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Australian Pork Limited
ABN: 83 092 783 278

PO Box 4746
KINGSTON ACT 2604

P 02 6285 2200

F 02 6285 2288

www.australianpork.com.au

Agvet Chemicals – Early Harvest and APVMA Reforms Team
GPO Box 858
CANBERRA ACT 2601

Via email: agvetreform@daff.gov.au

To the Early Harvest and APVMA Reforms Team,

RE: Australian Pork Limited's Submission on the Draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011

Australian Pork Limited (APL) is the peak national representative body for Australian pig producers. We are pleased to have the opportunity to comment on the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendments Bill 2011 (the Draft Bill) on behalf of the pork industry. Firstly, we congratulate the Government on progressing this well intended package of reforms. We can see positive aspects in all of the reforms proposed in the Exposure Draft of this Bill. However, we do have some suggestions and comments to make which may help the Reforms Team to address some potential negative impacts, before the Draft Bill is progressed.

1. Background information

APL represents primary producers, most of whom rely on timely access to the safest, most effective chemicals, especially veterinary chemicals, in order to produce the best quality, safest pork for Australian and overseas consumers. Our industry also relies heavily on the grains industry which also requires access to safe, effective, reasonably priced agvet chemicals.

The pork industry contributes approximately 2.13%¹ of total Australian farm production with roughly 1500 pig producers producing around 4.7 million pigs annually. The industry competes substantially with subsidised imports in the processed pork market (over \$9.4 million worth of pork imports arrive in Australia every week) but all fresh pork sold in Australia is Australian grown due to quarantine restrictions. The pork industry maintains a small export market to Asia and New Zealand with around 119 million² worth of pork exported from Australia in 2009-10.

¹ ABARES, Australian Commodities March Quarter, 2011.

² DAFF, 'Australian Food Statistics', 2009-10.

The pork industry takes responsible agvet chemical use seriously and self monitors safe chemical use through the Australian Pork Industry Quality Assurance Program (APIQ[✓]®) which covers 86 per cent of pig production. APIQ[✓]® requires producers to have documented standard operating procedures for chemical use; maintain detailed chemical use records; and be independently audited annually. Our National Residue Survey (NRS) results have not gone below 99.85% overall compliance with relevant Australian Standards for the past 10 years.

From the Australian Pork industry's perspective, efficient agvet chemical legislation must consider and balance the need to ensure: food safety, user safety, public safety, protection of environment and protection of trade markets; with the need to achieve efficient assessment times, be cost efficient, encourage innovation, and be practical.

Firstly it is positive to see progress on agvet chemical reforms. APL has participated in the agvet chemical reforms process beginning in 2010 when we made a submission for consideration in the Review of the Framework for Agvet Chemical Regulation. We also made a submission on the Policy Discussion Paper – *Better Regulation of Agvet Chemicals* in January 2011. Please refer to these submissions for a detailed overview of agvet chemical use in the pork industry and our further views on the chemical reforms process.

2. APL's Comments on the Draft Bill

While we can see positive aspects in all of these reforms, APL would like the Reforms Team to consider the following comments to assist in refining the Draft Bill before it is introduced into Parliament.

2.1 Decision-making using a risk based framework

APL supports the proposal to publish and implement a risk based framework to guide decisions about assessments, registrations and reviews of agvet chemicals to ensure a more efficient, predictable and timely registration process. We particularly support the intention to align assessment and regulatory effort with the level of risk posed by a chemical, in the interests of encouraging development and registration of safe, low risk agvet chemicals and to increase efficiency. It is difficult to comment further on the benefits and weaknesses of risk based decision making without access to the final risk based framework document.

2.2 Enhancing chemical review arrangement for existing approvals and registrations

We can see benefits in introducing a systematic, mandatory review process for existing chemicals rather than relying entirely on the current *ad hoc* system of chemical review. We agree with the need to be proactive rather than reactive when it comes to ensuring safety standards are met.

If a periodic review system is introduced, we believe it should exist alongside the current review system which allows the community, industry and the APVMA to trigger a review at any time a concern (e.g. a trade issue or user safety issue) arises. We also recommend the APVMA provides notification to agricultural industries when chemicals come under review and that chemical users are allowed to have input into chemical reviews, so that practical chemical use issues can be addressed in the review process. For example, chemical users can provide valuable information about changes in chemical application methods, changes in key trade markets, changes in production practices, and any issues with wording of labels that may have arisen since the chemical was last reviewed.

If periodic reviews are introduced this may present a risk that a perfectly safe and useful chemical may needlessly be taken off the market due to a delay in the review process, or due

to it not being profitable for a company or individual to participate in the review. This may negatively impact on agricultural producers needlessly. To help minimise the impact of this we recommend if a chemical is de-registered its use should be phased out, over a period of time, provided the risk associated with this is low. The review process should also be made as painless and least costly as possible for low risk chemicals to avoid discouraging their re-registration.

In general, it seems likely that introducing a periodic review system would put increased demand on APVMA resources which may counter the efficiencies gained from the reforms to the registration and assessment process for new chemicals. It may also add costs to the overall agvet chemical registration system which we believe would ultimately be paid for by agricultural producers. We suggest the Government should provide additional resources to the APVMA to implement this reform, especially considering that the need for reviews is partly due to changes in regulations and standards, and considering that the benefits of this reform - public and environmental health and safety - are public goods.

2.3 Improving the quality and efficiency of assessment and registration processes

We generally support the proposed reforms to speed up the chemical assessment and registration process. We support ensuring overseas data can be used to its full extent provided that all disparities between Australian and overseas production system have been considered fully. We recommend APVMA consult with the relevant agricultural industries when assessing the risk of using overseas data, to ensure all industry specific issues have been considered e.g. differences in production systems and environmental conditions in different countries.

We agree the proposed time frame measures for submitting data and completing applications are likely to increase efficiency and reduce the backlog of applications. This may give the chemical and agricultural industries more predictable timeframes for the availability of a chemical for use. However, care must be taken to set time frames that balance the need for efficiency with the need to ensure quality data is submitted and applications for useful, safe chemicals are not needlessly rejected due to time restrictions.

We can see some benefits in allowing the APVMA to omit trade and efficacy aspects from assessments of low risk chemicals where appropriate. This may make it more attractive or easier for companies to register low risk chemicals, or chemicals for minor uses where the expense of gathering trade or efficacy data may have been prohibitive. However, agricultural producers place high value on assurance in the areas of both trade and efficacy when using chemicals. We recommend brief consultation with relevant agricultural industries to establish whether or not it is appropriate to omit trade or efficacy components from assessments, to ensure all potential industry specific risks have been considered. Agricultural industry bodies can provide reliable data on key trade markets and potential risk of trade impact.

Where assessment components have been omitted, we suggest this should be noted on the product label if there is a risk associated with not doing so e.g. where there is potential that a vet might prescribe a drug meant for companion animals, for livestock, not realising it has not been assessed for trade impacts.

2.4 Enforcement

We support the proposed reforms that would provide APVMA with better investigative, compliance and enforcement powers, to improve compliance with their decisions. We agree this is a high priority reform, and important to maintaining public confidence in agvet chemical regulation. However, it may increase the workload of the APVMA and the cost of chemical regulation which may offset the impact of other efficiencies gained through this package of reforms.

2.5 Data protection

We support the proposed reforms to improve existing data protection provisions to ensure applicable data is not withheld from applications, and generation of data is not discouraged.

2.6 Arrangements for collecting Levies

We can see benefits in the proposal that levies be collected by a separate agency at arms length to APVMA, provided this does not lead to inefficiencies and increased administration costs. We understand that no levy increase is proposed in the Draft Bill though we have concerns that levy increases may result after the reforms have gone through based on the extra costs that seem likely to be associated with delivering these reforms.

From the Draft Bill it is hard to get a sense of how efficiencies gained will balance out with new workloads and costs associated with proposed new APVMA responsibilities such as mandatory periodic reviews for all chemicals and increased investigative and enforcement powers. It is particularly important to APL that these reforms do not inadvertently result in increased costs to agricultural producers, especially considering they are aimed at increasing efficiency and effectiveness of the agvet chemical regulatory system.

We remind the Reforms Team that any increased fees charged to chemical companies will simply be passed back to agricultural producers, increasing their cost of production and further reducing competitiveness with countries that subsidise inputs. We emphasise that many of the APVMA's functions directly benefit the community and can not be efficiently allocated to one party. The cost of providing safe chemicals, food and fibre to the community should not be borne by agricultural producers alone. We recommend the Government should provide increased funding if necessary to implement these reforms, rather than increasing levies charged on agvet chemicals and chemical registration fees.

In closing

APL can see positive aspects in all of the amendments proposed in the Draft Bill and we congratulate the Government and the Reforms Team on making progress in this important area of reform. We hope the Reforms Team now takes this opportunity to further refine this Draft Bill before it is introduced into Parliament, so that all potential benefits of these reforms can be realised.

Yours sincerely,



Kathleen Plowman
General Manager, Policy
Australian Pork Limited