March 2019

Risk Analysis Reference: Risk Management Considerations for Field Trials of GM Plants

The Regulator uses risk management to protect the health and safety of people and to protect the environment. A risk management plan is prepared for every *Dealings involving intentional release (DIR)* licence application of GM plants. It addresses the risks evaluated as requiring treatment and considers limits and controls proposed by the applicant, as well as general risk management measures. The risk management plan informs the Regulator's decision-making process and is given effect through the licence.

Under Section 56 of the Act, the Regulator must not issue a licence unless satisfied that risks posed by the dealings proposed to be authorised by the licence are able to be managed in a way that protects the health and safety of people and the environment.

All licences are subject to three statutory conditions. The licence also contains any conditions imposed by the Regulator. Examples of the matters to which conditions may relate are listed in Section 62 of the Act. Licence conditions are imposed to address risks and to maintain the context of the licence application. In addition, under Section 152 of the Act the Regulator has extensive powers to monitor compliance with licence conditions.

Risk treatment for substantive risks

If a risk is identified and its level is characterised as greater then negligible, then the Regulator may impose risk treatment measures. Risk treatment measures for a substantive risk would be evaluated and imposed on a case-by-case basis to reduce the risk to an acceptable level. Should an effective risk treatment not be available, then the Regulator must decide not to issue a licence.

Statutory licence conditions

Sections 63-65 of the Act specify conditions that must be imposed on all licences.

Sections 63 and 65 are reporting conditions:

- the licence holder must inform any person covered by the licence of the conditions that apply to them; and the cancellation, suspension and surrender of the licence and
- the licence holder must tell the Regulator if there is additional information on the risks posed by the authorised dealings, or any unintended effects from the dealings with the GMO or if there is a contravention of the licence.

Section 64 requires that the Regulator must be permitted to access premises where activities with a GMO are conducted under the licence.

Other general risk management

In making a decision whether or not to issue a licence, the Regulator must consider the suitability of the applicant to hold a licence and thus must take into account:

- any relevant convictions of the applicant
- any revocation or suspension of a relevant licence or permit held by the applicant under a law of the Commonwealth, a State or a foreign country and
- the capacity of the applicant to meet the conditions of the licence.

A condition is usually imposed which requires that any applicant organisation must have access to a properly constituted Institutional Biosafety Committee and be an accredited organisation under the Act.

If issued, all licences include conditions for general risk management, i.e. they

- specify the licence holder and those covered by the licence as well as the requirement for the licence holder to remain suitable to hold the licence
- include conditions that identify the GMO/s, the permitted activities, and where, when and for how long these activities may take place
- clarify that the permitted activities cannot be undertaken if prohibited by State law and
- mandate a detection method capable of identifying the GMO/s.

Risk management of field trial licences

All licences for the limited and controlled release (field trials) of GM plants also include conditions to maintain the context proposed for the trial as this was important to evaluate the level of risk. In particular, measures reducing the potential for exposure of humans and other organisms are included, e.g. measures to limit the likelihood of dispersal. Other conditions ensure a high level of oversight during and after the trial of the GM plants.

Licence conditions reducing the exposure of people and the environment

Several licence conditions are imposed in all field trial licences to reduce the likelihood of accidental or inadvertent dispersal of viable GM plant material and exposure of people and the environment to GM plant material.

Generally, the Regulator does not permit the GM plant or food derived from it in commercial food or animal feed. This reduces the potential of any viable GM plant material to be dispersed outside the trial as a result of, e.g. accidental dispersal during transport or animal feeding. In addition, this licence condition may be employed to counter any uncertainty regarding the potential for toxicity or allergenicity to people or for toxicity to animals.

The licence includes requirements and restrictions on the experimentation with the GM plants, and their transport, storage and destruction to reduce the potential for dispersal of viable GM plant material. For example, GM plants are typically required to be transported, stored or disposed of in accordance with the Regulator's *Guidelines for the Transport, Storage and Disposal of GMOs* as applicable to GM plants.

Licence conditions usually include that planting of GM plants must occur at least 50 m away from waterways to avoid the potential for water dispersal.

They also include that any non-GM plants grown in the trial site must be treated as if they were the GM plant; that plants in the trial site must be harvested separately from all other crops; and that all equipment used in connection with the GM plants must be cleaned before removing it from the trial site. These requirements effectively limit inadvertent intermingling of GM and non-GM plants or their seeds which may result in the GM plants or their seeds being moved off the trial site and remaining in the environment outside the trial.

There are also restrictions on which other plants can grow within and around the trial sites. These conditions are related to the biology of each plant species and may be different for different introduced genetic modification/s. These restrictions will limit the potential for pollen from the GM plants to fertilise sexually compatible plants. Therefore, inspection of the trial site and areas around the trial site during and after growing the GM plants is routinely required as well as inspection of specified areas after harvest of the GM plants. If any plants whose growth is prohibited are found during these inspections then they must be destroyed before they flower and disperse pollen. The Regulator must be satisfied that propagative GM plant material has been removed before the trial site and other areas can be used for other purposes. The licence holder must have access to all areas of land that are subject to conditions of the licence while these requirements are current to enable them to complete the requirements of the licence.

Field trial licences also cover for contingencies: generally, field trial licences require the licence holder to supply a contingency plan which must be enacted if the GM plants are found outside the trial. Also, severe adverse weather events must be reported to the Regulator. If an adverse weather event is reported, OGTR staff will then assess whether dispersal of propagative GM plant material may have occurred and decide if any follow-up actions must be taken.

GM plants not required for future experiments or planting must be destroyed to reduce the potential for accidental release of the GM plants.

Licence conditions ensuring ongoing oversight by the Regulator

A number of conditions are included in the licence to help with planning of compliance visits as well as keep the Regulator informed of

- how the trial is proceeding
- who is involved in activities with the GM plants
- whether people working with the GM plants know how to comply with the licence.

Reporting of the licence holder's intention to plant, dates of planting, harvest, cleaning, as well as how inspection activities will be carried out is required before planting. Changes to key personnel such as the project supervisor must also be notified.

The licence holder must not permit anyone to conduct dealings unless they have been informed of, and understood the conditions that apply to them and have signed a statement to this effect. The licence holder must tell the Regulator how they are planning to inform people and also keep a logbook. These records must be made available to the Regulator upon request.

Other licence conditions may be included on a case-by-case basis. These would be evaluated in the risk management plan for the particular field trial.