AusBiotech submission regarding a new OGTR application form specifically for the commercial release of GM plants

Application for a licence for dealings involving intentional release (DIR) of GM plants into the environment - commercial release

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Introduction

AusBiotech is pleased to submit to this consultation regarding a new OGTR application form specifically for the commercial release of GM plants.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology, food technology, industrial and agricultural biotechnology sectors. The industry consists of an estimated 900 biotechnology companies and employs in excess of 45,000 Australians.

Within AusBiotech, the agriculture, food and industrial biotechnology sectors are represented by the Agriculture Food & Industrial Biotechnology Committee, a special interest industry group dedicated to support AusBiotech with its mission to:

"…foster a growing, strong and profitable biotechnology and life science industry in Australia through representation, advocacy and the provision of services and benefits to its members to help the industry realise its nationally important economic potential"

AusBiotech welcomes the revision to the commercial release application form – *Application for a licence for dealings involving intentional release (DIR) of GM plants into the environment - commercial release* – and applauds OGTRs responsiveness to industry's concerns relating to providing guidance to applicants for the submission of commercial release applications.

Specific Comments

Comments and suggestions from AusBiotech members included:

1. Members are largely supportive of the new form although the revised format will be initially time consuming for some applicants.
    a. The application form largely requests the same information as the current commercial release form, although some duplication has been removed. The format appears simpler and provides an 'all-in-one' application rather than split across the current Form 5 and supplemented attachments provided by applicants.
    b. Example questions are provided for illustrative purposes. These are seen as useful and offer insight into what the OGTR is looking for.
    c. Applicants will need access to the new form in a format that is not fully locked down in order to complete all necessary fields. There are some accessibility and functionality issues across different computer platforms (e.g. different versions of Microsoft Word, different computer operating systems such as IOS and Windows). For example:
        - you may not be able to check any check boxes
        - you can cut and paste paragraphs of text but cannot enter information directly to maintain correct paragraph structure.

2. Section 10.3 of the new form asks questions about any proposed containment conditions that may be applied to the new commercial release. Industry is working towards the development of 'common' crop-specific licence conditions that relate to containment and monitoring. If successful, such questions could become irrelevant for commercial release DIR applications. Where possible the form could explore future proofing for such scenarios and linkage to industry best practices.
3. The application includes new questions and / or the format of some questions has been changed to align with the information required in order for OGTR evaluators to undertake Weed Risk Assessment (WRA) methodology adapted from the Australian/New Zealand Standards HB 294:2006 National Post-Border Weed Risk Management Protocol. Most comments received from members were around these questions and the additional level of detail requested that is not currently required in commercial DIR applications.
    a. Several members indicated that answering WRA questions about parent organisms (e.g. 14.7 to 14.11) may be subjective and in some cases members indicated difficulty in providing accurate answers or finding information that would support a particular answer. In other cases the information was readily available in the OGTR Biology Documents. OGTR may need to provide some additional guidance for applicants around the WRA methodology and how applicants can provide sufficient information for evaluation or whether information is required if documented in Biology Documents.
    b. The OGTR has undertaken WRAs for both Cotton and Canola and included the outcomes in their respective Biology Documents. WRAs should be completed for all plant species that Biology Documents that the OGTR has prepared. Further, DIR application forms could be simplified for species where OGTR has completed an WRA, with applicants only required to answer questions around the potential effect(s) of the trait on weediness. The WRA documented in the Biology Documents of parent organisms should suffice for the application.
    c. Section 14.12 '*Provide details of any State or Commonwealth restrictions on the movement of material from the parent species within and between producing regions*' has not previously been requested by the OGTR. It is unclear how this information informs the WRA and development of DIR licence conditions.
    d. Several questions in the new form ask for applicants to provide further information when an applicant answers YES (e.g. questions in Section 14). Some members felt obliged to also provide additional information to an answer when NO was selected. There was some confusion whether there was an expectation to provide additional information when the answer was NO because further information was provided in example answers provided by OGTR. Some assistance from OGTR maybe required for such questions.

Next steps

AusBiotech thanks the OGTR for engaging with industry on this new draft licence application and guidance document. Once published the document will provide useful advice to industry considering applications for commercial release of GM plants into the environment. Every effort should be made by the OGTR to balance the need for commercial detail versus the regulatory burden imposed, and risk mitigation achieved through requiring such information.

Some changes to formatting and refining of guidance will further enhance the application form and may help to minimise queries to the OGTR from applicants.

AusBiotech members would welcome the opportunity to provide further input into the document once feedback from industry has been considered and before the document is published.