Queensland

Subordinate Legislation 2002 No. 189

Gene Technology Act 2001

GENE TECHNOLOGY REGULATION 2002

TABLE OF PROVISIONS

PART 1—PRELIMINARY

1 Short title

This regulation may be cited as the *Gene Technology Regulation 2002*.

2 Commencement

Note—

Regulation 2 of the Commonwealth regulations provides when those regulations commence.

3 Definitions

The dictionary in schedule 5 defines particular words used in this regulation.

Note—

This section differs from regulation 3 of the Commonwealth regulations.

3A Numbering

(1) In order to maintain consistent numbering between this regulation and the Commonwealth regulations—

(a) if the Commonwealth regulations contain a regulation (**"Commonwealth regulation"**) that is not required in this regulation, the provision number and heading to the Commonwealth regulation is included in this regulation despite the omission of the body of the regulation; and

(b) if this regulation contains a section that is not included in the Commonwealth regulations, the section is numbered so as to maintain consistency in numbering between provisions common to both regulations.

(2) A provision number and heading mentioned in subsection (1)(a) form part of this regulation.

Note 1—

A note appears under each heading of a kind mentioned in subsection (1)(a) describing the omitted Commonwealth regulation.

Note 2—

A note appears under each section of a kind mentioned in subsection (1)(b) highlighting the non-appearance of an equivalent provision in the Commonwealth regulations.

Note 3—

This section does not appear in the Commonwealth regulations.

3B Notes

Notes do not form part of this regulation.

Note—

This section does not appear in the Commonwealth regulations.

PART 2—INTERPRETATION AND GENERAL OPERATION

4 Techniques not constituting gene technology

For the Act, schedule 3, definition "gene technology", paragraph (c), 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 Act, schedule 3, definition "genetically modified organism", paragraph (e), an organism mentioned in schedule 1, part 1 is declared not to be a genetically modified organism.

PART 3—DEALINGS WITH GMOs

Division 1—Licensing system

6 Dealings exempt from licensing

(1) For the Act, schedule 3, definition "exempt dealing", a dealing, in relation to a GMO, is an exempt dealing if—

(a) it is a dealing of a kind mentioned in schedule 2, part 1; and

(b) it does not involve a genetic modification other than a modification mentioned in schedule 2, part 1; 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) To avoid any doubt, it is declared that exemption under subsection (1) does not apply to a dealing that does not comply with the subsection, whether or not the dealing is related to a dealing that does comply with the subsection.

Note 1—

A dealing affected by this section may be any form of dealing mentioned in the definition "deal with" in schedule 3 of the Act.

Note 2—

Exemption from provisions of the Act does not preclude the application of another law of the State or a law of the Commonwealth or another State.

7 Application for licence—prescribed information

(**1**) For section 40(2)(a)[1] of the Act, the following information must be contained in an application for a licence—

1 Section 40 (Person may apply for a licence) of the Act

(a) for an application to which part 5, division 3[2] of the Act applies—the information stated in schedule 4, part 1;

(b) for an application to which part 5, division 4[3] of the Act applies—the information stated in schedule 4, part 2.

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

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

(a) as comprehensive as scientific knowledge, existing 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 subsection (3)(b) does not provide relevant data and references, the applicant must include each of the following in the application—

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

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

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

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

Note 1—

Additional information, specified in writing by the regulator, may also be required under section 40(2)(b) or 42(1) of the Act.

Note 2—

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

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2 Part 5 (Licensing system), division 3 (Initial consideration of licences for dealings not involving intentional release of a GMO into the environment) of the Act

3 Part 5 (Licensing system), division 4 (Initial consideration of licences for dealings involving intentional release of a GMO into the environment) of the Act

8 Time limit for deciding an application

(1) For section 43(3)[4] of the Act, the period within which the regulator must issue, or refuse to issue, a licence is—

(a) for an application to which part 5, division 3 of the Act applies—90 days after the day on which the regulator receives the application; or

(b) for an application to which part 5, division 4 of the Act applies—170 days after the day on which the regulator receives the application.

(2) For deciding the end of a period mentioned in subsection (1), each of the following days are not counted—

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

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

(c) if the regulator, under section 53[5] of the Act, publishes notice of a public hearing about the application, 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 can not proceed with the decision-making process or a related function because—

(i) the applicant has made a section 184 application; and

(ii) the regulator is either—

(A) considering the section 184 application; or

(B) waiting until any review rights under section 181 or 183[6] of the Act, for the section 184 application, are exhausted;

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4 Section 43 (Regulator must consider applications except in certain circumstances) of the Act

5 Section 53 (Regulator may take other actions) of the Act

6 Section 181 (Internal review) or 183 (Review of decisions by Administrative Appeals Tribunal) of the Act

(e) if the regulator requests the ethics committee to provide advice on an ethical issue relating to the application, a day in the period that—

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

(ii) subject to subsection (3), ends on the day when the advice is given or, if the advice is not given within a period stated under the subsection, on the last day of the period.

(3) When seeking advice under section 50(3) or 52(3)[7] of the Act, or advice from the ethics committee, the regulator—

(a) may state a reasonable period within which the advice must be received; and

(b) if the advice is not received within the stated period, must proceed without regard to the advice.

(**4**) In this section—

"section 184 application" means an application, under section 184 of the Act, for a declaration that information given about the applicant's licence application is confidential commercial information.

9 Prescribed authorities

For sections 50(3)(c) and 52(3)(c) of the Act, each of 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.

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7 Section 50 (Regulator must prepare risk assessment and risk management plan) or 52 (Public notification of risk assessment and risk management plan) of the Act

10 Risk assessment—matters to be taken into account

(**1**) For section 51(1)(d) and (2)(d)[8] of the Act, other matters to be taken into account for dealings proposed to be authorised by a licence include—

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

(b) the potential of the GMO to do any or all of the following—

(i) harm other organisms;

(ii) adversely affect any ecosystems;

(iii) transfer genetic material to another organism;

(iv) spread or persist in the environment;

(v) have a selective advantage in the environment;

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

(2) The regulator must also consider each of the following—

(a) in taking into account a risk mentioned in section 51(1)(a) of the Act—the risk for both the short term and the long term;

(b) in taking into account a potential capacity mentioned in subsection (1)(b)—the potential capacity for both the short term and the long term.

11 Prescribed conditions of licence

Note—

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

8 Section 51 (Matters regulator must take into account in preparing risk assessment and risk management plan) of the Act

Division 2—Notifiable low risk dealings

12 Notifiable low risk dealings

(1) For section 74(1)[9] 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 schedule 3, part 1 (other than a dealing of a kind also mentioned in schedule 3, part 2); and

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

(2) To remove any doubt, it is declared that subsection (1) does not apply to a dealing that does not comply with the subsection, whether or not the dealing is related to a dealing that does comply with the subsection.

Note 1—

A dealing affected by this section may be any form of dealing mentioned in the definition "deal with" in schedule 3 of the Act.

Note 2—

See section 11 of the Act for the definition of "intentional release of the GMO into the environment".

13 Requirements for 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 schedule 3, part 1; and

(b) within 14 days after completing the assessment, the committee has given the regulator a notice containing the information mentioned in schedule 3, part 3, about the proposed dealing; 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) When undertaken, a notifiable low risk dealing must comply with each of the following requirements—

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9 Section 74 (Notifiable low risk dealings) of the Act

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

(i) certified by the regulator to at least physical containment level 2, or another containment level the regulator considers suitable for conducting the dealing; and

(ii) of a design the regulator considers suitable 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 must be 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 the dealing involves transporting a GMO, the transportation must be conducted in accordance with any relevant guidelines, as in force from time to time, issued by the regulator.

(3) For subsection (1)(a), a proposed dealing is taken to be assessed if an assessment applies to—

(a) for the dealing—the particular GMO concerned, or a class of GMOs that includes the GMO; or

(b) for the particular GMO or class of GMOs—a class of dealings that includes the proposed dealing.

(4) For 2 years from the commencement of this regulation, a person may undertake a notifiable low risk dealing even if a requirement in subsection (1) has not been complied with, if—

(a) the person complies with subsection (2); and

(b) a notice, issued by or for the genetic manipulation advisory committee declaring that the dealing is a notifiable low risk dealing, is in force.

Division 3—Certification and accreditation

14 Regulator to decide certification application within 90 days

Note—

Regulation 14 of the Commonwealth regulations states 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

Note 1—

Regulation 15 of the Commonwealth regulations states that the regulator may refuse to certify a facility if the applicant fails, without reasonable explanation, to provide information requested under section 85 of the Commonwealth Act.

Note 2—

A refusal to certify a facility is a reviewable decision (see part 12, division 2 of the Act).

16 Regulator to decide accreditation application within 90 days

Note —

Regulation 16 of the Commonwealth regulations states 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

Note 1—

Regulation 17 of the Commonwealth regulations states that the regulator may refuse to accredit an organisation if the applicant fails, without reasonable explanation, to provide information requested under section 93 of the Commonwealth Act.

Note 2—

A refusal to accredit an organisation is a reviewable decision (see part 12, division 2 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, and expert advisers to, the gene technology technical advisory committee.

19 GTTAC members and advisers—resignation

Note—

Regulation 19 of the Commonwealth regulations provides for the resignation of members of, and expert advisers to, the gene technology technical advisory committee.

20 GTTAC members—disclosure of interests

Note—

Regulation 20 of the Commonwealth regulations states when and how members of the gene technology technical advisory committee must disclose an interest in a matter of a kind likely to be considered by the committee.

21 GTTAC members and advisers—termination of appointment

Note—

Regulation 21 of the Commonwealth regulations states the circumstances in which the appointment of members of, and expert advisers to, the gene technology technical advisory committee may be terminated.

22 GTTAC members—leave of absence

Note—

Regulation 22 of the Commonwealth regulations provides for leave of absence of the chairperson and members of the gene technology technical advisory committee.

23 Expert advisers—disclosure of interests

Note—

Regulation 23 of the Commonwealth regulations states when and how expert advisers to the gene technology technical advisory committee must disclose an interest in a matter of a kind likely to be considered by the committee.

Division 2—Committee procedures

24 Committee procedures generally

Note—

Regulation 24 of the Commonwealth regulations provides for the gene technology technical advisory committee to perform its functions informally and quickly and states how the committee may obtain information.

25 Committee meetings

Note—

Regulation 25 of the Commonwealth regulations states when and how meetings of the gene technology technical advisory committee may be held.

26 Presiding member

Note—

Regulation 26 of the Commonwealth regulations provides for a presiding member at meetings of the gene technology technical advisory committee.

27 Quorum

Note—

Regulation 27 of the Commonwealth regulations provides for a quorum for the gene technology technical advisory committee.

28 Voting

Note—

Regulation 28 of the Commonwealth regulations provides for the making of decisions of the gene technology technical advisory committee.

29 Records and reports

Note—

Regulation 29 of the Commonwealth regulations provides for the keeping of records of the gene technology technical advisory committee's proceedings and preparation of reports about the committee's activities.

Division 3—Subcommittees

30 Operation of subcommittees

Note—

Regulation 30 of the Commonwealth regulations states that regulations 24 to 26 and 28 of the Commonwealth 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 states that part 4, division 1 of the Commonwealth regulations applies to the conditions of appointment of the consultative committee's members.

32 GTCCC—consultative committee procedures

Note—

Regulation 32 of the Commonwealth regulations states that part 4, division 2 of the Commonwealth regulations applies to the procedures of the consultative committee.

33 GTCCC—operation of subcommittees

Note—

Regulation 33 of the Commonwealth regulations states that regulations 24 to 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 states that part 4, division 1 of the Commonwealth regulations applies to the conditions of appointment of members of, and advisers to, the ethics committee.

35 GTEC—committee procedures

Note—

Regulation 35 of the Commonwealth regulations states that part 4, division 2 of the Commonwealth regulations applies to the procedures of the ethics committee.

36 GTEC—operation of subcommittees

Note—

Regulation 36 of the Commonwealth regulations states that regulations 24 to 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—

At the commencement of this regulation, no decision has been declared under the Commonwealth Act to be a reviewable State decision mentioned in section 19 of the Act.

38 Review of decisions

Note—

Regulation 38 of the Commonwealth regulations deals with review of decisions about the termination of appointment of members of the gene technology technical advisory committee, the consultative committee and the ethics committee.

39 Record of GMO and GM product dealings

(1) For section 138(2)(b)[10] of the Act, the following particulars are prescribed for a notifiable low risk dealing notified to the regulator—

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

(b) with reference to the kinds of dealing mentioned in schedule 3, part 1, 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 section 138(3) of the Act, the following information is prescribed for 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; and

(ii) the GM product's common name as a product, or type or class of product;

Examples for subparagraph (ii)—

1. Bread.
2. Insulin.

(c) the following information about the GM product—

(i) the common and scientific names of any organism from which the GM product is derived or produced;

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

(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 permits supply of the GM product in Australia, takes effect;

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

(**3**) In this section—

"applicable Act" means whichever of the following Acts is applicable—

10 Section 138 (Record of GMO and GM product dealings) of the Act

(a) *Agricultural and Veterinary Chemicals (Queensland) Act 1994*;

(b) *Health Act 1937*;

(c) *Food Act 1981*.

"designated notification" has the meaning given by section 138(6) of the Act.

Note—

This section differs from regulation 39 of the Commonwealth regulations.

40 Inspector identity card

Note—

Regulation 40 of the Commonwealth regulations prescribes the form of an inspector's identity card. Under section 151 of the Act, the card must be in the approved form.

PART 8—TRANSITIONAL

41 Existing facilities—certification

Note—

Regulation 41 of the Commonwealth regulations deals with transitional arrangements for certification of existing facilities.

42 Existing organisations—accreditation

Note—

Regulation 42 of the Commonwealth regulations deals with transitional arrangements for accreditation of existing organisations.

SCHEDULE 1

ORGANISMS THAT ARE NOT GENETICALLY MODIFIED ORGANISMS

section 5

PART 1—ORGANISMS

1. A mutant organism in which the mutational event did not involve the introduction of 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) can not form a viable whole animal.

Example—

Hybridomas created to produce monoclonal antibodies.

4. An organism resulting 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.

SCHEDULE 1 (continued)

6. An organism resulting 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 resulting from an exchange of DNA between the donor species and the host species if—

(a) the exchange can happen 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 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

SCHEDULE 1 (continued)

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

SCHEDULE 1 (continued)

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

section 6(1)(a) and (b), schedule 3, sections 1.1(d) to (f), 2.1(d) to (g) and 3.1.2(a)(iv) and schedule 4, section 1.1.2(a)(iv)

Note—

Section 6(1) states other requirements for exempt dealings.

PART 2—EXEMPT DEALINGS

1. A dealing with gene-knockout mice, 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. A 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.

3. A 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.

SCHEDULE 2 (continued)

4. A dealing involving a host/vector system mentioned in part 2 of this schedule and producing no more than 10 L 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 a toxin for an organism with an LD50 of 100 µg/kg or less; or

(b) the donor DNA includes 1 or more viral sequences, but—

(i) is missing at least 1 gene essential for viral multiplication that—

(A) is not available in the cell into which the DNA is introduced; and

(B) will not become available through subsequent breeding; and

(ii) is incapable of complementing a defect in the host/vector system.

5. A dealing involving shotgun cloning of mammalian DNA in a host/vector system mentioned in part 2 of this schedule.

SCHEDULE 2 (continued)

PART 2—HOST/VECTOR SYSTEMS FOR EXEMPT DEALINGS

Column 1 Item	Column 2 Class	Column 3 Host	Column 4 Vector
1	bacteria	*Escherichia coli* K12 or *E. coli* B—a 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 (for example, 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 another pathogenic strain of bacillus
3		*Pseudomonas putida*—strain KT 2440	certified plasmids pKT 262, pKT 263, pKT 264
4		*Streptomyces*—specified species— (a) *S. coelicolor*; (b) *S. lividans*; (c) *S. parvulus*; (d) *S. griseus*	1. certified plasmids SCP2, SLP1, SLP2, PIJ101 and derivatives 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

SCHEDULE 2 (continued)

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 can not 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, including, for example, *Spodoptera frugiperda*, if the recombinants are also inclusion-negative (for example, polyhedrin minus)	baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedrin minus
	a host mentioned, or of a kind mentioned, in any of items 1 to 4	a non-biological vector, for example, electrocorporation or particle bombardment

SCHEDULE 3

NOTIFIABLE LOW RISK DEALINGS IN RELATION TO A GMO

sections 12(1)(a), 13(1)(a) and (b) and 39(1)(b)

PART 1—DEALINGS THAT ARE NOTIFIABLE LOW RISK DEALINGS

Note—

Under section 12(1), a dealing mentioned in this part is not a notifiable low risk dealing if it is also mentioned in part 2 of this schedule.

1.1 Kinds of dealings

The following kinds of dealings are notifiable low risk dealings—

(a) a 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) a dealing involving a genetically modified flowering plant not grown to flowering stage;

(c) a dealing involving a genetically modified flowering plant grown to flowering stage, if—

(i) the plant is male sterile and can not set seed; or

(ii) for a plant that is male sterile and can set seed—all vents and drains in the facility are screened with mesh or filters blocking the escape of viable pollen and seed; or

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

SCHEDULE 3 (continued)

(iv) for a plant that can be wind-pollinated—all vents and drains in the facility are screened with mesh or filters blocking the escape of viable pollen and seed; or

(v) for a plant that can be vector-pollinated only—all vents and drains in the facility are screened with mesh or filters blocking the escape of viable seed and excluding pollen vectors from the facility;

(d) a dealing involving a host and vector not mentioned as a host/vector system in schedule 2, part 2, if both the host and the vector are incapable of causing disease in human beings, animals, plants or fungi;

(e) a dealing involving a host and vector not mentioned as a host/vector system in schedule 2, part 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;

(f) a dealing involving a host/vector system mentioned in schedule 2, part 2, if the gene inserted is—

(i) a pathogenic determinant; or

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

(iii) an oncogene.

PART 2—DEALINGS (HIGHER RISK) THAT ARE NOT NOTIFIABLE LOW RISK DEALINGS

Note 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.

Note 2—

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

SCHEDULE 3 (continued)

2.1 Kinds of dealings

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

(a) a dealing involving cloning of DNA encoding a toxin for vertebrates with 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 that—

(i) is not a vector used in the dealing as part of a host/vector system mentioned in schedule 2, part 2; and

(ii) contains 1 or more sequences of genetic material modified or inserted by gene technology; and

(iii) 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 capable of causing disease in humans, animals, plants or fungi, unless—

(i) the host/vector system is a system mentioned in schedule 2, part 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 schedule 2, part 2, of genes determining pathogenicity;

(g) a dealing involving the introduction into a micro-organism, other than a host mentioned in schedule 2, part 2, of genes whose expressed products have a heightened risk of inducing an auto-immune 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 causing infectious agents capable of infecting cells of human, animal, plant or fungal origin;

SCHEDULE 3 (continued)

(i) a dealing involving recombination between—

(i) whole viral genomes; or

(ii) viroids; or

(iii) complementing fragments of the genomes, if 1 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 L of GMO culture;

(l) a dealing inconsistent with a policy principle issued by the Ministerial council.

PART 3—PRESCRIBED INFORMATION FOR NOTICE OF PROPOSED NOTIFIABLE LOW RISK DEALING

3.1 Information about proponent and proposed dealing

For a notice made under section 13(1)(b)[11] of this regulation, the following information must be included—

3.1.1 General information

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

(b) the name, position within the organisation and contact details of the proponent's project supervisor for the proposed dealing;

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

(d) with reference to the kinds of dealing mentioned in part 1 of this schedule, the kind of dealing proposed;

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SCHEDULE 3 (continued)

(e) a description of the GMO involved, including each of the following—

(i) the common name of the parent organism;

(ii) the scientific name of the parent organism;

(iii) the modified trait;

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

(f) a description of the proposed dealing;

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

(h) the address of the premises where the dealing is proposed to be undertaken;

(i) the proposed commencement and completion dates for the dealing.

3.1.2 Genetics of GMO

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

(i) the biological source of the donor DNA;

(ii) the intended host organism or tissue;

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

(iv) whether the intended host/vector system is a system mentioned in schedule 2, part 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 into the environment, including risks to—

(i) the health and safety of people; and

(ii) the environment.

SCHEDULE 3 (continued)

3.1.4 Risk management information

(a) details of the facility in which the proposed dealing is to be undertaken, and of its physical containment level as certified under part 7, division 2 of the Act;

(b) each of the following details about certification of the facility—

(i) the date of certification;

(ii) the certification number allocated to the facility by the regulator;

(iii) the date of the most recent inspection of the facility by the regulator or the facility's IBC;

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

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

(e) details of action proposed to be taken if the GMO is unintentionally released from containment;

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

(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 notice about a proposed notifiable low risk dealing involving 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 closely related weeds;

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

SCHEDULE 3 (continued)

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

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

3.3 Supporting information from IBC for a proponent

Information required for a notice about a proposed notifiable low risk dealing includes the following information given by an IBC—

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

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

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

(i) the date of the evaluation;

(ii) the full name of the IBC;

(iii) the names and contact details of the chairperson and 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 may be an IBC established by the proponent or by another accredited organisation.

SCHEDULE 4

PRESCRIBED INFORMATION FOR APPLICATION FOR A LICENCE

section 7(1) and schedule 5, definitions "division 3 application" and "division 4 application"

PART 1—DEALINGS NOT INVOLVING AN INTENTIONAL RELEASE OF A GMO INTO THE ENVIRONMENT (PART 5, DIVISION 3 OF THE ACT)

1.1 Information to be given by all applicants

For an application to which part 5, division 3[12] of the Act applies (a **"division 3 application"**), the following information is required—

1.1.1 General information

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

(b) the name, position within the organisation and contact details of the applicant's project supervisor for the proposed dealing;

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

(d) a description of the GMO involved, including each of the following—

(i) the common name of the parent organism;

(ii) the scientific name of the parent organism;

(iii) the modified trait;

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

(e) a description of the proposed dealing;

(f) a description of the purposes and aims of the proposed dealing;

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SCHEDULE 4 (continued)

(g) the address of the premises where the dealing is proposed to be undertaken;

(h) the proposed commencement and completion dates for the dealing.

1.1.2 Genetics of the GMO

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

(i) the biological source of the donor DNA;

(ii) the intended host organism or tissue;

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

(iv) whether the intended host/vector system is a system mentioned in schedule 2, part 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 into the environment, including risks to—

(i) the health and safety of people; and

(ii) the environment;

(c) details of all previous applications (whether successful or unsuccessful) made under the Act, or to the genetic manipulation advisory committee, for a proposed dealing with the GMO, stating the following about each application—

(i) any reference number given to the application by the regulator or the genetic manipulation advisory committee;

(ii) the date of the application;

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

SCHEDULE 4 (continued)

1.1.4 Risk management information

(a) details of the facility in which the proposed dealing is to be undertaken, and of its physical containment level as certified under part 7, division 2 of the Act;

(b) each of the following details about certification of the facility—

(i) the date of certification;

(ii) the certification number allocated to the facility by the regulator;

(iii) the date of the most recent inspection of the facility by the regulator or the facility's IBC;

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

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

(e) details of action proposed to be taken if the GMO is unintentionally released 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;

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

1.1.5 Suitability of the applicant

Unless it has already been given to the regulator for another purpose, the following information—

(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 of the applicant to which the regulator may have regard under the section;

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

(i) a provision of the Act or this regulation; or

SCHEDULE 4 (continued)

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

(d) details of any failure, by the applicant, to comply with an advice to proceed issued by the genetic manipulation advisory committee;

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

1.2 Additional information if volume of GMO culture exceeds 10 L

If a division 3 application relates to a GMO that will be produced as a culture of cells exceeding 10 L in volume, the following additional information must be included—

(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 each of the following—

(i) the main product or products of the intended dealing;

(ii) any by-products, including effluents;

(iii) the concentrations of the 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 each of the following—

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

(ii) the operational procedures of each unit;

SCHEDULE 4 (continued)

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

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

(i) supervision;

(ii) training;

(iii) health surveillance;

(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 section 1.1.3(a) and (b);

(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 if GMO 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 be used 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 closely related weeds;

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

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

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

SCHEDULE 4 (continued)

1.4 Additional information if GMO 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 be used in connection with an animal, the following additional information must be included—

(a) the number of—

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

(ii) other animals to be involved;

(b) details of proposed arrangements—

(i) for breeding the animals; or

(ii) for ensuring the animals do not breed;

(c) details of how the animals will be able to be readily identified, including, for example, by labelling cages or, for larger animals, branding or tattooing the animals.

1.5 Additional information if GMO 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 must be included—

1.5.1 Information about the purpose of the trial

(a) details of the disease to be treated, or prevented, by using 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, wholly or partly, into the genome of any cells of a treated person;

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

SCHEDULE 4 (continued)

(c) details of the period over which the GMO will be detectable in a person or in the person's 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 using the GMO is likely to preclude its subsequent use for vaccination against other diseases;

(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 any sterilising and anti-microbial agents 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 other species; and

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

Example for subparagraph (i)—

The person presents with immunosuppression or superimposition of disease.

(ii) other treatments, including, for example, drugs;

SCHEDULE 4 (continued)

(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 each of the following—

(i) the potential for dissemination of the GMOs through family contact or to the general population;

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

(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 section applies.

1.6 Supporting information to be given by IBC

Information required for a division 3 application includes the following information given by an 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 personnel intended to be involved in dealing with the GMO have adequate training and experience for the task;

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

(i) the date of the evaluation;

(ii) the full name of the IBC;

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

SCHEDULE 4 (continued)

(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 may be an IBC established by the organisation.

PART 2—DEALINGS INVOLVING AN INTENTIONAL RELEASE OF A GMO INTO THE ENVIRONMENT (PART 5, DIVISION 4 OF THE ACT)

2.1 Information to be given by all applicants

For an application to which part 5, division 4[13] of the Act applies (a **"division 4 application"**), the following information is required—

2.1.1 General information

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

(b) the name, position within the organisation and contact details of the applicant's project supervisor for the proposed dealing;

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

(d) a description of the GMO;

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

(f) a description of the purposes and aims of the proposed dealing;

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

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SCHEDULE 4 (continued)

(h) the proposed commencement and completion dates for the dealing.

2.1.2 Risk assessment information—the parent organism

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

(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 proposed dealing;

(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 each population;

(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, 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);

SCHEDULE 4 (continued)

(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 to be identified in the laboratory and under field conditions;

(h) details of the type of vector to be used in the transfer—

(i) including a description of the vector; and

(ii) 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 any intrinsic genetic features of the GMO that will regulate survival in the environment, including a statement on how stable the features are;

(p) details of any genetic changes that will be included in the GMO 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 with the GMO, 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

SCHEDULE 4 (continued)

(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 each of the following—

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

(ii) the area of land to be used;

(iii) the location of the proposed release or releases, including identification of the local government area in which a 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 will be released;

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

(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, including, for example, importing a GMO and transporting a GMO to or from a release site;

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

Examples for paragraph (k)—

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

SCHEDULE 4 (continued)

advisory committee, for a proposed dealing with the GMO, stating the following about each application—

(i) any reference number given to the application by the regulator or the genetic manipulation advisory committee;

(ii) the date of the application;

(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 each of the following—

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

(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;

(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 any dispersal mechanisms;

(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;

Examples of 'long term survival structures' for paragraph (e)—

1. Seeds.
2. 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

SCHEDULE 4 (continued)

surrounding environment and, if so, details of each of the following—

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

(ii) the transfer mechanisms involved;

(iii) the techniques used to demonstrate transfer;

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

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

(B) environmental risks posed by the advantage;

(g) a statement on whether interactions between pathogens and the transgene are possible (including, 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 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 for a period after release and, if so, details of—

SCHEDULE 4 (continued)

(i) the period; and

(ii) any environmental risks posed by the GMO during the 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—

(i) may be expressed by the proposed GMO; and

(ii) 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 each of the following—

(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;

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

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

(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;

SCHEDULE 4 (continued)

(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 supervision procedures for the release site 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;

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

(b) details of any previous licence under the Act for dealing with the GMO, or of a notice 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 consulted about the proposed dealings with the GMO, including names of contact officers;

SCHEDULE 4 (continued)

(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

Unless it has already been given to the regulator for another purpose, the following information—

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

(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 of the applicant to which the regulator may have regard under the section;

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

(i) a provision of the Act or this regulation; or

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

(e) details of any failure, by the applicant, to comply with an advice to proceed issued by the genetic manipulation advisory committee;

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

2.2 Additional information if GMO is a plant

If a division 4 application relates to a proposed GMO that is a plant, the following additional information must be included—

2.2.1 Information about the use of the parent plant

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

SCHEDULE 4 (continued)

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, including the likelihood of those events.

Examples of 'undesirable effects on the parent plant' for paragraph (a)—

1. Reduced fertility.
2. Increased disease prevalence.
3. Production loss.
4. Grain shedding.

2.2.3 Information about pollen and cross-pollination

(a) details of the mechanism of pollen spread, by insect vectors or 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 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 supporting the information.

SCHEDULE 4 (continued)

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 normally controlling populations of the affected species in the environment, including, for example, pathogens, and herbivory and physiological stress;

(b) details of any other possible adverse consequences;

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

2.2.6 Information about the GMO's seeds

(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 (including, for example, from 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.

SCHEDULE 4 (continued)

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 and, if so, details of all the change.

Example of 'substance' for paragraph (a)—

A nitrogen or toxic compound.

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 the likely effect;

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

(c) an assessment of whether the biodegradability of the GMO will be different to the biodegradability 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 each of the following—

(i) native species;

(ii) resistance of insect populations to an insecticide;

(iii) abundance of prey or parasites.

2.2.11 Information about the GMO's resistance to a chemical agent

(a) for a GMO that, as a result of the modification, will have resistance to a chemical agent other than a selective agent used in strain construction (including, for example, an antibiotic)—details of any environmental risks related specifically to the resistance.

SCHEDULE 4 (continued)

Example of 'a chemical agent' for paragraph (a)—

A herbicide.

2.2.12 Information about the GMO's resistance to a biological agent

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

2.3 Additional information if GMO is a micro-organism not living in or on animals and is not a live vaccine

If a division 4 application relates 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, including, 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 must be included in 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 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 any effect of the proposed GMO on the distribution and abundance of host plant species or other species with which the proposed GMO can interact;

SCHEDULE 4 (continued)

(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 GMO's impact on soil and water

(a) details of the expected effects of the proposed GMO on local soil chemistry, including, for example, pH, mineral leaching or 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 known to be beneficial to plants and likely to be in a release site.

Examples of 'soil organisms known to be beneficial to plants' for paragraph (c)—

1. *Rhizobium*.
2. *Azospirillum*.
3. *Frankia*.
4. Mycorrhizal fungi.

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.

SCHEDULE 4 (continued)

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 and 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 any sterilising and anti-microbial agents 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 if GMO is a micro-organism that lives in or on animals

If a division 4 application relates to a proposed GMO that is a micro-organism living in or on animals (including an organism like gut biota living in larger hosts, and a micro-organism applied externally to an animal, like bacteria to prevent fleece rot), the following additional information must be included—

2.4.1 Information about the GMO's impact 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, including, for example, the ability to degrade plant or pasture toxins;

SCHEDULE 4 (continued)

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

(e) details of any secondary effects expected to result from the introduction of the proposed GMO into or onto the host, including, 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 GMO's impact 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 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 any sterilising and anti-microbial agents 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 if GMO is a live vaccine for use in animals

If a division 4 application relates to a GMO that is a live vaccine for use in animals, the following additional information must be included—

SCHEDULE 4 (continued)

2.5.1 Information about the purpose of the vaccine

(a) identification of the disease to be treated or prevented by using 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, wholly or partly, 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 using the vaccine GMO is likely to—

(i) preclude its subsequent use for vaccination against other diseases; 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 any sterilising and anti-microbial agents that are active against the GMO;

SCHEDULE 4 (continued)

(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 the 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; or

Example—

The host presents with immunosuppression or superimposition of other disease.

(ii) other treatments, including, for example, 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.

SCHEDULE 4 (continued)

2.6 Additional information if GMO is a vertebrate animal

If a division 4 application relates to a GMO that is a vertebrate animal, other than an aquatic organism, the following additional information must be included—

2.6.1 Information about the GMO's effects 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 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 any feral populations of subject species 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 done on expression of the novel genetic material in feral animals and the results of the work;

Example of 'experimental work' for paragraph (b)—

Cross-breeding of GMOs with captive feral animals.

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

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

SCHEDULE 4 (continued)

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

Note—

All work involving animals should be conducted according to the National Health and Medical Research Council's 'Australian Code of Practice for the Care and Use of Animals for Scientific Purposes', which requires review by an Institutional Animal Ethics Committee and by the relevant authority administering State animal welfare legislation.

2.7 Additional information if GMO is an aquatic organism

If a division 4 application relates to a GMO that is an aquatic organism, including, for example, a fish, crustacean or mollusc, the following additional information must be included—

2.7.1 Information about the GMO's effects on the environment

(a) a statement on whether the GMO could produce any novel metabolites or toxins 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;

SCHEDULE 4 (continued)

(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, including, 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 done on phenotypic expression of the modified genetic material in naturally occurring organisms;

Example of 'experimental work' for paragraph (c)—

Cross-breeding 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;

SCHEDULE 4 (continued)

(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 if GMO is an invertebrate animal

If a division 4 application relates 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 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 the genetic material entering gene pools of natural populations;

(g) information about—

SCHEDULE 4 (continued)

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

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

(h) information about any experimental work done on the phenotypic expression of the novel genetic material in other genetic backgrounds;

Example of 'experimental work' for paragraph (h)—

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 the populations;

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

2.9 Additional information if GMO is to be used for biological control

If a division 4 application relates 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 1 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, and the expected evidence for the response.

SCHEDULE 4 (continued)

Example of 'genetic response' for paragraph (e)—

Increased resistance to the modified organism.

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

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

(b) a list of the non-target organisms 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 likely to be in the environment—details of any effects the 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 effect 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 if GMO is to be used for bioremediation

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

SCHEDULE 4 (continued)

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—

(i) can be metabolised by the GMO; and

(ii) can not 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, including, for example, the 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.

SCHEDULE 4 (continued)

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

If a division 4 application relates 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 producing the 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 human or animal consumer, including available data on toxicology, allergenicity and other possible adverse effects;

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

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

(e) a statement on whether the GMO is—

(i) a major component of the food as consumed; or

(ii) a minor component, like yeast cells in beer.

Note—

For a food for human consumption containing GMOs or GM products, see also the assessment requirements under the *Australia New Zealand Food Authority Act 1991* (Cwlth).

2.12 Supporting information to be given by IBC

Information required for a division 4 application includes the following information given by an IBC—

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

SCHEDULE 4 (continued)

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

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

(i) the date of the evaluation;

(ii) the full name of the IBC;

(iii) the names and contact details of the chairperson and 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 may be an IBC established by the organisation.

SCHEDULE 5

DICTIONARY

section 3

"advantage", for 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.

"advice to proceed" has the meaning given by section 190(3) of the Act.

"animal" means an animal other than a human.

"characterised", for DNA, means—

(a) the DNA has been sequenced; and

(b) there is an understanding of potential gene products of the DNA.

"code", for a toxin or other product, means has the amino acid sequence or nucleotide sequence of the toxin or other product.

"Commonwealth regulations" means the *Gene Technology Regulations 2001* (Cwlth).

"competitive advantage" means—

(a) for a GMO—a superior ability of the GMO, relative to the unmodified parental organism, to survive in an environment in competition with other organisms; and

(b) for the host of a GMO that is a micro-organism living in or on an animal—a superior ability of the host, relative to a host in or on which the GMO does not live, to survive in an environment in competition with other organisms.

"division 3 application" see schedule 4, section 1.1.

"division 4 application" see schedule 4, section 2.1.

"gene-knockout mice" means mice whose genetic modification involves deleting or inactivating a specific gene.

SCHEDULE 5 (continued)

"genetic manipulation advisory committee" means the Genetic Manipulation Advisory Committee under the Commonwealth regulations.

"IBC" means an institutional biosafety committee.

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

"licence" means a GMO licence.

"physical containment level", followed by a numeral, means a containment level stated in guidelines for the certification of facilities issued under section 90 of the Act.

"recombinant", for matter that is a sequence or an organism, means matter of a kind containing recombinant DNA.

"selective advantage", for a GMO, means a superior ability of the GMO, relative to another organism, to survive in a particular environment.

"shotgun cloning", for 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.

ENDNOTES

1. Made by the Governor in Council on 25 July 2002.
2. Notified in the gazette on 26 July 2002.
3. Laid before the Legislative Assembly on . . .
4. The administering agency is the Department of Innovation and Information Economy, Sport and Recreation Queensland.