

# Managing Food Allergens: Case Histories and How They Were Handled

**René W.R. Crevel<sup>1</sup>, Steven L. Taylor<sup>2</sup>,  
Sylvia Pfaff<sup>3</sup>, Anton Alldrick<sup>4</sup>**

<sup>1</sup>*Safety and Environmental Assurance Center, Unilever, Sharnbrook, Bedfordshire, UK*

<sup>2</sup>*Food Allergy Research & Resource Program, University of Nebraska, Lincoln, NE, US*

<sup>3</sup>*Food Information Service (FIS) Europe, Bad Bentheim, Germany*

<sup>4</sup>*Campden BRI, Chipping Campden, UK*

## CHAPTER OUTLINE

Introduction.....	169
Case Study 1 – Supply Chain.....	169
Background.....	169
Incident Investigation.....	169
Supplier’s Response .....	170
Traces.....	171
Analytical Methodology .....	171
Allergen Management.....	171
Actions.....	172
Concluding Comments.....	173
Case Study 2 – Supply Chain, Manufacturing – ‘All Nuts are Equal’ .....	173
Background.....	173
Investigation and Actions .....	173
Concluding Comments.....	173
Case Study 3 – Labeling.....	174
Background.....	174
Investigation .....	174
Actions.....	175
Concluding Comments.....	175

Case Study 4 – Manufacturing (Large Company).....	175
Background.....	175
Investigation .....	175
Actions.....	176
Risk Mitigation .....	176
Corrective Actions .....	176
Concluding Comments.....	177
Case Study 5 – Manufacturing (Rework).....	177
Background.....	177
Investigation and Actions .....	177
Concluding Comments.....	178
Case Study 6 – Manufacturing and Design – ‘Nut Snow’.....	178
Background.....	178
Investigation and Actions .....	178
Concluding Comments.....	179
Case Study 7 – Manufacturing (Small Company).....	179
Background.....	179
Investigation and Actions .....	179
Concluding Comments.....	180
Case Study 8 – Allergen Awareness – ‘No Protein = No Food Allergen: True or False?’.....	181
Background.....	181
Investigation and Actions .....	181
Concluding Comments.....	181
Case Study 9 – Product Development, Training, Allergen Awareness: – ‘Food Allergens: Never Heard of Them!’ .....	182
Background.....	182
Development and Actions.....	182
Concluding Comments.....	182
Case Study 10 – Training, Allergen Awareness, and Supplier Verification.....	183
Background.....	183
Investigation and Actions .....	183
Concluding Comments.....	184
Case Study 11 – Auditor’s Allergen Awareness and Understanding .....	184
Background.....	184
Risk Analysis .....	185
Concluding Comments.....	185
Case Study 12 – An Ethical Dilemma .....	186
Background.....	186
Actions.....	186
Concluding Comments.....	186
Conclusion .....	187
References.....	187

## INTRODUCTION

The principles of allergen management are described in some detail in other chapters in this book, and the body of knowledge that makes them up can often be reasonably derived from first principles. For instance, the principle of separating allergens from other food ingredients and from each other as a means of managing them is almost self-evident, even if implementation is rather more complex. Similarly, few, if any, could argue against the need for a thorough knowledge of the allergen status of supplied materials or the need for staff training. However, presented as a series of practices on their own, without direct reference to context, they cannot convey the full complexity of allergen management in operational circumstances. This chapter aims to overcome this issue by describing a series of case studies that have led directly to lessons being learned. The authors hope that these case studies will prove informative to readers seeking to put an allergen management system in place, as well as those who may wish to check that they have taken into consideration all necessary elements in their allergen management plans. The case studies have been selected to cover specific components of the supply chain and manufacturing and are based on the authors' combined experiences and knowledge. To protect the companies involved, some details may have been changed, but the essence of the issues have been retained.

## CASE STUDY 1 – SUPPLY CHAIN

### Background

The company received a report that a schoolgirl had had a reaction, which was severe enough to require hospital treatment. The girl had a severe allergy to egg and milk and suffered the allergic reaction after eating a meal at school that consisted of breaded fish and a white sauce provided by a caterer and supplied by the company in question. The ingredients of the white sauce were listed by the manufacturer and did not include milk or egg. Analysis of a sample of white sauce powder by the authorities indicated that it contained 553 mg casein/kg (ppm). None of the other foods eaten contained casein or egg protein, thereby firmly implicating the white sauce as the cause of the reaction.

### Incident Investigation

The white sauce contained no milk by formulation, nor did any of the ingredients used in its preparation. The milk was ultimately traced to a creamer, which constituted 23.7% of the sauce. Analyses by Enzyme-Linked Immunosorbent Assay (ELISA) (Neogen whole milk kit) of the implicated batch of non-dairy creamer showed that it contained 6650 mg/kg milk protein. Further analyses of retained samples of all the batches of creamer received by the factory that made the implicated product revealed milk protein contents ranging from 90 mg/kg to 1155 mg/kg (see table). These analyses also showed

that the lower milk protein content was found in the earliest batches received, following which the milk protein content not only increased but fluctuated more. The supplier of the creamer undertook their own analyses using the Kjeldahl total nitrogen assay (lower limit of detection 1000 mg/kg). Results broadly correlated with the ELISA results. They showed an association between the protein content of the preceding product and the milk protein content of the following creamer batch, a result consistent with observations made during studies to validate allergen management protocols. The conclusions drawn from these results were:

- A change in some aspect(s) of the production process for the creamer took place between the early batches and the later ones.
- Insufficient consideration was given to allergen management as part of the process for creamer production.
- No or inadequate methods were used to monitor possible changes in the extent of allergen cross contact during creamer production.
- The supplier of the creamer showed inadequate understanding of the factors affecting allergen cross contact and consequently made no attempt to mitigate them.

Batch	Goods Receipt Date	ppm Milk (ELISA)	ppm Milk Protein (ELISA)	Results of Kjeldahl Analysis (% Protein)	Protein Content of Previous Product	Partial Wet Cleaning?
1	15/01/2008	~250	~90	0.33%, < 0.1%		
2	12/02/2008	~250	~90	0.33%, < 0.1%	8%	No
3	17/04/2008	~300	~105	< 0.1%, < 0.1%	5%	No
4	27/05/2008	~3000	~1050	0.29%, 0.12%	2%	No
5	10/06/2008	ND		0.29%, 0.12%		
6	26/08/2008	~18000	~6300	0.4%, 0.37%	15%	No
7	23/10/2008	~33000	~11550	0.42%, 0.15%	23%	No
8	18/11/2008	~19000	~6650	0.17%, < 0.1%	9%	Yes

### Supplier’s Response

The supplier agreed that the analytical results showed that measurable amounts of milk protein were present in the creamer. However, it also asserted that the specification for the ingredient included the possibility of traces of milk protein and that the sauce manufacturer had implicitly accepted that specification. It claimed that the ingredient at all times complied with the specification. It also asserted that an external audit of its facilities did not highlight any allergen issues. From these discussions three questions therefore arose:

- Could the amounts of milk protein found in the product legitimately be described as ‘traces’?
- Did the supplier use adequate methods to monitor the possible changes in allergen cross contact?

- In view of the increasing and fluctuating milk protein content in the creamer, could the supplier maintain that its allergen control processes could be considered to be adequate?

Further information obtained from the supplier revealed that scheduling of the spray-drying of the creamer, which took place in the same spray-drying tower as milk powder, had changed. Instead of being confined to the start of the week, following a thorough cleaning of the tower over the weekend, it took place during the week with no special cleaning.

## Traces

According to the Oxford English Dictionary a trace is ‘*a very small quantity, especially one too small to be accurately measured*’. The definition implies that what a trace is depends on the analytical method used. Analytical measurements provided by the supplier imply a limit of detection of 0.1% (1000 mg/kg) using the Kjeldahl method, since it cites the lowest values as being < 0.1%. Using the conservative assumption that the lower limit of quantification is twice the limit of detection, five measurements on batches containing high amounts of milk protein (by ELISA) were above that limit. Since those quantities could be measured accurately by the supplier’s method, they cannot be described as ‘traces’, and the relevant batches fail the specification on that measure.

## Analytical Methodology

The analytical method used should be able to detect the milk protein at relevant levels, that is, at levels close to those known to provoke reactions (allowing for any dilution effects in the use of the ingredient, etc.). Knowledge of the incident available at the time indicated that the amount of milk protein capable of provoking reactions was of the order of low milligrams [1]. A milk content in the white sauce of 1 mg per portion corresponds to a milk content in the creamer of 100 mg/kg. Any assay used to manage milk cross contact in the creamer should therefore be able to measure 100 mg/kg milk protein. The Kjeldahl method, as applied by the supplier, does not meet this requirement. Very sensitive protein assays exist that would be adequate, but the preferred methodology is an ELISA-based immunoassay because of its specificity.

## Allergen Management

Allergen management principles and practices have been well defined and accepted over recent years. Guidelines have been produced by a number of regulatory authorities and other organizations and are available publicly, often at no cost. Some of the key principles, which should be incorporated into an allergen management plan, include:

- Risk assessment:
  - Determine allergen(s) of concern, which need to be managed