

Australian Grain Industry Guidelines for Notification of Release of non-GM Herbicide Tolerant Varieties

Issued by

The National Working Party on Grain Protection (NWPGP)



in association with

Australian Seed Federation



This document has the imprimatur of Australian Crop Breeders, CropLife Australia, GrainGrowers and Grain Producers Australia.

1. Purpose

These Guidelines suggest a recommended approach for the Australian grain industry in relation to notification of the impending release of non-GM herbicide tolerant varieties, in order to meet market requirements for chemical residues and thus maintain market access for those commodities.

2. Introduction

Herbicide tolerant varieties in the context of this document refer to “those varieties that are bred specifically to fully withstand the impacts of a particular chemical on the growing crop”. As such, when those herbicides are used, no detrimental effects on the growing crop arise.

The use of chemicals on grain in Australia takes into account a range of factors in relation to chemical residues including:

- The end user requirements of the Australian grain industry, being both domestic and export customers; and
- Regulatory requirements both in Australia and overseas.

Depending on the chemicals used and a range of other factors, there is a risk that chemical residues may arise in the harvested crop. If suitable maximum residue limits (MRLs) are not available in markets for that crop, market access may be at risk.

This document suggests a process for information sharing when these varieties are proposed to be released into the Australian grain industry. By using these Guidelines, international trade in these grains should continue and not be unnecessarily disrupted due to unmanageable chemical residues. Hence market access is supported.

These guidelines:

- Do not refer to the inherent resistance of a variety to a particular chemical;
- Do not apply to the release of GM crops, for which a separate industry agreed process occurs;
- Do not refer to any variety release where that commodity and chemical tolerant trait:
 - Has previously been released; and
 - Is approved for use with the same label directions; and
 - Is currently commercially available;
- Do not apply to non-herbicide tolerant crops;
- Apply only to chemicals used on herbicide tolerant crop varieties during the growing season, from prior to sowing to immediately prior to harvest.
- Include all varieties of grain (cereal grains, oilseeds and pulses).
- Are an adjunct to the emerging agreement being developed by the grain industry internationally on Plant Breeding Innovation.

- Do not prevent a Plant Breeding Company from releasing a variety under any circumstances, however it is the responsibility of the chair NWPGP to outline potential market access risks in relation to chemicals that may be used on those herbicide tolerant varieties due for release.

3. Key Industry & Government Stakeholders

Australian Pesticides and Veterinary Medicines Authority (APVMA)

- The APVMA is the Australian government statutory authority established to centralise the registration of all agricultural and veterinary chemical products into the Australian marketplace.
- The APVMA is responsible for assessing and registering pesticides and veterinary medicines proposed for supply in Australia.
- For further information see <http://apvma.gov.au/>.
- MRLs created by the APVMA are at <https://www.legislation.gov.au/Series/F2019L01105>.

Australian Seed Federation (ASF)

- The Australian Seed Federation (ASF) is the peak industry body for the Australian seed industry at the local, state, national and international level.
- Member companies of the ASF are listed on the website at <http://www.asf.asn.au/membership/asf-members/>

CropLife Australia

- CropLife Australia represents the innovators, developers, manufacturers, formulators and registrants of crop protection and ag-biotechnology products in Australia.
- Member companies of CropLife Australia are listed on the website at <https://www.croplife.org.au/about/our-members/>

Food Standards Australia New Zealand (FSANZ)

- FSANZ administers the 'Australia New Zealand Food Standards Code'.
- The code lists requirements for foods such as additives, food safety, labelling, GM foods and MRLs for Australian food.
- <http://www.foodstandards.gov.au/code/Pages/default.aspx>

Grain Growers Limited (GGL)

- Is a national body and leading voice for Australian grain farmers, representing their interests at a national and international level.
- For further information see <https://www.graingrowers.com.au>

Grain Producers Australia (GPA)

- GPA represents Australia's broadacre, grain, pulse and oilseed producers at the national level.
- Broadly stated, GPA was created to foster a strong, innovative, profitable, globally competitive and environmentally sustainable grains industry in Australia.
- For further information see <http://www.grainproducers.com.au>

Grain Trade Australia (GTA)

- GTA is the focal point for the commercial grains industry within Australia.
- It facilitates trade and works to provide an efficient, equitable and open trading environment by providing leadership, advocacy and commercial services to the Australian grain value chain.
- GTA provides commodity trading standards, develops and publishes trade rules and standardised grain contracts across the Australian grain industry.

National Residue Survey (NRS)

- The NRS monitors residues of agricultural and veterinary chemicals and environmental contaminants in Australian food commodities.
- For further information see <http://www.agriculture.gov.au/ag-farm-food/food/nrs/plant-product-testing>

National Working Party on Grain Protection (NWPGP)

- The NWPGP is the industry body responsible for providing management and leadership to industry in the areas of post-harvest storage, chemical use, market requirements and chemical regulations.
- Has members across the entire grain supply chain.
- Co-ordinates and provides government with industry views on chemical in use on grain and associated products.
- For further information see <http://www.graintrade.org.au/nwpgp>

4. Information Sharing on Release of Herbicide Tolerant Varieties

4.1 Variety Development and Release

Several plant breeding companies (including plant breeders, seed companies and other innovators, referred to in this document as a Plant Breeding Company) operate in Australia and are engaged in the development and release varieties for a number of grain crops.

Prior to commercial release, most varieties undertake an extensive review by each breeding company for a range of parameters including but not limited to:

- Agronomic traits such as yield
- Suitability to a cropping region
- Resistance to various diseases, pests etc.

As with all chemicals to be registered for use on a grain commodity, for those varieties bred specifically for tolerance to a particular chemical(s), there is the potential for residues to be produced on the harvested grain. Hence there is a need for a review of the implications on market access of release of that variety and the use of the particular chemical the variety is tolerant of.

Where that grain commodity / chemical combination with the same label directions has previously been commercially released on an herbicide tolerant crop, no review or action is anticipated to be needed.

Consideration of the use of these guidelines may include if:

- Market conditions (i.e., MRLs in destination markets) have altered since the initial release of the genetic trait.
- If the percentage of the commodity, with the herbicide tolerant trait, is likely to significantly increase (i.e., dominate) production in an agro-economic zone and may have a deleterious effect on market access.

4.2 Chemical Registration & Management of Chemical Residues

Prior to release of a new chemical or a proposed change in the label “Directions For Use” that includes a new crop commodity, the APVMA may release a Public Release Summary (PRS) or Trade Advice Notice (TAN) when there is a potential risk to international trade associated with the proposed use. The APVMA seeks community views on the implications of that use, including impacts on market access and international trade.

That APVMA public consultation process does not occur for chemicals already approved for use on specific commodities. It does not apply to a new variety that is tolerant to an already registered chemical as released by a plant breeding company when there is no change to the use of the chemical.

In Australia, all chemicals must be used as per the label “Directions For Use” and relevant legislation, for each commodity including application rates, crop growth stage restrictions and withholding periods. Different MRLs by commodity and chemical exist in Australia and overseas markets, with some markets also having different MRLs for grain intended for food and feed.

However, additional requirements apply to specifically bred herbicide tolerant varieties because residues may arise from the use of that chemical(s) that:

- May not be able to be managed by industry through normal supply chain quality assurance management programs; and
- May result in an MRL violation in a market where the MRL in that market is lower than that in Australia.

Given these varying MRLs, all stakeholders along the supply chain including breeding companies, chemical registrants, growers, storage providers and marketers should familiarise themselves with the MRL requirements of both their domestic and export markets before marketing those commodities.

Domestic and export grain is routinely screened for a range of chemicals. Targeted screening for specific herbicides occurs periodically in response to known use of those chemicals on an herbicide tolerant crop.

5. Information Sharing on New Herbicide Tolerant Varieties

This information-sharing process for reviewing the impending release of herbicide tolerant varieties has been designed specifically to determine if any chemical residues (through either the active ingredient or their breakdown products) have a deleterious effect on market access that cannot be managed by industry through various management practices. That is, the impending release and use of a specific herbicide on a crop that has been bred to be tolerant to a new herbicide use pattern that may lead to higher residues in that crop/commodity.

5.1 Scope of Information-Sharing

Only new varieties of a commodity being developed that are bred to be specifically resistant to one or more chemicals the use pattern of which are not currently commercially available are to be considered by this process.

The chemical(s) must be registered by the APVMA for use on that crop commodity.

5.2 Initial Consultation

For any contact, the lead is the Chair NWPGP. It is preferable that the information-sharing dialogue occur as early as possible during the development of those varietal traits, and well in advance of the anticipated commercial release of the variety. To provide as much notice as possible, the following timelines are suggested:

- For any new trait being developed, at least 5 years before release.
- For existing registered use patterns on a new crop or variety, at least 3 years notice.

5.3 Suggested Information to be Shared

A proforma document (Evaluation Process of Herbicide Tolerant Varieties due for Release) has been developed to document information that will assist in the evaluation of chemical residues and market access implications. In summary this document encourages provision of the following:

- The contact details of the Plant Breeding Company.
- The crop type of the variety to be released.
- The chemical(s) the variety will be bred to be tolerant to.
- The intended region of release of the variety (i.e., one or more States).
- The expected timeframe for commercial release.
- The expected market (i.e., domestic/export only, no restriction).
- Any chemical residue data to assist review of the implications of release on market access.
- If any commercial in confidence details exist.

It is recognised that in some circumstances residue data may not be available at the time of contact to progress development of MRLs in relevant markets.

5.4 Review Process

See the attached flow chart for a suggested consultation process.

Upon contact by the Plant Breeding Company, the Chair NWPGP, on behalf of industry, will review any material supplied and provide views on any potential market access impacts in relation to MRLs:

- a) If industry is expected to be able to manage any chemical residues arising and relevant MRLs are in place, and thus no significant market access impact is expected, advice will be provided and no further discussion is warranted.
- b) If industry is not expected to be able to manage any chemical residues arising (for example relevant MRLs are not in place) and thus significant market access impacts may arise, the Plant breeding Company will be advised. The Chair NWPGP will then in good faith, discuss the possible approaches to address any potential concerns.

All information provided by the Chair NWPGP will be provided in written form, in order for the Plant Breeding Company to fully understand industry views and for transparency in the process.

5.5 Timeline for Review Process

a) Initial Consultation

There is no set timeline for the assessment of any information provided by the Plant Breeding Company as this depends on a range of factors and each situation will be evaluated accordingly.

The Chair NWPGP will liaise with the Plant breeding Company in good faith to provide appropriate feedback as soon as practically possible.

b) Ongoing Consultation

Following initial consultation, if required, it is recommended that a timeline for ongoing consultation be agreed between both parties, in order to continue discussion on any matters to be addressed.

Given the market MRLs change over time, potentially prior to commercial release of the variety, the Chair NWPGP will provide updates on any changes or impending changes to MRLs in markets as they arise.

**PROCESS FOR INFORMATION SHARING OF NEW
HERBICIDE TOLERANT VARIETIES**

