

Low-digestible carbohydrates: the regulatory framework

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Legislation is described that impacts on the use of low-digestible carbohydrates in foods. This includes controls on the use of these carbohydrates, mandatory labelling concerned with gastrointestinal effects, nutrition labelling, and nutrition and other claims. Regional differences in approach to legislation have led to inconsistencies in the information that must be provided to consumers, even for the same food products. Also, within regions, different regulations apply to food carbohydrates that may be classified similarly from the physiological perspective. Consistency of food labelling globally and in application to similar carbohydrates would benefit from greater attention to the underpinning science.

Low-digestible carbohydrates: Polyols: Regulations: Food labelling: Nutrition labelling

Carbohydrates are now conventionally classified according to their degree of polymerisation (dp) into sugars (dp 1–2), oligosaccharides (dp 3–10) and polysaccharides (dp >10) (Cummings *et al.* 1997; FAO/WHO, 1997). This classification is not entirely appropriate from the perspective of dietary impact. This is because the nutritional and physiological characteristics of carbohydrates largely reflect their digestibility which does not correlate simply with the arbitrary division into classes according to degree of polymerisation. Also, commercially available foods and food ingredients often comprise mixtures of nominally similar carbohydrates of varying chain length such that the distinction between mono-, di-, oligo- and polysaccharides on the basis of discrete cut-off points is not meaningful. A common feature of carbohydrates in all these classes is that they show a range of susceptibility to digestion by the enzymes of the human gastrointestinal tract and all include carbohydrate that may be fermented by the microflora of the colon. For the purposes of examining the regulatory environment surrounding low-digestible carbohydrates (LDCs) it is more relevant to consider each species of carbohydrate on its own merits rather than to classify them into three or four broad families according to degree of polymerisation.

Controls on the use of LDCs

Food standards legislation world-wide commonly distinguishes between 'foods' and 'food additives', the distinction being that the former are considered primarily from the perspective of their contribution to nutrition whereas the latter are considered as being primarily added for technological effect. There has been general agreement that it is not appropriate to evaluate *foods* systematically from the point of view of their safety (unless they are

associated with known toxins or contaminants). By contrast it is normal for *food additives* to receive scrutiny before they are considered acceptable for use in food. As a result, food additives are usually subject to exhaustive legislation that specifies which substances can be used, the foods in which they can be used and, often, the maximum level at which they may be added. It follows that foods used as ingredients in other foods are subject to much less rigorous regulation than additives. There is an exception to this broad distinction and this takes the form of regulations establishing standards of identity for food products for which there has been a desire on the part of regulators to provide assurance of quality either in response to consumer concerns or to facilitate international trade. Standards exist at the level of the European Union (EU) and Codex Alimentarius, for example, for fruit juices, cocoa and chocolate products and certain dairy products. Standards of identity impact equally on foods and food additives that may be used in the foods they control. Such standards are not usually an absolute bar to the use of non-standard ingredients; they simply provide reserved descriptions, which may only be used in labelling if a standard recipe is complied with. Deviations from the standard may be permitted but then the reserved description cannot be used for the product – it has to be called by a different name.

One further development that does have the potential to impact on foods and food ingredients is the regulation controlling novel foods, novel ingredients and novel processes. The regulation came into effect in May 1997 in Europe (EC, 1997) and requires that all foods and food ingredients (developed after that date) undergo an evaluation process before introduction to the market. This requirement may (arguably) extend to foods and food ingredients that are traditionally present in the diet but which, through novel processing or fractionation, may be

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Table 1. Regulatory status of low digestible carbohydrates

Foods/food ingredients	Food additives
Raffinose	Sugar alcohols ('polyols': sorbitol, mannitol, maltitol, xylitol, lactitol, erythritol, hydrogenated isomaltulose)
Fructo-oligosaccharides	
Inulin	Polydextrose
Resistant starch	Modified starch
Cellulose (other than refined cellulose)	Refined cellulose
Hemicellulose	Microcrystalline cellulose
	Pectin
	Hydrocolloid gums (acacia, guar, carob, xanthan etc.)

presented to consumers in a non-traditional way. Generally speaking though, for foods and food ingredients present on the market before 1997, the Novel Food Regulation will not be relevant.

The outcome of the different regulatory approach to foods and food ingredients on the one hand, and food additives on the other is that legislation controlling use, and to some extent labelling, applies inconsistently across the family of LDCs; even though their functionality may be the same from the point of view of their low digestibility. A categorisation of LDCs with respect to their status as foods or food additives is given in Table 1. This is necessarily a summary and the precise details may vary on a world-wide basis. However, it does serve to illustrate the distinction made in general.

For those low-digestible carbohydrates controlled as food additives, as discussed above, the regulations may be both explicit (in that they comprise exclusive permitted lists of the substances which may be used) and restrictive (in that they impose conditions on the circumstances in which the substances may be used). The concept of 'food additive' usually relates to a technological functionality which the substance imparts to a food. Restrictions on use may reflect that functionality with respect to both the foods in which the additive may be used and the levels to which it may be added. In the EU, the sugar alcohols (polyols, isomalt, lactitol, maltitol, mannitol, sorbitol and xylitol) when used for sweetening purposes are controlled by the Sweeteners Directive (EC, 1994), and consequently by national legislation implementing it. However, they are also controlled by the Directive on food additives other than colours and sweeteners when used for other technological purposes (EC, 1995). According to the Sweeteners Directive, they may be used at levels in accordance with *quantum satis* (at a level sufficient to achieve the desired effect but no greater) in a range of desserts, breakfast cereals, edible ices, jams and fruit preparations, confectionery and bakery products which are energy-reduced or without added sugar. They may also be used at *quantum satis* in chewing gum with no added sugar and in sauces, mustard, foods for special dietary purposes and dietary supplements. For the purposes of the Sweeteners Directive, 'energy-reduced' means with an energy value reduced by at least 30 % with respect to an equivalent, conventional food. This Directive therefore places a severe limitation on the extent to which polyols may be used in conjunction with

sugar since the only circumstances where they could be used in such a combination would be where the food has a 30 % reduction in energy compared to its conventional counterpart.

In contrast, when polyols are used for those technological functions controlled by the Directive on food additives other than colours and sweeteners, they can be used in a wide range of foods at levels up to *quantum satis* irrespective of the presence of added sugar or whether the foods are energy-reduced. Those other LDCs considered as food additives can also be used according to the Directive on food additives other than colours and sweeteners in a wide range of foods at levels up to *quantum satis*.

Mandatory labelling

One other manifestation of an inconsistency stemming from the distinction made in regulations between foods and food additives is the requirement in several countries to place an indication on the label of foods containing LDCs, advising that excessive consumption may cause laxation. This is generally applied to those LDCs considered as food additives but not to those considered as foods. In the case of the USA, there are different levels of consumption which trigger the requirement for such labelling statements depending on the LDC concerned. Where foods are likely to contribute more than 20 g/day of mannitol (US Code of Federal Regulations, 21 CFR 180.25) or more than 50 g/day of sorbitol (21 CFR 184.1835), or where the customary serving size contains more than 15 g of polydextrose (21 CFR 172.841), a mandatory labelling statement is triggered. In the case of mannitol and sorbitol the package of the food must carry the prescribed statement: 'excess consumption may have a laxative effect'. In cases where the triggering level of polydextrose is exceeded, the package must carry the statement: 'sensitive individuals may experience a laxative effect from excessive consumption of this product'. In the case of the EU, there is a triggering level based on the amount of the LDC present in the food without reference to the likely level of consumption. Any food containing more than 10 % of added polyols must carry the statement: 'excessive consumption may produce laxative effects' (EC, 1996). The EU legislation has the merit of simplicity but takes no account of serving size and makes no distinction between the potency of the different polyols as regards their gastrointestinal effects.

Table 2. Energy values assigned to polyols and polydextrose (kcal/g)

	EU	USA	Canada	Aus/NZ
Isomalt	2.4	2	2	2.1
Lactitol	2.4	2	2	2.1
Maltitol	2.4	3	3	3.8
Mannitol	2.4	1.6	1.6	3.8
Sorbitol	2.4	2.6	2.6	3.8
Xylitol	2.4	2.4	3	—
Polydextrose	1–1.5	1	1	1

Nutrition labelling

In parallel with guidelines on healthy eating and sound dietary goals, legislation places obligations on food processors under certain circumstances to provide information to consumers on the nutritional properties of their products. Consumers will be enabled to meet dietary guidelines only when they are provided with meaningful nutrition information about the foods available to them. Provision of nutrition information generally remains optional but becomes mandatory when claims about the nutritional characteristics of a food are made. Where it is given, its form and extent must comply with certain regulatory requirements. In the EU it must include as a minimum, a statement as to the content of energy, protein, carbohydrate and fat (EC, 1990). Where claims are made relating to sugars, saturated fats, fibre or sodium, these trigger a requirement for an additional minimum package of information that includes the amounts of sugars, saturated fats, fibre and sodium. Information on the amounts of starch, polyols, mono- and polyunsaturates, cholesterol and certain vitamins and minerals is optional but becomes mandatory when these nutrients are the subject of a nutrition claim.

From the perspective of low-digestible carbohydrates, the elements of nutrition labelling of current interest are the energy value and the content of total carbohydrate, polyols and fibre. Carbohydrate is commonly defined by difference, that is by subtracting the weights of protein, fat, moisture and ash from the total weight of the food, although it is also defined in some regulatory regimes (for example, within the EU) as any carbohydrate substance available for metabolism by humans. Fibre is usually defined by method of analysis and this has been a point of contention in the EU where there has been a failure to agree on a common method. The energy value for carbohydrate is generally taken to be 4 kcal/g (17 kJ/g) but exceptions are made for polyols and fibre in recognition of the fact that

they are incompletely digested. Table 2 summarises the energy values presently assigned to polyols and polydextrose in the EU, USA, Canada and Australia/New Zealand, although the values assigned in Australia/New Zealand are currently under review.

Nutrition claims

Statements that a food has a reduced or an enhanced content of a particular nutrient constitute nutrition claims. Again, there is no global consensus on the criteria that must be met in order to qualify for making reduced or enhanced content claims. Tables 3, 4 and 5 summarise the criteria currently in force in various countries for reduced, low and 'free' claims for energy and sugar and for claims relating to fibre content. If consumers are to benefit from the use of reduced-energy, reduced-sugar and fibre-rich foods as tools in pursuing dietary goals, it will be important that the criteria for such claims, in addition to providing for meaningful nutrient reductions and enhancements for consumers, are such as to allow the food industry realistic possibilities for producing foods which can qualify for the claims.

Other claims

Nutrition information and nutrition claims are the subject of reasonably well ordered and established legislation. A further category of claim of relevance for LDCs is that concerning health-related effects. The making of such claims is problematic because medicines legislation commonly reserves to medicines the making of claims relating to curing, preventing or alleviating disease and care must be taken to avoid claiming such functions, even if only by implication, in relation to foods. If benefits attributable to LDCs in foods are to be realised, there is a need for a regulatory framework for such claims. Such a framework exists in Japan in the form of a regulation on foods for specified health uses (FOSHU, 1991) made under the Nutrition Improvement Law which establishes a procedure for evaluating and endorsing claims made in relation to specific food products. In the USA, the Nutrition Labelling and Education Act (NLEA 1990) provides for prior approval of claims that characterise the relationship of any substance to a disease or health-related condition. Also in the USA, the Dietary Supplement Health and Education Act (DSHEA) provides for statements of 'nutritional support' to be made without prior approval but subject to notification to the authorities in relation to dietary

Table 3. Definitions for 'reduced/low energy' and 'calorie-free'

	'Reduced'	'Low'	'Free'/'Zero'
Codex	25 % less	max. 40 kcal/100 g solids max. 20 kcal/100 ml liquids	max. 4 kcal/100 ml
USA	25 % less	max. 40 kcal/serving	<5 kcal/serving
Japan		max. 40 kcal/100 g solids max. 20 kcal/100 ml liquids	max. 5 kcal/100 g or 100 ml
EU	30 % less*	—	—
UK	25 % less	max. 40 kcal/100 g and 40 kcal/serving	—

* For the purpose of the definition of 'energy-reduced' in the EU sweeteners directive.

Table 4. Definitions for 'reduced/low sugar' and 'sugar-free'

	'Reduced'	'Low'	'Free'/'Zero'
Codex	25 % less	–	max. 0.5 g/100 g or 100 ml
USA	25 % less	–	<0.5 g/serving
Japan		max. 5 g/100 g solids max. 2.5 g/100 ml liquids	max. 0.5 g/100 g or 100 ml
UK	25 % less	max. 5 g/serving or per 100 g where serving is <100 g	max. 0.2 g/100 g or 100 ml

Table 5. Definitions for 'a source of', 'increased' or 'high in' dietary fibre

	'Source of'	'Increased'	'High in'
USA	2.5–4.75 g/serving	min. 2.5 g more per serving	min. 5 g/serving
Japan	3 g/100 g or 1.5 g/100 ml, and 1.5 g/100 kcal	–	6 g/100 g or 3 g/100 ml, and 3 g/100 kcal
UK	min. 3 g/100 g or 3 g/daily ration	25% more and min. 3 g/100 g or per daily ration	min. 6 g/100 g or 100 ml or per daily ration

supplements but not to foods. Products so labelled must also indicate that the statement has not been evaluated by the Food and Drug Administration and that the product is not intended to treat, cure or prevent any disease. There is presently no harmonised framework for such claims in the EU, rather there is a prohibition on any statement attributing to a food the property of preventing, treating or curing a human disease, or referring to such properties. The interpretation and enforcement of this prohibition in relation to claims is the responsibility of the authorities of the fifteen individual EU Member States. Claims can be made but at the risk of those making them that they contravene medicines or food labelling legislation as interpreted, often differently, by the Member States' authorities.

Conclusions

Legislation relating to the use and labelling of low-digestible carbohydrates in food impacts differently and sometimes inconsistently in different regions of the world. Such differences present obstacles to international trade in, and result in ambiguous messages about the nutritional and safety characteristics of, foods containing them. Industry and consumers would benefit from greater harmonisation of legislation at a global level but any moves to greater harmonisation must be directed by a consistent application of the science-base relating to the chemical, nutritional and physiological properties of this complex and nutritionally valuable group of food components.

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