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Purina Animal Nutrition LLC

Sourcing Ingredients and Raw Materials – Ensuring Safety and Quality

NGFA-PFI Feed and Pet Food Joint Conference

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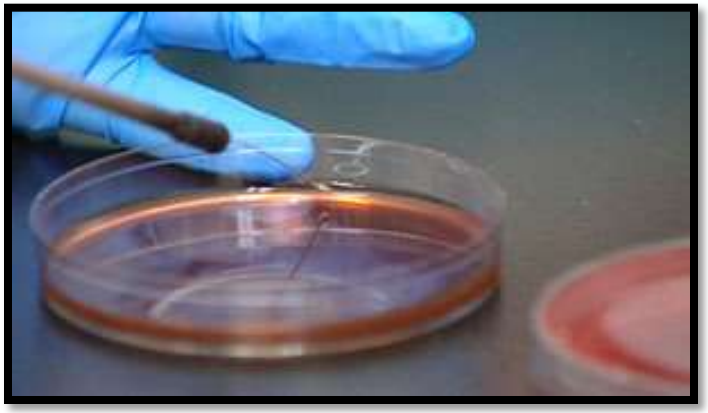
09/25/13

Agenda

- Considerations & limitations of *Salmonella* testing programs for feed and pet food ingredients
- Establishing expectations for suppliers and elements of a Supplier Approval Program

Considerations & Limitations of *Salmonella* Testing in Feed & Pet Food



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Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals

- Published as a Final CPG in July 2013
- Establishes Policy and Regulatory Action Guidance for:
  - *Salmonella*-Contaminated Pet Food
  - *Salmonella*-Contaminated Animal Feed

Available at:

www.fda.gov → Inspections, Compliance, Enforcement, and Criminal Investigations → Compliance Manuals → Compliance Policy Guides

Salmonella-Contaminated Pet Food Policy

- FDA considers a pet food to be adulterated when it is contaminated with *Salmonella* and will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella*.

Salmonella-Contaminated Animal Feed Policy

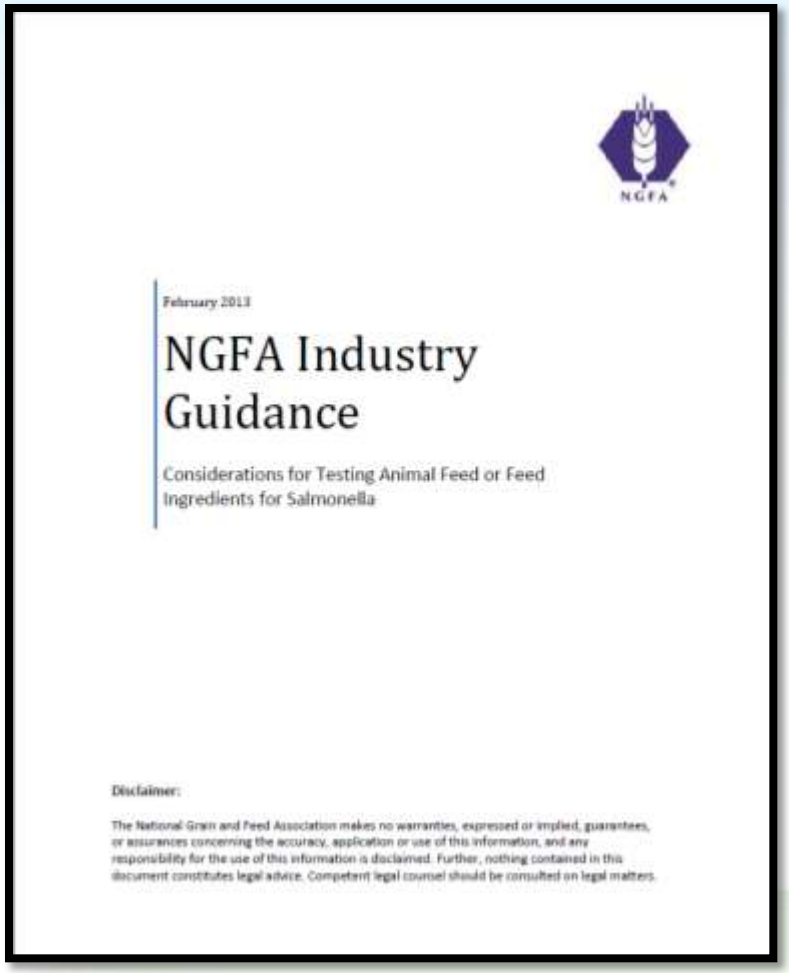
- FDA considers animal feed to be adulterated when it is contaminated with a *Salmonella* serotype that is considered pathogenic to the animal intended to consume the feed, and
- The animal feed will not subsequently undergo a commercial heat step or other commercial process that will kill the *Salmonella*.

Salmonella-Contaminated Animal Feed Policy

- Poultry feed with *Salmonella* Pullorum, *Salmonella* Gallinarum, or *Salmonella* Enteritidis
- Swine feed with *Salmonella* Choleraesuis
- Sheep feed with *Salmonella* Abortusovis
- Horse feed with *Salmonella* Abortusequi
- Dairy and beef feed(s) with *Salmonella* Newport or *Salmonella* Dublin

FDA should evaluate cases involving contamination of animal feed with other *Salmonella* serotypes on a case-by-case basis

NGFA Guidance on *Salmonella* Testing



- In response to the proliferation of *Salmonella* testing
- Available as a free download from the NGFA website

NGFA Home Page → Resources → Feed Quality Assurance

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Quick Facts on *Salmonella* Testing

You cannot test safety into a product

- *Salmonella* testing of product should be used only as verification that a company's feed safety system is working.
- Testing is not the only form of verification.
- Obtaining a negative result when testing for a *Salmonella* does not necessarily mean it is not there at some level.

Quick Facts on *Salmonella* Testing

A product that has tested and been confirmed positive for a known pathogen **may not be retested and released** based upon subsequent negative results.

- Unless there is a confirmed laboratory error that resulted in the initial positive result, retesting cannot be used to offset a positive result.

Quick Facts on *Salmonella* Testing

Poor sample collection practices can contaminate an otherwise clean sample

- Aseptic techniques always should be used to collect samples of feed or feed ingredients.
- Never do this →

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Quick Facts on *Salmonella* Testing

All testing laboratories and testing methods do not perform the same

- Selection of properly accredited laboratories and validated methods can increase confidence that the results are accurate.
- Performing *Salmonella* testing in a production facility is not recommended.

Quick Facts on *Salmonella* Testing

If a product sample tests positive for a pathogen and the product already has been released from your control, you may have created regulatory consequences.

Conversely, if you test a feed ingredient for a pathogen upon receipt, you may have created regulatory consequences for your supplier and any other manufacturers that have received the same ingredient lot from that supplier.

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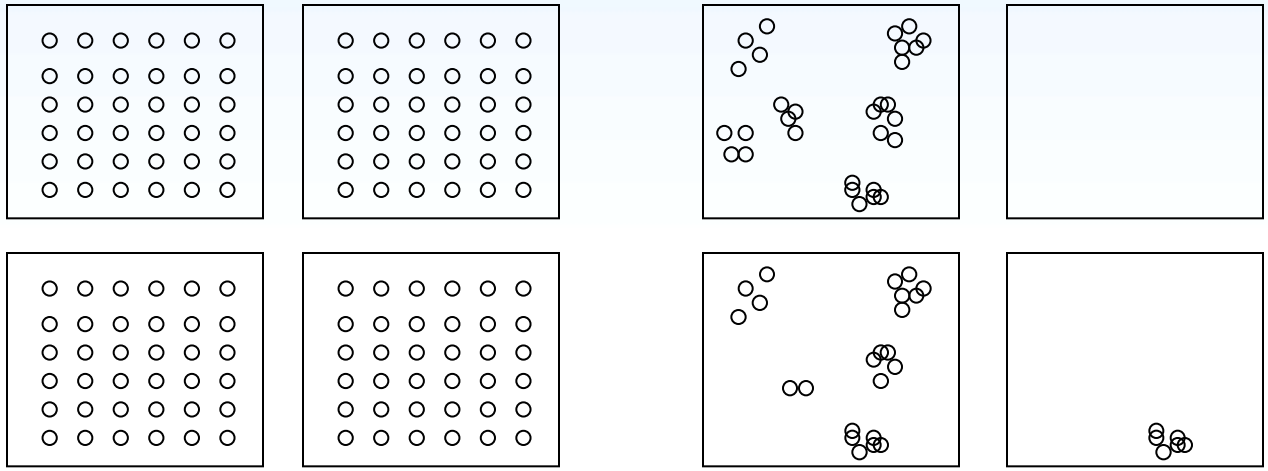
Limitations of *Salmonella* Testing

Probability of lot acceptance related to contamination rate

	If 5% of samples are contaminated			If 1% of samples are contaminated	
Number of samples per lot	Probability of Acceptance of lot	Probability of Rejection of lot		Probability of Acceptance of lot	Probability of Rejection of lot
1	0.95	0.05		0.99	0.01
5	0.77	0.23		0.95	0.05
15	0.46	0.54		0.86	0.14
30	0.21	0.79		0.74	0.26
60	0.05	**0.95**		0.55	0.45
300	<0.005	>0.995		0.05	**0.95**

Limitations of *Salmonella* Testing

The Effect of Distribution



Non - Random Distribution **Random Distribution**

Typically *Salmonella* contamination in a feed or feed ingredient is randomly distributed

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Limitations of *Salmonella* Testing

Given the low incidence rate and non-homogenous distribution of *Salmonella* in many raw materials, relying on testing may be the equivalent of looking for the needle in a haystack!

Usefulness of *Salmonella* Testing in Animal Feed or Pet Food

- To verify that a feed safety system designed to reduce or eliminate *Salmonella* from the feed is working; or
- To determine if a feed or feed ingredient is compliant with a desired specification

If you test for *Salmonella*, you must be ready to deal with the consequences of a positive result

Before Starting a *Salmonella* Testing Program

- Understand why you are testing
- Understand the implications of a positive
- Implement a positive release program

It is highly recommended that you consult a qualified microbiologist to assist with the development of any microbiological testing program

Salmonella Testing Summary

- Testing has limitations
- Testing has consequences that you must be prepared for
- If testing for pathogens, you should implement a positive release program
- If your process has a validated kill step, testing ingredients may not be necessary

Establishing expectations for suppliers and elements of a Supplier Program

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Why have a Supplier Program?

- Customers are demanding you have one
- Negative events are shared quickly
- Compliance to regulatory requirements
- Understand and manage the risks/hazards coming into your plants
- Reduce the risk of “surprises”

Supplier Approval Programs

You should know your suppliers and have a program for how you approve them

A supplier approval program may include:

- Supplier questionnaire
- Conversation with the responsible Quality personnel
- Document review
- Company (business) review – financial stability, history
- Agreement to a written set of expectations
- Audit of the manufacturing facility

Supplier Approval Programs

Assessing risk of a feed ingredient

What are the inherent biological, chemical and physical hazards associated with a feed ingredient?

What hazards may be more relevant based on a supplier's operation?

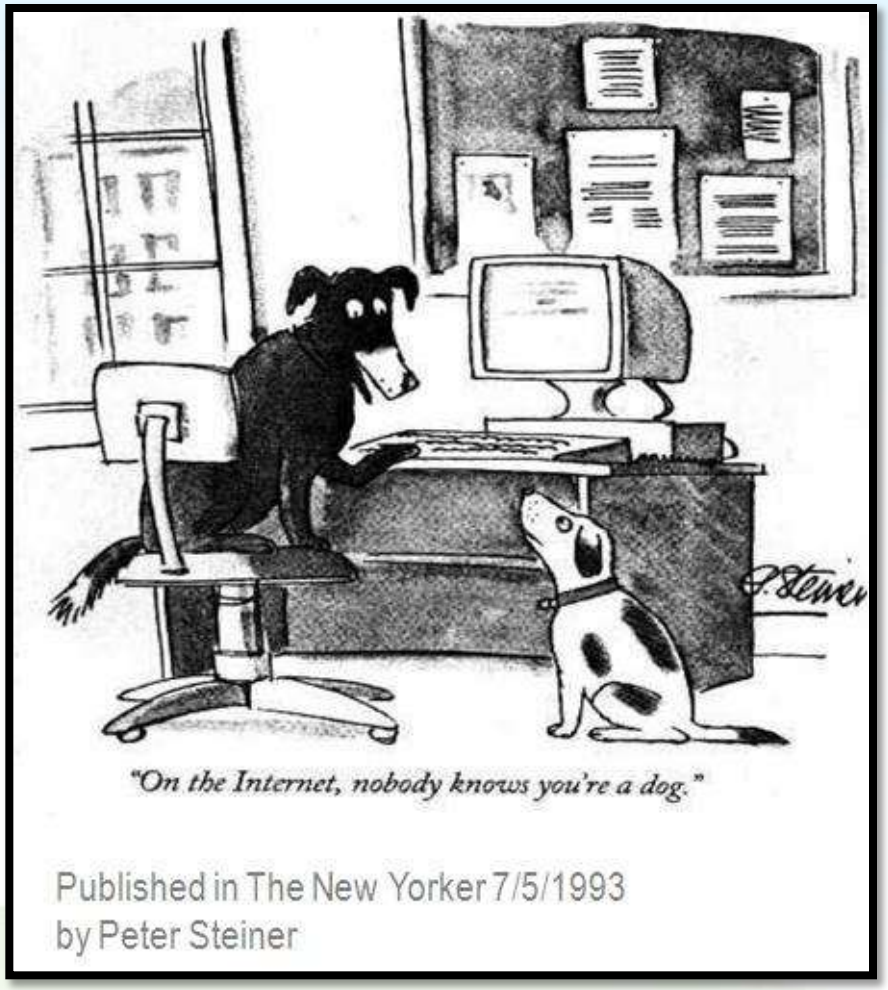
What hazards can you adequately control in your facility?

Supplier Approval Programs

- Based on your risk assessment of feed ingredients, develop an approach to supplier approval that adequately addresses risk
- Higher risk suppliers may require more information and diligence for approval

Supplier Approval Programs

- Approval of suppliers should always be specific to each manufacturing location, not company-wide approval

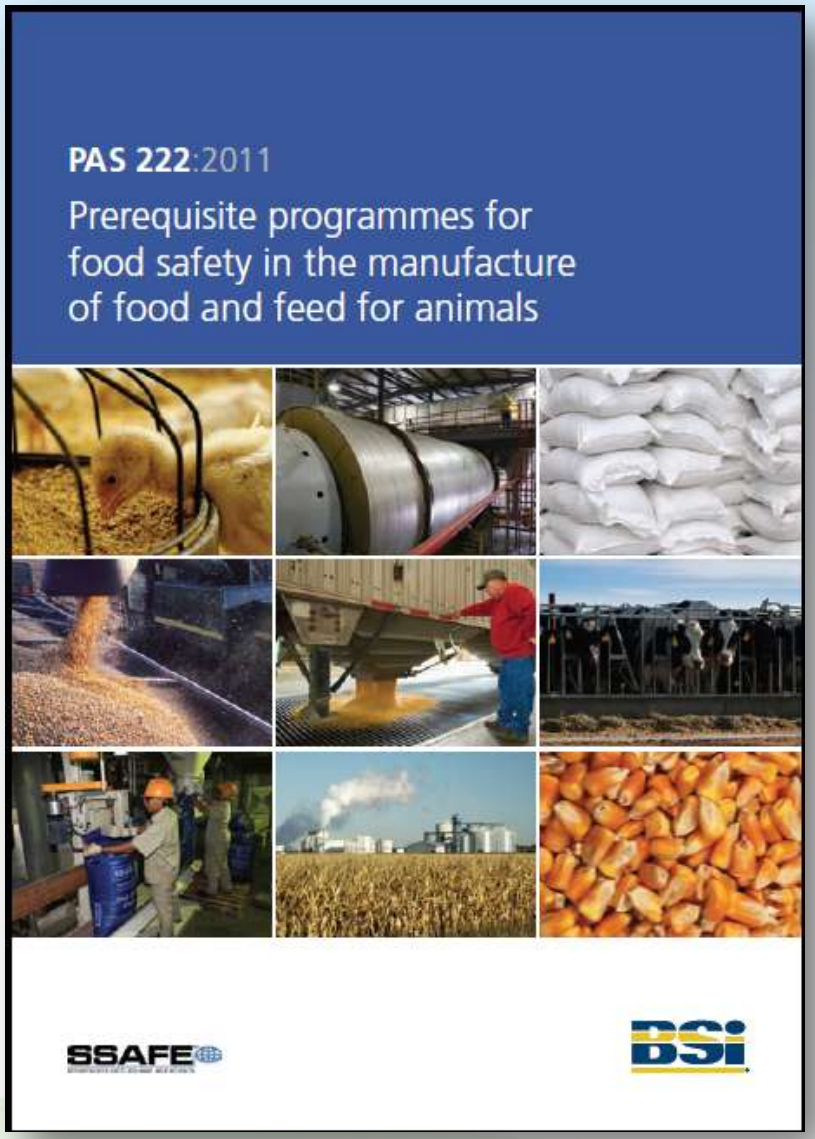


Collaborated with other Feed Industry leaders to develop PAS 222 for Animal Feed

SCOPE

- Commercial animal food/feed and ingredients
- Hazards affecting animal and/or human health
- Pertains to all animal classes and uses

This is a free download!



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Expectations Manuals

Name recently changed to Purina Animal Nutrition LLC

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Supplier Expectations

1. Management Responsibility	
3. Construction, Buildings & Utilities	9. Personnel & Production Practices
4. Facility Security	2. Regulatory Compliance
	8. Cleaning & Sanitation
12. Product Design & Spec Compliance	18. Maintenance & Calibration
5. Hazard Analysis & Risk Based Preventive Controls	10. Pest Management
20. Environmental Microbiological Monitoring & Control	
11. Chemical Control	14. Incoming Materials Management & Warehousing
7. Manufacturing Management & Control	22. Incident Management
21. Document Control & Facility Records	15. Lot Control & Trace Recall
6. Foreign Material Control	17. Positive Release/Critical Records Review
13. Supplier Control	19. Microbiological & Laboratory Management
16. Control of Nonconforming Product	23. Customer & Consumer Relations

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Management Responsibility

- The first Standard in every LOL Purina Animal Nutrition Quality Expectations Manual is Management Responsibility

Senior Management at the production location will demonstrate they are fully committed to the development, implementation and maintenance of a Feed Safety and Quality Management System

Management Responsibility

- Establish a documented Feed Safety & Quality policy
- Clearly assigned responsibility and accountability for Quality Management System (QMS) elements
- Adequate resources are provided at each location to implement & maintain the QMS requirements

Management Responsibility

- Written & implemented processes, procedures and/or work instructions
- Training is provided to support requirements of the QMS
- Senior management conducts periodic review meetings to monitor compliance to the QMS and track corrective actions

Management Responsibility

- Self-audits/assessments of the QMS are conducted to evaluate adequacy and effectiveness of the system
- Adequate records are maintained for the requirements of the QMS
- Plant management is familiar with Purina Animal Nutrition's requirements

Management Responsibility

- Change in producing location is communicated to Purina Animal Nutrition before a change is made
- Purina Animal Nutrition is notified immediately should a supplier recognize they are not in compliance with a requirement

Suppliers and CAPA

- When product safety or quality issues occur, a corrective action / preventive action (CAPA) is required

Corrective action – what did you do to address the immediate issue

Preventive action – what are you doing to make sure it doesn't happen again

Corrective Actions

Examples of corrective actions:

- Identify the affected product
- Notify all recipients of the affected material and remove material from market, if necessary
- Bring the process back under control, if necessary

Preventive Actions

Examples of preventive actions

- Identify the root cause
- Modify the process or equipment
- Implement new procedures
- Training, training, training!
- Verify and validate that the CAPA was effective

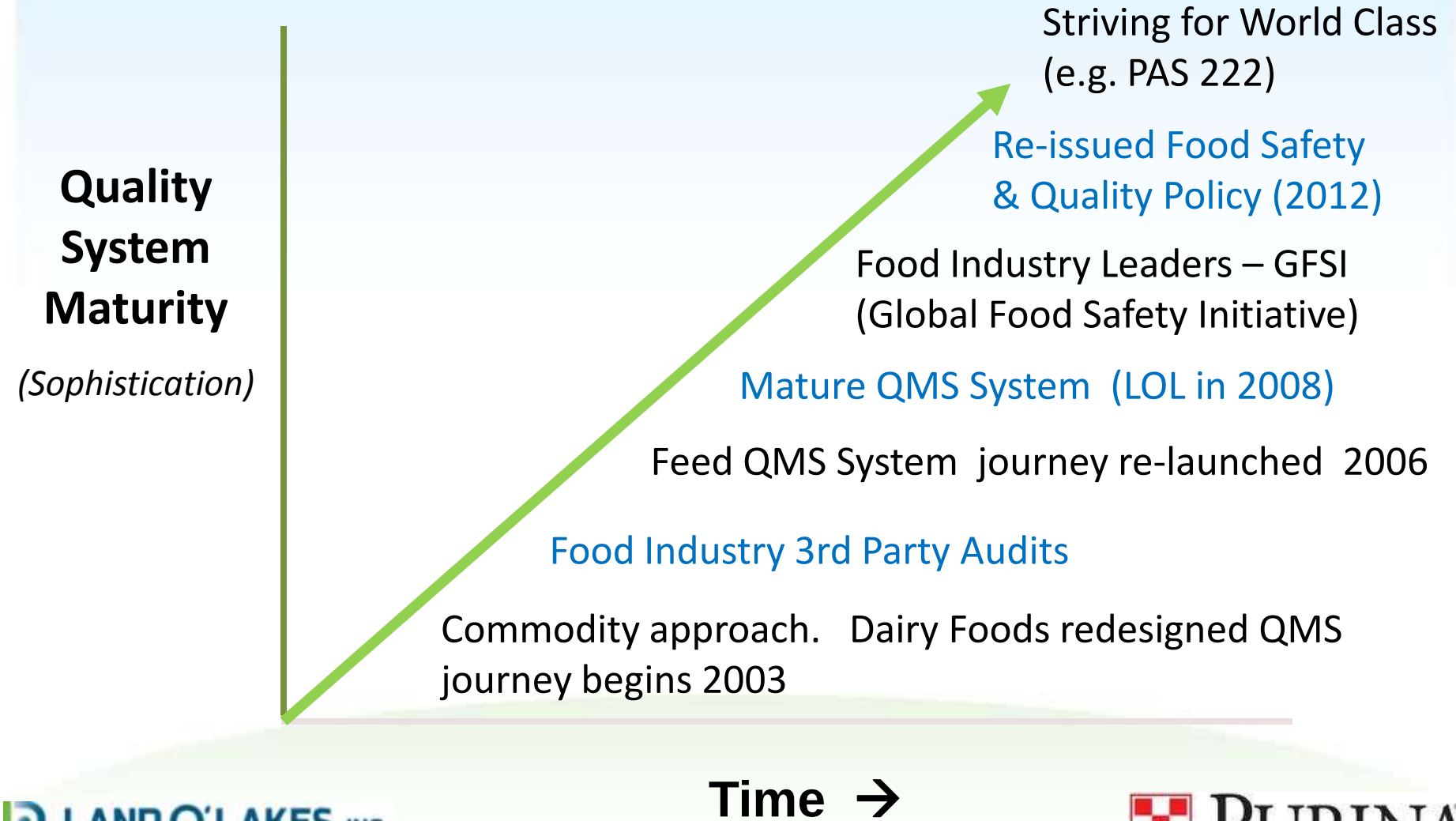
Supplier Program Summary

Supplier Approval and Verification is most likely going to be part of the Preventive Controls Rule for Feed

If you don't have a Supplier Program…get one!

The Land O'Lakes Journey

Quality Systems Continuum



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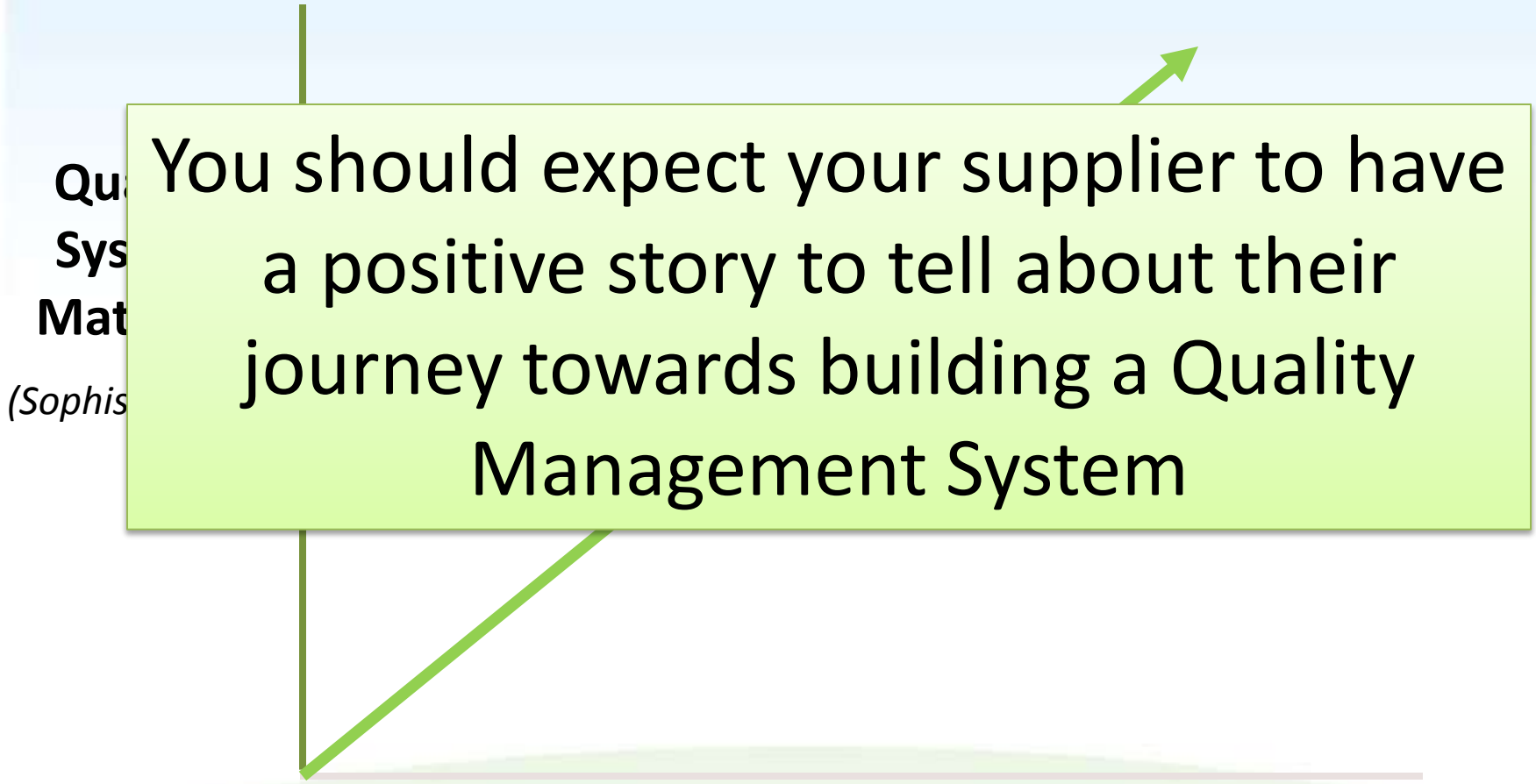
What is Your Journey?



You should expect your supplier to have a positive story to tell about their journey towards building a Quality Management System

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Thank You

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