

# Small-Town Codex, Big-World Impact

Written by the National Health Federation

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It started out well enough. Even though I arrived at the Cologne-Bonn airport in Germany late on a Saturday night, the taxi ride was fast and painless to the small hotel in Bad Neuenahr where I had booked a room. The owners and the staff were there to greet me and were exceedingly gracious throughout my stay. The next morning, as I made my way to the location of the Codex Alimentarius Risk-Assessment Working Group meeting, held specially on the Sunday morning just before the general meeting, I could see a bit of the town in the morning drizzle as I walked the four minutes that it took to get there, crossing a small, bucolic river on the way.

This year's Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) was set square in the middle of this German spa town of some 27,000 souls. Not too distantly west of Bonn, the town boasts several spas, a renowned natural water source (Apollinaris), and surrounding vineyards galore. But, for one week, from November 11th through the 16th, 2007, it could also boast being the gathering point for nearly 300 Codex delegates wanting to have a say in the creation of global food guidelines that will impact billions of human beings.

CCNFSDU meets in Bad Neuenahr, Germany November 2007

## The Food-Supplements Guidelines

Remember, when the CCNFSDU adopted its Guidelines for Vitamin and Mineral Food Supplements in November 2004, which were then rubber-stamped in haste by the CAC nine months later, it created a framework only and not a complete document. (See [http://www.codexalimentarius.net/download/standards/10206/cxg\\_055e.pdf](http://www.codexalimentarius.net/download/standards/10206/cxg_055e.pdf).) The framework now has to be filled in through the use of risk assessment to determine the Maximum Upper Permitted Levels (MUPLs) for the various vitamin-and-mineral food supplements that are subject to these Guidelines. And the CCNFSDU has decided to create a policy document of the risk-assessment *principles* that will be applied towards that process of setting the MUPLs.

That is why, even though the National Health Federation *bitterly* opposed the creation of the Codex Food-Supplements Guidelines for both principled and pragmatic natural-health reasons, the process has now arrived at that stage where great damage could be done to human nutrition if the risk-assessment principles adopted at these latter-stage meetings were to follow the one-dimensional, one-size-fits-all approaches suggested by certain member-country delegations. That is also why the Federation is seeking to minimize the enormous harm that could still be inflicted on all of us by proposing and pushing sensible risk-assessment principles as a viable alternative.

## The Risk-Assessment Working Group

In the same way that the Codex Alimentarius Commission (CAC) has given birth to various committees charged with certain tasks, these committees have in turn birthed “working groups” given the task of developing specific approaches to specific issues. It was just one such CAC grandchild – the Working Group on Risk Assessment – that had elicited my early arrival in Bad Neuenahr.

This particular Working Group, meeting on Sunday and chaired by Janine Lewis of Australia, discussed the creation of the previously-mentioned Codex policy document on risk assessment; and Dr. Robert Verkerk and I were there to take part as the National Health Federation delegation. The Federation is a Codex-recognized International Non-Governmental Organization (INGO), with the right to attend and speak out at these meetings. And we definitely did speak out.

In particular, we emphasized the need to avoid applying risk analysis to *groups* of food supplements. Instead, risk analysis, we argued, is to be applied only to *forms* of food supplements. In this way, for example, governments will avoid labeling as dangerous all chromium supplements (or else setting absurdly-low MUPLs for such supplements) simply because one particular form of the nutrient is more toxic than the others. The “grouping” approach is a real danger at Codex discussions because this is the simplistic, non-thinking approach favored by many delegations. Others have no opinion but are persuadable by the Federation, which is the only delegation at present pushing a more individualistic, “form” approach that will not punish all nutrients in a nutrient group just because one particular form (usually synthetic) of that group is perceived as being, or actually is, toxic at a lower dosage level.

The Federation also argued for Codex’s adoption of a prioritization approach to risk assessment. In fact, the Federation’s argument for this approach goes hand-in-glove with our argument that nutrient forms, and not nutrient groups, must be considered because there is a tendency for Codex member-countries to push risk assessment of groups and not forms due to the large number of risk assessments that would be required if nutrient forms were analyzed separately. Quick calculations show that for the most-common essential vitamins and minerals, a “nutrient group” approach would require just 28 assessments (13 vitamins and 15 minerals), whereas a “nutrient forms” approach would require at least 305 assessments (35 vitamin forms and over 270 mineral forms).

However, using a “prioritization approach would make the number of risk assessments very manageable. This approach would give priority to those nutrient forms known – either because of their biochemical properties and/or their historical safety profile – to present the greatest health risks when used at “high” dosages. An advantage of this approach would also be that *no* MUPLs might ever be set for many of the nutrient forms that were assigned to the “low-priority” category.

At one point during our discussions, and in a thinly-veiled rehash of the precautionary principle, the representative for the European Federation of Associations of Health Product Manufacturers (EHPM) argued that Codex *must* act against nutritional products even if the scientific data is not strong! With such an argument, this man sounded more like a Danish health regulator on steroids than a person representing the interests of the health-food industry. How does the saying go? With friends like these who needs enemies? Well, my retort was to tell him and the Working Group that he was mistaken, that sometimes the best decision is *no* decision,

and that his approach could cause more harm than help when acting on inadequate information. The precautionary principle (which states that action should be taken to prevent serious or irreversible harm to public health or the environment despite lack of scientific certainty as to the likelihood, magnitude, or causation of that harm) makes some sense when applied to toxic, man-made substances, but makes absolutely no sense whatsoever when applied to substances normally ingested and/or naturally present in animals and humans. It is overkill – both literally and figuratively. And the thoughtless application of this principle within the CCNFSDU is one of the greatest threats to health and health freedom imaginable.

The discussion then covered a number of other aspects of risk assessment with the Danish government representatives having been especially keen on preserving the right of their national authorities to assess risk at a stricter level than Codex. In turn, the U.S. government representative did not want to frame risk assessment in terms of risk-benefit but rather in terms of risk-risk (e.g., the risk of eating fish vs. the risk of not eating fish).

Speaking for the Federation, Dr. Verkerk made a strong statement that you want to test your risk-assessment principles against real data before adopting those principles. Some people, he continued, are not getting enough of certain nutrients. “Why is that a problem?” the EHPM representative then asked. His astounding question was met with a short, unanimous silence tinged with either disbelief or simply a strong desire for the meeting to end – or both. With that, the chairwoman called the meeting to an end and we, the participants, spilled outdoors into the rain, seemingly happier to be drenched with water and not words.

### **Amidst Splendor, the Committee Meets**

The *Kurhaus* in which the meeting was held sat proudly on the riverbank and shone with baroque glory, the interior winning out even over the handsome exterior. So it was on a clearer Monday morning, November 12th, that numerous Codex delegates and staff streamed into this beautiful structure for the first day of the regular CCNFSDU week-long meeting. The meeting, chaired once again by the German Dr. Rolf Grossklaus – this time handicapped by a foot injury, began a little late in a large room that on three sides had a mezzanine-balcony for public observers and any press members to occupy. On the main floor, the delegates, including the National Health Federation, were seated at long tables arranged in neat, orderly German rows with Dr. Grossklaus at the head table surrounded by Codex and other staff. Behind them loomed a large screen upon which were to be projected the camera images of those speakers recognized by the Chairman as well as whatever relevant Codex text the Committee would be discussing.

The day before, after the Working Group meeting, I had stopped by the meeting room to check on the Federation’s table. I was hugely disappointed to see that, contrary to the normal Codex practice of arranging member-country and INGO delegations *alphabetically*, the German Codex office had very conveniently placed the Federation completely out of alphabetical order at the back of the room so that I would have been staring at myself behind a large, mirrored pillar during the entire meeting! Of course, within minutes I had complained to the German Secretariat so that upon our delegation’s arrival the next day we found ourselves seated in an area with a much clearer view of the floor. Of course it would just be paranoid of us to think that the original out-of-order placement of the most vocal INGO delegation had been deliberate.

This year's NHF delegation consisted of Paul Anthony Taylor, the NHF's Chairman who had arrived just the evening before, Dr. Robert Verkerk, the NHF Scientific Advisor, and me, as the NHF President and delegation head. As we arrived, I sat down in the chair in front of the NHF microphone, with our other two NHF delegates to my immediate left. Other delegates settled into their chairs as well and the meeting began.

## **The Agenda Items**

After welcoming the delegates and addressing some preliminary items, such as the adoption of the Agenda, the Chairman turned the Committee's attention to matters referred to it by other committees and CAC. During this time, Dr. Grossklaus asked the chairman of the Biotech Task Force, Dr. Yoshikura, to review the annex on food-safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits. There was much discussion on this issue, with the general thrust being that use of recombinant-DNA technology was appropriate. However, because the NHF's membership generally finds such technology to not be perfected enough for use in human food, I asked for the floor and said, "The NHF opposes foods derived from recombinant-DNA biotechnology, a view supported by 95% of European consumers who have opposed it for 20 years." Scoffing at my statement, however, Dr. Grossklaus dictated, "These aspects cannot be discussed here and now." Rather he said that genetically-modified foods have benefit for the consumer. As he put it, "Consumers do not realize the benefits this provides. Many would benefit and consumers will change their minds." There, I guess we've been told how to behave.

The Committee then moved on to address **Agenda Item 3** concerning the Guidelines for the Use of Nutrition Claims, spending much time on the definition of fiber and the classification of carbohydrates. In particular, Professor John Cummings (who was a member of the WHO/FAO expert group on this subject) was asked by the Chairman to speak – as it turned out – at length on the issue of carbohydrates and fiber. Importantly, Professor Cummings did highlight the critical importance to health of glycemic index, glycemic load, sugars in relation to obesity, resistant starch, and the concept of whole grain. In short, the Committee was urged to take a broader view of carbohydrates, into which a definition of fiber could be fitted.

**Agenda Item 4** came next and with it, a consideration of the revised standard for gluten-free foods. This topic elicited much discussion and, of course, is extremely important for those individuals, such as celiac patients, sensitive to gluten-containing foods like wheat flour and various grains. The camps divided up into two, with one (led by the United States) wanting gluten-free foods to be limited to gluten content at not more than 20 milligrams per kilogram, while the other camp favored the same gluten-free food but also another category of reduced-gluten food.

When given the floor to speak, the NHF spoke in favor of consumers being provided with the maximum choice of a range of gluten-free and reduced-gluten foods and appropriate disclaimers on the food labels. The final draft Standards, however, that are being sent on to CAC for its rubber-stamp adoption permit only those foods with a gluten content of less than 20 mg/kg to be called "gluten-free" while national authorities are to be allowed to determine appropriate labelling for foods having 20 mg/kg up to 100 mg/kg of gluten so long as those higher-gluten-content foods are not called "gluten-free."

The next item of interest to the Federation was **Agenda Item 6**, concerned with establishing acceptable bases for health claims. A number of delegations, including the NHF, objected to the proposed criterion that would require *all* health claims to be based upon evidence from human clinical studies. This, we argued, would be unnecessary, burdensome, and impractical. The NHF had submitted written comments on this and other points to Codex in late 2006, which points were incorporated into the Proposed Draft Recommendations on the Scientific Basis of Health Claims used by this Committee to arrive at a later understanding that more work needed to be devoted to this topic.

In the meantime, the Committee argued over the exact wording of the Draft Recommendations, with the Federation arguing once again that many important health claims are based upon association and not causes (e.g., the Mediterranean diet) and therefore health claims should be able to be substantiated based on the *totality* of the available evidence and not just on human clinical trials. The Chairman actually shocked me by agreeing with this point.

In the end, instead of this Agenda Item advancing mechanically forward, the Committee moved it *backwards* from Step 4 to Step 2/3. In NHF's view, most probably this backwards move was necessary because the Draft Recommendations, as currently constituted, strayed too far from the European Commission's position and had they moved forward as is, there would have been less chance of the EC changing them later to fit the European blueprint. Moreover, if human clinical trials were required for all health claims, then certain basic health claims for, say, fruits and vegetables would have to be banned or discontinued.

**Agenda Item 7** covered the application of risk-analysis principles by CCNFSDU, and the NHF made numerous comments and suggestions throughout this Item's discussion. At the start, NHF attempted to have this risk-analysis mandate just be limited to this particular Committee and not broadly to CAC and all of its subsidiary bodies. NHF's language was on the road to being accepted until the Australian delegate challenged and derailed it.

Next, NHF supported the US delegate's shockingly sensible suggestion that "risk" (what true risk is there with these natural substances?) could be managed by the use of disclaimers. At the same time, we also commented on the very-noticeable fact that the EC representative was trying once again to make this document conform to the EU directive. Successfully adding in wording that clarified that a reduction in risk is not the only nutritional benefit, the NHF then got into a verbal exchange with the Chairman over NHF's request that any nutrient-related assessment intake consider the depletion of nutrients from the soils over the last 50 years. Dr. Grossklaus emphatically disagreed, saying a German study had found no such depletion. I countered that UK, US, and Canadian studies had all demonstrated dramatic nutrient depletion in soils over the last many decades. Without asking the Committee for its thoughts, Dr. Grossklaus unilaterally decided against the inclusion of the NHF wording.

With that exchange still clearly in his mind, Dr. Grossklaus then recognized NHF with a jaunty "A constructive comment from the NHF?" when I next asked to speak on the issue of the use of "appropriate international expert groups or organizations" and their need to be "independent." At our request, the word "independent" was inserted into the text until the European Commission representative objected and had it removed. I would guess that the word "controlled" (and less transparent) was more what he had in mind. With that, the Committee moved this Agenda Item up to Step 5 and further along the track to completion.

**Agenda Item 8** concerned Nutrient Reference Values (NRVs) for labeling purposes. The general view of those running the Committee was that of “one size fits all” and a single NRV could cover all categories of individuals from infants to the elderly, from those with special needs to those with general needs. Among those holding the general view, only the EC representative hazarded the view that perhaps it would be a good idea to have a separate category covering children from 6 to 36 months old. The Chairman, though, thought even these two categories might burden the Committee too much if undertaken at the same time but that they could be done sequentially. Into this astounding vacuum of ideas, the NHF raised the alarm of the danger involved in oversimplifying NRVs. What the Committee would get were it to proceed with this “one size fits all” approach, the NHF argued, would be numerical amounts that are meaningless. They would be too high for many individuals and too low for many others. We would need to have at least three categories (infants, general adult population, and adult population with greater needs) and the NHF paper previously submitted on the subject simply followed the Institute of Medicine’s approach of having an adequate number of NRV categories to reflect diverse population groups and their various nutritional needs. (*See <http://www.iom.edu/Object.File/Master/21/372/0.pdf>*) That, however, was too logical for the Chairman, who refused to accept this approach.

### **Following the EU Blueprint**

Overall, it was apparent that the CCNFSDU followed the track laid down for it by the European Union, the driving engine for food-standards harmonization here. Where the Codex guidelines tracked those of the EU, progress towards completion was made. Yet, for the issue of health claims, where the Codex recommendations were off-track from those of the EU, they were sent back to the drawing board – presumably so that whatever clueless persons were in charge of those recommendations could wake up and get with the EU program.

And in one interesting development – especially given the notable absence this year of the outspoken health-freedom advocate Antoinette Booyzen from the South African delegation – the Committee gave South Africa its reward: Next year’s CCNFSDU meeting will be held in South Africa. What a coincidence.

In the end, the NHF delegation was extremely vocal, having made more comments to the Committee than all other INGOs combined. More importantly, we made substantial contacts with other delegations and have seen an awakening to the need for Codex to adopt real, and not junk, science in its application of risk-analysis principles. The adoption of such sane science would go a long way towards minimizing the harm that the Codex Vitamin and Mineral Food Supplement Guidelines would otherwise do.