SAFEGUARDS

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RECENT US FDA RECALLS – 60 PERCENT DUE TO UNDECLARED ALLERGENS

On 19 August the ExpertRECALL Quarterly Index was published, summarizing key findings from recalls announced in the second quarter of 2013 in the United States (US). Among these findings, undeclared allergens have consistently been a top trend for US Department of Agriculture (USDA) and US Food and Drug Administration (FDA) administered recalls for the last several quarters and data trends indicate those numbers will continue to rise¹.

In the second quarter of 2013, 65 percent of recalls from the USDA were due to an undeclared allergen. Similarly, the FDA recorded that 60 percent of its recalls occurred due to undeclared allergens, which is an increase of 34 percent from the previous quarter. Undeclared allergens were the single largest cause in the second quarter with 11 recalls, followed by extraneous materials and Listeria, with two recalls each from the USDA. These results show that allergens continue to be a top recall trend quarter over quarter after they have consistently been a top trend for USDA and FDA recalls for the last six quarters².

In April, the US Food Safety and Inspection Service (FSIS) issued a notice³ with new instructions for inspection program personnel (IPP) for how to verify that establishments are accurately labeling the eight most common food allergens. The FSIS reports its list of "Big 8" allergens – wheat, crustacean shellfish, eggs, fish, peanuts, milk, tree nuts and soybeans – account for 90% of all food allergy reactions. These allergens are designated as "major food allergens" by the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004⁴. Food manufacturers must ensure that they are in complete compliance with all verification processes before an inspector arrives onsite, as it is almost guaranteed that records will be audited and production processes will be observed on a more frequent basis.

SGS has launched a survey on "CURRENT INDUSTRY PRACTICES ON ALLERGEN CONTROL AND MANAGEMENT". The main purpose of this survey is to understand current industry practices relating to allergen control and management. Sharing your current practices, issues and suggestions will help the industry and us to improve the consistency of allergen management, methods and practices. Please take some minutes to <u>PARTICIPATE</u>.



- ¹ ExpertRECALLQ2 Index Highlights Standards of Inspection for Pharma and Food
- ² ExpertRECALL-Recall Index Second Quarter 2013
- ³ FSIS NOTICE
- ⁴ <u>Food Allergens Guidance Documents &</u> Regulatory Information Guidance for Industry



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