



Australian Government
Department of Industry,
Innovation and Science

Business
Entrepreneurs' Programme



Food Allergen Series: Identification, Control and Management

**Presented by
The Allergen Bureau**

Hosted by the Department of Industry, Innovation and Science Entrepreneurs' Programme in collaboration with Food Innovation Australia Limited.



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Allergen Management & Allergen Analysis

Presented by The Allergen Bureau



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Food Allergy & Allergen Management Webinars

Webinar 1 – Food allergen fundamentals

Thursday 22nd March, 2018

Webinar 2 – Industry best practice for the identification, control and management of food allergens

Thursday 19th April 2018

Webinar 3 - Product labelling & recalls

Thursday 24th May 2018



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Introduction	Georgina Christensen The Allergen Bureau
Allergen Analysis – benefits and limitation and use in root cause analysis	Jasmine Lacis-Lee DTS Food Assurance
Allergen management – HACCP and beyond	Lisa Clark Simplot Australia



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Allergen Bureau Introduction

Georgina Christensen

VITAL Co-ordinator, The Allergen Bureau



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Who is the Allergen Bureau?

- The Allergen Bureau is the **peak industry body** representing food industry allergen management in Australia and New Zealand
- The Allergen Bureau is a **membership based** organisation established to provide food industry with rapid responses to questions about allergen risk management in food ingredients and manufactured foods
- Established 2005, **pre-competitive**, 'not-for-profit', industry volunteer Board

Full Members





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The Allergen Bureau – Our Vision and Mission

Vision

- The Allergen Bureau is a globally recognised and supported industry organisation promoting best practice food industry allergen management, risk review and consistent labelling to facilitate informed consumer choice

Mission

- To facilitate a globally accepted, consistent, science-based approach to food allergen risk assessment, management and communication that:
 - guides **industry** best practice
 - assists allergen sensitive **consumers** to make informed choices based on label information



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Recap from Webinar 1: Food Allergen Fundamentals

- Food allergy is significant and impactful in our community
- Importers, exporters, food manufacturers, food marketers, retailers, food service – all areas of the food industry are required to understand the allergens in their product and to communicate this to their customers
- It is mandatory to declare certain allergens which are present in your product
- Allergen management is important to produce safe food



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Allergen Management & Allergen Analysis

- Frequently asked about these topics via the free Allergen Bureau Helpline
- Allergen labelling decision must be underpinned by robust allergen management (even if you don't have any allergens on site)
- Allergen analysis an extremely useful – but it does have limitations so it should be applied and interpreted with care
- Allergen analysis is often used as part of allergen management



JOHN WEST



Allergen Management



Lisa Clark

Corporate Quality Officer, Simplot Australia

Allergen Management is owned by EVERYONE

Best in class Allergen Management starts with a Best in Class Quality Culture.

- All employees and contractors trained and knowledgeable.
- Signage and SOPs in support of our Allergen Management plans.
- Clear roles and accountability for everyone to speak up.
- Senior Management support via training, resources and procedures to control risks.

Components of an allergen management plan.

- Good manufacturing procedures and precursor programs
- Risk assessments for suppliers and ingredients
- Warehouse segregation
- Scheduling
- Validated cleaning
- Maintenance controls
- Training
- Equipment and building designs
- Control of labelling and packing.
- Change control procedures
- HACCP or Food Safety Plan

Supplier and Ingredient Risk Assessment

Is this ingredient / supplier from a high risk country?

- Food Allergy is less common in developing countries (Asia and Africa) for example. Products from these countries can be higher risk.
- Are the allergens labelled for in that country similar to those in Australia?

Can your supplier

- Confidently tell you the allergens that are intentionally present in the product /material they supply?
- Indicate to you the level of unintentional allergen that may be present due to cross contact contamination?
- Inform you of the steps that they use to mitigate risk.

You must know exactly what allergens are in your product to label and control allergens effectively.

Supplier and Ingredient Risk Assessment

How to assess?

- Request a Product Information Form (PIF)

Key sections of a PIF needed for Allergen risk assessment

- **2.6 INGREDIENT LIST**
- **2.7 PROCESSING AIDS**
- **3.2 ALLERGEN MANAGEMENT AND CONTROL (all questions)**
- **3.4 ALL SECTIONS**
 - Specs are often not detailed enough
 - Reluctance to fill in a PIF = Higher risk supplier

A fully completed PIF allows you to risk assess your supplier and your material.

Supplier and Ingredient Risk Assessment

2.6 INGREDIENT DECLARATION

Specify all ingredients including food additives in descending order, including percentage labelling of characterising components or ingredients. Compound substances must specify all ingredients and additives present and the characterising ingredient or component. Food additives must specify a functional class name and the food additive name or code number [e.g. antioxidants (304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000].

COMPONENT NAME	PERCENT OF TOTAL %	COMPOUND SUBSTANCE INGREDIENTS Full breakdown list of components in compound ingredient including additive code numbers	Characterising component %
Soy Flour	89.00%		
Yeast Extract	10.00%		
Natural Flavours	1.00%		

3.3 INGREDIENTS TO BE DECLARED AS ALLERGENS OR SULPHITE

Please insert YES or NO to indicate if the product contains, or was manufactured using, any ingredient, additive or processing aid which has been derived from the following food sources. Highly processed derivatives must always be declared. Carefully assess compound ingredients for hidden allergens. [** Lupin included as a possible future addition to the Food Standards Code.]

☒ **Yes** Cereals containing gluten & their products [*wheat, rye, barley, oats, spelt*]
☐ **No** Crustacea & crustacea products
☐ **No** Egg & egg products
☐ **No** Fish & fish products (including mollusc with or without shells and fish oils)
☐ **No** Lupin & lupin products [** not a mandatory labelling allergen at this time]
☒ **Yes** Milk & milk products
☐ **No** Peanut & peanut products
☐ **No** Sesame seed & sesame seed products
☒ **Yes** Soybean & soybean products
☐ **No** Tree nuts & tree nut products
☐ **No** Reserved for future allergen - left blank intentionally

☒ **Yes** Cereals containing gluten & their products Has processing rendered this GLUTEN FREE (no detectable gluten)?
☐ **No** Has processing rendered this FREE OF WHEAT PROTEINS ?
☐ **No** Sulphites, present in ingredients, additives or processing aids

3.4 ALLERGEN CROSS CONTACT

3.4.1 Except for any allergens listed in Section 3.3, does your company have on site and handle ANY OTHER allergenic substances listed below?
 IF NO, specify "No" to indicate allergens are NOT IN THE SAME FACILITY then go to Section 3.4

**Refer to VITAL procedure and decision tree. <http://www.allergenbureau.net/vital/>

3.4.2 All columns must be completed WHERE HIGHLIGHTED

ALLERGENIC SUBSTANCE	PRESENT IN SAME FACILITY Yes/No	PRESENT ON SAME LINE Yes/No	SOURCE FOOD The allergenic food from which ingredient is derived (e.g. wheat)	DERIVATIVE NAME Ingredient, additive or processing aid (e.g. maltodextrin)	TOTAL PROTEIN** protein level by VITAL, or specify "particulate" mg/kg
Cereals containing gluten & their products	No				
Crustacea & crustacea products	No				
Egg & egg products	Yes	Yes			
Fish & fish products (inc mollusc & oils)	No				
Lupin & lupin products	No				
Milk & milk products	Yes	Yes			
Peanuts & peanut products (inc peanut oil)	Yes	Yes			
Sesame Seed & sesame products	Yes	Yes			
Soybeans & soybean products (inc soybean oil)	No				
Tree nuts & tree nut products	No				
Reserved for future allergen					

Yes/No

No

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By answering No to the first question, it removes the additional allergen questions.

As such we do not have the information needed to understand risk

Be thorough - The risk is not always obvious. Pick up the phone!

Supplier and Ingredient Risk Assessment

Think beyond the obvious.

- Crops can be contaminated in the paddock.
- Ingredients can be contaminated during transport. (mixed loads, back loads).
- Ensure your suppliers don't change the location in which your material is grown, harvested or processed in without telling.
- Check information on a regular basis. E.g. High risk suppliers every 6-12 months.
- Don't forget your chemicals and lubricants.
- Consider testing as a means to validate the information your supplier has told you.

Allergen Management in the labelling area

- Try to make your labels visually distinctive from others in the range.
- Sample and review your packaging in the warehouse to ensure it is correct.
- Have a system that checks and records the correct packaging is issued to the line, at start up, product change over or when rolls or cartons run out.
- Only deliver what you need to the line.
- Clear all previous packaging from the line at product change over before the next products labels are delivered.
- Complete a mass balance of what you delivered vs how many you made and how many labels were returned.
- Consider technology optical imaging or QR codes, but calibrate equipment at each change over.
- If you add an allergen to your recipe, change your bar code.

**This is a high risk area that must be monitored and controlled.
Training is essential.**

Ingredient storage and segregation

Segregate allergens in your warehouse.

- Ensure all materials are fully sealed in intact packaging.
- Label packaging to clearly show what allergens they contain.
- Store like allergens with like allergens.
- Allergens on the ground, non allergens in bays above.
- Common allergens can be stored above each other. E.g. An ingredient with soy can be stored above an ingredient with milk and soy, not the other way around.
- Reseal open allergens and if possible store in a different area.
- When constrained try to work on solutions.
- Only manage ingredients containing intentionally present allergens.

Rework and WIP Management

- Label rework and WIP if they contain intentionally present allergens.
- Like for like use of rework.
- Store in closed containers and segregate like your warehouse.
- Use a document controlled rework matrix.
- If you change your recipe, check and change your rework matrix.

Scheduling and Ingredient movement

- Have a site allergen register or matrix.
- Monitor and control ingredient delivery. Are you using the correct ingredient in the correct formulation?
- The production schedule is an extremely important allergen management tool.
 - Allergen free first, allergen containing products last.
 - Where possible run in increasing allergen order.
 - Full allergen wash when the order does not work.
 - Allergenic ingredients that don't dissolve or that clump together in the mix are higher risk. Try to run them less often. E.g. once a month instead of weekly.

Appropriate scheduling and longer runs less often minimise risk.

People and Tool Movement

- Colour code implements in our weighing and dry goods areas.
- Compulsory washing, sanitation and drying of all tools after they have been used on an allergen.
- Control tools used in maintenance or at line change overs.
- Where have your contractors tools been?
- Could staff represent an allergen risk?
 - Do staff that work in allergen areas and get allergens on their uniform enter a non allergenic area?
 - Can they change their PPE before doing so?
 - Can they enter and leave via a dedicated door?

Look for the risks, assess the risks, Implement appropriate controls.

Building and line design

- Zone your Factory with Allergenic lines isolated from allergen free lines.
- Consider people movement and walking routes in your design.
- Ensure your equipment is easy to access and clean.
- Avoid line cross overs.
- Ensure designs do not have dead legs or hang up points.
- When validating CIP equipment or cleaning procedures check they are effective for removing allergens as well as bacteria.
- Consider dust minimisation or physical barriers.

Ensure equipment design and ease of cleaning is considered in your risk assessment.

Cleaning and Sanitation

- Where you run different allergen profiles after each other you must stop and complete a full allergen wash. Rinsing is not enough.
- It is preferable to use a consistent training crew who are well trained.
- You must validate whether your cleaning procedure removes allergens.
- Visual inspection, swabbing surfaces, testing wash water, catching airborne allergens, testing next product run are all validation techniques.
- You must validate whether your steps completely remove a risk, reduce the risk or can not control the risk.

Allergen Risk Assessment

- Consider all steps in your process end to end.
- Document risks, the controls you propose to use to manage the risks and the measurements you will take to verify your controls are effective.
- HACCP plan is the perfect place for this and will tie all activities together.
- If you can not remove a risk or prove you have removed a risk a precautionary allergen label (e.g. “May be present”) may be required.
- The Allergen Bureau VITAL[®] Program can help you do this.

Only use a precautionary allergen label where you have established that you may have a food safety risk for the allergen in question.

FOOD ALLERGEN ANALYSIS

The Benefits and Limitations

Jasmine Lacis-Lee
DTS Food Assurance
19th April 2018

Why test?

- Compliance to the Food Standards Code
- Compliance to Retailer Standards (WW, Coles, Aldi)
- To verify claims – i.e. Gluten Free, Dairy Free
- To check that the Allergen Management Plan is effective

When to conduct allergen testing?

- To check ingredients are as you expect them to be
 - Is the gluten free cornflour really gluten free?
- To validate and verify that cleaning is effective
- To check that your product meets the expected allergen profile
 - Dairy free sorbet and dairy ice cream produced in the same facility
- To verify your allergen risk assessment (i.e. VITAL)
- To assist in root cause analysis on equipment
- Importantly – test when you know what the result is likely to be!

Types of allergen testing available – non specific

Visual assessment – great when cleaning is poor

Protein Swabs – easy to use, not allergen specific

Allergen Protein Swabs – easy to use, not allergen specific

ATP swabs – easy to use, not allergen specific



Swab/Dip



Click



and Read

Types of allergen testing available – allergen specific

- Lateral Flow Devices – most are easy to use, allergen specific, positive / negative results only, best used for environmental monitoring and low level cross contact.
- ELISA methods – allergen specific, quantifiable, require expertise for testing and interpretation of results. Considered the most robust methodology currently available
- PCR & Mass Spec



Which type of test should you use? And when?

- Use the most robust method when:
 - Validating cleaning initially
 - Checking ingredients are as expected
 - Verifying any claims on products
 - Verifying that ongoing cleaning is effective
 - Verifying that risk assessment outcomes are as expected
- Use rapid methods in your facility:
 - To monitor and verify cleaning ongoing
 - As a go / no go tool in your facility to commence production

What is a cleaning validation?

Cleaning validation is performed to confirm that allergen cleaning procedures are correct

- Microbiological Validation is not appropriate
- Process
 - Know your target allergen
 - What if the allergen is not detectable?
 - Perform Before and After cleaning testing
 - Repeat it – the first time is just luck!
 - Use a robust analytical method

What is cleaning verification?

- Implemented and performed regularly after you have validated that the procedures used are appropriate
- May include current checks for cleaning:
 - Visual
 - ATP
 - Protein swabs
- Should include allergen specific checks, especially when producing high risk products (i.e. “Free from” products such as dairy free)
 - Lateral Flow Devices
 - Quantitative Allergen Testing - ELISA
 - Any other check currently used for cleaning efficacy – Data trend reviews, chemical checks etc

Myths about cooking and impacts on testing

- Cooking makes it less allergenic – in some cases yes, in other it can make it more allergenic
- “I tested it and my result is <LOQ, so it’s not there” – this may not be the case, it may be that the kit hasn’t been able to find it, the form the allergen will make detection harder, or there were not enough samples taken
- Any process that changes the protein structure – heating, hydrolysing, fermenting can change the structure making the protein harder to detect!

Example - Oil

- The same fryer is used for frying products containing gluten, dairy and non gluten containing products
- The oil is tested for the presence of Gluten and Dairy
 - Gluten is detected at a low concentration
 - Dairy is not detected
- The fines / crumbs are tested for the presence of Gluten and Dairy
 - Gluten is detected in higher level
 - Dairy proteins are still unable to be detected

What information do you need to tell the laboratory?

- Preferably what the ingredients are in the sample
 - “Why do I need to give them my IP?”
 - Choosing the right test methods – Gluten; Egg and Lysozyme
 - Gums
 - Tannins & Polyphenols (chocolate)
 - False positives & cross reactivity
- If you are expecting to get a positive result
- If it's positive, do you want to know exactly how much is there?

What questions do you need to ask the laboratory?

- What experience do they have in allergen testing?
- Are they NATA accredited for allergen testing?
- What method are they using for your samples?
 - Lateral Flow? ELISA?
- Is the method validated and verified?
- What experience do they have testing your type of samples?
 - How will they know if it is suitable?
- What are the reporting units?

How many samples should be tested?

- One is not enough!
- There is currently no internationally accepted sampling protocol
- Conduct a line survey to ensure all parts of the process are assessed
- Finished product testing should be risk based
 - If you are a completely Gluten Free site, increased surveillance on raw materials, then finished product
 - If you make dairy free and dairy products on the same line, consider testing each production of the dairy free product to reduce the risk
- $n = 5$ versus $n = 30$ (based on product / allergen profile)
- Compositing of finished products should be discouraged as it reduces the chances of detecting a problem, but does not reduce the risk to the allergic consumer

Result interpretation can be confusing

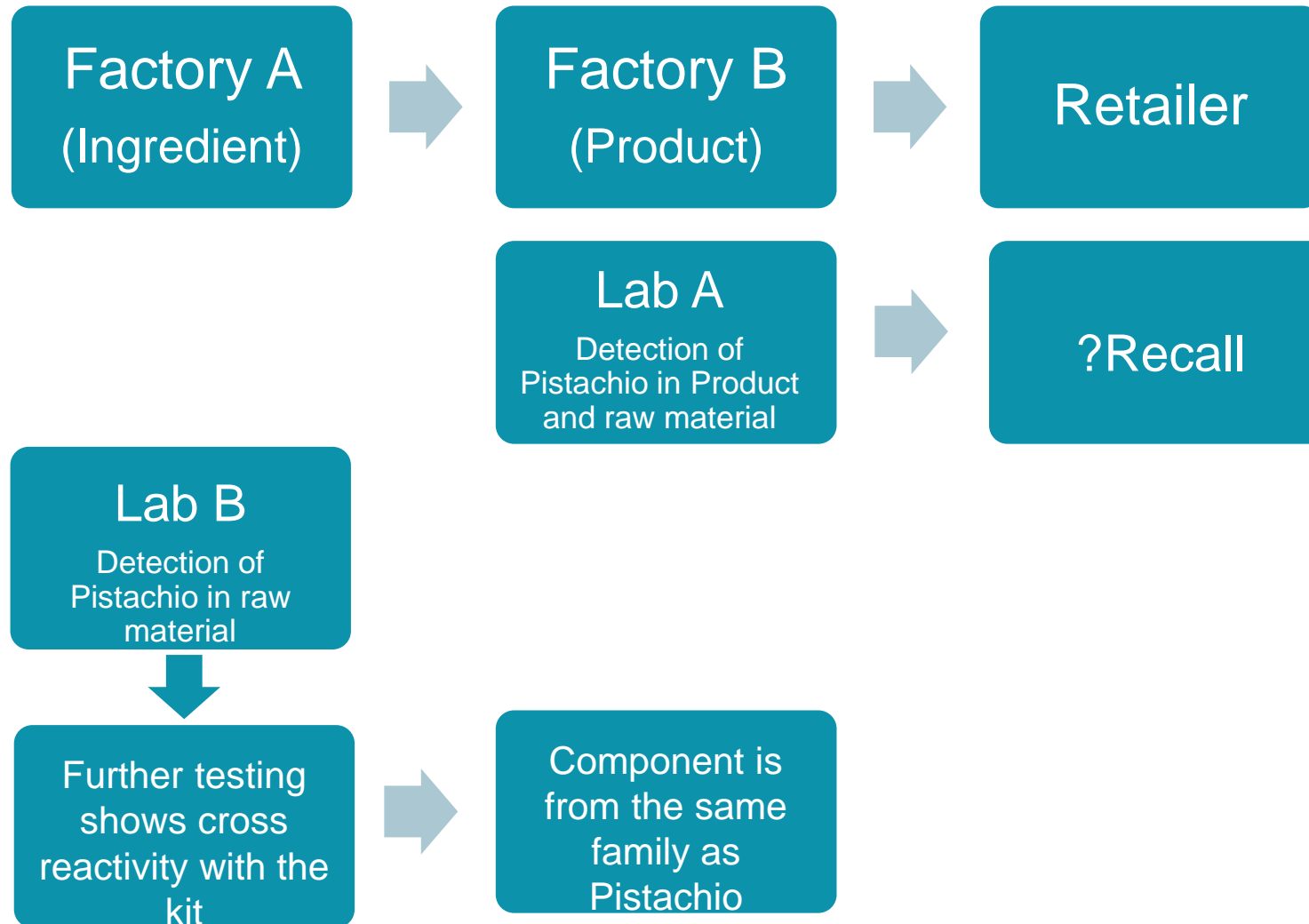
- Detected / Not Detected (ND)
- Limit of Detection (LOD)
- Limit of Quantification (LOQ)
- Limit of Reporting (LOR)
- Parts per million (ppm or mg/kg)
- Allergen target being reported – Peanut versus peanut protein

Example 1. When analysis can avert a recall

Dairy and Soy yoghurt produced in the same facility on the same line

Samples	Results for Dairy
Cleaning verification	Not Detected
Line samples	Not Detected
Finished product A	Detected
Finished product B	Not Detected
Finished product C	Not Detected
Retests of Product A	Detected throughout the run
Raw material product A	Detected

Example 2. – When analysis can be confusing



What actions are required when there is a detection?

A positive may lead to:

- Identification of unexpected allergens in ingredients or finished product
- Review of the process / HACCP / AMP
- A review of the cleaning practices
- Implement corrective actions, and retesting
 - 1 sample will not provide confidence
- Recall?

Summary: Thing to consider when testing for Allergens

- Do you understand your process?
- Is the process in control?
- Sampling number and frequency of testing needs to be based on risk
- Analysis forms part of ensuring all the process in place are effective
- Seek assistance from experienced analysts to ensure testing is appropriate and result interpretation is required

Thank You

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Further Information & Engagement

The Allergen Bureau

- Visit the website www.allergenbureau.net
- Subscribe to our free monthly Allergen Bureau eNews www.allergenbureau.net/news/
- Access the AllergenBureau Helpline
email: info@allergenbureau.net
Phone: 0437 918 959

Entrepreneurs' Program Learning Events

- EPLearningEvents@industry.gov.au

Webinar 3 Thursday 24th May 2018 - Product labelling & recalls

Thank you!



Australian Government
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Thank you for watching this Entrepreneurs' Programme Webinar

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