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Codex final definition of dietary fibre: issues of implementation

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Abstract

Introduction At its 30th session in South Africa in November 2008, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed on a definition of dietary fibre. Although many aspects of what can be called "dietary fibre" were resolved, the application of this definition raises additional issues in need of resolution. *Objectives* The goal of this paper is to discuss the major areas at issue in implementing the new Codex definition of dietary fibre: (1) the footnote that individual countries can decide whether they accept oligosaccharides with a degree of polymerization (DP) from 3 to 9 (included) as being fibre; and 2) guidance on which physiological effects are beneficial. Less critical but still important is the issue of animal sources of fibre not requiring proof of a beneficial physiological effect; and the effect of processing on fibre. *Results and conclusion* Unless all countries accept (or do not accept) that carbohydrate polymers with 3–9 monomeric units are dietary fibre, there will be two, rather than one definition. Again, if each country has its own criteria as to the physiological benefits of fibre and how to verify those benefits there will be as many "definitions" of fibre as there are effects accepted by all the member states. Given the importance to consumers, food companies, researchers, and regulatory agencies in having one definition, it is incumbent on all of us in the field to work toward that end.

Introduction

At its 30th session in South Africa from 3 to 7 November 2008, the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed on a definition of dietary fibre (Codex Alimentarius Commission, 2009) (see Table 1), and in June 2009 the Codex Alimentarius Commission adopted it at Step 8, the final step in the Codex approval process (FAO/WHO, 2009). This is a major accomplishment, and the result of a collaborative effort over a 16-year time period of many individuals, organizations and countries. A definition at Codex offers the benefit of a worldwide standard, which can be used as a basis for measurement, food labelling, setting reference nutrient values, and health claims.

At the time of the November 2008 CCNFSDU meeting there were essentially four different definitions, each of which had a certain amount of support. Those definitions included the Codex Step 6 definition (Codex Alimentarius Commission, 2007); the definition from the European Union (EU) (Commission of European Communities, 2008); the FAO/WHO consultation definition (Cummings & Stephen, 2007); and one from the Institute of Medicine (IOM), National Academy of Sciences in the United States (IOM, 2001). These definitions can be viewed as being on a continuum (Figure 1) in that all four definitions would include that of the FAO/WHO consultation: 'Dietary fibre consists of intrinsic plant cell wall polysaccharides' (Cummings & Stephen, 2007) but the IOM, Codex and EU definitions do not restrict the polysaccharides to those in the cell wall, and also include oligosaccharides, resistant starch and lignin. The Codex and EU definitions also allow non-digestible polysaccharides from animal products.

Table 1 The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) definition of dietary fibre (at step 8 of the procedure)

Definition
Dietary fibre means carbohydrate polymers[1] with 10 or more monomeric units[2], which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:
Edible carbohydrate polymers naturally occurring in the food as consumed
Carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities
Synthetic carbohydrate polymers that have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities

[1]When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in the plant cell walls and if these compounds are quantified by the Association of Official Analytical Chemists (AOAC) gravimetric analytical method for dietary fibre analysis: Fractions of lignin and the other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols, etc.) intimately 'associated' with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligosaccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non-digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances may provide additional beneficial effects (pending adoption of Section on Methods of Analysis and Sampling).

[2]Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

Of importance is how each definition deals with 'fibres' that are *added* to the foods. These would include isolated, extracted or synthesized non-digestible carbohydrates. Figure 1 shows that, if fibre-like substances were shown to provide beneficial physiological effects in humans then the FAO/WHO consultation would conclude that they should be able to describe their beneficial effects, but the substances should be called by their scientific name, not termed 'fibre'. The IOM definition would categorize them as 'functional fibres' rather than 'dietary fibres' after they have shown to produce a beneficial physiological effect. Both Codex and the EU definitions would include fibres added to the food supply and showing a beneficial physiological effect as 'dietary fibre', not requiring that they be called 'added fibre' or 'functional fibre'. The Codex definition is a compromise and a blending of these four definitions (Codex Alimentarius Commission, 2009). Many of the differences in the four definitions were resolved. However, there still remain unresolved issues for implementation, which will be addressed below.

Issues in need of resolution

Issue #1. Should non-digestible carbohydrate polymers with degree of polymerization (DP) 3–9 be included as dietary fibre?

The issue

In order to conclude the definition of dietary fibre at the November 2008 CCNFSDU meeting, a compromise was reached which leaves it up to national authorities to include or not carbohydrates from 3 to 9 monomeric units. The Codex Step 8 definition of fibre is shown in Table 1. The first sentence states that 'Dietary fibre means carbohydrate polymers* with 10 or more monomeric units,†Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities. which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories': Footnote dagger is 'Decision on whether to include carbohydrates from 3 or more monomeric units should be left to national authorities'. The issues of whether or not to include polymers from 3 to 10 monomers are both analytical and physiological. In some countries there is a formal definition of dietary fibre whereas in others accepted analytical methods define what constitutes fibre. For a summary of which countries use which process to define fibre see IOM (2001). The most commonly accepted analytical methods for defining total dietary fibre include an ethanol precipitation step (Cho S *et al*., 1997). Because oligosaccharides do not precipitate in alcohol they do not count as fibre by these methods. At this time many countries do not include a method that measures DP 3–9 as one of their approved methods. This means, for example, that fructo-oligosaccharides, which many consider as dietary fibre due to perceived physiological benefits, would not be counted as dietary fibre. In addition, the alcohol precipitation step is not specific for

*When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds associated with polysaccharides in the plant cell walls. These compounds may also be measured by certain analytical method(s) for dietary fibre. However, such compounds are not included in the definition of dietary fibre if extracted and re-introduced into a food (pending adoption of Section on Methods of Analysis and Sampling).

†Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities.

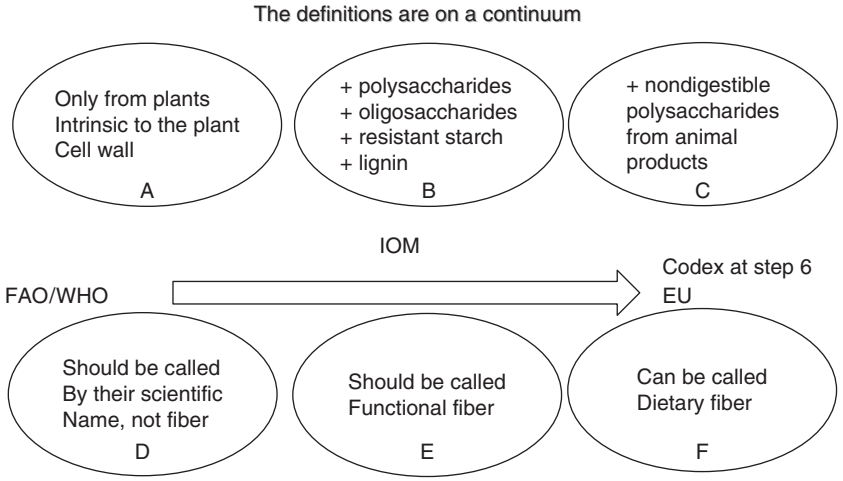

Figure 1 The four definitions discussed [FAO/WHO; Institute of Medicine (IOM); Codex at step 6 and European Union (EU)] are on a continuum in terms of what each accepts as 'dietary fibre'. All four definitions would include the FAO/WHO consultation definition of dietary fibre within their definitions (A) but the IOM definition would add polysaccharides that are in the plant but not necessarily in the cell wall plus oligosaccharides, resistant starch and lignin (B). The Codex at step 6 definition would accept everything the IOM definition includes but add non-digestible polysaccharides from animal products (C). (D–F) Show the continuum on how each of the four definitions deal with 'fibre' that is added to the food supply. According to the FAO/WHO consultation if fibre-like substances are shown to produce beneficial effects then the fibre like substance should be called by its scientific name and the particular benefits described (D). The IOM report states that fibres added to the food supply could be called 'functional fibre' if they are shown to have a health benefit (E). Both the Codex and EU definitions state that once 'added fibre' shows a health benefit it can then be considered 'dietary fibre' (F).

polysaccharides with DP $>$ 10. Some highly branched polysaccharides remain soluble which means that the supernatant has to be analysed for components with DP $>$ 10.

In addition to analytical considerations there are physiological issues with respect to the inclusion or not of DP 3–9 as dietary fibre. For example, these substances may not have the same mechanism of action (e.g. for laxation) as higher molecular weight substances. There is more of an osmotic effect with lower molecular weight substances as compared with a bulking effect with the higher molecular weight substances. Also, lower molecular weight carbohydrates are water soluble, and thus can be used in liquids. Some see this as an opportunity to complement fibre intake from more traditional sources, whereas others consider that fibre should only be part of a solid food matrix. There is also a concern regarding the perceived 'arbitrariness' of having a specific cut off at a DP of 9 as there are no data showing a specific abrupt change in physiological effects between DP 9 and 10.

Current status of inclusion or not of DP 3–9

As stated above, in order to conclude the definition at the November 2008 CCNFSDU meeting, a compromise was finally reached: a footnote that leaves it to national authorities to decide on the inclusion of carbohydrates from 3 to 9 monomeric units. Although most countries have not gone on record *subsequent* to November 2008, the status on inclusion of DP 3–9 is available for several countries. The EU definition of dietary fibre, published just prior to the 30th CCNFSDU meeting in South Africa, states that 'fibre' means carbohydrate polymers with three or more monomeric units', and the EU will stay with its previously published definition (Commission of European Communities, 2008). The EU definition was based, in part, on a document from the European Food Safety Authority that was issued in response to a request from the EU related to dietary fibre (European Food Safety Authority (EFSA), 2007). Australia and New Zealand include DP 3 or more (FSANZ) as do Japan and China. Over the course of the fibre deliberations at the CCNFSDU, a number of other countries also expressed support for the Codex definition that had previously reached Step 7 of the Codex process before being returned to Step 6 (Codex Alimentarius Commission Agenda Item 3, 2007; 2008) and *included DP 3 or more* in the definition. Their comments are recorded in the official comments of the CCNFSDU and in addition to those of Australia, EU, Japan and New Zealand, include Argentina, Canada, Costa Rica, Guatemala, Indonesia and Mali (Codex Alimentarius Commission Agenda Item 3, 2007; 2008) and many repeated their views at the 30th session in South Africa. Those opposed included Brazil, South Africa and Thailand (Codex Alimentarius Commission Agenda Item 3,

2007; 2008). The United States delegation did not endorse the CCNFSDU definition Step 8 in part because the Food and Drug Administration (FDA) had previously issued a Federal Register Advance Notice of Proposed Rulemaking (FDA Food and Drug Administration, 2007) that contained a discussion and questions about the definition of dietary fibre as proposed by IOM (2001) and the comments submitted to FDA had not been analysed by the time of the meeting in South Africa. The FDA has not yet decided (November 2009) whether or not it will adopt the IOM definition, or some modified version of it. The IOM definition includes DP 3–9 monomers as dietary fibre if they are endogenous to the food (IOM, 2001).

Towards a solution

It is interesting to note that for a number of years the Codex definition at step 6 stated that 'Dietary fibre means carbohydrate polymers with a degree of polymerization (DP) not lower than 3, which are neither digested nor absorbed in the small intestine. A DP not lower than 3 is intended to exclude mono- and disaccharides. It is not intended to reflect the average DP of a mixture . . .' (Codex Alimentarius Commission, 2007). Why the Codex definition at step 8 changed to read 'Dietary fibre means carbohydrate polymers* with 10 or more monomeric units† is unclear, as the emphasis had always been on 3 or more. In hindsight and given the previous thorough debate on this issue, it would have been more reflective of the scientific opinion to have included carbohydrates with DP 3–9 in the main body of the definition, with a footnote allowing national authorities to *ex*clude DP 3–9. Moreover it would have prevented misrepresentation of the true debate and final wording when the definition is incorrectly cited in articles without the all-important footnote (Harris & Pijls, 2009). Notwithstanding the above, a compromise seemed necessary in order to reach consensus, but poses real problems for implementation, and fails to establish one worldwide definition because definitions can now continue to vary from country to country. This in turn means that food labels will need to vary depending upon the decision of the national authority. Analytical procedures for measuring dietary fibre are also affected since a method that would measure total dietary fibre including DP 3–9 could not be used by national authorities that exclude DP 3–9 and a method that measures total dietary fibre excluding the lower molecular weight fractions would lose quantitation for higher molecular weight soluble fibres. Clearly the most straightforward choice would be *not* to have the footnote and make a decision either pro or con for the inclusion of DP 3–9. Alternatively, it would seem more likely that the final step 8 definition should have read: 'Dietary fibre means carbohydrate polymers* with 3 or more monomeric units†'. In other words, the exception for footnote† might have read 'Decision on whether to include *only* those carbohydrates from 10 or more monomeric units should be left to national authorities'. The fact that there was considerable debate at step 6 as to whether three or more monomeric units was an average or a cut-off indicates that the CCNFSDU had previously decided on three as the lower limit, not 10; and there was no clear debate or rationale on which to base this substantial change to 10.

Issue #2. Proving a beneficial physiological effect for dietary fibre.

The issue

The Codex definition calls out three categories of dietary fibre (naturally occurring in the food as consumed; obtained from food raw material by physical, enzymatic or chemical means; and synthetic carbohydrate polymers) (see Table 1). Carbohydrate polymers in the latter two categories, but not the first category, have to show a 'physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities' (Codex Alimentarius Commission, 2008). The rationale for this is that consumers expect dietary fibre to offer benefits. If the fibre is endogenous to the food there exists a long history of the physiological benefits of 'high-fibre foods' and thus no reason to re-prove these benefits (IOM, 2002). However, if the fibre is extracted from food or synthesized then it cannot take advantage of the long history of high-fibre foods as the resulting fibre may be more – or less – beneficial to health than endogenous fibre. The issue is what constitutes a beneficial physiological effect and what requirements should be in place to document such a beneficial effect.

Current status of establishing beneficial physiological effects

Intriguingly, the major driver for the pressure on isolated and synthetic components having to demonstrate beneficial physiological effects is the health effects attributed to naturally fibre-rich foods yet we are not sure that these health benefits can actually be fully or partially attributed to the fibre contained, or to associated components contained by these same foods. In other words, by applying the now agreed definition, health benefits will only be fairly certain

for isolated and synthetic fibres, but not or much less so for endogenous fibres *per se*.

What is a relevant beneficial physiological effect? The EU Directive 2008/100/EC provides that fibre 'has one or more beneficial physiological effects *such as*: decreased intestinal transit time, increased stool bulk, is fermentable by colonic microflora, reduces blood cholesterol, reduces LDL cholesterol, reduces postprandial blood glucose, or reduces insulin levels' (Commission of European Communities, 2008). This mirrors the list of non-inclusive examples that reached Step 7 of the Codex process (Codex Alimentarius Commission, 2008; Commission of European Communities, 2008), and also the conclusion of European Food Safety Authority (EFSA) (2007). These definitions also leave the door open for new physiological effects, which makes sense as long as any such effect can be shown to be, or can reasonably be considered to be, beneficial. Perhaps this list is a good place to start, given the length of time countries have discussed the dietary fibre definition at the CCNFSDU. Physiological effects often influence multiple aspects of health and most health aspects are influenced by several physiological effects. For this reason, while a beneficial physiological effect may be the same as a 'health claim', it equally may not be. Moreover, in the EU, all health claims must also be well understood by the 'average consumer' and unfortunately many reported physiological effects contain complex scientific terminology. This creates a further challenge, which can be avoided if the existence of the effect simply entitles the component concerned to qualify as dietary fibre. The ILSI Europe Concise Monograph on Dietary Fibre (Gray 2006) looks among other things at the physiological effects of colonic microflora and their fermentation products. These may act as immunomodulators (e.g. absorb procarcinogens, promote attack on malignant cells); inhibit growth of harmful yeasts and (peptolytic) bacteria; improve mineral absorption; reduce food intolerances and allergies; stimulate growth of healthy intestinal flora; reduce undesirable compounds (e.g. amines and ammonia, phenols, secondary bile acids); produce nutrients (B group vitamins) and digestive enzymes. These effects are variously linked to health outcomes such as improved bowel function, alleviation of bowel disorders, bone health and improved diabetes management.

Towards a solution

The single most important obstacle to successful application of the new Codex definition is the lack of an agreed upon list of qualifying beneficial physiological effects; the previous non-exhaustive list that was extensively debated during the Codex deliberations was also removed at the last minute during the 30th Session in 2008. Such effects need to be 'demonstrated by generally accepted scientific evidence to competent authorities' (Codex Alimentarius Commission, 2009). One has only to review the petitions, and decisions of the EU health claims to realize how difficult it is to characterize either 'generally accepted scientific evidence' or 'competent authorities'. Certainly the FDA has struggled with this since the adoption of NLEA, first for health claims based on significant scientific agreement and more recently on qualified health claims. Allowing each country to decide for itself, as to what constitutes a beneficial physiological effect, while a practical solution, will negate the opportunity for a worldwide definition as what would be accepted by one country might not be accepted by other countries. It may be helpful to look at what others have already enumerated as being significant physiological beneficial effects. For example, the IOM in its Dietary Reference Intake Macronutrient report reviewed the major physiological benefits of fibre intake and this review could be helpful as a first step (IOM, 2002). Health Canada put a major emphasis on establishing rules and regulations for 'novel fibres' and we can benefit from their outcomes and from the experiences in how their guidelines have influenced the introduction, or not, of fibres into the Canadian food supply. According to these guidelines, novel fibre sources refer to a food that is manufactured to be a source of dietary fibre, and (a) that has not traditionally been used for human consumption to any significant extent, or (b) that has been chemically processed, e.g. oxidized, or physically processed, e.g. very finely ground, so as to modify the properties of the fibre contained therein, or (c) that has been highly concentrated from its plant source (Health Canada, Revised 1997). It would be of interest to ask the original committee members whether they believe that their initial suggestions for qualifying as a novel fibre were too lenient or too restrictive, and how this contributed to their ultimate decisions on which fibres should be included in the food supply. Another helpful approach would be to start by sorting the beneficial physiological effects by the level of the evidence supporting them for example: (1) convincing evidence; (2) evidence that renders the effect likely to exist; (3) evidence indicating that an effect of interest may exist. In an exercise recently launched by ILSI Europe, at the occasion of the 4th International Dietary Fibre Conference, delegates were invited to contribute to this – the work is still underway and should provide a useful platform from which to move forward. As said, it might seem appropriate to consider establishing a Codex working group, through the CCNFSDU, to establish guidance.

Issues #3 and #4. Effect of processing and animal sources of fibre

Although not as significant as the other two issues at this time, there are two other aspects of the Step 8 definition, which require clarification. Processing of a food can result in a gain or loss of dietary fibre. Is the 'created fibre' as beneficial to health as the other endogenous fibre in that food? This is of concern as it is not necessary to show a physiologically beneficial effect for the endogenous fibre in a particular food yet it may be necessary to show such a benefit for a fibre that occurs due to processing. Where the bright line will be placed between endogenous and 'synthesized' fibre may not be so easy to determine. An additional issue is in regard to the Codex Step 8 definition not requiring that fibre sources be from plants. On closer scrutiny this may surprise/concern individuals who expect fibre-containing foods to be plant based. Further, if the fibre is endogenous to the food (not synthesized or extracted) it will not have to show a physiological benefit. The reason endogenous fibres get a 'pass' is due to their long history of intake and the overall beneficial physiological effects of high-fibre foods. There is no such long and established history for animal sources of fibre. This aspect of the new Codex definition was not raised at the meeting and may surface again in future discussions.

Summary and conclusion

Although agreeing on a worldwide definition of dietary fibre is a major achievement, issues remain for the interpretation and implementation of this definition. The two primary issues are: (1) how to resolve the compromise footnote[†] which states: 'Decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities' (Codex Alimentarius Commission, 2009); and (2) how to substantiate that carbohydrate polymers isolated from food raw material or synthesized have a beneficial physiological effect. Two other issues are of lesser significance but are still important: agreement on the extent and effect of processing on endogenous fibre as to when/if the fibre may be so altered that it also needs to 'prove' a beneficial physiological effect; and the interpretation of the Codex definition with respect to endogenous fibres of animal origin.

In conclusion, coming to an officially accepted Codex definition is a major accomplishment, and provides a global standard for member countries to use as a basis for interpretation for national legislation that will make a significant difference to food manufacturers, consumers, educators, researchers and regulatory agencies. It should encourage more research on fibre – now that we have a definition of what fibre is – and it should allow food manufacturers to reformulate and innovate products to make them healthier. Although setting guidance on beneficial physiological benefits of fibres may be difficult and time consuming, it is critical that we do not stop now when we have come so far.

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