

# Contents

Greeting .....	V
Acknowledgements .....	VII
Authors .....	IX
Abbreviations .....	XVII
Literature .....	XIX

## CHAPTER I Subject Matter, Scope and Definitions

Article 1 Subject Matter and Scope .....	1
1 Subject Matter regulated .....	3
2 Objectives of the Regulation .....	4
3 Direct Scope of Application .....	4
4 Application to Trademarks .....	22
5 Exception for General Designations .....	25
6 Relationship to other Provisions of Community Law .....	27
Article 2 Definitions .....	35
1 Subject Matter regulated .....	37
2 Definitions of Terms deriving from other European Legal Acts ...	37
3 Original Definitions in the Regulation .....	43

## CHAPTER II General Principles

Article 3 General Principles for all Claims .....	61
1 Subject Matter regulated .....	62
2 Nutrition and Health Claims .....	62
3 Specific Prohibited Claims .....	62
Article 4 Conditions for the Use of Nutrition and Health Claims ..	71
1 Subject Matter regulated .....	73
2 Excursus: Basic Principles for the Interpretation .....	74
3 The Principle of Nutrient Profiles .....	78
4 Exemptions for Nutrition Claims .....	86
5 Special Rules for Alcoholic Beverages .....	88
6 Application of National Rules for Statements on the Alcohol Content ..	91
7 Restrictions and Bans for other Foods .....	92

<b>Article 5 General Conditions</b>	93
1 Subject Matter regulated	94
2 Standard of Generally Accepted Scientific Data	94
3 Significant Quantities	98
4 Bioavailability	100
5 Reference to Specific Conditions	102
6 Understanding of Consumers	102
7 Food ready for Consumption	104
<b>Article 6 Scientific Substantiation for Claims</b>	105
1 Subject Matter regulated	105
2 Scientific Substantiation	106
3 Justification of the Use of the Claim	116
4 Obligations of the Food Business Operator	117
<b>Article 7 Nutrition Information</b>	119
1 Subject Matter regulated	120
2 Requirements governing Application	120
3 Provision of Nutrition Information for Nutrition Claims	123
4 Health Claims	128
5 Specifying Quantities of other Substances not indicated on the Nutrition Labelling	129
6 Overview	131
 <b>CHAPTER III Nutrition Claims</b>	
<b>Article 8 Specific Conditions</b>	133
1 Subject Matter regulated	134
2 List of Permitted Nutrition Claims	134
3 Procedure to amend the Annex	166
4 Codex Alimentarius	169
<b>Article 9 Comparative Claims</b>	171
1 Subject Matter regulated	171
2 History of the Provision	172
3 Scope of Application	175
4 Relationship to Comparative Nutrition Claims in Annex	177
5 Application without Prejudice to Directive 2006/114/EC	178

6	Comparative Nutrition Claims .....	179
7	Foods of the same Category .....	181
8	Taking into Consideration a Range of Foods.....	183
9	Obligatory Information .....	183
10	Comparison with other Brands .....	184
11	Checklist for Comparative Nutrition Claims .....	185

## CHAPTER IV Health Claims

<b>Article 10</b>	<b>Specific Conditions.....</b>	<b>187</b>
1	Subject Matter regulated .....	188
2	Ban with Reservation of Authorization .....	188
3	Obligations to provide Information.....	190
4	Non-Specific Health Claims .....	196
5	Guidelines.....	201
<b>Article 11</b>	<b>National Associations of Medical, Nutrition or Dietetic Professionals and Health-Related Charities ...</b>	<b>203</b>
1	Subject Matter regulated .....	203
2	History of Origins.....	204
3	Principle: Health Claim is essential.....	205
4	Recommendations and Endorsements .....	206
5	National Associations of Professionals .....	207
6	Medical, Nutrition or Dietetic Professionals and Health-Related Charities .....	207
7	Absence of Specific Community Rules.....	207
8	Recommendations of Individual Doctors or Representatives of Medical Professionals or of Associations not mentioned in Article 11.....	208
9	Relevant National Rules applicable .....	209
<b>Article 12</b>	<b>Restrictions on the Use of certain Health Claims ....</b>	<b>211</b>
1	Subject Matter regulated .....	211
2	Health Claims .....	212
3	Claims which suggest that Health could be affected by not consuming the Food.....	212

4	Claims referring to the Rate or Amount of Weight Loss .....	213
5	Claims referring to Recommendations of Individual Doctors or Health Professionals and other Associations not mentioned in Article 11. ....	214
<b>Article 13 Health Claims other than those referring to the Reduction of Disease Risk and to Children's Development and Health .....</b>		
1	Subject Matter regulated .....	219
2	Health Claims according to Article 13(1) HCR. ....	219
3	Procedure for the Establishment of a Community List .....	228
4	Modifications of the Community List, Article 13(4) HCR. ....	233
5	Procedure according to Article 13(5) HCR .....	234
<b>Article 14 Reduction of Disease Risk Claims and Claims referring to Children's Development and Health .....</b>		
1	Subject Matter regulated .....	238
2	Reduction of Disease Risk Claims .....	238
3	Claims referring to Children's Development and Health. ....	241
<b>Article 15 Application for Authorisation .....</b>		
1	Subject Matter regulated .....	249
2	Authorisation Procedure .....	249
3	Application. ....	254
4	Implementing Rules and Tools. ....	261
<b>Article 16 Opinion of the Authority .....</b>		
1	Subject Matter regulated .....	268
2	EFSA's Role in the Authorisation of Health Claims .....	268
<b>Article 17 Community Authorisation .....</b>		
1	Subject Matter regulated .....	276
2	Community Authorisation .....	276
<b>Article 18 Claims referred to in Article 13(5) .....</b>		
1	Subject Matter regulated .....	289
2	The „Accelerated“ Procedure. ....	289

<b>Article 19</b>	<b>Modification, Suspension and Revocation of Authorisations</b> .....	297
1	Subject Matter regulated .....	298
2	Scope of Application.....	298
3	Applicant/User.....	299
4	Procedure under Article 19(1) HCR.....	300
5	Procedure under Article 19(2) HCR.....	300
 <b>CHAPTER V General and Final Provisions</b>		
<b>Article 20</b>	<b>Community Register</b> .....	303
1	Subject Matter regulated .....	304
2	Community Register .....	304
<b>Article 21</b>	<b>Data Protection</b> .....	309
1	Subject Matter regulated .....	310
2	Background, Borderline and Scope of Application.....	311
3	Prerequisites of Data Protection .....	315
4	Legal Consequences .....	324
5	End of Data Protection .....	329
<b>Article 22</b>	<b>National Provisions</b> .....	333
1	Subject Matter regulated .....	333
2	Full Harmonization .....	333
3	Scope of the Ban .....	335
<b>Article 23</b>	<b>Notification Procedure</b> .....	337
1	Subject Matter regulated .....	337
2	Legislation .....	338
3	Procedure .....	338
<b>Article 24</b>	<b>Safeguard Measures</b> .....	339
1	Subject Matter regulated .....	339
2	Safeguard Measures .....	340
3	Further Procedure.....	342
<b>Article 25</b>	<b>Committee Procedure</b> .....	343
1	Subject Matter regulated .....	343
2	The Committee .....	343
3	Committee Procedure according to Article 25(2) and (3) HCR.....	344

<b>Article 26 Monitoring</b> .....	347
1 Subject Matter regulated .....	347
2 Monitoring .....	347
<b>Article 27 Evaluation</b> .....	349
1 Subject Matter regulated .....	349
<b>Article 28 Transitional Measures</b> .....	351
1 Subject Matter regulated .....	353
2 Original Fundamental Rule .....	354
3 Nutrient Profiles .....	355
4 Trade Marks or Brand Names.....	356
5 Nutrition Claims .....	357
6 Health Claims .....	358
7 Claims relating to both Nutrition and Health .....	367
8 Brief Overview.....	368
<b>Article 29 Entry into Force</b> .....	371
1 Subject Matter regulated .....	371
2 Legislative History .....	371
3 Entry into Force.....	372
4 Application.....	372
5 Legal Effects of the HCR .....	372
 <b>ANNEX</b>	
<b>Regulation (EC) No 1924/2006 of the European Parliament and of the Council</b>	
OJ L 404, 30.12.2006, p. 9, as corrected by OJ L 12, 18.1.2007, p. 3.	
Regulation as last amended by Commission Regulation (EU) No 116/2010 (OJ L 37, 10.2.2010, p. 16).....	
	377
 <b>Commission Regulation (EC) No 353/2008</b>	
OJ L 109, 19.4.2008, p. 11. Regulation as amended by Commission Regulation (EC) No 1169/2009 of 30 November 2009 (OJ L 314, 1.12.2009, p. 34).....	
	415
<b>Index</b> .....	427