

Risk Management for Food Allergy



Risk Management for Food Allergy

Edited by

Charlotte Bernhard Madsen,
DVM Research Leader Division of Toxicology
and Risk Assessment National Food Institute
Technical University of Denmark

René W. R. Crevel
Safety and Environmental Assurance Center,
Unilever, Sharnbrook, Bedfordshire, UK

Clare Mills
Manchester Institute of Biotechnology,
University of Manchester, UK

Steven L. Taylor
Food Allergy Research & Resource Program,
University of Nebraska, Lincoln, NE, US



AMSTERDAM • BOSTON • HEIDELBERG • LONDON
NEW YORK • OXFORD • PARIS • SAN DIEGO
SAN FRANCISCO • SINGAPORE • SYDNEY • TOKYO

Academic Press is an imprint of Elsevier



Academic Press is an imprint of Elsevier
The Boulevard, Langford Lane, Kidlington, Oxford, OX5 1GB, UK
225 Wyman Street, Waltham, MA 02451, USA

First published 2014

Copyright © 2014 Elsevier Inc. All rights reserved.

No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, or any information storage and retrieval system, without permission in writing from the publisher. Details on how to seek permission, further information about the Publisher's permissions policies and our arrangement with organizations such as the Copyright Clearance Center and the Copyright Licensing Agency, can be found at our website: www.elsevier.com/permissions

This book and the individual contributions contained in it are protected under copyright by the Publisher (other than as may be noted herein).

Notices

Knowledge and best practice in this field are constantly changing. As new research and experience broaden our understanding, changes in research methods, professional practices, or medical treatment may become necessary.

Practitioners and researchers must always rely on their own experience and knowledge in evaluating and using any information, methods, compounds, or experiments described herein. In using such information or methods they should be mindful of their own safety and the safety of others, including parties for whom they have a professional responsibility.

To the fullest extent of the law, neither the Publisher nor the authors, contributors, or editors, assume any liability for any injury and/or damage to persons or property as a matter of products liability, negligence or otherwise, or from any use or operation of any methods, products, instructions, or ideas contained in the material herein.

British Library Cataloguing in Publication Data

A catalogue record for this book is available from the British Library

Library of Congress Cataloguing in Publication Data

A catalogue record for this book is available from the Library of Congress

ISBN: 978-0-12-381988-8

For information on all Academic Press publications
visit our website at store.elsevier.com

Printed and bound in the United States

14 15 16 17 10 9 8 7 6 5 4 3 2 1



Contents

List of Contributors	xiii
Foreword	xvii
Introduction	xix

I FOOD ALLERGY: CAUSES, PREVALENCE, AND IMPACTS

1 Living with Food Allergy: Cause for Concern	3
<i>A. DunnGalvin, A.E.J. Dubois, B.M.J. Flokstra-de Blok, J.O'B. Hourihane</i>	
Introduction.....	3
Qualitative Studies on the Impact of Food Allergy on HRQL	6
Children and Teens: The Evolution of Uncertainty	7
The Parental Perspective: Living with Uncertainty	11
The Parental Perspective: Quantitative	14
The Child, Adolescent, and Adult Perspective: Quantitative	18
Discussion	19
Improving Risk Management and HRQL: A Better Way?.....	20
References.....	22
2 Which Foods Cause Food Allergy and How Is Food Allergy Treated?	25
<i>Montserrat Fernández-Rivas, Ricardo Asero</i>	
Introduction.....	26
Foods Involved in Allergic Reactions	26
Symptoms and Severity of Food Allergy	31
Management.....	35
References.....	37
3 The Epidemiology of Food Allergy	45
<i>Peter Burney, Thomas Keil, Linus Grabenhenrich, Gary Wong</i>	
Prevalence	46
Time Trends of Food Allergy Prevalence and Health Care Utilization	48
Risk Factors for Food Allergy	52
The Natural History of Food Allergies	55
The Consequences of Food Allergy	57
Conclusions.....	59
References.....	60

vi Contents

2 ALLERGEN THRESHOLDS AND RISK ASSESSMENT

4	How to Determine Thresholds Clinically	67
	<i>Barbara K. Ballmer-Weber, André C. Knulst, Jonathan O'B. Hourihane</i>	
	Introduction and Definitions	67
	Meal, Source Material, and the Matrix Issue.....	68
	Factors Affecting the Outcome of Challenges	69
	Inclusion and Exclusion Criteria for Patients to Undergo Titrated Challenges	69
	Safety Aspects of Titrated DBPCFC	70
	Pre- and Post-Challenge Assessments of Patients.....	71
	Which Symptom Defines the Individual Threshold Dose?	72
	Challenge Protocols and Dosing.....	73
	An Open Food Challenge Always Has to Follow a Negative DBPCFC	75
	References.....	75
5	Thresholds or ‘How Much Is Too Much?’	77
	<i>René Crevel, Barbara K. Ballmer-Weber, Steve Taylor, Geert Houben, Clare Mills</i>	
	Introduction.....	78
	What Is Meant by Thresholds in the Context of Food Allergy and Allergens?.....	78
	Thresholds Before EuroPrevall: What Data Were Available and How Useful Were They for Risk Assessment?	79
	How Have Threshold Data Been Generated? Protocols and Their Evolution.....	84
	Factors Affecting the Outcome of Challenge Studies and the Type of Data Generated	85
	Tools for the Analysis of Threshold Data	89
	Conclusions.....	96
	References.....	96
6	From Hazard to Risk – Assessing the Risk	101
	<i>C.B. Madsen, G.F. Houben, S. Hattersley, R.W.R. Crevel, B.C. Remington, J.L. Baumert</i>	
	Introduction.....	102
	Why and When Is It Necessary to Estimate the Risk from Allergenic Food?	103
	Safety Assessment in Food Allergy Using One Data Point (NOAEL or LOAEL) and an Estimated Food Consumption	104
	Safety Assessment in Food Allergy Based on All Available Challenge Data and an Estimated Intake Food Consumption (Benchmark Dose/Margin of Exposure Approach).....	106
	Exposure Assessment	108

Risk Assessment in Food Allergy Based on the Distribution of Input Data (Challenge, Contamination, Consumption) (Probabilistic Approach)	109
Examples of Risk Assessments Using All Three Approaches	114
Summary of Risk Assessment Examples	119
Uncertainty Factors	120
Severity Considerations in Risk Assessment.....	121
VITAL Program.....	123
Concluding Remarks	123
References.....	126

3 RISK MANAGEMENT OF GLUTEN

7 Celiac Disease and Risk Management of Gluten	129
<i>Steffen Husby, Cecilia Olsson, Anneli Ivarsson</i>	
Abbreviations	130
Introduction.....	130
Definition of Celiac Disease	130
Gluten Sensitivity	131
Wheat (Food) Allergy	132
Diagnosis of Celiac Disease	132
A Public Health Problem	133
Time, Place, and Person.....	134
Clinical Presentation.....	135
Associated Diseases.....	136
A Multifactorial Etiology	137
Etiopathogenetic Considerations.....	138
Case Identification.....	139
Living with Celiac Disease	139
Risk Assessment in Celiac Disease	142
Adherence Problems.....	144
How to Keep Celiac Customers Happy and Safe?	144
Support Strategies.....	145
Perspectives for the Future.....	145
Case Stories	146
References.....	147

4 PRACTICAL FOOD ALLERGEN RISK MANAGEMENT

8 Food Allergen Risk Management in the Factory – From Ingredients to Products.....	155
<i>Stella Cochrane, Dan Skrypec</i>	
Introduction.....	155
Allergen Risk Management: Principles and Systems	156
Employee Training and Awareness.....	157

viii Contents

Ingredients/Raw Materials – Suppliers, Storage, and Handling.....	157
Production – Material Flow, Factory and Equipment Design, Product Scheduling, and Rework.....	158
Production – Cleaning and Cleaning Validation.....	160
Labeling	164
References.....	166
9	Managing Food Allergens: Case Histories and How They were Handled..... 167
	<i>René Crevel, Steve Taylor, Sylvia Pfaff, Anton Alldrick</i>
Introduction.....	169
Case Study 1 – Supply Chain.....	169
Case Study 2 – Supply Chain, Manufacturing – ‘All Nuts are Equal’	173
Case Study 3 – Labeling.....	174
Case Study 4 – Manufacturing (Large Company).....	175
Case Study 5 – Manufacturing (Rework).....	177
Case Study 6 – Manufacturing and Design – ‘Nut Snow’	178
Case Study 7 – Manufacturing (Small Company).....	179
Case Study 8 – Allergen Awareness – ‘No Protein = No Food Allergen: True or False?’	181
Case Study 9 – Product Development, Training, Allergen Awareness: – ‘Food Allergens: Never Heard of Them!’	182
Case Study 10 – Training, Allergen Awareness and Supplier Verification.....	183
Case Study 11 – Auditor’s Allergen Awareness and Understanding.....	184
Case Study 12 – An Ethical Dilemma	186
Conclusion	187
References.....	187
10	Catering – How to Keep Allergic Consumers Happy and Safe..... 189
	<i>Sue Hattersley, Rita King</i>
Introduction.....	189
Why Do Consumers Currently Not Have the Information They Need to Make Safe Choices When Eating Out?.....	190
What Is the Current Legal Position and Are Any Changes Expected?.....	192
Best Practice Guidance Published by the UK Food Standards Agency in 2008 on the Provision of Allergen Information for Non-Prepackaged Foods.....	193
The Responsibilities of the Food Allergic Consumer.....	198
Future Developments and Recommendations	199
References.....	199

11	Food Allergen Risk Management in the United States and Canada	201
	<i>Steven M. Gendel</i>	
	Introduction.....	201
	US National Food Allergen Risk Management.....	202
	US State and Local Allergen Risk Management	204
	Canadian National Allergen Risk Management.....	205
	Conclusions.....	205
12	The Importance of Food Allergy Training for Environmental Health Service Professionals	207
	<i>I.S. Leitch, J. McIntosh</i>	
	Introduction.....	207
	The Effectiveness of an Avoidance Diet.....	208
	Legislative Basis for the Risk Management of Food Allergens.....	209
	The Role of the EHO in the Risk Management of Food Allergens.....	210
	Deficits in Training Resources for Catering Staff.....	210
	Deficits in Food Allergy Awareness Among Catering Staff.....	211
	A Food Allergy Training Program for the Island of Ireland.....	211
	References.....	212
13	Detecting and Measuring Allergens in Food	215
	<i>Joseph L. Baumert</i>	
	Introduction.....	215
	Immunochemical Methods for the Detection of Food Allergens.....	217
	Mass Spectrometry.....	222
	Polymerase Chain Reaction (PCR).....	223
	Conclusions.....	224
	References.....	225
14	Effect of Processing on the Allergenicity of Foods	227
	<i>E.N. Clare Mills, Phil E. Johnson, Laurian Zuidmeer-Jongejan, Ross Critenden, Jean-Michel Wal, Ricardo Asero</i>	
	Introduction.....	228
	Effects of Processing Major Allergenic Foods of Plant Origin.....	233
	Whole Food Effects of Food Processing.....	241
	Conclusions.....	243
	References.....	243
15	Communication with Food Allergic Consumers: A Win-Win Experience	253
	<i>George E. Dunaif, Susan A. Baranowsky</i>	
	Introduction.....	253

x Contents

	Start with the Basic Fact That Education and Sensitivity Training Related to Food Allergic Consumers Must Be Holistic and Inclusive	255
	Putting the Program into Practice and Selling the Benefits Beyond Your Company	258
	Conclusion and Summary	259
	References.....	260
16	May Contain – To Use or Not?	261
	<i>Robin Sherlock, Steve Taylor, Sylvia Pfaff, Kirsten Grinter, René Crevel</i>	
	Introduction.....	261
	History and Origins of Precautionary Labeling	262
	Legal and Regulatory Status of Precautionary Allergen Labeling.....	264
	How to Determine the Tolerable Level of Risk.....	269
	VITAL and a Threshold-Based Approach to Risk Assessment.....	269
	The Future of Precautionary Statements	271
	References.....	271
17	Regulatory Controls for Food Allergens	273
	<i>Sue Hattersley, Rachel Ward</i>	
	Introduction.....	273
	How Best to Protect the Public at Risk from Adverse Reactions to the Major Food Allergens?.....	274
	Why Do We Need Specific Allergen Labeling Rules?.....	275
	Codex	276
	European Legislation Regarding Food Allergen Risk Communication.....	277
	‘Gluten-Free’ and other ‘Free from’ Claims.....	280
	Regulatory Lists Around the World.....	281
	What Is Not Covered by Legislation?.....	281
	Conclusions.....	286
	References.....	286
18	Keeping Updated	291
	<i>David Reading, Erna Botjes, Pia Nørhede, Marjan van Ravenhorst</i>	
	Introduction.....	292
	The Allergen Bureau (Australia)	292
	The American Academy of Allergy, Asthma, and Immunology.....	293
	Canadian Food Inspection Agency	293
	Catering for Allergy (UK)	294
	The European Academy of Allergy and Clinical Immunology	294
	The European Food Safety Authority.....	294
	Food Allergy Information (EU).....	295
	The Food Allergy Research and Resource Program (US).....	296

Contents **xi**

Food Allergy Support (UK)	297
Food and Drug Administration (US)	297
The Food Standards Agency (UK)	298
The InformAll Database (UK)	299
Index	301