia) Act 1994*; and

(ii) its common name as a product, or type or class of product (for example, bread or insulin);

(c) information about the GM product, including—

(i) the common name and the scientific name of the parent organism involved; and

(ii) details of the introduced trait in the GM product; and

(iii) the identity of the introduced gene responsible for conferring the introduced trait;

(d) the date on which a decision under the applicable Act, that enables supply of the GM product in Australia, takes effect;

(e) details of any conditions attaching to that permission.

Note—

This regulation differs from regulation 39 of the Commonwealth Regulations.

40—Inspector identity card

For the purposes of section 151(2)(a) of the Act, an inspector's identity card must—

(a) display a recent photograph of the inspector's face; and

(b) state the date of issue; and

(c) state the period of its validity.

Part 8—Transitional

41—Existing facilities—certification

(1) If, at the commencement of Part 7 of the Act, there is in force for an existing facility a notice from the Genetic Manipulation Advisory Committee that the facility provides a specified physical containment level, the facility is taken to be certified to that physical containment level under section 84 of the Act.

(2) Subregulation (1) applies—

(a) subject to sections 86(b), 86(c), 87 and 88 of the Act; and

(b) for a facility in relation to which the notice specifies that it is a physical containment level 2 facility (other than a PC2 Large Scale facility), until the end of two years after the commencement of Part 7 of the Act, provided the facility maintains compliance with the Regulator's guidelines about the requirements for certification at that level; and

(c) for a facility in relation to which the notice specifies that it is a physical containment level 3 or level 4 facility, a PC2 Large Scale facility or a facility providing appropriate physical containment for a specified purpose, until the end of one year after the commencement of Part 7 of the Act, provided the facility maintains compliance with the Regulator's guidelines about the requirements for certification at its specified containment level.

(3) For the purposes of subregulation (2)—

PC2 Large Scale facility means a physical containment level 2 facility so described by the notice given in relation to the facility by the Genetic Manipulation Advisory Committee.

42—Existing organisations—accreditation

(1) If, at the commencement of Part 7 of the Act, there is in force for an existing organisation a notice from the Genetic Manipulation Advisory Committee that the organisation is an accredited organisation, the organisation is taken to be an accredited organisation under section 92 of the Act.

(2) Subregulation (1) applies—

(a) subject to sections 94(b), 94(c), 95 and 96 of the Act; and

(b) until the end of two years after the commencement of Part 7 of the Act, provided the organisation maintains compliance with the Regulator's guidelines, if any, under section 98 of the Act.

43—Advices to proceed

For the purposes of the definition of ***transition period*** in section 190(3) of the Act, the period of two years from the commencement of the Act is prescribed.

Schedule 1—Organisms that are not genetically modified organisms

(Regulation 5)

Part 1—Organisms

Item	Description of organism
1	A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).
2	A recombinant organism formed through integration into chromosomal or extrachromosomal DNA sequences of a genetic element that— (a) occurs naturally in the species concerned; and (b) moves sporadically between genome sites.
3	An organism that— (a) results from the fusion of 2 animal cells; and (b) is unable to form a viable whole animal. **Example—** Organisms of the kind described include hybridomas created to produce monoclonal antibodies.
4	An organism that results from protoplast fusion involving only non-pathogenic bacteria or non-pathogenic yeast.
5	A plant formed by— (a) embryo rescue; or (b) *in vitro* fertilisation; or (c) zygote implantation; or (d) protoplast fusion.

Item	Description of organism
6	An organism that results from an exchange of DNA if— (a) the donor species is also the host species; and (b) the vector DNA does not contain any heterologous DNA.
7	An organism that results from an exchange of DNA between the donor species and the host species if— (a) such exchange can occur by naturally occurring processes; and (b) the donor species and the host species are both mentioned in the same group in Part 2 of this Schedule; and (c) the vector used in the exchange does not contain heterologous DNA from any organism other than an organism that is involved in the exchange.

Part 2—Species known to exchange DNA by a known physiological process

Group 1

Alcaligenes
Campylobacter coli
Campylobacter fetus
Campylobacter jejuni
Citrobacter (including levinea)
Enterobacter
Erwinia
Escherichia
Klebsiella
Pseudomonas aeruginosa
Pseudomonas fluorescens
Pseudomonas mendocina
Pseudomonas putida
Rhizobium
Salmonella (including arizona)
Serratia marcescens
Shigella
Yersinia enterocolitica

Group 2

Bacillus amyloliquefaciens
Bacillus aterrimus
Bacillus globigii
Bacillus licheniformis
Bacillus nato
Bacillus niger
Bacillus pumilus
Bacillus subtilis

Group 3

Streptomyces aureofaciens
Streptomyces coelicor
Streptomyces rimosus

Group 4

Streptomyces cyaneus
Streptomyces griseus
Streptomyces venezuela

Group 5

Streptococcus mutans DNA and Streptococcus lactis DNA, in a one-way transfer into Streptococcus sanguis

Group 6

Streptococcus faecalis
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus sanguis

Group 7

Bacillus cereus
Bacillus thuringiensis

Schedule 2—Dealings exempt from licensing

(Regulation 6)

Note—

Regulation 6(1) sets out other requirements for exempt dealings.

Part 1—Exempt dealings

Item	Description of dealing
1	Any dealing with gene-knockout mice (that is, mice whose genetic modification involves deletion or inactivation of a specific gene), if no advantage is conferred on the adult animal— (a) by the deletion or inactivation of the gene concerned; or (b) for mice that also carry a selectable marker gene, by the selectable marker gene.
2	Any dealing with a whole animal, if— (a) naked recombinant nucleic acid has been introduced into its somatic cells; and (b) the introduced nucleic acid is incapable of giving rise to infectious agents.

Item	Description of dealing
3	Any dealing with an animal into which genetically modified somatic cells have been introduced, unless the cells— (a) are capable of giving rise to recombinant infectious agents; or (b) contain viral sequences that could recombine with, or be complemented by, genomes of introduced superinfecting viruses.
4	Any dealing involving a host/vector system mentioned in Part 2 of this Schedule and producing no more than 10 litres of GMO culture, if— (a) the donor DNA— (i) is not derived from micro-organisms capable of causing disease in human beings, other animals, plants or fungi, or is fully characterised and will not increase the virulence or host range of the host or vector; and (ii) is not an oncogene; and (iii) does not code for a toxin for vertebrates with an LD50 of less than 100 µg/kg; and (iv) does not code for a toxin for vertebrates with an LD50 of 100 µg/kg or more, if the intention is to express the toxin at high levels; and (v) is not uncharacterised DNA from a micro-organism that produces toxins with an LD50 of 100 µg/kg or less; or (b) the donor DNA includes a viral sequence or viral sequences, but— (i) is missing at least 1 gene essential for viral multiplication that is not available in the cell into which the DNA is introduced and that will not become available through subsequent breeding; and (ii) is incapable of complementing a defect in the host/vector system.
5	Any dealing involving shot-gun cloning of mammalian DNA in a host/vector system mentioned in Part 2 of this Schedule.

Part 2—Host/vector systems for exempt dealings

Item	Class	Host	Vector
1	Bacteria	*Escherichia coli* K12 or *E. coli* B—any derivative that does not contain— (a) conjugative or generalised transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	1 Non-conjugative plasmids 2 Bacteriophage (a) lambda (b) lambdoid (c) Fd or F1 (eg M13)
2		*Bacillus subtilis* or *B. licheniformis*—an asporogenic strain with a reversion frequency of less than 10^{-7}	Plasmids and phages whose host range does not include *B. cereus*, *B. anthracis* or any other pathogenic strain of bacillus
3		*Pseudomonas putida*—strain KT 2440	Certified plasmids: pKT 262, pKT 263, pKT 264
4		*Streptomyces*—specified species—	1 Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives

Item	Class	Host	Vector
		(a) S. coelicolor (b) S. lividans (c) S. parvulus (d) S. griseus	2 Actinophage phi C31 and derivatives
	Fungi	*Neurospora crassa*—laboratory strains	All vectors
		Pichia pastoris	All vectors
		Saccharomyces cerevisiae	All vectors
		Schizosaccharomyces pombe	All vectors
		Kluyveromyces lactis	All vectors
		Trichoderma reesei	All vectors
	Slime moulds	*Dictyostelium* species	*Dictyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2
	Tissue culture	Mammalian (including human) cells and cells of aquatic organisms	Non-viral vectors or defective viral vectors (including retrovirus or retroviral-helper combinations that cannot infect human cells)
		Avian cells	Avipoxvirus vectors (attenuated vaccine strains)
		Plant cell cultures	Non-tumorigenic disarmed Ti plasmid vectors in *Agrobacterium tumefaciens* and non-pathogenic viral vectors
		Insect cell cultures, such as *Spodoptera frugiperda*, if the recombinants are also inclusion-negative (eg polyhedrin minus)	Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus
5		Any host mentioned, or of a kind mentioned, in any of items 1 to 4	Any non-biological vector (for example, electrocorporation or particle bombardment)

Part 3—Definitions

In this Schedule—

advantage, in relation to an adult animal that is genetically modified, means a superior ability in its modified form, relative to the unmodified parental organism, to survive, reproduce or otherwise contribute to the gene pool;

characterised, in relation to DNA, means that the DNA has been sequenced and that there is an understanding of potential gene products of the DNA;

code for, in relation to a toxin, means to specify the amino acid sequence of the toxin;

inclusion-negative, in relation to a recombinant of insect cell cultures, means the vector baculovirus used is in a mutant form that is unable to make polyhedrin (a material surrounding a virus and protecting it from adverse environmental effects such as UV radiation);

recombinant, in relation to matter that is a sequence or an organism, means matter of that kind containing recombinant DNA (that is, DNA formed by joining, *in vitro*, segments of DNA from different organisms);

shot-gun cloning, in relation to mammalian DNA, means the production of a large random collection of cloned fragments of the DNA from which genes of interest can later be selected;

toxin producing organism means an organism producing toxin with an LD50 of less than 100 µg/kg.

Schedule 3—Notifiable low risk dealings in relation to a GMO

(Regulations 12 and 13)

Part 1—Dealings that are notifiable low risk dealings

Note—

Because of regulation 12(1) a dealing mentioned in this Part is not a notifiable low risk dealing if it is also a dealing of a kind mentioned in Part 2 of this Schedule.

1.1—Kinds of dealings

The following kinds of dealings are notifiable low risk dealings—

(a) any dealing involving whole animals (including non-vertebrates) that—

(i) involves genetic modification of the genome of the oocyte or zygote or early embryo by any means to produce a novel whole organism; and

(ii) does not involve gene-knockout mice;

(b) any dealing involving a genetically modified flowering plant, if—

(i) the dealing does not involve the plant being grown to flowering stage; or

(ii) for a dealing that does involve the plant being grown to flowering stage—

(A) the plant is male sterile and is unable to set seed; or

(B) if the plant is male sterile and can set seed, all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or

(C) before flowering, all inflorescences are wholly enclosed in bags designed to prevent escape of viable pollen and seed; or

(D) if the plant can be wind-pollinated, all vents and drains in the facility are screened with mesh or filters that block the escape of viable pollen and seed; or

(E) if the plant can be vector-pollinated only, all vents and drains in the facility are screened with mesh or filters that block the escape of viable seed and exclude pollen vectors from the facility;

(c) any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if—

(i) the host is incapable of causing disease in human beings, animals, plants or fungi; and

(ii) the vector is incapable of causing disease in human beings, animals, plants or fungi;

(d) any dealing involving a host and vector that are not mentioned as a host/vector system in Part 2 of Schedule 2, if, although the host or vector is capable of causing disease in human beings, animals, plants or fungi, the donor DNA is fully characterised and will not increase the virulence of the host or vector;

(e) any dealing involving a host/vector system mentioned in Part 2 of Schedule 2, if the gene inserted—

(i) is a pathogenic determinant; or

(ii) is uncharacterised DNA from a micro-organism that is capable of causing disease in human beings, animals, plants or fungi; or

(iii) is an oncogene.

1.2—Definitions

In this Part—

characterised, in relation to DNA, means that the DNA has been sequenced and that there is an understanding of potential gene products of the DNA;

gene-knockout mice, has the same meaning as in item 1 in Part 1 of Schedule 2.

Part 2—Dealings (higher risk) that are not notifiable low risk dealings

Notes—

1 The following list qualifies the list in Part 1, and is not an exhaustive list of dealings that are not notifiable low risk dealings.

2 A dealing that is not a notifiable low risk dealing, or an exempt dealing, can be undertaken only by a person who is licensed, under the Act, for the dealing (see section 32 of the Act).

2.1—Kinds of dealings

A dealing of any of the following kinds, or involving a dealing of the following kinds, is not a notifiable low risk dealing—

(a) a dealing involving cloning of DNA encoding a toxin for vertebrates having an LD50 of less than 100 µg/kg;

(b) a dealing involving high level expression of toxin genes, even if the LD50 is greater than 100 µg/kg;

(c) a dealing involving cloning of uncharacterised DNA from toxin-producing micro-organisms;

(d) a dealing involving a viral vector (except a vector that is used in the dealing as part of a host/vector system mentioned in Part 2 of Schedule 2), containing one or more inserted sequences, that codes for a product known to play a role in the regulation of cellular growth or to be toxic to mammalian cells;

(e) a dealing involving, as host or vector, a micro-organism that is capable of causing disease in humans, animals plants or fungi, unless—

(i) the host/vector system is a system mentioned in Part 2 of Schedule 2; or

(ii) the dealing involves only the cloning of DNA that is fully characterised and is known not to increase the virulence of the host and vector;

(f) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes that determine pathogenicity;

(g) a dealing involving the introduction into a micro-organism, other than a host mentioned in Part 2 of Schedule 2, of genes whose expressed products have a heightened risk of inducing an autoimmune response;

(h) a dealing involving cloning or transfer of fragments of a viral or viroid genome that are capable, in the host/vector system to be used, of giving rise to infectious agents that are capable of infecting cells of human, animal, plant or fungal origin;

(i) a dealing involving recombination between whole viral genomes, viroids or complementing fragments of such genomes (if one or more fragments contain virulence or pathogenic determinants);

(j) a dealing involving use of a viral vector to produce a transgenic animal, plant or fungus that secretes or produces infectious recombinant viral agents;

(k) a dealing involving the production of more than 10 litres of GMO culture;

(l) a dealing that is inconsistent with a policy principle issued by the Ministerial Council.

Part 3—Prescribed information—notification of proposed notifiable low risk dealing

3.1—Information about proponent and proposed dealing

For a notification made under regulation 13(1)(b) of these regulations, the following information must be included—

3.1.1 General information

(a) name, address, telephone number and other contact details, of the proponent organisation;

(b) name, position within the organisation and contact details, of the proponent's project supervisor for the proposed dealing, or dealings, with the GMO or GMOs involved;

(c) title of the project involving the proposed dealing or dealings;

(d) with reference to the kinds of dealings set out in Part 1 of this Schedule, the kind of dealing or dealings proposed;

(e) description of each GMO involved—

(i) the common name of the parent organism; and

(ii) the scientific name of the parent organism; and

(iii) the modified trait; and

(iv) the identity of the gene responsible for the modified trait;

(f) description of the proposed dealing or dealings;

(g) description of the purposes and aims of the proposed dealing or dealings;

(h) address of the premises where the dealing is, or dealings are, proposed to be undertaken;

(i) proposed date of commencement, and proposed date of completion, of the dealing or dealings.

3.1.2 Genetics of GMO

(a) details of the biological system intended to be used, including—

(i) the biological source of the donor DNA; and

(ii) the intended host organism, or tissue; and

(iii) the vector or vectors, or the method, intended to be used for the transfer of DNA; and

(iv) whether the intended host/vector system is a system mentioned in Part 2 of Schedule 2.

3.1.3 Risk assessment information

(a) details of all risks that could arise from the genetic modification, including occupational health and safety risks for persons involved;

(b) details of all risks that could arise from an unintentional release of the GMO or GMOs into the environment, including—

(i) risks to the health and safety of people; and

(ii) risks to the environment.

3.1.4 Risk management information

(a) details of the facility in which the proposed dealing or dealings are to be undertaken, and of its physical containment level (as certified under Division 2 of Part 7 of the Act);

(b) in relation to certification of the facility—

(i) the date of certification; and

(ii) the certification number allocated to the facility by the Regulator; and

(iii) the date of the most recent inspection of the facility by the Regulator or the facility's Institutional Biosafety Committee;

(c) if the GMO is, or GMOs are, intended to be transported or moved outside the facility, details of the arrangements for that transport or movement;

(d) details of any arrangements for disposal of the GMO or GMOs;

(e) details of action proposed to be taken in the case of an unintentional release of the GMO, or GMOs, from containment;

(f) details of other actions and precautions proposed to be taken by the applicant to minimise any risks posed by the proposed dealing or dealings;

(g) details of the qualifications and experience of the project supervisor for the proponent organisation.

3.2—Additional information if GMO is a whole plant, or is to be used in conjunction with a whole plant

For a notification about a proposed notifiable low risk dealing that will involve a GMO that is a whole plant, or the use of a GMO in conjunction with a whole plant, the following additional information must be included—

(a) a statement on whether the parent organism is a weed or closely related to plants that are weeds and, if so, identification of the weeds that are closely related;

(b) details of the stage of development that the plant, or plants, used in the dealing will be allowed to reach;

(c) details of the method that will be used to dispose of the plant, or plants, used in the dealing;

(d) a statement on whether soil, or soil substitute, will be used as the growing medium for the plant, or plants, used in the dealing, and, if so, details of how that medium will be subsequently sterilised or disposed of.

3.3—Supporting information from IBC for a proponent

The information required for a notification about a proposed notifiable low risk dealing includes the following information to be given in relation to the Institutional Biosafety Committee (IBC) concerned—

(a) confirmation that the information given to the Regulator in relation to the proponent has been checked by the IBC and found to be complete;

(b) confirmation that the IBC considers that personnel intended to be involved in dealing with the GMO or GMOs have adequate training and experience for the task;

(c) a statement that the IBC has evaluated the proposed project, and that includes the following details—

(i) the date of the evaluation;

(ii) the full name of the IBC;

(iii) the name and contact details of the chairperson and of the secretary of the IBC;

(d) a copy of the evaluation report, prepared in accordance with any guidelines issued by the Regulator;

(e) a statement that the IBC is established in accordance with the Regulator's guidelines under section 98 of the Act.

Note—

The IBC giving the information could be an IBC established by the proponent, or by another accredited organisation.

Schedule 4—Prescribed information—application for a licence

(Regulation 7)

Part 1—Dealings not involving an intentional release of a GMO into the environment (Division 3 of Part 5 of the Act)

1.1—Information to be given by all applicants

For an application to which Division 3 of Part 5 of the Act applies (a ***Division 3 application***), the following information is required—

1.1.1 General information

(a) name, address, telephone number and other contact details, of applicant;

(b) name, position within the organisation and contact details, of applicant's project supervisor in relation to the proposed dealing, or dealings, with the GMO or GMOs involved;

(c) title of the project involving the proposed dealing or dealings;

(d) description of the GMO or GMOs involved, including—

(i) the common name of the parent organism; and

(ii) the scientific name of the parent organism; and

(iii) the modified trait; and

(iv) the identity of the gene responsible for the modified trait;

(e) description of the proposed dealing or dealings;

(f) description of the purposes and aims of the dealing or dealings;

(g) address of the premises where the dealing is, or dealings are, proposed to be undertaken;

(h) proposed date of commencement, and proposed date of completion, of the dealing or dealings.

1.1.2 Genetics of the GMO

(a) details of the biological system intended to be used, including—

(i) the biological source of the donor DNA; and

(ii) the intended host organism, or tissue; and

(iii) the vector or vectors, or the method, intended to be used for the transfer of DNA; and

(iv) whether the intended host/vector system is a system mentioned in Part 2 of Schedule 2.

1.1.3 Risk assessment information

(a) details of all risks that could arise from the genetic modification, including occupational health and safety risks for persons involved;

(b) details of all risks that could arise from an unintentional release of the GMO or GMOs into the environment, including—

(i) risks to the health and safety of people; and

(ii) risks to the environment;

(c) details of all previous applications (whether successful or unsuccessful) made under the Act, or to the Genetic Manipulation Advisory Committee, in relation to a proposed dealing with the GMO or GMOs, setting out in relation to each—

(i) any reference number given to the application by the Regulator or the Genetic Manipulation Advisory Committee; and

(ii) the date of the application; and

(iii) the name of the applicant's project supervisor, or intended supervisor.

1.1.4 Risk management information

(a) details of the facility in which the dealing or dealings are to be undertaken, and of its physical containment level (as certified under Division 2 of Part 7 of the Act);

(b) in relation to certification of the facility—

(i) the date of certification; and

(ii) the certification number allocated to the facility by the Regulator; and

(iii) the date of the most recent inspection of the facility by the Regulator or the facility's Institutional Biosafety Committee;

(c) if the GMO is, or GMOs are, intended to be transported or moved outside the facility, details of the arrangements for that transport or movement;

(d) details of any arrangements for disposal of the GMO or GMOs;

(e) details of action proposed to be taken in the case of an unintentional release of the GMO, or GMOs, from containment;

(f) details of other actions and precautions proposed to be taken by the applicant to minimise any risks posed by the proposed dealing or dealings;

(g) details of the qualifications and experience of the project supervisor for the proponent organisation.

1.1.5 Suitability of the applicant

(if the information is not already provided to the Regulator for any other purpose)

(a) a copy of the applicant's statutory annual report, or other information about the financial viability of the applicant;

(b) for section 58 of the Act, details of any relevant convictions (within the meaning of that section) of the applicant or the project supervisor;

(c) for section 58 of the Act, details of any failure to comply with—

(i) a provision of the Act or the regulations; or

(ii) a condition of a licence or permit (within the meaning of section 58(1)(b) or 58(2)(c) of the Act), particularly if resulting in a revocation or suspension;

(d) details of any failure to comply with an advice to proceed issued by the Genetic Manipulation Advisory Committee;

(e) details of applicant's capacity to manage any risks posed by the proposed dealing or dealings.

1.2—Additional information if volume of GMO culture exceeds 10 litres

If a GMO will be produced as a culture of cells exceeding 10 litres in volume, the following additional information is required for a Division 3 application—

(a) details of the size of the proposed project, in terms of the volume of GMO culture to be produced and the area of the facility affected;

(b) details of the main product, or products, of the intended dealing, or dealings, by-products (if any, including effluents) and the concentrations of those products and by-products at different stages of the production process;

(c) details of precautions proposed to be taken to prevent any unintended dispersal of the GMO;

(d) details of how genetic stability of the GMO will be checked, and at what frequency;

(e) details of the plan, procedures and data collection program to be used to ensure the purity of the main product or products;

(f) details of the facility to be used for the proposed project, including—

(i) the physical arrangements for each working unit involved; and

(ii) the operational procedures of each unit; and

(iii) how the intended level of physical confinement of GMOs is to be achieved;

(g) details of arrangements for personnel management, including—

(i) supervision; and

(ii) training; and

(iii) health surveillance; and

(iv) emergency care;

(h) details of the justification for the containment level proposed;

(i) details of the project designs dealing with the risks mentioned in paragraphs (a) and (b) of item 1.1.3;

(j) a statement on whether the site, within the host genome, of integration of the resultant transgene is known, and, if so, details of any secondary effects that could result from the integration, or further integration, at the site.

1.3—Additional information—GMO that is a whole plant, or is to be used in conjunction with a whole plant

If a Division 3 application relates to a GMO that will be a whole plant, or is to be used in conjunction with a whole plant, the following additional information is required for the application—

(a) a statement on whether the parent organism is a weed or closely related to plants that are weeds and, if so, identification of the weeds that are closely related;

(b) details of the stage of development that plants used in the proposed dealing, or dealings, will be allowed to reach;

(c) details of the method that will be used to dispose of plants used in the proposed dealing or dealings;

(d) a statement on whether soil, or soil substitute, will be used as the growing medium for the plants, and, if so, details of how that medium will be subsequently sterilised or disposed of.

1.4—Additional information—GMO that is an animal, or is to be used in connection with an animal

If a Division 3 application relates to a GMO that will be an animal, or that is to be used in connection with an animal, the following additional information is required for the application—

(a) details of the number of—

(i) GM animals to be involved in the proposed dealing or dealings; and

(ii) other animals to be involved;

(b) details of proposed arrangements—

(i) for breeding the animals; or

(ii) for ensuring that the animals do not breed;

(c) details of how the animals will be able to be readily identified (for example, the use of labels on cages or, for larger animals, branding or tattooing).

1.5—Additional information—GMO that is for use in clinical trials with human beings

If a Division 3 application relates to a GMO that will be used in a clinical trial with a human being (as a vaccine or, in a gene therapy trial, as a vector), the following additional information is required for the application—

1.5.1 Information about the purpose of the trial

(a) details of the disease to be treated, or prevented, by use of the GMO;

(b) details of the host range of the parent organism from which the vaccine or vector is constructed.

1.5.2 Information about the vaccine or vector

(a) details of the potential for the genetic material of the vaccine organism or gene therapy construct to become incorporated in whole, or in part, into the genome of any cells of a treated person;

(b) details of the factors that prevent multiplication or spread of the vaccine organism or the vector in a treated person;

(c) details of the period over which the GMO will be detectable in a person, or his or her excretions;

(d) if the GMO is a defective virus, details of its potential for acquiring the capacity for viral replication by complementation or recombination with intracellular viruses;

(e) details of any deleterious effects the GMO may have on a pregnant person;

(f) a statement on whether the GMO has a teratogenic effect on a foetus at any stage of gestation and, if so, details of the effect;

(g) a statement on whether the use of the GMO is likely to preclude its use for vaccination against other diseases subsequently;

(h) a statement on whether the GMO produces spores;

(i) a statement on whether the viability of the GMO is compromised by desiccation;

(j) a list of sterilising and anti-microbial agents (if any) that are active against the GMO;

(k) a statement on whether the GMO is susceptible to ultraviolet or ionising radiation.

1.5.3 Information about the effect of the GMO on the environment

(a) details of—

(i) the potential for the GMO to spread from persons to whom the GMO has been administered to other persons or to other species; and

(ii) if the potential exists, the likely mechanism and frequency of such spread;

(b) a statement on whether a person who undergoes the treatment could be more susceptible to an adverse outcome because of—

(i) the state of health of the person at the time of treatment (for example, the person presents with immunosuppression or superimposition of disease); or

(ii) other treatments, such as drugs;

(c) details of the potential for the GMO to be disseminated into the environment through human waste during or after the trial;

(d) details of proposed methods for disposing of waste containing the GMO;

(e) a statement on whether, at the end of the trial, live GMOs will be carried by a person to whom the GMO has been administered and, if so, details of—

(i) the potential for their dissemination through family contact, or to the general population; and

(ii) measures intended to be taken to minimise the potential for dissemination; and

(iii) the potential for the organisms to cross the placenta of a pregnant person or animal.

Note—

For persons relying on National Health and Medical Research Council funding, additional requirements may apply (through the Gene and Related Therapies Research Advisory Panel) to dealings of the kind to which this item applies.

1.6—Supporting information to be given by IBC

Information required for a Division 3 application includes the following information to be given by an Institutional Biosafety Committee (IBC)—

(a) confirmation that the information given to the Regulator by the applicant has been checked by the IBC and found to be complete;

(b) confirmation that the IBC considers that personnel intended to be involved in dealing with the GMO or GMOs have adequate training and experience for the task;

(c) a statement that the IBC has evaluated the proposed project, and that includes the following details—

(i) the date of the evaluation;

(ii) the full name of the IBC;

(iii) the name and contact details of the chairperson and of the secretary of the IBC;

(d) a copy of the evaluation report, prepared in accordance with any guidelines issued by the Regulator;

(e) a statement that the IBC is established in accordance with the Regulator's guidelines under section 98 of the Act.

Note—

If the applicant is an accredited organisation, the IBC giving the information could be an IBC established by that organisation.

Part 2—Dealings involving an intentional release of a GMO into the environment (Division 4 of Part 5 of the Act)

2.1—Information to be given by all applicants

For an application to which Division 4 of Part 5 of the Act applies (a ***Division 4 application***), the following information is required—

2.1.1 General information

(a) details of the name, address, telephone number and other contact details, of applicant;

(b) details of the name, position within the organisation and contact details, of applicant's project supervisor for the proposed dealing, or dealings, with a GMO, or GMOs;

(c) title of the project involving the proposed dealing or dealings;

(d) description of the GMO or GMOs;

(e) description of the proposed dealing, or dealings, in terms of section 40(4)(a), 40(4)(b) or 40(4)(c) of the Act, as applicable;

(f) description of the aims and purposes of the proposed dealing, or dealings;

(g) identification of the person, persons or class of persons, intended to be authorised to undertake the dealing, or dealings;

(h) the proposed date of commencement, and proposed date of completion, of the dealing or dealings.

2.1.2 Risk assessment information—the parent organism

(a) details of the species to be released including, if relevant, information about the strain, cultivar etc;

(b) an assessment of whether the parent organism is capable of causing disease or other ill-health in people, plants or animals and, if so, details of the possible effects;

(c) details of the natural habitat of the parent organism, and its range;

(d) details of the location where the parent organism was originally isolated for the purpose of the proposed dealing or dealings;

(e) details of the distribution of the parent organism, and closely related organisms, in Australia;

(f) a statement on whether the parent organism, or a closely related organism, is present at or near the site of the proposed release and, if so, details of the population or populations;

(g) a statement on whether the parent organism is exotic in Australia;

(h) details of any known predators, or parasites, of the parent organism in Australia.

2.1.3 Risk assessment information—the GMO

(a) details of the origin of the DNA to be inserted;

(b) if the inserted DNA will come from an organism that causes disease or other ill-health in humans, animals, plants or fungi, details of the effects;

(c) details of the genetic modification that will be made, including details of the steps to be undertaken in its construction;

(d) details of the stability of the genotype of the GMO or GMOs, including a statement on whether it has a potentially unstable genotype;

(e) details of the extent to which the genetic modification has been characterised (that is, the DNA sequenced, and the potential gene products understood);

(f) details of the intended location of the inserted DNA in the final construct, and the number of copies that will be present;

(g) details of the markers or sequences that will enable the GMO or GMOs to be identified in the laboratory and under field conditions;

(h) details of the type of vector to be used in the transfer (including a description of the vector), showing the position of the inserted DNA and any other control sequences or markers in the vector;

(i) details of whether the vector has the ability to transfer to other hosts and, if so, details of the host range;

(j) details of whether the recombinant vector will be present in the final construct and if not, how it will be removed;

(k) if no vector will be involved, details of how the DNA will be introduced and how many copies of the gene will be inserted;

(l) details of how the modification will change the phenotype of the organism to be released, including information to demonstrate the effect of the modification;

(m) details of secondary genetic effects that may be anticipated;

(n) a statement on whether the site, within the host genome, of integration of the resultant transgene is known;

(o) details of the intrinsic genetic features, if any, of the GMO or GMOs that will regulate survival in the environment, including a statement on how stable those features are;

(p) details of the genetic changes, if any, that will be included in the GMO or GMOs to limit or eliminate any capacity to reproduce or transfer genes to other organisms.

2.1.4 Risk assessment information—proposed dealing with the GMO

(a) a description of the proposed dealing, or dealings, with the GMO or GMOs, including a description of the proposed intentional release into the environment;

(b) a statement of—

(i) the proposed date or dates for the intentional release into the environment; or

(ii) if release is to occur over a number of days, the proposed commencement and completion dates;

(c) a statement of the number of GMOs to be released;

(d) a statement of the number of releases of the GMO that are proposed;

(e) details of—

(i) the number of sites for proposed release; and

(ii) the area of land to be used; and

(iii) the location of the proposed release or releases, including identification of the local government area in which any release will take place and the geographical location, grid references and GPS coordinates of the site or sites;

(f) details of the reasons for the choice of location or locations for the release or releases;

(g) details of how the GMO or GMOs will be released;

(h) details of the methods to be used to test for batch to batch consistency, if large scale production is required to produce GMOs for release;

(i) details of the measures that have been taken, or will be taken, in the production process to ensure quality and purity of GMOs intended to be released;

(j) details of the arrangements for conducting any other dealings in association with the proposed release, such as importation of a GMO and transportation of a GMO to or from a release site;

(k) details of proposed uses of the GMO or GMOs, or of things derived or produced from the GMO or GMOs, following release into the environment;

Example—

1 Collecting field trial material for laboratory analysis.

2 Giving GM product to animals as stockfeed.

(l) details of all previous applications (whether successful or unsuccessful) made under the Act, or to the Genetic Manipulation Advisory Committee, in relation to a proposed dealing with the GMO or GMOs, setting out in relation to each—

(i) any reference number given to the application by the Regulator or the Genetic Manipulation Advisory Committee; and

(ii) the date of the application; and

(iii) the name of the applicant's project supervisor, or intended supervisor.

2.1.5 Risk assessment information—interaction between GMO and the environment

(a) a statement on whether release of a proposed GMO could prejudice any beneficial function of the parent organism in the environment;

(b) on the basis of contained experiments, details of—

(i) the survival times of the GMO in habitats relevant to the release; and

(ii) the growth rate (or generation time) of the parent organism and GMO in the ranges of environmental conditions characteristic for the place and date of release; and

(iii) the frequency of reversion or loss of the genetic change;

(c) details of the capability of the GMO to disperse from the release area or areas, and, if any, the dispersal mechanism;

(d) a statement on whether the GMO is likely to be able to establish in the environment outside the release site or sites;

(e) a statement on whether the GMO will be able to form long-term survival structures, such as seeds or spores;

(f) a statement on whether the inserted genetic trait will be able to be transferred to other organisms found at the release site and surrounding environment and, if so, details of—

(i) the organisms the trait can be transferred to and the frequencies at which it can be transferred, including information about the species that have been tested for transfer and the rationale for selecting the test species; and

(ii) the transfer mechanisms involved; and

(iii) the techniques that have been used to demonstrate transfer; and

(iv) any possible adverse effects of the transfer, including—

(A) any advantage that affected organisms are likely to have over members of the species that do not contain the transgene; and

(B) environmental risks posed by such an advantage;

(g) a statement on whether interactions between pathogens and the transgene are possible (for example, gene silencing) and, if so, details of—

(i) the incidence and distribution of relevant pathogens; and

(ii) possible effects of interaction;

(h) a statement on whether the GMO is likely to show any competitive advantages over its unmodified parent in mixed populations under the conditions at the release site or sites, and, if so, details of the nature of the advantages;

(i) a statement on whether the modified trait will confer a selective advantage on the GMO under certain conditions and, if so, details of the conditions, including data on growth rates with and without selection pressure;

(j) details of features of the physical environment of the release site or sites, particularly features that may minimise or exacerbate any undesirable effects of the GMO;

(k) details of the proximity of the release site, or sites, to population centres, centres of agricultural activity, or the habitat of biota that might affect, or be affected by, the proposed release;

(l) a statement on whether the GMO is expected to remain in the environment after release and, if so, details of—

(i) the period of time; and

(ii) any environmental risks posed by the GMO during that period;

(m) details of any other environmental risks that may be posed by the GMO.

2.1.6 Risk assessment information—risks GMO may pose to the health and safety of people

(a) details of any allergens or toxins that may be expressed by the proposed GMO that are not found in the parent organism;

(b) details of any pathogenic properties in the GMO that are not found in the parent organism;

(c) details of any occupational health and safety risks to personnel dealing with the GMO and safety risks to the wider community.

2.1.7 Risk management information

(a) details of proposed measures for monitoring any risks posed by the proposed GMO, including monitoring for—

(i) the survival or presence of the GMO, or transferred genetic material, beyond the proposed release site or sites, including specificity, sensitivity and reliability of detection methods; and

(ii) impacts on the characteristics, or abundance, of other species; and

(iii) transfer of the introduced gene to other species; and

(iv) any other hazards or deleterious effects;

(b) details of proposed measures for limiting the dissemination or persistence of the GMO, or its genetic material, in the environment;

(c) details of the methods that will be used to minimise the effects of any transfer of the modified genetic trait to other organisms;

(d) details of the specific experimental methods proposed for detecting the presence of the GMO, or transferred genetic material, in the recipient organism;

(e) details of proposed measures for disposing of—

(i) the GMO when the release is complete; and

(ii) any waste deriving from the GMO;

(f) details of proposed release-site supervision procedures and any safety procedures to be undertaken by staff, including a description of procedures for on-site supervision of the release if the release site is located at some distance from the location of the IBC;

(g) details of proposed measures for—

(i) informing persons covered by the licence of any licence conditions; and

(ii) informing the public about the proposed dealing or dealings;

(h) details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the Regulator;

(i) details of any contingency measures that will be in place to rectify any unintended consequence if a hazard becomes evident during the course of the release;

(j) details of ongoing monitoring to be undertaken after the release is completed.

2.1.8 Information about previous assessments or approvals

(a) details of results of any applications made for approval of the GMO, or any derived GM products, by any other regulator in Australia or overseas, including information about conditions (if any) attaching to the approval;

(b) details of any previous licence under the Act for dealing with the GMO, or of a notification of a dealing under the Act, from which the work in the present application has developed;

(c) if the GMO has been previously released in Australia or overseas, details of any adverse consequences of the release, including identifying references and reports of assessments;

(d) a list of Commonwealth and State government authorities that have been consulted about the proposed dealings with the GMO (including names of contact officers);

(e) for an imported GMO, the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the Australian Quarantine and Inspection Service (AQIS).

2.1.9 Suitability of the applicant

(if the information is not already provided to the Regulator for any other purpose)

(a) details of qualifications, experience and proposed role of each person to be involved in the dealing or dealings;

(b) a copy of the applicant's statutory annual report, or other information about the financial viability of the applicant;

(c) for section 58 of the Act, details of any relevant convictions (within the meaning of that section) of the applicant or the project supervisor;

(d) for section 58 of the Act, details of any failure to comply with—

(i) a provision of the Act or the regulations; or

(ii) a condition of a licence or permit (within the meaning of sections 58(1)(b) or 58(2)(c) of the Act), particularly if resulting in a revocation or suspension;

(e) details of any failure to comply with an advice to proceed issued by the Genetic Manipulation Advisory Committee;

(f) details of applicant's capacity to manage any risks posed by the proposed dealing or dealings.

2.2—Additional information—GMO that is a plant

If a Division 4 application relates to a proposed GMO that is a plant, the following additional information is required for the application—

2.2.1 Information about the use of the parent plant

(a) statement about whether the parent plant has an extended history of cultivation and safe use.

2.2.2 Information about any unintended pleiotropic effects

(a) details of undesirable effects on the parent plant that may result from expression of the transgene, or an associated insertion-related mutation, in the GMO (for example, reduced fertility, increased disease prevalence, production loss, grain shedding), including the likelihood of any such events.

2.2.3 Information about pollen and cross-pollination

(a) details of the mechanism of pollen spread (by insect vectors or by other means) in the plant population;

(b) details of pollen viability for the parent plant and the GMO;

(c) details of any potential pollinators for the parent plant and the GMO, and their range and distribution in Australia;

(d) quantitative data on successful cross-pollination between the parent plant, the GMO and its wild relatives;

(e) if sexually compatible plants live near a site of the proposed release, details of the quantity and the chances for cross-pollination with the GMO;

(f) if cross-pollination with the GMO were to occur, details of the likely resulting plants and an assessment of whether they would survive and compete well with unaffected plants.

2.2.4 Information about weeds

(a) details of members of the family of unmodified parent plants that are known to be weeds in any environment;

(b) details of cross-pollination between the species to which the GMO belongs and relatives known to be weeds, including a copy of any peer-reviewed reports that support the information.

2.2.5 Information about the possible result of the imparted characteristics being integrated into other species

(a) a statement on whether the novel characteristics of the GMO could be integrated into other species and, if so, details of its potential to affect—

(i) the distribution and abundance of populations of the affected species; and

(ii) factors that normally control populations of the affected species in the environment (for example, pathogens, herbivory and physiological stress);

(b) details of any other possible adverse consequences;

(c) details of proposed measures to minimise the risk (for example, by imparting male sterility or other means of reproductive isolation).

2.2.6 Information about the seeds of the GMO

(a) a statement on whether the GMO proposed to be released will be allowed to set seed and, if not, whether setting seed is planned for a later release;

(b) if the GMO is to be allowed to set seed, a statement on whether mature seed is expected to be shed (from, for example, an ear, capsule or pod), and, if so, an indication of the proportion of seed likely to remain in the environment following harvest;

(c) a statement on whether the seed has the potential to be dispersed by natural mechanisms and, if so, details of the mechanisms;

(d) details of the length of time the seeds will be capable of being dormant.

2.2.7 Information about whether the GMO can be dispersed by vegetative propagation

(a) a statement on whether the GMO proposed to be released can be dispersed by vegetative propagation and, if so, the possible mechanisms.

2.2.8 Information about whether the capacity of the GMO to add substances to, or subtract substances from, soil will change

(a) a statement on whether the novel characteristic of the proposed GMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such change.

2.2.9 Information about toxicity

(a) an assessment of whether there is any likelihood that the introduced trait could cause the proposed GMO to have greater toxicity (for animals, including human beings) than would an unmodified plant and, if so, details of that likely effect;

(b) an assessment of whether any products of the GMO could concentrate in the natural or human food chain to levels which become toxic, and available data (if any) on that subject;

(c) an assessment of whether the biodegradability of the GMO will be different to that of the parent organism and, if so, details of the differences.

2.2.10 Information about any secondary ecological effects that might result from the release

(a) an assessment of possible effects of the proposed release on—

(i) native species; and

(ii) resistance of insect populations to an insecticide; and

(b) abundance of prey or parasites.

2.2.11 Information about resistance of the GMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

(a) for a GMO that, as a result of the modification, will have resistance to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), details of any environmental risks related specifically to that resistance.

2.2.12 Information about resistance of GMO to a biological agent

(a) for a GMO that, as a result of the modification, will have resistance to a biological agent (for example, an insect or a fungal disease), details of any environmental risks related specifically to that resistance.

2.3—Additional information—GMO that is a micro-organism (not living in or on animals and not a live vaccine)

If a Division 4 application is in relation to a proposed GMO that is a micro-organism—

(a) including a micro-organism associated with plants, and a micro-organism that might be applied to modify the physical or chemical environment (for example, to modify soil properties); but

(b) not including a micro-organism living in or on animals, or a micro-organism that is a live vaccine—

the following additional information is required for the application—

2.3.1 Information about GM micro-organisms associated with plants

(a) details of any partner species of plant, including information about the specificity of the interaction and the range of plant species with which the proposed GMO can interact;

(b) an assessment of the effect of the proposed GMO on the partner plant species, and details of how it will be monitored;

(c) an assessment of any secondary effects that the proposed GMO might have on the partner plant species;

(d) an assessment of whether the modification is likely to cause any change to the range of host plant species susceptible to infection by the organism;

(e) an assessment of the effect, if any, of the proposed GMO on the distribution and abundance of host plant species or other species with which the proposed GMO can interact;

(f) an assessment of the effect the proposed GMO might have on insects, birds, animals or humans that may eat the plant.

2.3.2 Information if the parent organism has an extended history of use in agriculture

(a) if the parent organism has an extended history of use in agriculture, a description of the use.

2.3.3 Information if the GM micro-organism is associated with plant species that are food crops

(a) if the GM micro-organism is associated with plant species that are food crops, an assessment of whether the proposed GMO could affect the suitability of the resultant produce for consumption by animals or human beings and, if so, details of the effect.

2.3.4 Information about the impact of the GMO on soil and water

(a) details of the expected effects of the proposed GMO on local soil chemistry (for example, pH, mineral leaching and nutrient levels);

(b) details of the possible effects of the proposed GMO on local water quality;

(c) details of the effects the proposed GMO might have on soil organisms that are known to be beneficial to plants (for example, *Rhizobium*, *Azospirillum*, *Frankia* and mycorrhizal fungi) and that are likely to be in a release site.

2.3.5 Information about any interactions between the GMO and closely related micro-organisms

(a) details of any known interaction between the proposed GMO and closely related micro-organisms in any partner plant (if applicable) and in the environment of the release site.

2.3.6 Information about known genetic exchange between parent organism and plant pathogens

(a) details of any known exchange of genetic material between the parent organism and plant pathogens.

2.3.7 Other information

(a) information about the expected survival and dispersal of the proposed GMO, including dispersal in natural waters, soil and on other natural surfaces;

(b) a statement about whether the proposed GMO will produce spores;

(c) a statement about whether the proposed GMO will be resistant to desiccation;

(d) a list of sterilising and anti-microbial agents (if any) that are expected to be active against the proposed GMO;

(e) a statement about whether the proposed GMO will be susceptible to ultraviolet or ionising radiation.

2.4—Additional information—GMO that is a micro-organism that lives in or on animals

If a Division 4 application is in relation to a proposed GMO that is a micro-organism living in or on animals (including an organism such as gut biota living in larger hosts, and a micro-organism applied externally to an animal (for example, bacteria to prevent fleece rot)), the following additional information is required for the application—

2.4.1 Information about the impact of the GMO on the host

(a) identification of the animal host species;

(b) a statement about whether the parent organism has an extended history of use in agriculture and, if so, details of the use;

(c) an assessment of any new capacity the proposed GMO will provide for the host species (for example, ability to degrade plant or pasture toxins);

(d) an assessment of whether the competitive advantage, ecological fitness, biology or distribution, of the host will be altered, and relevant data (if any) on the subject;

(e) details of any secondary effects expected to result from the introduction of the proposed GMO into or onto the host (for example, information about any possibility of the genetic insert being transferred to other organisms in the host, or to host cells).

2.4.2 Information about the impact of the GMO on the environment (particularly the impact on other animals, plants, soil and water)

(a) any evidence that the proposed GMO might be capable of establishing in, or on, other animals, including feral animals;

(b) any evidence of other likely effects (including secondary effects) on other plants or animals in the agricultural and natural environments;

(c) if the proposed GMO will establish in an animal, information about whether the GMO will be excreted or otherwise leave the animal and, if so, the time period that it is expected the GMO can survive outside the animal;

(d) an assessment of the possible effects of the GMO on local water quality.

2.4.3 Other information

(a) a statement about whether the proposed GMO will produce spores;

(b) a statement about whether the proposed GMO will be resistant to desiccation;

(c) a list of sterilising and anti-microbial agents (if any) that are expected to be active against the proposed GMO;

(d) a statement about whether the proposed GMO will be susceptible to ultraviolet or ionising radiation.

2.5—Additional information—GMO that is a live vaccine for use in animals

If a Division 4 application is in relation to a GMO that is a live vaccine for use in animals, the following additional information is required for the application—

2.5.1 Information about the purpose of the vaccine

(a) identification of the disease to be treated, or prevented, by use of the vaccine;

(b) identification of the host species on which the vaccine is to be used;

(c) details of the host range of the parent organism from which the vaccine is constructed;

(d) details of the level, and duration, of immunity produced in the host species after administration of the vaccine.

2.5.2 Information about the vaccine

(a) an assessment of the potential for the genetic material of the vaccine organism to become incorporated in whole, or in part, into the genome of any cells of the vaccinated host;

(b) an assessment of the period over which the vaccine GMO will be detectable in a test animal, or its excretions;

(c) if the GMO is a viral vaccine, information about the potential for the nucleic acid of the virus in the vaccine to be rescued, or to be restored to wild type, by recombination or complementation with intracellular viruses;

(d) details of any deleterious effects the vaccine GMO may have on a pregnant animal;

(e) a statement on whether the vaccine GMO has a teratogenic effect on a foetus at any stage of gestation;

(f) a statement on whether the use of the vaccine GMO is likely to—

(i) preclude its use for vaccination against other diseases subsequently; or

(ii) affect its usefulness for other vaccinations;

(g) a statement on whether the vaccine GMO produces spores;

(h) a statement on whether the vaccine GMO is resistant to desiccation;

(i) a list of sterilising and anti-microbial agents (if any) that are active against the GMO;

(j) a statement on whether the GMO is susceptible to ultraviolet or ionising radiation.

2.5.3 Information about the effect of the GMO on the environment

(a) details of—

(i) the potential for the vaccine GMO to spread from vaccinated to unvaccinated animals or to other species (including human beings); and

(ii) if the potential exists, the likely mechanism and frequency of such spread;

(b) an assessment of whether the susceptibility of the host to the vaccine organism could be affected by—

(i) the state of the host at the time of vaccination (for example, immunosuppression, or superimposition of other disease); or

(ii) other treatments, such as drugs;

(c) details of proposed methods for disposing of waste containing vaccine GMO;

(d) details of the intended fate of vaccinated animals at the end of the trial;

(e) information about whether live vaccine organisms will be carried by an animal at the end of the trial and, if so—

(i) the potential for dissemination of the live vaccine organisms through the animal's family contact, or to the general population of the species; and

(ii) measures intended to be taken to minimise the potential for dissemination; and

(iii) the potential for the organisms to cross the placenta of a pregnant animal.

2.6—Additional information—GMO that is a vertebrate animal

If a Division 4 application is in relation to a GMO that is a vertebrate animal (other than aquatic organisms), the following additional information is required for the application—

2.6.1 Information about the effects of the GMO on the environment

(a) information about the likelihood of any unintended effect on an animal resulting from the release;

(b) information about any intended gains that are directly linked to changes in other characteristics of the subject species.

2.6.2 Information about any effects the expression of the modified trait might have on the animal

(a) information about expected effects on the physiology, behaviour and reproduction of the animal or animals.

2.6.3 Information about future dealings with the GMO

(a) a statement on whether an animal in the experiment is intended to be allowed to breed and, if not, whether breeding is planned in the future;

(b) a statement on whether the proposed arrangements for handling any offspring are the same as those for the experimental animal or animals, and, if not, the proposed different arrangements.

2.6.4 Information about feral populations of subject species, if any, that exist in Australia or that may be established

(a) details of any agricultural, environmental or disease-control problems caused by feral populations of the subject species;

(b) details of any experimental work that has been done on expression of the novel genetic material in feral animals (such as cross-breeding of GMOs with captive feral animals), and the results of such work;

(c) an assessment of the likelihood of the novel genetic material entering the feral gene pool (for example, by interbreeding with modified farm animals);

(d) an assessment of the effect that the entry of the novel genetic material into a feral gene pool might have—

(i) on the distribution and abundance of the feral population; or

(ii) on the ability of the feral population to cause agricultural or environmental problems; or

(iii) in contributing to the spread of infectious disease;

(e) if no feral population exists in Australia, information about—

(i) the likelihood of the imparted characteristic enhancing the ability of the species to establish feral populations; and

(ii) if there is a likelihood, the arrangements in place to prevent this from occurring.

2.6.5 Information about the capacity of the GMO to interbreed

(a) details of the capacity of the GMO to interbreed with any species native to, or currently present in, Australia.

2.6.6 Information about requirements for optimal expression of the introduced trait

(a) details of the management procedures and environmental factors, if any, that would be required for optimal expression of the introduced trait or traits.

Note—

All work involving animals should be conducted according to the NHMRC Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, under which it requires review by an Institutional Animal Ethics Committee and by the relevant authority administering State animal welfare legislation.

2.7—Additional information—GMO that is an aquatic organism

If a Division 4 application is in relation to a GMO that is an aquatic organism (for example, fish, crustaceans and molluscs), the following additional information must be included—

2.7.1 Information about effects of the GMO on the environment

(a) a statement on whether the GMO could produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators and, if so, the likely effect;

(b) details of any unintended effects that may result from the release;

(c) a statement on whether the expression of the modified gene is expected to be directly linked to undesirable changes in other characteristics of the subject organisms (for example, a decrease in nutritional value);

(d) information about—

(i) whether the modified genetic material can be transmitted to any other species; and

(ii) if so, the expected mechanism of transfer, the likely affected species and any likely consequences.

2.7.2 Information about any impact on natural populations

(a) information about whether natural populations of the parental organism, or a closely related species, exist in Australia (including in rivers, lakes, dams or coastal waters) and, if so, details about any problems the natural populations cause with other organisms;

(b) if no natural populations of the organism to be modified exist in Australia, information about the potential for the modified traits to enhance the ability of the species to establish populations in aquatic habitats;

(c) information about the results of any experimental work that has been done on phenotypic expression of the modified genetic material in naturally occurring organisms (such as cross-breeding of GMOs with wild or farmed stocks);

(d) an assessment of the likelihood of the modified genetic material entering the gene pool of natural populations;

(e) information about any impact the entry of the modified genetic material into the gene pool of a natural organism could have on—

(i) the distribution and abundance of the organism; or

(ii) associated aquatic farms; or

(iii) the environment; or

(iv) public health;

(f) information about mechanisms intended to be used to prevent dispersal of the GMO into other ecosystems.

2.7.3 Information about future dealings with the GMO

(a) a statement about whether an organism in the experiment is intended to be allowed to breed and, if not, whether breeding is planned in the future;

(b) a statement about whether the proposed arrangements for handling any offspring are the same as those for the experimental organisms and, if not, the proposed different arrangements.

2.8—Additional information—GMO that is an invertebrate animal

If a Division 4 application is in relation to a GMO that is an invertebrate animal, the following additional information must be included—

(a) information about the effect the GMO might have on the food chain;

(b) information about the potential for the GMO to produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators;

(c) information about other unintended effects that may result from the release;

(d) a statement on whether the GMO will be fertile and, if not, whether it is intended to use fertile organisms in later releases;

(e) information about whether populations of the parental organism, or a closely related species, exist in Australia and, if so, any environmental or public health problems, or benefits, caused by the populations;

(f) information about—

(i) whether the modified, genetic material can be transmitted by means other than by reproduction normal for the species; and

(ii) if so, the likelihood of that genetic material entering gene pools of natural populations;

(g) information about—

(i) whether the modified, genetic material can be transmitted to any other species; and

(ii) if so, the expected mechanism of transfer, and the likely affected species;

(h) information about any experimental work that has been done on the phenotypic expression of the novel genetic material in other genetic backgrounds (such as cross-breeding of modified strains with wild or caught stock);

(i) information about the effect, on the distribution and abundance of the natural populations of the organism, of the entry of the novel genetic material into the gene pool of those populations;

(j) details of the mechanisms proposed to be used to prevent dispersal of the GMO into other ecosystems.

2.9—Additional information—GMO that is to be used for biological control

If a Division 4 application is in relation to a GMO that is to be used for biological control, the following additional information must be included—

2.9.1 Information about the expected interaction between the GMO and the species targeted for biological control

(a) the name of the species targeted for biological control;

(b) details of any direct effects the parent organism has on the target species;

(c) details of any direct effects the GMO is expected to have on the target species;

(d) details of how the GMO is intended to be transferred from one target organism to another, and what factors affect the transferability;

(e) details of the genetic response that may be invoked in populations of the target organism as a result of the use of the GMO (for example, increased resistance to the modified organism), and the expected evidence for the response.

2.9.2 Information on the possible effects of the GMO on non-target organisms

(a) details of the host range of the GMO, and details of any difference between that host range and the host range of the parent organism;

(b) a list of the non-target organisms that have been tested for susceptibility to the GMO, and the rationale for the choice of species tested;

(c) if the modified traits can be transmitted to other organisms that are likely to be in the environment, details of any effects those other organisms are likely to have on non-target species.

2.9.3 Information on other possible effects of the GMO on the environment

(a) a statement about the secondary effects that can be envisaged on competitors, predators, prey or parasites of the target species;

(b) an assessment of the consequence of the removal, or reduction, of the target species on the management of agriculturally significant plants or farm animals;

(c) details of any predicted change in the ecosystem resulting from a reduction in the population of the target organism;

(d) information about—

(i) whether the GMO produces metabolites that may have deleterious effects on other organisms, including human beings—

(A) directly; or

(B) indirectly, through concentration in the food chain; and

(ii) if so, the likely effect.

2.10—Additional information—GMO that is to be used for bioremediation

If a Division 4 application is in relation to a GMO that is to be used for bioremediation, the following additional information must be included—

2.10.1 Information about the expected interaction between the GMO and the target substrate for bioremediation

(a) identification of the target substrate for bioremediation;

(b) details of the effect the parent organism has on the target substrate;

(c) details of the effect the GMO is expected to have on the target substrate;

(d) a list of the substances other than the target substrate that can be metabolised by the GMO and that cannot be metabolised by the parent organism.

2.10.2 Information about the GMO and its impact on the environment

(a) a statement about whether the GMO will be self-sufficient if added to the contaminated site or whether additional measures may be required (for example, provision of supplementary nutrients and growth factors, or other environmental modifications);

(b) a list of any metabolites produced by the GMO that may have deleterious effects on other organisms—

(i) directly; or

(ii) indirectly, through concentration in the food chain;

(c) details of effects the GMO might have on water, air or soil quality;

(d) details of effects the GMO might have on organisms that ingest it;

(e) a statement on whether the GMO will be dispersed from the site of application and, if so, the proposed mechanisms involved and the likely consequences.

2.11—Additional information—GMO intended to be used as food for human or vertebrate animal consumption

If a Division 4 application is in relation to a GMO that is intended to be developed for use as a food for consumption by human beings or animals, the following additional information must be included—

(a) details of—

(i) whether the parent organism or the donor organism is of a kind already in use as a food for consumption by human beings or animals, or used in the production of such a food; and

(ii) whether any processing is needed, or is commonly applied, before consumption;

(b) details of any metabolites produced by the GMO that may have adverse effects on the consumer (human or animal), including available data on toxicology, allergenicity and other possible adverse effects;

(c) details of any products of the GMO that are expected to concentrate in the food chain to levels which may become toxic;

(d) details of any expected changes to the nutritional quality of such food as a result of the genetic modification;

(e) a statement on whether the GMO is a major component of such food as consumed, or a minor component (for example, yeast cells in beer).

Note—

For a food for human consumption that contains GMOs or GM products, see also the assessment requirements under the *Australia New Zealand Food Authority Act 1991* of the Commonwealth.

2.12—Supporting information to be given by IBC

Information required for a Division 4 application includes the following information to be given by an Institutional Biosafety Committee (IBC)—

(a) confirmation that the information given to the Regulator by the applicant has been checked by the IBC and found to be complete;

(b) confirmation that the IBC considers that personnel intended to be involved in dealing with the GMO or GMOs have adequate training and experience for the task;

(c) a statement that the IBC has evaluated the proposed project, and that includes the following details—

(i) the date of the evaluation;

(ii) the full name of the IBC;

(iii) the name and contact details of the chairperson and of the secretary of the IBC;

(d) a copy of the evaluation report, prepared in accordance with any guidelines issued by the Regulator;

(e) a statement that the IBC is established in accordance with the Regulator's guidelines under section 98 of the Act.

Note—

If the applicant is an accredited organisation, the IBC giving the information could be an IBC established by that organisation.

Legislative history

Notes

- Variations of this version that are uncommenced are not incorporated into the text.
- For further information relating to the Act and subordinate legislation made under the Act see the Index of South Australian Statutes or www.legislation.sa.gov.au.

Principal regulations and variations

New entries appear in bold.

Year	No	Reference	Commencement
2002	8	*Gazette 15.1.2002 p244*	1.2.2002: r 2
2007	20	*Gazette 15.3.2007 p813*	31.3.2007: r 2