



Australian Government

Department of Health and Ageing

Office of the Gene Technology Regulator

Review of the *Gene Technology Regulations 2001*

Discussion Paper No. 5 (2010)

Review of timeframes and other administrative matters

Introduction

The Gene Technology Regulator (the Regulator) is currently reviewing the Gene Technology Regulations 2001 (the Regulations). As part of this process, a number of administrative changes are proposed in relation to timeframes for processing applications and correcting internal cross references.

The aim of the proposed changes to timeframes is to improve consistency and effective administration of the Regulations. They are based on extensive operational experience in administering the regulatory system.

Proposed changes

Proposal 1 – Time limit for decision on an application – consultation with GTTAC

Add to the list of days not counted in the decision making timeframe for DIR licences days on which the Regulator cannot proceed with the decision-making process, or a related function, because he is waiting for advice from GTTAC.

The proposed amendment is intended to provide a mechanism to avoid disruption of the decision making process for applications proposing dealings involving intentional release (DIR) of a GMO into the Australian environment, so that days on which the Regulator is waiting for advice from the Gene Technology Technical Advisory Committee (GTTAC) do not count in the statutory timeframe.

The Regulator is required to make a decision to issue or refuse to issue a licence within a timeframe specified in the Regulations (150 working days for limited and controlled release applications; 255 working days for other DIR applications). If the Regulator does not make a decision regarding a DIR licence application within the statutory timeframe, the application is deemed to be refused (Section 182 of the Act). Therefore circumstances which delay the decision making process have the potential to lead to refusal.

Section 52 (3) of the *Gene Technology Act 2000* (the Act) requires the Regulator to seek advice from GTTAC on the risk assessment and risk management plan (RARMP) prepared for each DIR application. For DIR applications which do not meet the criteria for 'limited and controlled' releases, advice from GTTAC must also be sought on matters relevant to the preparation of the RARMP.

The function of GTTAC is to provide expert scientific and technical advice to the Regulator, and GTTAC advice on RARMPs is an integral part of the assessment process for intentional releases. Although the Regulator can proceed with a licence decision if GTTAC advice has not

been received, this is not desirable. Historically, instances have occurred where obtaining GTTAC advice has been delayed, but not impacted the decision-making process, in the interim between expiration and reappointment of GTTAC membership.

It is proposed to address this issue by amending the Regulations to not count days when the Regulator cannot proceed with the decision-making process, or a related function, because he is waiting for advice from GTTAC on a RARMP prepared for a DIR application. This proposal is intended to avoid uncertainty for the applicant and the Regulator regarding the decision making process on licence applications. Based on operational experience this regulation would be expected to operate only in rare instances because the ‘trigger’ for operation of the amendment is days on which “the Regulator cannot proceed with the decision making process, or a related function”. For this reason, this proposal would not impact upon decision-making timeframes for most DIR applications.

Proposal 2 – Time limit for variations

Amend the 90 day time limit for decision-making on variation applications to count only working days and exclude days on which the Regulator cannot proceed with the decision-making process, or a related function, because he is waiting for information requested in writing from the applicant.

The Regulator can vary a licence on the Regulator’s own initiative or on application from the licence holder (Section 71 of the Act). Currently, regulation 11A specifies that the time within which the Regulator must vary or refuse to vary a licence is 90 days from receipt of the application. If the Regulator has not made a decision on a licence variation within the specified timeframe the application is deemed to be rejected under Section 182 of the Act. Therefore circumstances which delay the decision making process have the potential to lead to refusal.

The statutory 90 day timeframe was introduced following the independent review undertaken in 2005 – 2006 (the *Statutory Review of the Gene Technology Act 2000 and the Gene Technology Agreement*) in order to provide a level of certainty to applicants. The review recommended a 90 working day timeframe (Recommendation 5.9) but the actual amendment in the Gene Technology Amendment Regulations 2007 was expressed in days only. The current amendment is therefore proposed to correct a previous drafting oversight.

If a variation application contains insufficient information for the Regulator to make a decision, the Regulator may ask for additional information. Unlike other timeframes specified in the Act, no allowance is made in the legislation for days when the Regulator is waiting for additional information requested from the licence holder in relation to a variation application. If insufficient time is available this may result in the variation request being rejected and a new variation application being required.

To address this issue it is proposed to exclude from the timeframe days on which the Regulator cannot proceed with the decision-making process because he is waiting for information requested in writing from the applicant.

These proposals would make the provisions governing the timeframe for variation applications consistent with those for other applications.

Proposal 3 – Correcting cross references

Amend cross references in regulation 12 paragraph 1(a) and regulation 39 paragraph 1(b) to reflect previous changes to the schedules.

There are currently two incorrect cross references to Schedule 3 of the Regulations, as they were not adjusted to take into account changes made by the Gene Technology Amendment Regulations 2007. Two amendments are proposed to correct these cross references:

- amend regulation 12 paragraph 1(a) to read ‘it is a dealing of a kind mentioned in Part 1 or Part 2 of Schedule 3 (other than a dealing also mentioned in Part 3 of Schedule 3); and’
- amend regulation 39 paragraph 1(b) to read ‘in terms of Part 1 or Part 2 of Schedule 3 ...’