

GUIDELINES FOR EMERGENCY RESPONSE UNDER THE *GENE TECHNOLOGY ACT 2000* AND THE GENE TECHNOLOGY AGREEMENT

INTRODUCTION

This document is issued by the Gene Technology Ministerial Council (GTMC). The GTMC was established under the *Gene Technology Agreement 2001* (the Agreement) to oversee the scheme for the regulation of genetically modified organisms (GMOs).

The "scheme" as set out in the Agreement, is a cooperative national legislative scheme to protect the health and safety of people and to protect the environment, by identifying risks posed by, or as a result of, gene technology and by managing those risks through regulating certain dealings with GMOs.

More information on the regulatory scheme is available at www.ogtr.gov.au. These Guidelines should be read in conjunction with Part 5A of the *Gene Technology Act 2000* (the Act), as amended, and the Agreement, as amended.

AIM OF THIS DOCUMENT

The aim of this document is to provide guidance on when and how the emergency provisions of the Act and relevant clauses in the Agreement will be invoked.

The Commonwealth Minister responsible for the gene technology regulatory scheme (the Minister) is responsible for two emergency processes under the Act:

1. The Minister may, subject to advice, make an emergency dealing determination (EDD). The effect of the determination is to expeditiously authorise dealings with a GMO for a limited period, as necessary to meet an emergency. The dealings would otherwise be required to be authorised in accordance with more protracted procedures under Part 5 of the Act.
2. The Minister may, subject to advice and other preconditions, recommend that the Governor-General declare a thing to be a GMO by regulation for a limited period where the thing poses a threat, there is uncertainty that the thing meets the definition of a GMO in the Act and it is likely the declaration will address the threat (see section 20 and section 193 of the Act and clause 14 of the Agreement).

OBJECTIVE OF THE EMERGENCY PROVISIONS

The objective of the emergency provisions is to allow a cooperative, effective and timely response in an emergency situation while ensuring the health and safety of people and the environment.

EMERGENCY DEFINED

For the purposes of these guidelines, an emergency is defined as:

“an actual or imminent threat to health and safety of people or the environment.”¹

TYPES OF EMERGENCIES

Emergency Dealing Determinations to Exempt Specified GMOs from Licensing Requirements (Emergency Dealing Determination)

By making an EDD, the Minister can expedite the approval of a GMO in an emergency. The EDD will effectively authorise the specified dealings with the GMOs so that the penalty provisions of Part 4 of the Act will apply. The GMO may then be released into the environment without being subject to normal GMO licensing requirements, including the standard 150/170/255 day approval timeframes provided for intentional release applications required under the Act.

Situations in which an EDD may be made include, but are not limited to, the following:

- a threat from the outbreak of a plant, animal or human disease;
- a threat from a particular animal or plant, such as a pest or an alien invasive species; or
- a threat from an industrial spillage.

The GMO or class of GMOs, which is covered by the EDD may be used for a number of objectives, including:

- containing or eradicating a problem organism or its vectors;
- conveying immunity in humans and/or animals; or
- aiding in the degradation or dissipation of a hazardous substance.

¹ Section 10 of the Act defines ‘**environment**’ to include:

- (a) ecosystems and their constituent parts; and
- (b) natural and physical resources; and
- (c) the qualities and characteristics of locations, places and areas.

The Explanatory Memorandum to the Gene Technology Bill 2000 indicates that the definition of environment was also intended to include all animals (including insects, fish and mammals), plants, soils and ecosystems (both aquatic and terrestrial) (see page 48).

An EDD will serve to authorise dealings that would, or would be likely to, address the threat. The EDD cannot authorise activities which are not dealings as defined in section 10 of the Act.

The term “*deal with*”, in relation to a GMO, means the following:

- a) conduct experiments with the GMO;
- b) make, develop, produce or manufacture the GMO;
- c) breed the GMO;
- d) propagate the GMO;
- e) use the GMO in the course of manufacture of a thing that is not the GMO;
- f) grow, raise or culture the GMO;
- g) import the GMO;
- h) transport the GMO;
- i) dispose of the GMO;

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).”

Examples of when an EDD could be issued include in the case of a threat of an avian flu pandemic, or when there is a threat of major environmental damage from an oil spill. In these circumstances, the EDD could cover dealings in relation to a genetically modified vaccine for human or veterinary use, or a genetically modified bacterium to dissolve oil, respectively.

Emergency Regulation Declaring a Thing to be a GMO (Emergency GMO Regulation)

The Minister may recommend that the Governor-General declare a thing to be a GMO by regulation (under the definition of a GMO in section 10) for a limited period if the Minister believes on reasonable grounds that the thing is an actual or imminent threat to the health and safety of people or the environment and there is doubt that the thing meets the definition of a GMO in the Act.

If a thing is already being dealt with when the Emergency GMO Regulations declare that thing to be a GMO, any person dealing with that thing (the emergency GMO) must apply for a licence from the Regulator, unless the dealings with the emergency GMO are notifiable low risk dealings or exempt under the Act.

A person may be eligible to apply for an inadvertent dealings licence to dispose of the emergency GMO, if that person was unaware that it was a GMO when he or she came into possession of it.

PROCESS FOR MINISTER TO OBTAIN ADVICE ON AN EMERGENCY AND THE RECOMMENDED COURSE OF ACTION

The processes for the making of EDDs and Emergency GMO Regulations are described below and summarised in the flow charts in Appendix 1.

Emergency Dealing Determination

The Minister may only make an EDD after receiving advice from the most relevant of the Chief Medical Officer, the Chief Veterinary Officer, the Chief Plant Protection Officer (referred to below as the relevant Chief Officer) or a person prescribed by the Regulations that:

- there is an actual or imminent threat to the health and safety of people or the environment; and
- the dealings proposed to be specified in the EDD would, or would be likely to, adequately address the threat.

In preparing this advice the relevant Chief Officer or prescribed person should clearly articulate the nature of the actual or imminent threat to the health and safety of people and the environment and how the dealings would or would be likely to adequately address the threat.

Advice could include:

- the circumstances which have led to the existence of the emergency and/or its identification;
- the nature and seriousness of the threat, including as relevant, potential proportion of people, animals, plants or type or component of the environment that might be harmed, and potential degree of harm;
- whether the threat has been anticipated in national emergency preparedness arrangements or strategies;
- the range of options (operational measures) for addressing threats identified in those arrangements or strategies;
- if the threat has not been anticipated in national emergency preparedness arrangements or strategies, the status of national emergency response planning in progress at the time the relevant Chief Officer or prescribed person provides their advice;
- the proposed dealings with the GMO/s;
- how the relevant Chief Officer concluded that the GMO option was the most suitable;
- how those proposed dealings are to be managed;
- how the proposed dealings will integrate with or complement other measures that together form the overall emergency response; and
- what, if any, other regulatory approvals have been or will be sought in relation to the use of the GMO in the emergency response.

The Minister must also have received advice from the Regulator that any risks posed by the dealings proposed to be specified in the EDD are able to be managed in such a way as to protect the health and safety of people and the environment. The Minister will request advice from the Regulator once the advice from the relevant Chief Officer has been received.

Before issuing an EDD, the Minister must be satisfied that an emergency exists, that there are dealings with a GMO/s that would, or would be likely to, adequately address the emergency, and that any risks posed by those dealings are able to be managed to protect the health and safety of people and the environment. However, the existence of a GMO solution, to an emergency should not automatically justify the making of an EDD.

In practice, the Commonwealth Department of Health and Ageing will coordinate the provision of advice to the Minister in a manner consistent with the process set out in section 72B of the Act. The Department will obtain an accurate picture of the nature and extent of the emergency and the ability of the EDD to address the threat and other regulatory requirements by consulting with the relevant Chief Officer, the Regulator, and other relevant experts in States and Territories and other Commonwealth agencies.

On request from the Minister, the Regulator will assess whether the risks posed by those dealings are able to be managed to protect the health and safety of people and the environment and forward this risk assessment advice to the Minister. In preparing the risk assessment advice, if the threat is to the environment, or the dealing under the proposed EDD would be likely to lead to release of the GMO into the environment, the Regulator will consult with the Minister for Environment. The Regulator will also consult with other relevant regulators and personnel, such as the CMO and/or other experts as appropriate in preparing the risk assessment advice.

Emergency GMO Regulation

Before recommending that the Governor-General make an Emergency GMO Regulation (as defined in clause 5 of the Agreement), the Minister must have received advice from the relevant Chief Officer that the thing proposed to be declared an 'emergency GMO' poses an actual or imminent threat to the health and safety of people or the environment. In preparing this advice, the relevant Chief Officer should clearly articulate the nature and seriousness of the threat posed by the thing.

The Minister must not recommend that the Governor-General make an Emergency GMO Regulation unless he or she is satisfied that the thing poses a threat and that declaring the thing to be a GMO would help respond to the threat.

As for an EDD, the Commonwealth Department of Health and Ageing will coordinate the provision of advice on the Emergency GMO Regulation to the Minister, including any advice received from the relevant Chief Officer and the Regulator. In the case that there is an environmental impact, the relevant Chief Officer will consult with the Secretary of the Commonwealth Department of Environment before providing advice to the Minister.

After the relevant Chief Officer has provided advice, the Regulator will assess whether declaring a thing to be a GMO would help respond to the threat posed by it.

CONSULTATION WITH STATES AND TERRITORIES

The Commonwealth Department of Health and Ageing will consult with States and Territories throughout the process, as outlined below.

Emergency Dealing Determination

1. Initial notification will occur as soon as practicable after the Minister is advised by the relevant Chief Officer or prescribed person that there is a threat and that making an EDD would help address that threat. This notification should include the relevant Chief Officer's original advice. No formal consultation is required at this point but a teleconference could be held.
2. Following the initial notification, the Minister will undertake formal consultation by writing to State and Territory Ministers, providing:
 - the relevant Chief Officer's original advice and any further clarifying or amending information;
 - a draft of the Regulator's initial risk assessment advice;
 - details of associated approvals issued or being considered by other national regulatory authorities (eg. APVMA, AQIS) if any; and
 - description of the broader emergency response coordination (e.g. implementation under AusVETPLAN, PLANTPLAN, AQUAVETPLAN, AusBIOSEC etc).
3. States and Territories will be given 48 hours to comment on the making of the proposed EDD – failure to respond within this time will be taken as tacit consent. Within this 48 hours, the Commonwealth Department of Health and Ageing will arrange a Gene Technology Standing Committee (GTSC) teleconference with the States and Territories, and the Regulator to discuss the risk assessment advice, proposed EDD conditions and whether and how these link to conditions issued in regard to other approvals.
4. After the 48 hour comment period, the Minister will consider the advice and any State and Territory comments and consult the Regulator regarding any comments on the risk assessment before issuing an EDD. The States and Territories will then be notified, including the EDD as made and the Regulator's final risk assessment advice.

Emergency GMO Regulation

1. After receiving advice from the relevant Chief Officer that there is a threat and that making an Emergency GMO Regulation would help address that threat, the Minister will, as soon as practicable, provide notification. This notification should include the relevant Chief Officer's original advice.

2. States and Territories will be given 48 hours to comment on the making of the proposed Emergency GMO Regulation. Any States or Territories who have not responded within this period of time will be taken to have consented to the making of the Regulation. Within this 48 hours, the Commonwealth Department of Health and Ageing will arrange a GTSC teleconference with the States and Territories, and the Regulator.
3. After the 48 hour comment period, the Minister will consider the advice and any State and Territory comments and consult the Regulator before recommending that the Governor-General make an Emergency GMO Regulation. The States and Territories will then be notified, including the Emergency GMO Regulation as made.

Registration of an EDD or Emergency GMO Regulation

If either an EDD or Emergency GMO Regulation is made it will be registered publicly as a legislative instrument on the Attorney-General's Department Comlaw legislation website (www.commlaw.gov.au). In addition, the Regulator will update the Record of GMO and GM Product dealings (on the Regulator's website) to provide details of the EDD or a licence issued subsequent to the making of, and in relation to, an Emergency GMO Regulation. The Regulator will also provide details of any breaches of conditions as part of regular quarterly reporting to the Parliament. The Regulator will also notify the relevant jurisdiction where the breach occurred.

PROCESS FOR ISSUING CORRESPONDING STATE OR TERRITORY EMERGENCY REGULATIONS OR EMERGENCY DETERMINATIONS

States and Territories that do not automatically adopt the Commonwealth's EDD by virtue of provisions in their corresponding legislation or Emergency GMO Regulation will need to introduce corresponding legislative instruments. States and Territories will advise the Commonwealth when this has been done.

ORGANISATIONAL STRUCTURES AND FACILITATION OF ADVICE

Existing committees and office holders, which provide for State and Territory representation, that may facilitate the provision of advice to the Regulator and Minister, and the Commonwealth Department of Health and Ageing include, but are not limited to:

- Australian Health Protection Committee (AHPC);
- State and Territory counterparts of the Chief Veterinary Officer;
- State and Territory counterparts of the Chief Plant Protection Officer;
- Australian Health Ministers' Advisory Committee (AHMAC);
- Primary Industry Standing Committee (PISC);
- Natural Resource Management Standing Committee (NRMSC);
- Australian Maritime Safety Authority (AMSA);
- National Biosecurity Committee (NBC);
- Gene Technology Technical Advisory Committee (GTTAC); and
- Gene Technology Ethics and Community Consultative Committee (GTECCC).

Other groups may also be contacted depending on the nature of the emergency including Plant Health Australia, Animal Health Australia, and other bodies representing potentially affected sectors. In all cases, AHPC should be contacted immediately in the event of an emergency which is likely to affect the health and safety of people. States and Territories should also contact their relevant Chief Officer.

EXTENSION OF EMERGENCY RESPONSE

Emergency Dealing Determination

An EDD is valid for a maximum period of six months. The Minister may extend the EDD by legislative instrument for up to six months only if certain preconditions are met (as set out below), including that the majority of jurisdictions agree.

To extend an EDD the Minister must:

- have received advice from the relevant Chief Officer who originally provided advice on the need for the EDD that the emergency still exists and that extending the EDD would, or would be likely to, adequately address the threat;
- have received advice from the Regulator that any risks posed by the extension are able to be managed;
- be satisfied that the threat still exists, that the EDD would adequately deal with the threat and that any risks can be managed in a way which will protect the health and safety of people and the environment.

The Minister may extend the EDD more than once providing that the same preconditions described above are satisfied and that the majority of jurisdictions agree (see section 72C of the Act). Despite provision to extend an EDD more than once, the intention is that ongoing use of the GMO beyond emergency circumstances requires authorisation through normal assessment and licensing processes.

The relevant Chief Officer will be advised by the Minister that the determination will not necessarily be extended and recommend that they contact the potential licence holder to advise that for continued use they should apply for a licence under Part 5 of the Act as soon as practicable. This could remove the need to extend the EDD as the standard 150/170/255 day licence approval process could have concluded before the EDD has expired.

Emergency GMO Regulation

The GTMC must review the regulation within six months and as a result of the review can decide, by special majority, whether to amend, revoke or maintain the emergency regulation.

VARIATION OF EMERGENCY RESPONSE

Emergency Dealing Determination

The Minister may vary the conditions of an EDD by legislative instrument. If a variation is substantive rather than administrative in nature, then the States and Territories must be consulted about the variation.*

A substantive variation could include, for example, a variation to allow the GMO in the dealing to be released in a different or new location. An administrative variation could include a variation to correct a typographical error in a determination or to update the name of a position-holder.

*States and Territories that fail to respond within 48 hours of being notified of the proposed variation will be taken to have consented to the variation/s.

Emergency GMO Regulation

The Minister may recommend that the Governor-General amend an Emergency GMO Regulation after:

- receiving advice that the thing no longer poses an actual or imminent threat to the health and safety of people and the environment;
- receiving advice that the declaration of the thing to be a GMO is no longer required to respond to a threat; and
- consulting with States and Territories*.

*States and Territories that fail to respond within 48 hours of being notified of the recommendation to amend an emergency GMO will be taken to have consented to the variation/s.

SUSPENSION OR REVOCATION OF EMERGENCY RESPONSE

Emergency Dealing Determination

An EDD will come to an end six months from when the EDD took effect, or on an earlier date specified in the determination. The Minister may suspend or revoke an EDD before it is due to come to an end, if the States and Territories have been consulted* and the Minister:

- becomes aware of risks posed by the dealings that cannot be managed safely;
- is satisfied that the emergency no longer exists or is no longer sufficiently actual or imminent to justify an EDD; or
- is no longer satisfied that the dealings adequately deal with the threat.

*States and Territories that fail to respond within 48 hours of being notified of the proposed suspension or revocation of the EDD will be taken to have consented to the suspension or revocation.

Emergency GMO Regulation

The GTMC must review the Regulation within six months.

The Minister may recommend that the Governor-General revoke an Emergency GMO Regulation if the Minister:

- receives advice that the thing no longer poses an actual or imminent threat to the health and safety of people or the environment;
- receives advice that the thing no longer poses a threat and that the declaration of the thing to be a GMO is no longer required to respond to a threat; and
- has consulted with States and Territories.*

*States and Territories that fail to respond within 48 hours of being notified of the recommendation will be taken to have consented to the recommendation.

REVIEW OF THESE GUIDELINES

These Guidelines were reviewed after their first use for making the *Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007*. They will continue to be reviewed as the need arises, as identified by the GTMC.

