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[26–16]

Supporting Document 2

Summary of issues raised in the submissions and FSANZ
response – P1027

Managing Low-level Ag & Vet Chemicals without MRLs

Table 1: Summary of issues raised and FSANZ response

Issue	Raised by	FSANZ response
Support P1027 and the use of an evidence based risk assessment process in developing the approach.	<ul style="list-style-type: none"> • Grain Producers Australia • National Working Party on Grain Protection • CropLife Australia • Queensland Department of Agriculture and Fisheries and Department of Health • Safe Food Production Queensland • Australian Grape and Wine Authority • Victorian Departments of Health and Human Services, and Economic Development, Jobs, Transport and Resources 	<p>Noted.</p> <p>FSANZ is committed to the use of internationally recognised scientific methodologies based on the best available scientific evidence in its risk assessment approaches. The P1027 approach reflects that commitment.</p>
Commends FSANZ for its initiative in developing this approach.	<ul style="list-style-type: none"> • Australian Grape and Wine Authority 	<p>Noted.</p>
The approach is a practical and balanced way to manage low level inadvertent chemical residues in food commodities; provides marketing advantages for food imports and domestic food trade, relief from the application of 'zero tolerance' and gives certainty and national consistency for the food industry and regulators.	<ul style="list-style-type: none"> • Grain Producers Australia • National Working Party on Grain Protection • Food and Beverages Importers Association • Queensland Department of Agriculture and Fisheries and Department of Health • Victorian Department Economic Development, Jobs, Transport and 	<p>Noted.</p> <p>The establishment of <i>All other foods except animal food commodities</i> MRLs using the P1027 approach, prevents the application of 'zero tolerance' to low level inadvertent agvet residues in food commodities assessed as safe, and prevents the violation of the Code by such foods.</p> <p>As stated in the 2nd call for submissions assessment summary (April 2016), an important principle underlying the approach is national consistency for regulators and the food industry.</p>

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It is consistent with the approach being pursued in various international wine trade forums.	Resources <ul style="list-style-type: none"> Australian Grape and Wine Authority 	
Support the <i>All other foods except animal food commodities</i> MRLs established for the 19 chemicals used to trial the approach as the levels are assessed as not posing health concerns to consumers. The approach allows control of use regulators to take actions required to improve chemical use practices among food producers.	<ul style="list-style-type: none"> Food and Beverages Importers Association Safe Food Production Queensland (Safe Food) Australian Food and Grocery Council Victorian Departments of Health and Human Services, and Economic Development, Jobs, Transport and Resources Queensland Department of Health 	Noted
The approach is not appropriate for highly toxic chemicals and those not permitted for use in primary food production.	Queensland Department of Health	Agree. The technical paper that accompanied the 2 nd CFS assessment summary showed the use of a robust risk assessment process including dietary exposure assessment for the Australian population for each agvet chemical. For an <i>All other foods except animal food commodities</i> MRL to be considered the agvet chemicals must already be listed in Schedule 20. To further ensure that the established <i>All other foods except animal food commodities</i> MRLs do not pose any public health and safety concerns, niche chemicals, vertebrate poisons and chemicals listed only in Schedule 7 of the Poisons Standard (the SUSMP), were excluded.

Issue	Raised by	FSANZ response
<p>Support FSANZ's decision not to adopt the <i>Default MRL</i> approach which does not address the increasing sensitivity of analytical methods to detect low level agvet chemical residues in food commodities.</p>	<ul style="list-style-type: none"> • Safe Food Production Queensland • CropLife Australia 	<p>Noted.</p> <p>The P1027 approach overcomes the limitations of the <i>Default MRL</i> model, recognises the potential for increased detection of low levels of agvet chemicals with advances in analytical technology, and complies with the Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food¹. The approach adopted as a result ensures that for each agvet chemical, the residue level permitted has been assessed, does not exceed the relevant health based guidance value and does not pose public health and safety concerns to consumers.</p>
<p>Propose use of a provisional or complementary <i>Default MRL</i> for all the agvet chemicals in the Code until <i>All other foods except animal food commodities</i> MRLs are established according to the proposed approach and to include inadvertent low level agvet chemical residues in milk and milk products.</p>	<ul style="list-style-type: none"> • Dairy Australia • Australian Grape and Wine Authority • Grain Producers Australia 	<p>Disagree.</p> <p>The aim of the Proposal and the approach developed does not allow for the use of interim <i>Default MRLs</i>.</p> <p>The approach establishes <i>All other foods except animal food commodities</i> MRL for permitted agvet chemicals with legitimate low level inadvertent residues in food commodities assessed as safe.</p> <p>It is intended that the establishment of <i>All other foods except animal food commodities</i> MRLs as proposed in the draft variation would, if gazetted, be an additional step that would be integrated into the regular FSANZ/APVMA MRL setting process and become part of the risk assessment process for all agvet chemicals into the future.</p>
<p>Would prefer the use of a general <i>Default MRL</i> approach, noting this approach has been used for years by other regulators without significant impact on public health and safety.</p>	<ul style="list-style-type: none"> • Australian Food and Grocery Council • Dairy Australia • Food and Beverages Importers Association 	<p>Noted.</p> <p>For the reasons listed in the Approval Report, FSANZ considers the approach of establishing an <i>All other foods except animal food commodities</i> MRLs to be the better option, having regard to the statutory requirements governing standards development. FSANZ also considers a <i>Default MRL</i> to be contrary to the Ministerial Policy Guideline as stated in the 2nd CFS assessment summary (April 2016).</p>

¹ The Ministerial Policy Guideline on the Regulation of Residues of Agricultural and Veterinary Chemicals in Food is available at [Guidelines on residue regulation](#).

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<p>Remain concerned the P1027 approach will not resolve the issues described by FSANZ and acknowledged by all stakeholders.</p>	<ul style="list-style-type: none"> • Dairy Australia 	<p>Disagree.</p> <p>The approach addresses the issue of applying 'zero tolerance' to low level agvet chemical residues present in food commodities due to inadvertent exposure through a robust scientific risk assessment, and that is agreed by most stakeholders.</p> <p>FSANZ's approach has also ensured that for each agvet chemical, the residue level permitted has been assessed, does not exceed the relevant health based guidance value and does not pose public health and safety concerns to consumers.</p> <p>The approach is not intended for all agvet chemicals without MRLs in the Code and does not support the use of registered agvet chemicals contrary to label instructions and good agricultural practice (GAP).</p>
<p>The approach is unnecessarily complicated, resource intensive and not timely in dealing with the immediate needs of food producers. It provides no certainty and therefore is of minimal benefit to the Australian food industry.</p>	<ul style="list-style-type: none"> • Food and Beverages Importers Association • CropLife Australia • Australian Food and Grocery Council • Grain Producers Australia 	<p>Disagree.</p> <p>In the 2nd CFS assessment summary, FSANZ noted that the development of any new scientific risk assessment methodology requires considerable effort and time, and that was the case with developing the P1027 approach. However, it does not mean the application of the approach to establishing <i>All other foods except animal food commodities</i> MRLs into the future has the same time implications. The details provided in the report were to show the specific considerations and risk assessment processes used.</p> <p>The approach readily fits into current MRL-setting processes used by both FSANZ and the APVMA, and will be used to establish <i>All other foods except animal food commodities</i> MRLs for other chemicals into the future.</p> <p>Stakeholders that support the approach stated that it provides relief from the application of 'zero tolerance' to these foods and consider it a practical and balanced way to manage low level inadvertent agvet chemical residues in food commodities.</p>

Issue	Raised by	FSANZ response
<p>The approach should discourage misuse of agvet chemicals particularly 'off-label' use, noting that residues arising from misuse are not distinguishable from those resulting from inadvertent contamination.</p>	<ul style="list-style-type: none"> • Queensland Department of Agriculture and Fisheries, and Department of Health • Pesticide Action Group WA • FoodWatch Consumer Group 	<p>Agree.</p> <p>FSANZ is mindful of this issue and addressed it through one of the principles underpinning the establishment of <i>All other foods except animal food commodities</i> MRL. The principle ensures that the values are set to adequately manage the risk of deliberate off-label use of a chemical compared to the inadvertent presence of the chemical. It is for that reason the analytical level of detection and already established MRLs for each chemical were taken into consideration in proposing the <i>All other foods except animal food commodities</i> MRL (see section 4 of SD1 – April 2016).</p> <p>The principles for the approach provide a consistent, appropriate and scientifically robust risk assessment process that used internationally agreed methodologies, and support GAP based on the approved use of the agvet chemicals.</p>
<p>The principles and processes should be formally agreed by both FSANZ and APVMA, and documented for endorsement by the jurisdictions through FRSC to ensure consistent implementation, transparency and confidence.</p>	<ul style="list-style-type: none"> • Queensland Department of Agriculture and Fisheries and Department of Health • Safe Food Production Queensland 	<p>FSANZ and the APVMA have a formalised arrangement regarding processes and protocols for setting MRLs. The arrangement is through a Memorandum of Understanding (MoU) that has been in place for many years and is reviewed as appropriate through the legal areas of the two agencies.</p> <p>FSANZ also provides regular updates to the jurisdictions in relation to its standard-setting work.</p>
<p>All new agvet chemical registrations and amendments to the Code could include considerations for setting <i>All other foods except animal food commodities</i> MRLs so that the necessary risk assessments are undertaken at that time.</p>	<ul style="list-style-type: none"> • Queensland Department of Agriculture and Fisheries and Department of Health 	<p>Agree.</p> <p>This is how FSANZ has structured the approach to work into the future and it ensures the process integrates seamlessly into the current FSANZ/ APVMA MRL-setting process. It is also seen as an efficient and effective way to establish <i>All other foods except animal food commodities</i> MRLs over time for agvet chemicals approved for use in food production in Australia.</p>

Issue	Raised by	FSANZ response
<p>Have concerns the new MRL category may be interpreted as applying to manufactured and mixed foods rather than single agricultural commodities. It could then extend to foods contaminated by chemicals used in premises to manufacture and process foods.</p>	<ul style="list-style-type: none"> Queensland Department of Health 	<p>Disagree.</p> <p>The prohibition imposed by paragraph 1.1.1—10(6)(d) and the permissions provided by Standard 1.4.2 apply to chemicals present in a food as a result of the use of agricultural or veterinary chemical products. See subsection 1.4.2—3(1) which explains that <i>'the permitted residue, of an agvet chemical means a chemical that is identified in Schedule 20 or Schedule 21 as being a permitted residue in relation to the agvet chemical'</i>. The Code defines the term <i>agvet chemical</i> to mean an agricultural chemical product or a veterinary chemical product, within the meaning of sections 4 and 5 of the <i>Agricultural and Veterinary Chemicals Code</i>.</p> <p>The Food Acts prohibit the sale of unsuitable food. The Food Acts provide that a food is unsuitable if the food contains, among other things, a chemical agent that is foreign to the nature of the food. Food is not unsuitable if, when sold, it contains an agricultural or veterinary chemical product in an amount permitted by the Code.</p> <p>The approach adopted as a result of P1027 also ensures that the permitted residue for an agvet chemical has been assessed, does not exceed the relevant health based guidance value and does not pose public health and safety concerns to consumers.</p>
<p>Would like to emphasise that there may be cases and justification for the inclusion of some veterinary medicines into the P1027 approach.</p>	<ul style="list-style-type: none"> Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources 	<p>Noted.</p> <p>In the 2nd CFS assessment summary, FSANZ stated that the exclusion of veterinary chemicals from the list of chemicals used to pilot the approach was because their use is species-specific and because of concerns about potential antimicrobial resistance.</p> <p>In addition, the report also stated that an amendment of the Code to include <i>All other foods except animal food commodities</i> MRLs for specific veterinary chemicals can be considered in the future through Proposals or Applications where the APVMA, as the national body for the registration of veterinary medicines, would be consulted.</p>

Issue	Raised by	FSANZ response
<p>The <i>All other foods except animal food commodities</i> MRLs should be included only in the <i>Food Standards Code</i> only so that the <i>APVMA MRL Standard</i> continues to be the primary reference of GAP for regulators.</p>	<ul style="list-style-type: none"> Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources. 	<p>Agree.</p> <p>The approved draft variation covering the 19 chemicals with established <i>All other foods except animal food commodities</i> MRLs is at Attachment A to the Approval Report.</p> <p>Listing the new MRL category only in the Code ensures that regulators can use the APVMA MRL Standard for monitoring control of use and GAP by food producers as required.</p>
<p>Requires information on how the approach would be applied overtime to set low level MRLs on a case-by-case basis for all the chemicals involved.</p>	<ul style="list-style-type: none"> CropLife Australia Safe Food Production Queensland 	<p>On page 16 of the 2nd CFS assessment summary (April 2016) FSANZ provided a diagrammatic summary of how the P1027 approach would integrate into the current processes that exist between the APVMA and FSANZ in setting and reviewing MRLs listed in Schedule 20. Parallel dietary exposure assessments will be undertaken to assess agvet chemicals presented for new or review MRLs, for suitability to establish <i>All other foods except animal food commodities</i> MRLs.</p>
<p>Canada, NZ, EU and Japan are considering moving to the proposed FSANZ approach, in part to address ADI complexities from the use of default MRLs.</p>	<ul style="list-style-type: none"> Grain Producers Australia (GPA) 	<p>Noted.</p>
<p>The public may perceive the P1027 approach as permitting increased presence of agvet chemical residues in food commodities, and the interests and concerns of individuals and community networks have been ignored.</p>	<ul style="list-style-type: none"> Queensland Department of Health Pesticide Action Group Western Australia 	<p>The P1027 approach does not permit increases in agvet chemical residue levels in food commodities. It provides protection for consumers by using a robust scientific approach to manage situations where low level inadvertent agvet chemicals may legitimately be present in food commodities.</p> <p>The public interest has not been ignored and to safeguard the public's trust in our commitment to a safe food supply, FSANZ has adopted a scientific risk assessment approach and the processes used have been made open to public scrutiny.</p> <p>FSANZ provided avenues for the public to comment on the proposal through two formal CFS reports. It continues direct formal and informal engagement with the public and other stakeholders through the MRL Contact point, and by providing information through the various FSANZ communication fora.</p>

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		<p>FSANZ's ultimate goal in developing food standards for Australia and New Zealand is to have a safe food supply and well-informed consumers. It therefore actively engages and maintains communication with all relevant stakeholders including community/ consumers groups and public health professionals during the development of any proposal as required by the <i>Food Standards Australia New Zealand Act 1991</i>.</p>
<p>How would the P1027 approach be managed so that it does not impact FSANZ's annual MRL harmonisation process?</p>	<ul style="list-style-type: none"> Australian Food and Grocery Council 	<p>The P1027 approach will not impact the FSANZ annual MRL harmonisation proposals which is to facilitate importation of food commodities into Australia by ensuring that the absence or magnitude of an Australian MRL does not pose a barrier to trade. The intention is to integrate the P1027 approach once approved into the annual MRL harmonisation process and assess the suitability of establishing <i>All other foods except animal food commodities</i> MRLs for agvet chemicals requested in future harmonisation proposals.</p>
<p>The Proposal addresses marketing difficulties of the food industry, lowers food quality control and ignores consumer health issues.</p>	<ul style="list-style-type: none"> Pesticide Action Group Western Australia <i>FoodWatch</i> Consumer Group 	<p>The proposal ensures that any food commodity presented for sale on the Australian market is safe for consumers and complies with the requirements of the Code.</p> <p>The presence of low level inadvertent residues of agvet chemicals that have been used as permitted in food production does not necessarily represent a food safety risk. However, to verify that the levels do not pose health and safety concerns to consumers, the approach FSANZ has developed uses the full risk assessment process including dietary exposure to assess the safety of the proposed levels for the Australian population.</p> <p>The approach does not compromise in any way the safety and quality control measures currently in place by various Commonwealth and State/Territory regulators. It also does not diminish the implementation, monitoring and enforcement of the Code by state and territory governments within Australia and by the Australian Government Department of Agriculture and Water Resources (DAWR) at the national borders.</p>

Issue	Raised by	FSANZ response
<p>There is increased global awareness of the dangers associated with use of agvet chemicals in food production e.g. glyphosate.</p>	<ul style="list-style-type: none"> • <i>FoodWatch</i> Consumer Group 	<p>In Australia, agvet chemicals cannot be used in food production unless they are registered and approved for use by the Australian Pesticides and Veterinary Medicines Authority (APVMA).</p> <p>FSANZ and the APVMA work together to set MRLs for approved agvet chemicals based on their registered conditions of use and GAP. State and territory regulators also monitor the use of these agvet chemicals by food producers.</p> <p>FSANZ, the APVMA and DAWR monitor the scientific literature for developments in the use of agvet chemicals in food production, including implications for the health and safety of consumers. These government agencies and others have followed closely international discussions regarding the use of glyphosate and appropriate actions have been undertaken as required based on the scientific facts.</p> <p>Information on how the APVMA registers and monitors agvet chemicals permitted for use in Australia is available at the APVMA website.</p>