Suitability of the applicant

The OGTR designated DIR number that this form relates to is: **DIR 173**

Applicants are requested to complete this form in order for the Gene Technology Regulator (the Regulator) to assess their suitability to hold a licence under section 58 of the *Gene Technology Act 2000*.

Please select the appropriate option in the drop-down list ("Choose an item") to answer each question.

Please save the completed form as a pdf before lodging.

Submit the completed form by return email (Reply All).

Please keep a copy of the form for your records.

---

1. Has the **applicant**, since making the original application for a licence, been convicted of an offence against a law of the Commonwealth, a State or a foreign country which relates to the health and safety of people or the environment which is punishable on conviction by a fine of $5000 or more, or by a term of imprisonment of one year or more?

   No

   If Yes - please provide details of the following in an attachment and indicate attachment number;

   - The Act the offence was committed under,
   - The date the offence was committed,
   - The date of the conviction,
   - The penalty which was imposed.

   Attachment No.

<u>If the applicant answered **Yes** to the preceding question and is a body corporate:</u>

(a) Was any person who is currently a director of the applicant also a director of the applicant at the time that the offence was committed?

Choose an item.

If Yes, provide director's name:

(b) Was any person who is currently an officer or shareholder of the applicant, in a position to influence the management of the applicant, also such an officer or shareholder at the time that the offence was committed?

Choose an item.

If Yes, provide person's name:

2. Has the applicant had a licence or permit (however described) revoked or suspended under a law of the Commonwealth, a State or a foreign country being a law relating to the health and safety of people or the environment, since the original application for a licence was made?

   No

   If Yes, please provide details in an attachment and indicate attachment number.

   Attachment No.

3. To the best of the applicant's knowledge, will the applicant be financially viable for the foreseeable future?

Yes

4. What is the date of the applicant's latest financial statement? Date: (31/12/2019)

Was the latest financial statement prepared <u>after</u> the original application for this licence?

Yes

If No, proceed to Question 5

If Yes, please provide a copy of (or a link to) the applicant's latest financial statement and either a copy of the audit findings, or a statement from a director of the company (or a person otherwise authorised to make the statement), that the financial statement provided presents a true and fair view, in all material aspects, of the affairs of the applicant for the period covered by the statement?

Provided via email 11/08/2020

5. Can the applicant foresee any reasons why they would not be able to comply with the conditions set out in the draft licence outlined in the consultation Risk Assessment and Risk Management Plan?

No

If **Yes** – please provide details of the following in an attachment and indicate attachment number.

Attachment No.

Declaration

I DECLARE THAT:

- I am duly authorised to sign this declaration; and
- The information supplied on this form and any attachment is true and correct.

CEO (or delegate with authority to sign) of the Applicant Organisation

Printed name:	[redacted]	Signature:	[redacted]
Job title:	Regulatory Affairs Lead	Date:	12/08/2020

FINANCIAL SUITABILITY RATIOS Bayer CropScience Holdings Pty Ltd (Bayer) for the year ended 31 December 2019

1) Current Ratio	-	**Current Assets / Current Liabilities**	-	Measures ability to pay current liabilities from current assets in % terms
2) Working Capital	-	**Current Assets - Current Liabilities**	-	Measures ability to pay current liabilities from current assets in $ terms
3) Acid-Test (Quick) Ratio	-	**Cash+Short-term Investment + Net Receivables / Current Liabilities**	-	Shows ability to pay current liabilities from the most liquid assets.
4) Debt Ratio	-	**Total Liabilities / Total Assets**	-	Indicates % of assets financed through borrowing.

	Consolidated entity ($'000)			
1) Current Ratio	327,075 / 128,482	=	2.546	
2) Working Capital	327,075 less	128,482 =	198,593	
3) Acid-Test (quick)	155,055 / 128,482	=	1.207	
4) Debt Ratio	210,357 / 437,802	=	0.480	

Measuring Liquidity
The most common measure of liquidity is the Current Ratio. It is useful for businesses that have substantial current assets. Businesses with limited current assets have little liquidity no matter what the current ratio says

Current Ratio = Total Current Assets/Total Current Liabilities

Simple rules of thumb for evaluating your Current Ratio:
Strong - Over 1.75
Caution - 1.1 to 1.75
Vulnerable - Under 1.1

Businesses with a Strong Current Ratio have established a healthy risk management cushion for difficult economic times. Their challenge is to make sure they are earning a reasonable return on their liquid assets.

If the Current Ratio raises the Caution flag, management needs to monitor cash flows carefully. A low current ratio will not make the business unprofitable but it might make it difficult to take advantage of opportunities as they arise.

Businesses with a Vulnerable Current Ratio are in a precarious position. Businesses don't usually go out of business because they lose all their net worth; they go out because they can't pay their bills. Businesses that fall in this category need to take immediate action. Operators in this position should work very closely with financial advisors, creditors and others to craft a plan that will get their operation back on the road to financial security.

Monitoring and Compliance History for Monsanto Australia Pty Ltd

July 2011 – August 2020

Contents

Executive Summary

Monsanto Australia Pty Ltd (Monsanto) has held and continues to hold a large number of licences and subsequently has incurred a number of non-compliances since the Gene Technology Act came into force in 2001. Over the last 5 years a small number of non-compliances have been issued to Monsanto, most arising out of incidents self-reported by the organisation to the OGTR. All non-compliances identified have presented negligible risk to human health and safety and the environment.

Monsanto have displayed a good corporate culture and have been very pro-active in ensuring compliance with the OGTR regulatory requirements. In addition to their reporting obligations, Monsanto frequently contacts the OGTR to clarify licence conditions and to confirm that their proposed activities will be compliant with licence conditions.

Monsanto routinely meets their obligations for annual reporting against commercial-release licences, along with monthly reporting of licensed field trials.

Current Dealings

Field releases – limited and controlled

Monsanto currently have 11 active field trial sites under DIR-147 (cotton), all 11 sites are in the Post-Harvest Monitoring phase.

Field releases – commercial

Monsanto currently have eight DIR licences for the commercial or general release of GM cotton and GM canola.

Contained dealings

Monsanto has one certified PC2 laboratory, holds no DNIRs, and has six NLRD approvals for the most recent annual reporting period to the OGTR.

Incidents

Self-reported

Licence conditions require the licence holder to inform the Regulator of any occurrences or events that are inconsistent with licence requirements. Such self-reported incidents are managed in the same manner as issues identified during routine monitoring.

The table below lists the monitoring findings for self-reported incidents during the past five years.

Date	Site(s)	Issue and findings
8/11/2019	DIR-147 site 14 (current)	• **Possible gaps in pollen trap** (cotton) self-reported. • OGTR endorsed proposed mitigation strategy to replant gaps in pollen trap and increasing width of pollen trap through use of adjacent commercial cotton crop. • Compliant and no further action required.
26/11/2018	DIR-147, site 6 (current)	• **Possible gaps in pollen trap** (cotton) self-reported. • OGTR endorsed proposed mitigation strategy including not utilising access path through pollen trap and increasing width of pollen trap through use of adjacent commercial cotton crop. • Compliant and no further action required.
27/07/2018	DIR 147, site 4 (current)	• **Possible gaps in pollen trap** (cotton) self-reported. • Site had an additional 5m of pollen trap and is 1km distance to any other cotton plants. • Risk assessed as negligible. • Compliant and no further action required.
19/10/2016	DIR 120, site 7 (PHM)	• **Unapproved post-harvest crop** (cotton) self-reported. • Risk assessed as negligible. • OGTR endorsed management strategy including destruction of cotton plants with additional obligations imposed (delayed sign-off application, re-training grower, closer management of other PHM sites on same farm) • Monsanto found **non-compliant**

12/01/2016	DIR 120, site 7 (PHM)	• **Unapproved post-harvest crop** (soybean) self-reported. • Risk assessed as negligible. • Continued soybean cropping permitted with additional obligations imposed (stricter inspection activities, delayed sign-off application, re-training staff recognition and control of volunteers). • Monsanto found **non-compliant**
9/01/2016 Correction: 9/01/2014	DIR 101, site 14 (PHM)	• **Flowering cotton volunteers** were self-reported and destroyed. • Risk assessed as negligible following site inspection by OGTR. • Monsanto volunteered practices beyond licence obligations (inspections extended to adjacent land, with increased frequency), to ensure volunteers do not reach flowering. • Monsanto found **non-compliant**

Natural disaster

Date	Site(s)	Issue and findings
2/03/2020	DIR-147 sites 4 &10	• Report of adverse weather event • Follow up reports indicated no evidence of distribution of GMO from trial site

Other

Date	Site(s)	Issue and findings
n/a	n/a	• n/a

Monitoring Section Findings

Field release monitoring

OGTR routinely conducts announced and unannounced monitoring of Monsanto's limited and controlled release sites as part of our quarterly targets. OGTR also monitors release sites in response to incidents (findings listed under ***Incidents***). This table lists routine monitoring findings (listed by trip).

OGTR Inspections

Quarter	Site(s) monitored	Issue and findings
July – Sept 2019	DIR-147 sites 3 & 9	• No non-compliances or issues identified.
April – Jun 2019	DIR-147 sites 4 & 10	• No non-compliances or issues identified.
Jan – Mar 2019	DIR-147 site 8	• No non-compliances or issues identified.
Oct – Dec 2018	DIR-147 site 6	• No non-compliances or issues identified (also **see incidents** above)

July – Sept 2018	DIR-147 site 3	• No non-compliances or issues identified.
Jul – Sept 2017	DIR-147 site 1	• No non-compliances or issues identified.
Oct – Dec 2016	DIR-120 sites 9, 15 & 20	• No non-compliances or issues identified.
July – Sept 2016	DIR-120 sites 3, 5, 9, 11, 12 & 14	• No non-compliances or issues identified.
Oct – Dec 2015	DIR-120 site 7 DIR-120 site 10	• **See self-reported incident above** • No non-compliances or issues identified.
Jan – Mar 2015	DIR 120, site 4	• **Pollen trap not sufficiently established** for synchronous flowering with GMOs • Identified during **announced** OGTR inspection • Monsanto mitigated outcrossing via pesticide control of insect pollinators, synchronised site harvest, and identified procedural improvements to avoid reoccurrence. • Monsanto found **non-compliant**
Jan – Mar 2015	DIR 120, site 7	• **Pollen trap not sufficiently established** for synchronous flowering with GMOs • Identified during **un-announced** OGTR inspection • Monsanto mitigated outcrossing via pesticide control of insect pollinators, synchronised site harvest, and identified procedural improvements to avoid reoccurrence. • Monsanto found **non-compliant**
Oct – Dec 2014	DIR-105 Sites 4, 10, 11, 12 & 13	• No non-compliances or issues identified.
July – Sept 2014	DIR-105 Sites 8 & 9	• No non-compliances or issues identified.

Contained monitoring

OGTR has not undertaken monitoring of contained dealings in the previous five years.

Compliance Findings

Compliance history comment for Monsanto

The M&C assessment for this applicant included publicly available Australian legal databases, ASIC, online news, M&C TRIM records, and the entity's available online data. No adverse information was found in these searches which would impinge on the Regulator's decisions about suitability or capacity to meet regulatory requirements.

There are no M&C findings or relevant compliance activities underway in relation to the applicant which would impinge on the Regulator's decisions about suitability or capacity to meet regulatory requirements

Organisational Reporting

Site monitoring

Monsanto provides the OGTR with compiled reports noting the findings of monthly monitoring inspections which the organisation is obliged to perform under conditions of licence for previous intentional releases.

Annual reporting

Monsanto are required to supply OGTR with annual report for each commercial release licence, and have routinely met these obligations.

With regard to the annual reporting, on 29 August 2018 the staff of the OGTR Monitoring and Compliance Section met with Monsanto staff to conduct a Practice Review into Oversight of commercially approved GM crops in Australia. The aim of this review was to meet with licence holders of commercial DIR crops to discuss ‘post-release review’ obligations and to gather information related to ongoing oversight of these GMOs.

[redacted]

From: [redacted]
Sent: Friday, 17 July 2020 2:46 PM
To: [redacted]
Subject: FW: DIR 173 - Submission on commercial release of genetically modified cotton [SEC=OFFICIAL]

[redacted]

Was this forwarded to you?

[redacted]

From: VOICEMAIL, OGTR <OGTR.Voicemail@health.gov.au>
Sent: Friday, 17 July 2020 2:40 PM
To: [redacted]
Subject: RE: DIR 173 - Submission on commercial release of genetically modified cotton [SEC=OFFICIAL]

Thank you for your email. It has been forwarded to the appropriate area and will be responded to shortly.

Regards
OGTR Mailbox Administrator

Office of the Gene Technology Regulator Division | CMO Group
Regulatory Practice and Compliance Branch
Australian Government Department of Health
T: 1800 181 030 | E: ogtr@health.gov.au
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: [redacted]
Sent: Friday, 17 July 2020 1:26 PM
To: VOICEMAIL, OGTR <OGTR.Voicemail@health.gov.au>
Subject: Re: DIR 173 - Submission on commercial release of genetically modified cotton [SEC=No Protective Marking]

Hi OGTR,

I can't believe OGTR are even considering an application from greedy, polluting, poisoning the environment, multinational Monsanto for the commercial cultivation of genetically modified (GM) cotton so they can increase their profit margin.

Monsanto is seeking approval to commercially grow MON 88701 cotton in all cotton growing areas of Australia. The GM cotton and its products would enter general commerce, including use in human food and animal feed.

Monsanto don't care about our health or the environment, only $!

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed release would pose negligible risk to human health and safety or to the environment.

What does 'negligible risk to human health and safety or to the environment' actually mean? This is a non-committal statement which means nothing, but to placate the ignorant and careless.

What tests and trials have been done to absolutely prove that this proposal will cause no the side effects to humans and the environment. Any, or none?

I strongly oppose this license application and any granting of an approval to commercially grow MON 88701 cotton in all cotton growing areas of Australia, poisoning us and the planet for profit!

OPPOSE!

Not impressed,

[redacted]

On 13/7/20 1:48 pm, VOICEMAIL, OGTR wrote:

Invitation to comment on the commercial release of a genetically modified cotton

Australia's gene technology regulatory system is designed to protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology and managing those risks.

The Gene Technology Regulator is assessing licence application DIR 173 from Monsanto Australia Pty Ltd (Monsanto) for commercial cultivation of genetically modified (GM) cotton. The GM cotton (MON 88701) contains two introduced genes that confer herbicide tolerance.

Monsanto is seeking approval to commercially grow MON 88701 cotton in all cotton growing areas of Australia. The GM cotton and its products would enter general commerce, including use in human food and animal feed.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed release would pose negligible risk to human health and safety or to the environment. Draft licence conditions are proposed to ensure ongoing oversight of the release.

The Regulator welcomes written submissions in order to finalise the RARMP, which will then inform the decision on whether or not to issue the licence. The consultation RARMP and related documents can be obtained from the OGTR website under What's New or by contacting the Office. Please quote application DIR 173 in any correspondence.

Submissions should be received by close of business on **24 August 2020**.

Office of the Gene Technology Regulator, MDP 54, GPO BOX 9848 CANBERRA ACT 2601
Telephone: 1800 181 030 **E-mail: ogtr@health.gov.au**
OGTR website

Australian Government
Department of Health
Office of the Gene Technology Regulator

DIR application		MINUTE 3	
Licence decision for application DIR-173 for the General and Commercial Release of GMOs into the environment			
To	Raj Bhula Gene Technology Regulator	**Cleared. Web upload & mailout approved**	14 October 2020
	Click here to enter text.		
Through	[redacted] Assistant Secretary Evaluation Branch	Cleared and tweet text approved	30 September 2020
	Click here to enter text		
Through	[redacted] Director Plant Evaluation Section	**Cleared and forwarded for decision**	25 September 2020
	Changes completed		
Action officer	[redacted] Evaluator, Plant Evaluation Section	Submitted	17 September 2020
Application number	DIR-173		
Name of Applicant	Monsanto Australia Pty Ltd		
Title of application	Commercial release of cotton (*Gossypium hirsutum*) genetically modified for herbicide tolerance		
Date(s) received	23 January 2020		
Date decision due	1 February 2021		
Application file	E20-107268H		
CCI number	N/A	**CCI file**	N/A
Associated records	This Minute and its Attachments are located in PH20/19475		
Purpose of this minute	- advise you of the actions which have been, or are being, taken on your behalf in relation to the above DIR licence application - advise you of the results of the OGTR's risk assessment in relation to the dealings proposed by the application - advise you of the details of the OGTR's risk management plan for the dealings proposed to be authorised by the licence - advise you of the proposed conditions to be imposed if a licence is issued with respect to the application - seek your decision on whether or not to issue a licence for this application - seek your agreement to a process for advising stakeholders of your decision on whether or not to issue a licence with respect to the application.		
Legislative basis	The Act sets out a number of steps and considerations that you must undertake, prior to deciding whether or not to issue a licence, in response to an application for a licence to conduct dealings which involve the intentional release of a GMO into the environment (DIR licence).		

	Those steps and considerations relevant to this stage of the DIR application assessment process are set out below.

Consideration / Action taken	Analysis / Recommendation	Action required
1. As required by division 4 of the Act, a RARMP was prepared and publicly notified. This was the subject of Minute 2 which the Regulator cleared on 9/07/2020		
Following consideration of submissions, a final RARMP has been drafted.	The final **RARMP** has been prepared and is at D20-2020980.	Approved?
	When D20-2020980 has been approved, the summary of the RARMP will be extracted to form a stand-alone document.	Noted
2. In accordance with division 5 of the Act, you must now consider your decision on the licence for this DIR application.	Relevant matters for your consideration are set out below (considerations 3 – 6). However, you are not limited to these matters in deciding on the licence.	Noted
3. You must not issue a licence unless satisfied that the risks posed by the proposed dealings are able to be managed to protect the health and safety of people and the environment (s56(1)). You must have regard to:		
- both the risk assessment and risk management plan prepared under section 50 in relation to the dealings (s56(2)(a) and (b))	The risk assessment concludes that the dealings proposed to be authorised pose negligible risks to people and the environment. The risk management plan concludes that these negligible risks do not require specific risk management but proposes conditions to maintain oversight of the release (D20-2020980).	Satisfied
- any submissions received under section 52 in relation to the licence (s56(2)(c))	Draft GTTAC minutes are at D20-2268778. Submissions received from GTTAC and prescribed agencies and authorities under s52 are summarised, along with information on the consideration of the issues raised by prescribed agencies, states and territories and LGAs, in D20-2100355**.** The full submissions are available in PH20/19476 for your consideration. Once this Minute is cleared, a redacted version of the submission summary will be added to the RARMP as Appendix B.	Noted
	Six submissions were received from the public. They are summarised along with information on the consideration of the issues raised, in D20-2100358. The full submissions are available in PH20/19477 for your consideration. One submitter	Noted

Consideration / Action taken	Analysis / Recommendation	Action required
	(GeneEthics) provided a lengthy submission largely concerned with suitability of the applicant to hold a licence. The legal officer has provided advice on this submission for your consideration in D20-2293324 (also noted in section 5 below). Once this Minute is cleared, a redacted version of the submission summary will be added to the RARMP as Appendix C.	
	The applicant made no formal submission on the RARMP or draft licence conditions for DIR 173.	Noted
- any policy guidelines in force under section 23 that relate to: · risks that may be posed by the dealings (s56(2)(d)(i)) · ways of managing such risks so as to protect the health and safety of people or to protect the environment (s56(2)(d)(ii))	No policy guidelines are currently in force under section 23.	Noted
4. You must not issue a licence if you are satisfied that issuing the licence would be inconsistent with a policy principle in force under section 21 [s57(1)].	The Gene Technology Ministerial Council has issued The Gene Technology (Recognition of Designated Areas) Principle 2003. Section 7 expressly states that it is not intended to affect the Regulator's obligation to make a decision on whether to refuse or issue a GMO licence or her duty to consider all matters required by the legislation to be considered prior to issuing a licence. A licence for the proposed dealings would **not be inconsistent** with the policy principle.	Agree
5. You must not issue a licence unless you are satisfied that the applicant is suitable to hold the licence [s57(2)] and must have regard to the following in deciding this suitability [s58(2)]: - any relevant convictions of the body corporate; - any relevant revocation or suspension of a licence or permit relating to the health and safety of people or the environment; and - the capacity of the applicant to meet the conditions of the licence.	The applicant's declaration of suitability is at D20-2138204. Consideration of the suitability of the applicant by the relevant OGTR staff is provided in the Compliance assessment and monitoring history D20-2293653 and the financial suitability report D20-2136936. .	Noted
	It is recommended that you determine whether or not you are satisfied that the applicant is suitable to hold the licence on the basis of the above attachments and considerations.	Satisfied

Consideration / Action taken	Analysis / Recommendation	Action required
However, you are not limited to these matters in deciding on suitability.	Additional matters are raised in the GeneEthics submission at D20-2195587. As noted in section 3 above, the legal officer has provided advice on applicant suitability issues in D20-2293324. Please note if you have concluded that there are no additional matters that you consider relevant to suitability.	Noted
6. You must decide whether to issue or refuse to issue a licence (s55(a)).	If satisfied with the above considerations, it is recommended that a licence be issued.	Agree
7. If you decide to issue a licence, you may impose conditions to which the licence is subject [55(b)] - Section 60 of the Act provides that a licence may be issued for a specific period. If no period is specified subsection, 60(1)(b) provides that the licence remains in force until it is either cancelled or surrendered.	Standard practice is to keep the licence in force until you consider that it is appropriate to release the licence holder from any further obligations, taking into consideration any risks to human health and safety or to the environment which may be posed before consenting to surrender of the licence. Recommend that you do not specify a particular period for which the licence is in force.	Agree
- Sections 61 – 65 of the Act set out the range of conditions which may or must be included in a licence and a range of matters to which the conditions may relate, including: · conditions that may be imposed to limit and control the release and manage risk (s62) · that any person covered by the licence must be informed of the conditions (s63) · that monitoring and auditing of the dealings must be allowed by persons dealing with the GMO (s64) · that additional information about the dealings must be supplied to the Regulator (s65)	As detailed in the RARMP D20-2020980, conditions in the licence address the requirements of s61 – s65. [redacted] The monitoring and compliance section reviewed the licence and suggested that, given 'dealings' is included in the definitions for a recent licence for vaccines, it may also be good to do the same for this licence (D20-2293653). However, since dealings are defined by the Act, and all dealings are permitted for commercial releases of GM plants, no changes to the licence is made in this regard. The licence for public release is at D20-2026488.	Noted Noted Approved
8. After deciding whether or not to issue a licence, you must:	Draft at D20-2053638.	Approved

Consideration / Action taken	Analysis / Recommendation	Action required
- Notify the applicant in writing of your decision and the conditions imposed (section 59), and of the terms of the decisions, the reasons for the decisions and the particulars of the applicant's review rights (section 180). - If a licence is issued, update the Record of GMO Dealings to reflect your decision (section 138).	Recommend that the GMO Record be updated to include the details of the licence.	Agree
9. Other actions may be taken (s53). It is standard practice that licence decisions are communicated to other stakeholders. The following documents have been prepared: 10. 'Notification of decision'	Draft at D20-2053639. This document will be posted on the OGTR website and sent to prescribed experts, agencies and authorities and local government authorities which were consulted on the RARMP, as well as people on the OGTR mailing list.	Approved
- 'Questions and Answers'	Draft at D20-2053640. This document will be posted on the OGTR website.	Approved
- Notification through social media	Due to the COVID-19 arrangement, notification though the Department's twitter account is temporally unavailable.	Noted
- Email to agencies/states and territories	While in some cases individual emails are sent to agencies that have raised significant issues, it is considered that no individual emails are warranted in this case.	Agree
- Email to public submitters	A sample email to public submitters is at D20-2053641. A separate email to GeneEthics is at D20-2319456.	Approved
- Email for you to send to the office of Minister Colbeck ahead of public notification of your decision.	Draft at D20-2053642, for you to send two working days before issuing the licence.	Approved
- Email to the Minister for the Environment advising that the licence has been issued.	Draft at D20-2053799, to be sent without a signature.	Approved

Consideration / Action taken	Analysis / Recommendation	Action required
- Consider need for additional briefing material, such as a media release or Question Time Brief, considering likely level of public interest in the proposed release.	There has been limited public interest in this commercial release, with six submissions from the public in response to the consultation on the RARMP. There was limited media reporting following the release of the consultation RARMP. For these reasons, the proposed dealings are not considered to be contentious and are not expected to attract media attention; therefore, no media release or QTB is proposed.	Agree
11. Approve upload to the OGTR website and mailout of emails and letters.	Clearance of this Minute will approve the upload of the RARMP, licence, Notification of Decision and Questions and Answers to the DIR-173 webpage and mailout.	Approved
12. Clearance of 3rd minute from the Regulator	Clearance of this Minute is requested by **13 October 2020** to meet the proposed timeframe for the web upload and mail out.	Cleared

gene ethics
working for a GM-free future
ABN: 67 104 140 918
PO Box 400, Emerald Vic 3782
T: 03 5968 2996 E: info@geneethics.org

August 24, 2020

Office of the Gene Technology Regulator
MDP 54, GPO BOX 9848
CANBERRA ACT 2601
T: 1800 181 030
E: ogtr@health.gov.au

Re: : MON 88701 dicamba and glufosinate tolerant cotton

Thank you for the opportunity to comment on Monsanto's application DIR 173, for commercial dealings with genetically manipulated (GM) cotton event MON 88701 that tolerates over-the-top spraying with both dicamba and glufosinate herbicides.

Recommendations

That the application DIR 173 be rejected on the grounds that OGTR must:

- Disqualify Monsanto/Bayer from holding a DIR licence, as ovewhelming evidence shows the corporations' actions have been frequently and intentionally egregious, without regard for the environment and public health, making it unsuitable and unfit to hold a DIR licence;
- Only make a decision on DIR 173 after the APVMA and Environment Department have assessed and approved both dicamba and glufosinate for over-the-top spraying on cotton;
- Consider the collateral environmental damage that licensing MON 88701 multi-herbicide-tolerant cotton would do, by enabling the repeated spraying of dicamba and glufosinate over cotton grown in river catchments, especialy those that drain near the Great Barrier Reef;
- Disclose the content of all its consultations with the APVMA and the Department of Agriculture, Water and the Environment, that aim to minimise all the environmental and public health hazards, risks and impacts of granting a licence for DIR 173;
- Know and assess exactly what formulations of dicamba and glufosinate the APVMA will approve for spraying on the GM herbicide tolerant cotton, before reaching any final decisions about DIR 173;
- Consult other personnel within the Department about public exposure to the glufosinate to be sprayed over herbicide-tolerant cotton as it is set to increase the exposure of Australians to glufosinate in water and food.

Applicant Unsuitable

In our submission, the OGTR must conclude that Monsanto is unsuitable to hold the commercial DIR 173 licence for which it has applied, as extensive, persistent and overwhelming evidence shows that the company's actions (and Bayer's too) were often egregiously insidious, were premeditated, and lacked due regard for the environmental and public health impacts of its dealings, with negative effects on the users of its GM and other seed and chemical products, and also the public at large.

Monsanto Company and Bayer Cropscience are unsuitable to hold licence DIR 173, within the meaning of Sections 57 and 58 of the Gene Technology Act 2000. The Act requires the GTR to have regard to the companies' history of law breaking and non-compliance around the world over the past ten years, as it applies to human health, safety and the environment.

If the GTR's discretion under Section 54 (2) (b) of the Act was exercised in Monsanto's favour, please advise the basis on which this was reached as the documents on corporate suitability to be licensed are hidden from public view. In light of Bayer's and Monsanto's egregious record of law breaking and non-compliance we counsel you not to issue licence DIR 173.

GeneEthics submits that the Monsanto/Bayer application for DIR 173 is in direct, serious and extensive breach of legal requirements in Sections 57 and 58 of the Gene Technology Act 2000. Sections 57(2) and 58(2) of the Gene Technology Act 2000 require the OGTR to be satisfied of the applicants' suitability to hold licences. Licence holders are required to meet contemporary community standards of probity, good standing and ethical behaviour.

By even the most lenient standards, the vast body of examples of Monsanto and Bayer's criminal and civil convictions and adverse judgments show unequivocally that the companies are not good corporate citizens, They comply with the standards of propriety required to be an applicant suitable to hold any licence, including DIR 173. As this is a public interest requirement we submit that the evidence, which the OGTR considered in deciding the companies' suitability, should be published, so the process and the decision are transparent and open to public scrutiny.

As part of the OGTR's suitability tests, Section 58 (2) (c) of the Gene Technology Act 2000 says disqualifying actions include, "any revocation or suspension of a license or permit (however described) held by the body corporate under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment."

Yet in April 2020 the U.S. Court of Appeals for the Ninth Circuit found the Trump Administration's 2018 registration of dicamba was unlawful, disallowed Monsanto's registration of the chemical, so using the new dicamba formulations has been illegal in the USA since June 2020.[1]

The three Appeal Judges wrote that, "the EPA substantially understated the risks that it acknowledged" and "entirely failed to acknowledge other risks" and the colateral damage dicamba spray-drift causes.[2,3] The EPA also failed to collect accurate data on the damage the herbicide was doing in the agricultural landscape across the country.[4]

But the EPA's failure to properly explore the collateral damage of the new dicamba formulations was not the regulator's alone. Monsanto, BASF and Corteva AgriScience all gained EPA approval to market new formulations of dicamba herbicides for widespread spraying over dicamba-tolerant cotton and soybeans, as they claimed their new versions of dicamba would not volatize and spray-drift on to other farms in the way that older dicamba weed killing products were known to do. Those assurances and the data provided were false, and deliberately so.

Punitive or exemplary damages are, "damages assessed in order to punish the defendant for outrageous conduct and/or to reform or deter the defendant and others from engaging in conduct similar to that which formed the basis of the lawsuit. … punitive damages are awarded only in special cases, usually under tort law, if the defendant's conduct was egregiously insidious. … In Australia, punitive damages … are (also) possible for tort cases."[5]

Australian class action lawyers Maurice Blackburn have, "launched a class action against Monsanto on behalf of all people who have been diagnosed with non-Hodgkin lymphoma (NHL) by reason of using or being exposed to Roundup or Monsanto-branded products that contained glyphosate (Roundup Products). We allege that Monsanto was negligent in selling Roundup products which they knew (or ought to have known) could cause cancer. We also allege that the Roundup Products had a safety defect and were not of acceptable quality under consumer protection legislation."[6]

Carbone Lawyers have already lodged a writ against Monsanto in the Victorian Supreme Court on behalf of Michael Ogalirolo, aged 54. He was diagnosed in 2011 with NHL, after more than 18 years of exposure to glyphosate, the active ingredient in Monsanto's Roundup formulations. The writ charges that, "The defendant (Monsanto) knew or ought to have known that the use of

Roundup products were dangerous for the plaintiff ... in particular causing DNA and chromosomal damage in human cells, cancer, kidney disease, infertility and nerve damage among other devastating illnesses."[7]

These cases will present compelling evidence of corporate misbehaviour that challenges the suitability of Monsanto and its owner Bayer CropScience to hold DIR licences, for commercial dealings involving intentional release (DIR) into the environment of Genetically Manipulated (GM) organisms.

More compelling and conclusive evidence of egregious misbehaviour is now available from the USA, where courts and juries have found Monsanto and Bayer persistently acted dishonestly and with scant regard for the environment, public health and the livelihoods of those affected.

Three separate US juries awarded very substantial damages – both punitive and compensatory - against Monsanto Company, to plaintiffs suffering from NHL that prolonged exposure to the herbicide Roundup's active ingredient glyphosate had induced.

The cases are:

- Johnson vs Monsanto Company: a jury awarded $289 million but this was reduced, after Monsanto's final appeal was denied, to $10,253,209.32 in compensatory damages and $10,253,209.32 in punitive damages, plus $519,772.18 in legal costs. The Appeal Court says Johnson's "substantial evidence supports the award of punitive damages."[8]

- Hardeman vs Monsanto Company: the jury found that Mr Hardeman had proved "by clear and convincing evidence that he is entitled to punitive damages" and therefore awarded him $75 million in punitive damages, plus $5,267,634.10 in other compensation.[9]

- Pilliod vs Monsanto Company: Monsanto was ordered to pay $55 million in compensatory damages and $2 billion in punitive damages ($1 billion each for Mr. and Mrs. Pilliod).[10] And "The jury determined that exposure to Roundup was the underlying factor which caused the Pilliod couple to develop NHL, finding that:
    - Roundup was defectively designed;
    - Monsanto had failed to warn consumers of the cancer risk; and
    - the company acted negligently in doing so."[11]

Bayer/Monsanto is now in the process of settling and litigating many other cases pending against them, for recklessly damaging the environment and public health. For instance, Attorneys Gray, Ritter & Graham, P.C. filed a class action lawsuit on behalf of Missouri farmers who suffered economic damage due to Monsanto's commercialisation of GM dicamba resistant cotton and maize seeds without a safe formulation of the dicamba herbicide available to spray over the top of the plants grown from those seeds. When put on sale, the new dicamba formulations were prone to drift off target and damage crops, trees and other vegetation that is not dicamba tolerant.[12]

Monsanto which supplied the GM seed and BASF which supplied the chemical were both fully aware of the spray-drift problem decades earlier but lied to regulators and growers. Internal documents unearthed during discovery in a court case show Monsanto and BASF were "aware for years that their plan to introduce a new agricultural seed and chemical system would probably lead to damage on many US farms. … Risks were downplayed even while they planned how to profit off farmers who would buy Monsanto's new seeds just to avoid damage. … Monsanto opposed some third-party product testing in order to curtail the generation of data that might have worried regulators. … Monsanto's own projections estimated that dicamba damage claims from farmers would total more than 10,000 cases, including 1,305 in 2016, 2,765 in 2017 and 3,259 in 2018. … Monsanto also saw "new users" in farmers who suffered drift damage."[13]

In the Bader Farms vs Monsanto and BASF case, the plaintiffs charged the companies with destroying their peach orchards and said they showed "complete indifference to or conscious

disregard for the safety of others, were also reckless, intentional, knowing, malicious, and willful, and entitle Plaintiffs to a recovery of punitive damages against Defendants in a fair and reasonable amount."[14]

After a three-week trial which presented a mass of expert evidence, the jury agreed with the plaintiffs and awarded the Baders $265 million - $15 million in compensatory damages and $250 million in punitive damages against the two GM seed and chemical companies. The jury found Monsanto negligent in releasing the dicamba-tolerant seeds without the herbicide, and in later releasing new versions of dicamba that they advertised as less likely to move off-target. The jury also found Monsanto and BASF engaged in a, "conspiracy to create an ecological disaster to increase profits."[15]

In another class action, Bayer has, "agreed to pay $1.6 billion to settle about 90% of the 39,000 legal claims in the U.S. over injuries women said were related to their use of the German pharmaceuticals company's Essure birth control device."[16] Essure has caused thousands of women to suffer from debilitating pain, perforated organs, and countless other serious medical complications, some of which can be fatal**.** Despite the dangers, Bayer failed to warn doctors and patients about the risks of using Essure, and even hid evidence that the device could hurt and harm the people who used it.

In a 2010 lawsuit Bayer was fined $3.3 million for false health claims that one of its supplements reduced the risk of developing prostate cancer when the opposite was true. The FDA declared Bayer had made claims with "no credible evidence".[17] As the result of a 2011 lawsuit, Bayer was ordered to pay farmers, exporters and distributors $750 million damages for contamination from unapproved Liberty Link Rice.[18] Also in 2011, Bayer was among four companies fined $49 million for artificial price inflation, which resulted in the poor being denied access to medicine.[19] Bayer was also ruled in breach of several pharmaceutical codes of practice when the UK Code regulator, the PMCPA, ruled Bayer breached clauses 22.1 (which bans advertising prescription-only medicines to the public) and 22.2 (which says information for the public must be factual and presented in a balanced way).[20]

All this evidence shows that Monsanto and its new owner Bayer have both engaged in systematic patterns of egregious, anti-social and irresponsible misbehaviour that harms the environment and public health. When assessing the suitability of Monsanto/Bayer to hold a licence, the OGTR must, conclude from the evidence provided here and published during the histories of both corporations, that they are unsuitable to hold DIR licences and must therefore reject application DIR 173.

Environment

The Gene Technology Act 2000 requires the OGTR to apply the precautionary principle and exercise a duty of care to dealings that may adversely affect the environment and public health.

So the OGTR should only make a decision on DIR 173, when and if the APVMA and the Department of Agriculture, Water and the Environment have comprehensively assessed and cleared both dicamba and glufosinate for over-the-top spraying onto the cotton with GM traits.

The Department of Environment has a key role to play in decisions about DIR 173 but its engagement is opaque and any advice it may have tendered is unpublished. All notes, transcropts, advice and correspondence between the OGTR, APVMA and the Department related to DIR 173 should be published and available for review as part of this public consultation.

The RARMP claims "The risk assessment process considers how the genetic modification and activities conducted with the GMO might lead to harm to people or the environment," but then, "concludes that risks to the health and safety of people or the environment from the proposed dealings, either in the short or long term, are negligible. No specific risk treatment measures are required to manage these negligible risks."

But the OGTR must not ignore the collateral environmental damage that licensing MON 88701 herbicide-tolerant cotton would cause by enabling the repeated spraying of dicamba and glufosinate over cotton, anywhere in Australia. That can only effectively occur through an open, transparent and public process between the OGTR, the product regulators and the Department of Environment. Chemical and GMO residues left in the environment, that may affect human food and animal feed supplies, also require such precautionary assessment.

In our opinion the OGTR is duty bound to consider not only the genetics of MON 88701 herbicide-tolerant cotton but also the direct and indirect collateral environmental damage that licensing a crop with dicamba and glufosinate tolerance traits would cause. These traits would enable the unchecked and repeated spraying of dicamba and glufosinate over cotton plantations growing anywhere in Australia, including near major waterways and in water catchments that drain to the sea. Some of these watercourses would drain, for example, the Ord catchment in East Kimberley WA, into the Murray Darling Basin, the Fitzroy River, and into the seas around the Great Barrier Reef, a fragile and protected World Heritage area.[21]

On the Great Barrier Reef, leading marine scientists have found high levels of pesticides, many banned in other countries. Their 2019 report blasts the APVMA for failing to prevent the ongoing pollution of Great Barrier Reef catchments. “In the freshwater and estuarine reaches of Barratta Creek south of Townsville, with a catchment dominated by irrigated sugarcane cultivation and smaller areas of cotton and horticulture, a total of 43 pesticide residues were detected with seven pesticides exceeding ecologically relevant water quality guidelines/trigger values during the study period and four (including Atrazine) of these exceeding guidelines for several months.”[22]

As the RARMP notes, Dicamba herbicide is very volatile and has an extremely high propensity to drift from where it is sprayed and damaging all other vulnerable vegetation - crops, gardens, orchards, trees, and shrubs. Field reports of off-field and non-target damage from aerial dicamba spraying in the USA are very widespread.[23]

In 2018, US farmers planted 56 million acres of dicamba-resistant cotton and soybean in several states, which resulted in multiple aerial sprayings of the herbicide.[24] Complaints of dicamba spray-drift damage to vulnerable crops and orchards were also widespread. Some estimates found 3.6 million acres of cropss were damaged in 2017[25] and over 1 million acres of crops were reportedly damaged in 18 states, in 2019.[26] Natural habitats and some endangered species were also at substantial risk of harm.[27]

In April 2020 the U.S. Court of Appeals for the Ninth Circuit found the Trump Administration’s 2018 registration of dicamba was unlawful so its registration was disallowed and use of the chemical has been illegal in the USA since June 2020.[28] This resulted from the US Center for Food Safety and other organisations sucessfully arguing that the Environment Protection Agency’s assessment of the impacts on threatened and endangered species from the proposed new uses of dicamba, on dicamba-resistant GM cotton and soybean, was scientifically flawed and illegal.[29]

The three judges wrote of the EPA’s dicamba herbicide approval that, “the EPA substantially understated the risks that it acknowledged” and “entirely failed to acknowledge other risks” and the colateral damage dicamba spray-drift causes.[30,31] The EPA had also failed to collect accurate data on the damage the herbicide was doing in the agricultural landscape across the country.[32]

So the OGTR’s approval of commercial dealings with dicamba-tolerant cotton would legitimize and promote the spraying of a harmful herbicide recently banned by court order in the USA.[33] Licensing the unrestricted growing of dicamba-tolerant cotton could lead to devastating damage to crops that are not genetically engineered to tolerate the chemical.[34]

The Commonwealth Department of Environment previously reported that in a herbicide tolerant crop (canola), “a well-known side effect of glyphosate and glufosinate ammonium is the emergence of “herbicide synergists”—opportunistic root pathogens that accelerate the death of herbicide sensitive roots – that … because of the increased mass of decaying root material. … and

root exudates that may be proportional to the rate at which herbicide is applied to the crop. … may lead to more acute and chronic impacts on leaf litter communities, soil microbes, non-target insects, birds, mammals, reptiles, amphibians etc. and increase levels of surface water pollution." This line of research requires further investigation in relation to the DIR 173 application.[35]

The RARMP claims that, "To date, at least eight and three weed species from around the world are reported to have resistance to dicamba and glufosinate, respectively, but no dicamba-resistant or glufosinate-resistant weed species have been recorded in Australia (Heap, 2020)." But if dicamba and glufosinate are widely and repeatedly sprayed on cotton here, we can be reasonably certain that dicamba and glufosinate herbicide tolerant weeds will be generated before long, as they have with the repeated and ubiquitous spraying of glyphosate-based-herbicides. Indeed, widespread glyphosate-tolerance in a variety of weeds in cotton crops appears to be driving the push for new herbicide tolerant GM cotton varieties like those proposed in DIR 173. Industry promises of a future in which less toxic and destructive chemicals would be deployed on farms are a blatant lie.

The APVMA PubCRIS database[36] shows three registrations of glufosinate and glufosinate ammonium, but the applicants for DIR 173 approval are not the registrants.

> **Product No:** 81838 ZHEJIANG XINAN CHEMICAL INDUSTRIAL GROUP CO., LTD Formulation type: Unknown
> **Product No:** 81459 AUSTRALIS CROP PROTECTION PTY LTD Formulation type: SOLUBLE CONCENTRATE
> **Product No:** 81287 CONQUEST CROP PROTECTION PTY LTD Glufosinate ammonium (manufacturing concentrate) Formulation type: Unknown
> **Product No:** 88319 Foison Scitech Co., Limited Product type: ACTIVE CONSTITUENT Formulation type: Unknown

The OGTR must know and assess exactly what formulations of dicamba and glufosinate the APVMA will approve for spraying on the GM herbicide tolerant cotton, before reaching any final conclusions on application DIR 173.

Public Health

Approving MON 88701 cotton, that would facilitate the intense and frequent spraying of glufosinate must come within the OGTR's purview as it is an agency of the Commonwealth Health Department. It has a clear public welfare responsibility to consult other personnel within the Department about public exposure to the glufosinate to be sprayed over herbicide-tolerant cotton as it is set to increase the exposure of Australians to glufosinate in water and food.

The EU restricted the spraying of glufosinate in 2013 due to the chemical's human health risks. In contrast, GM herbicide-tolerant canola is widely cultivated in Canada[37] and glufosinate residues were found in the blood of Canadians eating an average diet.[38] Dicamba was among several pesticides also reported in Canada to contain the potent toxin and teratogen, dioxin. In 2005 the APVMA was reportedly looking into this evidence but as far as we can ascertain the results of this review are unavailable, if they even exist.[39]

The US National Pesticide Information Center's Technical Fact Sheet on the toxicity of dicamba to humans and animals reports that ingesting or inhaling dicamba can be toxic to humans.[40] Symptoms may include vomiting, shortness of breath, slow heart rate, loss of appetite, cyanosis, muscle spasms, vomiting, diarrhoea, abdominal pain, and coma.

Glufosinate herbicides and their metabolites have been linked to various adverse effects, including neurotoxic effects such as learning and memory deficits, structural changes in the brain and impaired brain development in laboratory animals[41,42,43,44,45,46]. In humans, paternal exposure has been linked to developmental defects in their children[47].

People handling or consuming dicamba-tolerant food or feed may also be exposed to the harmful effects of residues of the herbicide. Dicamba inhalation may cause dizziness, irritation of the nose, pharynx and chest, coughing, and peripheral neuromuscular and gastrointestinal symptoms.

Resolution of these public health hazards and risks is required prior to any OGTR decision on MON 88701 cotton. If it is to be commercially cultivated in Australia, the APVMA must first consider and resolve issues around the toxicity of dicamba and glufosinate and their metabolites, "by the APVMA in its assessment of a new use pattern for registration," as the RARMP notes.

It is totally unacceptable that the RARMP states that, "Data regarding the toxicity of DCSA (3,6-dichlorosalicylic acid) is limited and some uncertainty exists." But then it asserts that, "From the available information, DCSA appears to be less toxic or equally toxic as parent dicamba for aquatic organisms on an acute basis, but may be substantially more toxic on a chronic basis to terrestrial organisms, specifically mammals (US EPA, 2016b, 2018a)."

This narrative is more troubling than reassuring. There are clearly big data and evidence gaps, which the OGTR would fill with best guesses under the Regulatory Science Regime that Australian regulators use. Approval of MON 88701 cotton would facilitate exactly the circumstances in which terrestrial organisms, specifically mammals (including humans), would be chronically exposed to harmful dicamba and glufosinate herbicides and their metabolites.

Conclusion

The OGTR must reject application DIR 173 as it would enable the selling, sowing and spraying of commercial MON 88701 dicamba and glufosinate tolerant cotton seed. The known hazards, risks and impacts of the crop itself, and the chemicals sprayed over-the-top of vast tracts of the crop, make this application absolutely unacceptable.

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Australian Government
Department of Health
Office of the Gene Technology Regulator

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Application for a licence

for dealings involving intentional release (DIR) of genetically modified (GM) plants into the environment - commercial release

Title of the application:	Commercial release of
	Gossypium hirsutum
	genetically modified for
	herbicide tolerance in Australia
Applicant organisation name:	Monsanto Australia Proprietary Limited
Accreditation number: (If the organisation is accredited by the Gene Technology Regulator.)	ACCR034/2002

Are you proposing to conduct a field trial (according to section 50A of the Act)? Please see Information for Applicants section.

☐Yes ☒No If Yes, this is not the correct application form.

Is this application accompanied by an application for a declaration that certain information be treated as Confidential Commercial Information (CCI)?

☐Yes ☒No

If any information provided is covered by a previous CCI application or declaration, please provide:

the relevant CCI application number(s): Enter numbers

and the organisation name(s): Enter name

If any information provided is covered by a previous CCI declaration and can now be made available to the public, please contact the Office of the Gene Technology Regulator to have the declaration revoked.

Time taken to complete this form: Enter hours Enter minutes

Information for applicants

We encourage prospective applicants to contact the Office of the Gene Technology Regulator (OGTR) before submitting a written application to obtain advice on selecting the appropriate application form and discuss information requirements. **This is particularly important if the parent plant is not present in the Australian environment.** Additionally, we welcome comments to improve this form. You can call (1 800 181 030) or email.

What is this application form for?

This application form is for dealings (activities) involving the release of GM plants into the environment that would **not qualify** as a limited and controlled release under section 50A of the *Gene Technology Act 2000* (the Act). Generally this is because the main aim of the release is not experimental and/or minimal or no limits and controls are proposed. Although not specifically named in the Act, we have referred to this type of release as a **commercial release.**

Do not use this form if your application involves intentional release of a GMO other than a plant, qualifies as a limited and controlled release of a GM plant or does not involve environmental release of a GMO. Appropriate application forms can be found on the OGTR website.

What information do you need to provide?

This application for a licence must contain correct and adequate answers. You must answer each question unless otherwise instructed.

The Regulator is not required to consider applications for a licence which do not contain the information specified.

If you wish to protect any information on this form from public disclosure, you must also fill out an *Application for declaration that specified information is confidential commercial information (CCI)* form. Please submit it together with this DIR licence application form.

Further explanatory material with respect to the information requirements associated with an *Application for declaration that specified information is CCI* is provided on the form.

What will we use the information provided in this form for?

We will use the information in the application to prepare a Risk Assessment and Risk Management Plan (RARMP) in relation to the proposed dealings (activities). The Regulator's decision whether or not to issue a licence is based upon the RARMP.

Information in this application may be released to the public (refer to section below 'What else do you need to know?' for further information).

What is the application fee for a commercial release application?

There is currently no application fee.

How should you fill out this form?

- We prefer you sending your application electronically in a searchable format. We recommend you read through all the questions, including the guidance text, and also the separate document containing example answers before filling out the form. This will help you focus your answers on the information we need to evaluate the application.
- Ensure you answer each relevant question in sufficient detail. Not providing the required information could delay a decision, or the Regulator may not consider your application (section 43 of the Act).
- Ensure you answer each question to the best of your knowledge. Deliberately providing false or misleading information is a punishable offence (section 192 of the Act).
- Ensure you answer each question with adequate supporting material. Scientific information should be comprehensive and supported by data and references. We may ask you to provide electronic or hard copies of journal publications and unpublished information.
- Modifying text formatting in this form can be difficult. However, if you first draft the answer in a separate document and then paste it into the answer field, it should retain its formatting. Alternatively,

you may provide those answers in attachments. Clearly reference any attachments you provide in response to a question, and cross-reference each attachment to the applicable question.

- Do not repeat information. If necessary, refer to your answer to other questions.
- Contact us if you have any questions or would like our comments on a draft application.

How can you submit this form?

Once you have obtained the relevant signatures, you can submit a hard copy or an electronic copy by:

- **email** to: ogtr.applications@health.gov.au
- **by mail** to: Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra, ACT, 2601.

Please keep a copy of the application for your records.

When emailing an application containing sensitive information (such as CCI), it will be transmitted via an unclassified internet connection and will not be protected in the process. Within a reasonable time of receipt of the application, staff in the OGTR will securely store the sensitive information as appropriate. If you wish to make alternative arrangements to securely transmit CCI information, please contact this office.

What will happen after you have submitted the application?

We will acknowledge receipt of the application by email and assign it an OGTR reference number. Please cite this reference number whenever you contact us regarding the application.

Please contact us if we have not confirmed receipt within two weeks of submission.

We will notify the public about the application and consult with experts, agencies and authorities about matters to consider in the preparation of the RARMP. Once a RARMP is prepared, including proposed licence conditions, it will be released for expert and public consultation. You will also be invited to comment, particularly on whether you would be able to comply with the proposed licence conditions. We will finalise the RARMP considering the comments received. The RARMP forms an important part for the basis on which the Regulator will decide whether or not to issue a licence. Once issued, a licence is a legally binding instrument and penalties may apply for breaches of conditions.

Please refer to the fact sheet on the Application assessment process for dealings involving intentional release (DIR) of a GMO into the environment for more information.

How long will it take the Regulator to decide whether or not to issue a licence?

The Regulator must make a decision to issue, or to refuse to issue, a licence for a DIR application within 255 working days (weekends and ACT public holidays are excluded).

We may ask you for additional information in relation to your application. Any days on which the Regulator cannot proceed with decision making while awaiting requested information do not count for purposes of determining the end of the decision-making period. The Regulator may cease to consider your application if you fail to provide requested information within the specified timeframe.

Will the Regulator need additional information after deciding to issue a licence?

Licence conditions require a licence holder to:

- provide details of any adverse or unintended effect that becomes evident during the release
- detail a detection method specific for the GM plant and introduced genetic modification and
- report annually in relation to permitted activities.

What else do you need to know?

The Regulator must provide a copy of a submitted DIR application to anyone requesting it (see section 54 of the Act). Any information in your application, including personal information in Parts 1, 2, 5 and 6, may be made public, except:

- information declared or under consideration as confidential commercial information (CCI) by the Regulator (see section 185 of the Act)
- information in the application about relevant convictions (see section 58 of the Act)

- information subject to the *Privacy Act 1988*.

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Personal Information

Personal information is collected by the OGTR to enable the Gene Technology Regulator to perform the functions set out the *Gene Technology Act 2000* (the Act). Personal information specified in this form is collected for the purpose of assessing applications under the Act, and is handled in accordance with the Australian Privacy Principles set out in the *Privacy Act 1988*. More information can be accessed at the Department of Health's APP privacy policy web page. The Department's APP privacy policy explains detail how the Department collects, stores, uses and discloses personal information, including how a person may seek access to, or correct their personal information, and how a complaint about a breach of the APPs can be made.

Part 1: Authorised Person for the Application

The person named in this Part must be authorised to act on the applicant's behalf in relation to this application. Additionally, if a licence is issued, this person must also be authorised to act on the licence holder's behalf in all matters relating to the administration by the Regulator of the issued licence. This may include requests by the Regulator for information; matters related to compliance with licence conditions; and requests on the licence holder's behalf for variations to licence conditions. The authorised person identified here may also be the person nominated in Part 2.

Personal title, e.g. Ms/Mr/Dr:	Dr
Surname:	[redacted]
First name:	[redacted]
Preferred first name if different:	NA
Phone number:	[redacted]
Mobile number:	[redacted]
Fax number:	NA
Email address:	[redacted]
Job title:	[redacted]
Organisation:	Monsanto Australia Pty Ltd
Street number and name:	[redacted]
Town/city/locality:	[redacted]
State/territory:	[redacted]
Postcode:	[redacted]
Country:	Australia
Postal address, if different:	

Part 2: Project Supervisor/Technical Contact

The project supervisor/technical contact may be contacted by OGTR staff during assessment of the application. This person should be familiar with the application and have suitable technical knowledge and skills to answer questions about the proposed dealings.

Please consider whether additional persons with appropriate technical knowledge and skills could be listed for this purpose. If you wish to list more than one project supervisor/technical contact, please duplicate this page for each person.

The project supervisor/technical contact will **not** be taken to be authorised to apply for licence variations, transfers and surrenders unless they are also the authorised person for the application in Part 1.

Is the person nominated in this Part the same as the authorised person for the application in Part 1?

If yes, answer the last question only. If no, complete all questions.

☒Yes ☐No

Personal title, e.g. Ms/Mr/Dr:	
Surname:	
First name:	
Preferred first name, if different:	
Phone number:	
Mobile number:	
Fax number:	
Email address:	
Job title:	
Organisation:	
Street number and name:	Enter street number and name
Town/city/locality:	Enter town/city
State/territory:	Enter state/territory
Postcode:	Enter postcode
Country:	Enter country
Postal address, if different:	Enter postal address
Relevant qualifications and skills:	

Part 3: Applicant Type

This information is required to establish whether your proposed dealings are subject to the *Commonwealth Gene Technology Act 2000* or to your corresponding State[1] legislation. It is advisable to check with your organisation's legal area or executive before completing this Part.

3.1 This application is being made by:

☐ a natural person (proceed to Part 4)

☒ an organisation

3.2 Information about the applicant organisation type

If the application is by an organisation, indicate below which of the following best describes your organisation. You may need to tick more than one box.

a. For an organisation which is a constitutional corporation, i.e. a trading, foreign or financial corporation within the meaning of paragraph 51(xx) of the Constitution, is the organisation a:

☐ Higher Education Institution

☐ Hospital

☐ Research Institute or similar

☐ Commonwealth Authority which is a body corporate established under an Act and/or a company in which a controlling interest is held by the Commonwealth or a Commonwealth authority

☐ State instrumentality which is a body corporate established under an Act and/or a company in which a controlling interest is held by that State or by a State instrumentality

☒ Corporation which is none of the above? Please provide details.

Monsanto Australia Proprietary Limited

b. For an organisation which is NOT a constitutional corporation, is the organisation a:

☐ Higher Education Institution

☐ Hospital

☐ Research Institute or similar

☐ Commonwealth Department

☐ State Government Department

☐ Organisation which is none of the above? Please provide details.

Enter details

[1] 'State' includes the Australian Capital Territory and the Northern Territory (Section 10 of the Act).

Part 4: Suitability of the Applicant

The Act requires the Regulator to be satisfied that an applicant is suitable to hold a licence before issuing a licence. Information provided in this Part will assist the Regulator in making this determination.

4.1 Has the applicant been convicted of an offence against a law of the Commonwealth, a State or a foreign country which relates to the health and safety of people or the environment where the offence was committed within a period of ten years immediately before the making of the application for this licence and which was punishable on conviction by a fine of $5000 or more, or by a term of imprisonment of one year or more?

☐Yes ☒No

If yes, provide details of:

- the Act the offence was committed under
- the date the offence was committed
- the date of the conviction
- the penalty which was imposed and
- why the Regulator should still consider the applicant suitable to hold a licence.

Enter details

4.2 If the applicant answered yes to the preceding question and is a body corporate:

a. Was any person who is currently a director of the applicant also a director of the applicant at the time that the offence was committed?

☐Yes ☐No

If yes, provide director's name.

Enter details

b. Was any person who is currently an officer or shareholder of the applicant, in a position to influence the management of the applicant, also such an officer or shareholder at the time that the offence was committed?

☐Yes ☐No

If yes, provide details.

Enter details

4.3 Has the applicant had a licence or permit (however described) revoked or suspended under a law of the Commonwealth, a State or a foreign country, being a law relating to the health and safety of people or the environment?

☐Yes ☒No

If yes, provide details.

Enter details

4.4 To the best of the applicant's knowledge, will the applicant be financially viable for the foreseeable future of the licence?

☒Yes ☐No

If no, justify why the Regulator should consider the applicant suitable to hold a licence.

Enter details

4.5 What is the date of the applicant's latest financial statement?

31/08/2018

4.6 Attach copies of the applicant's latest financial statement and either the audit findings or a statement from a director of the company (or a person otherwise authorised to make the statement) that the financial statement provided presents a true and fair view, in all material aspects, of the affairs of the applicant for the period covered by the statement.

The Regulator will not consider an application unless it is accompanied by the required financial information. If available, an electronic copy of the financial statement can be provided, e.g. by providing the URL for the statement on the internet.

Appendix 1.

4.7 What is the expected date of the applicant's next financial statement?

If the applicant's next financial statement is prepared prior to the Regulator reaching a decision on this application a copy of the financial statement must be sent to the OGTR as soon as it is available.

31/12/2019

Part 5: Supporting Information from the Institutional Biosafety Committee (IBC)

This Part must be completed by the IBC for the applicant organisation. Parts 5 and 6 must be completed after the applicant has completed all other Parts.

Name of IBC:	Monsanto Australia Proprietary Limited IBC
Name of IBC Chair:	[redacted]
Phone number of the IBC Chair:	[redacted]
Fax number of the IBC Chair:	N/A
Email address of the IBC Chair:	[redacted]
Date of IBC evaluation of this application	19/12/2019

5.1 Has the information contained in this form been checked by the IBC and have all relevant questions been answered satisfactorily?

☒Yes ☐No

Provide more detail, where appropriate.

Signed IBC forms can be found in Appendix 2.

5.2 When considering the information contained in this application, was the IBC constituted in accordance with the relevant provisions of the Regulator's *Guidelines for the Accreditation of Organisations*?

☒Yes ☐No

Provide more detail, where appropriate.

Enter information

Part 6: Declarations

Parts 5 and 6 must be completed after the applicant has completed all other Parts.

I DECLARE THAT:

- I am duly authorised to sign this declaration; and
- to the best of my knowledge, the information supplied on this form and any attachments is not false or misleading.

CEO (or Delegate with Authority to Sign) of the Applicant Organisation

Print name:	[redacted]
Signature:	[redacted]
Job title:	MANAGING DIRECTOR
Date:	16th January, 2020

Authorised Person for the Application as nominated in Part 1 (if different from the CEO)

Print name:	[redacted]
Signature:	[redacted]
Job title:	Regulatory Affairs Lead ANZ
Date:	15th January, 2020

Project Supervisor/Technical Contact (if different from the Authorised person)

Print name:	
Signature:	.....
Job title:	Enter job title
Date:	Select date

IBC Chair

Print name:	[redacted]
Signature:	[redacted]
Job title:	Monsanto Australia Proprietary Limited IBC Chairperson
Date:	15th January, 2020

Part 7: Summary Information

Provide a brief summary of the proposed dealings with the GM plants intended for release.

This summary will be used to inform the public about the proposed DIR.

The summary should be brief but thorough and written in plain, non-technical English. It should include:

- a description of the GM plants proposed for release, including the:
  - plant species
  - introduced trait(s) and
  - OECD Unique Identifier (if available). Details on how to assign an OECD Unique Identifier may be found here).
- the aim of the DIR
- where the introduced genetic material originated
- proposed limits on the size and location of the release area (if any)
- proposed controls to restrict the spread and persistence of the GM plants (if any)
- any previous releases of the GM plants in Australia or overseas and whether the release resulted in harm to human health and safety or the environment
- any assessments (both pending or finalised) by other Australian or overseas regulators.

Monsanto seeks a determination from the Regulator of the environmental and human safety for the commercial release of GM cotton (*Gossypium hirsutum*) event MON 88701, which is tolerant to the herbicides dicamba and glufosinate. The event has been assigned the unique OECD identifier MON-887Ø1-3. The GM cotton contains a demethylase gene derived from *Stenotrophomonas maltophilia*, an aerobic environmentally ubiquitous gram negative bacteria commonly present in aquatic environments, soil and plants, that expresses a dicamba mono-oxygenase (DMO) protein which makes the cotton tolerant to dicamba herbicide. MON 88701 also contains a bialaphos resistance (*bar*) gene derived from *Streptomyces hygroscopicus*, a common soil-borne bacterium, that expresses the phosphinothricin N-acetyltransferase (PAT) protein to confer tolerance to glufosinate herbicide.

The aim of the release is for the commercial production of GM cotton lines throughout Australia. There are no limits or controls proposed on the release. The cotton would be grown and utilised in the same way that commercial cotton is currently grown and utilised, including as feed for animals, cotton seed oil for humans, and for fibre production (e.g. denim or other cotton products).

The GM cotton MON 88701 has been released into the environment in Australia for field trials (DIR120/2013) and has been approved for commercial release in stacked events in Australia (DIR145/2016). There have been no reports of harm to human health and safety or the environment resulting from field trials or commercial release.

Part 8: Parent Plants(s)

Information about the parent plant(s) forms a baseline against which the GM plant is assessed to determine if the modification introduced by gene technology increases the level of risk or introduces additional risks compared to the parent plant.

8.1 What is the common name of the parent plant(s)?

Include all common names that are widely used in Australia and elsewhere.

The common name of the parent organism is cotton which can more specifically be known as Upland cotton, American Upland cotton, Acala cotton, Mexican cotton, Bourbon cotton, Golden cotton, or common cotton.

8.2 What is the scientific name of the parent plants(s)? If the GM plant(s) is the result of crossing between more than one species, please specify both parents.

Include both genus and species names along with scientific names previously used in the scientific literature.

Gossypium hirsutum L.

8.3 Has the OGTR prepared a biology document on the parent species?

Refer to the OGTR website to find out if a biology document has been prepared.

☒Yes ☐No

If No, please complete all sections in the remainder of the application.

If Yes, please read the biology document. Provide any new information or information relevant for the application about the parent species which is not present in the biology document (including citations) in the field below (or in an attachment). Complete the remainder of the application form, except Part 14.

The OGTR has prepared a biology document for *G. hirsutum*, which can be found at the following link:

http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/5DCF28AD2F3779C4CA257D4E001819B9/$File/The%20biology%20of%20cotton%202016.pdf

As such, Part 14 has not been completed.

Part 9: Description of the GM Plant(s) and Details of the Genetic Modification

This Part includes information on:

- the method of gene technology used to generate the GM plants
- details of the introduced genetic modification (alteration, insertion &/or deletion of DNA) present in the GM plants
- how to specifically identify the GM plants and
- the properties of the GM plants resulting from the introduced genetic modification.

This information can assist in risk assessment and determining appropriate control measures to manage risk.

Provide supporting evidence, including available data, published literature, and/or other regulatory assessments.

Note that this Part focuses on intended (Parts 9.1 to 9.10) as well as any unintended phenotypic changes (Part 9.11). The effects of phenotypic changes on spread and persistence of the GM plants and potential for harm to people or the environment are considered in Parts 12 and 13, respectively.

9.1 What GM plants are proposed for release?

Provide details of the GM plant lines (whereby a line encompasses the progeny from a single transformation event) proposed for release, their commercial names and, if applicable, OECD Unique Identifiers. If two or more GM plant lines are intended to be crossed to produce offspring containing GM traits from each parent line, the resulting GM plants must be described in this application.

For each GM plant line briefly describe which of their traits is different compared to the parent species and what modifications were introduced. Include selectable markers in your description, if used.

Herbicide tolerant cotton event MON 88701, designated by the OECD Unique Identifier MON-887Ø1-3. MON 88701 is an herbicide tolerant GM cotton with tolerance to dicamba and glufosinate herbicides. Both herbicide tolerance traits were used as selectable markers in the development of this GM event.

9.2 What genetic material was introduced, deleted or modified compared to the parent plant(s)?

Provide a table containing the details of any nucleic acids introduced into the parent species for stable integration.

The table should provide details of the components to adequately identify any introduced genetic material. Genetic material includes the genes or partial gene sequences (e.g. for RNAi silencing constructs) as well as the associated regulatory elements (e.g. promoters, targeting sequences, terminators, introns) and vector sequences that have been introduced into the parent plant.

For synthetic genes or gene silencing constructs, provide information on the gene(s) on which the introduced sequence is based, and on the source organism(s) for the sequence(s) and how the genetic material has been modified or synthesised.

For each construct that has been used, list the genetic elements in the order they occur.

Include in the table:

- the name of the genetic element
- its expected or observed function in the GM plant or in plasmid, as applicable
- the source organisms, if applicable
- the gene accession number, if available, and
- the relevant citation.

Details regarding genetic material introduced into MON88701 has been assessed by the OGTR for DIR147/2017, Limited and controlled release of cotton genetically modified for insect resistance and herbicide tolerance.

Table 1. Summary of Genetic Elements in PV-GHHT6997

Genetic Element	Location in Plasmid Vector	Function (Reference)
T-DNA		
B[1]-Right Border Region	1-331	DNA region from *Agrobacterium tumefaciens* containing the Right Border sequence used for transfer of the T-DNA (Depicker *et al.*, 1982; Zambryski *et al.*, 1982)
Intervening Sequence	332-433	Sequence used in DNA cloning
P[2]-*PC1SV*	434-866	Promoter from the Full-Length Transcript (FLt) of peanut chlorotic streak caulimovirus (*PC1SV*) that directs transcription in plant cells (Maiti and Shepherd, 1998)
Intervening Sequence	867-872	Sequence used in DNA cloning
L[3]-*TEV*	873-1004	5' UTR leader sequence from the RNA of tobacco etch virus (TEV) (Niepel and Gallie, 1999) that is involved in regulating gene expression
Intervening Sequence	1005-1005	Sequence used in DNA cloning
TS[4]-*CTP2*	1006-1233	Targeting sequence of the *ShkG* gene from *Arabidopsis thaliana* encoding the EPSPS transit peptide region that directs transport of the protein to the chloroplast (Herrmann, 1995; Klee *et al.*, 1987)
CS[5]-*dmo*	1234-2256	Codon optimised coding sequence for the dicamba mono-oxygenase (DMO) protein of *Stenotrophomonas maltophilia* that confers dicamba tolerance (Herman *et al.*, 2005; Wang *et al.*, 1997)
Intervening Sequence	2257-2310	Sequence used in DNA cloning
T[6]-*E6*	2311-2625	3' UTR sequence of the *E6* gene from *Gossypium barbadense* (cotton) encoding a fiber protein involved in early fiber development (John, 1996) that directs polyadenylation of mRNA
Intervening Sequence	2626-2637	Sequence used in DNA cloning
P-*e35S*	2638-3249	Promoter for the 35S RNA of cauliflower mosaic virus (CaMV) (Odell *et al.*, 1985) containing the duplicated enhancer region (Kay *et al.*, 1987) that directs transcription in plant cells
Intervening Sequence	3250-3252	Sequence used in DNA cloning

Table 1. Summary of Genetic Elements in PV–GHHT6997 (continued)

Genetic Element	Location in Plasmid Vector	Function (Reference)
L-*Hsp70*	3253-3348	5' UTR leader sequence of the *DnaK* gene from *Petunia hybrida* that encodes heat shock protein 70 (*HSP70*) (Rensing and Maier, 1994; Winter *et al.*, 1988) that is involved in regulating gene expression
Intervening Sequence	3349-3354	Sequence used in DNA cloning
CS-*bar*	3355-3906	Coding sequence for the phosphinothricin N-acetyltransferase (PAT) protein of *Streptomyces hygroscopicus* that confers glufosinate tolerance (Thompson *et al.*, 1987)
Intervening Sequence	3907-3911	Sequence used in DNA cloning
T-*nos*	3912-4164	3' UTR sequence of the nopaline synthase (*nos*) gene from *Agrobacterium tumefaciens* pTi encoding NOS that directs polyadenylation (Bevan *et al.*, 1983; Fraley *et al.*, 1983)
Intervening Sequence	4165-4183	Sequence used in DNA cloning
B-Left Border Region	4184-4625	DNA region from *Agrobacterium tumefaciens* containing the Left Border sequence used for transfer of the T-DNA (Barker *et al.*, 1983)
Plasmid Vector Backbone		
Intervening Sequence	4626-4711	Sequence used in DNA cloning
OR[7]-*oriV*	4712-5108	Origin of replication from the broad host range plasmid RK2 for maintenance of plasmid in *Agrobacterium* (Stalker *et al.*, 1981)
Intervening Sequence	5109-6616	Sequence used in DNA cloning
CS-*rop*	6617-6808	Coding sequence for repressor of primer protein from the ColE1 plasmid for maintenance of plasmid copy number in *E. coli* (Giza and Huang, 1989)
Intervening Sequence	6809-7235	Sequence used in DNA cloning
OR-*ori-pBR322*	7236-7824	Origin of replication from plasmid pBR322 for maintenance of plasmid in *E. coli* (Sutcliffe, 1979)
Intervening Sequence	7825-8354	Sequence used in DNA cloning
aadA	8355-9243	Bacterial promoter, coding sequence, and 3' UTR for an aminoglycoside-modifying enzyme, 3"(9)-*O*-nucleotidyltransferase from the transposon *Tn7* (Fling *et al.*, 1985) that confers spectinomycin and streptomycin resistance
Intervening Sequence	9244-9379	Sequence used in DNA cloning

[1]B, Border
[2]P, Promoter
[3]L, Leader
[4]TS, Targeting Sequence
[5]CS, Coding Sequence
[6]T, Transcription Termination Sequence
[7]OR, Origin of Replication

9.3 Are any of the source organisms for the introduced genetic modification:

a. present in the Australian environment?

☒Yes ☐No

Provide details to support your answer.

Agrobacterium tumefaciens is a non-spore forming, rod-shaped bacterium commonly found in the soil. *Arabidopsis thaliana* is a small, flowering plant belonging to the cabbage family, Brassicaeae. *S. maltophilia* is ubiquitous in the environment and is found associated with the rhizosphere of plants. *S. maltophilia* has also been isolated from cotton seed, bean pods, and coffee (Nunes and de Melo, 2006; Swings *et al.*, 1983); thus, *S. maltophilia* can be found in a variety of foods and feeds. *S. maltophilia* is also widespread in the home environment and can be found around dishwashers, sponges, toothbrushes, flowers, plants, fruits, vegetables, frozen fish, milk, and poultry (Ryan *et al.*, 2009). *S. hygroscopicus* is a saprophytic, soil-borne bacterium with no known safety issues. *Petunia hybrida* is an ornamental annual, commonly grown in Australia for it's large colourful flowers.

b. known to be allergenic to people, or toxic or pathogenic to people or other organisms?

☒Yes ☐No

Provide details to support your answer.

Agrobacterium tumefaciens is the causative agent of crown gall disease on a broad range of plant species, notably woody and herbaceous species but also monocotyledons (Otten *et al.*, 2008). The natural transfer system of *A. tumefaciens* has been adapted to deliver desired genetic material into a wide range of plant species without causing adverse effects. It has been used in scientific research and for generation of biotechnology products for many years.

Stenotrophomonas maltophilia is an aerobic, environmentally ubiquitous gram negative bacterium commonly present in aquatic environments, soil, and plants. *S. maltophilia* is ubiquitously associated with plants and has been isolated from the rhizosphere of wheat, maize, grasses, beet, cucumber, potato, strawberry, sugarcane, and rapeseed (Berg *et al.*, 1996; Berg *et al.*, 1999; Berg *et al.*, 2002; Denton *et al.*, 1998; Echemendia, 2010; Juhnke and des Jardin, 1989; Juhnke *et al.*, 1987; Lambert *et al.*, 1987). *S. maltophilia* has also been isolated from cottonseed, bean pods, and coffee (Nunes and de Melo, 2006; Swings *et al.*, 1983); thus, *S. maltophilia* can be found in a variety of foods and feeds. *S. maltophilia* is also widespread in the home environment and can be found around sponges, flowers, plants, fruits, vegetables, frozen fish, milk, and poultry (Berg *et al.*, 1999; Denton and Kerr, 1998; Echemendia, 2010). Strains of *S. maltophilia* have been found in the transient flora of hospitalised patients as a commensal organism (Echemendia, 2010).

Streptomyces hygroscopicus (Thompson *et al.*, 1987) is a saprophytic, soil-borne bacterium that is widespread in the environment. *S. hygroscopicus* is a saprophytic, soil-borne bacterium with no known safety issues. *S. hygroscopicus* is not considered pathogenic to plants, humans or other animals (Cross, 1989; Goodfellow and Williams, 1983; Locci, 1989). *S. hygroscopicus* history of safe use is discussed in Hérouet *et al.*, (2005) and this organism has been extensively reviewed during the evaluation of several glufosinate-tolerant events with no safety or allergenicity issues identified by regulatory agencies.

Petunia hybrida is a commonly grown ornamental with no know safety issues.

9.4 What methods were used to genetically modify the parent plant(s)?

Describe the methodology used to introduce the genetic modification into the parent species, citing references as appropriate. The description should include (where applicable) the vector used to introduce the genetic modification (e.g. *Agrobacterium*, biolistic or particle bombardment, microinjection, or other), and how transformation events were selected. If *Agrobacterium*-mediated transformation was used, indicate which measures were used to ensure that *Agrobacterium* is not present in the GM plant. Where a single GM plant contains two or more genetic modifications, describe how the different modifications were combined.

MON 88701 was developed through *Agrobacterium*-mediated transformation of PV-GHHT6997 into cotton hypocotyls, based on published methods (Duncan, 2010; Duncan and Ye, 2011). In summary, hypocotyl segments were excised from dark grown seedlings of germinated Coker 130 seed. After co-culturing with the Agrobacterium carrying the vector, the hypocotyl segments were placed on a sequence of media for callus growth containing carbenicillin and cefotaxime to inhibit the growth of excess *Agrobacterium* and glufosinate to inhibit growth of untransformed cells. The somatic embryos developing on the culture medium were then placed on medium that

contained plant growth regulators conducive to shoot regeneration, but no antibiotics or glufosinate. Rooted plants (R0) with normal phenotypic characteristics were selected and transferred to soil for growth and further assessment.

The R0 plants generated through the *Agrobacterium*-mediated transformation were self-pollinated to produce R1 seed. R0 and R1 plants were evaluated for tolerance to dicamba and glufosinate and screened for the presence of the T-DNA (dmo and bar expression cassettes) and absence of plasmid vector backbone (oriV). Subsequently, the dmo and bar homozygous positive R1 plant was self-pollinated to give rise to R2 plants. Homozygous positive R2 plants containing only a single T-DNA insertion, were identified by a combination of analytical techniques including dicamba and glufosinate sprays, polymerase chain reaction (PCR), and Southern blot analysis, resulting in production of dicamba and glufosinate-tolerant cotton MON 88701. MON 88701 was selected as the lead event based on superior herbicide tolerance characteristics and its molecular characteristics. This information was previously assessed by the OGTR in its evaluation of DIR120/2013 (OGTR, 2013).

9.5 What traits of the parent species were intentionally altered by the genetic modification?

Provide details on the function/mode of action of the genetic modification and the intended phenotypic effects. Effects may be based on observation of the GM plants eg from experiments under laboratory conditions, previous releases or overseas data. If applicable, effects may be based on the observed phenotype of other plants or plant species genetically modified with the same or similar genetic material. This information may include your research and/or other published scientific literature (provide relevant citations and unpublished reports).

MON 88701 contains a herbicide tolerance gene (*dmo*), derived from *Stenotrophomonas maltophilia*, an aerobic environmentally ubiquitous gram negative bacteria commonly present in aquatic environments, soil and plants, that expresses a dicamba mono-oxygenase (DMO) protein which makes the cotton tolerant to dicamba herbicide. MON 88701 also contains a gene derived from *Streptomyces hygroscopicus* (*bar*), a common soil-borne bacterium, that expresses the phosphinothricin N-acetyltransferase (PAT) protein to confer tolerance to glufosinate herbicide.

9.6 Provide evidence to indicate the number of complete or partial copies of the genetic material introduced into the GM plants.

Describe the methodology used, including detection limits and whether or not vector backbone sequence was also introduced into the GM plants. Typically Southern blot analysis has been provided, but other data may also be acceptable.

Characterisation of the DNA insert in MON 88701 presented to the OGTR previously (DIR120/2013) was conducted by Southern blot, PCR and DNA sequence analyses (OGTR, 2013). The results of this characterisation demonstrate that MON 88701 contains a single copy of the *dmo* and *bar* expression cassettes, lacks plasmid backbone, the T-DNA is stably integrated at a single locus and is inherited according to Mendelian principles over multiple generations. These conclusions were based on several lines of evidence: 1) Southern blot analyses assayed the entire cotton genome for the presence of the T-DNA and absence of the plasmid backbone sequences derived from PV-GHHT6997, and demonstrated that only a single copy of the T-DNA was inserted at a single genomic site and that the insert is stably inherited; 2) DNA sequence analyses to determine the exact sequence of the inserted DNA and the DNA sequences flanking the 5' and 3' ends of the insert, allowing a comparison to the T-DNA sequence in the plasmid vector to confirm that only the expected sequences were integrated; 3) DNA sequences flanking the 5' and 3' ends of the insert were compared to the sequence of the insertion site in conventional cotton to identify any rearrangements that occurred at the insertion site during transformation. Taken together, the characterisation of the genetic modification demonstrates that a single copy of the T-DNA was stably integrated at a single locus of the cotton genome and that no plasmid backbone sequences are present in MON 88701.

9.7 Does the inserted or deleted genetic material differ from the insertion or deletion proposed in Part 9.2?

☐Yes ☒No

Provide evidence (e.g. sequence data). If Yes, indicate where differences occur and any effect the differences may have on the introduced trait.

Sequencing data demonstrated that the insert is intact and that the contiguousness of the functional elements within the insert as intended in PV-GHHT6997 has been maintained (OGTR, 2013).

9.8 Provide evidence that the introduced genetic modification is stably inherited in successive generations

Evidence provided should include the methodology used to determine stable inheritance of the modification, frequency of reversion or loss of the genetic modification (if any) and any potential harm if the introduced genetic material was lost.

In order to demonstrate the stability of the insert in MON 88701, Southern blot analysis was performed using genomic DNA extracted from leaf tissues from five breeding generations of MON 88701 ([redacted] *et al.*, 2011; Appendix 3).

9.9 Provide evidence that the genetic modification is functioning in the GM plants

Evidence provided should be appropriate to the genetic modification, e.g. expression of a novel protein; expression of a microRNA or RNAi molecule and the changes in expression of the protein or other compounds they moderate; or lack of a protein for a gene deletion. Ideally, evidence should include changes in expression levels in different plant tissues, as well as expected phenotypic data (e.g. tolerance to herbicide, resistant to insects, altered oil or starch composition, changed flower colour, etc.)

MON 88701 DMO and PAT (*bar*) protein levels in various tissues of MON 88701 relevant to the risk assessment were determined by a validated enzyme linked immunosorbent assay (ELISA). Tissues of MON 88701 were collected from four replicate plots planted in a randomized complete block field design during the 2010 growing season from the following eight field sites in the U.S. MON 88701 plots were treated at the 3-5 leaf stage with glufosinate herbicide at the label rate (0.5 lbs active ingredient [a.i.]/acre) and at the 6-10 leaf stage with dicamba herbicide at the proposed label rate (0.5 lbs acid equivalent [a.e.]/acre). The field sites were representative of cotton-producing regions suitable for commercial production. Seed, pollen, root, and overseason leaf (OSL 1 through OSL 4) tissue samples were collected from each replicated plot at all field sites. MON 88701 DMO protein levels were determined in all seven tissue types. The mean MON 88701 DMO protein levels were highest in leaf (ranging from OSL-2 and OSL-3 at 240 µg/g dw, OSL-4 at 230 µg/g dw to OSL-1 at 180 µg/g dw), followed by root at 43 µg/g dw, seed at 21 µg/g dw, and pollen at 14 µg/g fw. PAT (*bar*) protein levels were determined in all seven tissue types. The mean PAT (*bar*) protein levels were highest in seed at 6.6 µg/g dw, followed by leaf (ranging from OSL-2 at 6.4 µg/g dw to OSL-4 at 3.2 µg/g dw), root at 1.8 µg/g dw, and pollen at 0.56 µg/g fw. Further details are provided in [redacted] (2015; Appendix 4). Agronomic and phenotypic data was demonstrated in Australia by [redacted] (2015; Appendix 5).

9.10 Provide testing methodology specific for each GM plant line proposed for release

The testing methodology (e.g. PCR analysis, ELISA) should be able to distinguish different GM plant lines proposed for release from one another (if more than one type of GM plant is proposed for release), from non-GM plants and from other GM plants approved for release by the Gene Technology Regulator under other licences.

Protein-based methods exist for the detection of DMO, PAT protein. Additionally, Monsanto has developed proprietary DNA-based methods for the detection of MON 88701 in the laboratory.

9.11 Unintended changes in the GM plants

With any method of genetic modification there may be predictable or unpredictable unintended changes in the resulting GM plant, e.g. due to insertion of an introduced gene into another coding sequence.

a. Compared to the parent species, are there any changes in the GMO with respect to levels of known endogenous toxins, allergens or anti-nutritive substances?

☐Yes ☒No

Provide rationale for your answer.

Evidence provided should focus on changes to levels of known toxins, allergens or anti-nutritive substances endogenous to the parent species. These substances may already limit use of this plant species for animal feed or human food and/or may deter pests or pathogens which play a role in the spread and persistence of the plant species (e.g. gossypol and cyclopropenoid fatty acids in cotton; erucic acid and glucosinolates in canola).

Cotton tissue, particularly the seeds, can be toxic if ingested in large quantities by non-ruminant animals because of the presence of toxic and anti-nutritional factors including gossypol and cyclopropenoid fatty acids (e.g. dihydrosterculic, sterculic and malvalic acids).

Compositional assessments of genetically modified cotton MON 88701 had been previously assessed by FSANZ and the cotton lines were determined to be compositionally equivalent to conventional cotton. A compositional assessment of genetically modified cotton events MON 88701 is provided in [redacted] *et al.* (2012; Appendix 6).

Samples of acid-delinted cottonseed were collected from MON 88701 treated with dicamba and glufosinate herbicides and were compared with the conventional control (Coker 130) grown in a 2010 U.S. field production. Nine unique conventional cotton varieties, known as reference substances, were included across all sites of the field production with four varieties per site to provide data on natural variability of each compositional component analysed. The sites were planted in a randomized complete block design with four blocks per site. All cotton plants including MON 88701, the conventional control, and the reference varieties were grown under normal agronomic field conditions for their respective geographic regions, including maintenance pesticides as needed. In addition, MON 88701 plots were treated at the 3-5 leaf stage with glufosinate herbicide at the label rate (0.5 lb a.e. /acre; 445 g/ha) and at the 6-10 leaf stage with dicamba herbicide at the label rate (0.5 lb a.e. /acre; 445 g/ha).

Compositional analyses were conducted to assess whether levels of key nutrients and anti-nutrients in MON 88701 were equivalent to levels in the conventional control and also comparable to the composition of conventional reference varieties. A description of nutrients and anti-nutrients present in cotton is provided in the OECD consensus document on compositional considerations for cottonseed (OECD, 2009). The anti-nutrients assessed in this analysis included free gossypol, total gossypol and cyclopropenoid fatty acids (dihydrosterculic, malvalic and sterculic).

For the combined-site analysis, statistically significant differences ($p < 0.05$) in nutrient and anti-nutrient components were evaluated further using considerations relevant to the safety and nutritional quality of MON 88701 when compared to the conventional control. The evaluation included: 1) the relative magnitude of the significant difference in the mean values of nutrient and anti-nutrient components of MON 88701 compared to the conventional control; 2) whether the MON 88701 component mean value is within the range of natural variability of that component as represented by the 99% tolerance interval of conventional reference varieties grown concurrently in the same trial; 3) analyses of the reproducibility of the significant combined-site component differences at individual sites; and 4) assessing the combined-site statistically significant differences and reproducible individual site significant differences within the context of natural variability of commercial cottonseed composition published in the scientific literature and/or in the International Life Sciences Institute Crop Composition Database (ILSI, 2011).

There were no statistically significant differences ($p < 0.05$) in mean values between MON 88701 and the conventional control for two cyclopropenoid fatty acids (malvalic and sterculic).

This analysis provides a comprehensive comparative assessment of the levels of key nutrients and anti-nutrients in cottonseed of MON 88701 and the conventional control discussed in the context of natural variability in composition of commercial cotton. Results of the comparison indicate that the composition of the cottonseed of MON 88701 is equivalent to that of conventional cotton. The components that showed statistically significant differences in mean values between MON 88701 and the conventional control in the combined-site analysis were the cyclopropenoid fatty acid dihydrosterculic, free gossypol, and total gossypol. The statistically significant differences in anti-nutrients were further evaluated using the four previously described considerations relevant to the safety and nutritional quality of MON 88701 when compared to the conventional control.

The three cottonseed anti-nutrient statistically significant differences between MON 88701 and the conventional control observed in the combined-site data analysis were attributed to small differences in one cyclopropenoid fatty acid (dihydrosterculic expressed as % total fatty acid), free gossypol and total gossypol (expressed as % dw). For dihydrosterculic acid, free gossypol and total gossypol, the relative magnitude of the differences between the mean values for MON 88701 and the conventional control were increases of 9.59% for dihydrosterculic acid, 6.23% for free gossypol and 6.75% for total gossypol. These anti-nutrient differences between MON 88701 and the conventional control observed in the combined-site analysis were within the 99% tolerance interval established by conventional commercial reference varieties grown concurrently in the same trial. Details are provide in Howard *et al*, 2012.

Overall, observed differences in anti-nutrient values between MON 88701 and the conventional control were not considered to be meaningful from a food and feed safety or nutritional perspective because they were generally small, and the mean MON 88701 values were within the 99% tolerance interval established by conventional commercial reference varieties grown concurrently in the same trial and within the context of the natural variability of commercial cotton composition as published in the scientific literature and/or available in the ILSI Crop Composition Database (ILSI, 2011).

b. Compared to the parent species, are there any changes in the GMO with respect to levels of known beneficial substances such as vitamins or antioxidants?

☐Yes ☒No

Provide rationale for your answer.

Evidence provided should focus on changes to levels of known beneficial substances endogenous to the parent species. These substances may be important components of the parent species for animal feed or human food (e.g. vitamin C in oranges or potatoes) and/or may deter pests or pathogens which play a role in the spread and persistence of the plant species (e.g. canola root exudates which reduce fungal inoculum).

Compositional analyses comparing MON 88701 treated with dicamba and glufosinate herbicides to the conventional control variety (Coker 130) and commercial reference varieties demonstrated that MON 88701 is compositionally equivalent to conventional cotton. Samples of acid-delinted cottonseed were collected from MON 88701 and the conventional control grown in a 2010 U.S. field production. Nine unique conventional cotton varieties, known as reference substances, were included across all sites of the field production with four varieties per site to provide data on natural variability of each compositional component analysed. The sites were planted in a randomized complete block design with four blocks per site. All cotton plants including MON 88701, the conventional control, and the reference varieties were grown under normal agronomic field conditions for their respective geographic regions, including maintenance pesticides as needed. In addition, MON 88701 plots were treated at the 3-5 leaf stage with glufosinate herbicide at the label rate (0.5 lb a.e. /acre; 445 g/ha) and at the 6-10 leaf stage with dicamba herbicide at the label rate (0.5 lb a.e. /acre; 445 g/ha).

Compositional analyses were conducted to assess whether levels of key nutrients and anti-nutrients in MON 88701 were equivalent to levels in the conventional control and also comparable to the composition of conventional reference varieties. A description of nutrients and anti-nutrients present in cotton is provided in the OECD consensus document on compositional considerations for cottonseed (OECD, 2009). Nutrients assessed in this analysis included proximates (ash, calories and carbohydrates by calculation, fat, moisture, and protein), acid detergent fiber (ADF), neutral detergent fiber (NDF), crude fiber (CF), total dietary fiber (TDF), amino acids (AA, 18 components), fatty acids (FA, C8-C22), minerals (calcium, copper, iron, magnesium, manganese, phosphorus, potassium, sodium and zinc) and vitamin E.

In the combined-site analysis of nutrient levels in cottonseed, the following components had no statistically significant differences ($p < 0.05$) in mean values between MON 88701 and the control: one proximate (protein), one type of fiber (crude fiber), 15 amino acids (alanine, aspartic acid, cystine, glutamic acid, glycine, histidine, isoleucine, leucine, lysine, phenylalanine, serine, threonine, tryptophan, tyrosine and valine), seven fatty acids (16:0 palmitic acid, 16:1 palmitoleic acid, 18:0 stearic acid, 18:1 oleic acid, 18:3 linolenic acid, 20:0 arachidic acid and 22:0 behenic acid), and four minerals (copper, iron, phosphorus and sodium).

The components that had significant differences in mean values between MON 88701 and the conventional control in the combined-site analysis were: five proximates (ash, calories, carbohydrates, moisture and total fat), three types of fiber (ADF, NDF and TDF), three amino acids (arginine, methionine and proline), two fatty acids (14:0 myristic acid and 18:2 linoleic acid), five minerals (calcium, magnesium, manganese, potassium and zinc) and vitamin E.

The statistically significant differences in nutrients were further evaluated using the four previously described considerations relevant to the safety and nutritional quality of MON 88701 when compared to the conventional control:

1) All nutrient component differences observed in the combined-site statistical analysis, whether reflecting increased or decreased MON 88701 mean values with respect to the conventional control, were 14.09% or less. The relative magnitudes of the differences were : 0.66 to 5.00% for proximates, 4.08 to 5.72% for fibers, 2.61 to 4.82% for amino acids, 0.69 to 2.69% for fatty acids, 4.94 to 14.09% for minerals and 6.70% for vitamin E.

2) With the exception of methionine, mean values for all significantly different nutrient components from the combined-site analysis of MON 88701 were within the 99% tolerance interval established from the conventional commercial reference varieties grown concurrently in the same trial.

3) Assessment of the reproducibility of the combined-site differences at the eight individual sites showed significant differences for: NDF, methionine, proline and 18:2 linoleic acid at one site; carbohydrates, total fat, ADF, manganese and zinc at two sites; TDF, arginine, 14:0 myristic acid, potassium, and vitamin E at three sites; magnesium at four sites, ash at six sites and calcium at seven sites. Moisture and calories were not affected at any site. With the exception of methionine, arginine and zinc, all individual site mean values of MON 88701 for all nutrient components with significant differences were within the 99% tolerance interval established from the conventional commercial reference varieties grown concurrently in the same trial.

4) All combined-site mean values and individual mean values of MON 88701 for all nutrient components, including those that were significantly different, were within the context of the natural variability of commercial cotton composition as published in the scientific literature and/or available in the ILSI Crop Composition Database (ILSI, 2011).

Five of the 19 cottonseed nutrient statistically significant differences between MON 88701 and the conventional control that were observed in the combined-site data analysis were attributable to small differences in proximates (ash, carbohydrates, total fat expressed as % dw, calories expressed as Kcal/100g dw and moisture expressed as % fw). For ash, calories and total fat the relative magnitude of the differences between the mean value for MON 88701 and the conventional control were all small increases (5.00% for ash, 0.66% for calories, and 3.71% for total fat). The differences for carbohydrates and moisture between the mean value for MON 88701 and the conventional control were both small decreases (2.60% for carbohydrates and 4.51% for moisture). All of the nutrient mean values for MON 88701 observed in the combined-site analysis for proximates were within the 99% tolerance interval established by conventional commercial reference varieties grown concurrently in the same trial and were within the context of the natural variability of commercial cotton composition as published in the scientific literature and/or available in the ILSI Crop Composition Database (ILSI, 2011). Details are provide in [redacted] *et al*, 2012 (Appendix 6).

c. Aside from any changes noted in Parts 9.11a & 9.11b have any other unintended changes to the phenotype of the GM plant been observed?

☐Yes ☒No

Provide rationale for your answer.

To evaluate phenotypic, agronomic, and environmental interaction characteristics of MON 88701 compared to the conventional control, field trials were conducted at 15 field locations in the U.S. during 2010. These 15 field sites provided a diverse range of environmental and agronomic conditions representative of commercial cotton production areas in North America. The experimental design at each site was a randomized complete block with four replications. MON 88701, the conventional control, and four commercial reference varieties were evaluated at each site. Across sites, a total of 11 commercial reference varieties were evaluated. All plots of MON 88701, the conventional control, and the commercial reference varieties at each site were uniformly managed in order to assess whether the introduction of the dicamba and glufosinate-tolerance traits altered the phenotypic and agronomic characteristics of MON 88701 compared to the conventional control. In each of these assessments, MON 88701 was compared to a conventional control, Coker 130, which has a genetic background similar to MON 88701, but does not possess the dicamba and glufosinate-tolerance traits. In addition, multiple commercial reference varieties developed through conventional selection and breeding were included to provide a range of comparative values that are representative of the variability in existing commercial cotton varieties for each characteristic. Data collected for the various characteristics from the commercial reference varieties provides context for interpreting experimental results.

Thus, the phenotypic, agronomic, plant mapping, and environmental interaction assessment of MON 88701 included the parental conventional control as a comparator. This evaluation used a weight-of-evidence approach and considered statistical differences between MON 88701 and the conventional control with respect to reproducibility, magnitude, and directionality. The observations were taken on plants not treated with dicamba or glufosinate, in order to evaluate the impact of the introduced traits in MON 88701. To further support the trait assessment, similar supplemental observations were also conducted on the agronomic system that includes MON 88701 treated with dicamba and glufosinate herbicides. Comparison to a range of commercial reference varieties established the range of natural variability for cotton, and provided a context from which to further evaluate any statistical differences. Characteristics assessed included: seed dormancy and germination, pollen morphology, plant phenotypic observations, plant mapping, and environmental interaction evaluations conducted in the field. The phenotypic, agronomic, and environmental interaction assessment demonstrated that MON 88701 is comparable to conventional cotton. Thus, MON 88701 is unlikely to have adverse environmental impact compared to commercially cultivated cotton. Details are provided in [redacted], 2012 (Appendix 7).

d. What unintended changes due to the genetic modification may be predicted?

Knowledge of gene function and/or previous experience with the same genetic modification in other plant species may enable predictions of possible unintended changes in the GM plants proposed for release. For example, the introduction of a transcription factor to enhance drought tolerance (intended change) may also provide cold tolerance (predictable unintended change).

Provide details on any unintended but predictable changes.

Unintended changes to the phenotype are not predicted because the introduced genetic elements have known function and independent mode of action (MOA) that confers tolerance to specific herbicides such as dicamba and glufosinate. None of the introduced genetic elements are known to affect other metabolic pathways within the cotton plant. Observation of the GM plants grown in glasshouse, in field trials or commercial releases did not indicate any unexpected phenotype.

e. Have you tested the GM plants for any predicted potential changes identified in (d) above?

☐Yes ☒No

Provide evidence and/or rationale for your answer and results of any testing.

Unintended changes were not predicted (see above) thus specific testing was not conducted.

Part 10: Proposed Dealings with the GM Plant(s), including any Limits and Controls on the Dealings

The Act requires regulation of certain dealings (activities) with GMOs. Dealings with a GMO are defined in section 10 of the Act and listed in Part 10.1.

The information provided will be used to conduct risk analysis as described in the Regulator's *Risk Analysis Framework* when preparing a RARMP in accordance with the legislation. The proposed dealings (activities) with the GM plants and any limits and controls on those activities set the context for both:

- the risk assessment (which arrives at an estimate for the level of risk for the proposed dealings) and
- the risk management plan (the scheme for managing risks from the proposed dealings).

The risk management plan forms the basis for the licence conditions, should the Regulator decide to issue a licence (section 62 of the Act). Once a licence has been issued, the licence holder can only conduct those dealings permitted by the licence.

10.1 Details of proposed dealings (activities) with the GM plants

Are you proposing to:

a. conduct experiments with the GMOs?

☒Yes ☐No

If Yes, provide the aim and a brief description of the experiments you are proposing to conduct. If the principal aim of the release is experimental, and limits and controls are proposed you should contact the OGTR to check whether you are using the correct application form.

The GMO may be used in experiments to compare the efficacy of the MON 88701 event against other existing commercial herbicide-tolerant events, or with other novel insect tolerant events covered under a future Limited and Controlled Release Direct Intentional Release.

b. make, develop, produce or manufacture the GMOs?

This dealing incudes the initial transformation events in which the GM plants were created. As this is an application for commercial release, creating new GM plants is not expected. Making and developing the GM plant would have occurred before seeking a licence for commercial release. Breeding and propagation of the GMO are dealings considered in Parts (10.1c) and (10.1d).

☐Yes ☒No

If Yes, provide details.

c. breed the GMOs?

This includes the production and selection of progeny involving sexual crosses with another cultivar or strain of the same or different species. Examples include a GM plant that is crossed or backcrossed with elite germplasm or with other GM plants.

Note that if independent GM plants are intended to be crossed to produce offspring containing the genetic modifications of the independent GM parents, the resulting GM plants should be described in this application (e.g. Part 9). Similarly, breeding to intentionally transfer the genetic modification from the GMO to a different species should be described in this application

☒Yes ☐No

If Yes, provide details.

Controlled crossing between the GMO and elite non-GM cotton lines may occur to introduce the GM traits into modern advanced cotton lines. Crossing between MON 88701, other insect resistant and herbicide tolerant GM lines will occur to produce herbicide tolerant, insect resistant GM cotton lines as approved under DIR145/2016 or future commercial release DIRs.

d. propagate the GMOs?

This includes maintaining GM plants via asexual propagation or sexual reproduction, e.g. multiplication of a GM plant during seed production.

☒Yes ☐No

If Yes, and the propagation differs from the industry standard practices for this plant species, provide details.

The GMO may be multiplied by sexual reproduction to produce seed for sowing.

e. use the GMOs in the course of manufacture of a thing that is not a GMO?

This includes processes which destroy the viability of GM plant materials. Resulting products may or may not contain genetic material. Examples include: ginning of cotton fibres and linters, extraction of oil from cotton or canola seeds, production of processed animal feed, and milling of wheat or barley seed to produce flour.

☒Yes ☐No

If Yes, and any of these uses differs from the industry standard practices for this plant species, provide details.

The GMO may be processed to produce a thing that is not a GMO. Manufacture of the GMO by ginning of cotton fibres and linters, extraction of oil and production of processed meal for animal feed may result in products that do not contain genetic material.

f. grow, raise or culture the GMOs?

☒Yes ☐No

If Yes, and growing, raising or culture of the GM plant differs from the industry standard practices for this plant species, provide details.

Practices do not differ from industry standards.

g. import the GMOs?

☒Yes ☐No

If Yes, provide a brief description of what GM plant material would be imported, where it would be imported from and if a permit has been applied for and/or obtained from the Department of Agriculture and Water Resources (Biosecurity). Also indicate if importation has been authorised by the Gene Technology Regulator.

Seed for sowing may be imported from the USA as authorised under an appropriate NLRD issued by the OGTR and import permit from the Department of Agriculture and Water Resources.

h. transport the GMOs?

☒Yes ☐No

If Yes, and transport of the GM plant or plant material differs from the industry standard practices for this plant species, provide details.

Practices do not differ from industry standards.

i. dispose of the GMOs?

☒Yes ☐No

If disposal of the GM plant or plant material differs from the industry standard practices for this plant species, provide details.

Practices do not differ from industry standards.

j. possess, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned above?

☒Yes ☐No

If possession, supply or use of the GM plant or plant material differs from the industry standard practices for this plant species, provide details.

Practices do not differ from industry standards.

10.2 Proposed limits for the DIR

Depending on the genetic modification and the nature of activities you are proposing, you may need to propose limits on the release to restrict the spread and persistence of, or exposure to, the GM plant and its genetic material (i.e. limits on the scope, scale, size, and access to the release). For example, limits are likely required on a commercial release of a GM plant that produces a therapeutic drug or industrial compound, particularly if the plant species is normally cultivated for use as human food or animal feed. In contrast, limits may not be proposed if dealings with the GM plants do not differ from usual practices.

a. Are any limits proposed on the dealings to restrict the spread and persistence of the GM plant and its genetic material which differ from standard industry practice for the plant species?

☐Yes ☒No

If Yes, complete the remaining Parts of 10.2. If No, go on to Part 10.3.

If answering yes to any of the following questions, provide a rationale for the effectiveness of the proposed limits.

Are you proposing to limit:

b. the scope of the dealings with the GMOs?

Scope can be considered in terms of the range of activities which are proposed to be conducted. In part this includes the dealings intended to be conducted, which is already addressed in Part 10.1. Other limitations of scope may be any limitation on activities with, or use of, the GM plant beyond those that normally apply to the parent species, e.g. only growing a GM plant to a particular life stage or not using the GM plant or its products for animal feed or human food.

☐Yes ☒No

If Yes, briefly describe how the scope of the dealings would be limited.

Enter answer

c. the scale of the dealings with the GMOs?

☐Yes ☒No

If Yes, provide details on any limitations to the scale of the release (e.g. the overall size of the release).

Enter answer

d. the locations of the dealings with the GMOs?

☐Yes ☒No

If Yes, provide any details on limitations on where the release may occur (e.g. the State, Territory and/or LGAs for the proposed release or list those that are excluded). Indicate if the proposed release includes expansion into new areas compared to the parent species.

Enter answer

e. the duration of the dealings with the GMOs?

☐Yes ☒No

If Yes, include details on the intended production cycle, such as the growing season, and total number of months or years proposed for the release. If applicable, provide the anticipated start and end dates for the growing of the GM plants.

In considering the potential start date, note the timeframes in which the Regulator must make a decision to issue, or refuse to issue, a licence, detailed in the Information for Applicants at the front of the application form.

Enter answer

f. the persons who are to be permitted to conduct the dealings with the GMOs?

☐Yes ☒No

If Yes, provide the roles, positions or relationship to the applicant of people who would conduct the dealings, i.e. the persons covered by the licence.

Note that should a licence be issued, it is a condition of all licences that any person covered by the licence must be informed of any licence conditions applicable to them.

Enter answer

10.3 Proposed controls for the DIR

Depending on the genetic modification and the nature of activities you are proposing, you may need to propose controls on the release to restrict the spread and persistence of or exposure to the GM plant and its genetic material while conducting the proposed dealings with the GM plants. For example, controls may be required on a commercial release of a GM plant that produces a therapeutic drug or industrial compound to restrict gene flow to the same non-GM plant species which is cultivated for use as human food or animal feed. In contrast, controls may not be proposed if dealings with the GM plant(s) do not differ from usual practices.

a. Are any controls proposed to restrict the spread and persistence of the GM plant and its genetic material which differ from standard industry practice for the plant species?

☐Yes ☒No

If Yes, complete the remaining Parts of 10.3. If No, go to Part 10.4.

If answering yes to any of the following questions, provide a rationale for the effectiveness of the proposed controls.

b. Are you proposing controls to restrict gene flow via pollen dispersal from sexually reproducing GM plants while the GM plants are growing?

☐Yes ☒No

If Yes, provide details. Examples include: site selection to exclude sexually compatible plants in the vicinity; monitoring for and removal of sexually compatible species outside the release site; the use of pollen traps; isolation zones; use of sterile or low fertility GM lines, cultivars or varieties; bagging flowers; use of insect nets; preventing flowering.

Enter answer

c. Are you proposing controls to restrict the spread of seeds or asexual propagules from the GM plants while they are growing?

☐Yes ☒No

If Yes, provide details. Examples include: criteria for site selection; cleaning equipment and clothing after use with the GM plants; distancing GM plantings from waterways; bagging of fruit; using particular seeding or harvesting methods or equipment known to minimise dispersal.

Enter answer

d. Are you proposing to control access to the GM plants or site(s) by people or animals?

☐Yes ☒No

If Yes, provide details. Examples include: site selection in a remote area to restrict access by unauthorised people; fencing; locked gates; and animal baiting/traps.

Enter answer

e. Are you proposing controls to restrict persistence (and spread) of the GM plants post-harvest?

☐Yes ☒No

If Yes, provide details. Examples include: monitoring areas for a specified time period and destruction of GM plants; tilling and watering to encourage germination of any seed bank; seed reduction measures; harvest procedures to minimise seed bank build-up.

Enter answer

f. Are you proposing controls to restrict dispersal of the GMOs during transport?

☐Yes ☒No

If Yes, provide detail. Describe who would transport the GM plants or GM plant material; how it would be contained during transport and how it would be transported, including the use of specific transport equipment or commercial courier services.

g. Are you proposing controls to restrict dispersal of the GMOs during storage?

☐Yes ☒No

If Yes, provide details about any relevant controls such as where and how the GMO would be stored, how access may be controlled, how dispersal may be minimised (e.g. monitoring for and controlled rodents).

h. Are you proposing controls to restrict dispersal of the GMOs during disposal?

☐Yes ☒No

If Yes, provide detail. Include what destruction methods would be used and relevant controls such as monitoring of destruction areas, using specific methods or equipment for destruction or cleaning of areas used outside of the site (s).

10.4 Approval for the use of the GM plants, or products from the GM plants, from other Australian regulatory schemes.

Some uses of GMOs or GM products are covered by legislation administered by other regulatory agencies such as:

- Food Standards Australia and New Zealand (FSANZ) – regulation of food products, labelling GM foods
- Australian Pesticides and Veterinary Medicines Authority (APVMA) – regulation of agricultural chemicals used on or produced by crops and veterinary therapeutic products
- Therapeutic Goods Administration (TGA) – regulation of human therapeutic products
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS) – regulation of chemical safety
- Department of Agriculture and Water Resources (Biosecurity) – regulation of importation of animals, plants and biological products (see also Part 10.1.g)

Information provided here assists co-ordination with these other regulatory agencies.

You will be asked to provide details about current assessments and previous approvals of the GM plants proposed for release in Part 11 of this application.

a. Is use in or as a commercially available human food intended?

☒Yes ☐No

If Yes, briefly describe how the GMO will be used for human food and if this use differs from standard use of the species for human food.

Oil extracted from seed by processing will be used for human food. This is a standard use of the species for human food and resulting oil does not contain genetic material. FSANZ approved MON 88701 for food use in 2014 under A1080.

b. Is use as an agricultural chemical intended?

☐Yes ☒No

If Yes, briefly describe how the GMO will be used as an agricultural chemical, e.g. the GM plant may produce a compound which is toxic to specific insect pests.

c. Would agricultural chemicals be used on the GM plants?

☒Yes ☐No

If Yes, briefly describe which chemicals (e.g. herbicide, insecticides, fungicide) would be used and if the usage differs from the industry standard practices. Note that question 11.2 asks about the regulatory approval for chemical use on the GM plant.

Pesticides may be used on the GM plants following standard industry practice for the production of cotton in Australia.

d. Is use in or as a veterinary medicine intended?

☐Yes ☒No

If Yes, briefly describe how the GMO would be used in or as a veterinary medicine.

e. Is use in or as a human therapeutic intended?

☐Yes ☒No

If Yes, briefly describe how the GMO would be used in or as a human therapeutic.

f. Is use in or as an industrial chemical intended?

☐Yes ☒No

If Yes, briefly describe how the GMO would be used in or as an industrial chemical.

10.5 Will any of the proposed dealings with GM plants involve the use of nanotechnology, or inclusion or production of engineered nanomaterials?

The Australian Government has committed to taking a proactive approach in monitoring developments in nanotechnology so as to ensure the regulatory frameworks charged with protecting public health, safety and the environment keep pace with these changes (Australian Government, Department of Industry).

Nanotechnology is engineering at the atomic or molecular level, involving the manipulation of matter at the nanoscale (generally from 1 to 100 nanometres) to create new materials, structures and devices. For the purpose of this question, **nanotechnology does not include standard techniques of molecular biology/gene technology**.

Manufactured nanomaterials are materials designed at the molecular level to take advantage of novel properties which are generally not seen in their conventional counterparts.

☐Yes ☒No

If Yes, provide details.

Part 11: Assessments and Approvals by Regulatory Authorities

In accordance with Regulation 10(1)(a), information on current and previous assessments of the GM plants, both in Australia and overseas, will be taken into account in the evaluation of this application. It may also assist in risk identification or provide additional information related to impact from the history of use of the GM plant or its products, e.g. whether or not adverse outcomes or unintended effects have been observed.

11.1 Provide details of previous approvals for release into the Australian environment of the GM plant(s).

Include approvals by the Regulator (or the Genetic Manipulation Advisory Committee) and details of any adverse consequences resulting from the previous release(s), including identifying references and reports of assessments.

The GM cotton-MON 88701 has been released into the environment in Australia for field trials in stacked GM cotton lines (DIR120/2013). MON 88701 has also been approved for commercial release in stacked events (DIR145/2016). There were no adverse effects resulting from the field trials or commercial release.

11.2 Provide details of any previous and/or current assessments of the GM plants, or products derived from them, by any other regulatory authority in Australia.

Include assessments by other regulatory agencies such as FSANZ, APVMA, NICNAS, TGA and Department of Agriculture and Water Resources (Biosecurity). Also provide details of any adverse consequences associated with use of the GM plants or GM products covered in these assessments, including identifying references and reports of assessments.

FSANZ has approved MON 88701 cotton for food use (A1080).

11.3 Provide details on approvals for human food and/or animal feed use or environmental release of the same GM plant(s) in other countries.

If the GM plant(s) has been released overseas, provide details of the approvals (i.e. countries and type of release/approval), including when and if they are still current. Also provide details of any adverse or unintended consequences associated with the GM plants or their products following their approval in other countries, including identifying references and reports of assessments.

Monsanto has made or will make applications to several overseas Government Authorities. Agencies which have granted approval for MON 88701 cotton include: the Canadian Food Inspection Agency (CFIA)-Feed, Health Canada-Food; Colombia's Instituto Colombianoagropecuario (ICA)-Feed and Instituto Nacional de Vigilancia de Medicamentos y Alimentos(INVIMA)-Food; Japan's Ministry of Agriculture, Forestry and Fisheries (MAFF)-Feed and Environment, Ministry of Health, Labour and Welfare (MHLW)-Food; Ministry of Food and Drug Safety (MFDS)-Food, Korean Rural Development Administration (RDA)-Feed and Environment, Mexico's COFEPRIS-Food and Feed; Singapore Food Agency-Food and Feed; Taiwan Food and Drug Administration- Food, Taiwan Council of Agriculture-Feed; United States Department of Agriculture-Cultivation-Food, Feed, and Cultivation, US Food and Drug Administration-Food and Feed. All approvals are current. No adverse or unintended consequences have been reported. Details of these approvals are available at the Biosafety Clearing House (http://bch.cbd.int/) or at specific country regulatory authority websites. Additionally, field trials have been conducted as outlined in Part 7. Breeding stack products that contain MON 88701 have also been approved in several countries, including Australia (DIR145/2016).

11.4 Have the GM plant(s) been refused an approval, or had an approval for environmental release, or for use in human food or animal feed suspended or revoked in any country?

☐Yes ☒No

If Yes, provide details including the country, date and rationale for refusal, including identifying references and reports of assessments.

Part 12: Spread and Persistence of the GM Plant(s) in the Environment

Characteristics that influence the persistence (establishment, survival and reproduction) and spread (dispersal of the plant or its genetic material) of a plant species impact on the degree of its invasiveness. The degree of invasiveness of a plant species in a particular environment gives an indication of the likelihood of it causing harm in that environment. The information required in this Part helps to establish whether plant characteristics relating to spread and persistence might be altered in the GM plant or any of its hybrids compared to the parent species.

In the preparation of the risk assessment, this information will contribute to the estimation of the exposure of people or the environment to the GM plant. In the preparation of the risk management plan, this information is used when considering any limits and/or controls proposed in Part 10.

Potential adverse effects, i.e. harms, due to exposure of the GM plant to people or the environment are considered in Part 13.

The OGTR has prepared biology documents for a number of parent species. Some of these documents contain a weed risk assessment for the species which may be useful when considering the following questions.

12.1 Provide details on the likelihood of spread and persistence of the GM plants in the environment.

Mechanisms by which the GM plants might spread under both normal and extreme environmental conditions (e.g. floods, cyclones or bushfires), as well as proposed limits and controls (if any), are important in determining the likelihood of spread and persistence occurring.

a. Are the GM plants more likely to be spread in the environment than the parent species?

☐Yes ☒No

Provide evidence or a rationale for your answer. Factors influencing likelihood of spread may include GM plants with lower seed weight than the parent species or with altered seed shattering characteristics. Take into account spread of the GMO by wind, water, flying animals, other animals and people (including deliberate and accidental).

Cotton seed is known to be dispersed deliberately by humans for cultivation and accidentally by humans via transport on vehicles, or possibly on clothing. Cotton seed may also be spread by animals (i.e. on feet), in stock feed or by wind.

The introduced genes are not known to confer any phenotypic changes that would affect any of the mechanisms by which cotton is normally spread. There were no observed phenotypic changes which would change dispersal of the cotton seed. The agronomic/phenotypic performance of cotton plants derived from transformation Event MON 88701 was compared with that of a conventional cotton, in order to assess whole plant growth and agronomic characteristics. Traits that indicate agronomic performance were evaluated and compared between MON 88701 cotton plants and conventional cotton plants grown in field trials conducted at fifteen locations in the USA during 2010.

Thus, the phenotypic, agronomic, plant mapping, and environmental interaction assessment of MON 88701 included the parental conventional control as a comparator. This evaluation used a weight-of-evidence approach and considered statistical differences between MON 88701 and the conventional control with respect to reproducibility, magnitude, and directionality. The observations were taken on plants not treated with dicamba or glufosinate, in order to evaluate the impact of the introduced traits in MON 88701. To further support the trait assessment, similar supplemental observations were also conducted on the agronomic system that includes MON 88701 treated with dicamba and glufosinate herbicides. Comparison to a range of commercial reference varieties established the range of natural variability for cotton, and provided a context from which to further evaluate any statistical differences. Characteristics assessed included: seed dormancy and germination, pollen morphology, plant phenotypic observations, plant mapping, and environmental interaction evaluations conducted in the field. The phenotypic, agronomic, and environmental interaction assessment demonstrated that MON 88701 is comparable to conventional cotton. Thus, MON 88701 is unlikely to have adverse environmental effects compared to commercially cultivated cotton. Details are provided in [redacted], 2012 (Appendix 7).

b. Are the GM plants more likely to persist amongst existing plants compared to the parent species?

☐Yes ☒No

Provide evidence or a rationale for this expectation of a competitive advantage and, if applicable, indicate in what environments or under what circumstances this may occur. Include any alterations to the GM plant's ability to persist in the environment. This would include consideration of its ability to form long-term survival structures such as seed or vegetative propagules and changes in seed dormancy, seedling vigour, germination frequency, time to germinate or time to reach reproductive maturity compared to the parent species.

Plant characteristics relating to persistence of MON 88701, containing herbicide tolerance are not expected to be altered.

MON 88701 was compared to a conventional control, Coker 130, which has a genetic background similar to MON 88701, but does not possess the dicamba and glufosinate-tolerance traits. In addition, multiple commercial reference varieties developed through conventional selection and breeding were included to provide a range of comparative values that are representative of the variability in existing commercial cotton varieties for each characteristic. Data collected for the various characteristics from the commercial reference varieties provides context for interpreting experimental results.

Seed dormancy and germination characterization demonstrated that MON 88701 cottonseed had germination characteristics similar to cottonseed of the conventional control. In particular, the lack of hard seed, a well-accepted characteristic of weediness affecting seed germination, supports a conclusion of no increased weediness of MON 88701 when compared to the conventional control. Additionally, there were no statistically significant (5% level of significance) differences observed between MON 88701 and the conventional control for pollen viability and diameter, and no visual differences in general pollen morphology were observed. Collectively, these results support the conclusion that MON 88701 is not likely to exhibit increased plant pest potential compared to commercially cultivated cotton.

Seed dormancy (e.g., hard seed) is an important characteristic that is often associated with plants that are considered weeds (Anderson, 1996; Lingenfelter and Hartwig, 2007). Cotton does not exhibit significant levels of seed dormancy as this characteristic has been removed through selection and conventional breeding (Christiansen and Moore, 1959). To assess germination characteristics, standardized germination assays are routinely used. The Association of Official Seed Analysts (AOSA), an internationally recognized seed testing organization, recommends a temperature range of alternating 20/30°C as optimal for testing the germination characteristics of cottonseed (AOSA, 2007; AOSA, 2010b; AOSA, 2010a; AOSA/SCST, 2010). The seed lots for MON 88701, the conventional control, and the commercial reference varieties were produced in three replicated field trials during 2010. These geographic areas represent environmentally relevant conditions for cotton production. In addition to the AOSA recommended temperature range of 20/30°C, seed was tested at five additional temperature regimes of 10, 20, 30, alternating 10/20, and alternating 10/30°C to assess seed germination properties.

In the combined-site analysis, in which the data were pooled from the three individual sites, no statistically significant differences (5% level of significance) were detected between MON 88701 and the conventional control for any characteristic at the AOSA temperature regime (alternating 20°C/30°C), or at the temperature regimes of 10°C, 20°C, alternating 10°C/20°C, or alternating 10°C/30°C. MON 88701 had a significantly higher percentage of germinated seed (96.7 vs. 94.4, respectively) and lower percent dead seed (3.3 vs. 5.6, respectively) than the conventional control at 30°C. These differences were small in magnitude, not observed at other temperatures and the mean values of percent germinated and dead seed for MON 88701 were within the range of commercial reference varieties. Therefore, the differences in percent germinated and dead seed at 30°C are not considered to be biologically meaningful in terms of altered dormancy or germination characteristics.

The dormancy and germination characteristics evaluated were used to assess MON 88701 in the context of plant pest risk. The results of this assessment, particularly the fact that no hard seed were observed at any temperature, support the conclusion that there are no seed germination characteristic differences between MON 88701 and the conventional control. Thus, the introduction of the dicamba and glufosinate-tolerant traits into cotton is not likely to result in increased plant pest potential, increased weediness, or an altered environmental impact from MON 88701 compared to commercially cultivated cotton. Details are provided in [redacted] 2012 (Appendix 7).

c. Will environmental factors which naturally limit the spread and persistence of the parent species also limit the spread and persistence of the GM plants?

☒Yes ☐No

Provide evidence or a rationale for your answer.

In Australia cotton is known to be limited by a number of environmental factors, with water availability (northern Australia) and frosts (southern Australia) being the main limiting factors. Other limiting factors include nutrient availability, temperature and soil type. The factors naturally limiting spread and persistence of cotton are not expected to be changed as a result of the genetic modification. The introduced genes are not known to confer any other phenotypic changes that would mitigate the environmental factors which normally limit the spread and persistence of cotton in Australia. Cotton is susceptible to water availability and frosts (see Part 14 / the OGTR Biology document for cotton).

12.2 If the GM plants are able to reproduce sexually, which sexually compatible plants may be present in the receiving environment?

Include the parent species, any compatible commercially approved GM plants and any other sexually compatible species in your considerations.

The proposed release is for throughout Australia, thus non-GM *G. hirsutum* and *G. barbadense*, and any GM cotton (*G. hirsutum* and *G. barbadense*) already approved for commercial release may be present in the receiving environment. Native Australian cotton species are not sexually compatible with *G. hirsutum*.

12.3 Are any characteristics expected to be altered in the GM plants compared to the parent species that affect the efficiency of gene transfer and introgression into any sexually compatible species?

☐Yes ☒No

Characteristics that may affect the efficiency of gene transfer and introgression include the timing of flowering, flower fragrance, pollen size or shape, pollen production, pollen viability, the mechanism of pollen transfer or altered expression of genes involved in meiosis or sexual reproduction. Should a genetic modification be targeted at decreasing or abolishing the ability of the plant to reproduce sexually, include a consideration about how likely reversion would be and if any proposed controls would still be applicable. Provide the rationale for your response.

The introduced genes are not known to confer any changes that would affect either the mechanism of pollen transfer or the efficiency of gene transfer and introgression into the sexually compatible species.

Cotton is considered to be a predominantly self-pollinating crop with lower potential for wind and insect-mediated pollen transfer, some potential pollinators are honey bees (Apis mellifera), pollen beetles, moths, wasps and flies (Mungomery and Glassop, 1969; Richards et al., 2005; Llewellyn and Fitt, 1996). Based on agronomic and phenotypic data presented in Part 12.1, MON 88701 are no more likely to become weeds or plant pests than other commercially cultivated cottons in Australia and are expected to be similar to commercially cultivated cotton regarding their potential for, and impacts from, gene flow. MON 88701 will only have a competitive advantage over conventional cotton in the presence of application of glufosinate and/or dicamba herbicides. In the absence of these pressures, there will be no competitive advantage.

12.4 If the introduced genetic modification were transferred to a different sexually compatible species (not the same species as the GMO), would the presence of the genetic modification enhance the ability of the resultant GMO to spread and persist compared to the non-GM sexually compatible species?

☐Yes ☒No

Provide evidence or a rationale for your answer.

The introduced herbicide tolerant trait gene in MON 88701 cotton specifically confers resistance to application of glufosinate and/or dicamba herbicides. The vast majority of commercial cotton grown in Australia is GM and already contains herbicide tolerance trait. Hybrids would still be susceptible to the limiting factors of cotton (frost and water availability) as well as other herbicides and/or mechanical control. Other cotton species that are sexually compatible with *G. hirsutum* are susceptible to the same environmental limitations as *G. hirsutum*: germination, nutrition, water availability, herbivory, intra- and inter-specific competition, grazing, trampling, and fire (Eastick, 2002; Eastick and Hearnden, 2006). The introduced genes are not known to confer any phenotypic changes that would affect any of the mechanisms by which cotton is normally spread or any unintended survivability characteristics (see section 9.11.).

Part 13: Potential Harms of the GM Plants

When preparing a RARMP the Regulator must take into account the potential of a GMO to cause harm. The GMOs in this application are GM plants. Plants may cause harms including:

- adverse effects on the health of people and/or animals
- reduction in the establishment, yield and/or quality of desired plants
- restriction in the physical movement of people, animals, vehicles, machinery and/or water
- adverse effects on environmental health, such as providing food and/or shelter to pests, pathogens and/or diseases, or adverse changes to fire regime, nutrient levels, soil salinity, soil stability or the soil water table.

In the long term, plants may also cause more complex harms such as adverse changes to biodiversity.

Parts 13.1, 13.2 and 13.3 of this section seek to determine whether the potential of the GM plant or its offspring to cause harm would be **greater** than that of the **parent plants**, i.e. the non-GM parent species including any relevant commercially approved GM plants within that species. Part 13.4 seeks to determine whether the transfer of the genetic modification to sexually compatible species has potential to cause **greater** harm than the **non-GM** sexually compatible species.

The potential of a GM plant to cause harm is considered in the context of the proposed release, including the limits and controls described in Part 10 (if any). Occupational health and safety requirements by other relevant regulatory authorities may also be important factors and should be included in the answers.

For each question below, provide details on the properties of the GM plant or its products that may cause harm to human health and safety or the environment due to the introduced genetic modification. The OGTR has prepared biology documents for a number of parent species which may be useful when considering the following questions.

For all 'Yes' responses provide details on:

- how people or the environment may be harmed
- the degree of harm (eg for people: acute or chronic illness, physical injury or allergy; for other organisms: displacement, toxicity or disease)
- the number of people or type of organism potentially exposed and susceptible (eg lepidoptera for Cry1 insect toxin)
- the value of potentially harmed species (eg protected/ threatened *versus* pest) and their relative abundance at the location(s) of the release
- which part of the GM plant, stage of growth or use (such as stockfeed) would cause the harm and
- whether or not the harm is reversible.

13.1 Is the GM plant expected to be more harmful to people than the parent species?

☐Yes ☒No

The evidence or rationale for your answer should consider:

- the type and degree of harm (e.g. acute or chronic illness, physical injury or allergy) and whether or not the harm is reversible
- any studies or assessments of the GM plant or plant products related to potential harm to human health or safety (e.g. changes to compositional analysis, human feeding trials, approval for human food use in Australia or overseas).

Note that any changes in the GMO with respect to endogenous levels of known toxins or allergens were considered in Part 9.11 and can be referenced here if needed.

The introduced genes specifically confer herbicide tolerance. The genetic modifications regarding herbicide tolerance are aimed at providing tolerance to application of glufosinate and/or dicamba herbicides. Part 9.11 of this application addresses the levels of known toxins and allergens.

The OGTR has previously assessed the function and safety of herbicide tolerant GM cotton containing MON 88701 (DIR145/2016). The same GM cottons, have been released into the Australian environment and overseas with no known ill-effect (see Part 11).

Food Standards Australia and New Zealand (FSANZ) has completed a comprehensive safety assessment of food derived from cotton line MON 88701-A1080. No potential public health and safety concerns were identified in the assessment of food derived from cotton line MON 88701. The FSANZ executive summary stated that 'A history of safe use has been demonstrated for both MON 88701 DMO and PAT (*bar*) proteins. MON 88701 DMO was fully characterised and the enzymatic activity was found to be specific for dicamba when tested using structurally similar cotton endogenous substrates. The specificity of PAT proteins has been extensively documented in the literature. Neither protein has relevant amino acid sequence similarities to known allergens, gliadins, glutenins, or toxins that may have adverse effects on mammals. Detailed compositional analysis, in accordance with OECD guidelines, were conducted to assess whether levels of key nutrients and anti-nutrients in MON 88701 cottonseed were comparable to levels in the conventional cotton Coker 130, with similar background genetics, and several commercial reference cotton varieties. All these results support the overall food and feed safety of MON 88701.

13.2 Is the GM plant expected to be more toxic to organisms other than people when compared to the parent species?

This question intends to cover all organisms other than humans, including all animals, plants and microorganisms, in terrestrial or aquatic environments.

☐Yes ☒No

The evidence or rationale for your answer should consider:

- the degree of harm to organisms other than people and whether or not the harm is reversible
- any studies or assessments of the GM plant or plant products related to harm to organisms other than people (e.g. compositional analysis of plant tissues consumed by animals, toxicity studies).

Note that any changes in the GMO with respect to endogenous levels of known toxins were considered in Part 9.11 and can be referenced here if needed.

MON 88701 cotton is not expected to be more toxic than non-transgenic cotton to any organisms. Other than its herbicide tolerant traits, MON 88701 is substantially equivalent to the conventional comparator and within reference ranges, as demonstrated in section 9.11.

13.3 Is the GM plant expected to be more harmful to the environment when compared to the parent species?

☐Yes ☒No

The evidence or rationale for your answer should consider:

- the type of harm such as:
    - reduction in the establishment, yield and/or quality of desired plants
    - restriction in the physical movement of people, animals, vehicles, machinery and/or water
    - providing food and/or shelter to pests, pathogens and/or diseases
    - adverse changes to fire regime, nutrient levels, soil salinity, soil stability or the soil water table
    - adverse changes to biodiversity.
- where the harm may occur (e.g. conservation areas, national parks, agricultural areas) and whether or not the harm is reversible.
- any studies or assessments of the GM plant or plant products related to potential harm to the environment (e.g. changes to compositional analysis, competition studies among plants).

The introduced genes are not known to confer any phenotypic changes that would affect any of the mechanisms by which cotton is normally spread any survivability characteristics (see section 9.11.)

The OGTR has previously assessed the function and safety of insect resistant GM cottons containing MON 88701 (DIR145/2016). The same GM cottons, have been released into the Australian environment and overseas with no known ill-effect (see Part 11).

13.4 If the introduced genetic material were transferred to a different sexually compatible species (not the same species as the GM plant), would the resultant GM plant be more harmful to people, other organisms or the environment than the non-GM sexually compatible species?

☐Yes ☒No

The evidence or rationale for your answer should consider:

- the type and degree of harm to humans, animals and microorganisms
- the type of harm to the environment such as:
    - reduction in the establishment, yield and/or quality of desired plants
    - restriction in the physical movement of people, animals, vehicles, machinery and/or water
    - providing food and/or shelter to pests, pathogens and/or diseases
    - adverse changes to fire regime, nutrient levels, soil salinity, soil stability or the soil water table
    - adverse changes to biodiversity.
- where the harm may occur (e.g. conservation areas, national parks, agricultural areas) and whether or not the harm is reversible.

Note that Parts 12.3 and 12.4 considered the potential for sexually compatible species to form hybrids with the GMO and whether or not the introduced genetic material would enhance spread and persistence of such hybrids.

The DMO and PAT proteins are not known to confer any phenotypic changes that would cause harm to people or organisms other than tolerance to dicamba and glufosinate application when expressed in *G. hirsutum* (see section 9.11); the same proteins are not predicted to act differently if transferred to a sexually compatible species. The OGTR has previously assessed the function and safety of insect resistant GM cottons containing MON 88701 (DIR145/2016). The same GM cotton have been released into the Australian environment and overseas with no known ill-effect (see Part 11).

Part 14: Additional Information about the Parent Plants(s)

This Part is only required if the OGTR **has not** prepared a biology document for the parent species. **Do not complete if the OGTR has prepared a biology document. However, any new information or information relevant for the application about the parent species which is not present in the biology document must be provided (see Part 8.3).**

If the parent species is not present in the Australian environment, we advise you to discuss this with OGTR staff before submitting an application.

Not applicable as The OGTR has prepared a biology document for *G. hirsutum*, which can be found at the following link:

http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/5DCF28AD2F3779C4CA257D4E001819B9/$File/The%20biology%20of%20cotton%202016.pdf

As such, Part 14 has not been completed.

14.1 Production and use of the parent species

a. Is the parent species grown in Australia?

☐Yes ☐No

If Yes, provide details of the production methods used in the areas proposed for release. If a production manual is available, provide the reference.

If No, or no information is available, provide details of the information sources checked.

Enter answer

b. Is the parent species or products derived from it used in Australia?

☐Yes ☐No

If Yes, provide details of the major uses in Australia, and briefly describe its history of use.

If No, or no information is available, provide details of the information sources checked.

Enter answer

14.2 Distribution of the parent species in Australia

In considering the distribution of the parent species in Australia we have adopted elements of the Australian Land Use and Management (ALUM) classification system for describing various land use areas. The ALUM classification has six primary classes of land use that are distinguished in order of generally increasing levels of intervention or potential impact on the natural landscape. In this document we have followed this classification with the exception of combining the dryland and irrigated agricultural and plantation classes into one class. A description of each class is provided as background in the following questions.

a. Is the parent species present in conservation or natural environments?

Conserved or natural environments are areas that have had relatively low levels of human intervention. These areas include national or state parks, nature reserves, World Heritage sites, Ramsar wetlands, habitats for a protected species, residual native cover and areas undergoing rehabilitation.

☐Yes ☐No

If Yes, provide information on the distribution of the parent species in these areas in Australia.

If No, or no information is available, provide details of the information sources checked.

Enter answer

b. Is the parent species present in relatively natural land use areas?

Relatively natural land use areas are areas used for primary production, with limited change to native vegetation. These areas are generally subject to relatively low levels of intervention (very limited weed control or other inputs), e.g. areas of natural vegetation used for grazing and native forests used for wood or other forest products.

☐Yes ☐No

If Yes, provide information on the distribution of the parent species in these areas in Australia.

If No, or no information is available, provide details of the information sources checked.

Enter answer

c. Is the parent species present in areas used for agricultural or plantation production (either dryland or irrigated land use)?

Relevant areas include land used for primary production based on dryland or irrigated farming systems. The range of activities in this category includes plantation forestry, pasture production, cropping and fodder production and a wide range of horticultural production.

☐Yes ☐No

If Yes, provide information on the distribution of the parent species in these areas in Australia.

If No, or no information is available, provide details of the information sources checked.

Enter answer

d. Is the parent species present in intensive use areas?

Intensive use areas include areas that experience high levels of interference with natural processes, generally in association with closer settlement, such as some areas used for horticulture (e.g. glasshouses, shadehouses), intensive animal production (e.g. dairy cattle, poultry), areas of manufacture or industry, residential areas, service areas (e.g. shops, markets, education, sportsgrounds), areas of transport and communication (e.g. along roadsides or railways, ports, radar stations), areas used for utilities (e.g. facilities that generate electricity, substations, along power lines, gas storage or treatment areas), mine sites (including tailings), and areas used for waste treatment and disposal.

☐Yes ☐No

If Yes, provide information on the distribution of the parent species in these areas in Australia.

If No, or no information is available, provide details of the information sources checked.

Enter answer

e. Is the parent species present in aquatic environments?

Aquatic environments include lakes, reservoirs/dams, rivers, channels/aqueducts, marshes/wetlands, estuaries, or coastal waters.

☐Yes ☐No

If Yes, provide information on the distribution of the parent species in these areas in Australia.

Enter answer

14.3 How does the parent species reproduce?

Include details of sexual and/or asexual reproduction such as:

- the means of reproduction, e.g. seed, rhizome, stolon, bulb, corm, detached stem/branch
- the time for completion of a lifecycle, e.g. from seed to seed
- the longevity and dormancy of propagules.

For each relevant land use identified in 14.1, indicate how many propagules may be produced per square metre.

Enter answer

14.4 For sexually reproducing species, what are the pollen dispersal mechanisms?

Include information on the methods of spreading (biotic or abiotic vectors), the maximum dispersal distance and the viability of the pollen. For insect or animal vectors of pollination, include details of their range and distribution in Australia (where known).

Enter answer

14.5 For sexually reproducing species, what sexually compatible relatives are present in Australia and what is their efficiency of hybridisation with the parent species?

Please provide the scientific name and common names of the sexually compatible relatives, as well as cultivated or wild members of the same species. Describe the efficiency with which hybridisation occurs under natural conditions and the fitness, survival and competitiveness of the resulting progeny, providing supporting scientific evidence where available.

Enter answer

14.6 What harms does the parent species cause?

For the purpose of this document, invasive plants causing significant levels of one or more of the following harms are called weeds:

- adverse effects on the health of people and/or animals
- reduction in the establishment, yield and/or quality of desired plants
- restriction in the physical movement of people, animals, vehicles, machinery and/or water
- provision of food and/or shelter to pests, pathogens and/or diseases
- adverse effects on environmental health, such as providing food and/or shelter to pests, pathogens and/or diseases, or adverse changes to fire regime, nutrient levels, soil salinity, soil stability or the soil water table.

A plant species may be weedy in one or more land uses or ecosystem types. The questions to determine the weediness of the parent species have been adapted from HB 294:2006, National Post-Border Weed Risk Management Protocol (Standards Australia; Standards New Zealand).

For parent species that are deliberately planted and grown, e.g. in silviculture, agriculture or horticulture, answer the questions in relation to the plant as a volunteer or otherwise outside of cultivation, not in relation to situations in which it is the desired plant.

If the answer provided to any of the following questions is Yes, provide details of the harms for all the relevant land uses (agricultural or plantation production; intensively used areas; relatively natural environments; conservation or natural environments; or aquatic environments).

a. Does the parent species have an adverse effect on the health of people and/or animals?

For example, gluten in wheat can cause ill health for coeliacs (gluten intolerance), and grain dust can cause allergies in workers in a flour mill. Cotton seed contains gossypols that can be toxic to livestock if provided at high doses (e.g. if eaten as cotton seed meal). Additionally, toxins may be produced by organisms which normally infect or form symbiotic relationships with the parent, such as endophytes harboured in perennial ryegrass that may cause staggers in grazing animals, or fungal pathogens of plants may produce mycotoxins which affect animals or people consuming the grain from the infected plant.

☐Yes ☐No

If Yes, provide details.

If No, or no information is available, provide details of the sources checked.

Enter answer

b. Does the parent species cause a reduction in the establishment or yield of desired plants?

☐Yes ☐No

Describe the impact in each relevant land use, including information on which plants are valued in those areas.

Enter answer

c. Does the parent species cause a reduction in the quality of products, diversity or services obtained from a relevant land use?

A plant may cause a loss in the supply, quality or usage of desired products, diversity or services obtained from a particular land use area. A plant may affect products by tainting of meat or milk, discolouration, tainting or otherwise reducing the quality of water, weed seed contamination of grain, seed, hay, wool, fruit or timber.

Indigenous use of native bush tucker and materials, and the quality of products of sustainable harvesting, should be considered here if applicable. Adverse impacts on fishing and hunting by all members of the community are also considered here.

In native vegetation, the decline of native plant species diversity and abundance are the main concerns (with flow on effects to animal diversity). This affects ecosystem structure and function and eventually conservation significance, recreational and tourism values. Plants may threaten biodiversity by harming threatened plant and animal species or communities.

In residential areas the plant may cause damage to physical infrastructure such as buildings, roads, fences and footpaths or it may reduce visibility, which may lead to harm to human health.

☐Yes ☐No

If Yes, describe.

If No, or no information is available, provide details of the sources checked.

Enter answer

d. Does the parent species cause a restriction in the physical movement of people, animals, vehicles, machinery and/or water?

Plants may restrict movement by being tall, thorny, tangled and/or dense. Examples of plants restricting movement by creating a physical barrier include:

- Blocking or slowing access of cars, bikes, quad bikes, farm/forestry machinery or other machinery
- Impeding movement of people on foot
- Interfering with boat access or manoeuvrability
- Blocking or slowing water flow
- Preventing livestock access to pasture or water
- Preventing animal access to nesting sites.

☐Yes ☐No

If Yes, describe.

If No, or no information is available, provide details of the sources checked.

Enter answer

e. Does the parent species provide food and/or shelter to pests, pathogens and/or diseases?

☐Yes ☐No

If Yes, describe.

If No, or no information is available, provide details of the sources checked.

Enter answer

f. Does the parent species cause adverse effects on environmental health?

Adverse effects on environmental health include adverse changes to nutrient levels, fire regime, soil salinity, soil stability or soil water table.

☐Yes ☐No

If Yes, describe.

If No, or no information is available, provide details of the sources checked.

Enter answer

14.7 What is the ability of the parent species to establish in competition amongst existing plants in each relevant land use?

Indicate which statement about the parent species' ability to establish is most applicable. Select more than one statement if the plant's ability to establish is different for the relevant land uses.

Relevant land uses may include conservation or natural environments; relatively natural land use areas; agricultural or plantation production (dryland and irrigated land use); intensive use areas; aquatic environments. Please see Part 14.2 for a description of land uses. Answer this section with reference to all relevant land uses.

☐The plant readily establishes within dense vegetation, or amongst thick infestations of other weeds, i.e. it has a very high ability to establish.

☐The plant readily establishes within more open vegetation, or amongst average infestations of other weeds, i.e. it has a high ability to establish.

☐The plant mainly establishes when there has been moderate disturbance to existing vegetation, which substantially reduces competition, i.e. it has a medium ability to establish. Moderate disturbance could include intensive grazing, mowing, raking, clearing of trees, brief floods or summer droughts.

☐The plant mainly needs bare ground to establish, including removal of stubble/leaf litter, i.e. it has a low ability to establish. This will occur after major disturbances such as cultivation, overgrazing, hot fires, grading, long-term floods or long droughts.

☐The plant's ability to establish is unknown.

Provide a rationale/evidence for the indicated ability to establish in each relevant land use.

Enter answer

14.8 What factors normally contribute to the long distance (>100 metre) spread of the parent species in the environment?

Factors that normally contribute to the dispersal of the parent species are likely to apply to the GM plant and may need to be managed in order to control the release. Consider all forms of dispersal, including seed, roots, corms, rhizomes, stolons, stems etc.

a. Is the parent species spread by flying animals?

Indicate which statement about the parent species' spread via flying animals is most applicable.

☐Flying animals, such as birds or bats, are well known to defecate, regurgitate or discard viable plant material or to spread it on fur, feathers, skin or feet, e.g. due to stickiness, small size or the presence of hooks or burrs.

☐Occasionally, flying animals spread viable plant material.

☐Flying animals do not disperse viable plant material or the species is avoided.

☐The ability for the parent species to be spread by flying animals is unknown.

Provide a rationale/evidence for your answer. If flying animals are known to spread the parent species, provide their common and scientific names.

Enter answer

b. Is the parent species spread by wild animals other than flying animals?

Indicate which statement about the parent species' spread is most applicable.

☐Wild animals other than flying animals are well known to defecate or discard viable plant material or spread it on hairs, skin or feet, e.g. due to stickiness, small size or the presence of hooks or burrs.

☐Occasionally, wild animals other than flying animals spread viable plant material.

☐Wild animals other than flying animals do not disperse viable plant material or avoid the species.

☐The ability for the parent species to be spread by wild animals other than flying animals is unknown.

Provide a rationale/evidence for your answer. If wild animals other than flying animals are known to spread the parent species, provide their common and scientific names.

Enter answer

c. Is the parent species spread over long distances via water?

Indicate which statement about the parent species' spread via water is most applicable.

☐Viable plant material is known to be spread by water, e.g. the propagules float or the species is located in or near to moving water or in areas that flood frequently.

☐Occasionally, viable plant material is spread by water.

☐The species is not spread by water.

☐The ability for the parent species to be spread over long distances via water is unknown.

Provide a rationale/evidence for your answer.

Enter answer

d. Is the parent species spread over long distances via wind?

Indicate which statement about the parent species' spread via wind is most applicable.

☐Viable plant material is known to be spread over large distances by wind, e.g. the species grows tall and produces small and light seeds or the species produces light seeds with wings, plumes or hairs.

☐Occasionally, viable plant material is spread by wind.

☐The species is not spread by wind.

☐The ability for the parent species to be spread long distances via wind is unknown.

Provide a rationale/evidence for your answer.

Enter answer

e. Is the parent species deliberately spread by people?

Indicate which statement about the parent species' deliberate spread by people is most applicable. Note that this may differ for different relevant land uses, e.g. a species may be used as a pasture species and deliberately spread in a pasture land use; it may not be deliberately spread in a nature conservation area. Select more than one statement if there are differences between the relevant land uses.

☐Viable plant material is or has been deliberately spread by people, e.g. it is used in agriculture, silviculture, horticulture, for medicinal, aquatic, turf, amenity, windbreak, shelter or soil protection purposes.

☐Viable plant material is occasionally spread deliberately by people.

☐The species is not known to be spread deliberately by people.

☐The ability for the parent species to be spread deliberately by people is unknown.

Provide a rationale/evidence for your answer.

Enter answer

f. Is the parent species accidentally spread by people?

Indicate which statement about the parent species' accidental spread by people is most applicable. Note that this may differ for different relevant land uses, e.g. it may not be accidentally spread in a nature conservation area as these areas may not be accessed by humans as much as other land use areas. Select more than one statement if there are differences between relevant land uses.

☐Viable plant material is known to be accidentally spread by people, e.g. the species grows in heavily trafficked areas, such that transport by footwear, clothing or vehicles, including farm machinery and boats, may occur or the species is often dragged by farm machinery or propagules have hooks, barbs or sticky substances to attach to objects or the species produces small propagules which can lodge in cracks in footwear, clothing or vehicles.

☐Occasionally, viable plant material is spread accidentally by people.

☐The species is not known to have been accidently spread by people.

☐The ability for the parent species to be spread accidentally by people is unknown.

Provide a rationale/evidence for your answer.

Enter answer

g. Is the parent species spread via domestic or farm animals?

Indicate which statement about the parent species' spread via domestic/farm animals is most applicable. Select more than one statement if there is a difference between the relevant land uses.

☐Domestic or farm animals are known to defecate, regurgitate or discard viable plant material or to spread it on feathers, hair, skin or feet, e.g. due to stickiness, small seed size or the presence of hooks.

☐Occasionally, viable plant material is spread via domestic or farm animals.

☐The species is not known to be spread via domestic or farm animals.

☐The ability for the parent species to be spread via domestic or farm animals is unknown.

Provide a rationale/evidence for your answer.

Enter answer

h. Is the parent species spread via contaminated produce?

Indicate which statement about the parent species' spread via contaminated produce is most applicable. Select more than one statement if there is a difference between the relevant land uses.

☐Viable plant material is commonly spread by contaminated produce, e.g. in crop or pasture seed, hay, grain, soil, sand, gravel, manures or mulches; or through by-products or waste of industries such as stockfeed manufacturers or tanneries; or through seeds on or in rolled turf.

☐Occasionally, viable plant material is spread via contaminated produce.

☐The species is not spread via contaminated produce.

☐The ability for the parent species to be spread via contaminated produce is unknown.

Provide a rationale/evidence for your answer.

Enter answer

14.9 What environmental factors (abiotic and biotic) naturally limit the spread and persistence of the parent species in the environment?

Details provided should include factors such as temperature, moisture, disease, predators and domestication (e.g. reduced fertility or loss of seed pod shattering) which naturally limit the spread and persistence of the parent species in the environment.

Enter answer

14.10 What weed management practices are typically used to restrict the spread and persistence of the parent species in each relevant land use?

Typical weed management practices refer to measures used which are intended to kill or prevent the parent species from establishing and surviving, spreading to a new location or reproducing. Practices may include the use of herbicides, mechanical measures (such as mowing or ploughing), crop rotation, hand pulling or other methods. The types and timing of these practices may vary between and within different environments or land uses. Describe the current weed management practices.

Enter answer

14.11 What is the parent species' tolerance to typical weed management practices?

The effectiveness of control measures in killing the parent species or preventing it from establishing and surviving, spreading to a new location or reproducing may determine the need and extent of additional control measures should the GM plant be released.

Classify the effectiveness of typical management practices used on the parent for each relevant land use. Select more than one statement if there is a difference between the relevant land uses.

☐No specific management is applied on the species in the land use.

☐Over 95% of plants survive typical weed management, i.e. the parent species has very high tolerance.

☐More than 50% of plants survive, i.e. the parent species has high tolerance.

☐Less than 50% of plants survive, i.e. the parent species has medium tolerance.

☐Less than 5% of plants survive, i.e. the parent species has low tolerance.

☐The parent species' tolerance to standard weed management practices is unknown.

Provide supporting evidence for each relevant land use.

Enter answer

14.12 Provide details of any State or Commonwealth restrictions on the movement of material from the parent species within and between producing regions.

Examples include restrictions on the movement of fruit and vegetables between states and/or growing regions to control spread of fruit fly and the movement of banana plants to control spread of disease.

Enter answer

14.13 What are the standard practices to restrict the transfer of genetic material from the parent species to other plants by sexual reproduction (if applicable)?

Methods may be according to industry standards (such as seed certification guidelines). They may be physical, biological or a combination of both, e.g. isolation distances, use of selfing bags, use of sterile cultivars or the use of a triticale border around grass breeding trials.

Enter answer

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Summary of submissions on consultation RARMP received from the public

Application: DIR 173 – Commercial release of cotton genetically modified for herbicide tolerance (MON 88701)

GMO: Cotton modified for herbicide tolerance

Applicant: Monsanto Australia Pty Ltd

Submissions closed: 24 August 2020

Abbreviations **Act**: *Gene Technology Act 2000*; **APVMA**: Australian Pesticides and Veterinary Medicines Authority; **FSANZ:** Food Standards Australia New Zealand; **DCSA:** 3,6-dichlorosalicylic acid; **DIR:** Dealing involving intentional release; **EPA:** United States Environmental Protection Agency; **GM**: Genetically modified; **GMO:** Genetically modified organism; **RARMP:** Risk Assessment and Risk Management Plan; **Regulator**: Gene Technology Regulator

Submitter	Summary of issues raised	Comment
1 [redacted] 14 July 2020	Wants to remind the OGTR of the introduced species that turned to pests, such as cane toad and rabbit/hare, as well as the drug thalidomide. Strongly opposes the commercial release of GM cotton. Long-term consequences of this release are unknown, but believes this will not be good judging by the previous examples.	The RARMP concludes that the commercial release of this GM cotton poses negligible risks to the health and safety of people and the environment. Cotton is an agricultural crop that has been grown widely in Australia for many decades. It is not identified as a weedy species and the genetic modification in DIR 173 is not expected to change its characteristics in this regard. Other GM cottons have been grown since 1996 and they now comprise over 99% of the commercial cotton crop. No adverse effects from these GM cottons have been reported.
2 [redacted] 17 July 2020	Cannot believe OGTR is even considering an application from multinational Monsanto for the commercial cultivation of GM cotton because they do not care about our health or the environment, only money. Asks what 'negligible risk to human health and safety or to the environment' actually means and suggests it is a non-committal statement which means nothing. Asks what tests and trials have been done to absolutely prove that this proposal will cause no side effects to humans and the environment.	The commercial motives of biotechnology companies are outside the scope of responsibility of the Regulator. The Regulator's approach to risk analysis can be found in the Risk Analysis Framework on the OGTR website, and includes definitions of the various terminology used. The Regulator is required to assess GMO applications in accordance with the Act and prepare a risk assessment and risk management plan (RARMP). The RARMP includes a thorough and critical assessment of data supplied by the applicant, together with a review of other relevant national and international scientific literature. It is finalised following an extensive consultation process involving prescribed experts, Australian Government authorities and agencies, experts, State and Territory Governments, relevant Australian local councils, the Minister for the

Submitter	Summary of issues raised	Comment
	Strongly opposes this licence application and any approval for commercially planting MON 88701 cotton in all cotton growing areas of Australia.	Environment and the public. The Regulator cannot issue the licence unless satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in such a way as to protect the health and safety of people and the environment. The RARMP concludes that the commercial release of this GM cotton poses negligible risks to the health and safety of people and the environment.
3 [redacted] 28 July 2020	Strong objection to release of herbicide tolerant GM cotton being used in human food and animal feed. Particularly concerned about the amount of herbicide retained by the crop, and accumulates and moves down the food chain, which may affect the health of future generations. Asks that the GM crops not be used in food for humans or animals.	The APVMA is responsible for registering agricultural and veterinary chemicals. The registration process involves scientifically evaluating the safety of using herbicides on GM crops in order to protect the health and safety of people, animals, plants and the environment. FSANZ has regulatory responsibility for food safety assessments in Australia. FSANZ has approved food from the GM cotton. More information about their assessments is available from the FSANZ website.
4 [redacted] 21 August 2020	Supports the granting of a licence to Monsanto allowing it to commercialise this trait in cotton in Australia on the following basis: • Endorses the rigorous scientific review and approval process applied by OGTR to independently assess to the trait for cultivation in Australia. • MON 88701 has been approved for cultivation in other jurisdictions and by other comparable regulatory agencies. • The opportunity for Australian growers to cultivate cotton containing this trait does not pose an unacceptable risk to public health or the environment. • The technology will provide Australian cotton growers an opportunity to apply the herbicides glufosinate and dicamba in crop to more effectively manage weeds, should appropriate herbicides be approved for such purposes. Further, we note that these herbicides are currently approved for certain uses in Australia by the APVMA. • Access to biotechnology traits is important to our customers as it greatly assists their ability to sustainably manage their cotton production practices.	Noted. As indicated in the RARMP, if MON 88701 cotton is to be commercially cultivated in Australia, the formulations and new use patterns of the herbicides dicamba and glufosinate for use on the GM cotton must be approved by APVMA.

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	• Australia cotton growers have demonstrated their ability to responsibly manage cotton varieties containing both insect protection and herbicide tolerance traits since 1996. The technology has supported the continual improvement in environmental sustainability for the cotton industry since introduction.	
5 [redacted] 24 August 2020	Opposes the patenting of life forms, including genetically modified cultivars – supports the principle of non-patentability of gene sequences.	Patenting is outside the remit of the OGTR; any patenting issues should be addressed to IP Australia.
	Advocates alternatives to the use of herbicide resistant plants created by genetic modification. Argues that genetically modified cotton should not be used in Australia.	Matters relating to choice of different farming systems is outside the scope of the Regulator's assessment required by the Act.
	Should the licence be granted, there are a number of requirements that should be included. We need strong, transparent, precautionary, regulatory compliance and monitoring systems, to prevent GM contamination events.	The licence includes a number of conditions to ensure ongoing oversight of the release. This oversight will be achieved through post release review (PRR) activities that, depending on the outcome, may result in no change to the licence or could result in the variation, cancellation or suspension of the licence.
	Aware that a consultation RARMP has been prepared, which concludes that the proposed release would pose negligible risk to human health and safety or to the environment. Claims that this conclusion is based on limited evidence and does not adequately support ongoing oversight of the use of the organism.	The RARMP concludes that the commercial release of this GM cotton poses negligible risks to the health and safety of people. The RARMP was prepared using a combination of critical assessment of data provided by the applicant, review of published scientific literature, information on relevant previous approvals and any adverse effects of these releases, and advice received from a range of Australian government authorities, agencies, experts and the public. It was supported by a previous assessment by FSANZ who found that food derived from the GM cotton is safe for human consumption. In the context of the activities proposed by the applicant and considering both the short and long term, none of the risk scenarios postulated in the RARMP gave rise to any substantive risks associated with the GMO that could be greater than negligible. As mentioned above, ongoing oversight will be achieved through PRR activities.
	Suggests that the OGTR should require the applicant to provide the complete genome sequences of the parent and the GM cottons before any licence is	The full genome sequence of the parent organism *Gossypium hirsutum* is already publicly available, and the applicant has provided

Submitter	Summary of issues raised	Comment
	granted. Claims that these genome sequences are necessary for assessing the likely risks including those posed by genetic drift, making sure that the backbone sequences of plasmids used to transfer the genes into the cotton have not been transferred, and ongoing monitoring to identify any outcrossing or inter- or intra-species transfer of the (herbicide) tolerance genes. Suggests that as part of the post [release] review, there should be a requirement to monitor the GMO progeny population at different sites over time to identify if genetic drift has occurred and to precisely reveal the basis of any changes by genome sequencing. These sequencing steps would inform a better risk assessment of the organism and provide rigorous objective benchmarks, and enable standards and quality assurance systems to be effective. These steps would help to ensure that any license requirements are met and provide information that could alert regulators if unexpected genetic changes occur over time that could be problematic and require adaptive management, including cessation of use. Ideally, this research should be carried out independently and peer reviewed by an independent scientific panel.	data to show that the introduced genes are inserted into the genome as a single copy of the T-DNA containing the gene expression cassettes; no plasmid backbone sequences are present (see Chapter 1, Section 4.3.1 of the RARMP). The potential for harm to result from transfer of herbicide tolerance genes to other cotton or closely-related species (gene flow) have been considered in Chapter 2, Sections 2.2.2 and 2.4.4 of the RARMP and the associated risk was considered to be negligible. The applicant has provided data showing that the introduced herbicide tolerance genes are stably inherited through many generations in MON 88701 cotton without change (see Chapter 1, Section 4.3.1 of the RARMP). Genetic changes occurring by natural means, such as mutations and random genetic drift unrelated to the genetic modification, are outside the scope of the Regulator's assessment required by the Act. The licence holder is required to report any adverse or unintended effects of dealing with the GMO. The Regulator has the ability to vary, cancel or suspend a licence if a risk to human health and safety or to the environment is identified.
6 [redacted] 24 August 2020	Requests rejection of the licence application DIR 173 for reasons summarised below. 1. **Applicant unsuitable to hold a DIR licence:** challenges the suitability of the applicant to hold a licence because of litigation and overseas regulatory actions relating to the applicant and related companies. • Claims that overwhelming evidence shows that Monsanto/Bayer's actions have been frequently and intentionally egregious, without regard for the environment and public health, making the applicant unsuitable to hold a DIR licence. • Cites a list of court cases against Monsanto/Bayer in the USA as evidence to show that Monsanto/Bayer's 's products including herbicides, medical devices and medicines, have caused damages to the environment and public health, and have been punished by the US courts.	The RARMP prepared in relation to the proposed dealings considers the risks to human health and safety and to the environment posed by genetic modification being assessed in the application. The Regulator's decision regarding the suitability of the applicant to hold the licence involves a separate and additional consideration in accordance with sections 57 and 58 of the Act. The majority of the matters raised in this submission relate to the suitability of the applicant rather than the matters of the RARMP.

Submitter	Summary of issues raised	Comment
	• Claims that DIR 173 application is in breach of legal requirements in Sections 57 and 58 of the Act. Sections 57(2) and 58(2) of the Gene Technology Act 2000 require the OGTR to be satisfied of the applicants' suitability to hold licences. Claims that licence holders are required to meet contemporary community standards of probity, good standing and ethical behaviour.	The actions of related corporates internationally do not necessarily reflect on the Australian registered company (the applicant for DIR 173).
	• Requests that if the GTR's discretion under Section 54 (2) (b) of the Act was exercised in Monsanto's favour, the public needs to be advised of the basis on which this decision was reached and the evidence should be published, so the process and the decision are transparent and open to public scrutiny.	No such discretion exists with respect to providing documents to a person under Section 54 (2) (b). The subsection is clear that documents provided pursuant to that section must not include information about relevant convictions.
	2. **Environment:** The Gene Technology Act 2000 requires the OGTR to apply the precautionary principle and exercise a duty of care to dealings that may adversely affect the environment and public health. So the OGTR should only make a decision on DIR 173, when and if the APVMA and the Department of Agriculture, Water and the Environment have comprehensively assessed and cleared both dicamba and glufosinate for over-the-top spraying onto the cotton with GM traits.	The Regulator is required to seek advice from both the APVMA and the Department of Agriculture, Water and the Environment on the RARMP before making a decision.
	• Claims that the OGTR is duty bound to consider not only the genetics of MON 88701 cotton but also the direct and indirect collateral environmental damage that licensing a crop with dicamba and glufosinate tolerance traits would cause by enabling the repeated spraying of dicamba and glufosinate over cotton, anywhere in Australia. States that can only effectively occur through an open, transparent and public process between the OGTR, the product regulators and the Department of Environment. Chemical and GMO residues left in the environment, that may affect human food and animal feed supplies, also require such precautionary assessment. • Asserts that dicamba and glufosinate tolerance traits would enable the unchecked and repeated spraying of the herbicides over cotton plantations growing anywhere in Australia, including near major waterways and in water catchments that drain to the sea.	Many of the concerns raised in this submission relate to application of herbicides to the GM cotton and persistence of residues. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides, in Australia. The APVMA considers risks to human health, animals and the environment in assessing agricultural chemicals for registration and in setting maximum application rates, use patterns and maximum residue levels. The Regulator is also obliged to consult with the Department of Agriculture, Water and the Environment (formerly Department of Environment and Energy) on environmental aspects of the proposed release.
	• Comments that the Department of Environment has a key role to play in decisions about DIR 173 but its engagement is opaque and any advice it may have tendered is unpublished. Believes that all notes, transcripts, advice and correspondence between the OGTR, APVMA and the	Summaries of advice received for DIR 173 application and how they were considered are included in the Appendix A and Appendix B of the final RARMP. This includes any advice from the Department of

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	Department related to DIR 173 should be published and available for review as part of this public consultation.	Agriculture, Water and the Environment (formally Department of Environment and Energy).
	• Speculates that although no dicamba-resistant or glufosinate-resistant weed species have been recorded in Australia as described in the RARMP, it can be reasonably certain that dicamba and glufosinate resistant weeds will be generated before long if the herbicides are widely and repeatedly sprayed on cotton here. Claims that widespread glyphosate-tolerance in a variety of weeds in cotton crops appears to be driving the push for new herbicide tolerant GM cotton varieties like those proposed in DIR 173.	Managing the development of herbicide resistance comes under the regulatory oversight of the APVMA. The APVMA has approved registrations of glufosinate and dicamba herbicides for various weed control applications in Australia. Monsanto would need to apply to the APVMA for registration of over-the-top (OTT) use of these herbicides on the GM cotton. Issues relating to herbicide use are outside the matters to which the Regulator may have regard when deciding whether or not to issue a licence.
	• States that the APVMA PubCRIS database shows three registrations of glufosinate and glufosinate ammonium, but the applicants for DIR 173 approval are not the registrants. Believes that the OGTR must know and assess exactly what formulations of dicamba and glufosinate the APVMA will approve for spraying on the GM cotton, before reaching any conclusions on application DIR 173.	
	3. **Public Health**	
	• Links the approval of MON 88701 cotton with intensive spraying of glufosinate and dicamba herbicides. Claims that the OGTR has a clear responsibility to consult other personnel within the Health Department about possible increased public exposure to the herbicides to be sprayed over the GM cotton.	The Act requires the Regulator to identify and manage risks to human health and safety and the environment posed by or as a result of gene technology. The RARMP concluded that the commercial release of this GM cotton poses negligible risks to the health and safety of people and the environment.
	• Cites several journal articles about the adverse effects of glufosinate and dicamba to human health including some symptoms.	Issues relating to herbicide use are outside the scope of the Regulator's assessments. The APVMA has regulatory responsibility for agricultural chemicals, including herbicides, in Australia. The APVMA considers risks to human health, animals and the environment in assessing agricultural chemicals for registration and in setting maximum application rates and use patterns. Although the Regulator has approved dealings with MON 88701 cotton, APVMA approval would be needed before OTT herbicides can be applied to the GM cotton.
	• States that resolution of public health hazards and risks is required prior to any OGTR decision on MON 88701 cotton. If it is to be commercially cultivated in Australia, the APVMA must first consider and resolve issues around the toxicity of dicamba and glufosinate and their metabolites.	
	• Claims that it is unacceptable that the RARMP states "Data regarding the toxicity of DCSA is limited and some uncertainty exists." But then it asserts that, "From the available information, DCSA appears to be less toxic or equally toxic as parent dicamba for aquatic organisms on an acute basis, but may be substantially more toxic on a chronic basis	A brief discussion about the toxicity of dicamba metabolite DCSA is included in the RARMP (Chapter 1, Section 4.2.4) because DCSA is produced in the GM cotton following dicamba application. It is the responsibility of the APVMA to carry out a thorough risk assessment on the herbicides and their metabolites and make decision on

Submitter	Summary of issues raised	Comment
	to terrestrial organisms, specifically mammals." Claims there are big data and evidence gaps, which the OGTR would fill with best guesses under the Regulatory Science Regime that Australian regulators use. Approval of MON 88701 cotton would facilitate the exposure of terrestrial organisms, specifically mammals (including humans), to harmful dicamba and glufosinate herbicides and their metabolites.	whether or not to register the herbicides to be used on the GM cotton if such an application is received in the future.
	4. **Conclusion**	
	The OGTR must reject application DIR 173 as it would enable the selling, sowing and spraying of commercial MON 88701 dicamba and glufosinate tolerant cotton seed. The known hazards, risks and impacts of the crop itself, and the chemicals sprayed over-the-top of vast tracts of the crop, make this application absolutely unacceptable.	Noted.

[redacted]

From: [redacted]

Sent: Wednesday, 12 August 2020 11:33 AM
To: [redacted]
Cc: [redacted]
Subject: Financial suitability assessment for Monsanto Australia Pty Ltd [SEC=OFFICIAL:Sensitive]
Attachments: Bayer CropScience Holdings Pty Ltd financial assessment.xlsx; DIR-173 - Bayer CropScience Holdings Annual Report for the year ended 31 Dec 2019.pdf

Hi [redacted]

The following financial suitability statement for Monsanto Australia Pty Ltd is based on the information provided (Bayer CropScience Holdings Pty Ltd (Bayer) Annual Report 2019 – Parent company of Monsanto Australia Pty Ltd) to me, Bayer Financial Report for the year ended 31 December 2019 and the Auditor's report (conducted by Deloitte Touche Tohmatsu). Bayer has a financial standing with a **2.546 current ratio (total current assets/total current liabilities) and $198.593m working capital (excess current assets over current liabilities).**

In the Auditor's opinion, the accompanying financial report of Bayer CropScience Holdings Pty Ltd and its subsidiaries (together the "Group") is in accordance with the *Corporations Act 2001*, including:

(i) Giving a true and fair view of the Group's financial position as at 31 December 2019 and of its financial performance for the year then ended; and
(ii) Complying with Australian Accounting Standards – Reduced Disclosure Requirements and the Corporations Regulations 2001.

On the basis of the liquidity ratios and the auditor's report, there are no reasons to conclude that Monsanto Australia Pty Ltd would be incapable of meeting the conditions of its licence for reasons related to its financial position.

Note – Monsanto Australia Pty Ltd is a 100% owned subsidiary of Bayer CropScience Holdings Pty Ltd.

Should you have any queries, please do not hesitate to contact me.

Kind regards,

[redacted]
Finance Officer
Regulatory Support Unit

Office of the Gene Technology Regulator | CMO Group
Australian Government: Department of Health
[redacted]
Location: Level 11, Scarborough House, 1 Atlantic Street, Woden, ACT 2606
MDP 54, GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

Availability:
Working remotely – Monday to Thursday
Working in the office – Friday

From: [redacted]
Sent: Tuesday, 11 August 2020 4:19 PM
To: [redacted]
Cc: [redacted]
Subject: Financial suitability assessment for Monsanto_DIR 173 Minute 3 [SEC=OFFICIAL]

Hi [redacted]

I am currently preparing the Minute 3 package for DIR 173. Could you please provide an updated financial suitability assessment for Monsanto by 25 August?

Monsanto Australia no longer generates its own financial statement but it is covered by the Bayer CropScience Australia statement. Attached please find the latest Bayer CropScience Australia annual report for your assessment.

Thanks,

[redacted]