



ANTIBIOTIC MANAGEMENT AND MONITORING POLICY

AUSTRALIAN DAIRY REGULATORS' FORUM

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BACKGROUND

AUSTRALIAN DAIRY REGULATORS FORUM¹

Purpose

To outline the policy, management and minimum monitoring arrangements for managing antibiotics in the dairy sector.

Scope

This policy applies to the production of dairy products in Australia and was endorsed by dairy food safety regulators in State and Commonwealth jurisdictions (Competent Authorities) and dairy industry stakeholders at the Industry Working Group meeting held on 24th November 2020.

Background

Antibiotics have been used to treat serious bacterial diseases in Australian livestock for more than 60 years. They offer great benefits to industry and food production but also present risks to human health, food production and markets (domestic/export) that must be managed.

The responsibilities and accountabilities of all industry members for appropriate use and management of antibiotics through the supply chain are incorporated into food safety programs.

Systems to manage the risk of antibiotics entering food products are comprehensive and include regulatory and commercial controls along the supply chain.

"The safe use of agricultural and veterinary chemicals in Australia is managed by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA determines maximum residue levels (MRLs) for each chemical in association with a crop or veterinary use, to ensure that the chemical is used appropriately for the agricultural conditions [Good Agricultural Practice (GAP)] and treatment of animals. The APVMA then assesses, and FSANZ confirms, that any residue of the chemical or nominated metabolites in foods as a result of its use on a crop or in food-producing animals, does not pose a safety concern. MRLs are subsequently listed in the Code and apply in Australia only."

(Risk Analysis in Food Regulation, Food Standards Australia New Zealand 2013)

The national Australian dairy food safety regulatory framework is an integrated preventative system developed by Commonwealth and state regulatory authorities in consultation with industry organisations.

"Australia's domestic food safety regulatory requirements are administered by State and Territory food safety regulatory authorities (SRAs) and reference the Australian New Zealand Food Standards Code (FSC). The FSC comprises of outcome-based standards which are more general in relation to the appropriate level of health protection. For example, Chapter Three – Food Safety Standards, and Chapter Four – Primary Production and Processing Standards are focused on control measures for risks associated with microbiological and chemical hazards in food.

These standards use a variety of risk management strategies and place responsibility for compliance on the food industry.

The Code requires certain food businesses to develop and implement food safety programs based on a systematic identification and control of hazards as identified in the hazard analysis critical control point (HACCP) system.

The Code also provides specific requirements in relation to the production of certain primary produce including eggs, dairy, seafood, poultry meat, ready-to-eat meat, seed sprouts and specific cheeses. Primary production standards are broad-based and consider all aspects of production including general safety requirements, potential contamination and handling, storage, transportation, packaging, disposal, hygiene requirements, as well as premises and equipment."

(Risk Analysis in Food Regulation, Food Standards Australia New Zealand 2013)

Food safety programs are mandated for the production and processing of dairy products by Standard 4.2.4 of the Food Standards Code. The Standard requires that a dairy producer, transporter or processor controls potential food safety hazards by implementing a documented food safety program.

¹ The Australian Dairy Regulators' Forum comprises of representatives of the following Commonwealth and State Regulators: Department of Agriculture, Water and the Environment (DAWE); Safe Food Production Queensland (SFPQld); NSW Department of Primary Industries (NSW DPI) / NSW Food Authority (NSWFA); Dairy Food Safety Victoria (DFSV); Tasmanian Dairy Industry Authority (TDIA); Dairysafe (Dairy Authority of South Australia); Department of Health, Western Australia (WA Health).

Businesses and supply chains that produce dairy products destined for export are also regulated by the Department of Agriculture, Water and the Environment (DAWE) under Commonwealth legislation. Dairy goods are 'prescribed goods' and Australia's export requirements ensure that export goods meet Australia's strict export requirements and those of the importing country.

Dairy processors regularly define regulatory as well as company specifications within food safety programs. Dairy farms often adopt or are mandated to use the company food safety programs that have been approved by state-based regulators.

Potential risks are monitored on an ongoing basis with routine consultation between industry and government to discuss possible challenges. The risk management process is science-based and industry applies a preventive outcomes-based approach to managing the hazard.

The prevalence of chemical residues in milk is extremely low with testing for antibiotics being routinely undertaken by dairy companies at the farm vat, tanker, silo and product levels of the supply chain. In addition, a survey of raw milk from 1,000 tankers from all regions of Australia is taken each year for analysis for a wider range of antimicrobials, animal parasite control chemicals, feed contaminants and environmental contaminants. The results of both the dairy company and tanker survey testing results are reported annually in the Australian Milk Residue Analysis (AMRA) survey report.

The results tell an overwhelmingly positive story with close to 100% compliance over the history of the Australian Milk Residue Analysis (AMRA) survey across all chemical classes. In the rare event that antibiotics are confirmed in raw milk at the factory, the milk is removed from the supply chain under regulatory supervision. Company testing data shows that antibiotics are rarely if ever identified in consumer products.

These results are evidence that the Australian dairy industry's approach to agricultural and veterinary chemical usage is responsible, effective and in accordance with good agricultural practice. It also demonstrates that the food safety management systems adopted by the dairy industry are successful in managing potential residue contaminations.

Principles

- 1 Risk assessments for veterinary medicines have been conducted and resulted in Australia's maximum residue limits (MRLs). Antibiotic residues above Australia's MRLs are unacceptable in dairy products².
- 2 Producers and dairy processors are each responsible for the management of antibiotics along the primary production and processing supply chain.
- 3 Industry and regulators accept that food safety hazards are managed in Australia by risk-based food safety programs underpinned by regulation.
- 4 The risk-based approach mandated in Australia's regulatory standards is science-based and fundamentally concerned with risk management and reduction (as opposed to elimination).
- 5 Identification, traceability, monitoring, and corrective and preventive action form the basis of a risk-based approach.
- 6 Dairy businesses are encouraged to manage antibiotic residue detections at the earliest opportunity and prevent milk that may contain unacceptable levels of antibiotic residues from entering the food chain.
- 7 Residue testing can vary between dairy processors and between sites as residue risks vary depending on the milk supply base, the products being manufactured and the size and distribution of the processor.
- 8 A dairy processor antibiotic testing program is proportionate to the risk and designed to verify that the milk and dairy products being processed do not contain residues above Australia's MRLs.

² FSC 1.4.2–4 Maximum residue limit of agvet chemicals in foods

(1) A food for sale may contain a permitted residue of an *agvet chemical if:

(a) the agvet chemical is listed in Schedule 20; and

(b) the food consists of, or has as an ingredient, a food that is listed in relation to that agvet chemical in Schedule 20; and

(c) the amount of the permitted residue of the agvet chemical in the food complies with subsection (2) or subsection (3), as appropriate.

Risk Management

The basis for developing and reviewing risk management options involves consideration of the following:

- 1 What could go wrong?
- 2 How likely is the event to happen, based on supply chain, size and distribution of the dairy processor?
- 3 What would be the consequence if this event happened, and what mitigation and monitoring options exist.

Hazard identification – antibiotic residues above the Australian MRLs.

Hazard characterisation – antibiotic residues pose a potential threat to direct toxicity in humans, second is whether the low levels of antibiotic exposure would result in alteration of microflora, cause disease and the possible development of resistant strains which cause failure of antibiotic therapy in clinical situations.

Residues in milk can also impair the quality of fermented products.

Additionally, consumer perceptions are a major barrier to the trade of food items and if consumers perceive that a product may be of inferior quality and/or safety, they will not purchase it.

Risk Level – in terms of determining risk level, a matrix is applied to evaluate:

- 1 Severity of consequence
- 2 Likelihood of occurrence

In this instance the following rating for consequence and likelihood could be applied based on a risk matrix (figure 1):

- 1 'consequence' can be rated as 'severe' (fatality is extremely unlikely but still possible),
- 2 the 'likelihood' of a medium to large dairy processor (processing above 1 million litres/year) linked to a residue incident could be rated higher than small processors³ (under 1 million litres/year) where there is intimate knowledge of, and contact with, the supply chain.

Figure 1 – Risk Matrix

			Potential consequences				
			Minor injuries or discomfort. No medical treatment or measurable physical effects	Injuries or illness requiring medical treatment – temporary impairment	Injuries or illness requiring hospital admission	Injury or illness resulting in permanent impairment	Fatality
			Not significant	Minor	Moderate	Major	Severe
Likelihood	Expected to occur regularly under normal circumstances	Almost certain	Medium	High	Very high	Very high	Very high
	Expected to occur at some time	Likely	Medium	High	High	Very high	Very high
	May occur at some time	Possible	Low	Medium	High	High	Very high
	Not likely to occur in normal circumstances	Unlikely	Low	Low	Medium	Medium	High
	Could happen, but probably never will	Rare	Low	Low	Low	Low	Medium

Exposure assessment – AMRA results and reports to Australian regulators of antibiotic residues in milk loads over time, indicate the level of exposure in dairy products under current management arrangements is low.

The final 'RISK' ratings are allocated using the risk matrix (Figure 1 – likelihood vs consequence):

- medium to large dairy processors: possible/severe = **VERY HIGH**
- small processors: rare to unlikely/severe = **MEDIUM to HIGH**

³ 'Small processors' include on-farm and organic processors processing less than 1 million litres of raw milk per year, where the risk is significantly reduced due to the absence (or appropriate controls) of antibiotic treatments within the food safety program.

Antibiotic Management

Controls for managing the risk of antibiotics entering the food-chain include:

- regulated supply of veterinary drugs by prescription
- Government regulated registration of antibiotics for use in livestock species
- Australian maximum residue limits (MRLs)
- identification of treated livestock
- segregation of milk from treated livestock for the duration of the withholding period
- appropriate record keeping including usage monitoring
- identify points in production-to-consumption where food safety measures could be implemented
- routine antibiotic testing by processors in accordance with their food safety program
- national Australian Milk Residue Analysis (AMRA) survey
- Dairy regulators' antibiotic management policy and approved protocol for screening raw milk (this document)
- Competent authorities verify compliance with national standards and investigate breaches of MRLs in milk and milk products.

Financial disincentives applied to producers by dairy processors for failing to meet product specifications can also act as a 'control' in this instance.

Antibiotic Monitoring

Competent Authorities and dairy companies follow the approved Protocol for Screening Tankers for Antibiotic Residues (see Appendix 1). The Flow Chart should be read in conjunction with this Policy.

A risk-based monitoring program for antibiotic residues in milk can include one or more of the following along the milk supply chain:

- systems in place to test suspect vats by farmer request
- random milk vat testing
- milk tanker testing on arrival at the factory
- in-line testing during processing (silo testing)
- finished product testing

There is no single antibiotic milk screening test that perfectly aligns with the MRLs set for each antibiotic used in Australia. However, industry, businesses and regulators keep a watching brief on the screening tests available in Australia and engage with test kit manufacturers to ensure Australian businesses have access to a range of suitable options. Businesses are responsible for ensuring that the appropriate test is selected and applied to address their specific circumstances.

Rapid narrow spectrum tests

It's acknowledged that 77% of all antibiotic treatment courses supplied for Australian dairy cows will be detected by a rapid, narrow spectrum beta-lactam test⁴.

The rapid, narrow spectrum beta-lactam test takes around 1-5 minutes to provide a result. The benefits of the rapid beta-lactam test are that it can quickly detect minute levels of beta-lactam antibiotics, which are the most commonly supplied antibiotics for use on dairy cows, and so allows for prompt unloading and rotation of tankers at the dairy processor.

A negative result provides assurance the raw milk tested doesn't contain residues above the Australian MRL for the antibiotic compounds most commonly used in Australia's dairy industry, and therefore the milk is suitable for unloading and processing.

A positive result indicates that a beta-lactam antibiotic residue may be present in the milk and the tanker milk needs to be held for further confirmatory testing.

Expected Minimum Testing Frequency

Dairy companies must manage antibiotic residue risks with a raw milk screening program that:

- Screens all tankers with a narrow spectrum beta-lactam test

Broad spectrum microbial inhibition tests (MIT)

The MIT test (eg Delvotest or Copan Milk Test) takes 2-3 hours to provide a result and can be used as a general screening test and as a confirmatory test for milk which has given a positive result to the rapid, narrow spectrum test.

MIT tests detect beta-lactam antibiotics to levels at or below the Australian MRL and also detect a range of other antibiotic actives.

A negative result to a broad spectrum MIT indicates the concentration of any beta-lactam residues in the milk is below the Australian MRL and the milk is safe to process.

Expected Minimum Testing Frequency

Dairy companies must manage antibiotic residue risks with a raw milk screening program that:

- Screens all tankers with a broad spectrum test, or
- Another risk based and validated alternative to manage the risks of antibiotics.

⁴ Survey of dairy vets in SE Australia 2016-17, Dairy Australia (2018)

Alternative raw milk screening programs

Dairy companies may seek regulatory approval from the competent authority to use a suitably validated alternative raw milk screening program to manage the risks of antibiotics, particularly for the non beta-lactam classes of antibiotics. Example guidelines for the documentation required to support an alternative are provided at Appendix 3.

Corrective and Preventive Action

Dairy companies follow the approved Antibiotic Notification & Follow-up Protocol (see Appendix 2). The Flow Chart and supporting tables should be read in conjunction with this Policy.

Where tanker or silo testing indicates antibiotic residue above the MRL the company must:

- immediately notify the Competent Authority (SRA and/or DAWE).
- undertake a traceback to the farm of origin to determine the source of the residue, the cause of the contamination and the veterinary drugs used.
- complete a trace forward to ensure that products manufactured from the affected milk are isolated and tested or undergo a risk assessment to demonstrate they are below the MRL.
- ensure appropriate corrective and preventive actions are implemented at the farm.

Where farm vat testing indicates antibiotic residue above the MRL during traceback or testing in a company-run random vat testing program:

- immediately notify the Competent Authority (SRA and/or DAWE).
- undertake an investigation to determine the cause of the contamination and the veterinary drugs used.
- ensure appropriate corrective and preventive actions are implemented at the farm.

Responsibilities

Dairy companies in Australia must prevent unacceptable antibiotic residues from entering the food chain.

All antibiotics and most other veterinary chemicals are only available by prescription through registered veterinarians.

The dairy supply chain must play a key role in helping prevent antibiotic resistance.

Farmers must use veterinary medicines in accordance with label directions, observe recommended withholding periods for milk and keep records of all treatments.

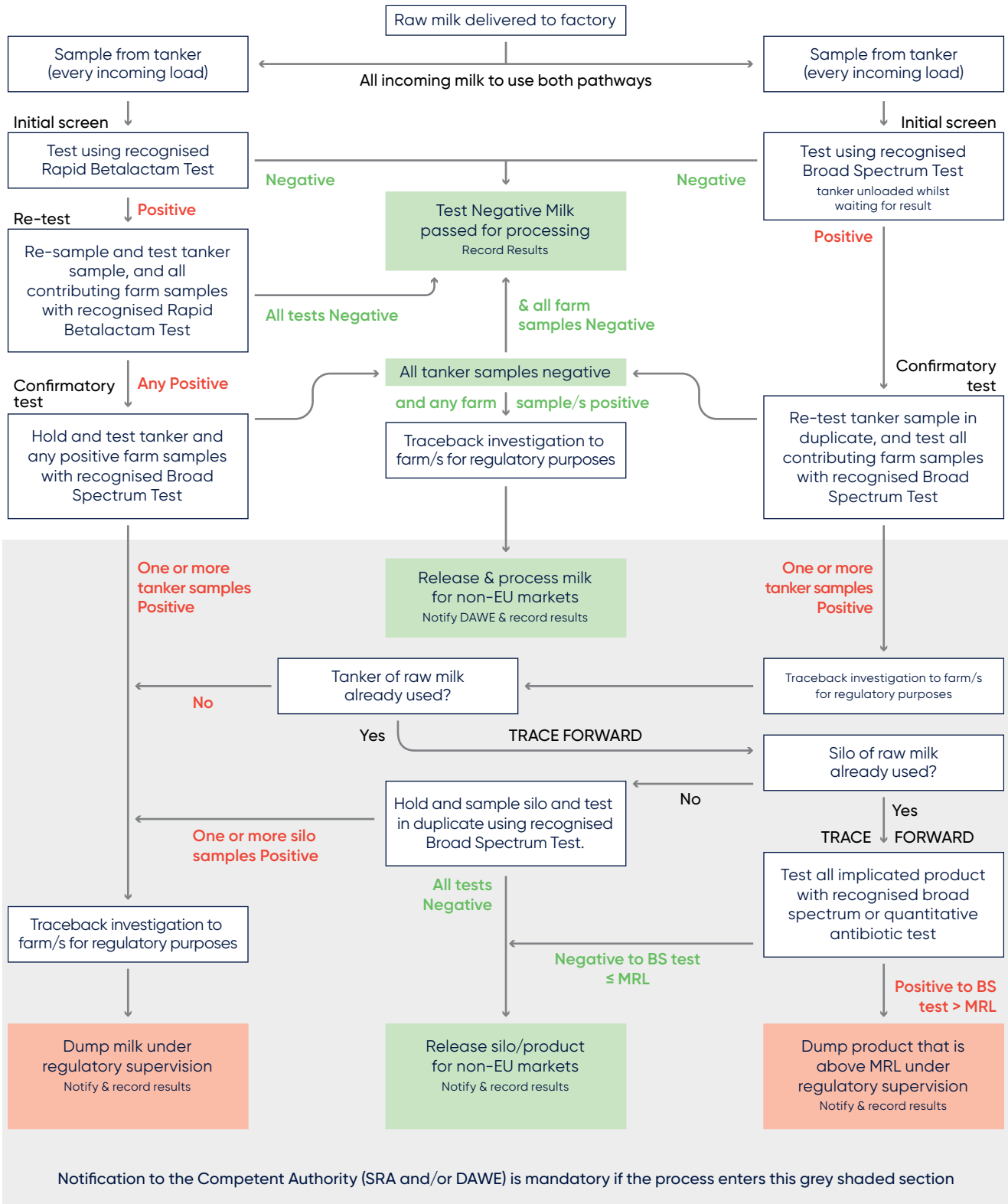
All livestock must be individually identified from birth to death to ensure lifetime traceability.

Farmers must have a system in place to identify treated livestock and keep appropriate antibiotic risk management records.

Processors must have a monitoring program to verify that the controls applied to manage the hazard of antibiotic residues in milk are effective.

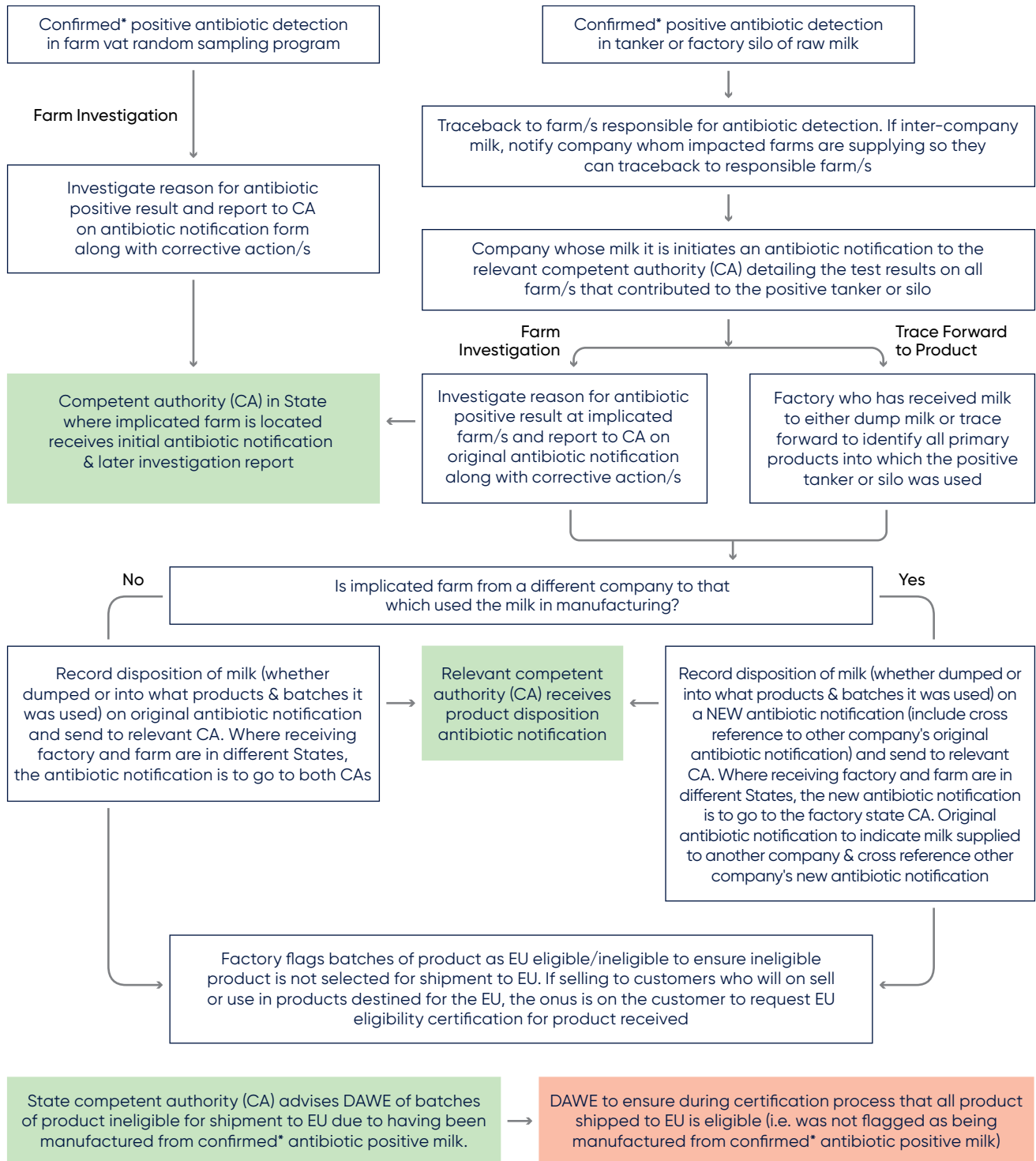
Competent Authorities verify compliance with national standards and investigate breaches of MRLs in milk and milk products.

APPENDIX 1 - PROTOCOL FOR SCREENING TANKERS FOR ANTIBIOTIC RESIDUES*



* Additional surveys are undertaken at the farm and tanker level to monitor antibiotic use and compliance, including dairy company random farm sampling programs and the Australian Milk Residue Analysis (AMRA) survey.

APPENDIX 2 – ANTIBIOTIC NOTIFICATION AND FOLLOW UP PROTOCOL



* Confirmed positive means a positive result is found in one or more of the recognised broad spectrum tests undertaken

EU EXCLUSION, DISPOSAL, NOTIFICATION AND TRACEBACK RULES (IN TABLE FORMAT)

The Actions described in Table 1 must be taken for a "Confirmed Positive" tanker - that is a tanker with a positive result at a confirmatory test.

Table 1

Milk in the Positive tanker already used?	Silo of milk already used?	Product result?	Action	Notification to SRA
YES	YES → trace forward	All implicated products Negative on broad spectrum and/or quantitative tests	Release products for non- EU markets	Notify the SRA including on-farm traceback report
		Implicated products Positive on broad spectrum and/or quantitative tests	Dispose products that are above the MRL under regulatory supervision	Notify the SRA including on-farm traceback report
	NO → test silo using broad spectrum in duplicate	Silo broad spectrum test Both tests Negative	Release silo for non- EU markets	Notify the SRA including on-farm traceback report
		Silo broad spectrum test One or both tests Positive	Dispose milk in the silo under regulatory supervision	Notify the SRA including on-farm traceback report
NO	NA	NA	Dispose milk in the tanker under regulatory supervision	Notify the SRA including on-farm traceback report

Table 2 shows all possible scenarios that can occur after the initial Positive result on tanker sample by narrow spectrum beta-lactam test. These are the combination of narrow spectrum and broad spectrum test results on tanker and supplier samples (8 scenarios).

In Summary after tanker sample returns a Positive result on narrow spectrum beta-lactam test, the ONLY time that no traceback on farm and no notification to the SRAs is needed is when confirmatory broad spectrum test results for the tanker and ALL supplier samples are Negative (scenario 4 and 8 in Table 2).

Table 2

Initial tanker result by narrow spectrum	Supplier sample result by narrow spectrum	Tanker Broad spectrum test result	Scenario	Likelihood	Traceback on farm	Notification to SRA
Positive (i.e. 1 out of 2 or 2 duplicates Positive by narrow spectrum)	One or more supplier sample Positive on narrow spectrum	Positive	1. One or more supplier sample Positive on broad spectrum	Almost certain	Yes	Notify the SRA including on-farm traceback report
			2. ALL supplier samples Negative on broad spectrum	Rare	Yes	Notify the SRA including on-farm traceback report
		Negative	3. One or more supplier sample Positive on broad spectrum	Rare	Yes	Notify the SRA including on-farm traceback report
			4. ALL supplier samples Negative on broad spectrum	Unlikely	No	No notification to SRAs (optional traceback)
	ALL supplier samples Negative on narrow spectrum	Positive	5. One or more supplier sample Positive on broad spectrum	Rare	Yes	Notify the SRA including on-farm traceback report
			6. ALL supplier samples Negative on broad spectrum	Rare	No	Notify the SRA and advise no supplier was identified as responsible
		Negative	7. One or more supplier sample Positive on broad spectrum	Rare	Yes	Notify the SRA including on-farm traceback report
			8. ALL supplier samples Negative on broad spectrum	Unlikely	No	No notification to SRAs

For a tanker that was accepted based on site QCP and pumped into the silo based on Negative test result prior to unload and one or more supplier samples return a Positive antibiotic test on a random test performed at the testing laboratory:

- The relevant SRA must be notified as per the SRA's agreed procedures.

APPENDIX 3 – EXAMPLE GUIDELINES FOR THE DOCUMENTATION OF ALTERNATIVE RAW MILK ANTIBIOTIC RESIDUE SCREENING PROCEDURES

Under the agreed policy, dairy companies may use a different protocol than the 'standard' protocol for screening tankers outlined in Appendix 1, subject to approval/advice from the relevant regulator.

Alternative procedures need to be clearly described and justification provided on how they adequately address the risks posed by antibiotic residues in milk. The following headings may help in preparing this documentation.

Assessment of the hazard posed by antibiotics

Insert statistics/data on the types of antibiotics being used by suppliers

- Beta-lactam
- Non beta-lactam

Controls in place to address the risks of all antibiotic residues

Provide a list of the controls in place to address antibiotic risks in your supply chain. Suggested headings:

- Antibiotic registration & supply
- Antibiotic use
- Farm level testing
- Tanker level testing
- Testing during manufacture

Remember to reference or attach relevant company procedures.

Include policies and/or procedures used by your company to address issues (i.e. hold/divert positive milk, traceback, trace forward etc)

Verification that controls are effective

Insert company results of verification testing. Compare these with industry-wide figures (reported in AMRA).

Insert a summary of findings from traceback investigations (especially the level of non beta-lactam antibiotics being implicated from farm-level detections). Does this support the 'alternative' approach to managing these residues?

Conclusion

Discuss how the results show the risks of antibiotic residues are being appropriately managed using the company's existing framework, particularly for non beta-lactam antibiotics.

Include what steps are undertaken to monitor and review the effectiveness of the controls on an on-going basis.

