

## ADVERSE EVENT REPORTS IN CONTEXT

### Part 2: Dietary Supplements: Benefits Considered Irrelevant

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Adverse event reports for dietary supplements are being taken very seriously by the FDA as one way to prepare consumers for the application of risk assessment analysis to all over-the-counter supplements. Risk assessment analysis was originally designed to limit the level of contaminants—such as pesticide residues—in our food. Guidelines for dietary supplements, finalized at the last meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses, are scheduled for approval in July, 2005.<sup>1</sup> Once they go into effect, dosages for all vitamins and minerals will be based on risk assessment analysis instead of multiples of the Recommended Daily Allowance (RDA).

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This is not good news because risk assessment analysis considers the nutritional benefits of vitamins and minerals irrelevant to the “scientific” search for possible side effects. Codex standards will require risk assessment analysis for all vitamins and minerals available in over-the-counter supplements.

#### International supplement standards

The GATT/WTO **Sanitary Phyto-Sanitary Agreement (SPS-Uruguay, 1995)**<sup>2</sup>, commits member nations to international standards, guidelines or recommendations,<sup>3</sup> including Codex and the Technical Barriers to Trade Agreement<sup>4</sup>, and to measures “based on an assessment...of risks”<sup>5</sup>

In 1998, a **Mutual Recognition Agreement** to produce a single set of dietary supplement standards was signed by the US and the EU for presentation to the World Health Organization.<sup>6</sup> Although the SPS does not specifically rule on domestic standards, “governments are encouraged to use international standards where they exist.”<sup>7</sup>

The **National Academy Sciences** (a non-government agency) drafted a paper for Dr. Elizabeth Yetley of the FDA to present to the Codex Alimentarius Committee on Dietary Supplements. Entitled, “A Risk Assessment Model for Establishing Upper Intake

Levels for Nutrients, this paper proposed extremely limited doses for over-the-counter supplements.<sup>8</sup>

The Dietary Supplement Working Group of the **Trans-Atlantic Business Dialogue (TABD)** has aimed at encouraging “evaluation of the safety of total intakes of vitamins and minerals” as far back as 2000.<sup>9</sup>

#### Global Risk Assessment Framework

Under the general title *A framework for Evaluating Safety*, the Institute of Medicine of the National Academies of Science has begun evaluating individual dietary supplements to establish upper limits.<sup>10</sup>

The 2004 meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses, it was agreed that safe upper limits for nutrients—from foods and supplements combined—are to be based on risk assessment analysis. At the same 2004 meeting, Dr. Christine Taylor of the FDA announced a new Joint FAO/WHO project “to create a framework for risk assessment of nutrients and related substances.”<sup>10</sup>

#### EU and Codex Parallel Supplement Guidelines

Language in the Codex guidelines<sup>11</sup> closely parallels the European Union Vitamin Directive, scheduled for implemented in 2005. This is significant because the EU defines therapeutic doses of vitamins and minerals as “medical products” and restricts ingredients for use in over-the-counter supplements to a specific list.<sup>12</sup>

#### Participation by producers

Producers of dietary supplements are required to provide all the information deemed necessary for risk assessment analysis. For new dietary ingredients (NDIs), producers must satisfy the FDA’s information requirements or take the product in question off the market.<sup>13</sup> “A NDI is defined as one that was not marketed prior to the passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994. Before such ingredients can be marketed, safety data must be reviewed and accepted by the FDA.”<sup>14</sup>

FDA approval is withheld if a company has failed to “adequately describe the identity and composition of  
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