Codex 2003 - The EU Tightens Its Grip

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A report on the Codex discussions regarding the Proposed Draft Guidelines for Vitamin and Mineral Supplements, prepared by Paul Anthony Taylor.

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES Twenty-fifth Session. Bruckenforum, Bonn, Germany, 3-7 November 2003.

Monday 3rd November 2003 Agenda item 5. Proposed Draft Guidelines for Vitamin and Mineral Supplements

The Chairman opened discussions on this agenda item by saying that for a long time no progress had been made on this issue, but that people had become aware of the need to develop these proposals. He also stated that he intended to make a major breakthrough on this occasion, and suggested that the discussions should include the issue of the maximum values for nutrients.

Title

The first issue to be discussed by the Committee was that of the title of the guidelines. (Proposed Draft Guidelines for Vitamin and Mineral Food Supplements). Malaysia proposed to delete the word "food" from the title, and South Africa supported them on this. The EC (European Commission) Observer (Mr. Basil Mathioudakis) did

not agree to this however, saying that it was not acceptable. The general pattern of the debate began to become apparent from this point onwards, as the Chairman stated that he did not share the concerns of Malaysia and South Africa, and said that we could leave the title as it is. In effect (and not for the last time in these meetings) the Chairman was no longer acting as a moderator, but as a judge. With regard to this point, it is notable that the text of the Draft Report that was issued on the Friday stated the following:

After an exchange of views it was however agreed to retain the current title.

As will be seen later, this was by no means the only instance where the Draft Report did not reflect what had actually happened.

Preamble

The debate then passed quickly on to the text of the preamble. South Africa read out their proposed alterations, which included wording to the effect that people should "be encouraged to select a healthy diet and supplement this diet with those nutrients for which the intake from the diet is insufficient to meet the requirements necessary for the prevention of chronic diseases and/or for the promotion of health beyond the demands of preventing micronutrient deficiencies." The National Health Federation supported this, saying that this text merely states what we know to be true.

The EC Observer however said that food and the prevention of diseases do not go together. He was supported by the Chairman in this, who said that drugs are to mitigate and prevent diseases, and that the role of food supplements is to support the diet.

CRN talked about the classic nutritional diseases, the nutrient responsive diseases, and nutrients used as drugs, and said that this sort of categorization should be the way forward. The EC Observer, however, said that health claims for vitamin and mineral supplements should be prohibited. The Chairman pointed out that the situation in the United States was different, and that the Codex Committee has a certain conflict regarding this issue. Medical supervision is important in this field, he said, and we should not talk about the prevention of diseases. The National Health Federation refuted the Chairman's statement however.

Tunisia said that most people who have access to a balanced diet get sufficient nutrients, and that people should be encouraged to aim for a balanced diet. The Chairman then intervened in the discussion, saying that he wanted to stick to the preamble as it is, as the Codex Committee had been discussing this issue for years. Yet again then, rather than acting as a moderator the Chairman was playing the role of judge, and the discussions moved, or rather, were forced, onto the next paragraph of the Guidelines.

Interestingly however, the Draft Report described this intervention as follows:

After some discussion, the Committee agreed to retain the current text as it resulted from considerable discussion and consensus at the last session.

Once again, it would appear that the Draft Report did not accurately reflect what had actually happened.

Scope

South Africa read out their proposed alterations to this paragraph, and said that the sentence "It is left to national authorities to decide whether vitamin and mineral supplements are drugs or foods" should be deleted. They argued that this sentence creates a potential barrier to trade, and that the Codex mandate is to remove existing barriers to trade and to harmonize legislation globally. South Africa was supported by the USA, who said that Codex guidelines only apply to foods and that it is not necessary to reiterate this. After some discussion the Committee eventually agreed to delete this sentence.

During the discussions on Scope, the Chairman inferred that the EU wanted to leave the door open for the Draft Guidelines on Vitamins and Minerals to be extended to other nutrients. The EC Observer replied by saying that they did not want this, but that if the Scope was defined too rigidly some products might be taken out of the Guidelines by the addition of other nutrients, thus claiming that they were not vitamin and mineral supplements. As a result of this, the Committee added the following sentence to the Guidelines:

Food Supplements containing vitamins and/or minerals as well as other ingredients should also be in conformity with the specific rules on vitamins and minerals laid down in these Guidelines.

Definitions

Following a short tea-break, the Chairman stated that there was consensus that the Committee wanted to draw up guidelines, and the discussions eventually moved on to the issue of definitions.

The New Zealand delegation wanted to delete the square brackets around the following:

They serve to supplement the daily diet with these nutrients in cases when the intake from food is insufficient or where the consumers consider their diet requires supplementation.

The delegations of Thailand and India both supported this.

The EC Observer however stated that the definition is wrong, and that it was necessary to come to a decision. He also complained that the discussion could easily take up the rest of the allotted time.

The word "dose" was discussed, and the USA stated that this word can imply a drug use rather than a food use, adding that they are unaware of what a "significant amount of energy" means. (The term "a significant amount of energy" was originally contained in the draft definitions, but was eventually deleted by the Committee).

Malaysia wanted to add wording to the effect that supplements should not be used to replace a balanced diet, but the Chairman said that this was mentioned in the preamble.

The EC Observer wanted to add the words "measured small unit quantities" to the definition, so that vitamins and minerals could not be added to a drink and taken in large doses. South Africa stated however that they could not support the EU on this, and said that if this wording was to stay it should be defined properly. Nigeria was of the opinion that "measured small unit quantities" made the definition too long. India agreed with this, saying that the existing definition serves the purpose. The EC Observer was not happy with this however, and asked whether a can of Coca-Cola containing vitamins and minerals is a food supplement. "This is what we want to avoid," he said. Germany said that the concept of "measured small unit quantities" should be included in the definition. France also supported this proposal.

The USA said that they would be willing to consider other language, but that the burden of the language should be on the EU, since they were the ones proposing the language!

After some further discussion the Chairman eventually said that "small unit quantities" should be put into square brackets.

Composition

The USA proposed the following:

The sources of vitamins and minerals may be from either natural sources or synthetic sources... IADSA and the UK both supported the USA regarding this suggestion. The EC Observer was not happy with this however, and asked if acerola was going to be used as a source whether it would be labeled as a source of acerola or vitamin C. He also wanted to know what "natural or synthetic" means. CRN were of the opinion that the source would be acerola and that the vitamin C content would be listed

in brackets. The EC Observer replied that vitamin C can either be extracted from natural sources or it can be one of the natural constituents, adding that the words "natural or synthetic sources" should go in square brackets. The Chairman then told the Committee that the USA proposal re: "natural or synthetic sources" should go into square brackets, and the discussion moved on to the next sentence of the Guidelines.

The USA proposed to delete the following sentence, on the grounds that the issue of safety was addressed in the section on Contents.

The use of individual vitamins and minerals in supplements can be [limited] for reasons of health protection and consumer safety, taking into account regional or national peculiarities concerning the supply situation of the population.

This was put to the Committee by the Chairman, and as a result was removed from the Guidelines.

With regard to the reference to the FAO and WHO in 3.1.2, the EC Observer asked whether this is referring to a specific FAO/WHO document:

The sources of vitamins and minerals may be from either [natural or synthetic sources] and should be based on consideration such as safety and bio-availability. In addition, purity criteria should take into account FAO/WHO standards, or if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources national legislation may be used.

In his answer the Chairman invited the EU to propose a list for this section of the Guidelines. The USA however stated that they could not see how having a list would help. Although this was not clarified, one was left wondering whether this was the first mention of a possible "positive list", along the lines of the EU Food Supplements Directive.

Contents

Japan was of the opinion that a minimum level of 15% for each vitamin and mineral contained in a supplement is too low. The USA however said that a logical basis for setting a percentage value should be employed, and reminded the Committee that it was not possible to include more than 15% to 33% of the recommended daily intake of calcium and magnesium in a capsule as it would be overly large. Malaysia supported the USA on this, as did South Africa and the Philippines. Thailand however said that the minimum should be at least 33%. The Chairman stated that the majority of comments wanted to maintain the 15% minimum, adding that the issue as to what is a significant amount still needed to be clarified to the Labeling Committee.

The EC Observer said that 3.2.1 contained a reference to the RDA, and that the Committee needed to know which RDAs would be used, since the FAO/WHO recommendations did not include all nutrients.

When the discussion eventually passed on to the issue of maximum levels (3.2.2), the Chairman stated that the vast majority wanted upper limits to be based on risk assessment.

Delegations in favor of scientific-based risk assessment included the EU, South Africa, USA and Switzerland. Delegations in favor of the maximum level of each vitamin and/or mineral contained in a supplement not being allowed to exceed RDA levels included Norway, Malaysia and Thailand.

The National Health Federation said that 3.2.2 (b)

the daily intake of vitamins and minerals from other dietary sources.

should be deleted, because it was not necessary to take the daily intake of vitamins and minerals from other dietary sources into account when setting the maximum levels that can be contained in a supplement. The Chairman replied by saying that this would be counter-productive.

The USA wanted to delete the following:

When the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population.

The EC Observer stated however that he could not support this.

A number of delegations however supported the USA on this, including Tunisia, IADSA, New Zealand, Philippines, South Africa and the National Health Federation. CRN also supported this, but said that if it must be kept then the RDA could be used as a floor so that the risk assessment could not deliver a level below the RDA. In addition to the EC Observer, other delegations who wanted account to be taken of the reference intake values of vitamins and minerals when the maximum levels are set included Norway and Italy.

It was eventually agreed to retain this sentence in square brackets.

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At the beginning of day two, the Chairman proposed that the Committee should deal with the items in square brackets first.

Labeling

With regard to the name of the product, the EC Observer proposed the following:

The name of the product shall be food supplement with an indication of the categories of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be.

IADSA however wanted "The labeling of the product", and were supported by South Africa on this. The EC Observer replied that this would be grammatically incorrect. The National Health Federation supported IADSA and South Africa. IADSA then suggested that "The specified name of the product..." would be better. The National Health Federation then proposed, "shall be identified as a food supplement", and suggested the use of square brackets. The Chairman however stated that he did not want the use of square brackets, and accepted the proposal of the EC Observer.

The Draft Report however wrote this up as follows:

The Committee deleted the square brackets in section 5.2, agreed that the name of the product should be "food supplements" for consistency with the rest of the text, and reworded the sentence for clarification purposes.

Once again, it would appear that the Draft Report did not accurately reflect what had actually happened.

With regard to 5.3, the Committee decided upon the following text:

The amount of the vitamins and minerals present in the product shall be declared in the labeling in numerical form. The units to be used shall be units of weight.

(Interestingly however, when the Draft Report was distributed on the Friday the word "shall" had been replaced by the word "should". (Errors of this sort are somewhat commonplace in the Draft Report).

When the discussion passed on to 5.4, the USA suggested the following:

The amounts of the vitamins and minerals present in the product declared shall be those amounts per portion of the product recommended on the labeling for single use and if different the amounts per day.

The EC Observer disagreed with the USA however, saying that in the EU they had decided that consumers would be confused by this.

The text displayed on the screen at the front of the meeting then became:

The amounts of the vitamins and minerals declared shall be those per portion of the product as recommended for daily consumption on the labeling and if different the amounts per single use.

The EC Observer was still unhappy however, and said that EU consumers would not understand this!

The National Health Federation made a couple of interventions in support of the US proposal, saying that it was safer.

After some discussion it was agreed to retain the square brackets in section 5.4, as the Committee were unable to agree upon whether the declaration of vitamin or minerals should be the amount per portion of the product recommended for daily consumption or the amount per single use.

When the discussion turned to 5.5, and the issue of nutrient reference values, the Chairman suggested that an electronic working group should be set up, and that one of the tasks of this working group should be to set new nutrient reference values. The USA was in agreement with this proposal, and noted the inadequacy of the current nutrient reference values, saying that they need to be updated. The EC Observer asked whether the working group would be setting population recommended daily intakes or population reference values, and the Chairman confirmed that it would be the latter. CRN meanwhile said that a guide as to what would be a reasonable amount was necessary, and quoted 100mg of vitamin C as an example!

The Chairman said that the Committee should be talking about nutrient reference values as defined in the Helsinki Consultation (1988), and that values for different age groups should be set.

The National Health Federation then informed the Chairman that they would like to take part in this electronic working group, and the Codex Secretariat offered to send out a Circular Letter to ask for proposals for additional or revised nutrient reference values for labeling purposes.

5.7 had originally read as follows:

The label must contain a warning statement [if the product contains a significant amount of a nutrient with respect to the toxicity level.]

The USA and South Africa both wanted to delete this, and were supported by CRN and the National Health Federation.

Switzerland however wanted the following:

Where appropriate and as determined by risk assessment the label should advise consumers not to exceed the maximum one-day dose.

The EC Observer meanwhile, proposed:

The label must contain a warning statement not to exceed the stated recommended daily dose [if the product contains a significant amount of a nutrient with respect to the toxicity level.]

Germany, Slovenia and Denmark supported the EC Observer's proposal, and the Chairman stated that the EC Observer's proposal was reasonable if consumers want to do something good for their health. This then became the wording that was displayed on the screen at the front of the hall.

Following a short coffee break it was announced that South Africa had spoken to the Chairman, and had agreed to chair the electronic working group looking into the issue of nutrient reference values.

Once discussion resumed on the matter of labeling, Austria said that the warning statement should begin with:

"The label must..."

The head of the National Health Federation delegation then intervened, complaining that the Chairman was fashioning the document according to what the EU wants. "What the EU wants, the EU gets," he said, adding that the Committee did not have a consensus and so some things needed to remain in brackets.

The delegation from Kenya however wanted the word "shall", as opposed to the word "must". There then followed a great deal of disagreement amongst the delegations over this point, and much discussion ensued as to whether the guidelines were recommendations or mandatory. Eventually however, the following was agreed:

The label shall contain advice to the consumer not to exceed the maximum one-day amount.

The Committee then passed on to section 5.8, which had formerly read as follows:

The label must contain a statement: supplements can not be used for the replacement of meals on long-term basis.

The EC Observer wanted to replace this with the following:

The label must contain a statement that supplements can not be used for the replacement of a varied diet.

The USA meanwhile proposed:

The label should not state or imply that supplements can be used for the replacement of meals or a varied diet.

China however wanted to use "replacement of meals or drugs", and New Zealand wanted to delete this section entirely, but were prepared to support the USA if this were not possible. After much discussion the USA proposal was eventually accepted by the Committee.

When it came to section 5.9, which had originally stated that all labels should bear a statement that the supplement should be taken on an advice of a nutritionist, a dietician or a medical doctor, the South African delegation said that they wanted to delete this. The Philippines and Malaysian delegations meanwhile wanted to keep this statement. The Chairman however stated that we are not speaking about drugs here, and it was accordingly agreed to delete this section.

At this point all of the items that were originally contained in brackets had now been dealt with, and the Committee proceeded to discuss some of the other issues relating to these Guidelines.

Packaging

With regard to 4.3, which had stated that vitamin and mineral supplements should be distributed in child-resistant packaging, the EC Observer proposed to delete this, and wanted a statement to the effect that the products should be stored out of the reach of young children, such as:

The label must contain a statement to the effect that the product must be stored out of the reach of young children.

The Chairman commented that it is true that vitamins are often consumed by children as if they were colorful sweets (!!), and went on to say that child-resistant packaging is often difficult for the elderly to open.

Poland and Bulgaria both supported the EC Observer on their proposed amendment. This was then agreed by the Committee, and became section 5.9, whilst the original section 4.3 was deleted.

Contents of Vitamins and Minerals

The Committee then turned its attention to 3.2.3, and the South African delegation stated that they would be in favor of:

For vitamins and minerals with a narrow safety margin between the recommended daily intake and the adverse effect level, different maximum limits for the daily dose may be established at the national level, if the national authority can show scientifically that a level lower than that established by Codex is appropriate.

The EC Observer however suggested taking out section 3.2.3, and this was duly done.

Advancement from Step 4 to Step 5

The Chairman then proposed to advance the Proposed Draft Guidelines for adoption at Step 5, and this was agreed by the Committee.

Analysis and Comment

One of the most interesting aspects of these Codex meetings was that the 15 EU member states generally only entered into the debate when the EC Observer, Basil Mathioudakis, was in need of support to defend his position. Mr Mathioudakis is now a major contributor to the Codex Committee discussions, and he manages to exert a tremendous amount of influence both over the drafting of the Codex Guidelines and the meetings themselves. Interestingly, the delegate from IACFO (International Association of Consumer Food Organizations), during the discussions that took place on the Friday regarding the Draft Report, actually asked the Chairman for clarification of the EU's status at Codex, given that Basil Mathioudakis had been described as the EC 'Observer'. Following the Chairman's reply, Italy stated that at the beginning of the week the EU countries had decided that Mr Mathioudakis would speak for them. Upon further questioning from the IAFCO delegate, the Chairman then stated that the EU would have full membership status at Codex "within 24 hours". It was also announced by the Chairman that from this year onwards the official Codex Report will not name individual countries who were in favor of the motions being passed, and will instead only name those countries who were against the motions being passed and who had asked for their opposition to be mentioned in the official report.

A number of books, booklets and leaflets were left out on trestle tables this year for the delegates to take away. Many of these had somewhat patronizing titles, such as "*Understanding Codex Alimentarius*" and "*Consumers: Are you concerned about the quality and safety of your food*". It was no coincidence that this was the first year in which consumers were allowed to attend the meetings as observers, and several people commented to me that these publications were clearly a (somewhat clumsy) attempt by the Codex Committee to address the negative image that it has amongst consumers.

One of the most obvious ways in which the Codex process could be made more transparent would be if an official written record of everything that was said at the meetings was made available to the public, similar to the way in which Hansard records everything that is said in the British Parliament. The lack of this (along with the lack of a transparent voting procedure where real votes are cast and then made public afterwards) are major failings that the Committee seems to be in no hurry to address.

Germany, incidentally, had by far the largest delegation at these meetings, with a total of 22 members. Almost without exception the German delegation all appeared to be keeping copious notes on everything that was said and done. Germany also had a further 6 Secretariat representatives present at these meetings, who were from the German Ministry for Consumers, Nutrition and Agriculture. The United States, by way of a comparison, had a total of 10 delegates, not all of whom were present for the entire week. The UK, meanwhile, had only one delegate (from the Food Standards Agency), who left following the conclusion of Wednesday's discussions.

Finally, this report would not be complete without a few words concerning the 'victory' that some have been proclaiming following the conclusion of the discussions over the Draft Guidelines for Vitamin and Mineral Supplements. Although it is of course true to say that things would have been very much worse had the Committee agreed to recommend RDA levels only, it by no means follows that just because scientific risk assessment will be used we can assume that the safe upper limits will be set at reasonable levels. Scientific risk assessment was used by the EU Scientific Committee on Food (SCF), for example, when they were setting the tolerable upper intake levels in connection with the EU Food Supplements Directive. As a result of their 'scientific' risk assessment, the SCF recommended that the tolerable upper intake level for niacin should be set at only 10mg, an amount which is just over half of the EU RDA for vitamin B3. Similarly with their evaluation of vitamin B6, the SCF relied strongly upon a Dalton & Dalton study from 1987 that has been largely discredited by most acknowledged experts in the field of nutritional science. Based upon this study, the SCF set a tolerable upper intake level of only 25mg for vitamin B6.

To make matters worse, the preamble to the EU Food Supplements Directive states that: *When maximum levels are set, therefore, account should be taken of the upper safe levels of the vitamins and minerals, as established by scientific risk assessment based on generally acceptable scientific data, and of intakes of those*

nutrients from the normal diet. Due account should also be taken of reference intake amounts when setting maximum levels.

Clearly then, the text of the Food Supplements Directive strongly indicates that when setting the maximum levels a further amount will be deducted to account for dietary intake. Given the influence that the EU now clearly has upon the Codex Alimentarius Committee, it is unthinkable that a similar process will not be used when setting the upper safe levels for the Guidelines for Vitamin and Mineral Supplements. Indeed, most of the text for this is already in place.

Consider the following, which now forms part of the Codex text, as agreed this year:

3.2.2 Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

1.upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

2.the daily intake of vitamins and minerals from other dietary sources. [When the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population.]

Bearing the above in mind, proclaiming 'victory' following the agreement of Codex to utilize 'scientific' risk assessment in the setting of the upper safe levels seems both premature and naive.

These growing similarities, and others, between the text of the EU Food Supplements Directive and the Codex Draft Guidelines for Vitamin and Mineral Supplements are no coincidence. Basil Mathioudakis (the EC Observer), who drafted the text of the EU Food Supplements Directive, will now be representing 25 EU countries at the next Codex meeting in Bonn in November 2004. Clearly the long-held fear that the EU will eventually win the vote at Codex over the vitamin and mineral issue, through being able to outvote all of the other countries, could soon become a reality. This therefore raises the grim possibility that discussions regarding the Codex Draft Guidelines for Vitamin and Mineral Supplements could even be concluded at next year's meeting. This eventuality could have grave implications for the legal challenge to the EU Food Supplements Directive, because if the Codex Guidelines are agreed before the legal challenge is complete the UK lawyers would in essence be arguing for the European Court of Justice to overturn legislation that is fully in line with a newly agreed global standard.

In summary then, Codex is the trump card. Even if the legal challenge to the Food Supplements Directive is successful the Codex proposals could still be implemented globally, effectively overruling any short-term victory for health freedom in Europe. Proof of this comes from recent research by the American Holistic Health Association, which confirms that implementation of the Codex Guidelines for Vitamin and Mineral Food Supplements is not optional.

Clearly then, the next couple of years are going to be crucial ones for the future of natural healthcare and freedom of choice.

Paul Anthony Taylor, from the United Kingdom was welcomed as an NHF Advisory Board member November 2003.

Paul Anthony Taylor's background is in the music industry, working as a musician, arranger and producer. In recent years however he has been spending an increasingly large amount of time campaigning for health freedom. He became interested in natural health after falling ill with Myalgic Enchephalomyelitis in 1991, and subsequently made a full recovery via the use of high-dose nutritional supplements. As a result of this he has been campaigning for over 10 years against the global moves to restrict consumer access to these safe and effective health-promoting substances. He lives in the UK and can be contacted by e-mail at paulandpolly@btinternet.com