

29 January 2013

Dr Raj Bhula
Program Manager – Pesticides
Australian Pesticides and Veterinary Medicines Authority
18 Wormald Street
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Email: pesticides@apvma.gov.au

Dear Dr Bhula

RE: Call for public comment on ‘Draft Operational Notice – Data requirements for herbicides used in genetically modified crops’

On behalf of CropLife Australia, I provide the following comments on the *Draft Operational Notice – Data requirements for herbicides used in genetically modified crops*.

CropLife and our member companies acknowledge the proactive mechanism adopted by the APVMA in its consultation on this Operational Notice. The Authority’s approach to CropLife to provide early feedback in respect of the initial draft of the Operational Notice prior to making it available for public comment was greatly appreciated, and is a consultation model that CropLife would encourage the APVMA to maintain.

CropLife members had a number of overarching general concerns with the Operational Notice that are outlined below. These general concerns were brought to the attention of the APVMA at a meeting with CropLife on 15 January 2013, and are reiterated below. A ‘marked up’ version of the Operational Notice with specific suggested amended wording is provided at *Attachment 1*, as is a ‘clean’ version with the suggested changes accepted - *refer Attachment 2*.

General Concerns

CropLife is concerned that the APVMA has provided no scientific justification for limiting the Operational Notice to genetically modified (GM) herbicide tolerant crops. The three areas of risk identified in the Operational Notice are relevant to all herbicide tolerant crops, regardless of production method. The justification given to CropLife by the Authority that “GM crops are where the APVMA receives the most enquiries” is not based on science and is therefore not acceptable to CropLife. CropLife **recommends** that all references to ‘GM crops’ in the Operational Notice be replaced by reference to ‘herbicide tolerant crops’.

CropLife is also concerned that the scope of the Operational Notice does not accurately identify the range of applications that would be subject to the Notice. CropLife **recommends** that the scope of the Notice be clearly defined to only apply to applications for herbicide uses over the top of a crop that contains a herbicide tolerant trait where the particular herbicide tolerant crop has been previously commercially released in the Australian market.

The Operational Notice presently lacks consistency in regard to how it describes the method by which the herbicide is to be applied to the crop. CropLife **recommends** that 'over the top' usage of a herbicide product replaces any reference in the Notice to application of a herbicide 'to' or 'on' a crop.

CropLife **recommends** that reference to 'scientific argument' be included only in the 'Scope' section of the Operational Notice, with the intention that it applies to all sections of the Notice. Currently, there is confusion as to where 'scientific argument' will or will not be acceptable.

CropLife also **recommends** that reference to a 'Resistance Management Plan' be removed and replaced with a reference to 'Resistance Management'. CropLife has suggested revised wording for this section in the attached marked up version of the Operational Notice. CropLife has also suggested revised wording for the APVMA to consider around 'formulation adaptation' and 'conditions of registration'.

CropLife recognises that there may be a need for additional consultation should its recommendations be accepted, as this could increase the number of potential applications to the APVMA that would be affected by the Operational Notice. Taking into account the extent of consultation to date, CropLife would support a constrained additional consultation process, if required.

Please do not hesitate to contact CropLife's Policy Manager – Crop Biotechnology, Mr Osman Mewett, should you require clarification in respect of these comments. CropLife looks forward to the APVMA's consideration of the comments and to them being incorporated in the final version of the Operational Notice.

Yours sincerely

Matthew Cossey
Chief Executive Officer

ATTACHMENT 1
DRAFT OPERATIONAL NOTICE CROPLIFE MARK-UP SPECIFIC COMMENTS

Draft Operational Notice—Data requirements for herbicides used in-over the top of genetically-modified herbicide tolerant crops

Products covered: Agricultural chemical products

Purpose: Requirement

Takes effect: Upon publication on APVMA Website

Scope

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This notice clarifies the existing data requirements for registering a new chemical product or a variation to a chemical product that contains a herbicide active constituent for use in crops that have been genetically modified for tolerance to these active constituent over the top of a crop that contains a herbicide tolerant trait where the particular herbicide tolerant crop has been previously commercially released in the Australian market. For example, this includes, but is not limited to, the use of glyphosate or glufosinate on genetically modified (GM) herbicide resistant crops such as GM cotton and GM canola.

Herbicide resistant tolerant GM crops cultivars are designed-developed to be treated repeatedly over the top with the a relevant herbicide during an application window that is wider than would be the case in a non-GM herbicide tolerant crop.

The application of a herbicide to over the top of a GM herbicide tolerant crop may present increased risk in regards to:

- the efficacy & crop safety or phytotoxicity of the herbicide
- the resulting residues and
- potential development of weed resistance.

The An applicants for such herbicide product registrations, must address these areas of risk via the provision of appropriate data and/or scientific argument. The data requirements for each of the above identified risks arising from over the top use patterns for such products are described below.

Applicants should also refer to the applicable requirements and guidelines in the Agricultural Manual Of Requirements And Guidelines (Ag MORAG) in regards other relevant legislative criteria, relating to public, occupational and environmental health and safety. As the circumstances associated with chemical applications to GM crops are significantly different compared to conventional crops, it would be it is always beneficial to consider discussing requirements with the APVMA prior to commencing trials for data generation or lodging the registration application.

Comment [OM1]: It is better to be more concise here as it could be interpreted that criteria relating to public, occupational and environmental health and safety are somehow different in herbicide tolerant crops.

Efficacy & Crop Safety data

Efficacy and crop safety data must be provided from trials over two growing seasons of the GM herbicide tolerant crop using the specific formulation contained in the proposed new or varied product application. The trials must be conducted in-over the top of most recently-released cultivar of the GM crop that contains the relevant-specific herbicide tolerant trait crop for which over the top

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~~use is being sought and as per the contemporary industry practice.~~ Data from trials conducted on ~~GM cultivars with crops with superseded commercial herbicide tolerant~~ traits ~~or varieties previously released and superseded by new ones may not be~~ not acceptable.

~~GM crop cultivars~~ Herbicide tolerant crop varieties are grown under a wide variety of climatic and edaphic conditions. Therefore, crop safety data for the relevant herbicide must be generated from an appropriately representative number of growing regions. For example, GM herbicide tolerant cotton crops grown in hot (tropical) conditions are more susceptible to phytotoxicity when treated with certain herbicides. Applicants must provide appropriate data ~~and/or scientific argument on formulation adaptations to deal with such situation specific crop safety issues to satisfy the APVMA that the particular formulation for which over the top registration is being sought does not affect crop safety of the specific herbicide tolerant crop in all such representative environments.~~

Residue data

The ~~GM~~ trait conferring herbicide tolerance may alter the way in which the herbicide is transformed into a residue. Those transformation pathways may be quite different to the pathways in a conventional crop. OECD Test Guideline 501 clearly describes the situations under which additional metabolism studies need to be conducted for a GM herbicide tolerant crop to determine if the residue definition resulting from the application of a herbicide ~~to over the top of a GM herbicide tolerant~~ crop is different to the definition that results from use in a ~~conventional non-herbicide tolerant~~ crop. OECD Residue Chemistry Test Guidelines (external site) are available on the OECD website.

~~The requirement for a metabolism study applies for the use of a herbicide product to a new GM crop (including the use of a new gene or possibly a combination of genes in an existing GM crop), rather than to an existing GM crop.~~

~~The APVMA requires residues trials for the purposes of setting a Maximum Residue Limit (MRL) to be conducted on most recently released cultivar of the GM crop that contains the relevant trait. Data from trials conducted on GM cultivars with traits previously released and superseded by new ones are unacceptable.~~ GM Herbicide tolerant crops may modify the behaviour of the chemical

degradation pathways which therefore impacts upon the resulting residue profile. These pathways may respond differently to variations in formulation, application timings and rates when compared to those of conventional crops. The arguments that would be made for a ~~conventional non-herbicide tolerant~~ crop do not apply to GM herbicide tolerant crops and the over-the-top use of a herbicide. Assessment of residues data ~~for glyphosate and glufosinate~~ have established that the differences in residues concentrations of a herbicide used ~~in a GM over the top of a herbicide tolerant~~ crop when compared to a ~~conventional non-herbicide tolerant~~ crop can be significant and residues data will be required to support these uses.

~~The requirement for bridging or confirmatory data applies to the use of an existing herbicide to any new GM crop (or new use pattern for an existing herbicide), as well as use of an existing herbicide to an existing GM crop (or existing use pattern for a herbicide in a GM crop).~~ Comparability of

formulation, application timing and use rates are not considered sufficient grounds on which to make a determination on the adequacy of an existing MRL. Data or ~~Sc~~ scientific argument that may be provided for a ~~conventional non-herbicide tolerant~~ crop is not acceptable for a GM herbicide

Comment [OM2]: Suggest deleting this sentence to avoid confusion given the Scope of the notice is not to apply to new herbicide tolerant crops or new combinations.

Comment [OM3]: Suggest deleting this sentence as it is effectively repeated below.

Comment [OM4]: Suggest deleting this sentence as the Scope of the notice is limited in any case and this is simply a continuation of the data requirements.

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tolerant crop owing to possible variations in the response of the GM herbicide tolerant plant to the herbicide.

Residue Guideline 24 (RGL 24) outlines the numbers of trials that are required for different crops for the purposes of setting an MRL.

As with efficacy & crop safety trials, the APVMA requires residues trials ~~should to~~ be conducted on ~~appropriate cultivars~~ the specific herbicide tolerant crop for which over the top use is being sought, and in locations that are representative of the main growing regions in Australia. Data from trials conducted with superseded commercial herbicide tolerant traits or varieties are not acceptable. The maximum use pattern (as per label) must be trialled and samples collected, in accordance with the guidance provided in RGL 24. If the directions for use specify a variety of application timings, each trial must include a number of treatment regimens to ensure that the maximum residue scenario is addressed.

Please contact the ~~contact the~~ APVMA and discuss the trial protocol if unsure about the required number of confirmatory trials. ~~As current~~ Where the GM commercially available herbicide tolerant crops is are considered to be a major crops, GLP requirements will apply.

Resistance Management ~~Plan~~ and Conditions of Registration

The repeated application of a herbicide increases the potential for weeds to develop ~~ment~~ resistance to the active constituent/s contained in the herbicide product/s. The APVMA will impose specific conditions of registration that are designed to enforce the practice of preventative weed resistance management by users of the chemical product. ~~Applicants-Registrants are will therefore be~~ required to provide-implement an appropriate resistance management strategy that ~~provides users with~~:

1. Provides users with adequate instructions regarding the need for preventative resistance management on the product label.
2. ~~a specific resistance management plan (RMP) that is acceptable to the relevant grower organisation as signified by written approval from a duly designated/authorised officer of that organisation. Where a specific grower organisation is not identifiable or does not exist for the particular GM crop, the APVMA will consider imposing conditions on the registrant to convene~~ Includes consultation with a group of suitable group of experts ~~persons~~ for the purposes of consultation on matters of resistance management. Typically, for products used on GM cotton, approval of the CMP/RMP is required from the Transgenic and Insect Management Strategies (TMS) committee of the ACGRA, reviewing the ongoing adequacy of the strategy for managing resistance, determined in consultation with the APVMA.

Conditions of registration

~~Where appropriate, t~~ The APVMA will impose specific conditions of registration that are designed to enforce the practice of preventative weed resistance management by users of the chemical product and to also place obligations on registrants regarding the conduct of weed audits, the reporting of weed escapes identified from such audits, and taking follow up action to deal with weed escapes. These conditions are necessary as the use pattern is recognised as increasing the potential for the development of weed resistance to the active constituent.

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~~Applicants should also refer to the applicable requirements and guidelines in the Agricultural Manual Of Requirements And Guidelines (Ag MORAG) in regards other relevant legislative criteria relating to public, occupational and environmental health and safety. As the circumstances associated with chemical applications to GM crops are significantly different compared to conventional crops, it would be beneficial to discuss requirements with the APVMA prior to commencing trials for data generation or lodging the registration application.~~

ATTACHMENT 2
DRAFT OPERATIONAL NOTICE CROPLIFE – CLEAN

Draft Operational Notice—Data requirements for herbicides used over the top of herbicide tolerant crops

Products covered: Agricultural chemical products

Purpose: Requirement

Takes effect: Upon publication on APVMA Website

Scope

This notice clarifies the existing data requirements for registering a new chemical product or a variation to a chemical product that contains a herbicide active constituent for use over the top of a crop that contains a herbicide tolerant trait where the particular herbicide tolerant crop has been previously commercially released in the Australian market.

Herbicide tolerant crops are developed to be treated over the top with a relevant herbicide during an application window that is wider than would be the case in a non-herbicide tolerant crop.

The application of a herbicide over the top of a herbicide tolerant crop may present increased risk in regards to:

- the efficacy & crop safety or phytotoxicity of the herbicide
- the resulting residues and
- potential development of weed resistance.

An applicant for such herbicide product registration, must address these areas of risk via the provision of appropriate data and/or scientific argument. The data requirements for each of the above identified risks arising from over the top use patterns for such products are described below.

Applicants should also refer to the applicable requirements and guidelines in the [Agricultural Manual Of Requirements And Guidelines \(Ag MORAG\)](#) in regards other relevant legislative criteria. It is always beneficial to consider discussing requirements with the APVMA prior to commencing trials for data generation or lodging the registration application.

Efficacy & Crop Safety data

Efficacy and crop safety data must be provided from trials over two growing seasons of the herbicide tolerant crop using the specific formulation contained in the proposed new or varied product application. The trials must be conducted over the top of the specific herbicide tolerant crop for which over the top use is being sought. Data from trials conducted on crops with superseded commercial herbicide tolerant traits or varieties are not acceptable.

Herbicide tolerant crop varieties are grown under a wide variety of climatic and edaphic conditions. Therefore, crop safety data for the relevant herbicide must be generated from an appropriately representative number of growing regions. For example, herbicide tolerant cotton crops grown in hot (tropical) conditions are more susceptible to phytotoxicity when treated with certain herbicides. Applicants must provide appropriate data to satisfy the APVMA that the particular formulation for which over the top registration is being sought does not affect crop safety of the specific herbicide tolerant crop in all such representative environments.

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Residue data

The trait conferring herbicide tolerance may alter the way in which the herbicide is transformed into a residue. Those transformation pathways may be quite different to the pathways in a conventional crop. OECD Test Guideline 501 clearly describes the situations under which additional metabolism studies need to be conducted for a herbicide tolerant crop to determine if the residue definition resulting from the application of a herbicide over the top of a herbicide tolerant crop is different to the definition that results from use in a non-herbicide tolerant crop. [OECD Residue Chemistry Test Guidelines \(external site\)](#) are available on the OECD website.

Herbicide tolerant crops may modify the behaviour of the chemical degradation pathways which therefore impacts upon the resulting residue profile. These pathways may respond differently to variations in formulation, application timings and rates when compared to those of conventional crops. The arguments that would be made for a non-herbicide tolerant crop do not apply to herbicide tolerant crops and the over-the-top use of a herbicide. Assessment of residues data have established that the differences in residues concentrations of a herbicide used over the top of a herbicide tolerant crop when compared to a non-herbicide tolerant crop can be significant and residues data will be required to support these uses.

Comparability of formulation, application timing and use rates are not considered sufficient grounds on which to make a determination on the adequacy of an existing MRL. Data or scientific argument that may be provided for a non-herbicide tolerant crop is not acceptable for a herbicide tolerant crop owing to possible variations in the response of the herbicide tolerant plant to the herbicide.

[Residue Guideline 24 \(RGL 24\)](#) outlines the numbers of trials that are required for different crops for the purposes of setting an MRL.

As with efficacy & crop safety trials, the APVMA requires residues trials to be conducted on the specific herbicide tolerant crop for which over the top use is being sought, and in locations that are representative of the main growing regions in Australia. Data from trials conducted with superseded commercial herbicide tolerant traits or varieties are not acceptable. The maximum use pattern (as per label) must be trialled and samples collected, in accordance with the guidance provided in RGL 24. If the directions for use specify a variety of application timings, each trial must include a number of treatment regimens to ensure that the maximum residue scenario is addressed.

Please contact the APVMA and discuss the trial protocol if unsure about the required number of confirmatory trials. Where the commercially available herbicide tolerant crop is considered to be a major crop, GLP requirements will apply.

Resistance Management and Conditions of Registration

The repeated application of a herbicide increases the potential for weeds to develop resistance to the active constituent/s contained in the herbicide product/s. The APVMA will impose specific conditions of registration that are designed to enforce the practice of preventative weed resistance management by users of the chemical product. Registrants will be required to implement an appropriate resistance management strategy that:

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1. Provides users with adequate instructions regarding the need for preventative resistance management on the product label.
2. Includes consultation with a suitable group of experts for the purposes of reviewing the ongoing adequacy of the strategy for managing resistance, determined in consultation with the APVMA.

The APVMA will also place obligations on registrants regarding the conduct of weed audits, the reporting of weed escapes identified from such audits, and taking follow up action to deal with weed escapes. These conditions are necessary as the use pattern is recognised as increasing the potential for the development of weed resistance to the active constituent.