# Examination of Export Slaughter Intervals

## Final Report

**11 December 2018**

Building a better working world

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The results of EY's work, including the assumptions and qualifications made in preparing the report, are set out in EY's report dated 11 December 2018 ("Report"). The Report should be read in its entirety including this public release notice, the applicable scope of the work and any limitations. A reference to the Report includes any part of the Report. No further work has been undertaken by EY since the date of the Report to update it.

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# 1. Executive summary

EY was engaged by the Department of Agriculture and Water Resources (the department) to conduct an examination of the Australian Export Slaughter Interval (ESI) System. An ESI is the period that must elapse, between chemical application to livestock and their slaughter for export purposes, or after removal of grazing livestock to clean pasture or feed and slaughter where the livestock have been grazing the crop or pasture before the expiry of the export animal feed interval.[1] ESIs manage differences between Maximum Residue Limits (MRLs) in animal commodities allowed from uses of chemical products in Australia and the MRLs set by its trading partners.[2]

The project has involved a detailed study of residue management of both veterinary and agricultural chemicals in the current Australian ESI system. The system in Australia has been compared to the international market, specifically Brazil, New Zealand (NZ) and the United States of America (US). An analysis has been performed on the economic costs and consequences of the current system. Improvements based on findings have been suggested, and a series of recommendations have been put forth, based on the conclusions reached.

To inform the project, EY engaged in consultations with 37 stakeholders impacted by the regulation of chemical residues in domestic and international markets. Despite the international market's reluctance to share information due to concerns in regard to compromising competitive advantage, EY undertook extensive measures to organise consultations with relevant governing bodies in the international market, and these findings are documented within this report.

Based on the information and views provided by stakeholders, supported by desktop research and analysis, the following conclusions and recommendations have been identified.

## 1.1 Approach to trade risk management

There are differing points of view in relation to the current Australian approach to risk management. Stakeholders, particularly holders of registrations for chemical products, believe the approach is too conservative and warrants reform. Others, including those from the red meat industry, believe it is appropriate and should be maintained. The primary argument supporting the stance that Australia is too conservative is the claim that there is no equivalent ESI system in place in competitor countries, alongside the fact that violations have been infrequently detected.[3] Conversely, support for the current ESI system is based on ensuring market access is maintained given the importance of exports to the meat industry in Australia. When considering these two points of view the following has been noted:

- Market access is vital to the Australian meat industry.
- There is support from the meat industry for the ESI system, despite some economic consequences, and a willingness to trade off some productivity benefits to ensure market access is maintained.
- The Australian red meat supply chain is not integrated, with animals supplied for processing by a large number of producers from different properties and management regimes. This, combined with the variety of destinations to which red meat is exported, means that it would be expensive and inefficient to manage chemical residue requirements for individual products (in particular meat and offal). While Australia has strong traceability systems, extensive effort and additional cost would be required to segregate products for different markets. This is compounded by the reduction in flexibility it would create, as Australia has access to 77 different markets, and parts of a single animal may be exported to up to 30 different markets. Flexibility in determining the destination of different products is necessary to maximise profitability. Chemical residue management solely through specific segregation activities along a supply chain will therefore not be sufficiently effective in the current operating environment

[1] "Definition", APVMA, https://apvma.gov.au/node/1017, accessed 14/3/18

[2] "Pesticides and veterinary residues", APVMA, https://apvma.gov.au/node/26536, accessed 14/3/18

[3] Please refer to section 5.1.1.2 for historical evidence of international market concerns about specific residue limits, which if not addressed through the ESI system could have led to potential violations, and violations in the international market which have led to market access issues.

- Approaches taken by other countries cannot be directly compared with the Australian approach as there are a number of factors that differentiate Australia from its competitor countries. These include differences in relation to the importance of exports to the meat industry, reliance on quality and reputation to remain competitive in the market, trading partners and climate and production systems. There is a lack of appropriate alternative approaches to the management of chemical residues in the current operating environment that enable the achievement of the desired outcomes whilst mitigating the risk of exceeding chemical residue requirements of export markets. These outcomes include ongoing market access to major trading partners, maintenance of Australia's reputation as 'clean and green' with high value and high quality product, and the maintenance, growth and expansion of exports.

**Trade risk**

The approach to the regulation of chemical residues in exported meat products in Australia is based on ensuring international market access for Australian exporters with a low appetite for trade risk. There are mixed stakeholder views on the size of this risk and the likelihood of violations. This in turn meant that some stakeholders from the chemical industry questioned the appropriateness of the approach. Stakeholders noted two elements to the potential for residue violations to occur:

1. Firstly, meat products had to have chemical residue present at levels that did not meet importing countries' residue requirements.
2. Secondly, there needed to be identification and detection that these chemical residues were exceeding requirements.

Many stakeholders focused on the second element when raising issues with the current approach. However, it is noted that this does not necessarily reflect the management of trade risk but rather the probability of violation detections occurring. These stakeholders pointed to the international approaches outlined in Table 1 as illustrative of the successful management of risk, suggesting that these show different approaches which could be appropriate for Australia. However, there is a variety of factors which affect the implementation of these regimes that influence their applicability to the Australian market. These include the importance of exports to the meat industry (and therefore the effect of any trade market access issues), the operating environment including the nature of production and supply chain operation differences, and the requirements of markets to which meat is exported given that target markets vary.

As can be seen in Table 1, key differences have been found between the management of agvet chemical residues in animal commodities in Australia, and approaches in the international regulatory environment. Focusing on Australia's key competitors (the US, NZ and Brazil), Australia is the only country which has a separate slaughter interval for exports. The 'ESI endpoint' for each tissue in Australia is usually the lowest relevant MRL of a significant export market, or is a reasonable level of quantification (LOQ) in situations where no relevant MRL has been established by a significant export market.

Brazil, NZ and the US do not differentiate between slaughter intervals for domestic and international markets:

- Brazil relies on industry leading the management of chemical residues through its control of activities along the supply chain;
- NZ relies on the considerations of residue limits of its major trading partners and Codex Alimentarius (Codex), as well as on discussions and negotiations with importing countries; and
- The US does not take residue limits from major trading partners into consideration when managing residues, as its focus is on the domestic market.

**Table 1: Comparing the Australian and international approaches to managing chemical residues**

| Country | Approach to managing chemical residues | Similarities to Australia | Differences to Australia |
|---|---|---|---|
| ► NZ | ► No differentiation in slaughter intervals for the domestic and international market.<br>► WHP are determined through an assessment of the reference health standards such as the Ministry of Health's most recent National Nutrition Survey, chemical residue standards of major trading partners, Codex maximum residue limits, and correspondence with importing | ► MRLs are set and managed by the Government.<br>► The residue limits of different trading partners are considered when setting MRLs.<br>► Ongoing discussions are held with importing countries to manage residue requirements, e.g. acceptance of international (Codex) standards, acceptance of NZ standards. | ► One withholding period is set for products both in the domestic and export market, rather than a dual system (ESI and WHP).<br>► NZ will not register a chemical product with an export-driven WHP (not dealt with by OMARs) which is impracticable from an animal management perspective, i.e. is determined not to support good agriculture practice. Australia has |

| Country | Approach to managing chemical residues | Similarities to Australia | Differences to Australia |
|---|---|---|---|
| | markets to understand their requirements.<br>► Where countries do not have a MRL and they represent a significant market, Overseas Market Access Requirements (OMARs) can be used. OMARs are the requirements that the New Zealand government has agreed with governments of export destinations.<br>► If a WHP is considered too long and not in line with good agriculture practice, and could potentially lead to violations, the product is not registered. | ► A MRL can only be accepted if the estimated exposure is less than the relevant reference health standard.<br>► Where countries do not have a MRL and they represent a significant market, tighter sale and use restrictions can be put in place, such as OMARs, rather than imposing a longer WHP for all export markets. OMARs are the requirements that the NZ government stipulates for export destinations. OMARs can be used to place prohibitions or limitations on products destined for certain markets. OMARs are similar to the department's Market Access Advice (MAAs) and Meat Notices (MNs). | more flexibility in this scenario as it can still have a domestic WHP, even if the ESI is impractical.<br>► NZ often considers a different pool of country trading requirements, given NZ sell meat products to trading partners other than Australia.<br>► A smaller number of trading partner MRLs are considered.<br>► The residue limits are generally not decreased to the limit of quantification to accommodate trade with countries without MRLs, except where there is a particular sensitivity.[4] Instead, NZ places a larger reliance on Codex. It is noted this is not always the case in Australia but anecdotal evidence suggests this happens more often. |
| *Applicability of chemical residue management in NZ to Australia* | | ► The use of one withholding period for products in both the domestic and export markets could be applied in Australia but it would decrease flexibility (i.e. would no longer allow shorter domestic WHP if the ESI was unworkably long). It is found that while the current system may often default to the ESI (due to uncertainty about the final market destination of parts of an animal), the dual system still provides some additional flexibility, particularly if other measures have been taken to differentiate products for the domestic market.<br>► OMARs could be implemented in Australia but may limit the number of markets Australia has the ability to export to. Australia implements Meat Notices (MNs) and Meat Access Advices (MAA) that have a similar role to NZ OMARs. However, market specific requirements make the system more complicated to implement and increasingly prone to failure.<br>► Rather than ensuring residue levels are decreased to the level of quantification, greater reliance could be placed on Codex in Australia. However, this will increase risk to market access, and give less importance to countries with residue requirements more stringent than Codex. | |
| Brazil | ► No differentiation in slaughter intervals for the domestic and international market.<br>► Industry leads management of chemical residues in export markets, and it is the responsibility of processors to ensure compliance.<br>► Residue management for vertically integrated industries such as pork and poultry is managed in Brazil through industry-led control activities along the supply chain, based on the destination intended for consumption. Vertically integrated industries have a greater ability to manage market eligibility for different parts of a commodity based on the slaughter interval i.e. different parts of a commodity can have different WHPs applied. | ► Samples are collected to perform testing by the Federal Inspection Service, similar to the NRS in Australia, to verify controls on veterinary drugs and residues are adequate.<br>► Investigation sub-programs are established when a violation is detected. | ► Chemical residues are managed only through activities along the supply chain, in comparison to Australia where additional measures such as WHP and ESIs have been introduced to ensure appropriate chemical residue limits are applied.<br>► Brazilian abattoirs separate product based on the interval between treatment and slaughter and different product types (liver, kidney, muscle etc.) might have different slaughter intervals for the same market and for different markets. Different parts of an individual animal have different set withholding periods, for instance a different limit can be set for offal in comparison to the remaining parts of the carcass. This occurs for beef, and vertically integrated supply chain products such as poultry.<br>► Compliance with importing country residues limits are industry-led rather than through a government department or agency. |
| ► *Applicability of chemical residue management in Brazil to Australia* | | ► Brazil's approach relies on supply chain control by industry and represents a higher risk appetite. Chemical residue management solely through activities along the supply chain is not appropriate for Australia in the current operating environment due to the large number of producers, the large number of trading partners, the importance of exports, and the inefficiency and expense which will be currently generated to trace animals on an individual basis. It | |

[4] There have been instances in Australia where the reasonable LOQ for ESI considerations may not be the lowest validated LOQ for and active constituent if the APVMA has previously used a higher LOQ as an ESI endpoint for that active. See section 3.4.

| Country | Approach to managing chemical residues | Similarities to Australia | Differences to Australia |
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| | | has been deemed that this would not be sufficient to maintain market access to the many premium markets Australia currently has access.<br>► Residue management could be industry-led rather than through the department, and initially this was the case when ESIs were established and monitored previously by Meat Livestock Australia about nine years ago. Under the trade criteria set in Australia, however, the system is relied on to help meet a regulatory responsibility (that the APVMA be satisfied there is no undue trade risk when registering a chemical use) and should sit with government to enable appropriate oversight and to ensure the criteria are met. While it is still the registrant that must provide evidence to satisfy the APVMA, it is more logical that residue limits are set by the APVMA as it has access to relevant data (other than supplied by the applicant) and the relevant expertise. | |
| USA | ► No differentiation in slaughter intervals for the domestic and international markets.<br>► The MRLs of trading partners are not taken into consideration when determining residue standards for veterinary drugs, as the focus is primarily on the domestic market in the US. The tolerance is determined after a final Acceptable Daily Intake (ADI), safe concentration, target tissue and marker residue are selected. | ► Management of chemical residues is initiated and monitored by the federal government.<br>► Information on petitions to create tolerances, and documents that establish or revoke tolerances, or creates exceptions to tolerances is made publically available. | ► Most animal products are consumed domestically and, as a result, residue management focuses on the domestic market, rather than the export market.<br>► Established veterinary drug MRLs used by trading partners are not taken into consideration at all in the US. The tolerance is determined after a final ADI, safe concentration, target tissue and marker residue are selected. |
| ► *Applicability of chemical residue management in the US to Australia* | | ► The approach taken by the USA (for veterinary drugs not to take trading partners MRLs into consideration) is not applicable in Australia where there is far greater dependency on the export market. The degree of risk this approach would generate in Australia is not appropriate.<br>► The large domestic market in the US means there is less of an industry-wide consequence should there be a problem of access to an export market i.e. a higher risk tolerance for industry. | |

The approach taken to the management of trade risk in Australia demonstrates a low appetite for risk by the meat industry, due to the large dependency on the export market. While other countries have different levels of risk tolerance, much of this can be attributed to differences in operating environments, target markets, the relative importance of exports to the domestic industry and government policy positions based on assessments of risks and consequences.

**The importance of ESIs to Australia's reputation**

When considering the importance of ESIs to Australia's reputation as 'clean and green', EY noted the following:

► The current 'clean and green' reputation Australia holds is vital in supporting trade and underpinning the value proposition of exports. All stakeholders unanimously held the view that it is Australia's reputation for quality products which provides Australia with competitive advantage within the market.

► Australia's reputation for high quality, safe products allows higher prices to be charged for products, while still remaining competitive in the market.

► The ESI system is one of many factors that has contributed to Australia's reputation over time. There are many rigorous systems and standards, in addition to the ESI system, that have been put in place to protect the meat product integrity (including residue controls, traceability and animal welfare) which exist throughout the entire supply chain, including farms, feedlots, saleyards, transportation, processing and distribution.

► The susceptibility of Australia's reputation to violations is evident, where the detection of one violation alone has sometimes been sufficient to stop market access to a country.

As Australia's reputation is a result of multiple systems and standards which are in place to ensure quality products, it is difficult to determine the extent to which ESIs have contributed to this reputation. The extent to which ESIs have influenced Australia's reputation will also vary between countries. However, measures

taken to ensure the quality of Australian products plays an important role in maintaining Australia's reputation, and ESIs are providing a positive contribution to this.

**The economic impact of the current approach**

In Australia, recent practice has been for ESIs generally to apply only to cattle, sheep and pigs.[5] The APVMA expects that these species will continue to account for the significant majority of Australian ESIs (almost all in fact). This study has therefore focused on these commodities, with a particular emphasis on red meat.

There are a limited number of cattle and sheep products with ESIs significantly longer than the set WHP. Long ESIs can affect productivity if a product is avoided, due to the ESI setting. It can impact the welfare of sheep or cattle, profitability and flexibility (if other treatment options are not available). Producers may be reluctant to apply products with long ESIs as it may limit flexibility in their management practices particularly the ability to offload stock at short notice.

The current Australian approach therefore influences producer access to chemicals and places limitations on innovation with consequential economic impacts, such as reduced producer productivity and flexibility. It also creates additional costs for agvet product manufacturers and places limitations on their ability to sell certain products.

However, market access is a key priority for producers. From the meat industry's perspective the priority given to market access outweighs the costs to productivity since a violation that hinders access to a market could significantly impact the returns earned by producers.

As the meat industry is willing to make the trade-off to maintain market access, it was concluded that, although there are costs to producers associated with the current approach, the economic impact is relatively low in the short term at least, for the meat industry. There is a need for the longer-term economic effects to be monitored by the department, the APVMA and the meat industry. For example, chemical resistance may become more significant in the future (due in part to restrictions on available chemical tools due to ESI concerns, where producers may have no tool for treating an expanding range of pests as a result of a great increase in the economic impact).

While Australia is the only country of those examined with a dual system in place (ESI and WHP) it is recommended that the dual system remains. The WHP gives the Australian meat industry the ability to sell strictly to the domestic market if needed.

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| **Recommendation 1** | It is recommended that the current ESI approach be maintained, noting there are areas for improvement as outlined. This is because the low risk appetite and the current regulatory approach is supported by all sectors within the meat industry, given the importance of exports. The meat industry expressed a view that while there may be trade-offs (such as access to chemicals and the effects on costs and/or productivity) it is willing to accept these trade-offs to ensure there is a low risk of affecting market access. |

**Alternative approaches**

Stakeholders have identified a number of alternative approaches, these include:

- Enhanced supply chain control resulting in the ability to set different ESIs for different parts of a commodity or for different destination countries and the management of products to ensure differing requirements are met.
- A less conservative methodology for setting ESIs which does not result in relying on LOQ when a country does not have an MRL established; and/or
- Solely relying on government trade policy and additional in-market support to work with countries to build capacity and an understanding of risks.

5 "Markets for consideration in export slaughter interval determination for cattle, pigs and sheep", APVMA, https://apvma.gov.au/node/618, accessed 14/3/18. This study has therefore focused on these commodities, with a particular emphasis on red meat.

Details on the potential alternative approaches have been outlined in section 5.1.5. These alternative approaches, however, all have challenges in terms of implementation and/or effectiveness in the current operating environment. The current operating environment influences the practicality of these approaches as well as the ability of these approaches to manage risk to the same level as the ESI framework.

Currently none of the suggested alternatives will produce the same outcome as the existing ESI system. The outcomes include the level of risk management which ensures confidence within the market to maintain ongoing relationships with major trading partners, maintaining Australia's current reputation as 'clean and green' with high value and high quality product and the growth and expansion of exports within the meat industry.

As technological advancements occur over time, and the operating environment changes, the feasibility and appropriateness of alternative approaches may change. For instance, the enhanced use of technology may lead to improved traceability of specific carcass portions and enhance the ability to transfer of information at lower costs. This may allow chemical residues to be managed through alternative methods such as additional supply chain controls where eligibility decisions for individual animal parts/products are made based on animal specific information rather than the current situation where decisions are based on information for a cohort (lot) of animals.

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| **Recommendation 2** | Changes in the operating environment should be monitored by the department and the APVMA, and when significant changes are identified, consideration should be given to the appropriateness of alternatives to the current Australian ESI system.<br><br>A key element of this process would entail all affected parties (particularly government, and stakeholders such as the meat industry and chemical industry) working collaboratively to design, test and implement any changes. |

**International approaches**

A number of holders of registrations for chemical products suggested that international approaches to manage residues were more appropriate than the Australian ESI system. However, there was a lack of understanding about the actual residue management process in these overseas markets, and the unique factors that influenced their appropriateness.

Factors which influence chemical residue management, such as reliance on exports, climate, population, other regulatory and industry measures and trading profile, were often not taken into consideration by the chemical industry stakeholders when comparing the Australian system with the international market. While competitors may share aspects of the following factors, these factors combined often differentiate Australia from competitors within the international market:

- **Reliance of exports:** as the size of Australia's domestic market is relatively small in comparison with the quantity of production, Australia is heavily dependent on its export market. Australia exports to a wide spread of markets, and the continuation of trade to these markets sometimes requires compliance with more restrictive market access requirements, in comparison to competing countries. The benefits of exporting to a wide spread of export markets is the return made on trade. Different commodities (and parts of a commodity), can be traded with trading partners that will pay the highest return, due to preferences and value held for certain products.

- **Reliance on reputation to remain competitive in the market:** as the cost of labour is high, Australia heavily relies on product quality and attributes to focus on high value markets, this includes its reputation as 'clean and green' to remain competitive in the market.

- **Trading partners:** Different countries have different trading partners who in turn have different requirements and approaches to trade. Australia has a significant number of trading partners, with different requirements to maintain market access.

- **Climate and production systems:** Australia's climate, production systems and supply chains encompass a wide range of animal husbandry and management regions, which may require different treatment options with different chemical product compositions.

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| **Recommendation 3** | There are roles for different players such as the department, the APVMA, meat industry stakeholders and chemical industry member representation organisations to work with the agvet industry to raise stakeholder understanding of approaches in the international market for managing trade risk and the reasons for any differences. Key differences between country profiles and the broader regulatory frameworks should be highlighted.<br><br>It is noted that the research and analysis undertaken for this project could be used to facilitate this. |

## 1.2 Improvements to the current system

There are differences between stakeholders' understanding of how the APVMA determines an ESI and what happens in practice in Australia. Transparency in the process is required to provide a consistent understanding of the application of the APVMA's methods and factors the APVMA actually considers when setting an ESI. The list of trading partners considered, for instance, has left many registrants with the impression that the requirements of all trading partners within the list will be determining factors for each product, when in practical terms this is not the case and can vary on a product-by-product basis.

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| **Recommendation 4** | Although there is publicly available information published by the APVMA on the methodology it uses to determine ESIs, it needs to include more detail on the process implemented, with easier navigation and a rationale for certain elements of those methods. The current guidance in relation to the methods used to set ESIs should be updated and made publicly available. The focus of this guidance should take into account the issues raised by stakeholders, such as a need for a clearer understanding of the approach taken when a country does not have an established MRL. |
| **Recommendation 5** | The current application of trade partner consideration should be clarified. In addition, the trade partner list should be updated in line with changes in major markets. The frequency of the updates should reflect a balance between providing industry with certainty, and consistency, and providing up-to-date market information. EY recommends that an update be undertaken every 5 years. |

Communication between the APVMA and stakeholders (including the chemical industry and state regulators) could be improved. Although there are channels for contacting the APVMA directly, both formally and informally[7], the frequency of communication and the ability to have targeted discussions are all factors raised when stakeholders commented on the sufficiency of communication avenues. Discrepancies in regard to understanding the ESI process, the methodology and associated issues are stemming from inadequate communication. It is noted that existing avenues for contacting APVMA are available but stakeholders have reported that these are mostly generic contact numbers and stakeholders suggested that it was difficult to understand the exactly who would be able to assist them.

Additional communication avenues will enable greater stakeholders understanding of the ESI process, and aid relationship-building between stakeholders within the sector.

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| **Recommendation 6** | Additional communication channels should be developed to provide industry guidance on the methods, process and issues associated with the development and management of ESIs. A number of different channels should be developed, such as between the chemical industry registrants and the APVMA (specifically between chemical industry representative bodies and the APVMA), peak meat industry bodies and the APVMA, and state regulators and the APVMA. These channels should allow for the initiation of discussions by the chemical industry, the meat industry, state regulators and the APVMA. |
| **Recommendation 7** | While there are generic contact details provided on the APVMA site, clarity should be provided by the APVMA to the agvet chemical and meat industry on the most appropriate personnel within APVMA to contact about ESI issues. |

[7] The information currently published on appropriate personnel has been detailed in section 3.4.

There is a lack of understanding of the factors needed to trigger an ESI review as well as the processes in place to do so. While there is a willingness on the part of the APVMA to undertake regular reviews, given the resource requirements involved, the periodic review of all ESIs is not practical. Further, the analysis undertaken in this report demonstrates that not all products have ESIs significantly longer than WHPs and therefore may not need regular review. Further clarity on the process in place to review ESIs from the APVMA, will allow for greater pro-activity from the chemical registrants to initiate ESI reviews more regularly.

Currently any applicant can apply at any time to have any relevant label particular reviewed (this is detailed further in section 3.4). Any lack of understanding of the factors needed to trigger an ESI review can be addressed by providing clarity on the processes in place to conduct an ESI review. For example, there may be a misconception that any ESI review needs to be supported by new, expensive technical data but this may not be the case if the driver behind the review is a market factor such as a less restrictive residue requirement for a market.

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| **Recommendation 8** | The process in place to review ESIs should be included in publicly available guidelines, and transparency should be provided on the methodology used to conduct a review. The APVMA should document the process of review and the factors that can change ESIs, such as a new trading partner or a new MRL. This will enable the chemical industry to have a clearer understanding on when and how to initiate ESI reviews. |

# 2. Background and context

This chapter provides the background and context to the study by outlining the details of the project, the limitations, the approach used, and the structure of the report.

## 2.1 This project

EY was engaged by the Department of Agriculture and Water Resources (the department) to conduct an examination of the Australian Export Slaughter Interval (ESI) system.

An ESI is the minimum time that should elapse:

- between the last treatment of an animal with a veterinary chemical product and the slaughter of that animal for export, or
- after the removal of grazing livestock to clean pasture or feed and slaughter, where the livestock have been grazing the crop or pasture before the expiry of the export animal feed interval.[8]

ESIs manage differences between Maximum Residue Limits (MRLs) in animal commodities allowed from uses of chemical products in Australia and the MRLs set by its trading partners.[9]

In Australia, recent practice has been for ESIs generally to apply only to cattle, sheep and pigs.[10] The APVMA expects that these species will continue to account for the significant majority of Australian ESIs (almost all in fact). This study has therefore focused on these commodities, with a particular emphasis on red meat.

The aim of the study is to undertake an examination of Australia's ESI system to evaluate whether the current arrangements are the most appropriate for meeting the residue standards of Australia's export markets. In particular the project was required to:

- Deliver a detailed report examining the Australian ESI system that is suitable for public release.
- Examine how and why some ESIs set by other countries (via government or industry arrangements) differ from those established by the Australian system, and the costs/consequences of these differences (as assessed qualitatively).
- Reach conclusions about whether the Australian ESI system is the most appropriate mechanism for meeting the residue standards of our export markets and recommendations on what, if any, viable alternatives exist and what improvements can be made.

The study sought to investigate four primary elements:

- The current Australian ESI system.
- International approaches to the management of chemical residues and associated trade risks.
- An examination of the importance of ESIs to Australia's trade reputation in relation to export of red meat.
- A qualitative exploration of the economic consequences of applying different ESIs to certain chemicals and diseases.

The study's full terms of reference can be found at Appendix A.

This study is one of a number of studies initiated by the department to investigate factors influencing the productivity of the agricultural and veterinary (agvet) regulatory system.

8 "Definition", APVMA, *https://apvma.gov.au/node/1017*, accessed 14/3/18

9 "Pesticides and veterinary residues", APVMA, *https://apvma.gov.au/node/26536*, accessed 14/3/18

10 "Markets for consideration in export slaughter interval determination for cattle, pigs and sheep", APVMA, https://apvma.gov.au/node/618, accessed 14/3/18

## 2.2 Limitations of the study

It is noted that detailed information on the operation of chemical residues management and the approaches to the management of trade risk in the international market is not generally publicly available. As a result, this study has had to rely on stakeholder consultations to gain this information. Therefore the study has been limited to the extent of knowledge of the stakeholders consulted, and their willingness to share this information. For example, the extent to which residue testing is conducted by importing countries could not be obtained by direct consultation with the importing countries. This was most likely due to concerns about allowing such information to be disclosed in a public report.

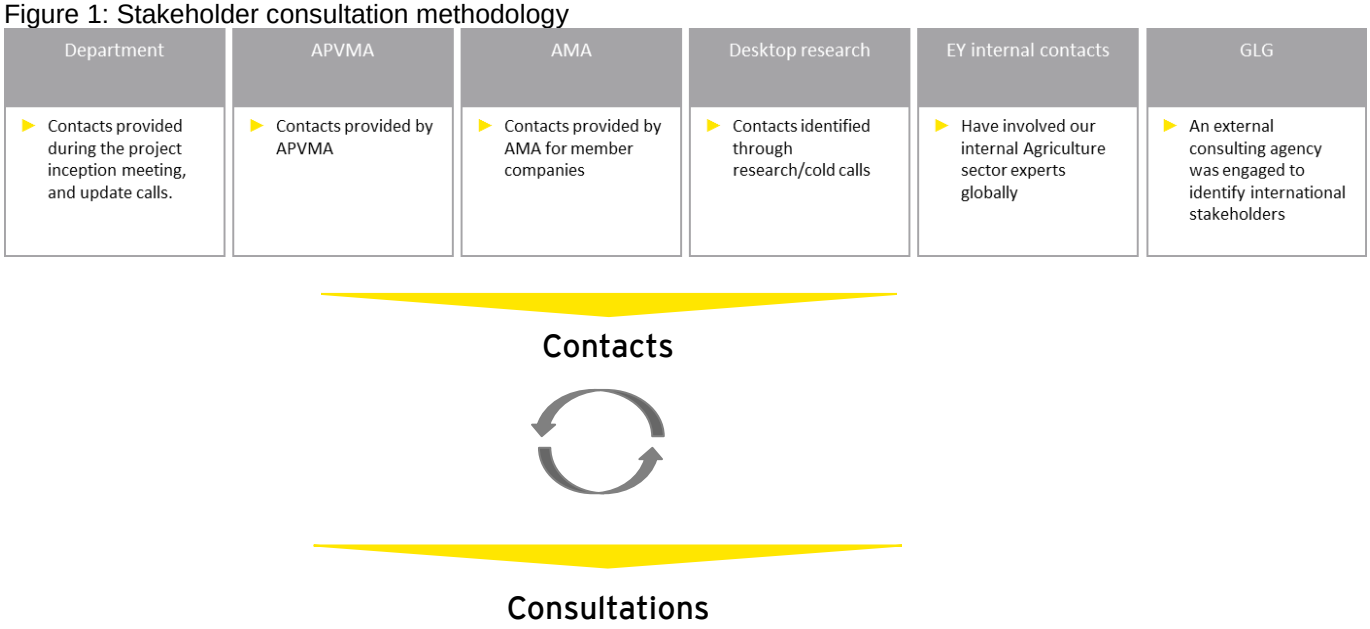
## 2.3 The approach

The project entailed:

- A detailed desktop study of the current Australian ESI system, including both agricultural and veterinary chemicals.
- A consolidation of views of stakeholders from organisations in the production-meat export supply chain about their understanding and the application of the ESI system, key issues associated with the current regulatory framework and potential alternative approaches.
- An examination of how and why some ESIs set by other countries for equivalent products, specifically Brazil, NZ and the US (government or industry arrangements) differ from those established by the Australian system, and the costs/consequences of these differences. Specific focus was given to the management of risk in Australia, through the establishment of ESIs, in comparison with the international market.
- An investigation of the value of Australia's ESIs to Australia's broader trading reputation as a 'clean and green' source of export produce.
- A qualitative analysis of the economic consequences of applying differing ESIs for Australian exported produce compared with the same produce exported to the same overseas market by other countries supplying that market.
- Conclusions about whether the Australian ESI system is the most appropriate mechanism for meeting the residue standards of Australia's export markets and recommendations on any viable alternatives or improvements which could be made.

Findings within this report were obtained through a mixture of desktop research, consultations with key stakeholder groups and workshops with staff from the APVMA and Department of Agriculture and Water Resources. Numerous avenues were used to engage with stakeholders. Figure 1 shows the methodology used to obtain contacts. Contacts were obtained through the department, the APVMA, Animal Medicines Australia (AMA), desktop research, EY's global network and Gerson Lehrman Group (GLG). GLG is an external research and consulting firm that facilitates consultations with key global industry bodies and it was specifically engaged by EY to ensure that informative and experienced international stakeholders were consulted.

Figure 1: Stakeholder consultation methodology




EY engaged in numerous consultations with a variety of stakeholders involved in the regulation of chemical residues in the domestic and international markets, including the export meat industry, key government departments, chemical manufacturers and regulatory bodies. A total of 37 stakeholders were consulted to inform the project. A full list of stakeholders can be found at Appendix B. In the international market, specific focus was given to Australia's key meat export competitors – Brazil, NZ, and the US. It should be noted that whilst ESIs apply to a broad range of commodities, the majority of stakeholders that participated in the study from a farm production point of view were red meat and pork industry stakeholders (despite other industry representative organisations being contacted).

EY worked closely with the department and the APVMA to understand and document the current Australian regulatory framework. In addition to regular meetings and reviews, EY facilitated a workshop and key meetings with department staff, non-government representatives and APVMA representatives to confirm the methodology of the current system, gain an understanding of the history of ESIs and discuss issues identified during stakeholder consultations. This supplemented the consultations held with meat and chemical industry stakeholders.

## 2.4 This report

This report outlines findings from the independent assessment of the ESI system. It includes views from both domestic and international market stakeholders, a qualitative assessment of economic consequences, reputational consequences, and information on other frameworks implemented to manage residue limits by other countries. The structure is as follows:

- Chapter 3 outlines the current Australian framework including the role of ESIs, the approach to establishing ESIs, the operation of the ESI system, the roles of participants and the regulatory framework.
- Chapter 4 details international approaches to the management of chemical residues in exported meat in key competitor countries – Brazil, NZ, and the US.
- Chapter 5 reports the findings in relation to the operation of the Australian ESI system in two key sections. The first section outlines views and analysis in relation to the current approach to risk management, and the second section explores suggested improvements to the current system.

# 3. The current Australian framework

This chapter details the operation of ESIs in Australia. It begins by providing an overview of Australian red meat and pork production and exports to provide context. It then details the role of ESIs, the current regulatory framework, the approach to establishing ESIs and the operation of the ESI system.

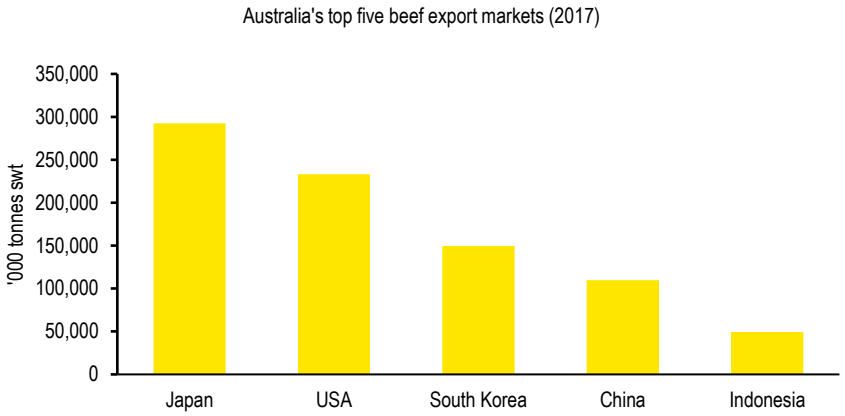
## 3.1 Country profile[11]

Australia is a key player in the global meat export market. In 2017, it was the third largest beef exporter (following India and Brazil) and the largest exporter of sheepmeat (followed by New Zealand and the United Kingdom).

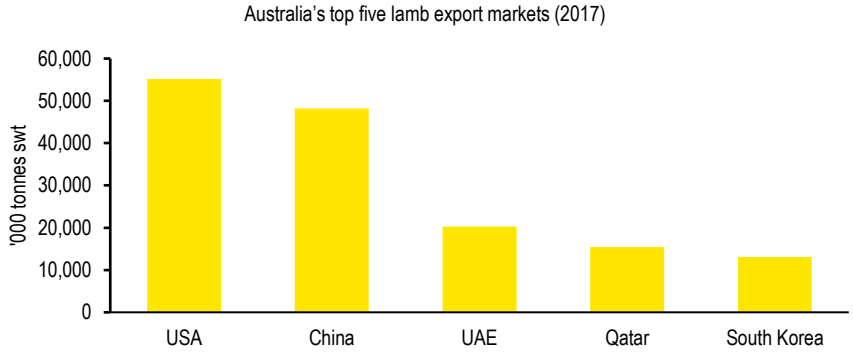
Red meat and livestock exports totalled approximately $13.3 billion in 2016–17, approximately 41% above 2012–13 levels. Australian beef exports totalled 1.01 million shipped weight tonnes (swt) 2017.The value of Australian sheepmeat (lamb and mutton) exports in 2017 was $3.04 billion.

Australia's trading partners span numerous countries. As shown in, Japan was Australia's largest beef export market in 2017, taking 292,364,000 swt. Japan's market share of Australian beef exports in 2017 was 29%, followed by the US (23%) and Korea (15%).

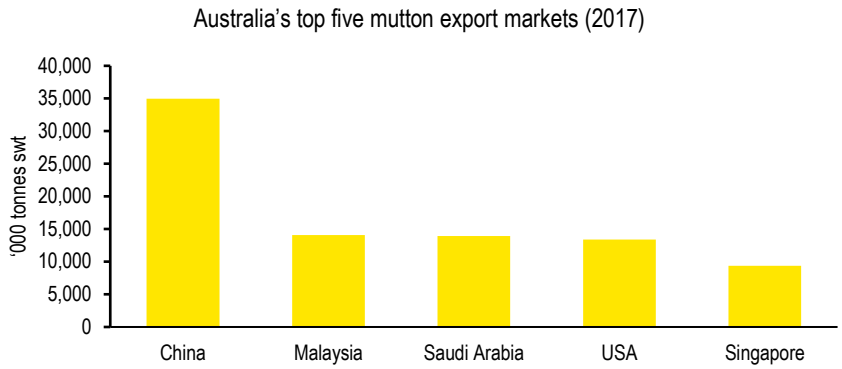
**Figure 2: Australian beef exports (2017)**




Australia's top three lamb export markets include the United States (55,158,000 swt), China (48,209,000 swt) and United Arab Emirates (~20,244,000 swt), and top three mutton export markets include China (~34,985,000 swt), Malaysia (~14,102,000 swt) and Saudi Arabia ( ~13,936,000 swt).




11 "State of the Industry Report 2018", Meat & Livestock Australia, *http://rmac.com.au/wp-content/uploads/2018/09/SOTI18.pdf,* accessed 2/12/18




Australian meat exports are marketed on attributes such as world-leading quality, food safety and a clean and green reputation.

## 3.2 The role of ESIs

Agvet chemical treatments are intended to promote animal health and/or destroy, repel and control pests and diseases of agricultural commodities, and serve as a vital backbone of the red meat export industry in Australia.[21] Agvet chemicals play a pivotal role in supporting farm production. For example, a study undertaken by the Australian Farm Institute found that the cost of disease in livestock industries could be as high as 10% of the total value of annual production, amounting to approximately $2 billion per year.[22]

However, while there are many benefits from agvet chemicals, this comes with the risk of unwanted chemical residues. These residues are the traces of a chemical or its breakdown products that remain in or on treated produce after a particular time.[23] To maintain the quality of meat products, Australian meat producers need to ensure appropriate chemical residue limits are maintained in all meat products exported. This is done through the application of withholding periods (WHPs) and ESIs which usually reflect the Australian or overseas MRLs.

An MRL is the highest level of an agvet chemical residue that is legally permitted to be present in a food, agricultural commodity or animal feed in accordance with approved label instructions.[24] The MRL is expressed in milligrams of the residue per kilogram of the commodity or food (mg/kg) or in milligrams of the residue per litre (mg/L) in a liquid commodity.[25] Differing MRLs are set for agvet chemical residues depending on the approved use of the product. MRLs are often misunderstood by the public as only a safety standard, when it is actually set to reflect good agriculture practice in Australia i.e. it is the maximum residue that could occur from the approved use of an agvet chemical product, including the approved label use, dosage instructions and withholding period. Good agricultural practice is underpinned by the general principle of using the lowest effective dose to minimise any unnecessary exposure to chemicals. The safety limits are, in contrast, the safe acceptable daily intake (ADI) from all sources. An MRL for a product that leads to consumer exposure that exceeds an ADI will not be approved.

In Australia, ESIs for international markets can be quite different to domestic WHPs. The objective of a WHP is to provide users with the information they need to ensure that residues in their treated produce will not exceed the MRL set in Australia.[26] WHPs and ESIs are used to reduce residues and ensure MRLs are not exceeded in the domestic and international markets. Both ESIs and WHPs ensure that a sufficient amount of time has elapsed to allow residues to fall to or below the permitted maximum limit.[27]

[21] "Residues in Food and Fibre", Tasmanian Government, Department of Primary Industries, Parks, Water and Environment, October 2017, *http://dpipwe.tas.gov.au/agriculture/agvet-chemicals/residues-in-food-and-fibre*, accessed 15/3/18

[22] "The economic importance of Australia's livestock industries and the role of animal medicines and productivity- enhancing technologies" Animal Medicines Australia, 2015, *http://animalmedicinesaustralia.org.au/wp-content/uploads/2016/02/Animal-Medicines-Project-FINAL-FINAL.pdf* accessed 15/3/18

[23] "Chemical residues", Agriculture Victoria, May 2017, *http://agriculture.vic.gov.au/agriculture/farm-management/chemical-use/agricultural-chemical-use/chemical-residues*, accessed 15/3/18

[24] "Pesticides and veterinary residues", APVMA, *https://apvma.gov.au/node/10806*, accessed 15/3/18

[25] "Definition of terms", APVMA, *https://apvma.gov.au/definition-of-terms/m*, accessed 15/3/18

[26] "Withholding Periods", APVMA, *https://apvma.gov.au/node/1020,* accessed 15/3/18

[27] "Withholding Periods", APVMA, *https://apvma.gov.au/node/1020,* accessed 15/3/18

An Australian ESI is applied where significant importing countries (refer to table 3) have set a lower MRL than is used in Australia, or expect no residue (and so have not set an MRL), and therefore more time is needed (than that required by the domestic WHP) for any residue to fall below the lower MRL or LOQ[28] or other suitable endpoint (detailed below in section 3.4) in the case of no residue being permitted.[29]

An Australian ESI may reflect one or more overseas market standards (depending on the number of significant trading partners a commodity is exported to), whereas the Australian WHP reflects only the local systems of good agricultural practice as approved by the APVMA on label or permit. A range of 0 to 140 days exists for WHPs of chemicals currently registered in Australia. As set out in section 5.1.4, the variance between WHP and ESI can be between 0 and 91 days in some cases.[30]

## 3.3 The regulatory framework

ESIs are determined under the Agricultural and Veterinary Chemicals Code (the Agvet Code), a schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth), and the *Agricultural and Veterinary Chemical Code Regulations 1995* (Cth) (the Agvet Code Regulations), made under the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth). Regulation of the supply of agvet chemicals is discharged by APVMA.

A key element of the regulation of chemical residues in meat and the management of trade risk is the satisfaction of Australia's trade criteria, as this requires consideration of trade implications when registering agvet chemicals. The APVMA is obliged to be satisfied that the use of the proposed product according to the registered use pattern would not unduly prejudice trade or commerce between Australia and other countries. ESIs provide a framework that enables the APVMA to ensure compliance and satisfaction under the Agvet Code that a chemical product meets the trade criteria.

The *Agricultural and Veterinary Chemicals Code Act 1994* outlines the requirements for a chemical product to meet the trade criteria (section 5C(1) of the Agvet Code):

> *A chemical product meets the trade criteria if use of the product, in accordance with instructions approved, or to be approved, by the APVMA or contained in an established standard, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.*[31]

For an agvet chemical product to be legally manufactured or supplied it must be registered by the APVMA (unless it has an exemption under the Agvet Code or its supply and use is authorised by an APVMA permit). It is not a legal requirement to include an ESI on all products, it is a measure that the APVMA may employ to enable it to be satisfied that the product meets the trade criteria.[32]

The APVMA can rely on the ESI for this purpose since a declaration of compliance with the ESI is required by the mandatory Livestock Production Assurance program (see section 2.5) National Vendor Declaration, which is when consigning cattle, goats and sheep (and each time livestock are bought, sold or moved off a property).

ESIs also form part of the broader environment which ensures the quality and integrity of Australia's meat, and its valuable reputation, are preserved. Three industry-owned elements of the red meat integrity system are[33]:

- National Livestock Identification System (NLIS).
- Livestock Production Assurance program (LPA).
- LPA National Vendor Declaration (LPA NVD).

28 The reasonable LOQ for ESI considerations may not be the lowest validated LOQ for an active constituent if the APVMA has previously used a higher LOQ as an ESI endpoint for that active. See section 3.4.

29 Australia Pork, "Fact Sheet", 2012, https://australianpork.com.au/wp-content/uploads/2013/09/FACT-SHEET-Sectn3-withholding-periods_APL-Final_Jan-2012.pdf

30 "ESIs of veterinary chemicals for use in cattle", APVMA, 1 February 2017, https://apvma.gov.au/node/10806 , accessed 22/3/18

31 Federal Register of Legislation, October 2016, https://www.legislation.gov.au/Details/C2016C00999, accessed 23/3/18

32 See section 0 for EY's analysis on the effectiveness and efficiency of the use of labels.

33 "Red Meat Integrity System", Meat and Livestock Australia, 2016, https://www.mla.com.au/meat-safety-and-traceability/red-meat-integrity-system/, accessed 23/3/18

The NLIS is Australia's scheme for the identification and tracing of livestock.[34] It is endorsed by major producer, feedlot, agent, saleyard and processor bodies. In addition, it is underpinned by state/territory legislation, which forms the regulatory framework for the system.[35] The NLIS combines three elements to assist with traceability; an animal identifier (a visual or electronic ear tag known as a device), identification of a physical location by means of property identification code, and a web-accessible database to store and correlate movement data and associated details.

LPA is an independently audited, on-farm assurance program covering food safety, animal welfare and biosecurity. It provides evidence of livestock history and on-farm practices when transferring livestock through the value chain.[36] As part of the LPA program, an NVD is required for all livestock movements, including property to property, through saleyards, direct to processors and feedlots, and to the live export trade. The NVD is the main document used to support Australia's reputation as a reliable supplier of safe red meat to domestic and international markets. ESI advice is particularly important for quality assurance schemes, and especially for producers filling out the NVD forms as part of the whole-of-chain management of exported product.[37]

In addition, the department also issues export documentation required by the *Export Control Act 1982* and the authorities of importing countries.[38] Export documentation verifies that the commodity has been produced using a system that provides confidence that the product meets legislated export requirements and the requirements of the importing country. The department provides information through MAA and MN to ensure specific market access requirements are known and complied with. The Australian systems in place to control residues, including ESIs, provides the department with the confidence to issue export certificates.

Despite the benefits of having these system controls in place to assist with traceability and identification, there are limitations to relying on traceability to control residue through supply chain controls. This is due to two key factors:

1. The supply of meat to a number of different markets with diverse requirements.

2. Multiple producers, including producers with small lots.

The setting of ESIs is therefore a vital component of the broader measures in place to ensure the integrity of Australia's meat industry.[39]

The department is unaware of any major markets accepting exporting country MRLs or amending import testing policies to suit a particular exporting country (that is, exported commodities must comply with the importing country's MRLs). Like Australia, China, the EU, Japan, Republic of Korea, Taiwan and the US all require imported commodities to meet their legislated MRLs. Some countries with less developed regulatory systems do reference MRLs from major regulators like Australia, but this is not a widespread practice and such countries are not usually among the major destinations for Australian exports of animal commodities.

The department continues to work with industry to reduce risks associated with residues by seeking better alignment of MRLs through mechanisms such as import tolerances, which allow for chemical residues in imported foods to obtain an MRL in an importing country when that country does not use that chemical domestically. These efforts are part of a broader role in negotiations for access to overseas markets, including technical consultations about the importing nation's biosecurity, animal health, food safety and residue requirements. The department also plays a significant role in rectifying problems with Australian agricultural goods on entry to their foreign destinations. The department, including overseas counsellors, works closely with industry, overseas authorities, and other parts of the Australian government in the process.

The department also provides in-country support which includes sixteen agricultural specialists currently working in Australian missions in key overseas markets, including in Bangkok, Beijing, Brussels, Dubai,

[34] "National Livestock Identification System, Department of Primary Industries, 2018, *https://www.dpi.nsw.gov.au/animals-and-livestock/nlis,* accessed 23/3/18

[35] National Livestock Identification System, 2018, *https://www.nlis.com.au/NLIS-Information/*, accessed 23/3/18

[36] "Ref Meat Integrity System", Meat and Livestock Australia, 2016, *https://www.mla.com.au/meat-safety-and-traceability/red-meat-integrity-system/,* accessed 23/3/18

[37] "Export Slaughter Intervals (ESIs) of veterinary chemicals for use in cattle", APVMA,2017, *https://apvma.gov.au/sites/default/files/publication/26531-cattle-esi-list-updated-1-february-2017.pdf* ,accessed 23/3/18

[38] "Australian export documents and certification", Department of Agriculture and Water Resources, September 2017, *http://www.agriculture.gov.au/export/certification,* accessed 28/3/18

[39] EYs analysis and view on the process involved in setting ESIs is further explored in section 5.1

Hanoi, Jakarta, Kuala Lumpur, New Delhi, Riyadh, Rome, Seoul, Tokyo and Washington. The department will soon have additional posts in London, Santiago and Mexico City, and additional staff will also be posted to existing posts, specifically Tokyo, Brussels and New Delhi. With technical and strategic support from the department, these counsellors work in market to support the department's efforts to develop and maintain markets for agricultural exports.

There have been instances in the past where the department has worked with veterinary companies to obtain import tolerances, and mitigate trade risk in importing countries. For example, products containing fluazuron were first registered in Australia in the mid-1990s. However, as no other country had maximum residue limits for fluazuron, marketing of the product was delayed until MRLs were developed in Australia's major beef markets and by Codex. The department's engagement led the USA to develop a regulatory process to enable import tolerances to be set. An import tolerance for the USA was obtained in 1996.[40] Australia also takes the opportunity to respond to notifications that countries make to the WTO of changes in MRLs. Recently, Australia successfully negotiated an MRL in Japan for abamectin in sheep commodities that better aligned with the Australian standard.[41] Australia also develops MRLs to facilitate trade between Australia and the international markets.[42]

When ESIs were first instituted to address a market access issue, Meat and Livestock Australia (MLA) held the ESI database and regularly published an updated list. However, it was taken over by the APVMA more than nine years ago.

## 3.4 The APVMA's approach to establishing ESIs

Before an agvet chemical product can be legally imported, supplied, sold, promoted or advertised in Australia, the APVMA must register it (unless it has an exemption under the Agvet Code or its supply and use is authorised by permit). In deciding whether to register a product (or issue a permit) the APVMA is obliged to consider a number of criteria, including that the product will not unduly prejudice overseas trade. Where the APVMA identifies that such a risk might exist it can take steps to mitigate the risk to an acceptable level which can include the establishing of an ESI.

APVMA implement the following process when establishing ESIs:[43]

1. The APVMA's registration process commences with an application being submitted.

2. The APVMA conduct trade assessments (where relevant) with Australia's major trading partners (in recent years only necessary for those for cattle, sheep and pigs), when registering new chemical products and determining ESIs.[44] Trade assessments are also conducted for any affected animal group(s) if the treated commodity or its stubbles or other by-products is used as stock food, or produces quantifiable residues in animal tissues when fed to any animal group listed in the major export food commodity groups.

3. To conduct an assessment APVMA requires, from applicants, chemicals depletion data which would allow the determination of an ESI that supports the lowest MRL or tolerance among the major trading markets for that commodity. The overseas trade information required for the establishment of, or a change in MRL for each commodity is listed in Table 2, and the current list of major trading partners considered is detailed in Table 2.

4. When a trading partner has no established MRL or tolerance, the target value is the analytical LOQ or another suitable endpoint/common screening method. The LOQ for a method is the lowest concentration of a veterinary drug or pesticide residue that can be quantitatively measured in a sample with an acceptable degree of certainty.[45] The LOQ is a number that is method specific, and may change over time as new methods are developed. When a market without a standard is identified, the APVMA

[40] "Import Tolerances", US Food & Drug Administration, 11/05/18, https://www.fda.gov/AnimalVeterinary/Products/ImportExports/ucm315830.htm

[41] "Japanese sheep meat trade disruption over abamectin sheep drench averted", Sheep Central, https://www.sheepcentral.com/japanese-sheep-meat-trade-disruption-over-abamectin-sheep-drench-averted/

[42] "Maximum residue limits – variations", Food standards Australia New Zealand, http://www.foodstandards.gov.au/code/changes/limits/Pages/default.aspx

[43] "Overseas trade (Part 5B), APVMA, *https://apvma.gov.au/node/1017,* accessed 28/3/18

[44] WHPs are set by APVMA to provide users with the information they need to ensure that residues in their treated produce do not exceed the MRL in Australia, and do not require trade assessments of the standards in the international market.

[45] "Residue analytical methods (Residues)",APVMA, *https://apvma.gov.au/node/1031*, accessed 28/3/18

determines if there is a high degree of concern for a particular compound (e.g. banned drugs), and a likely LOQ for methods used by regulators. In cases where there is not a high degree of concern for a residue, the LOQ of a typical screening method may be applied e.g. 0.01 mg/kg. Other suitable endpoints, rather than deferring to the LOQ, may be used in the following situations:

- If an ESI was originally set under the MLA system that utilised fewer markets and has been shown to effectively mitigate risk, then that endpoint will often continue to be used in ESI estimation for new products containing that active.

- Some markets on the significant market list are major destinations for meat but not offal. If the residue in question depletes rapidly in meat but is more persistent in offal, lesser emphasis will be placed on standards of the markets that are of lesser importance for offal and they may be excluded from endpoint determination.

5. The APVMA consults relevant parties, including Australian and state and territory government authorities and grower or producer organisations, before approving the use of an agvet chemical product when trade implications are relevant. This consultation includes the publication of a notice of relevant information relating to the chemical product. They may also separately publish a summary of the relevant information, for example, a trade advice notice or public release summary inviting public submissions before the registration or variation approval of an agvet product.

6. Once the assessment is finalised, the APVMA sets Australian ESIs for a given commodity/chemical, based on the MRLs of the most significant market(s). In practice, the ESI then applies to all international markets for that commodity/chemical. For generic agvet products the APVMA applies the ESI associated with a reference product.

7. ESIs can be changed, as tolerances within the importing market change (particularly if it is a significant market that previously had the most restrictive residue requirements for the chemical/commodity). Product registrants or industry bodies can apply for a variation of the ESI/reconsideration of trade risk at any time. There are APVMA data requirements (detailed in Table 2) when a registrant applies for a variation.[46] It is not current practice for the APVMA to review ESIs or make changes independent of an application.[47]

8. Applicants and state regulators and producer industries can contact the APVMA at any time. The APVMA has both informal methods of communication (with direct correspondence with key members involved in establishing ESIs) and a formal pre application assistance scheme for applicants (which can be obtained via the enquiries telephone number and email address on the APVMA website: *https://apvma.gov.au/contact-us*. In addition, the APVMA participates in other industry fora involved in assessing and managing trade risk such as the SAFEMEAT committee.

9. The department issue MAA and MN to inform industry of trade residue limitations for countries without MRLs, when findings are gathered through negotiations with the international market. This has been used to manage Hormone Growth Promotants (HGPs) and ractopamine.

**Table 2: Data requirements for the establishment of, and a change in, MRLs[48]**

| Subject | Information required |
|---|---|
| **Table of contents** | A listing of the sections included in the submission and their page numbers. |
| **Summary** | A brief summary of the overall situation.<br>Identification of the food commodities concerned and the countries to which Australia exports the commodities.<br>Specification of whether any potential trade problem exist with the countries concerned.<br>Indication of the nature of any potential problem. |
| **Overseas registration status** | Indication of overseas registrations or impending registrations. Also indication of where registration has been withdrawn. |
| **Use patterns in relevant overseas countries** | Indication of registered or approved use patterns in overseas countries where the commodity is traded. |

[46] "ESIs for Veterinary Chemicals", 2017, *https://apvma.gov.au/sites/default/files/publication/26536-sheep-esi-list-updated-1-february-2017_0.pdf* ,accessed 28/3/18
[47] EY analysis and view on APVMA not independently reviewing ESIs has been detailed in section 5.2.3
[48] "Overseas Trade (Part 5B), APVMA, *https://apvma.gov.au/node/1017*, accessed 28/3/18

| Subject | Information required |
|---|---|
| **MRLs in overseas countries** | Specification of the current relevant MRLs and residue definitions that apply in overseas countries. Alternatively, indication of any action taken, or planned to be taken, to obtain/amend MRLs (including 'import tolerances') in overseas countries. |
| **Codex MRLs (CXLs)**[49] | Indication of the current relevant CXLs and residue definitions.<br>Indication of any action taken, or planned to be taken, to obtain or amend CXLs. |
| **Label** | A copy of the label, including appropriate trade statements. |
| **Other relevant information** | Any other information considered relevant.<br>Details of any proposed trade risk management strategies and the associated communication strategy. |
| **Export interval proposal** | An export interval proposal and an outline of the methodology and assumptions used in the estimation of the export interval. |
| **Draft information for public consultation** | Trade advice information for consideration for inclusion in public consultation. |
| **Release of trade advice information to authorities and growers** | Indication at what stage during the assessment of the application the draft trade advice information could be released for comment by authorities and growers. |

The list detailing trading partners (outlined in the table below) was established in 2009 by the APVMA, to prevent the need to define major markets for each product case. The chosen markets represented more than 90% of exports and/or were the top 10 destinations with additional markets added by red meat industry. At the time the list was set, according to the APVMA it was expected that the list would be revisited every five years by the APVMA, which has not been the case. As it has not been updated for five years it may not reflect all the current markets of interest. It is understood that an update to the current trade partners list is being considered, and should be made in the near future.

**Table 3: Significant markets for trade considerations for cattle and sheep**[50]

| Standard | Cattle | Pig | Sheep |
|---|---|---|---|
| **Codex** | Yes | Yes | Yes |
| **China** | | | Yes |
| **European Union** | Yes | | Yes |
| **Japan** | Yes | Yes | Yes |
| **Republic of Korea** | Yes | | |
| **Russia** | Yes | | Yes |
| **Saudi Arabia** | | | Yes |
| **Singapore** | | Yes | |
| **Taiwan** | Yes | | |
| **United Arab Emirates** | | | Yes |
| **United States of America** | Yes | | Yes |

[49] Codex Alimentarius is a central part of the Joint FAO/WHO Food Standards Programme. It represents a set of international standards, guidelines and codes of practice to protect consumer health and promote fair practices in the food trade. See http://www.fao.org/fao-who-codexalimentarius/en/, accessed 28/3/18

[50] The APVMA, *https://apvma.gov.au/node/1017#markets_for_consideration*, accessed 28/3/18

## 3.5 Operation of the ESI system

The operation of the ESI system involves various stakeholders from both government and industry in Australia. Figure 3 summarises the input by key stakeholder groups to ensure the ESI system operates effectively. The roles of these participants are further described in Table 4.

**Figure 3: Operation of the ESI system**

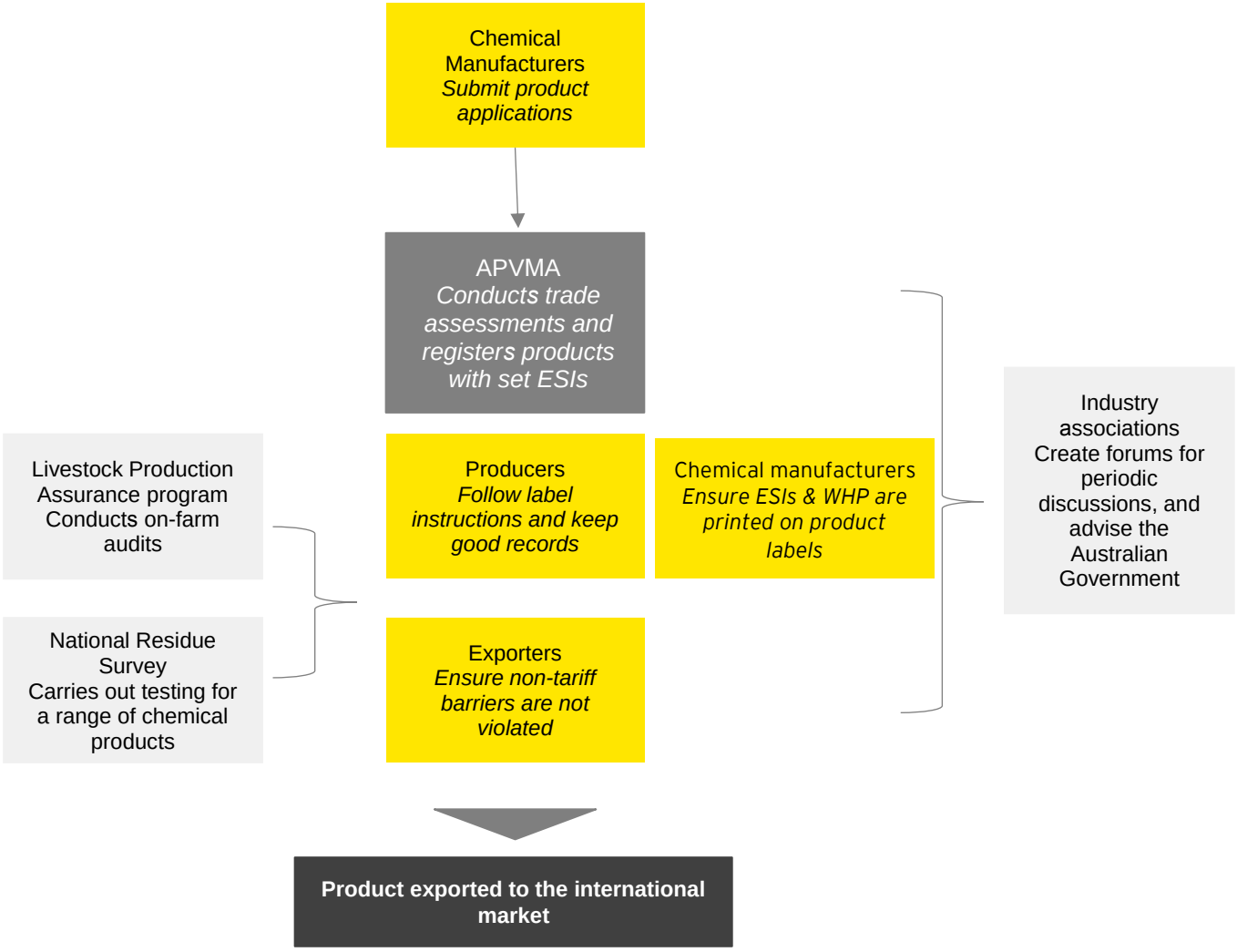


**Table 4: Role of participants in the ESI system**

| Participant | Role description |
|---|---|
| **Chemical manufacturers** | Chemical manufacturers have the responsibility to provide APVMA with the data required to register a product before it can be legally imported, supplied, sold, or advertised in Australia.[52] Once registered, chemical manufacturers and product suppliers must ensure ESIs and WHPs for pesticides and veterinary medicines are available on the product label of registered products.[53] |
| **APVMA** | Before agvet chemical products can be legally sold, supplied or used in Australia, they must be evaluated and registered by the APVMA (unless it has an exemption under the Agvet Code or its supply and use is authorised by permit).[54]<br>The APVMA is involved in assessing the information provided by chemical manufacturers on Australia's major trading partners' standards and conducting trade assessments and (if necessary) setting ESIs prior to registering the chemical products.<br>The APVMA also consults relevant parties, including the Australian Government and state and territory government authorities and grower or producer organisations, before approving an agvet product when trade implications are relevant.[55] Relevant parties are also consulted when there is a breach in export markets, and the response is managed by the department and the relevant state.<br><br>The APVMA is also involved with the setting of MRLs through Codex through attendance at the bi-annual (Codex Committee of Residues of Veterinary Drugs) and annual (Codex Committee of Pesticide Residues) Codex meetings, participating in the electronic working groups, and participating in the scientific assessments (joined meeting between the World Health Organization and the Food and Agriculture Organization for the United Nations). |
| **Producers** | Australian producers are required to follow label instructions, to ensure compliance with ESI requirements set by the APVMA to be satisfied that the product meets the trade criteria under the Agvet code (refer to section 3.3 above), and keep good records which enable them to give evidence of management practices that minimise and eliminate the risk of livestock contamination.[57] |
| **Exporters** | Australian exporters need to ensure that no non-tariff barriers are violated, and products exported meet the importing countries' residue requirements. Exporters need to ensure that they comply with the export certificate requirements, required by the department. |
| **LPA program** | The LPA program is the Australian cattle, goat and sheep livestock industry's on-farm assurance program covering food safety, animal welfare and biosecurity. It provides evidence of livestock history and on-farm practices when transferring livestock through the value chain.[58] The LPA randomly audits the records of producers to ensure compliance with ESI standards.[59] |
| **Department of Agriculture and Water Resources including the National Residue Survey (NRS)** | The NRS is an administrative unit within the department that manages programs monitoring agricultural products and meat producing animals for residues of primarily agvet chemicals.[60] The NRS carries out testing for a range of chemical compounds which current technology can detect at very low concentrations. Product testing is done through either random or specifically designed sampling protocols.[61]<br>The purpose of residue monitoring is to quantify the occurrence of residues in products and to verify that residues in products are within both the domestic and internationally acceptable limits. Should acceptable limits be exceeded appropriate authorities are contacted, and corrective action is taken. The product may be removed from the food chain if there is a public health concern, however this is often not the case with non-compliant residues.<br>The department is also responsible for the following:<br>► Policy oversight and administration of legislation for agvet chemicals.<br>► For certification of exports. This includes compliance with importing country requirements such as MRLs. The department works with the industry (mainly producer and processor/exporter groups) to develop systems to ensure importing country requirements are met and the department can be confident in its certification. The department also negotiates the technical aspects of market access.<br>► Overarching market access. The department negotiates access including trade agreements, generally these relate to tariffs and quotas.<br>► The Australian contact point for Codex Alimentarius, as well as leading a number of delegations to Codex committees. |

52 "Supplying chemicals and chemical products in Australia", APVMA, https://apvma.gov.au/node/1107, accessed 28/3/18

53 "Pesticides and veterinary residues", APVMA, https://apvma.gov.au/node/10806, accessed 28/3/18

54 Department of Agriculture and Water Resources, 2017, http://www.agriculture.gov.au/search?k=APVMA#k=APVMA, accessed 28/3/18

55 "Overseas trade (Part 5B)", APVMA, https://apvma.gov.au/node/1017, accessed 28/3/18

56 Codex Alimentarius Commission (Codex) is the international food standards setting body established by the United Nation's Food and Agriculture Organization. Codex develops international food standards, guidelines and codes of practice for an international food code that contributed to the safety, quality and fairness of food trade. ["Codex Alimentarius Commission" , Food Standards Australia New Zealand, November 2016, http://www.foodstandards.gov.au/science/international/codex/pages/default.aspx]

57 "Chemical Residues", Safe Meat, http://safemeat.com.au/key-issues/chemical-residues.htm, accessed 28/3/18

58 "Livestock Production Assurance Program", Meat Livestock Australia, 2016, https://www.mla.com.au/meat-safety-and-traceability/red-meat-integrity-system/about-the-livestock-production-assurance-program/, accessed 28/3/18

59 "Livestock Production Assurance program", MLA, https://www.mla.com.au/lpa, accessed 28/3/18

60 "Chemical Residues", Safe Meat, http://safemeat.com.au/key-issues/chemical-residues.htm, accessed 28/3/1

61 "National Residue Survey", 2016, http://www.agriculture.gov.au/ag-farm-food/food/nrs, accessed 28/3/18

| Participant | Role description |
|---|---|
| **Industry Associations** | There are a variety of industry associations which represent the agriculture sector. Industry associations representing red meat, pork and crops all play a role in contributing to the establishment of ESIs.<br>The red meat industry is made up of six main sectors: grass-fed cattle producers, grain-fed cattle producers, sheep producers, goat producers, livestock exporters and processors (comprising retailers, small goods manufacturers and packers). Each of these individual sectors has an elected body for policy formulation; these are known as Peak Industry Councils, or PICS, and are the following[62]:<br>► Australian Livestock Exporters Council<br>► Australian Lot Feeders Association<br>► Australian Meat Industry Council<br>► Cattle Council of Australia<br>► Goat Industry Council of Australia<br>► Sheep meat Council of Australia.<br>These six bodies come together to form the Red Meat Advisory Council Ltd (RMAC), essentially making it the Peak Council of the PICs.<br>RMAC's primary role is to provide the PICs with a forum for periodic discussion and policy formulation regarding matters that impact on two or more sectors within the meat industry. RMAC is the body responsible for advising the Federal Government on cross-sectoral and whole-of-industry issues over which the Government has influence. RMAC is also responsible for the development and revision of the Meat Industry Strategic Plan (MISP).<br>Other industry representative bodies which similarly provide forums for discussion and the provision of advice to the Government include:<br>► Australian Pork<br>► Australian Beef Association<br>► Grain Producers Australia<br>► Meat Livestock Australia<br>► Dairy Australia<br>► Cotton Australia<br>**EY notes this list of industry associations within the agriculture sector in Australia is not exhaustive but includes those specifically relevant to this study.* |
| **SAFEMEAT** | SAFEMEAT is a partnership between the red meat and livestock industry and the state and federal governments of Australia. SAFEMEAT initiates research and development, develops communication linkages, monitors the states of Australia's products, reviews standards and examines emerging issues that could have an impact on the industry in the future.[63] It is a significant source of advice on residue issues. |
| **State regulators** | State regulators are also consulted with comments requested during the product registration/permanent application stage. State regulators are involved in monitoring the NRS results, and lead on-the-ground investigations when violations are identified. They are in direct correspondence with the APVMA when violations are identified. |

[62] "Meat Industry Strategic Plan", Australia's Red Meat and Livestock Industry, 2010-2015, *https://www.mla.com.au/globalassets/mla-corporate/generic/about-mla/meat-industry-strategic-plan.pdf,* accessed 28/3/18

[63] "Overview", SAFEMEAT, *http://safemeat.com.au/about-safemeat/overview.htm,* accessed 28/3/18

# 4. International approaches

A number of countries regulate the level of chemical residues in exported meat, but there is no binding internationally standardised approach and the approaches taken by various countries across the globe differ. Countries regulate exports to the extent required for trade and have adopted different approaches for providing assurances regarding residues in meat. The World Trade Organization's Agreement on Sanitary and Phytosanitary measures (SPS Agreement) references Codex food safety standards giving weight to Codex standards for resolving trade disputes, by providing an online database for the MRLs for agvet chemicals, which can be relied on by the international market.[64] Countries can however choose to implement specific requirements which differ from the Codex requirements and may be required to justify these measures scientifically. The process for developing a Codex MRL can take three to five years.

Brazil, NZ and the US are Australia's primary meat export competitors. Each has their own systems established to manage chemical residues in meat exports. The following section details how these countries manage chemical residues in meat exports.

## 4.1 NZ's approach to chemical residue management

The approach to risk management of chemical residues in NZ has been detailed below, which takes into account the country profile and the regulatory framework in place.

As detailed in section 2.2 there is limited publicly available information on the operation of chemical residues management and the approaches to the management of trade risk in the international market. As a result, the information below on NZ's approach to chemical residue management was obtained mostly through anecdotal evidence in consultation with the Policy and Trade Branch of the Ministry of Primary Industries (MPI) in NZ. The information documented below was also reviewed by those consulted.

### 4.1.1 Country profile

The meat industry is one of NZ's biggest export earners. Beef and lamb exports alone are worth more than $5 billion. In 2016 it was found that NZ exports were approximately 68% of beef/veal produced (423,000 tonnes), 67% of lamb (303,000 tonnes), and 86% of mutton (83,000 tonnes).[66] NZ's primary export markets for beef are the US, China and Taiwan[67], and the UK, China and US for its lamb.[68] The export market for pork in NZ is small in comparison with other meat commodities.

### 4.1.2 Regulatory framework

NZ relies on a single approach to manage agricultural compound residues in meat products for both the domestic market and for exports to the international market. This entails the setting of MRLs and WHPs.[69]

This is managed under two pieces of legislation: The *Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997* which establishes WHPs for relevant agricultural compounds, and the *Food Act 2014* for establishment of MRLs. Both pieces of legislation are administered by the MPI.

Under the *ACVM Act*, the establishment of WHPs are associated with applications for registration (or variation to a registration) of trade name products with uses relating to food producing animals. In conjunction with this, MRLs are determined based on consideration of a good agricultural practice.

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64 "Codex Alimentarius", Food and Agriculture Organization of the United Nations and World Health Organization, 2018, *http://www.fao.org/fao-who-codexalimentarius/en/,* accessed 5/4/18

66 "Beef and Lamb NZ", Beef + Lamb New Zealand Economic Service, 2018, https://beeflambnz.com/sites/default/files/data/files/B%2BLNZ%20mid%20season%20update%202017-18.pdf*,* accessed 5/4/18,

67 "New Zealand Cattle and Beef Production Annual Report", USDA Foreign Agriculture Service, 2017, *https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Livestock%20and%20Products%20Annual_Wellington_New%20Zealand_8-23-2017.pdf,* accessed 5/4/18

68 "International Lamb Profile", Agriculture Marketing Resource Centre, 2018, *https://www.agmrc.org/commodities-products/livestock/lamb/international-lamb-profile/*, accessed 5/4/18

69 "Maximum residue Limits", Ministry for Primary Industries, New Zealand, *https://www.mpi.govt.nz/food-safety/whats-in-our food/chemicals-and-food/maximum-residue-levels/,* accessed 5/4/18

The other main piece of legislation is the *Animal Products Act 1999* which sets equivalent limits for MRLs along with limits for non-agricultural compound chemicals and contaminants.

The primary legislation for management of chemicals include:

- *Agricultural Compounds and Veterinary Medicines Act 1997* – A legal framework for managing four risk areas as well as compliance with domestic residue standard for agricultural compounds.
- *Animal Products Act 1999* – A legal framework for processing animal material into food, such as meat and dairy products. It establishes a risk management system that requires all animal products traded and used to be 'fit for intended purpose' through meeting NZ animal product standards.[70]
- *Food Act 2014* – Ensures all business are following good safety practices and keeping records.
- *Hazardous Substances and New Organisms Act (HSNO) 1996* – Protects the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.[71]
- *Biosecurity Act 1993* – Aimed to effectively manage risk associated with the importation of goods.[72]

### 4.1.3 Approach to establishing NZ WHPs

While the approach to establishing WHPs in NZ detailed below focuses on veterinary medicines, it should be noted that the principles outlined for establishing NZ WHPs for veterinary medicines are applicable to agricultural chemicals.

MPI establishes WHPs for veterinary medicines used on food producing species as part of the assessment of applications for registrations (or variations) under the *ACVM Act*. The assessment of applications is in line with international practice (the same as in Australia). The NZ risk assessment takes into account several factors[73] before establishing a WHP:

1. The establishment of good agricultural practice for the minimum effective dose of the veterinary medicine.
2. Assessment of residue information to determine the likely residues based on a proposed WHP.
3. The trade impacts of the residue profile associated with the proposed WHP.

Companies applying to register new veterinary medicines or seeking approval for new uses of existing veterinary medicines must submit detailed scientific data from studies of the veterinary medicines.[74] MPI assesses the studies and any additional information (such as information on the use of the product overseas or similarities to already registered veterinary medicines) before approving the new veterinary medicine use.[75]

Data from the studies must demonstrate:[76]

- The lowest amount of compound that can be used to get the maximum benefit for each use.

[70] "An Overview of the Animal Products Act 1999", Ministry for Primary Industries, New Zealand Government, *https://www.mpi.govt.nz/dmsdocument/15991/loggedIn,* accessed 9/4/18

[71] "Hazardous Substances and New Organisms Act 1996", Ministry for the Environment, 2016, *http://www.mfe.govt.nz/more/acts-and-regulations/hsno-act-1996,* accessed 9/4/18

[72] Biosecurity Act 1993, New Zealand Legislation, *http://www.legislation.govt.nz/act/public/1993/0095/latest/whole.html#DLM315268,* accessed 9/4/18

[73] "Maximum residue levels", Ministry for Primary Industries, New Zealand Government, *https://www.mpi.govt.nz/food-safety/whats-in-our-food/chemicals-and-food/maximum-residue-levels/,* accessed 9/4/18

[74] "Documents for veterinary medicines", Ministry for Primary Industries, New Zealand Government, https://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/veterinary-medicines/documents-for-veterinary-medicines/, accessed 9/4/18

[75] "Agricultural compounds and residues", Ministry for Primary Industries, New Zealand Government, *https://www.mpi.govt.nz/food-safety/whats-in-our-food/chemicals-and-food/agricultural-compounds-and-residues/,* accessed 9/4/18

[76] "Document", Ministry for Primary Industries, New Zealand Government, https://www.mpi.govt.nz/dmsdocument/19367/loggedIn , accessed 9/4/18

- What residue levels may remain in food at harvest or slaughter so athat withholding period (time between the last application and harvest or slaughter) can be set (if the residue data are not available, the MPI can set a default period of 91 days (3 months) for cattle and sheep to apply).[77]

Stakeholders reported that MPI does not have a rolling assessment process in place which triggers regular review under the *ACVM Act*. Reviews can be conducted when:

- There is new information on a compound, it has been re-assessed and the reference health standard has been changed.[78]
- Agricultural practices change.[79]
- An overseas market's requirements change.

Reviews can be triggered by the regulator, the public, chemical companies or the meat industry if they have concerns with the registration of certain products. The frequency of the reviews triggered by a regulator on certain products is variable, depending on the circumstances, but according to the MPI there are at least a few reviews each year.

### 4.1.4 Approach to establishing NZ MRLs

The following factors are taken into consideration when establishing MRLs:

1. The likely residue levels at slaughter/harvest, based on using the lowest possible amount of chemical needed to be effective. This residue level determines the proposed MRL.
2. The potential dietary intake of foods containing the residue, based on the most recent Ministry of Health's National Nutrition Survey.
3. How the potential dietary intake compares with reference health standards (like the acceptable daily intake) for the substance. MPI can accept the proposed MRL if the potential dietary intake is less than the relevant reference health standard.

The residues are compared with health-based guidance values set by the NZ Environmental Protection Authority (EPA) under the HSNO Act to confirm whether they are acceptable in-diet. Acceptable residue limits are then set and recorded in the Maximum Residue Levels Food Notice under NZ law.

### 4.1.5 The management of trade risk

As part of the registration of veterinary medicines and the determination of WHPs consideration is given to trade risk and importing market requirements, with a risk based approach taken. During consultations stakeholders stated that the following factors are considered when registering products:

1. What are the requirements of importing countries?
2. How important is the importing country as a trade partner?
3. Are importing countries testing?
4. How would trade relationships be effected, if residues were detected above an importing countries requirements (a violation was to occur)?
5. How much will a violation cost the meat industry?

[77] *"Default withholding periods for veterinary medicines",* Ministry for Primary Industries, *https://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/veterinary-medicines/using-veterinary-medicines/default-withholding-periods-for-veterinary-medicines/,* accessed 9/4/18

[78] "Maximum residue limits", Ministry for Primary Industries, New Zealand Government, *https://www.mpi.govt.nz/food-safety/whats-in-our-food/chemicals-and-food/maximum-residue-levels/,* accessed 9/4/18

[79] "Maximum residue limits", Ministry for Primary Industries, New Zealand Government, *https://www.mpi.govt.nz/food-safety/whats-in-our-food/chemicals-and-food/maximum-residue-levels/,* accessed 9/4/18

Stakeholders suggested that when considering the questions above, the following approach will be taken:

- If the MRL of an international trading partner is higher (less restrictive which allows for a shorter WHP) than the domestic limit, then there is no market access concern.

- If the MRL of an importing country is lower (lower MRL or LOQ) than the existing NZ MRL, and the residues are likely to be detected in the sorts of commodities commonly traded to that country (not all markets import much offal which is where many residues mainly accumulate), the market access team may advise the setting of lower MRLs and longer WHP that better aligns with the markets expectations. Variations to this policy occur where there is already an international standard, where a proposed standard is almost through the development process for international standards, where the veterinary drug is of key importance to NZ agriculture, or where it is restricted for use in a species not commonly exported (e.g. pigs and poultry).
    - The NZ market access team are involved when required with negotiations with importing countries on generic residue assurance requirements. NZ manages the risk to trade partnerships through on-going discussions and promoting the rigor of its assessment process and use controls, along with the relatively low use of agvet chemicals within NZ relative to many other countries, in line with NZ good agricultural practice.
    - NZ encourages trading partners to align MRL requirements with Codex (or accept Codex MRLs for imported food) and emphasise that MRL's should be risk based and adhere to international standards. Stakeholders involved with chemical residues management in NZ hold the view that emphasising NZ's good track record, and measures taken to ensure safety with the domestic market, gives general reassurance to international markets. MPI rarely provides detailed official assurances with regards to meeting MRLs of an importing country especially from a heterogeneous product such as meat. It remains an exporter responsibility to ensure compliance with the importing countries regulations.
- If the WHP determined after assessment of trade matters is considered impractical/ ineffective for a farmer it is not considered good agriculture practice. It also increases the risk that a user will breach the WHP. These concerns mean such products may not be registered. Good agricultural practice is determined by the likelihood of product being used by a farmer or vet, which is based on a number of practicality factors such as the species the product can be used on, and whether the species can be isolated from other species the product cannot be used on.

- Where countries do not have an MRL and they are a significant market, in certain rare cases, tighter sale and use restrictions and animal treatment identification requirements may be put in place to ensure either the major traded commodities are not affected (e.g. ractopamine can be used in pigs but is prohibited in cattle), or to allow product from treated animals to be redirected away from the sensitive markets. In the situations requiring channelling of product from identified treated animals away from certain markets (e.g. hormonal growth promotants) this requirement is mandated under further instruments under the *Animal Products Act 1999,* such as requirements on producers to notify the treatment status to all subsequent purchasers (via the animal status declaration), and for processors to have auditable systems in place to exclude any such product from the specified markets (via specified overseas market access requirement (OMARs)). OMARs outline the requirements NZ need to meet, to access markets in different countries.[80] Depending on the situation, OMARs can limit exports or individual products that can be exported. It is the responsibility of the producer and exporter to ensure that product complies with OMARs for each country.
    - However, it was stated that cases requiring separation are relatively rare due to the increased production cost associated with segregation of lines of products. In addition to this, there are complementary controls (for example, the product is only to be used as the label instructions, must be tagged) placed on these products under the ACVM Act to manage the trade risk.
- Like Australia, the requirements of all trading partners are not taken into consideration when setting an MRL, just key strategic markets.

The residue limits in general are not decreased to the LOQ for countries without MRLs except where there is a particular sensitivity. If there are no country specific MRL's, or Codex MRL's for a particular country, the

[80] "Overseas market access requirements", Ministry for Primary Industries, New Zealand Government, *https://www.mpi.govt.nz/law-and-policy/requirements/overseas-market-access-requirements/,* accessed 9/4/18

WHP for a product is generally based on the known MRLs (or prohibitions) of major trading partners (noting the use of OMARs above).

### 4.1.6 Summary of chemical residue management in NZ

Table 5 outlines the key similarities and differences in chemical residue management in NZ in comparison to Australia. The factors which lead to differences in the treatment of chemical residue management in NZ are analysed in Chapter 5.

**Table 5: Summary of chemical residue management in NZ**

| Similarities to Australia | Differences to Australia | Applicability |
|---|---|---|
| ► MRLs are set and managed by the Government.<br>► The residue limits of different trading partners are considered when setting MRLs.<br>► On-going discussions are held with importing countries to manage residue requirements. E.g. acceptance of international (codex) standards, acceptance of NZ standards.<br>► An MRL can only be accepted if the estimated exposure is less than the relevant reference health standard.<br>► Where countries do not have a MRL, and they are a significant market, tighter sale and use restrictions can be put in place (such as OMARs) rather than imposing a longer WHP for all export markets. OMARs are the requirements that the NZ government stipulates for export destinations. OMARs can be used to place prohibitions or limitations on products destined for certain markets. OMARs are similar to the departments MAAs and MNs. | ► One WHP is set for products in both domestic and export markets, rather than a dual system (ESI and WHP) in Australia.<br>► NZ will not register a chemical product with an export driven WHP (not dealt with by OMARs) which is impracticable from an animal management perspective i.e. is determined not to support good agriculture practice. Australia has more flexibility in this scenario as it can still have a domestic WHP, even if the ESI is impractical.<br>► NZ often considers a different pool of countries trading requirements, given NZ sell meat products to different trading partners than Australia.<br>► A smaller number of significant trading partners' are considered.<br>► The residue limits are generally not decreased to the LOQ to accommodate trade with countries without MRLs, except where there is a particular sensitivity. NZ instead place greater reliance on Codex. It is noted this is not always the case in Australia but anecdotal evidence suggests this happens more often. | ► The use of one withholding period for products in both domestic and export markets could be applied in Australia, however it will decrease the degree of flexibility (i.e. would no longer allow shorter domestic WHP if the ESI was unworkably long). It was found that while the current system may often default to the ESI (due to uncertainty about the final market destination of parts of an animal), the dual system still provides some desirable flexibility, particularly if additional measures have been taken to differentiate products for the domestic market to understand their requirements.<br>► OMARs could be implemented in Australia, however may limit the number of markets Australia has the ability to export to. Australia implements MN and MAA that have a similar role to NZ OMARs. However, market specific requirements make the system more complicated to implement and increasingly prone to failure.<br>► Rather than ensuring residue levels are decreased to the level of quantification, greater reliance could be placed on Codex in Australia. However, this will increase risk to market access, and give less importance to countries with residue requirements more stringent than Codex. |

## 4.2 Brazil's approach to chemical residue management

The approach to risk management of chemical residues in Brazil has been detailed below, which takes into account the country profile and the regulatory framework in place.

As detailed in section 2.2 there is limited publicly available information on the operation of chemical residues management and the approaches to the management of trade risk in the international market. As a result, the information below on Brazil's approach to chemical residue management was obtained mostly through anecdotal evidence through consultation with a key person within the International Beef Alliance, who also has strong involvement with the ABIEC (Brazilian Beef Trade Association) in Brazil.

### 4.2.1 Country profile

In 2016, Brazil's beef exports represented approximately 18% of total production (1.7 million tonnes), and pork exports represented 22% of total production (832,000 tonnes).[81] The primary export markets for Brazilian beef are Hong Kong, Egypt, China and Russia.[82] Lamb and mutton are not exported from Brazil.

### 4.2.2 Regulatory framework

In Brazil, one set of withdrawal periods are put in place for the domestic and international markets. The meat industry leads management of chemical residues and it is the responsibility of processors and exporters to ensure compliance.

The assessment, management, and communication of chemical residues is undertaken by the Ministry of Agriculture (Ministério da Agricultura, Pecuária e Abasteciment (MAPA).[83] MAPA coordinates the National Plan for Control of Residues and Contaminants (Plano Nacional de Controle de Resíduos e Contaminantes (PNCRC), a Federal Program of food inspection and surveillance, based on risk analysis. This program aims to verify the presence of residues of chemicals potentially harmful to the consumer, such as residues of veterinary medicines, pesticides, and contaminants such as aflatoxins and heavy metals.

### 4.2.3 Approach to establishing chemical residue standards

Health-based guidance values are used for the establishment of maximum action or tolerance levels in foodstuffs. This ensures that consumer exposure, including individuals at different scenarios of intake, is considered low risk.

Programs have been implemented in Brazil to address concerns held by the importing markets about inadequate regulation, safety and oversight. These programs gain assurance about the quality of meat through reliance on the health-based values used to determine maximum tolerance levels, and aim for longevity in Brazil's relationship with trading partners. These programs include:

- The Brazilian government created a program in 2016 (Programa de Acesso a Mercados do Agronegócio Brasileiro) to improve market access for all agricultural products and targets Asia (especially China) as a key market. The program focuses on adding value to products and highlighting Brazil's quality and sustainable production systems.[85]

- The Brazilian Beef Exporters Association (ABIEC) was founded in 1979, and became the main representative of industry in the areas of international trade regulations, health requirements and open markets in Brazil.[86] The primary object of ABIEC is to synthesise, coordinate, represent, promote and defend the interests of Brazilian companies exporting unprocessed and processed beef, conducting studies and interfacing with public and private bodies to seek solutions for general and specific problems that affect the sector.[87]

[81] "Livestock and Poultry: World Markets and Trade", United States Department of Agriculture, 2018, *https://apps.fas.usda.gov/psdonline/circulars/livestock_poultry.pdf,* accessed 12/4/18

[82] "Market supplier snapshot: Beef", Meat and Livestock Australia, 2017,*https://www.mla.com.au/globalassets/mla-corporate/prices--markets/documents/os-markets/red-meat-market-snapshots/mla-ms_brazil_-snapshot-2017.pdf,* accessed 12/4/18

[83] "Food quality and safety progress in the Brazilian food and beverage industry: chemical hazards Food Quality and Safety", 2017, *https://academic.oup.com/fqs/article/1/2/117/3798231,* accessed 12/4/18

[85] " Market supplier snapshot: Beef", Meat and Livestock Australia, 2017, *https://www.mla.com.au/globalassets/mla-corporate/prices--markets/documents/os-markets/red-meat-market-snapshots/mla-ms_brazil_-snapshot-2017.pdf,* accessed 12/4/18

[86] "Brazilian Beef",2017, *http://www.brazilianbeef.org.br/History.aspx,* accessed 12/4/18

[87] "Brazilian Beef",2017, *http://www.brazilianbeef.org.br/Mission.aspx,* accessed 12/4/18

### 4.2.4 The management of trade risk from residues

Distinct from many countries, residues are managed in Brazil solely by industry through activities along the supply chain, based on the requirements of the intended destination. Different parts of an individual animal have different set withholding periods. For instance a different withholding period can be set for offal in comparison to the remaining parts of the carcass. As part of this system's requirements, different parts of an animal are separated within an abattoir and follow different supply chain pathways. This allows the exporter to have control over where a commodity is going. This occurs particularly for vertically integrated supply chain products such as poultry and pork.

Measures have been put in place by both government and industry to monitor products within the supply chain to aid compliance, such as:

- Animals cannot enter an abattoir without declaration or paperwork, and specific paperwork requirements for each export market are required.
- There is full traceability in the slaughterhouse (animals not mixed), and each carcass has a separate tag.
- Monitoring is conducted through visual inspection of signs of injections which may indicate residues.
- In some circumstances, different facilities focus on different markets, for instance some slaughterhouses focus specifically on one export market to manage risk.

Under the National Plan for Control of Residues and Contaminants program, annual plans are drawn up for the sampling of animals sent to slaughter in establishments under Federal Inspection. Samples are collected by the Federal Inspection Service (FIS) of lots of animals and products from a single source, which allows the traceability of the rural property of origin. Tests include a wide range of authorised veterinary drugs and banned pesticides, inorganic contaminants, mycotoxins and dioxins (including hormones).[88]

Analyses of samples are carried out in laboratories of the National Network of Agricultural and Livestock Laboratories (LANAGRO Network), which comprises National Agricultural Laboratories (MAPA official laboratories) and other public/private laboratories accredited by MAPA.[89] In the event of a violation, investigation subprograms are established, including inspections of the rural property of origin of the sampled lot to identify causes of the violation, application of any administrative sanctions and control of the risk of new violations.[90] Any infringing properties have their next batches of animals and products subject to a special test regime, during which time the products obtained from the sampled lots are retained by the official service until the analysis indicates their compliance. Sampling of batches of animals and products of infringing property is maintained until five consecutive batches have complied.[91]

When consulting stakeholders it was mentioned that having different WHPs for different parts of an animal is easier in the poultry and pork industries as they have integrated supply chains, however, it is quite difficult to implement different WHPs for different parts in cattle given the fragmented nature of production.

Market access and sanitary status remain major obstacles to increasing Brazil's presence in global markets, particularly in Australia's key export markets, such as the US, Japan, Korea, and Indonesia.[92] Brazil is limited in the number of export markets meat products can be exported to due to different environmental and safety precautions taken by the international market for a number of reasons, such as Brazil's failure to pass safety checks due to corruption involving Brazil's health inspectors[93] and issues with residues.

[88] "National Plan for Control of Residues and Contaminants program", Agriculture, Livestock and Farming, 2017, *http://www.agricultura.gov.br/assuntos/inspecao/produtos-animal/plano-de-nacional-de-controle-de-residuos-e-contaminantes,* accessed 12/4/18

[89] "National Plan for Control of Residues and Contaminants program", Agriculture, Livestock and Farming, 2017, *http://www.agricultura.gov.br/assuntos/inspecao/produtos-animal/plano-de-nacional-de-controle-de-residuos-e-contaminantes,* accessed 12/4/18

[90] "National Plan for Control of Residues and Contaminants program", Agriculture, Livestock and Farming, 2017, *http://www.agricultura.gov.br/assuntos/inspecao/produtos-animal/plano-de-nacional-de-controle-de-residuos-e-contaminantes,* accessed 12/4/18

[91] "National Plan for Control of Residues and Contaminants program", Agriculture, Livestock and Farming,, *http://www.agricultura.gov.br/assuntos/inspecao/produtos-animal/plano-de-nacional-de-controle-de-residuos-e-contaminantes,* accessed 12/4/18

[92] "Brazil", Meat and Livestock Australia, 2017, *https://www.mla.com.au/globalassets/mla-corporate/prices--markets/documents/os-markets/red-meat-market-snapshots/mla-ms_brazil_-snapshot-2017.pdf*, accessed 17/4/18

[93] 'US bans fresh Brazil beef imports over safety concerns', REUTERS, 2017, *https://www.reuters.com/article/us-usa-brazil-beef/u-s-bans-fresh-brazil-beef-imports-over-safety-concerns-idUSKBN19D2VE*, accessed 17/4/18

### 4.2.5 Summary of chemical residue management in Brazil

Table 6 outlines the key similarities and differences in chemical residue management in Brazil in comparison to Australia. The factors which led to differences in the treatment of chemical residue management in Brazil are analysed in Chapter 5.

**Table 6: Summary of chemical residue management in Brazil**

| Similarities to Australia | Differences to Australia | Applicability |
|---|---|---|
| ► Samples are collected to perform testing by the Federal Inspection Service, similar to the NRS in Australia, to verify controls on veterinary drugs and residues are adequate.<br><br>► Investigation sub-programs are established when a violation is detected. | ► Chemical residues are managed only through industry activities along the supply chain, in comparison to Australia where additional measures such as WHP and ESIs have been introduced to ensure appropriate chemical residue limits are applied.<br><br>► Brazilian abattoirs separate product based on the interval between treatment and slaughter and different product types (liver, kidney, muscle etc) might have different slaughter intervals for the same market and for different markets. Different parts of an individual animal have different set withholding periods. For instance, a different limit can be set for offal in comparison to the remaining parts of the carcass. This occurs for beef, and vertically integrated supply chain products such as poultry.<br><br>► Compliance with importing country residues limits are industry-led rather than through a government department or agency. | ► Brazil's approach relies on supply chain control by industry and represents a higher risk appetite. Chemical residue management solely through activities along the supply chain is not appropriate for Australia in the current operating environment due to the large number of producers, the large number of trading partners, the importance of exports, and the inefficiency and expense which will be currently generated to trace animals on an individual basis. It has been deemed that this would not be sufficient to maintain market access to the many premium markets Australia currently has trade access to.<br><br>► Residue management could be industry led rather than through the government department, and this was initially the case when ESIs were established/ monitored previously by Meat Livestock Australia approximately nine years ago. Under the trade criteria set in Australia however the system is relied on to help meet a regulatory responsibility (the APVMA being satisfied there is no undue trade risk when registering an agvet chemical use) and should sit with government to enable appropriate oversight and to ensure the trade criteria are met. While it is still the registrant that must provide evidence to satisfy the APVMA, it is more logical that residue limits are set by the APVMA as it has access to relevant data (other than supplied by the applicant) and the relevant expertise. |

## 4.3 US's approach to chemical residue management

The approach to risk management of chemical residues to meet specific outcomes sought after in the US has been detailed below, which takes into account the country profile and the regulatory framework in place.

As detailed in section 2.2 there is limited publicly available information on the operation of chemical residues management and the approaches to the management of trade risk in the international market. As a result, the information below on the US' approach to chemical residue management was obtained mostly through anecdotal evidence through consultation with a key personnel within the US Centre for Veterinary Medicine - Food and Drug Administration (FDA) in the US.

### 4.3.1 Country profile

In 2016, US beef exports represent 10% of total production (1,159,000 tonnes) and pork exports about 21% of total production (2,377,000 tonnes).[94] The USA exports a small amount of lamb and mutton. The primary export markets for US beef are Japan, Mexico and South Korea.[95] The primary export markets for US pork are Mexico, Hong Kong, China and Japan.[96]

[94] "Livestock and Poultry: World Markets and Trade, United States Department of Agriculture,2018, *https://apps.fas.usda.gov/psdonline/circulars/livestock_poultry.pdf,* accessed 17/4/18

[95] "Total U.S Beef Exports", US Meat Export Federation, 2017, *http://www.usmef.org/downloads/Beef-2008-to-2017.pdf,* accessed 17/4/18

[96] "Fact Sheet – Pork and Exports", Australian Pork*, https://australianpork.com.au/wp-content/uploads/2013/09/FACT-SHEET-Pork-and-Exports.pdf*, accessed 17/4/18

### 4.3.2 Regulatory framework

In the US, one set of residue limits, withdrawal periods, are set in place for both domestic residue management and international market access. Chemical residue management in the US is managed by a number of governing bodies:

- The Food and Drug Administration (FDA), which is under the Department of Health and Human Services, is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs for animals.[99]

- The Centre for Veterinary Medicine (CVM), is part of the Food and Drug Administration (FDA). CVM conducts research that helps FDA ensure the safety of animal drugs, food for animals, and food products made from animals.[100] The United States Environmental Protection Agency (EPA). The EPA is an agency of the federal government of the United States. The EPA regulates pesticides under broad authority granted in two major statutes, the *Federal Insecticide, Fungicide, and Rodenticide Act* and the *Federal Food, Drug, and Cosmetic Act*. These laws have been amended by the *Food Quality Protection Act* and the *Pesticide Registration Improvement Act*.[101]The US Department of Agriculture's (USDA) Foreign Agricultural Service (FAS) aims to enhance export opportunities and global food security through linking US agriculture to the world.[102]

State regulators in the US are involved in performing on the ground investigations when a particular violation is detected, however primary responsibility for the management of chemical residues is held by the Federal government.

### 4.3.3 Approach to managing chemical residues

As part of the registration process the US EPA and FDA examine the ingredients/actives of products, the particular site or crop where it is to be used, the amount, frequency and timing of its use, and storage and disposal practices.[104] Based on this examination chemical tolerances, which are the limits on residues left in foods, are determined.[105] The following process is followed in the US to set chemical residue tolerances:

1. Chemical companies submit an application to the EPA or the FDA for a registration action, such as to register a new active ingredient, new product, or adding a new use to an existing product.

2. International food and agriculture regulations informed by FAS are taken into consideration when residue limits are set by the EPA. FAS maintains an online system to inform the US agriculture industry regarding changes in international food and agriculture regulations that could affect US exports.[106] FAS also provides access to a database that lists maximum acceptable levels of pesticides and veterinary drugs in food and agricultural products in the United States, as well as 70 other countries, the European Union and the Codex Alimentarius Commission.

3. The EPA establishes chemical tolerances based on the potential risks to human health posed by a pesticide. The EPA publishes petitions to create tolerances, and documents that establish or revoke tolerances, or create exceptions to tolerances.[107]

4. The FDA does not take the established MRLs used by trading partners for veterinary drugs into consideration in the US. The tolerance is determined after a final ADI, safe concentration, target tissue and marker residue are selected. The tolerance is the maximum concentration of the marker residue (or

[99] "About the Centre for Veterinary Medicine (CVM)", US Food and Drug, 2018, https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm, accessed 17/4/18

[100] "About the Centre for Veterinary Medicine (CVM)", US Department of Health and Human Services, 2018, *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm*, accessed 17/4/18

[101] "Pesticide Registration", United States Environmental Protection Agency, 2018, *https://www.epa.gov/pesticide-registration/about-pesticide-registration*, accessed 17/4/18

[102] "Foreign Agriculture Service", U.S Embassy & Consulate in Poland", *https://pl.usembassy.gov/embassy-consulate/government-agencies/foreign-agricultural-service-fas/*, accessed 17/4/18

[104] "Pesticide Registration", United States Environmental Protection Agency, https://www.epa.gov/pesticide-registration/about-pesticide-registration, accessed 17/4/18

[105] "Pesticide Tolerances", Federal Register – The Daily Journal of the United States Government, *https://www.federalregister.gov/pesticide-tolerances*, accessed 17/4/18

[106] "Pesticide Registration", United States Department of Agriculture, *https://www.fas.usda.gov/topics/regulations-and-requirements*, accessed 17/4/18

[107] "Pesticide Registration", *https://www.federalregister.gov/pesticide-tolerances*, accessed 17/4/18

other residue indicated for monitoring purposes) that can be legally present in the target tissue. It is determined by evaluating depletion data consisting of total residue concentrations and marker residue concentrations measured by the proposed analytical method and examining when the level has depleted to less than the safe concentration level. The safe concentration level is determined by taking into consideration the amount of the acceptable daily intake (ADI) assigned to one commodity (either liver, kidney, muscle, fat, milk, eggs or honey) and the daily consumption values.

### 4.3.4 The management of trade risk

The profile of the consumption of meat where approximately 84% is consumed domestically means a lower focus on the export market.[108] Stakeholders suggested that there is a view that if a product is safe to consume in the domestic market it is fit for export to the international market.

Therefore the approach taken by the US is not to take trading partners MRLs into consideration. The large domestic market in the US means there is less of an industry-wide consequence should there be a problems accessing an export market, i.e. a higher risk tolerance for industry.

### 4.3.5 Summary of chemical residue management in the US

The table below outlines the key similarities and differences in chemical residue management in the US in comparison to Australia. The factors which led to differences in the treatment of chemical residue management in the US is analysed in Chapter 5.

**Table 7: Summary of chemical residue management in the US**

| Similarities to Australia | Differences to Australia | Applicability |
|---|---|---|
| ► Management of chemical residues is initiated and monitored by the Federal government.<br><br>► Information on petitions to create tolerances, and documents that establish or revoke tolerances, or creates exceptions to tolerances is made publically available. | ► Most animal products are consumed domestically, and as a result chemical residue management has a focus on the domestic market.<br><br>► The established veterinary drug MRLs used by trading partners are not taken into consideration in the US. The US tolerance is determined after a final ADI, safe concentration, target tissue and marker residue are selected. | ► The approach taken by the US not to take trading partners MRLs into consideration, is not appropriate in Australia since there is far greater dependence on the export market. As such the degree of risk this approach would generate in Australia is not considered suitable.<br><br>► The large domestic market in the US means there is less industry wide consequence should there be a problem to access an export market i.e. a higher risk tolerance for industry. |

[108] "Livestock & Meat Domestic Data", United States Department of Agriculture, *https://www.ers.usda.gov/data-products/livestock-meat-domestic-data/,* accessed 17/4/18

# 5. Assessing Australian ESIs

This chapter reports EY's findings in relation to the operation of the current ESI system in two key sections, reflecting the broad categories of issues raised. The first section outlines views and analysis related to the current approach to risk management. EY undertook stakeholder consultations, and a detailed analysis, to form conclusions and recommendations on:

1. The current approach to trade risk management.

2. The importance of ESIs to the meat industry, particularly Australia's reputation.

3. The impact of the current approach, including the difference between ESIs and WHPs domestically and internationally and the impact on innovation and producers.

4. The potential of alternative approaches to meet the outcomes achieved through the current approach.

The second section explores suggested improvements to the current system. The section details key issues with the current system as raised by stakeholders, and provides key recommendations for improvements.

## 5.1 Approach to trade risk management

In Australia, various approaches have been taken to manage trade risk over time. The current ESI system was introduced in order to facilitate ongoing relationships with major trading partners, support Australia's reputation as 'clean and green', and provide growth with the meat export industry. An assessment of the ability of the current system to meet desired outcomes is detailed below.

### 5.1.1 Current approach to trade risk management

There were distinct differences in the views of stakeholders in relation to the appropriateness of the current system, specifically the approach to risk management. These differences are outlined in the sections below.

#### 5.1.1.1 Change to the current system

Stakeholders within the chemical industry expressed the view that the current management of risk to market access (through setting ESIs) is highly conservative and not commensurate with the likelihood of residue violations and/or the likelihood of violations being detected. It was suggested that the current approach is not fit-for-purpose as it does not achieve an appropriate balance between accessibility to chemical products and market access considerations.

This was reinforced by views that the Australian approach is significantly more conservative than approaches used by direct competitors in export markets, particularly the approach used in NZ (noting that despite these suggestions there is a general lack of understanding of the specifics of the approach taken in other countries as discussed further below in section 5.1.4).

It was also suggested that the current approach manages a perceived risk rather than an actual risk. Support for this stance was provided by suggesting that older similar products with no ESIs are administered to animals and have not resulted in market violations, demonstrating limited risk. Additionally, these stakeholders reported that there was limited evidence of market closures or residue violations in competitor countries that have alternative approaches in place.[109]

Some stakeholders suggested that importing countries do not frequently test imports for chemical residues. As a result, it was reported that relying on Australia's regulatory system, and in particular the testing performed by NRS, should be adequate to maintain market access.

It was also suggested that importing countries would continue to trade with Australia, even if ESIs were not in place, if negotiations were made with importing countries emphasising that Australia would not impose unsafe regulations on domestic residents and that testing is performed domestically.

[109] See section 5.1.1.2 for evidence of potential residue violations in Australia, and residue violations noted in the international market.

#### 5.1.1.2 Support for the current system

All stakeholders within the meat industry suggested that the current approach is appropriate and while it may be conservative, this conservatism is necessary. They stated that the ESI system is fundamental to ensuring that market access for Australian meat products is maintained. These stakeholders suggested that, given the proportion of meat exported from Australia, it is critical to ensure market access is not jeopardised by chemical residue violations. Further, some said that maintaining market access was the single most important priority for the industry. In their view a conservative approach was warranted and fit-for-purpose.

These stakeholders suggested that the risk to market access was real. Their view was that any violations could have significant consequences for the industry. In addition, it was stated that importing countries monitor NRS results as well as undertake their own testing. One stakeholder suggested that whether or not importing countries were testing was irrelevant since they had the ability to do so at any time and any residues violations could seriously jeopardise market access. These stakeholders also responded to claims that low rates of violations for older products with no ESIs reflected a low risk of any violations. They noted that many chemicals used in older products have set MRLs or Codex within the international market, and therefore do not result in MRLs being based on LOQ (or low level default, e.g. 0.01m/kg).

A further reason for support of the current system articulated was that countries can use chemical residue testing and resultant violations as non-tariff trade barriers. It was stated that as an increasing number of Free Trade Agreements (FTAs) are put in place, countries may be looking for alternative barriers to trade. Therefore, ensuring residue limits are not violated will be increasingly important to protect against the potential for residue detection to be used as a non-tariff barrier.

It was also suggested by a meat industry stakeholder that if ESIs were removed, a default ESI would need to be put in place by industry. For instance, currently the industry body SAFEMEAT has applied a Provisional Russian ESI to veterinary medicines and feed additives that contain oxytetracycline and/or chlortetracycline. To meet Safemeat's requirements for slaughter of sheep for the Russian meat market, the Safemeat Provisional Russian ESI of 90 days is required. Alternatively, importing countries with higher risks of detecting a breach of their MRL would need to be avoided. The avoidance of importing countries would limit the profitability of commodities, and result in a flow on effect, leaving producers with lower prices for production. The reasoning behind this stance was the view that ESIs are critical in maintaining the exporter's business reputation. It was suggested that the consequence of just one violation would be detrimental to an entire business and potentially the industry. Further it was suggested that alternative approaches such as increased segregation of product during processing are not appropriate due to limitations in the current operating environment (this is explored further in section 5.1.4).

Stakeholders suggested that the risk to market access had stemmed from multiple concerns in the international market in relation to specific residue limits, which if not addressed through the ESI system, could have led to potential violations. A few examples of these occurrences provided were:

- *Russia – Tetracycline:* In 2011 products imported into the Russian Federation and its Customs Union Partners Belarus and Kazakhstan were required to comply with the residue limits contained in the Customs Union standard. The standard recognised 0.01 mg/kg as the level of detection for the tetracycline group of antibiotics. This residue level was lower than what was permitted in Australia. Port-of-entry testing by Russian authorities detected residues at levels above the Customs Union standard. Management of differences in standards was subsequently addressed through ESIs to provide the necessary assurances to Russia to maintain access.

- *Bayticol Pour–on for live export cattle:* Although Bayticol Pour-on for live export cattle was intended for immediate live export, there was a chance that treated animals rejected for live export could enter the export meat chain where the residue levels would be too high. APVMA established ESI parameters and revised restraints to manage this risk.

- *Egypt* – hormone growth promotants (HGPs) and ractopamine: The Egyptian Organization for Veterinary Services advised that testing of imported meat for the presence of HGPs and ractopamine was going to commence in 2015. The standards required that no synthetic HGPs or ractopamine were present during the time of slaughter, and that only natural hormones were present with specific limits. Restrictions on processors sourcing livestock were developed to ensure compliance ahead of January 2015.

- *China – Trenbolone and Zeranol:* Chinese regulations list HGPs including trenbolone and zeranol as drugs prohibited for use and for which residues must not be detected in animal derived food. To provide

assurances to China, the department issued market access advices and meat notices restricting sourcing of livestock by processors.

- *Indonesia – Trenbolone:* Until recently, Indonesia had no MRL for trenbolone. Indonesian authorities have been undertaking testing for the chemical in Australian beef and, without an MRL, any detection would be considered a violation. Following advocacy from the department Indonesia has recently established an MRL for trenbolone, reducing the risk of violations

Stakeholders also pointed to violations which had occurred in the past and resulted in market access issues to demonstrate that the risk was real. The following table details examples of impacts to market access as a result of chemical residues.

**Table 8: Trade disruptions**

| Year | Issue | Market |
|---|---|---|
| 1987 | DDT & Dieldrin | US |
| 1990 | Antibiotics | US, Japan |
| 1991 | Penicillin/ Tick control chemicals | US, Canada, North Asia |
| 1992 | HGP's | Europe |
| 1993 | HGP's<br>Tick control chemicals | Europe<br>US |
| 1994 | DDT | US, Asia |
| 1995 | Chlorfluazuron | US, Asia |
| 1996 | Endosulfan | US, Asia |
| 1997 | BHC | Local |
| 1998 | Endosulfan | US, Asia |
| 1999 | HGP's | Europe |
| 2001 | Bioresmethrin | Korea |
| 2002 | Endosulfan | US |

The following case study on *China's 2016 Food Import Situation*[110] shows that residue testing is conducted and multiple chemical residue violations have been detected in the international market recently. The findings from the case study provides evidence that although Australia was not on the list of chemical residue violations, testing does occur and multiple violations for food products have been found.

**Case Study – AQSIQ Releases White Paper on China's 2016 Food Import Situation**

In July 2017, China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) released the 2016 White Paper on the Safety and Quality of Imported Foods. China is a major import market for Australia and it imports from approximately 187 countries. The study was based on data from April 2017 – March 2018. The study identifies that veterinary drug residue problems occurred as the exporting countries' competent authorities and manufacturers failed to control veterinary medicine use effectively. There were a total of 39 residue violations noted for nine countries (including New Zealand), with one residue violation in meat (chloramphenicol) in Kyrgyzstan. It was noted, however, that there were no residue violations in Australia.

### 5.1.2 International approaches

Comparisons were made by stakeholders between Australia and other countries with different approaches to the management of trade risk in meat products from chemical residues. Many registrants referred to the international market to highlight that the approach in Australia is too conservative. Although these comparisons were made, there was a lack of understanding of the processes in place to manage residues in different markets. This was specifically the case for NZ and significant reference was made to the less conservative approach taken in NZ. However, apart from the absence of ESIs and the use of WHPs to manage product for domestic and international consumption, the approach taken to risk management was

[110] "China's 2016 Food Import Situation", 2017, Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), *https://gain.fas.usda.gov/Recent%20GAIN%20Publications/AQSIQ%20Releases%20White%20Paper%20on%20China%27s%202016%20Food%20Import%20Situation_Beijing_China%20-%20Peoples%20Republic%20of_8-14-2017.pdf*, accessed 05/7/18

unknown by many registrants. Chapter 4 provides a detailed description of the approaches taken in key competitor markets. Table 9 provides a summary of the risk management measures.

**Table 9: Approach to managing chemical residues in the international market**

| Country | Approach to managing chemical residues | Similarities to Australia | Differences to Australia |
|---|---|---|---|
| ► NZ | ► No differentiation in slaughter intervals for the domestic and international market.<br>► WHP are determined through an assessment of the reference health standards such as the Ministry of Health's most recent National Nutrition Survey, chemical residue standards of major trading partners, Codex maximum residue limits, and correspondence with importing markets to understand their requirements.<br>► Where countries do not have a MRL and they are a significant market, Overseas Market Access Requirements (OMARs) can be used. OMARs are the requirements that the New Zealand government has agreed with governments of export destinations.<br>► If a WHP is considered too long, not in line with good agriculture practice, and potentially leading to violations, the product is not registered. | ► MRLs are set and managed by the Government.<br>► The residue limits of different trading partners are considered when setting MRLs.<br>► On-going discussions are held with importing countries to manage residue requirements, e.g. acceptance of international (Codex) standards, acceptance of NZ standards.<br>► A MRL can only be accepted if the estimated exposure is less than the relevant reference health standard.<br>► Where countries do not have a MRL, and they are a significant market, tighter sale and use restrictions can be put in place, such as OMARs, rather than imposing a longer WHP for all export markets. OMARs are the requirements that the NZ government stipulates for export destinations. OMARs can be used to place prohibitions or limitations on products destined for certain markets. OMARs are similar to the departments Market Access Advice (MAAs) and Meat Notices (MNs). | ► One withholding period is set for products both in the domestic and export market, rather than a dual system (ESI and WHP).<br>► NZ will not register a chemical product with an export driven WHP (not dealt with by OMARs) which is impracticable from an animal management perspective, i.e. is determined not to support good agriculture practice. Australia has more flexibility in this scenario as it can still have a domestic WHP, even if the ESI is impractical.<br>► NZ often considers a different pool of countries' trading requirements, given NZ sells meat products to different trading partners than Australia.<br>► A smaller number of trading partners' MRLs are considered.<br>► The residue limits are generally not decreased to the limit of quantification to accommodate trade with countries without MRLs, except where there is a particular sensitivity.111NZ instead places more reliance on Codex. It is noted this is not always the case in Australia but anecdotal evidence suggests this happens more often. |
| *Applicability of chemical residue management in NZ to Australia* | | ► The use of one withholding period for products both in the domestic and export market could be applied in Australia, however it would decrease flexibility (i.e. would no longer allow shorter domestic WHP if the ESI was unworkably long). It was found that while the current system may often default to the ESI (due to uncertainty about the final market destination of parts of an animal), the dual system still provides additional flexibility, particularly if other measures have been taken to differentiate products for the domestic market.<br>► OMARs could be implemented in Australia, however they may limit the number of markets Australia has the ability to export to. Australia implements Meat Notices (MNs) and Meat Access Advices (MAA) that have a similar role to NZ OMARs. However, market specific requirements make the system more complicated to implement and increasingly prone to failure.<br>► Rather than ensuring residue levels are decreased to the level of quantification, greater reliance could be placed on Codex in Australia. However, this will increase risk to market access, and give less importance to countries with residue requirements more stringent than Codex. | |
| Brazil | ► No differentiation in slaughter intervals for the domestic and international market.<br>► Industry leads management of chemical residues in export markets, and it is the responsibility of processors to ensure compliance.<br>► Residue management for vertically integrated industries such as pork and poultry is managed in Brazil through industry lead control activities along the supply chain, based on the destination intended for consumption. Vertically integrated industries have a greater ability to manage market eligibility | ► Samples are collected to perform testing by the Federal Inspection Service, similar to the NRS in Australia, to verify controls on veterinary drugs and residues are adequate.<br>► Investigation sub-programs are established when a violation is detected. | ► Chemical residues are managed only through activities along the supply chain, in comparison to Australia where additional measures such as WHP and ESIs have been introduced to ensure appropriate chemical residue limits are applied.<br>► Brazilian abattoirs separate product based on the interval between treatment and slaughter and different product types (liver, kidney, muscle etc) might have different slaughter intervals for the same market and for different markets. Different parts of an individual animal have different set withholding periods, for instance a different limit can be set for offal in comparison to the remaining parts of |

[111] There have been instances in Australia where the reasonable LOQ for ESI considerations may not be the lowest validated LOQ for and active constituent if the APVMA has previously used a higher LOQ as an ESI endpoint for that active. Please refer to section 3.4.

| Country | Approach to managing chemical residues | Similarities to Australia | Differences to Australia |
|---|---|---|---|
| | for different parts of a commodity based on the slaughter interval i.e. different parts of a commodity can have different WHPs applied. | | the carcass. This occurs for beef, and vertically integrated supply chain products such as poultry.<br>► Compliance with importing country residues limits are industry led rather than through a government department or agency. |
| ► *Applicability of chemical residue management in Brazil to Australia* | | ► Brazil's approach relies on supply chain control by industry and represents a higher risk appetite. Chemical residue management solely through activities along the supply chain is not appropriate for Australia in the current operating environment due to the large number of producers, the large number of trading partners, the importance of exports, and the inefficiency and expense which will be currently generated to trace animals on an individual basis. It has been deemed that this would not be sufficient to maintain market access to the many premium markets Australia currently has trade access to.<br>► Residue management could be industry led rather than through the government department, and this was initially the case when ESIs were established/monitored previously by Meat Livestock Australia approximately 9 years ago. Under the trade criteria set in Australia however the system is relied on to help meet a regulatory responsibility (the APVMA being satisfied there is no undue trade risk when registering an agvet chemical use) and should sit with government to enable appropriate oversight and to ensure the trade criteria is met. While it is still the registrant that must provide evidence to satisfy the APVMA, it is more logical that residue limits are set by the APVMA as it has access to relevant data (other than supplied by the applicant) and the relevant expertise. | |
| US | ► No differentiation in slaughter intervals for the domestic and international market.<br>► The MRLs of trading partners are not taken into consideration when determining residue standards for veterinary drugs, as the focus is primarily on the domestic market in the US. The tolerance is determined after a final Acceptable Daily Intake (ADI), safe concentration, target tissue and marker residue are selected. | ► Management of chemical residues is initiated and monitored by the Federal Government.<br>► Information on petitions to create tolerances, and documents that establish or revoke tolerances, or creates exceptions to tolerances is made publically available. | ► Most animal products are consumed domestically, and as a result chemical residue management has a focus on the domestic market, rather than the export market.<br>► The established veterinary drug MRLs used by trading partners are not taken into consideration at all in the US. The tolerance is determined after a final ADI, safe concentration, target tissue and marker residue are selected. |
| ► *Applicability of chemical residue management in the US to Australia* | | ► The approach taken by the US (for veterinary drugs not to take trading partners MRLs into consideration) is not applicable in Australia where there is far greater dependency on the export market. The degree of risk this approach would generate in Australia is not appropriate.<br>► The large domestic market in the US means there is less industry wide consequence should there be a problem to access an export market i.e. a higher risk tolerance for industry. | |

As illustrated, Australia has a different approach to international markets. Australia is the only country which has separate slaughter intervals for livestock processed for the exports and domestic markets. Brazil, NZ and the US do not routinely differentiate slaughter intervals for the domestic and international market. Brazil relies on industry to lead residue management solely through activities in the supply chain without relying on other tools such as WHPs and ESIs, where industry is left to determine which animal/part of an animal will go to which export market (allowing tailored WHPs). NZ relies on the considerations of residue limits of major trading partners, Codex, and OMARs to place limitations on products destined for specific markets, as well as discussions and negotiations with importing countries, and sets domestic residue levels accordingly (this system does not allow for a lower domestic WHP).The US does not take major trading partners MRLs into consideration when setting residue limits for veterinary drugs, focusing instead on its domestic market.

#### 5.1.2.1 Conclusion: Current approach to risk management

There are clear differing points of view held by the chemical manufacturers and the meat industry in relation to the current approach to risk management. A primary argument to support the stance that the Australian system is too conservative is based on the view that as violations have not been detected the system is not necessary, and that there is no equivalent ESI system in place in competitor countries. Those arguing to

support the current ESI system point to the fundamental need to ensure market access is maintained. When considering these two points of view EY has noted the following:

1. Market access is vital to the Australian meat industry: Australia's heavy reliance on exports makes access to international markets vital to ensure growth and profitability in the meat industry. Australia currently has access to over 77 importing countries[112], including countries with more stringent residue requirements. The current approach to setting a single ESI reflecting the needs of the most restrictive of its significant markets enables Australia to maximise returns on different parts of commodities, by providing flexibility to sell products to the most profitable market at any given point in time.

2. The current system is supported by the meat industry: The ESI system is regulation for the benefit of the meat industry and is strongly supported by that industry. When consulting representatives of producers in the meat industry, it was clear that producers were willing to make the trade off on productivity gains that can be brought by the application of new chemical products, to ensure market access is maintained. This is explored further in section 5.1.3.3. Producers' willingness to make this trade-off is influenced by historic evidence of trade disruptions due to chemical residue violations. For the case study included on China's import situation, there was insufficient evidence to conclude that the removal of ESI system is justified since violations were not detected in Australia and it could have been the system which prevented the violations. It is noted that, during consultations carried out by EY, the department confirmed that importing countries also undertake testing.

3. The supply chain is not integrated: Producers do not have control over which market meat or offal derived from their livestock will be going to. As market access requirements differ significantly between markets, producers and processors have few means of controlling chemical residues for a specific market.

4. Approaches taken by the international market are not necessarily comparable: While there is different levels of risk acceptance in the international market there are aspects of the meat export industry which are unique to Australia. Although Australia is the only country to have separate standards for the domestic market and the international export market, this needs to be considered in light of a number of factors which differentiate Australia from the international market. While competitors may share aspects of the following factors, these factors combined differentiate Australia from competitors within the international market:

- **Reliance of exports to a wide number of trading partners:** as the size of Australia's domestic market is relatively small in comparison with the quantity of production, Australia is heavily depended on its export market. Australia exports to a wide spread of markets, and the continuation of trade to these markets sometimes requires compliance with more restrictive market access requirements, in comparison to competing countries. The benefits of exporting to a wide spread of export markets is the return made on trade. Different commodities (and parts of a commodity), can be traded with trading partners that will pay the highest return, due to preferences and value held for certain products.

- **Reliance on reputation to remain competitive in the market:** As the cost of labour is high, Australia heavily relies on product quality and is increasingly targeting high value markets. Attributes supporting this include its reputation as 'clean and green' to remain competitive in the market.

- **Trading partners:** Different countries have different trading partners who in turn have different requirements and approaches to trade. Australia has a significant number of trading partners, with different requirements to maintain market access.

- **Climate and production systems:** Australia's climate, production systems and nature of supply chains, encompass a wide spread of different husbandry and animal management regions, which may require different treatment options with different chemical product compositions. The differences in chemical product compositions, and quantity, leads to the need to comply with a greater number of residue limits for chemicals within these products in the international market.

[112] Meat & Livestock Australia, 2017, *https://www.mla.com.au/globalassets/mla-corporate/prices--markets/documents/trends--analysis/fast-facts--maps/mla_beef-fast-facts-2017_final.pdf*, accessed 17/4/18

5. There are a lack of appropriate alternative approaches in the current operating environment to foster ongoing relationships with major trading partners which leads to growth and expansion of exports within the meat industry, and ensure the maintenance of Australia's reputation as 'clean and green', whilst mitigating current concerns. This is explored further in section 5.1.4.

When taking the importance of market access, conditions specifically applicable to the Australian meat export market, and the fact that there are no practical alternative approaches in the current operating environment into consideration, EY concludes that the current approach to risk management is suitable.

### 5.1.3 The importance of ESIs to Australia's reputation

The majority of stakeholders agreed ESIs contribute to Australia's reputation in some form. However, there were differences in opinion as to whether ESIs contribute to the reputation of meat products directly or indirectly and as to how important ESIs are relative to other factors which contribute to the reputation of meat products.

Stakeholders reported that the range of factors contributing to Australia's reputation in international markets included the regulatory system, product and Australian branding, quality of meat, measures to control biosecurity status, industry systems, culture, testing overlay, company best practices, land use and wildlife conservation. As noted, differences of opinion were evident between stakeholder groups as detailed below.

- Red meat industry stakeholders suggested that:
  - ESIs are critical in maintaining Australia's reputation and brand in international markets which facilitates market access. They also noted that market access is particularly important given the prominence of exports in the Australian red meat industry.
  - While there are a range of factors that contribute to Australia's trade reputation, ESIs are fundamental in underpinning the confidence in Australian products and any violations of chemical residue standards in international markets could cause consumers to seriously question the product.
  - While international consumers (and potentially regulators and importers) may not directly understand the ESI system, they do believe Australia's products are high quality and safe and this reputation and confidence in our products is a result of ESIs (and the broader regulatory system).
  - Markets are extremely sensitive to residue violations, both from a government and consumer perspective. Governments will suspend trade if they have concerns about residues. Consumers do not differentiate between market access requirements and concerns for their health and safety so any violations are viewed as a risk to their health with detrimental impacts on demand.
- Australian Government regulators suggested that:
  - ESIs play an important role in upholding Australia's reputation as 'clean and green', and maintaining market access.
  - ESIs contribute to Australia's reputation, but it is only one of many contributing factors. The reputation Australia holds has been built through a number of factors over the course of history.
  - Importers place importance on ESIs. It was noted that the removal of ESIs could significantly compromise the confidence trade partners currently hold for Australian exports.
- A number of chemical manufacturers suggested that:
  - Australia's reputation is built on a long history of quality products and is not really influenced by ESIs. Many importing countries are not aware of ESIs, and very few people will be concerned about ESIs.
  - NZ has managed to uphold a reputation as 'clean and green', despite its perceived less conservative approach. It is therefore an ideal example that the ESI system brings little value to Australia's reputation.

- Others suggested that while ESIs contribute to Australia's reputation it was only one of many factors.

- Some suggested that consumers in international markets would never have heard of ESIs. Others did note that importers placed importance on ESIs.

- Australia's reputation as clean and green gives it a competitive advantage in competing with lower cost beef imports from competitor countries.

#### 5.1.3.1 Conclusion: The importance of ESIs to Australia's reputation

When considering the importance of ESIs to Australia's reputation as 'clean and green', EY noted the following:

- The current 'clean and green' reputation Australia holds is vital in supporting trade and underpinning the value proposition of exports. All stakeholders unanimously held the view that it is Australia's reputation for quality products which provides Australia with competitive advantage within the market.

- Australia's reputation for high quality, safe products allows higher prices to be charged on products, while still remaining competitive in the market. The higher price compensates costs associated with exporting products from Australia, as a result of having a distant location from the majority of the international markets and high costs of production.

- The ESI system is one of many factors that has contributed to Australia's reputation over the course of history. There are many rigorous systems and standards, in addition to the ESI system, which have been put in place to protect meat product integrity throughout the entire supply chain, including farms, feedlots, saleyards, transportation, processing and distribution.

- The susceptibility of Australia's reputation to violations has been made clear, where the detection of one violation alone has historically stopped market access to a country.

The extent to which the ESI system has contributed to Australia's overall reputation varies. As Australia's reputation is a result of multiple systems and standards which are in place to ensure quality products, it is difficult to determine the extent to which ESIs have contributed to this reputation. The extent to which ESIs have influenced Australia's reputation will also vary between countries. As stated in section 2.2, the extent to which residue testing is conducted by importing countries could not be obtained by direct consultation with the importing countries, likely due to concerns about allowing such information to be disclosed in a public report. Direct consultation feedback by importing countries on the impact of ESIs on Australia's reputation could not be obtained. Australian exporters consulted did emphasise the importance the ESI system plays in maintaining Australia's reputation, and stated that if the ESI system was not in place a very similar system would need to be instituted. The measures taken to ensure the quality of Australia's products play an important role in maintaining Australia's reputation as 'clean and green', and ESIs are adding a positive contribution to this reputation.

### 5.1.4 The economic impact of the current approach

The current approach to risk management has consequences and involves trade-offs. This section explores the economic impact of the current approach by examining the scale and magnitude of the problem. It then discusses the impact on innovation and product availability and producers.

#### 5.1.4.1 The scale and magnitude of the problem

The below analysis explores the scale and magnitude of the problem by assessing the number of products where ESIs differ from WHPs in Australia and comparing the length of ESIs with their equivalents in relation to international standards. The analysis has been performed for cattle and sheep, as these are the two meat products with publicly available ESI and WHP lists.[114]

The analysis below is based on the publicly released data from February 2017, which lists the ESIs and WHPs for products used on cattle and sheep. It should be noted that since this list was published the ESI days for NitroFluke injection flukicide for cattle (the outlier with an ESI to WHP difference of 140 days in

[114] It is noted that the decision to publish data only for cattle and sheep by the APVMA was due to an industry request to publish data for these species.

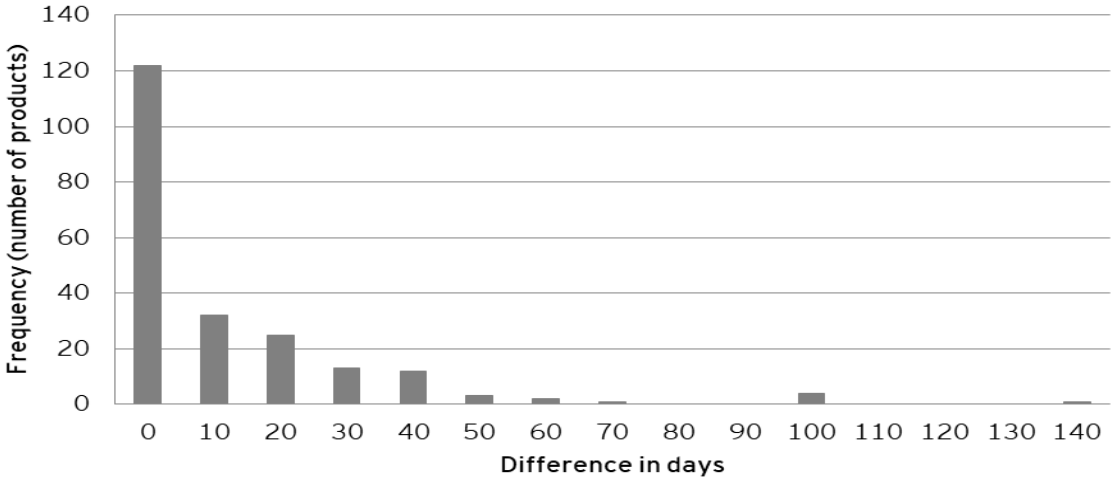
Figure 4) was decreased on 23rd of February 2018 from 210 days to 140 days.[115] This decline illustrates how significant changes to ESIs can follow when a review is conducted.

A total of 215 veterinary chemical products for use in cattle are listed in APVMA's product list.[116] WHPs for these products range from 0 to 70 days, while ESIs for these products range from 0 to 210 days.

The analysis undertaken explores the differences in days between WHPs and ESIs which range from 0 to 140 days, with an average difference of 9 days.

As shown in Figure 4, there is no difference between WHP and ESI for the majority of cattle products (57% or 122). A further 15% have a 1-10 day difference while 12% have a difference of between 11-20 days. A further 6% of products have a difference between WHP and ESI of 21-30 days, with the same proportion having a difference of 31-40 days. A total of 3% or 6 products have a difference of 41-70 days. Four products (2%) had a difference of between 90-100 days and one product a difference of 140 days.[117]

**Figure 4: Difference in days - ESI versus WHP (cattle)**




A total of 317 veterinary chemicals for use in sheep are listed in APVMA's product list.[118] WHPs for these products range from 0 to 126 days, while ESIs for these products range from 0 to 164 days.

The analysis undertaken explores the differences in days between WHPs and ESIs which range from 0 to 101 days, with an average difference of 16 days.

As can be seen in Figure 5, there is no difference between WHP and ESI for just over a third of sheep products (35% or 111). A further 16% have a 1-10 day difference while 20% have a difference of between 11-20 days. A further 8% of products have a difference between WHP and ESI of 21-30 days, with 4% having a difference of 31-40 days. A total of 14% or 42 products have a difference of 41-60 days. Eight products (3%) had a difference of between 61-101 days.

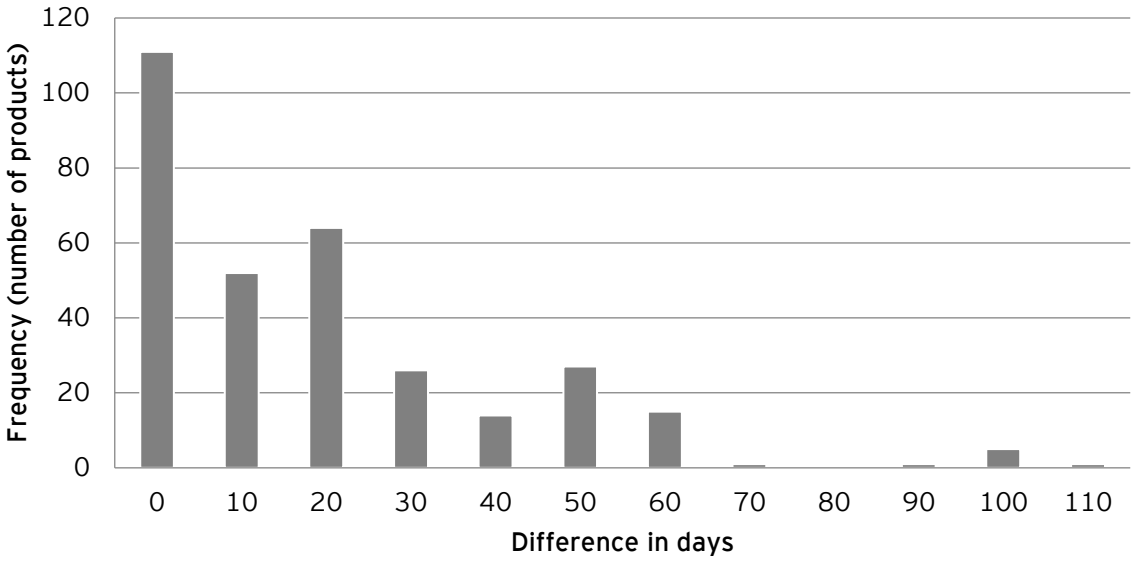
115 Infopest, February 2018, http://websvr.infopest.com.au/LabelRouter?LabelType=L&Mode=1&ProductCode=70184, accessed 17/4/18

116 It is noted that for a further 41 products containing oxytetracycline or chlortetracycline, the product labels do not specify ESIs. Based on MRLs established by current trading partners for Australian cattle products, label Withholding Periods (WHPs) are considered to be acceptable for the management of oxytetracycline and chlortetracycline residues in exported cattle meat and offal. For these products, the ESIs are currently considered to be equivalent to the WHPs.

117 The analysis is based on public data from February 2017 listing ESI and WHP for cattle and sheep products. It should be noted that since the list was published, ESI days for NitroFluke injection flukicide for cattle (the outlier with an ESI to WHP difference of 140 days in Figure 4) was decreased on 23rd of February 2018 from 210 days to 140 days.

118 It is noted that SAFEMEAT has applied a Provisional Russian Export Slaughter Interval (ESI) to veterinary medicines and feed additives that contain oxytetracycline and/or chlortetracycline. To meet SAFEMEAT's requirements for slaughter of sheep for the Russian meat market, the SAFEMEAT Provisional Russian ESI of 90 days is required for sheep to be eligible for the Russian meat market. This affects 16 products which were excluded from analysis.

Figure 5: Difference in days - ESI versus WHP (sheep)




**International differences**

This section explores the differences in ESIs set for use of products in Australia, compared with equivalent standards in competitor countries to understand the magnitude of issues identified.

During the consultations, chemical manufacturers provided examples of products where there are significant differences between ESIs in Australia and other countries. The following products were identified:

- Zolvix Monepantel Broad Spectrum Oral Anthelmintic for Sheep
- Zolvix Plus Broad Spectrum Oral Anthelmintic for Sheep
- Elanco Cyrx Liquid Sheep Blowfly and Lice Treatment
- CLiK Extra Spray-On Sheep Blowfly Treatment (Actives – Dicyclanil)
- Bayticol – tick product

It is noted that these products have larger differences between WHPs and ESIs than most as illustrated in the above analysis. As a result, in addition to those products identified during consultations, a range of products from varying bands of differences between WHPs and ESIs have been included for the analysis:

- Virbac Virbazine Liquid sheep blowfly treatment
- Young's Cyromazine Liquid sheep blowfly treatment
- Closal Broad Spectrum Oral Anthelmintic, Flukicide and sustained action Haemonchicide for Sheep
- Virbac Nitromec injection Endectocide and Flukicide for Cattle
- Genesis Ultra pour-on roundworm, liver fluke and external parasiticide for Cattle.

Table 10 compares Australian WHPs and ESIs with withdrawal periods and withholding periods (in NZ) for these products (or chemicals).

**Table 10: Comparison of slaughter interval limits (February 2017)**

| Product | Australia | NZ |
|---|---|---|
| ZOLVIX MONEPANTEL BROAD SPECTRUM ORAL ANTHELMINTIC FOR SHEEP) | 14 day WHP, 115 day ESI | 7 day WHP |
| ZOLVIX PLUS BROAD SPECTRUM ORAL ANTHELMINTIC FOR SHEEP | 14 day WHP, 84 day ESI | 14 day WHP |
| ELANCO CYREX LIQUID SHEEP BLOWFLY AND LICE TREATMENT | 35 day WHP, 84 day ESI | 7 day WHP |
| CLIK EXTRA SPRAY-ON SHEEP BLOWFLY TREATMENT | 28 day WHP, 120 day ESI, (when used on 6 weeks wool growth or less) | 21 day WHP |
| BAYTICOL POUR-ON LIVE EXPORT CLEARING TICKICIDE | Nil WHP, ESIs not required | Nil WHP |
| BAYTICOL CATTLE DIP AND SPRAY | Nil WHP, 0 day ESI | 14 day WHP |
| VIRBAC VIRBAZINE LIQUID SHEEP BLOWFLY TREATMENT | 7 day WHP,<br>14 day ESI | 7 day WHP |
| YOUNG'S CYROMAZINE LIQUID SHEEP BLOWFLY TREATMENT | 7 day WHP, 21 day ESI | 7 day WHP |
| CLOSAL BROAD SPECTRUM ORAL ANTHELMINTIC, FLUKICIDE AND SUSTAINED ACTION HAEMONCHICIDE FOR SHEEP | 28 day WHP, 60 day ESI | 28 day WHP |
| VIRBAC NITROMEC INJECTION ENDECTOCIDE AND FLUKICIDE FOR CATTLE | 56 day WHP, 120 day ESI | 56 day WHP, 91 day WHP if intramuscular injection occurred |
| GENESIS ULTRA POUR-ON ROUNDWORM, LIVER FLUKE & EXTERNAL PARASITICIDE FOR CATTLE | 49 day WHP, 140 day ESI | 91 day WHP |

As detailed in section 5.1.2.1 the approach taken by NZ to set residue limits differs from Australia primarily due to the following factors:

- Different, and a smaller number, of trading partners are considered
- Greater use of system such as OMARs to place limitations on products destined for certain markets. Greater reliance is placed on Codex.[119]

There are different production systems and environments.

The outcome of this approach can be seen through the differences noted in Table 10.

119 EY notes this is based on anecdotal evidence due to restricted access of documents detailing the chemicals OMARs have been applied to - *https://www.foodsafety.govt.nz/industry/exporting/market-access/omars.htm*

#### 5.1.4.2 The impact on innovation and product availability

Some stakeholders reported that ESIs limit innovation, in particular the incentive for chemical manufacturers to invest in new products or in research and development to bring new products to market.

It was suggested that as a result of the potential for long ESIs some products were not making it to market in Australia. For instance, if a product was assessed during development as likely to have a long ESI attributed to it on registration, further Australian-specific research and/or the Australian commercialisation of the product would not be undertaken in those cases where the ESI would impractically restrict use. In such cases, even where such products do make it to market, demand for products can be limited. Producers are reluctant to use them as it limits flexibility in their management practices, particularly the ability to offload stock at short notice.

Chemical manufacturers noted that this was a particular concern where the use of the product was only applicable to specific species, production systems or certain locations, making it difficult to justify significant research and development spends. It was stated that this was particularly the case for products for sheep in Australia.

#### 5.1.4.3 The impact on producers

Higher ESIs for certain products impacts producers in a variety of ways:

- If animals are required to be treated with a certain product that has an ESI of an extended length then the producer may incur costs to feed and maintain animals until the ESI has expired. Alternatively producers may lose the flexibility to make different marketing and selling decisions in response to certain situations (such as the influence of weather).

- Producers may not use certain products if they are concerned with the ability to hold animals or limitations on flexibility. As a result, productivity (such as weight gain) or animal welfare may be impacted.

- Producers are put at a competitive disadvantage vis-à-vis producers in competitor countries when products do not make it to market in Australia.

A secondary effect of the latter two points is the continued use of existing products and/or the limited use of products with higher ESIs. As a result, more limited options for the treatment of certain diseases or parasites are available for producers. It was noted that this may impact on future productivity through a limit on the tools available to producers. A number of chemical manufacturing company representatives suggested this was of particular concern where resistance to certain products has or is developing. For example, it is highly beneficial to have a range of products available to treat parasites and worms, particularly for herd and flock treatments where chemical resistance has been identified as an issue.

It was also suggested that given the nature of Australia's meat industry and the limited ability to differentiate between export and domestic product, ESIs effectively become the default requirement and product is used (or not used) to ensure compliance with ESIs. This means that while some products could be used to treat animals for domestic consumption they are not.

Meat industry stakeholders acknowledged that there were impacts on producers as a result of the current approach. However, they suggested that producers have not raised concerns that ESIs are causing major productivity or flexibility issues. One stakeholder expressed that in most situations producers are not impacted by the longer ESIs as they have set processes in place during the course of the year, with routine applications of products, and do not frequently have the need to sell in the short term. Others suggested that the short term benefits of increased productivity and flexibility to industry are not worth the risk trade off.

It is noted that some stakeholders suggested that if ESIs were not in operation, and as a result, a violation resulted in impacts on market access, then there would be significant economic consequences for producers (as well as businesses across the meat industry supply chain), given the importance of exports to the industry. As such the meat industry has a low appetite for risk and strongly hold the view that the risk consequences outweigh the productivity benefits.

#### 5.1.4.4 Conclusion: The economic impact of the current approach

When assessing the economic impact on the current approach the following findings can be stated:

- There are a limited number of products with ESI days which are significantly longer than the set WHP for cattle and sheep. The average difference for cattle between WHPs and ESIs was a difference of 9 days, and the average difference for sheep between WHPs and ESIs was 16 days. For cattle a total of 6 products (3%) have a difference of 41-70 days, and four products (2%) have a difference between 90-100 days. For sheep 42 products (14%) have a difference between 41-60 days, and 8 products (3%) have a difference between 61-101 days.
    - It should be noted that the impact of WHP and ESIs is very specific to the use of the product. A product can have a large difference between WHPs and ESIs, but if it is, for example, early treatment of sheep that are primarily for wool with slaughter being well down the track then even a 100-200 WHP/ESI difference would have no consequence. On the other hand a product for fattening lambs would be much more sensitive and a month could be the difference between tradability or not.
- The consequence of having significantly longer ESI periods can affect productivity if a product is avoided, due to the ESI set, which can significantly impact the wellbeing of sheep or cattle, profitability and flexibility. Producers can be reluctant to apply products with long ESIs as it limits flexibility in management practices particularly the ability to offload stock at short notice.
- The current system can hinder the development and use of new and innovative products where MRLs are not established in export markets, with ESIs as a result being based on residue limits of LOQ (or other suitable endpoint see section 3.4), which can mean much longer ESIs.
- Market access is a key priority for producers. From the meat export industry's perspective the priority given to market access outweighs the costs to productivity, since a violation that hinders access to a market can significantly impact the returns earned by producers.
- It was found that while a dual system of WHP and ESI is in place, due to the limited ability to differentiate between export and domestic products, ESIs can become the default requirement. The dual system, however, still provides the flexibility to have a shorter slaughter interval, if additional measures can be taken to differentiate products specifically targeted at the domestic market, and therefore has the potential to provide a benefit.
- The difference in residue management in NZ and Australia as a result of exporting to different (and a smaller number of) trading partners greater reliance on a system such as OMARs to place limitations[120] and NZ's greater reliance on Codex, has sometimes led to notable differences in slaughter intervals.

The meat industry will bear the greatest cost if the market access currently held by Australia is constrained due to a violation. As the meat industry is willing to make the trade-off between improved productivity and/or flexibility to ensure market access is maintained, EY concludes that although there are associated costs with the current approach, the economic impact of the current approach is acceptable for the meat industry. The economic impact should however be monitored by the department, the APVMA, and the meat industry so that if resistance becomes an issue in the future, and the number of products with higher ESI days increases, it could increase the economic impact on the industry. For example, agvet chemical resistance may become more significant in the future (due in part to restrictions on available chemical tools due to ESI concerns, where producers may have no tool for treating an expanding range of pests as a result of a great increase in the economic impact).

[120] EY notes this is based on anecdotal evidence due to restricted access of documents detailing the chemicals OMARs have been applied to - *https://www.foodsafety.govt.nz/industry/exporting/market-access/omars.htm*

### 5.1.5 Potential alternative approaches

A broad spectrum of views were expressed in relation to potential alternative approaches for the ESI system. On one end of the spectrum is the view that the ESI system is fundamental to market access and no alternatives would be appropriate. On the other end, stakeholders suggested the removal of the ESI system completely. Stakeholders who held this view stated that Australia can maintain trade relationships with importing countries by stating that the NRS conducts testing domestically and hazardous residues will not be contained in product supplied to local residents with domestic WHP being adequate.

A few stakeholders expressed a need to better understand the level of trade risk and obtain clearer guidance and transparency on the intention of ESIs, prior to being in a position to suggest alternatives. They suggested that further work needs to be done to understand importing countries' requirements and testing regimes. It was suggested that importing countries need to be consulted to understand the likelihood of testing and therefore the potential for violations. It is noted however, that other stakeholders suggested that talking to importing governments would not enable a better understanding of risk as they may be hesitant to reveal their approaches and that these approaches may change if circumstances (such as political tension) changed and therefore this would change the nature of risk.

A number of stakeholders suggested ways in which the current ESI system could be improved. However the practicality and applicability of the suggestions were questioned by other stakeholders. Suggestions identified and alternative views included:

- New products should be matched with ESI limits set for similar older products.

  Alternative views: Older products may have different combinations of actives, and the residue combinations may be different. It is current practice of the APVMA to use the same target residue level (endpoint) for ESI establishment for new products that was used for the (similar) innovator.

- Setting different ESIs for different parts of a commodity or for different destination countries and then tracing specific carcasses or parts of a commodity through the supply chain to ensure they are destined for appropriate export markets based on their level of residue.

  Alternative views: This would require separation of products and lead to a large loss of a potentially valuable product where product (such as offal) was determined to have levels of residue that do not meet importing market requirements. Navigation through the production process would also be difficult logistically. For instance, it was estimated by an Australian exporter that meat from one carcass can potentially end up in 30 different countries. Further, exporters need the ability to send products to the most suitable market which will make the highest return, to maximise price for different cuts, which varies at each point in time and therefore country specific ESIs are not feasible.

- Not defaulting to LOQ[121] when a country does not have a MRL, but relying on safety nets such as the domestic withholding period, the CODEX MRL and the EU MRL, to set a shorter, more 'reasonable' ESI.

  Alternative views: Violations may occur despite the use of equivalent MRLs in other countries. As such, this would generate significant trade risks, and represents a higher appetite for risk for the meat export industry, which is not appropriate given the importance of exports in Australia.[122]

- Changing government trade policy and additional in-market support to work with countries to build capacity and an understanding of risks. It was suggested that through focus on capacity building in markets to understand risk, potential bilateral trade policy negotiations could occur.

  Alternative views: It is difficult to negotiate positions with countries, as the list of countries a product is exported is extensive and difficult to manage, and the government currently uses this approach as part of its risk mitigation.

[121] There have been instances in Australia where the reasonable LOQ for ESI considerations may not be the lowest validated LOQ for and active constituent if the APVMA has previously used a higher LOQ as an ESI endpoint for that active. See section 3.4.

[122] The government and the chemical industry is, and can continue, working towards an import tolerance based MRL for countries without one. See section 3.3.

- More emphasis on carving out individual markets with specific requirements, through agreement with export destinations by the government. These requirements can be communicated through the MMA and MN.

  Alternative views: This has been done for HGP in the past, however was very complex. The large number of markets Australia has access to, and issues with navigating through the supply chain (as detailed above) will make this approach problematic.

- Technical changes to testing methodology. Currently the tools relied on to determine LOQs are capable of detecting residues at low levels which are highly conservative in comparison to detection levels at which screening is conducted in importing countries, and it was questioned whether this level of assurance is appropriate.[123]

  Alternative views: Using less conservative testing methods may lead to potential violations and market access issues.

#### 5.1.5.1 Conclusion: Alternative approaches

A number of alternative approaches have been identified by stakeholders. These alternative approaches, however, all have challenges in implementation and/or effectiveness in the current operating environment. The current operating environment influences the practicality of these approaches as well as the ability of these approaches to manage risk to the same level as the ESI framework.

Currently the suggested alternatives will either not produce the same outcome that the ESI system achieves, or cannot be implemented in the current operating environment. The specific outcomes include the current level of risk management which increases confidence within the market, which aids in maintaining ongoing relationships with major trading partners, and maintaining Australia's current reputation.

Further negotiations with importing countries, and the integration of global systems in place over time may allow further reliance on safety nets such as Codex and the EU MRL. This may lead to less frequent use of the LOQ as a target for ESIs, which may support the setting of shorter ESIs.

As technological advancements occur over time, and the operating environment changes, the feasibility and appropriateness of these approaches may change.

### 5.1.6 Recommendations on approach to risk management

The approach to the regulation of chemical residues in exported meat products in Australia is based on ensuring international market access for Australian exporters with a low appetite for trade risk.

There are mixed views on the size of the trade risk and the likelihood of violations and therefore the appropriateness of this risk appetite.

Stakeholders noted two elements to the potential for residue violations to occur:

- Firstly, meat products had to have chemical residue present at levels that did not meet importing countries' residue requirements.

- Secondly, there needed to be identification and detection that these chemical residues were exceeding requirements.

Many stakeholders focused on the second element when raising issues with the current approach. However, it is noted that this does not necessarily reflect the management of trade risk but rather the probability of violation detections occurring. The current approach is seen by EY as important in positively contributing to Australia's reputation as 'clean and green'. It also does have consequential economic impacts such as reduced producer productivity and flexibility and additional cost for veterinary product manufacturers and limitations on the ability to sell some products. However, the majority of stakeholders reported that the consequence of any violation and associated impact to market access would be large. As a result EY concludes that this trade-off is appropriate and notes that the meat industry is willing to accept the impacts to limit trade risk.

[123] There have been instances in Australia where the reasonable LOQ for ESI considerations may not be the lowest validated LOQ for and active constituent if the APVMA has previously used a higher LOQ as an ESI endpoint for that active. See section 3.4.

Although Australia is the only country with a dual system in place (ESI and WHP) whilst having key competitors (US, NZ and Brazil) with one system in place, it is recommended the dual system stays in place. The WHP gives the Australian meat export industry the ability to sell strictly to the domestic market if needed, and provides greater flexibility within the market.

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| **Recommendation 1** | It is recommended that the current ESI approach be maintained, noting there are areas for improvement as outlined. This is because the low risk appetite and the current regulatory approach is supported by all sectors within the meat industry, given the importance of exports. The meat industry expressed a view that while there may be trade-offs (such as access to chemicals and the effects on costs and/or productivity) it is willing to accept these trade-offs to ensure there is a low risk of affecting market access. |

When assessing alternative approaches it was found that there are no approaches which can generate the same positive outcome that the ESI framework provides in the current operating environment. Changes to the operating environment in the future however may allow more alternate avenues to become appropriate.

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| **Recommendation 2** | Changes in the operating environment should be monitored by the department and the APVMA, and when significant changes are identified, consideration should be given to the appropriateness of alternatives to the current Australian ESI system.<br><br>A key element of this process would entail all affected parties (particularly government, and stakeholders such as the meat industry and chemical industry) working collaboratively to design, test and implement any changes. |

Many stakeholders point to international approaches as illustrative of the management of risk, suggesting that these show different approaches could be appropriate. However, there are a variety of factors which impact on the appropriateness of these regimes and influence their applicability to the Australian market. These include the importance of exports and therefore the impact of any trade market access issues, the operating environment including the nature of production and supply chain operation and the requirements of markets to which meat is exported given target markets vary.

While other countries have different levels of risk tolerance, much of this can be attributed to differences in operating environments, target markets, the relative importance of exports to the domestic industry and government policy positions based on assessments of risks and consequences.

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| **Recommendation 3** | There are roles for different players such as the department, the APVMA, meat industry stakeholders and chemical industry member representation organisations to work with the agvet industry to raise stakeholder understanding of approaches in the international market for managing trade risk and the reasons for any differences. Key differences between country profiles and the broader regulatory frameworks should be highlighted.<br><br>It is noted that the research and analysis undertaken for this project could be used to facilitate this. |

## 5.2 Improvements to the current system

During consultations stakeholders identified issues with the current ESI system. These include issues with the current methodology, the levels of communication and the review of ESIs. This section outlines the issues raised and draws recommendations for improvement.

### 5.2.1 Methodology

Stakeholder concerns were raised in relation to the methodology used to calculate ESIs. This section explores these concerns including:

- Consistency in application.
- Understanding of the process and methodology.
- The use of the LOQ as a target.
- The ability to use data from other studies to set and review ESIs.

#### 5.2.1.1 Consistency in application

Stakeholders reported that there are inconsistencies between ESIs set for products with the same chemicals and/or actives. It was suggested that there are some cases where products with similar chemicals and/or actives have ESIs set which are significantly longer than for similar products registered in the past.

Further, it was suggested that older products that were introduced prior to the introduction of ESIs have been approved to be applied without ESIs, while newer products with the same chemicals and actives have set ESIs. It was noted that the older products without ESIs have been in use for a long period of time and had not lead to residue issues to date.

In consultation with APVMA it was stated that while newer products with similar actives and formulations may have obtained longer ESIs in the past, this does not currently occur. All products are currently measured to a set end point scale. APVMA stated if a product has the same active and route of administration it will have the same ESI.

#### 5.2.1.2 Understanding of the process and methodology

The understanding of the methodology used, and the information required to calculate ESIs, was inconsistent across different stakeholders. There were differences in the understanding of the processes applied and a lack of understanding about some of the changes in the calculation of ESIs over time.

It was expressed that a lack of understanding of the methodology was a factor which hindered registrants from applying to the APVMA to vary existing ESIs. It was suggested by some stakeholders that there is inadequate transparency on how ESIs are set and as a result they did not know what elements of products they should target for further work in order to reduce ESIs or as new products were being developed. These stakeholders suggested that more information on the methodology used to calculate ESIs is required.

Alternatively, some stakeholders suggested that they understood the process and the assessment reports provided. They expressed that APVMA's assessment provided clear guidelines as to the basis of the assessment, which has enabled them to learn over time.

Some stakeholders noted that the current APVMA assessment team is pragmatic and is willing to discuss applications and other information, and in general is more consistent and robust than it has been in the past. However, other stakeholders reported that the methodology applied and information considered can be dependent on which APVMA staff member assesses applications. This was also a key finding in the 'Independent Review of Assessment Performance of the APVMA' which found inconsistencies in the approach taken by different assessors at the APVMA.[124]

It was also noted that the APVMA is currently working on improving its published guidance about how it uses the data submitted to assess the safety, efficacy and trade criteria for the products that it regulates.

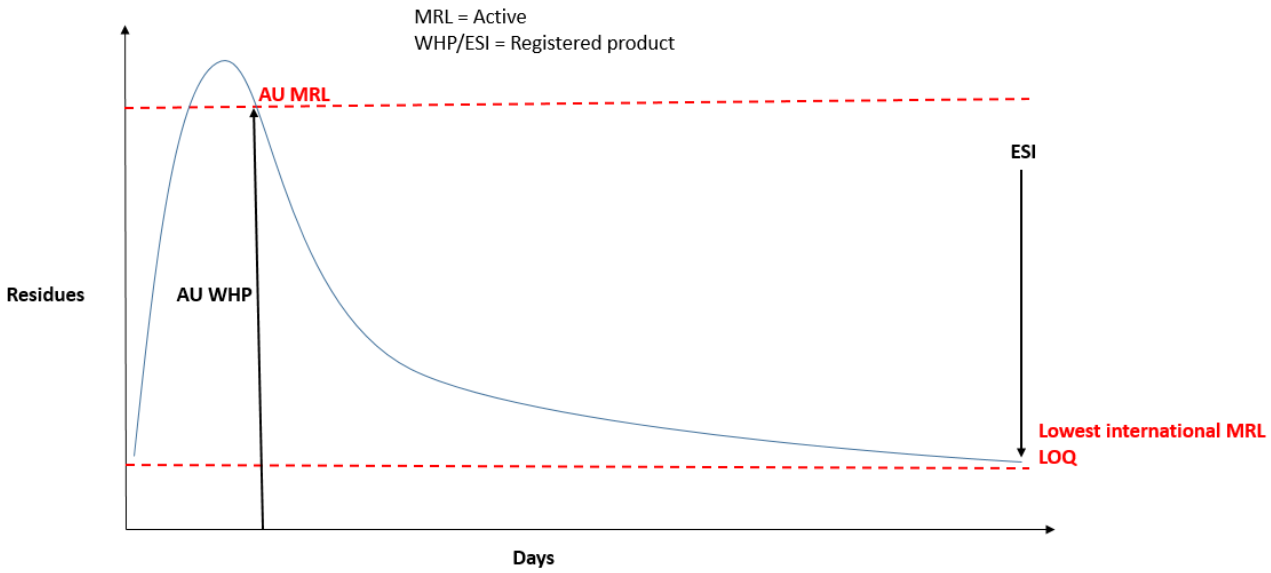
[124] 'Independent Review of Assessment Performance', Reason Group, December 2017, *https://apvma.gov.au/sites/default/files/publication/28811-final_apvma_report_20171222.pdf*, accessed 17/4/18

### 5.2.1.3 LOQ

As outlined in section 3.4, a LOQ is used as a target when a product does not have an MRL set in a significant importing country.[125] Based on this approach, stakeholders stated that the management of risk has become more conservative over time due to the ability to test to reduced levels of residue. It was suggested that the frequency of referring to LOQ's is quite common and it was anecdotally reported that approximately 80% of combination products have a country without an MRL. The chemical industry suggested that this is a highly conservative approach to the setting of ESIs and results in ESIs of significant length, well beyond levels of chemical residue that may pose health risks. New and innovative chemicals and actives are more likely to be impacted as it is more likely that these will not have MRLs in importing countries.

Figure 6 provides an example of the timeframe required to reach LOQ, in comparison to the Australian MRL.

**Figure 6: Limit of quantification**




There is concern that as technology advances, the LOQ will improve and ESIs will be extended further.

Chemical companies stated that they can initiate work in importing countries to obtain MRLs, however it was noted that this is costly, resource intensive and takes a long time to undertake. The department informed that the application for a Codex MRL through the CCRVDF would take approximately 3-7 years, and an application through the CCPR would take 2-5 years.

Section 3.4 details the trading partners considered when conducting trade assessments to set an ESI. The chemical industry expressed a concern in relation to the resource effort and costs in performing research on all trading partners within the list when this does not necessarily reflect current trading partners.

The list detailing trading partners was established in 2009 by APVMA, to prevent the need to define major markets for each product case. At the time the list was set, according to the APVMA it was expected that the list would be revisited every 5 years by APVMA, which has not been the case. It is understood that an update to the current trade partners list is being considered, and should be made in the near future.

[125] Please refer to section 3.4 for details on when other suitable endpoints, rather than LOQ, may be used.

#### 5.2.1.4 Ability to use data from other studies to set and review ESIs

As detailed in section 2.4, the APVMA is open to reviewing ESIs if appropriate studies with supporting evidence for changes are provided. During consultations the chemical industry noted that there are constraints in performing work to request changes of ESIs as these studies are costly and require significant resources. Based on the published fees by the APVMA, an application for a technical assessment for ESI consideration only, will apply the module 5.4 (minor residues assessment for a product) and 11.2 (finalisation) will apply (in addition to the often high cost of generating the data). The total fee would be $9,010 and the timeframe would be six months if the submitted data is complete.[126] However, updating an ESI due to new market conditions only (i.e. relying on existing technical data held by the APVMA) involves a variation to label particulars, and results in a lower fee of $1,170 and a timeframe of three months (and usually requires no new data generation).

Another issue with reviewing (and setting) ESIs reported by stakeholders was that there is limited ability to leverage data from one study to another between different countries in the international market. It was suggested that residue studies to outline new scientific data are expensive and can cost between $100,000 and $200,000 and are therefore a strong barrier to ESI review. The cost of these studies and the limited ability to use data from other studies was also reported as a barrier to registering products in Australia.

Furthermore, some stakeholders within the chemical industry suggested that as the methodology of setting ESIs is not clear, the incentive to invest in studies is further reduced as they are unsure what impact this will have on the ESI set.

The APVMA reported that the data provided data met its requirements, it would be used in assessments. However, it noted that given the differences in methodologies applied by different regulators, data used for other assessments internationally may not meet Australian requirements for setting ESIs.

#### 5.2.1.5 Conclusion and recommendations

Concerns have been identified about the methodology of the current ESI system, mainly due to a lack of transparency. The lack of transparency is causing misinterpretation of the current practice, particularly in relation to the following:

- Differing length of ESIs for similar products, leading stakeholders to believe that the current application of the system is inconsistent.
- An inconsistent understanding of the methodology used and the information required to calculate ESIs. Many expressed that it was this lack of understanding which prevented registrants from applying to the APVMA to vary existing ESIs.
- A lack of clarity in relation to understanding when to use data from relevant studies, and concerns associated with the limited ability to leverage data from one study to another between countries in the international market.

In regards to these concerns EY has found the following:

- There is consistency in the ESIs set for a particular formulation. The APVMA has established steps to ensure products are currently measured to a set target residue levels to ensure consistency. The APVMA has acknowledged that while newer products with similar actives/chemicals may have obtained longer ESIs in the past, the only factor which will allow newer products to have longer ESIs are the different formulations of the products.
- The current methodology can lead to ESIs for certain products to be set based on the LOQ as a target. This results in significantly longer ESIs than WHPs and is particularly the case for new innovative products with chemicals and actives which are likely not to have MRLs in importing countries.
- The trading partners list has not been updated as the APVMA had originally planned, and does not necessarily reflect the current trading partners.
- Although chemical companies stated that it is costly and time consuming to initiate work for importing countries to obtain MRLs, if the ESI system was not in place, work for a different system may need to be

[126] 'Timeframe and fees', APVMA, *https://apvma.gov.au/node/1088,* accessed 17/4/18

performed to ensure trade risk mitigation would occur, and could also be costly. To aid with the cost and timeline the APVMA could however provide further guidance and clarification on when data used in other assessments or internationally can meet the data requirements needed for assessments.

The issues identified with the current system methodology can be addressed by providing more visibility on the methodology applied, and regular updates.

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| **Recommendation 4** | Although there is publicly available information published by the APVMA on the methodology it uses to determine ESIs, it needs to include more detail on the process implemented, with easier navigation and a rationale for certain elements of those methods. The current guidance in relation to the methods used to set ESIs should be updated and made publicly available. The focus of this guidance should take into account the issues raised by stakeholders, such as a need for a clearer understanding of the approach taken when a country does not have an established MRL. |
| Recommendation 5 | The current application of trade partner consideration should be clarified. In addition, the trade partner list should be updated in line with changes in major markets. The frequency of the updates should reflect a balance between providing industry with certainty, and consistency, and providing up-to-date market information. EY recommends that an update be undertaken every 5 years. |

### 5.2.2 Communication

Insufficient communication has been identified as a significant barrier to understanding the ESI process. A number of different stakeholder groups mentioned the need for more opportunities to have open discussions with the APVMA about the ESI process, methodology, and associated issues. Regular workshops and consultation sessions were suggested.

State regulators expressed an interest in being further consulted when an ESI is set in order to allow them more visibility and let them build relationships with stakeholders in the sector, particularly with producers.

It is noted that the APVMA reported that there are formal avenues for communication during the registration process as well as informal opportunities to discuss issues with staff.

EY has found that communication of ESIs through labels are beneficial. Registrants expressed that the updating of labels does not act as a barrier to request for a review of an ESI. While a centralised database can be another option to communicate ESIs of products, this may lead to a decline in priority given to comply with the ESI standards i.e. there is a risk of non-compliance if farmers are required to look at a database rather than a label. A change in the channel of communication of ESI requirements will therefore decrease the effectiveness and efficiency obtained through labels.

#### 5.2.2.1 Conclusion and recommendations

Communication between the APVMA and the chemical industry and state regulators could be improved. Frequency of communication, the ability to have targeted discussions, and location are all factors which were taken into consideration when stakeholders commented on sufficiency of communication avenues. Discrepancies in regards to the ESI process, methodology and associated issues can be attributed to inadequate communication.

Additional communication avenues will enable a greater understanding of the ESI process, and aid in building relationships between state regulators and stakeholders within the sector.

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| **Recommendation 6** | Additional communication channels should be developed to provide industry guidance on the methods, process and issues associated with the development and management of ESIs. A number of different channels should be developed, such as between the chemical industry registrants and the APVMA (specifically between chemical industry representative bodies and the APVMA), peak meat industry bodies and the APVMA, and state regulators and the APVMA. These channels should allow for the initiation of discussions by the chemical industry, the meat industry, state regulators and the APVMA. |
| **Recommendation 7** | While there are generic contact details provided on the APVMA site, clarity should be provided by the APVMA to the agvet chemical and meat industry on the most appropriate personnel within APVMA to contact about ESI issues. |

### 5.2.3 Review of ESIs

Stakeholders stated that reviews of ESIs are not generally requested or undertaken because they see the process as resource intensive and costly. There was a lack of understanding of the factors that would trigger the APVMA's approval of changes in ESIs, and limited understanding of the APVMA's internal processes and method used for ESI reviews. Many stakeholders suggested that ESI reviews would require new scientific testing, while it is noted that other factors (such as changes to importing countries MRLs or the establishment of MRLs) could generate changes to ESIs without the need for additional testing.

Registrants noted that the data packages are often quite old, and there is limited incentive for registrants to seek review from the APVMA, unless a specific trade violation occurs. This view is due to the effort required on the part of stakeholders to conduct trials involving the slaughter of multiple animals and allocation of staff and resources to conduct the trials.

The views held by the registrants however did not take into consideration that the APVMA may approve changes to ESIs without updated data packages. This was confirmed by the APVMA as being possible, and has occurred historically. There is no routine APVMA process that leads to regular ESI reviews, and reviews can occur as a result of different sources of information provided, if triggered at request of registrant (or other interested parties) and payment of fee under normal application process.

The uncertainly of obtaining a change in ESI after conducting trials was reported as another disincentive, since the assessment may not go in favour of the desired outcome (it was suggested that the methodology applied wasn't clear as discussed in section 5.4.1). For instance it is possible that a review of an ESI could lead to a higher ESI. As a result, it was expressed that registrants rarely seek reviews, and as a result ESIs are rarely reviewed. However, APVMA noted that if a product has been in the marketplace for a time without incident it is highly unlikely that the ESI would be increased.

Some stakeholders suggested that the APVMA should undertake reviews of all ESIs to maintain consistency and ensure that the most up to date considerations are factored in to the applicable ESI. However, other stakeholders noted that this would require considerable resources.

#### 5.2.3.1 Conclusion and recommendations

There is a lack of understanding of the factors needed to trigger an ESI review as well as the processes in place to do so. While there is a willingness on the part of the APVMA to undertake regular reviews, given the resource requirements involved, the periodic review of all ESIs is not practical or appropriate. Further, the analysis undertaken in section 4.1 demonstrates that not all products have ESIs significantly longer than WHPs and therefore may not need regular reviews. Further clarity on the understanding of ESI reviews will allow for greater proactivity from the chemical registrants to initiate ESI reviews more regularly.

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| **Recommendation 8** | The process in place to review ESIs should be included in publicly available guidelines, and transparency should be provided on the methodology used to conduct a review. The APVMA should document the process of review and the factors that can change ESIs, such as a new trading partner or a new MRL. This will enable the chemical industry to have a clearer understanding on when and how to initiate ESI reviews. |


# Appendices

# Appendix A Terms of reference

In delivering this report the successful tenderer will:

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| **Research and analyse the current Australian ESI system and the issues the ESI system aims to address. The successful tenderer will:** |
| a. Consider publicly available information on both government and industry roles in the Australian ESI system as well as the basis (including legislative) for determining and maintaining ESIs in Australia.<br><br>Identify any other Australian legislation or industry systems that also act, or could act (for example, Export Control Orders), to ensure the quality of Australian exported meat. This may also assist the successful tenderer in considering potential alternatives to the current Australian ESI system. |
| **Seek, and consider, the views of stakeholders from key points in the production-export chain (see point 6) about their understanding and use of the Australian ESI system. The successful tenderer will:** |
| a. Work with the department to develop a set of consultation questions, spanning:<br><br>i. Coverage of the ESI - how significant a priority is ESI for a stakeholder's particular industry and is this serious enough to justify more/less/no regulatory intervention?<br>ii. What prevents some registrants applying to the APVMA to vary an existing ESI (timeframes, fees, label change implications)?<br><br>Any stakeholder suggestions for improving / alternatives to the current system (including different roles for government and industry). |
| **Examine how and why some ESIs set by other countries (government or industry arrangements) differ from those established by the Australian system. The successful tenderer will:** |
| a. Compare the Australian approach establishing ESIs to the scientific, or other, basis for establishing ESIs used by other countries (at a minimum Brazil, New Zealand, and the United States of America plus any additional countries the successful tenderer considers necessary) – if the comparison country does not use ESIs, an examination of what they do use (such as reliance on their domestic withholding period).<br><br>b. Investigate how successful the various ESI systems have been at managing residue risks. The successful tenderer will:<br><br>Consider and compare the experiences of exporters in Australia and overseas, with residue violations over the past decade. This includes the relative frequency, causes and sources of any violation as determined by an industry or regulatory body and the ESI information available at the time of the breach. The successful tenderer is not to re-investigate any violation. |
| **Estimate the economic consequences of applying differing ESIs for Australian exported produce compared to the same produce, exported to the same overseas market, by other countries supplying that market. The successful tenderer will:** |
| a. Identify and tabulate ESIs (or withholding periods where these are relied on to also fulfil the ESI function) for meat produce exported from Australia and the competitor exporting countries (identified in point 3a) to the same export market. This will include consideration of existing APVMA information. At a minimum this must cover:<br><br>i. Three to five key diseases, pests or animal health conditions common between Australia and at least one of the international comparison exporting countries<br>ii. At least four distinct chemical products across three active constituents available both in Australia and the relevant competitor exporting country/countries (at least three veterinary products and 1 agricultural chemical product)<br>iii. At least beef and sheep meat for export.<br><br>b. Comment on the qualitative economic effect on Australian producer enterprises for each of the tabulated ESIs under 4a, where the Australian ESI differs from the ESI/withholding period used by the competitor exporting countries. This includes considering the impact (such as disease exposure, resistance risks, and the timing of turnoffs) on costs, productivity and supply chains. |

| **Consider the value of Australia's ESIs, if any, to Australia's broader reputation as a 'clean and green' source of export produce.** |
|---|
| **Seek input from a range of stakeholders, including:** |
| a. Meat producers.<br><br>b. Export-focused feed lot enterprises (as relevant).<br><br>c. Export-focused meat processors.<br><br>d. Meat exporters.<br><br>e. Chemical manufacturers of relevant products identified through the study.<br><br>f. Safe Meat, Red Meat Advisory Council, Australian Meat Industry Council, the Australian Meat Processor Corporation and Meat and Livestock Australia.<br><br>g. Cattle Council of Australia, Australian Lot Feeders Association, Sheep Meat Council, Australian Beef Association, Australian Pork Limited and other relevant industry associations.<br><br>h. State and territory produce quality regulators.<br><br>i. The Australian Pesticides and Veterinary Medicines Authority.<br><br>j. Department of Agriculture and Water Resources (including Sustainable Agriculture, Fisheries and Forestry Division, Exports Division and Trade and Market Access Division). |

# Appendix B Stakeholder consultations

A number of stakeholders have been consulted in the domestic and international market (NZ, Brazil, US), who are involved or effected by the establishment of ESIs or the equivalent chemical residue limit in other countries. These stakeholders have been detailed below:

**Chemical Manufacturers**

- AMA
- Boehringer Ingelheim
- Merck Animal Health
- Bayer
- Virbac
- Elanco Animal Health
- Zoetis
- Phibro

**Industry Bodies**

- Red Meat Advisory Council
- Australian Meat Industry Council
- Meat & Livestock Australia
- Cattle Council of Australia
- Australian Lot Feeders Association
- Sheep Meat Council of Australia
- Australian Pork Limited
- Australian Livestock & Property Agents

**Exporters**

- JBS
- TEYS
- Food & Veterinary Services

**Government/State Regulators**

- Department of Primary Industry and Fisheries, NT
- Department of Agriculture and Fisheries, QLD
- Department of Agriculture, VIC
- National Residue Survey
- APVMA
- Department of Agriculture and Water Resources - Exports
- Department of Agriculture, WA
- Department of Primary Industries, SA
- Department of Primary Industries, NSW

**NZ**

- NZ Pork
- NZ Ministry for Primary industries
- Andrew McKenzie - NZ Director Andrew McKenzie & Associates Ltd
- Andrew McKenzie (2010-present), Chief Executive Officer at New Zealand Food Safety Authority (2007 -2010), Executive Director at New Zealand Food Safety Authority (2002 -2007)

**USA**

- US Food & Drug Administration – Centre for Veterinary Medicine (CVM)
- Bayer US

**Brazil**

- Marcio Caparroz - General Secretariat at Iba International Beef Alliance (2017 -Present), Market Access Director at Agri Strategy Consulting Service (2015-present)

**Other**

- Argentina – EY team
- Brazil – EY team
- China – EY team and internal EY client

# Appendix C Acronyms

| Term | Description |
|---|---|
| ABIEC | Brazilian Beef Exporters Association |
| Agvet | Agricultural and veterinary |
| AMA | Animal Medicines Australia |
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| CCPR | Codex Committee of Pesticide Residues |
| CCRVDF | Codex Committee of Residues of Veterinary Drugs in Foods |
| CXLs | Codex Maximum Residue Limits |
| Department | Department of Agriculture and Water Resources |
| EGI | Export Grazing Interval |
| ESI | Export Slaughter Intervals |
| FIS | Federal Inspection Service |
| GAP | Good Agricultural Practice |
| HGP | Hormone Growth Promotants |
| LOQ | Limit of Quantification |
| LPA | Livestock Production Assurance Program |
| LPA NVD | Livestock Production Assurance National Vendor Declaration |
| MAPA | Ministry of Agriculture (Ministério da Agricultura, Pecuária e Abasteciment) |
| MAA | Market Access Advice |
| MN | Meat Notices |
| MRL | Maximum Residue Limit |
| NLIS | National Livestock Identification System |
| NRS | National Residue Survey |
| NZ | New Zealand |
| NZ MPI | New Zealand Ministry of Primary Industries |
| OMAR | Overseas Market Access Requirements |
| PNCRC | National Plan for Control of Residues and Contaminants (Plano Nacional de Controle de Resíduos e Contaminantes |
| PRS | Public Release Summary |
| TAN | Trade Advice Notice |
| US | United States of America |
| US EPA | United States Environmental Protection Agency |
| US FDA | United States Food and Drug Administration |
| WHP | Withholding period |

EY | Assurance | Tax | Transactions | Advisory

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