



Animal Health Alliance
SOLUTIONS FOR THE FUTURE

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Quarantine and Biosecurity Review Secretariat
Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

Dear Sir/Madam

Quarantine and Biosecurity Review

The Animal Health Alliance (Australia) Ltd [the Alliance] is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community. A list of member companies is given in **Attachment A**. The Alliance welcomes the opportunity to comment on the *Quarantine and Biosecurity Review Issues Paper*.

The Alliance supports the principle intent of Australia's quarantine and biosecurity policies and risk assessment measures that manage the risk of entry, establishment or spread of pests and diseases not present in Australia that could cause significant harm to people, animals, plants and other aspects of the environment.

The Alliance has structured its submission to the Issues Paper by focussing on 4 key areas that have day to day impacts on Alliance member companies in dealings with AQIS and Biosecurity Australia (BA). These 4 key areas are:

- **ATTACHMENT B AQIS vaccine assessment timelines**
- **ATTACHMENT C AQIS assessment for pharmaceuticals containing ingredients of animal origin**
- **ATTACHMENT D AQIS TSE Policy**
- **ATTACHMENT E Export permit issuance**

The Alliance is available to clarify any issues detailed in this submission.

Yours sincerely

Dr Peter Holdsworth
Chief Executive Officer
Animal Health Alliance (Australia) Ltd

ALLIANCE MEMBER COMPANIES

Bayer Australia

Boehringer Ingelheim Pty Ltd

Elanco Animal Health

Fort Dodge Australia Pty Ltd

Intervet Australia Pty Ltd

Merial Australia Pty Ltd

Novartis Animal Health Australasia Pty Ltd

OzBioPharm

Pfizer Animal Health

Schering-Plough Animal Health

Virbac (Australia) Pty Limited

Ancare Scientific Ltd

Ruth Davis

Judith De Groot

Robyn Hammond

Allan Ross Runge

Tarj Mavi

Gordon Simpson

AQIS VACCINE ASSESSMENT TIMELINES

The Biologicals Program (BP) of AQIS issues 2-year import permits for veterinary vaccines and animal/plant/microbial ingredients for vaccine manufacture.

The veterinary vaccine and pharmaceutical industry (“Industry”) is strongly of the opinion that for many years the AQIS vaccine assessment timelines have been unacceptably long. Industry has repeatedly expressed this concern to AQIS senior management. Disruption to existing markets, delayed availability of goods and of new, contemporary vaccines to end-users is a direct result of AQIS’ long and unpredictable timelines and highly conservative approach to risk assessment. We have attempted to capture these reasons under the following points. Each point is structured to identify the **issue** and **impact** on Industry and other stakeholders.

1. Timelines for the assessment of new veterinary vaccines

Issue

Assessment of applications to import new veterinary vaccines by the BP is unacceptably slow. Over the last few years vaccine importers and manufacturers have found that new applications wait in a queue for up to 18 months before assessment is started. In an attempt to improve the situation the BP permits applicants to re-prioritise applications within their own list, meaning that 1 application can jump over another from the same company yet the delay to commence AQIS assessment is still too long and too unpredictable.

Once underway, assessment takes months to years to complete. Applications may spend months waiting for advice from Biosecurity Australia (BA) and applicant’s responses to AQIS questions can wait for many weeks before an assessor has time to recommence assessment.

AQIS committed in early 2007, after 2 years of intensive Industry lobbying, to maintain 1.8 FTE vaccine assessors. Over the subsequent 12 months this commitment has not been met, due to staff reallocation away from assessment of vaccine applications. AQIS has informed Industry that they are unable to fund more vaccine assessor positions to deal with the current backlog, or shorten assessment timelines because they operate on a cost recovery basis. Current fees are reportedly not even sufficient to cover 1.8 FTEs, let alone increase this level.

Industry has met with AQIS management on many occasions over the past 3 years, either individually or via the Alliance, to express concern about assessment timelines and staffing levels. Industry has proposed a number of initiatives to the BP including; Industry-funded assessors to deal with the vaccine backlog, providing a list of independent experts for use by AQIS and BA, arranging for industry employees to be on hand to provide additional information whilst applications are being assessed, participating in the training of new assessors, paying increased fees to allow increased resources in assessing vaccines.

Industry’s efforts have not been successful in improving the level of service provided by the BP. A lack of resources has been blamed on a number of occasions for the level of service provided but AQIS has been unwilling to consider increasing fees until 2008, or accepting additional resources. Most recently, several months after moving into new offices, AQIS has attributed resourcing problems to a simultaneous lack of suitable staff and available desk space. Further, it appears that new fees are currently under review and there is no movement to increase fees to appropriately staff this area.

Background

- Australia’s general public and production farming stakeholders rely on veterinary vaccines to prevent and control diseases in companion and production animals, to minimise death and debilitation, reduce antibiotic use and maximise animal production.
- Vaccines are made overseas and in Australia. Both Australian and overseas sourced animal, plant and microbial components are used, which require assessment by AQIS.

- All veterinary vaccines and animal, plant and microbial ingredients are assessed every 2 years by the BP against the relevant veterinary vaccine policies¹. These policies are peculiar to Australia and contain a number of specific requirements that are not consistent with international vaccine regulations. It is estimated by Industry that most new vaccine applications do not meet all points of AQIS' very conservative vaccine policy upon first review and therefore require time-intensive risk-assessment by AQIS and BA.

Veterinary vaccine manufacture is highly internationalised, due in part to the high building costs and regulatory requirements for vaccine manufacturing facilities. Vaccine seeds frequently originate from overseas research and development laboratories and are in almost all instances manufactured to meet European and /or USA vaccine and biosecurity requirements. Because the AQIS requirements depart so markedly from other international regulations, manufacturers have to conduct additional testing, change sourcing, or generate additional data to ensure that the requirements of AQIS vaccine policies are met either directly or via scientifically equivalent means.

Consequently, AQIS cannot simply assess applications rigidly against the policy but must frequently request advice from BA and make science based decisions about equivalent measures to address quarantine risk.

- Vaccine assessment is usually undertaken by senior science staff with a background or training in microbiology, an understanding of the specifics of vaccine manufacture and of relevant international regulations. Because of their background and seniority these staff are frequently reprioritised away from vaccines to other areas when there is need for senior technical staff. Examples of this over the last 12 months include the reprioritisation to address the Foot and Mouth Disease outbreak in the UK and the equine influenza issues in Australia.

Industry feels that at least 2.5 FTE senior technical officers are required to ensure sufficient staff levels to assess new and renewal vaccines, vaccine raw materials and in-vivo applications, to reduce the backlog, minimise delays in assessment times and ensure sufficient staff to provide input into other unplanned or emergency issues where a senior scientist is required.

- The BP has to operate on a cost recovery basis. Industry supports this concept and has experience with cost-recovered regulators such as the APVMA (Australian Pesticides and Veterinary Medicines Authority) and TGA (Therapeutic Goods Administration). Industry has been told that the BP cannot increase vaccine assessors to deal with the backlog because the vaccine application fees are not set high enough to cost recover².

Fees were last raised in 2006 and according to the BP manager at the time they were not set high enough to cost recover even then, yet no subsequent move was made by AQIS to increase fees until the first quarter of 2008, despite ongoing lobbying from Industry. Industry has repeatedly supported measures to increase staff levels and has investigated cross-funding an additional assessor or AQIS contracting-out components of the assessment to address the staff shortage. AQIS has repeatedly rejected these suggestions. Further, Industry is concerned that the currently mooted fee (April 2008) is still not sufficient to ensure an adequate number of vaccine assessors on a cost recovery basis. Industry supports increased fees as long as this results in increases assessors and reduced turnaround times.

Impact

- Australian production and companion animals are exposed to vaccine-preventable disease and deaths because international vaccines are not available in Australia in a timely fashion. Serious animal welfare issues have resulted in the past from the unavailability of certain vaccines such as a Pinkeye vaccine for cattle.

¹ AQIS Guidelines for Submissions to Import Veterinary Vaccines (1995)
Specific Quarantine Requirements for the Importation of Inactivated Bulk and Finished Veterinary Vaccines (1997)
Australian Quarantine Policy and Requirements for the Importation of Live and Novel Bulk and Finished Veterinary Vaccines (1999)

² AQIS assessment fees for new and renewal applications are based on a flat initial application fee for the first 4 hours assessment, then an ongoing hourly rate for assessment of \$15 per 15 minutes (\$60 per hour). This system should theoretically address the issue of cost recovery for large or complex applications that require many assessor hours.

- New veterinary vaccines developed overseas do not become available in Australia until 3 to 7 years after they have become available in the rest of the world. Part of this delay is due to the APVMA requirement for local efficacy trials for new production animal vaccines. These trials cannot be undertaken until AQIS assessment is complete.
- Industry is unable to predict the timeline to get a vaccine imported into Australia. This unpredictability makes it difficult to plan a vaccine development and registration project for Australia. Some companies have simply given up trying to import certain veterinary vaccines into Australia.
- Australian primary producers do not have access to contemporary international vaccine technology. They may not be able to use the best disease preventative available which ultimately negatively impacts their ability to compete in a global market. They may also be limited in choice of product and competitive cost. This ultimately impacts on primary producer costs and cost and quality of exported animal products.
- The cost of AQIS delays is unacceptably high. Time wasted in the AQIS “backlog queue” can be directly related to lost sales. Imported vaccines are assessed by AQIS and then APVMA. The APVMA has prescribed timelines which can be factored into a new vaccine development project whereas AQIS does not have time accountability and additional months or years spent in the AQIS “backlog queue” flows directly to months and years that the vaccine cannot be sold in Australia.

Cost of lost sales due to AQIS backlog and timelines is frequently calculated at over 1 million dollars per year. Industry argues that this cost is too high and can be readily remedied by AQIS via appropriate fees and staffing, yet AQIS appears to be unwilling to do so.

To address this issue the Alliance proposes as a solution that:

- AQIS sets the vaccine assessment fees at a suitable level to fund appropriate level of vaccine assessment staff.
- The BP to have fixed statutory assessment turnaround times to enable predictability.
- The BP recruit suitable staff and progress suitable training in vaccine manufacture, international regulatory requirements and science-based risk evaluation and management.

2. Timelines for the renewal³ of permits for veterinary vaccines

Issue

AQIS issues permits for both finished vaccines and for biological raw materials used for local veterinary vaccine manufacture. These permits are valid for 2 years. AQIS has committed to assess applications for permit renewals within an average of 21 days and while this target is acceptable to industry, it is not always met.

The 2 year permit duration is arbitrary. The BP undertakes reassessment even if there has been no change to the policies, the product and the level of risk since the primary assessment.

Because of staff shortages the BP usually asks the applicants to prioritise their assessments. Frequently a new application is delayed because staffing is short and it is more critical to existing sales to obtain a permit renewal. There are rarely enough staff for the BP to undertake a renewal and a new vaccine from the same company simultaneously.

Impact

- Products may become unavailable whilst awaiting renewal, negatively impacting both pharmaceutical companies and their customers (farmers, veterinarians and pet owners). Materials may be stranded on the docks and pharmaceutical companies are required to pay cold storage fees because of delays at AQIS.

³ The word “renewal” is informal and applies to the situation where the vaccine has already undergone a full AQIS risk assessment and a minor review is undertaken at the next 2-yearly assessment. AQIS import permits are valid for two years. Live veterinary vaccines are different and each batch of live vaccine requires a new permit which entails a minor review style assessment. For this reason in this document “renewals” refers to 2-year, inactivated vaccines, 2-year in-vivo permits and batch specific live vaccine permits.

- New vaccine assessments are delayed.
- Substantial resources are required by the applicants to prepare and submit renewal applications.

To address this issue the Alliance proposes as a solution that:

- The BP is appropriately staffed to enable acceptable timelines for assessment of renewals.
- AQIS and BA review the need for a 2-year permit duration. AQIS has the capacity to recall all permits of certain classes if there is a change in policy or in country or commodity disease risk.

3. Timelines for the receipt of advice for Biosecurity Australia and AQIS

Issue

Industry does not receive advice from AQIS and BA within a reasonable timeframe.

Where the product does not meet all of the conditions of the relevant policies AQIS formally requests advice from BA. This process is slow and is not transparent. BA is not accountable to industry, and cannot be contacted directly about a given application. Communication between AQIS and BA is a slow and bureaucratic process.

This results in long timelines as the application is shuffled between AQIS and BA to make a decision. There is a lack of transparency in BA decisions and frequently little explanation is provided by BA to identify the factors taken into consideration when making their decision. This is especially frustrating when the applicant has taken some time and cost to research and present a science based argument.

It appears that BA staff have minimal formalised training in vaccine manufacture or in international regulatory requirements. The consequences can be seen in the current vaccine policies where the policy requirements are at times almost unworkable within the framework of contemporary international vaccine manufacture.

Impact

In addition to the impacts listed previously, this results in significant delays in BA and AQIS advice and reduced confidence in the efficiency and effectiveness of these regulators.

To address this issue the Alliance proposes as a solution that:

- AQIS develops a service charter and commits to assessing applications and renewals within a fixed statutory timeframe (similar to other regulatory agencies such as the APVMA).
- BA is included in this charter and Industry becomes a direct stakeholder of BA.

AQIS ASSESSMENT FOR PHARMACEUTICALS CONTAINING INGREDIENTS OF ANIMAL ORIGIN

The Biologicals Program (BP) of AQIS issues 2-year import permits for veterinary pharmaceuticals which use animal or plant origin ingredients.

Many of the points raised in attachment B similarly relate to problems with AQIS assessment of permits for veterinary pharmaceuticals containing animal or plant ingredients. Industry is also dissatisfied with AQIS processes for assessment of this category of imported products.

Issue

Time and quality problems with re-issuing permits for products that have previously been imported into Australia.

There is an unacceptable level of inconsistency between assessors and over time. Different assessor's interpretations frequently result in different permit conditions at every 2 year renewal, despite no change to the policy, the product or its risk profile. This is exacerbated by the very high turnover of assessing officers. Permits frequently contain errors and have to be re-issued, reflecting on the quality control within the BP.

Changes to permit wording can result in major complications for overseas manufacturing sites preparing the import documentation for Australia. Manufacturer's declarations and declarations from overseas government inspection services have to be changed. The manufacturer must subsequently explain any AQIS changes to these organisations. The whole process results in time loss and frustration, with no apparent gain in risk mitigation for AQIS.

In some instances the permit requirements are unworkable. BP staff have a generally poor understanding of how USA and European government inspection services function and have issued permits with conditions that these agencies cannot realistically meet. Further, AQIS officers appear unwilling to consider advice from the applicant or the manufacturer about the suitability of permit conditions.

The BP does not review previous assessments, but repeats each assessment every 2 years. There is high staff turnover, limited corporate memory amongst assessors and apparently poor filing systems limiting access to previous assessments for the same product. This is inefficient and results in extended permit assessment timelines and unnecessary changes to permits as issues that have previously been assessed and adequately addressed are reopened.

Recently, an Alliance member company has had a product sold under valid AQIS Import Permits for 18 years referred to BA for re-evaluation. No reason was offered by AQIS for this need beyond seeking an assessment of risks relevant to the OIE lists of pathogens exotic to Australia. The TSE risk of the product was re-evaluated several times at past permit renewals. This repeated reassessment causes delay and uncertainty for supply of a product that has been imported and widely used in Australia for a number of years, has had its risk assessed many times previously, and is not subject of any newly-identified risks.

Extended assessment timelines mean that permits may expire before a reissued permit is completed. AQIS does sometimes provide an interim permit where they are directly responsible for timelines, but this only extends the period of uncertainty, and postpones the final AQIS decision, to a further round of increasingly desperate calls for attention from the applicant as the interim expiry date looms. Each delay results in product stranded on the docks and customers unable to access products they have been using for years.

AQIS officers set some requirements that do not address risk reduction. It appears this may be motivated by addressing the perceived obligation of AQIS to be implementing requirements of the Act or Regulations even when the procedures demanded do not reduce the actual risks, or are changed in a way that actually increases them. As an example, USDA (United States Department of Agriculture) declarations about origin and quality of biological ingredients were rendered inapplicable to an ingredient because AQIS insists that the USDA Inspector include in the declaration the batch identity numbers of the finished product! This despite manufacture of the product being remote from the preparation of the ingredient by several months and several thousand kilometres. Lengthy explanation to various AQIS assessing officers has failed to get

this changed. Indeed it appears the assessors are deaf to the illogic of separating the sanitary declaration from the inspector best situated to attest to the quality of the ingredient.

Lack of consultation is reflected in the BP telephone policy. There is only one number published, so all enquiries relating to veterinary vaccine and pharmaceutical enquiries, as well as all other enquiries to the BP, must phone this number. Direct telephone numbers for assessors are not available. The phone is manned only from 9.00am to 11.00am and 2.00pm to 4.00pm and it is frequently engaged. Receptionists refuse to address follow up enquiries (that is, not new matters) except by taking messages or connecting to a requested officer who has previously handled the matter if that officer happens to be at her or his desk. (Usually they are not). It is therefore difficult to directly contact the officer who is handling the application except via email. It is impossible to obtain a predicted timeline for permit issuance or to resolve an issue.

This communication procedure demonstrates an official view that enquiries are not to be encouraged and the needs of applicants for prompt information is of low importance to AQIS.

Issue

It is difficult or impossible to predict a timeline for new permits or renewals. This impacts significantly on shipping and supply. It is difficult to predict the conditions on a reissued permit. It is difficult to communicate with the BP if there is a problem with permit conditions or shipments.

To address this issue the Alliance proposes as a solution that:

- BP improve the filing system to enable them to retain and review previous assessments for a given product. BP to take previous assessments into consideration as well as safe history of use in Australia when assessing a renewal permit.
- BA and AQIS to review the need for 2-year permit life. As mentioned previously, the policies and the product rarely change. AQIS has systems to recall all permits should a country's disease risk change.
- BP improve telephone accessibility of reviewers for applicants.

AQIS TSE POLICY

Attachment B gives some insight into the culture in AQIS as one of “nil-risk”, unwilling or unable to make science-based risk evaluations. This is compounded by AQIS’ unwillingness to address concerns about veterinary vaccine and therapeutics assessment timelines. BA and AQIS approach to the vaccine and therapeutics TSE policy⁴ highlights the results of this “nil-risk” culture.

Completion of the vaccine and therapeutics TSE (transmissible spongiform encephalopathy) policy⁴

Background

The policy used by AQIS to assess the TSE risks for veterinary vaccines and therapeutics was initiated in the early 2000s and has been used by AQIS in its current draft form for the last 3 years, with no real commitment by BA to finalise the policy. Industry has made repeated requests to AQIS and BA to finalise the TSE policy, so that Industry can move forward in the knowledge that the draft policy will not change over the short term. In 2007 BA advised that it would be reactivated in Q1 2008, with a public consultation round, yet it appears that this work is currently “not prioritised” by BA for 2008.

The current draft policy is not based on contemporary scientific knowledge of TSEs and is not always in alignment with other Australian government TSE policies.

Industry is additionally concerned about the policy’s consideration of milk. The EU, USA, NZ and most other countries do not consider milk to present a significant TSE risk, while the AQIS policy does. This impacts significantly on imported vaccines and media, and has resulted in a series of inconsistent decisions by AQIS in 2007 when an international consignment of vaccine media, containing French-origin milk, was used in locally produced vaccines and overseas vaccines destined for Australia. Some products were permitted release and others prohibited, with no explanation of the inconsistency by AQIS and BA.

The cost of this inconsistency, and more broadly of the policy’s lack of consideration of contemporary science, was unacceptably high to Industry. Recently Industry requested BA to specifically review the TSE risk of milk, in recognition of the long timeline to complete the broader TSE policy, but this has yet to be prioritised within BA.

Impact

- Industry and AQIS are forced to operate with the uncertainty of an out-of-date, draft policy.
- Maintaining the policy in the draft form means that it is difficult to mount a legal challenge to the science behind inconsistent decisions made using this policy.
- The TSE policy’s consideration of milk creates a non-scientific and unnecessary burden on Industry.

To address this issue the Alliance proposes as a solution that:

- BA to prioritise review of the draft TSE policy for alignment with contemporary scientific knowledge, alignment with other Australian government policies via the Transmissible Spongiform Encephalopathies Advisory Committee and review by BA’s Eminent Scientist Group. The Industry-requested round of public consultation should be undertaken.
- BA and AQIS to provide transparency behind their decision making.
- BA to specifically review the TSE risk of milk in light of contemporary science, international regulations and other Australian government policies.

⁴ Requirements for Minimising the Risk of Transmitting Transmissible Spongiform Encephalopathies (TSEs) via Veterinary vaccines and Other In-Vivo Veterinary Products (Draft) August 2005

EXPORT PERMIT ISSUANCE

Attachment E considers the current regulatory approach to establishing approval to export traded commodities following application of veterinary medicines. The areas of discussion relate to:

- Process used to provide formal approval for export certification
- Transparency around the roles and responsibilities of key groups in this process
- What is an Appropriate Level of Protection (ALOP)

1. Perception of “nil risk” used in the decision process

The perception of “nil” apparent risk in regulatory decision making by AQIS and BA is manifested by the strict process of regulatory review and criteria used to satisfy the APVMA that registration of a veterinary chemical product will not unduly impact Australia’s trade in food produce that has been produced using the veterinary chemical.

APVMA seeks guidance from AQIS during the trade risk assessment of individual veterinary chemical product applications it receives. While the applicant will supply relevant scientific/analytical data on residue depletion for a product application, and also may provide evidence of industry producer support of the product application, AQIS is invariably approached by APVMA for advice on trade risk. The apparent “nil risk” attitude of AQIS is clearly seen in the position taken by APVMA in approving Export Slaughter Intervals (ESIs) for veterinary chemical products. The ESI time periods set can be manifestly conservative and make commercial reality for marketing many veterinary chemical products unlikely. To our knowledge, no other regulator of an OECD country manages trade risk by use of ESIs.

The issue industry is facing with setting ESIs has been compounded since the management of trade risk for veterinary chemical products has shifted from the Meat Livestock Australia (MLA) to the APVMA in 2005. Criteria for achieving a successful trade risk review by the APVMA have become more regimented given the change in group responsible for these assessments. It is apparent that historical decisions (pre 2005) that provide manifestly evident trade risks to Australia (e.g. Triflumuron products and Taiwan), will not be reviewed but that products currently being reviewed are assessed with a “tick the box” approach that was not apparent under the previous ESI assessment system. The industry also recognises the extensive recent changes to the global food trade industry where import tissue residue criteria are frequently used as non tariff trade barriers and all countries are driven to protect their export trade industries. An effective regulatory system designed to protect Australia’s export trade is essential, but Australian producer groups must also be able to remain competitive with other players by being able to access new technologies in a timely manner. Further discussion surrounding options to allow beneficial technologies to enter the Australian industry in the light of “apparent” export trade risk needs to be tabled. A suggested approach is to investigate the opportunities for trade agreements to involve more opportunities for transfer of technology without trade risk. The consistency of the current regulatory approach in providing equal market opportunities for similar products will continue to be explored by product registrants.

The previous system of ESI assessments conducted under the MLA must be considered to have been successful given the lack of trade issues caused by a tissue residue violation due to inappropriate ESIs being allocated. While the system of trade risk review has changed, registrants contend that the review process for assessing trade risk currently does not take into account any of the subtleties of trade risk assessment, e.g. Limit Of Quantification (LOQ) of the assay methodology used in the importing country, the sampling methodology used by the importing country and presence/absence of import testing procedures or lack of prior historical precedents.

2. Roles and Responsibilities for Trade Risk Sign-off

While legislation requires that the APVMA has the final sign-off on the trade risk assessment (Part 5b of the data package to register a product with APVMA) in assessing veterinary chemical product applications, the APVMA will not sign-off until AQIS have stated they will certify shipments of food produce containing acceptable residues of the veterinary chemical product in question to all key export markets.

The actual process remains unclear as AQIS are very firm that they do NOT make the final decision on trade risk as they do not “sign-off”, but will provide opinion on APVMA chemical product submissions when requested by that regulator. However, the opinion of AQIS forms a critical part of the final decision from APVMA.

Transparency and clarity surrounding the respective roles of AQIS and APVMA in signing off trade risk assessments would help with the perception of “nil risk” approach taken by the APVMA. The APVMA are currently using ABARE data to designate the key import markets to use for their ESI calculations. The make up of these key markets is currently under review as part of the ESI process review. Defined lists of countries required to be included into ESI calculations for smaller producer industries (e.g. sheep) are developed according to trade volume. The current approach to sheep is that the APVMA will take the top 6-10 countries as opposed to the beef sector where they currently assess the top 3 countries (to assess 90% of the trade). It must be noted that in only choosing 6-10 countries for the major sheep export markets, the APVMA is not taking a totally “nil risk” approach as this approach only covers approximately 65% of the total sheep meat export trade from Australia. However, a scenario where the ‘nil risk’ approach is evident is when a chemistry that would not need to be assessed within one country if it was a cattle product but **does** need to be assessed when submitted as a sheep product. This “nil risk” thought is accentuated when the value of the export market for sheep is much less than for cattle.

3. No clarity in use of science with respect to ALOP for ESI advice to APVMA

Currently with AQIS, the ALOP appears to industry to be the presence/absence of an approved Maximum Residue Level (MRL) in an importing trading country of Australia – nothing else. The presence/absence of the MRL within a country is the lowest risk approach by a regulator. It is a quantifiable country specific approved standard against which all tissue residues can be assessed. There appears to be no room for any interpretation of testing methodologies used, frequency of testing, current political activities in the country within this approach. While the system of trade risk review for new products has changed, registrants contend that a “tick the box” review of trade risk now does not take into account any of the subtleties of trade risk assessment that appeared to be included in pre 2005 assessments, e.g. LOQ of the assay methodology used, the sampling methodology used by the importing country, presence/absence of import testing or also historical precedents of products designed for the same species, using identical chemistry but manufactured in different formulations, being already used in Australia.

Use of LOQ as the ALOP

Currently the LOQ is used to control trade risk to countries that do not have an established MRL for the specific chemistry and where that country also does not refer to CODEX food standards. This is a key issue with respect to maintaining the product/chemistry innovation flow from the rest of the world into Australia. The current approach means that until the veterinary chemical product is registered and/or a MRL is set in the major trading partners of Australia, the product will not be available for use here due to the extended ESI that will be set. A suggestion is to incorporate mutual recognition of domestic MRL’s into Free Trade Agreements (c.f. NZ and Australia) to ensure innovation access for the Australian producer industries is not delayed.

Conclusion

The desired outcomes of the review our industry is seeking in relation to export issuances are:

- Improved transparency of AQIS processes and involvement in assisting APVMA in ESI determinations
- Predictability of outcomes by understanding the “risk culture” of AQIS with use of ALOP and advice on ESIs – what is AQIS’ understanding of ALOP and what training does AQIS staff have in ALOP?
- Clearer relationships between agencies/regulators and AQIS and clear allocation of decision making responsibilities to regulators.

Delayed access of product innovation into the Australian producer industries is a consequence that needs to be considered due to the current “nil risk” approach of using LOQ as the ALOP. The use of the LOQ as the ALOP for countries that do not have a MRL, nor do they recognize CODEX standards, creates a potentially unworkable product marketing situation in Australia which will deter companies from proceeding to market.