CODEX ALIMENTARIUS COMMISSION

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CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECCIAL DIETARY USES

Thirty-eighth Session

Hamburg, Germany, 5 – 9 December 2016

REVIEW OF THE *STANDARD FOR FOLLOW-UP FORMULA* (CODEX STAN 156-1987)

Physical Working Group

PWG Side Session report: Modelling Macronutrient Levels

Prepared by the New Zealand

Recommendation 10: Energy Contribution from Macronutrients

That CCNFSDU agree to include a maximum limit for total carbohydrates as follows:

[Available carbohydrates]

The level of available carbohydrates should not exceed [12 [**or 12.5**] g per 100 kcal (2.9 g per 100 kJ)]

[The level of protein shall not be less than 1.8 g/100 kcal].

[The level of total fats shall not be less than [**3.5**] [or 4.0] [**or 4.4**] g/100 kcal].

That CCNFSDU agree that no requirements are needed for:

- Minimum levels for carbohydrate
- Maximum limit for protein
- Maximum limit for fat

Overall summary

While several scenarios are feasible, the Committee will need to make a decision as to which are the critical aspects of the macronutrient levels which need to be defined.

The modelling workshop discussed at length the macronutrients for which the establishment of levels was considered of greater importance. The conclusion was that establishment of a maximum limit for carbohydrate and minimum level for protein were of more importance.

Background

During the physical working group (pWG) it was agreed that a small working group meet to discuss further Recommendation 10. Recommendation 10 relates to the establishment of minimum and/or maximum levels for macronutrients. The session was chaired by New Zealand[1] with attendees from Australia, Canada, Chile, the European Union, IFT, and ISDI.

The pWG reiterated the importance of reviewing all macronutrients together to ensure the nutritional balance of the product and that a workable approach is taken. Conclusions of the pWG were that an energy density

[1] New Zealand is the Chair of the eWG and pWG in the Review of the Follow-up Formula Standard

of 60 to 70 kcal/100 mL were set, with the ability for national/regional authorities to deviate based on their dietary guidelines and the nutritional needs of the population. In addition to this it was agreed that:

- a maximum limit was established for carbohydrates
- no minimum limit was established for carbohydrates
- no maximum limit was established for protein.

No conclusions were made as to the need for a minimum levels for protein or fat.

For further background information relating to this Recommendation, please refer to Section 5.3 of the Agenda Paper (CXNFSDU 16/38/6; pages 26-30) and the physical working group report in CRD1.

Modelling scenarios

The modelling working group discussed scenarios based on the above considerations and the levels for maximum carbohydrate, minimum protein and minimum fat as proposed during the pWG. It was highlighted that while several scenarios were feasible, the Committee will need to make some conclusions as to which are the critical aspects of the macronutrient levels which need to be defined to progress this item.

The modelling workshop discussed at length the macronutrients for which the establishment of levels was considered of greater importance. The conclusion was that establishment of a maximum limit for carbohydrate and minimum level for protein were of more importance.

It was highlighted that the establishment of requirements for specific fatty acids provided some assurance that fat must be added, and that issues of nutritional integrity related to fat could potentially be addressed through the specification of essential fatty acids. This is discussed under Recommendation 12.

Based on the pWG discussions the modelling workshop conducted scenarios whereby the maximum limit for carbohydrate was established (at either 12; 12.5 or 14 g/100 kcal) and the minimum protein content was established. The minimum levels for protein that were considered important to model, were those that are under consideration for the protein requirements for follow-up formula for older infants which is yet to be agreed upon by the Committee but levels of 1.8 g/100 kcal and 1.6 g/100 kcal (Recommendation 1).

The models were based on follow-up formula for young children containing 65 kcal per 100 mL (the mid-point of the recommended energy density in Recommendation 9. In addition to this, a further set of scenarios in appendix 2 are based on product containing 45 kcal/100 mL which under Recommendation 9 could be used by national/regional authorities. Models are conducted with fixed levels of carbohydrate and protein, and calculated energy required from fat to provide 100% of the energy density required.

Results

A total of 32 product variations were evaluated and results presented per 100 kcal, per daily serve of 300 mL, and as a percentage of total energy in the product. A summary is presented below and incremental variations in protein and fat levels are presented in the Appendices. Also presented in Appendix 1 for information are the macronutrient levels in full fat, reduced fat cows' milk and the recommended formulation of follow-up formula for older infants as presented in the Agenda Paper (Note: protein levels are still to be agreed to).

Summary of modelling scenarios

Per 100kcal

Maximum Carbohydrate	**Minimum Protein**	**Residual Fat**	***% of Energy***		
			CHO (%)	***Protein (%)***	***Fat (%)***
14	1.6	4.18	*56*	*6.4*	*37.62*
14	1.8	4.09	*56*	*7.2*	*36.81*
12.5	1.6	4.84	*50*	*6.4*	*43.56*
12.5	1.8	4.76	*50*	*7.2*	*42.84*
12	1.6	5.07	*48*	*6.4*	*45.63*
12	1.8	4.98	*48*	*7.2*	*44.82*

To explain briefly the model above, if product was formulated at the maximum carbohydrate content of 14 g/100 kcal and the minimum protein of 1.6 g/100 kcal, then the product **must** contain 4.18 g of fat per 100 kcal to make up the energy density of the product. At maximum carbohydrate levels and minimum protein levels, the fat content of the product cannot be any higher unless the protein levels are increased; or carbohydrate levels decreased.

As agreed at the physical working group, no minimum carbohydrate or maximum limit for protein is proposed to be established. As such protein levels can be increased to provide lower fat formulations; or carbohydrate lowered and the protein level increased.

Establishment of maximum carbohydrate levels

As presented in the Agenda paper, if the Committee are mainly concerned with limiting excessive added sugars and other glycaemic carbohydrates, an approach which firstly specifies appropriate maximum total carbohydrates can ensure this outcome is attained. An approach which establishes carbohydrate levels based on residual energy from protein and fat can lead to carbohydrate levels in excess of those recommended when low fat **and** protein formulations are selected. As presented in the agenda paper, limiting the amount of available carbohydrates will also ensure that other glycaemic carbohydrates which may have similar metabolic affects to sugar are also limited in their addition.

It is noteworthy, that under the scenarios presented, the establishment of any maximum limit for carbohydrate (12 – 14 g/100 kcal) will ensure that product formulation could be either low fat content or low protein content; but not both.

An extreme scenario has been presented in Table 4 of Appendix 1, whereby no fat content was assumed, very high protein levels would be required if only a maximum carbohydrate content was set.

Formulation to align with cows' milk

To develop requirements which can accommodate the macronutrient levels in cows' milk and follow-up formula for older infants will require flexible approach to be agreed to by the Committee. There are no scenarios which establish minimum and maximum limits for all macronutrients which would allow for both to be accommodated.

If minimum limits for protein are established, both 1.6 and 1.8 g/100 kcal would accommodate the macronutrient content of cows' milk.

If minimum limits for fat are established, a minimum level of 3.5 g/100 kcal would be required to accommodate reduced fat cows' milk. A level of 4.0 g/100 kcal and above would be required to accommodate full fat cows' milk.

If maximum limits are established for carbohydrates, levels between 12 and 14 g/100 kcal are able to accommodate the macronutrient content of cows' milk.

If the Committee does not want to establish requirements for all macronutrients, then a protein or carbohydrate content could be set without impacting on the ability to formulate a product which can accommodate cows' milk.

APPENDIX 1: Modelling macronutrient content of products with an energy density of 65 kcal/100 mL

Table 1: Residual fat content of product with varying protein levels and a maximum carbohydrate level of 12 g/100 kcal

12 g CHO		Product 1				Product 2				Product 3				Product 4				Product 5			
	Unit	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E
Energy	kcal		65	195			65	195			65	195			65	195	-		65	195	
Fat	g	5.2	3.4	10.2	46	5.1	3.3	10.0	45	4.8	3.1	9.4	42	4.4	2.8	8.5	38	3.4	2.2	6.7	30
Protein	g	1.6	1.0	3.1	6	1.8	1.2	3.5	7	2.5	1.6	4.9	10	3.5	2.3	6.8	14	5.5	3.6	10.7	22
Carbohydrate	g	12.0	7.8	23.4	48	12.0	7.8	23.4	48	12.0	7.8	23.4	48	12.0	7.8	23.4	48	12.0	7.8	23.4	48

Table 2: Residual fat content of product with varying protein levels and a maximum carbohydrate level of 12.5 g/100 kcal

12.5 g CHO		Product 6				Product 7				Product 8				Product 9				Product 10			
	Unit	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E
Energy	kcal		65	195			65	195			65	195			65	195	-		65	195	
Fat	g	5.0	3.3	9.8	44	4.9	3.2	9.6	43	4.6	3.0	9.0	40	4.1	2.7	8.1	36	3.2	2.1	6.3	28
Protein	g	1.6	1.0	3.1	6	1.8	1.2	3.5	7	2.5	1.6	4.9	10	3.5	2.3	6.8	14	5.5	3.6	10.7	22
Carbohydrate	g	12.5	8.1	24.4	50	12.5	8.1	24.4	50	12.5	8.1	24.4	50	12.5	8.1	24.4	50	12.5	8.1	24.4	50

Table 3: Residual fat content of product with varying protein levels and a maximum carbohydrate level of 14 g/100 kcal

14g CHO		Product 11				Product 12				Product 13				Product 14				Product 15			
	Unit	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E
Energy	kcal		65	195			65	195			65	195			65	195	-		65	195	
Fat	g	4.3	2.8	8.4	38	4.2	2.7	8.2	37	3.9	2.5	7.6	34	3.4	2.2	6.7	30	2.5	1.6	4.9	22
Protein	g	1.6	1.0	3.1	6	1.8	1.2	3.5	7	2.5	1.6	4.9	10	3.5	2.3	6.8	14	5.5	3.6	10.7	22
Carbohydrate	g	14.0	9.1	27.3	56	14.0	9.1	27.3	56	14.0	9.1	27.3	56	14.0	9.1	27.3	56	14.0	9.1	27.3	56

Table 4: Feasibility of product manufacture with no fat

		No fat				No fat			
	Unit	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E
Energy	kcal		65	195			65	195	
Fat	g	0.0	0.0	0.0	0	0.0	0.0	0.0	0
Protein	g	11.0	7.2	21.5	44	12.5	8.1	24.4	50
Carbohydrate	g	14.0	9.1	27.3	56	12.5	8.1	24.4	50

Table 5:Comparison of milk and follow-up formula for older infants

12 g CHO		Full Fat Cows' Milk				Reduced Fat Cows' Milk				Follow-up Formula Older Infants minimum*				Follow-up Formula Older Infants maximum*			
	Unit	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E
Energy	kcal		60	180			45	135			60	180			70	210	
Fat	g	5.5	3.3	9.9	64	3.5	1.6	4.7	30	4.4	2.6	7.9	57	6.0	4.2	12.6	37
Protein	g	5.4	3.2	9.7	6	7.3	3.3	9.9	29	1.8	1.1	3.2	7	1.8	1.3	3.8	7
Carbohydra	g	7.5	4.5	13.5	30	10.1	4.5	13.6	40	9.0	5.4	16.2	36	14.0	9.8	29.4	56

APPENDIX 2: Modelling macronutrient content of products with an energy density of 45 kcal/100 mL

Table 6: Residual fat content of product with varying protein levels and a maximum carbohydrate level of 12 g/100 kcal

12 g CHO		Product 18				Product 19				Product 20				Product 21				Product 22			
	Unit	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E
Energy	kcal		45	135			45	135			45	135			45	135	-		45	135	
Fat	g	5.2	2.4	7.1	46	5.1	2.3	7.0	45	4.8	2.2	6.5	42	4.4	2.0	5.9	38	3.4	1.6	4.7	30
Protein	g	1.6	0.7	2.2	6	1.8	0.8	2.4	7	2.5	1.1	3.4	10	3.5	1.6	4.7	14	5.5	2.5	7.4	22
Carbohydrate	g	12.0	5.4	16.2	48	12.0	5.4	16.2	48	12.0	5.4	16.2	48	12.0	5.4	16.2	48	12.0	5.4	16.2	48

Table 7: Residual fat content of product with varying protein levels and a maximum carbohydrate level of 12.5 g/100 kcal

12.5 g CHO		Product 23				Product 24				Product 25				Product 26				Product 27			
	Unit	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E
Energy	kcal		45	135			45	135			45	135			45	135	-		45	135	
Fat	g	5.0	2.3	6.8	44	4.9	2.2	6.6	43	4.6	2.1	6.2	40	4.1	1.9	5.6	36	3.2	1.4	4.3	28
Protein	g	1.6	0.7	2.2	6	1.8	0.8	2.4	7	2.5	1.1	3.4	10	3.5	1.6	4.7	14	5.5	2.5	7.4	22
Carbohydrate	g	12.5	5.6	16.9	50	12.5	5.6	16.9	50	12.5	5.6	16.9	50	12.5	5.6	16.9	50	12.5	5.6	16.9	50

Table 8: Residual fat content of product with varying protein levels and a maximum carbohydrate level of 14 g/100 kcal

14g CHO		Product 28				Product 29				Product 30				Product 31				Product 32			
	Unit	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E	100 kcal	100 mL	300 mL	% E
Energy	kcal		45	135			45	135			45	135			45	135	-		45	135	
Fat	g	4.3	1.9	5.8	38	4.2	1.9	5.7	37	3.9	1.8	5.3	34	3.4	1.6	4.7	30	2.5	1.1	3.4	22
Protein	g	1.6	0.7	2.2	6	1.8	0.8	2.4	7	2.5	1.1	3.4	10	3.5	1.6	4.7	14	5.5	2.5	7.4	22
Carbohydrate	g	14.0	6.3	18.9	56	14.0	6.3	18.9	56	14.0	6.3	18.9	56	14.0	6.3	18.9	56	14.0	6.3	18.9	56