INSTITUTE FOR TRADE, STANDARDS, AND SUSTAINABLE DEVELOPMENT

February 26, 2008

Ms. Anne Meininger
National Center for Standards and Certification Information (NCSCI)
National Institute of Standards and Technology
100 Bureau Drive MS 2100
Gaithersburg, MD 20899-2100

Re: U.S. Enquiry Point
G/TBT/N/COL/65/Add.3

Ms. Audrey Talley
Processed Products and Technical Regulations Division
Office of Scientific and Technical Affairs
Foreign Agricultural Service (FAS)
1400 Independence Avenue, N.W.
Room 5552 South Building
Washington, DC 20250

Re: U.S. Enquiry Point
G/SPS/N/COL/98/Add.3

Dear Madames Meininger and Talley:

Please find attached for submission to the Republic of Colombia the following comments prepared by the Institute for Trade, Standards and Sustainable Development (ITSSD), a nonprofit legal research and educational organization incorporated within the State of New Jersey, in response to notifications G/TBT/N/COL/65/Add.3 and G/SPS/N/COL/98/Add.3 referenced above.

These notifications concern a draft amendment to Decree No. 3249 of 18 September 2006 "Regulating the manufacture, marketing, packaging, marking or labeling, sanitary registration, quality control, sanitary surveillance and sanitary control of dietary supplements, setting forth other provisions and repealing Decree No. 3636 of 2005" of the Ministry of Social Welfare, previously notified in document G/TBT/NCOL/65/Add.2 of 3 November 2006.

The ITSSD appreciates the liaison provided by your offices in submitting these comments to the appropriate enquiry point in Colombia.

Very truly yours,

Lawrence A. Kogan, Esq.

LAK

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ITSSD Comments Submitted In Response To Draft Amendment of Colombian Decree 3249 (9/18/06)

WTO Notifications: G/TBT/N/COL/65/Add.3 and G/SPS/N/COL/98/Add.3

Submitted February 26, 2008

The Institute for Trade, Standards and Sustainable Development (ITSSD) wishes to thank the Colombian Ministry of Social Protection for the opportunity to submit the following comments in response to the October 29, 2007 and October 26, 2007 WTO notifications referenced above in connection with a draft amendment(s) to Colombian Decree No. 3249 of Sept. 18, 2006. The ITSSD looks forward to having them thoughtfully reviewed, considered and responded to.

The ITSSD is a nonprofit legal research and educational organization with international recognition and standing, the charitable mission of which is to examine evolving international and foreign laws, regulations and technical standards for the purpose of assessing their impact on free enterprise, private property rights and the rule *of* law. In undertaking its charitable mission, the ITSSD looks closely at whether or not emerging international and national laws, regulations and product and process standards are premised on transparent (not opaque), proportionate (not preferential), rational and objective (not subjective) science and economics-based substantive benchmarks and procedures. It undertakes this exercise in order to discern whether such rules, norms and standards promote legitimate state policy objectives or are actually creatively disguised technical barriers to market access which unfairly discriminate between otherwise 'like' products and processes and/or unnecessarily or arbitrarily restrict international trade and innovation in favor of local industry interests, in contravention of the law and spirit of the WTO agreements.

The ITSSD is submitting comments to these notifications because it is concerned that the draft amendments to Colombian Decree No. 3249 neither comport with existing international standards/ guidelines prepared by the Codex Alimentarius Commission, nor reference in any meaningful way existing national standards of other WTO member states that provide transparent, proportionate, rational and objective science and economics-based substantive benchmarks and procedures that would fulfill the same or similar public policy goals identified by the Colombian regulatory authorities in their draft amendments.

These ITSSD comments are divided into two parts: 1) specific; and 2) general contextual.

1) Specific Comments:

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- **DRAFT ARTICLE 1, AMENDING DECREE 3249, ARTICLE 3, ITEM #1**: ('the product [Dietary Supplements] should not be adjusted to [i.e., should not conform to] established definitions for *food products*, drugs, phytotherapeutic products or pharmaceutical preparations based on natural resources...').

The ITSSD recommends that the draft amendment language of DRAFT ARTICLE 1, AMENDING DECREE 3249, ARTICLE 3, ITEM # 1 be changed to read as follows:

> *"The food products based in natural resources* ***presented in pharmaceutical form*** *accepted by the Invima's Review Commission,* ***and without*** *therapeutical indications* ***(i.e., not specifically used, labeled and marketed as a drug, phytotherapeutic or pharmaceutical preparation)****,* ***are classified as food products*** *and are subject to the regulations established for those products. In the case of the Good Manufacturing Practices (GMP), they should meet with all the norms established for the pharmaceutical products based in natural resources."*

Such a change in statutory language would clearly be consistent with prior Colombian law – the law as it existed BEFORE the enactment of subsection b of Article 12 of Decree 337 of 1998.[1] Decree 337, in part, regulated natural herbs having medicinal qualities as over-the-counter pharmaceuticals and as an independent regulatory category.[2] Prior to Decree 337, however, food products derived from natural resources and presented in capsule form *without* therapeutic indications were classified as '*food*',[3] and had long enjoyed widespread use without concerns about potentiation and concentration limits. Such new statutory language would also serve to fulfill INVIMA's long held public policy goal of ensuring public safety and preventing fraudulent or misleading marketing/advertising by refocusing government attention back to educating consumers about how they could safely choose from among and use dietary supplement products and dietary ingredients derived from natural resources, not otherwise deemed scientifically harmful to human health (unsafe), as an addition to and enhancement of their daily food

[1] That earlier law had been derogated by Article 53 of Decree 3636 (10/11/05), and then further derogated by Decree 3249.

[2] "No national pharmacopoeia exists, nor is one planned; in lieu of this, the United States pharmacopoeia, Codex francés and British herbal pharmacopoeia are used. The information is considered legally binding. National monographs exist, but they are not legally binding... Regulatory requirements for manufacturing include adherence to the information contained in pharmacopoeias and monographs, the same rules of GMP as for conventional pharmaceuticals, and special rules... Safety assessment requirements include traditional use without demonstrated harmful effects, reference to documented scientific research on similar products and clinical studies. Compliance with these requirements is ensured by a health registry. There is a registration system for herbal medicines" *See* "National Policy on Traditional Medicine and Regulation of Herbal Medicines - Report of a WHO Global Survey", World Health Organization (2005) at: http://www.who.int/medicinedocs/index.fcgi?a=d&d=Js7916e.9.2#Js7916e.9.2 . According to the WHO, there are "seven possible regulatory categories for herbal medicines...prescription medicines, over the counter medicines, self medication only, herbal medicines as a separate regulatory category, dietary supplements, health foods, functional foods and other status." *Id*., at 'Section 3.2 – Regulatory Status of Herbal Medicines'. In the U.S. for example, herbs are treated under DSHEA as dietary supplements – i.e., as plant-based 'food'.

[3] Decree 337 then provided that "food based in natural resources on pharmaceutical presentations as capsules with no therapeutic indications can no longer be classified as food". Decree 337 prescribed sanitary regulations for natural resources used in 'pharmaceutical processes', the elements of which could potentially cause contamination or need special service while being collected or stored. While the regulation ostensibly was concerned with the pharmaceutical processes employed to ensure safety and products' intended uses, it effectively focused on the form / presentation of products.

diet.[4]

- **DRAFT ARTICLE 1, AMENDING DECREE 3249, ARTICLE 3, ITEM # 2:** ("The maximum quantity permitted of vitamins, minerals and trace elements for...Dietary Supplements...for daily consumption will be the level of daily maximum consumption indicated in Annex 1 of this decree, which abrogates annex 1 of Decree 3249 of 2006").

The ITSSD wishes to remind the Ministry of Social Protection of the criteria set forth within the *Guidelines for Vitamin and Mineral Food Supplements*[5] established by the Codex Alimentarius which are applicable to dietary supplement products and ingredients regulated as 'foods'. Assuming that the draft amendments to Colombian Decree 3249 are actually intended to treat certain dietary supplement products and ingredients as 'foods' rather than as 'medicines', then the Codex guidelines' discussion of the recommended process for determining maximum daily dosage limits for certain vitamin and mineral substances should be equally relevant and instructive, and perhaps, even controlling.

These guidelines recommend that "upper safe levels of vitamins and minerals [should be] 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". They also recommend that the "maximum amounts of vitamins and minerals in vitamin and mineral food supplements...shall be set, taking...into account the daily intake of vitamins and minerals from other dietary sources."[6]

The problem is that the *prescriptive* language of the draft amendment to Decree 3249, like that of Decree 3249 itself, merely refers to a predetermined list of maximum thresholds set forth in an amendment to Annex 1 of Decree 3249, which derogates Annex 1 of original Decree 3249. It is thus clearly inconsistent with the *quantitative and qualitative* standard contained in the international Codex Alimentarius guidelines, pursuant to which maximum daily thresholds are to be determined in accordance with *an evidentiary and science-based process/method*.

In addition, the language in DRAFT ARTICLE 1, AMENDING DECREE 3249, ARTICLE 3, ITEM # 2 is even more prescriptive and less science-based than that which it derogated/superceded in Article 3, Item #3 in original Decree 3249. That earlier provision required that vitamin, mineral and oligoelement (trace element) ingredients exceeding maximum recommended daily dosage must be 'justified', but it did *not* indicate what was meant by 'justification'; did it refer to a scientific justification? The uncertain standard it established was also less qualitative and quantitative than that which it derogated in Article 3,

[4] Article 2 of Decree 3636 (9/18/06) defined 'product for specific use' as a "Product, which without satisfying or meeting the requirements established to be a conventional food product, drug or phytotherapeutic product or pharmaceutical preparation based on natural resources or alcoholic beverages, adds elements or composites which may be coadjutants to maintaining the organism metabolic process and which contain such ingredients as vitamins, proteins, fiber, minerals, natural products, carbohydrates, amino acids, fat acids, plants, herbs, or algae, among others. Its purpose is to complement the intake of these nutrients taking as a basis the daily diet." Decree 3636 reflected a half-hearted attempt to recognize that although other countries had created a unique legal classification for dietary supplements and dietary ingredients in food supplements, such products were nevertheless treated as 'food'. For example, Article 2 of Decree 3636 stated that "Imported products already called at its country of origin 'dietary supplement' or 'dietary complement' or alimentary complement', 'nutraceutic', provided they comply with any and all provisions contained herein, are understood as products for specific use."

[5] *See* CAC/GL 55-2005, Article 1.3.

[6] *Ibid*., at Article 3.2.2.

Item #s 2 and 7 of prior Decree 3636 (10/11/05). Item #2 required that vitamin and mineral content for food supplements and dietary supplement ingredients exceeding maximum strengths established for food products to be "justified...with *scientific evidence* showing the effects in the quantities requested." Item #7 required "justification of specific functions of a component or components" of products for specific use "with studies based on *scientific evidence*".

Perhaps the departure of DRAFT ARTICLE 1, AMENDING DECREE 3249, ARTICLE 3, ITEM # 2 from the prior law's case-by-case evidentiary and science-based approach to one that relies almost entirely on prescribed limits contained in amended Annex 1, reflects a conscious effort to move Colombian dietary supplement regulatory law away from the more complex German and European Union model. Alternatively, it may signal Colombia's uncertainty concerning how best to merge both methods into an even more opaque regime intended to disguise the protection of Colombia's already strong domestic pharmaceutical sector from less expensive and more natural non-pharmaceutical products.[7]

[7] "The German administrative position has long been that of allowing a maximum of 3 times the RDA amount in the formulation of supplements of water soluble vitamins and correspondingly less (1 x RDA level) for vitamins with a narrower safety margin and for minerals. Any supplements with nutrients in higher dosage [were] kept off the market as 'illegal medicines' by a refusal to grant marketing authorization. Where such authorization was not sought, products were forced off the market...[T]he Commission took legal action against Germany, charging that the low-dose policy for supplements constituted an artificial barrier to European trade. The EU Court of Justice decided in April 2004, stating in its judgment that Germany was wrong to apply an across-the-board limit of 3 times the RDA to vitamin products. It was therefore no longer possible to consider all higher dosed products to be medicines to keep them out of the German market [,u]nless...it could be shown that each substance had been evaluated on its own merits. The European Food Supplements Directive [subsequently] decree[d] that maximum amounts of vitamins and minerals in food supplements shall be set, taking into account safety levels derived from what is referred to as 'scientific risk assessment'. The directive add[ed] 'varying degrees of sensitivity of population groups' as a parameter to be considered as well as expected nutrient intake 'from other dietary sources'... consistent with what Codex Alimentarius Nutrition Committee...decided would be best for the international market as well...[T]he EU directive was based on...a risk assessment model for deducing maximum safe levels of nutrients provided in supplements and fortified foods...established [during 2004 by]...[t]he "German Federal Institute for Risk Evaluation, formerly the Federal Office for Consumer Health Protection...[Pursuant to the] German...risk assessment strategy for vitamins and minerals...[u]pper safe levels as set by previous committee work, such as the European Scientific Committee on Foods, the U.S. Food and Nutrition Board and the UK's Expert Consultation on Vitamins and Minerals [were] not [to be] directly challenged. Instead... those previously established 'upper safe levels' [were to be]...use[d] and...re-interpret[ed]...in...light of further data. No mention of the fact that these previous levels [had] already...been set so low as to avoid any and all conceivable risks...Where previous committee recommendations appear[ed] too high by German standards... the amount [was to be] lowered by subtracting the highest possible estimates of intake from consumption of foods and fortified foods. The levels so obtained [were] then [to be] subjected to further 'risk assessment' to make sure no one ever, not even the most sensitive individual, w[ould] have too much of any one nutrient... Where that 'risk based' approach yield[ed] levels for a nutrient that [were] still considered too high, or where this approach d[id] not allow to determine an upper limit because there simply [wa]sn't any conceivable risk, [a]...fall[back] [was] proposed [-]...what the Germans call[ed] the 'nutritional-physiological' approach [-] adopting an upper level for supplementation consistent with the RDA, with 'nutritional need'...[For example, with respect to] vitamin B12...'no unwanted side effects ha[d] [yet] been described that could be connected to an excessive consumption of vitamin B12 from foods or supplements[;] so no tolerable upper level could be established. Therefore, an upper level based on mainly toxicological considerations is not possible and the proposed formula is not applicable'. 'For reasons of precaution and because of the incomplete knowledge base, the Risk Evaluation Institute (BfR) recommend[ed] that supplements should not contain more than a maximal dosage of 3 to 9 micrograms/day. The limitation [was] justified because of a physiologically limited capacity for absorption and because a significant increase of the recommended daily consumption does not bring any nutritional-physiological gains.' Scientific risk assessment [wa]s being used here to provide cover for a very different agenda. Consider that supplements on the international market of 300, 500, 1000 and more micrograms of vitamin B12 are by no means rare, and have never caused any problems to those consuming

- **DRAFT ARTICLE 1, AMENDING DECREE 3249, ARTICLE 3, ITEM #s 2 and 3**: ("...vitamins, minerals and trace elements for these products [with]...ingredients *established* by the following references sources... the [U.S.] FDA...and [its] respective updates...which can be found included in the reference sources list, annex three (3) of this decree...*will be accepted*...for production and commercialization...").

The ITSSD wishes to remind the Ministry of Social Protection that although dietary supplements generally fall under the jurisdiction of the U.S. Food and Drug Administration (FDA) which has the primary responsibility for administering and enforcing the U.S. Federal Food, Drug and Cosmetic Act (FD&C Act) and related statutes, the FDA does NOT 'establish', 'approve' or otherwise 'affirm' dietary supplements or their ingredients.[8] While it is possible to obtain an export certificate or a kind of verification from the FDA's Center for Drug Evaluation and Research (CDER), *the supplement product* for which such certification/verification is sought must first go through the complete FDA drug approval process which is *not* required as a matter of U.S. law, *unless* certain conditions prevail. For example, a dietary supplement product must be deemed: a) to pose an imminent hazard to public health or safety;[9] b) to contain an ingredient that renders it adulterated;[10] *or* c) to contain a new dietary ingredient for which there is inadequate safety information,[11] pursuant to Section 402 of the FD&C Act, as amended by the U.S. Dietary Supplement Health and Education Act of 1994 ('DSHEA').

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them, indeed it is acknowledged that 'no unwanted side effects have been described'. Yet, quantities available in supplements are to be limited to what is absolutely necessary, if the German authorities will have their way. *The whole of this German approach is extremely prescriptive. There [wa]s no latitude for consumers to decide for themselves, just like there [wa]s no space for real health outcomes to be pursued with supplements...Every detail [wa]s accounted for by the 'authorities'*...Supplements...[were] only and exclusively to be used for making sure that foods do not outright kill us by way of overt deficiency disease. Any use of supplements over and above avoiding certain death and disease, say, any extra to ensure optimal health or to avoid having to take pharmaceutical medication is definitely VERBOTEN... ***There [was] no winner, except the pharmaceutical business*** *with disease...Germany has long been one of the most restrictive countries on vitamin and mineral products, perhaps because of the relative strength of its pharmaceutical industry, which sees a threat to profits on pharmaceutical drugs as more and more people seem to turn away from drugs and try the 'natural option'"* (italicized emphasis added). *See* Josef Hasslberger, "Food Supplements: German Risk Institute Takes Dim View" (Jan. 20, 2005) at: http://www.newmediaexplorer.org/sepp/2005/01/20/food_supplements_german_risk_institute_takes_dim_view.htm . *See also* "Germany Develops Maximum Safe Levels for Vitamin, Mineral Intake", Nutra Ingredients.com Europe (Jan. 18, 2005) at: http://nutraingredients.com/news/ng.asp?id=57408&n=dh18&c=lmqbgluszkwtiej .

[8] The U.S. FDA does not possess the authority under DSHEA to 'approve' supplements. Dietary supplements are not subject to pre-market review or approval by the FDA before being marketed. Manufacturers and distributors are not required to submit to FDA scientific information about product safety or any benefits that its dietary supplement product may be represented to have; rather manufacturers and distributors are held totally responsible for their products – they must guarantee that their products are safe. And, consumers must exercise their judgment in deciding whether to purchase such products. In order for the FDA to regulate dietary supplements, it must first establish that dietary supplements are harmful to human health or that they are otherwise labeled incorrectly or in a misleading manner such as to be potentially unsafe. For example, the FDA may treat a dietary supplement as a drug for regulatory purposes (i.e., require extensive clinical trials before pre-market approval) and may even cause removal of dietary supplements from the marketplace if mislabeled, i.e., where the manufacturer has made medical claims on their packaging or on their website. The FDA's usual role, in other words, is to verify that products sold do not bear labels that mislead consumers or make exaggerated claims regarding the properties of the product such that they may pose harm to human health.

[9] *See* DSHEA Sec. 402 (f)(1)(A) or (C).

[10] *See* DSHEA Sec. 402(f)(1)(D) and Sec. 413.

[11] *See* DSHEA Sec. 402(f)(1)(B).

Apart from and notwithstanding these conditions, a dietary *ingredient* contained in a dietary supplement product, as set forth in Section 201(ff)(1) of the FD&C Act, as amended by the DSHEA, is otherwise deemed to be a 'food' within the meaning of Section 201(ff) of the FD&C Act. Consequently, it is *not* treated as a 'food additive' under Section 201(s)(6) of the FD&C Act added as part of the 1958 Food Additives Amendment to the FD&C Act,[12] and thus it is *not* subject to FDA regulation – i.e., it is not established or approved by the FDA.

Further, still, it is recognized that "some dietary ingredients that may be used in a dietary supplement may otherwise escape FDA regulation if they are considered 'GRAS' (Generally Recognized as Safe) [13] *for use in a conventional food* (e.g., vitamin C; calcium carbonate),"[14] pursuant to Section 201(s)(4) of the FD&C Act. This regulatory exclusion (of food supplements as GRAS) is separate and distinct from the prior regulatory exclusion for dietary ingredients (of dietary supplements from the definition of food additive) under Section 201(s)(6) of the FD&C Act.[15]

The ITSSD therefore recommends that the language of DRAFT ARTICLE 1, AMENDING DECREE 3249, ARTICLE 3, ITEM # 3 be changed to read as follows:

> *"Those ingredients, additives or substances expressly restricted by current Colombian legislation on this matter, or in the Codex Alimentarius, shall not be accepted; but, all ingredients, substances or additives along with their concentrations, presentations, mixes, classification, labeling, containers and claims shall be accepted, as long as they are in the FDA's entire regulatory system which provides protection to public health for processing and manufacturing of products (including dietary supplements DSHEA Public law 103-417) and/or the European Community, 2002-46-CE of the European Parliament and/or by the Alimentarius Codex regulated by Directive CAC/GL 55-2005."*

- **DRAFT ARTICLE 1, AMENDING DECREE 3249, ARTICLE 3, ITEM # 4** ("The substances not included in the previous listings will be considered *new dietary supplement ingredients*...").

The ITSSD once again wishes to emphasize to the Ministry of Social Protection that the U.S. FDA does *not* regulate and need *not* 'approve' prior to manufacture or sale *substances added to foods* if any one of the exclusions described above applies. To reiterate, a substance used in a dietary supplement as a

[12] "The term 'food additive'…does not include an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement. *See* Sec. 201(s)(6) of the FD&C Act. *See also* "GRAS: Time-Tested, and Trusted, Food Ingredients", FDA *Consumer Magazine* U.S. Food and Drug Administration (March-April 2004) at: http://www.fda.gov/Fdac/features/2004/204_gras.html .

[13] A GRAS substance is one that has a long, safe history of common use in foods or that has been determined to be safe based on proven published scientific evidence, though a GRAS designation does not guarantee a substance's safety. A substance may be GRAS for one use but not for others.

[14] *See* "Frequently Asked Questions About GRAS", at par. 7, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN) (Dec. 2004) at: http://www.cfsan.fda.gov/~dms/grasguid.html and http://www.cfsan.fda.gov/~dms/grasguid.html#Q7 .

[15] "Thus, it is meaningless to refer to a GRAS exclusion from the food additive definition for dietary ingredients that are already excluded from that definition." *Ibid.*

'dietary ingredient' within the meaning of Section 201(ff) of the FD&C Act [21 U.S.C. 321(ff)(1)]/*DSHEA* for *the purpose of supplementation* is outside the scope of the separate *food additive/GRAS provisions* of Sections 201(s)(4) and 201(s)(6) of the FD&C Act [21 U.S.C. 321(s)(4) and(6)].[16] Accordingly, except if used for a technical purpose, within the meaning of Section 201(s) and 409 of the FD&C Act [21 USC 348], [17] the agency's food additive regulations do *not* apply to the use of section 201(ff)(1) ingredients in dietary supplements. [18]

Despite the clear distinctions between these provisions which were designed to serve different policy objectives, it nevertheless appears that the Colombian government is endeavoring to conflate, confuse and treat said provisions as if they were one, for Colombian law purposes. The cross reference in Item #4 to the 'sources of reference' and 'reference sources list' in Item #3 arguably reflects such an effort, because the Colombian government recognizes that 'lists' are most relevant for GRAS purposes.

The ITSSD therefore recommends that the draft amendment language of DRAFT ARTICLE 1, AMENDING DECREE 3249, ARTICLE 3, ITEM #4 be changed to read as follows:

> *"A substance used in a dietary supplement as a 'dietary ingredient' within the meaning of 21 U.S.C. 321(ff)(1) for the purpose of supplementation is outside the scope of the food additive/GRAS provisions of the Act (per 21 U.S.C. 321). Colombian legislation should not require, that the Dietary Ingredient, must be GRAS."*

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[16] "Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information. Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers." *See* "Frequently Asked Questions About GRAS", at pars. 1-2, *supra*.

[17] Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a **food additive, that is subject to pre-market review and approval by FDA**, ***unless*** the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, *or unless the use of the substance is otherwise excluded from the definition of a food additive*. For example, substances whose use meets the definition of a pesticide, ***a dietary ingredient of a dietary supplement***, a color additive, a new animal drug, or a substance approved for such use prior to September 6, 1958, are excluded from the definition of food additive, and thus deemed GRAS. Dietary ingredients (e.g., vitamins, minerals, amino acids, herbs, etc.) are specifically excluded from the GRAS/food additive provisions of the act and U.S. FDA does not 'approve' or otherwise affirm their safety or lawfulness. Some dietary ingredients that may be used in a dietary supplement may also be GRAS for use in a conventional food (e.g., vitamin C; calcium carbonate).

[18] Pursuant to DSHEA, if a dietary ingredient has not been previously marketed as a dietary supplement in the United States, it may be deemed a 'new dietary ingredient' that must comply with the statutory requirements in section 413 of the Act. A dietary supplement that contains a new dietary ingredient shall be deemed adulterated pursuant to that provision unless it meets one of two requirements: (1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or (2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. *See* DSHEA Sec. 413 (a).

Moreover, although the FDA is not required to regulate GRAS,[19] it monitors and maintains several GRAS substance/use notification lists.[20] The ITSSD wishes to emphasize, however, that these lists are *not* all-inclusive, as the notification procedure itself has not been finalized by FDA, and thus remains voluntary.[21] Since the use of a GRAS substance is not subject to FDA pre-market review and approval, it is impracticable for the FDA to list all GRAS substances that are actually used in food. This means that the use of a substance may be GRAS even if it is not listed by FDA as GRAS.[22]

Consequently, if DRAFT ARTICLE 1, AMENDING DECREE ARTICLE 3, ITEM #4 is adopted as currently drafted such that it treats as 'new dietary supplement ingredients', for which sanitary registrations and pre-market authorizations are required, all GRAS substances/uses *not* included within a 'positive' FDA GRAS list, Decree 3249 would have the practical effect of banning from Colombian markets many U.S-based GRAS ingredients. In other words, it will become apparent to the world based on the source listings contained in Annex 3 that the likely aim of this draft amendment to Decree 3249 is to create new technical barriers to trade.

- **DRAFT ARTICLE 2, AMENDING DECREE 3249, ARTICLE 7 and Paragraphs 2 and 3**: ("For the dietary supplements that are produced in the country or imported, the Certificate of Fulfillment of the Good Practices of Manufacture *for Medicines* will be accepted...When...dietary supplements [are] manufactured in laboratories of Phytotherapeutics...the Certificate of Fulfillment of the Good Practices of Manufacture ...or the Certificate of Productive Capacity...will be accepted...Additionally, the interested party should contribute, prior to the

[19] Generally speaking, a substance may not be found to be GRAS because it: i) has no proven track record of safety, and thus deemed a 'food additive'; ii) is being employed for new uses not previously sanctioned; *or* iii) has long been GRAS but raises new health concerns subject to investigation ('GRAS Affirmation') "GRAS affirmation is a process that FDA developed in the 1970s. In response to concerns raised by new information on cyclamate salts, then-President Nixon directed FDA to re-examine the safety of substances considered to be GRAS. FDA announced that the agency would evaluate, by contemporary standards of the time, the available safety information regarding substances considered to be GRAS. If the revaluation of current data confirmed that use was GRAS, FDA would promulgate a new GRAS regulation, affirming that finding. FDA also established procedures whereby an individual could petition FDA to review the GRAS status of substances that would not have been considered as part of the agency's GRAS review." *See* "Frequently Asked Questions About GRAS", at par. 9, *supra* at: http://www.cfsan.fda.gov/~dms/grasguid.html#Q9 .

[20] *See, e.g.*, "Numerical Listing of GRAS Notices", U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, CFSAN/Office of Food Additive Safety (Jan. 2008), at: http://www.cfsan.fda.gov/~rdb/opa-gras.html .

[21] "On April 17, 1997, FDA issued a proposed rule (the GRAS proposal; 62 FR 18938) that would establish a notification procedure whereby any person may notify FDA of a determination by that person that a particular use of a substance is GRAS. Although the proposed notification procedure is not yet final, FDA started accepting GRAS notices in 1998." *See* "About the GRAS Notification Program", U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, CFSAN/Office of Food Additive Safety (Aug. 2007) at: http://www.cfsan.fda.gov/~dms/gras-ov.html . The GRAS notification program provides a voluntary mechanism whereby a person may inform FDA of a determination that the use of a substance is GRAS, rather than petition FDA to affirm that the use of a substance is GRAS. Although operating under an interim procedure, pending the publication of a final rule, FDA has received and responded to nearly 200 GRAS notices for a variety of substances including carbohydrates, lipids, proteins, and chemicals such as gases, inorganics [and] organics..." *See* Paulette Gaynor and Sebastian Cianci, "Regulatory Report: FDA's GRAS Notification Program Works", U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition (Dec. 2005/Jan. 2006) at: http://www.cfsan.fda.gov/~dms/grasov2.html .

[22] "The use of a substance is GRAS because of widespread knowledge among the community of qualified experts, not because of a listing or other administrative activity." *See* "Frequently Asked Questions About GRAS" *supra* at pars. 16-17.

request of the sanitary registration and production of the dietary supplement, a written petition validating the cleanliness or sanitation *of the product* before the Subdivisions of Medicines and Biological Products of the National Institute for Monitoring Medicines and Foods, INVIMA...The authorization for the production of dietary supplements in laboratories that make medicines or Phytotherapeutics will be subject to the maintenance of the...*hygienic, technical and...quality control conditions* under which the production capacity was granted [consistent with]...the Good Practices of Manufacture [i.e., inspections]...[F]or...manufacture of dietary supplement products...in food plants, the producer will have to obtain the Certificate of Fulfillment of the Good Practices of Manufacture of Dietary Supplements...").

DRAFT ARTICLE 2, AMENDING DECREE 3249, ARTICLE 7 and Paragraphs 2 and 3 essentially mandate that dietary supplements imported into Colombia satisfy more extensive and expensive 'drug' rather than 'food' Good Manufacturing Practices (GMPs) and inspections. This is likely to create difficulties given the many differences between dietary supplements and pharmaceutical products. Curiously, this draft amendment to Decree 3249 does *not*, unlike Article 7 of original Decree 3249, permit the dietary supplement manufacturer and/or importer to secure "a Certificate of Good Manufacturing Practices *for Food Products* issued by...INVIMA *or an equivalent document issued by the competent authority in the country of origin*" – e.g., the U.S.

The ITSSD wishes to remind the Ministry of Social Protection of the U.S. FDA's recent issuance of "a final rule establishing regulations [that] require current good manufacturing practices (cGMP) for dietary supplements", which could arguably be considered as an 'equivalent' process for purposes of obtaining a Certificate of Good Manufacturing Practices for Food Products under Article 7 of original Decree 3249, or obtaining a Certificate of Fulfillment of the Good Practices of Manufacture of Dietary Supplements under Article 7, Third Paragraph of the draft amendment to Decree 3249.

"The new FDA final rule ensures that dietary supplements are produced in a [consistent] manner, [meet] quality [standards,] do not contain contaminants or impurities, and are accurately labeled."[23] The cGMP applies "to all domestic and foreign companies that manufacture, package, label or hold dietary supplements, including those involved with the activities of testing, quality control, packaging and labeling, and distributing them in the U.S... [T]he rule has a staggered three-year phase-in for small businesses...[t]o limit any disruption for dietary supplements produced by [such] businesses. The final cGMP is effective in June 2008 for large companies. Companies with less than 500 employees have until June 2009 and companies with fewer than 20 employees have until June 2010 to comply with the regulations...[There is also an]...interim final rule (IFR) [that] establishes a petition process for a manufacturer to apply for exemption from the 100 percent identity testing requirements for dietary ingredients used in manufacturing dietary supplements...The IFR is effective in June 2008 when the cGMP final rule becomes effective. [24] These more specific rules supplement the more basic and general

[23] *See* "FDA Issues Dietary Supplements Final Rule", FDA News, U.S. Food and Drug Administration (June 22, 2007) at: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01657.html . *See also* "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Final Rule", 72 *Federal Register* 34751 (June 25, 2007) at: http://www.cfsan.fda.gov/~lrd/fr07625a.html .

[24] "The manufacturer would have to provide data in its petition demonstrating that less than 100% identity testing does not materially diminish assurance that the dietary ingredient is the correct dietary ingredient." *See* "Fact Sheet: Dietary Supplement Current Good Manufacturing Practices (CGMPs) and Interim Final Rule (IFR) Facts" U.S. Food and Drug

food GMPs, and should be seriously considered by the Ministry of Social Protection before adopting the draft amendments to Article 7 of Decree 3249.[25]

2) General Comments:

Administration, Center for Food Safety and Applied Nutrition, CFSAN (June 22, 2007) at: http://www.cfsan.fda.gov/~dms/dscgmps6.html . *See also* "Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements", 72 Federal Register 34959 (June 25, 2007) at: http://www.cfsan.fda.gov/~lrd/fr07625b.html .

[25] "The general food CGMPs in part 110 (21 CFR part 110) largely address practices designed to ensure that food is manufactured, processed, packed, and held under sanitary conditions and that the food is safe, clean, and wholesome. Although the general food CGMPs in part 110 apply to a variety of food products, including dietary supplements, they do not address the unique characteristics of certain specific types of food products. The agency has implemented separate, and more specific, CGMPs for various types of food products to provide for process controls in manufacturing that are not captured by the more general part 110 food CGMPs...Dietary supplements are a type of food product for which specific food CGMPs also are needed. Manufacturing process controls are needed to ensure that a dietary supplement contains what the manufacturer intends. Unlike most foods, the majority of dietary supplements are packaged into tablets, gelcaps, and capsules. Some dietary supplements may contain bioactive ingredients for which certain, controlled amounts are intended to be in each tablet or capsule. The process controls that must be in place to ensure the tablet or capsule contains what it purports to contain are different than those that must be in place to ensure a food is manufactured, processed, packed, and held under sanitary conditions. Process controls for dietary supplement manufacture include establishing and meeting specifications to ensure the finished dietary supplement contains the correct ingredient, purity, strength, and composition intended. Vitamins can present a concentrated source of biologically active components. A vitamin, for example, that contains too high a concentration, such as vitamin D at levels that are many times greater than intended, can lead to illness and hospitalization (Refs. 7 and 8). A manufacturer must establish a process for manufacturing a dietary supplement product in order to produce the product consistently and reliably each time. In order to achieve consistency and reliability, there must be process controls in place to ensure, for example, that appropriate tests and examinations are conducted, a master manufacturing record is prepared, each batch production follows the master manufacturing record, and the finished tablet or capsule is placed in the intended package with the intended label. These same types of controls are needed for herbal and botanical dietary supplements. Botanicals are often complex mixtures that can vary in composition depending on factors such as the part of the plant used, the location of harvesting and growing conditions that can vary from year to year even in the same location. It can be difficult to distinguish between closely related species of botanicals, and the biological activity of components of an incorrectly identified species can lead to adverse consequences. In addition, different species may be present in different ratios or blends in a particular product. Various products might contain different parts of the plant--flower, leaf, root, stem, extract--and the test methods for each can vary in the nature, sensitivity, and specificity of the test. Well-established principles of CGMP require process controls at each step of the manufacturing process as early in the production process as possible. Quality cannot be tested into the product only at the end (Ref. 9). Instead, the quality of the dietary supplement must be built into the product throughout the manufacturing process; quality begins with the starting material and continues with the product being manufactured in a reproducible manner according to established specifications. It is not sufficient, nor effective, to rely solely on end product testing to assure the quality of the individual dietary supplement product sold to the consumer. CGMPs are intended to establish a comprehensive system of process controls, including documentation of each stage of the manufacturing process, that can minimize the likelihood of, or detect, problems and variances in manufacturing as they occur and before the product is in its finished form. These process controls that are a part of CGMPs are essential to ensure that the dietary supplement is manufactured, packaged, held, and labeled in a consistent and reproducible manner. Manufacturing according to CGMP means that the manufacturing process incorporates a set of controls in the design and production processes to assure a quality finished product. CGMPs specific to dietary supplements are necessary to help ensure that these products have the identity, purity, strength, and composition that meet specifications established in the master manufacturing record and that they are not adulterated... To clarify what dietary supplement CGMP requirements are intended to achieve, we have added a definition of quality in the final rule. As defined, quality means 'that the dietary supplement consistently meets the established specifications for identity, purity, strength, and composition and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the Federal Food, Drug, and Cosmetic Act.'" *Id*. at 34761-62.

For all intensive purposes, the draft amendments to Decree 3249, along with original Decree 3249, arguably set forth a more opaque and onerous scheme of dietary supplement regulation than is otherwise necessary to achieve fulfillment of what might be characterized as legitimate public policy objectives, within the meaning of the WTO Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements. Consequently, the draft amendments each must be viewed in light of their underlying public policy goals, the manner in which such goals are to be achieved, and the economic industry dynamic surrounding and informing the policy decisions proposed and adopted.

Article 1 of original Decree 3249 sets forth public policy objectives of "protect[ing] people['s] health and...prevent[ing] practices that may mislead consumers." To achieve this goal, it establishes rules to regulate the procedure of sanitary registration, manufacturing, packaging, labeling, quality control, marketing, publicity, usage, Good Manufacturing Practices and the system for surveillance and sanitary control of national and imported dietary supplements being marketed in the country..." Article 2 of original Decree 3249 indirectly sets forth another public policy objective through its definition of a dietary supplement – i.e., as a "product whose objective is to add normal diet and is a concentrated source of nutrients and other substances having physiological or nutritional value which may also have vitamins, minerals, proteins, amino acids, nutrients and nutrients derivatives, plants and pure or combined plant extracts."

There are five categories/classifications for virtually the same products described in the Codex Alimentarius guidelines (CAC/GL 55-2005), three of which are designated as 'medicines'[26] based either on presentation and/or ingredient concentration /maximum dosage thresholds which are determined in a *prescriptive* manner rather than pursuant to an empirical process grounded on objective science-based risk assessment. In this regard, original Decree 3249 and its draft amendment are little different from prior Decree 3636, Article 3, Paragraphs 2 and 3, which classified dietary supplements and vitamin preparations, as well as vitamins and minerals serving as the sole active principle in food products or combinations thereof, as 'medicine products', pursuant to the provisions of the 2002 Pharmacological Norms Manual adopted pursuant to Resolution 0620 of 2002.

Remarkably, even the complexity-prone European Commission classifies food into only *three* broad groups: 1) foods for particular nutritional uses (dietary foods); 2) food supplements; and 3) normal foods. Substances which may be added for nutritional purposes include vitamins, minerals, and certain other categories of nutrients such as amino acids and other nitrogen-containing substances in foods for particular nutritional uses. Such nutritional substance add-ons are controlled through several positive lists.[27]

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[26] The five categories and their classifications are as follows: 1) Dietary Supplements (Not classified as food nor medicine); 2) Phytotherapeutics (Regulated as medicines); 3) Pharmaceutical preparation of natural origin (Regulated as medicines); 4) Medicines; and 5) Foods in non pharmaceutical presentation (rule for some ingredients in certain powder or liquid concentrations – according to resolution 11488 of 1984).

[27] *See* Administrative Guidance on Submission s for Safety Evaluation of Substances Added for Specific Nutritional Purposes in the Manufacture of Foods", EUROPEAN COMMISSION HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL (12/7/06) at: http://ec.europa.eu/food/food/labellingnutrition/nutritional/adm_guidance_safety_substances_en.pdf ; "Labeling & Nutrition, Food Supplements: Food Safety - From the Farm to the Fork", Europa Website at: http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm ; Directive 2002/46/2002 (June 10, 2002) at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:183:0051:0057:EN:PDF , amended by Directive 2006/37/EC (March 30, 2006) at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:094:0032:0033:EN:PDF

While it may be agreed that the regulatory model of the U.S. and Colombia need not be so similar as to be indistinguishable, it may nevertheless be argued that the policy goals concerning food supplements and dietary ingredients need not be so dissimilar as to justify a costly divergent health risk management approach that could significantly affect U.S. exports of such products and substances to Colombia. If the Colombian Ministry of Social Protection is serious about setting the appropriate maximum concentrations for dietary supplement products and related ingredients in order to protect the public interest, then it should openly welcome a more scientific, transparent and less prescriptive method of determining those thresholds.

In addition, Article 9 of original Decree 3249 requires a manufacturer, importer and marketer/seller of dietary supplement products within Colombia to obtain a sanitary registration from the National Drug and Food Surveillance Institute, INVIMA. Section B. of Article 11 of original Decree 3249 provides that, in addition to all of the documentation required to obtain a sanitary registration in Colombia for national products, *imported products* must also be accompanied by a certificate of authorization for human consumption *issued by the sanitary authority of the exporting country*. Since the U.S. Food and Drug Administration does not approve dietary supplements, the 'certificates of free sale'[28] issued by the U.S. FDA contain no language affirming that a product is safe, is approved by the FDA, or that it is lawful and may be freely marketed in the United States.

As noted above in Section 1 of these Comments, the Colombian Ministry of Social Protection should recognize that the FDA does NOT establish or approve dietary supplements or their ingredients. While it is possible to obtain an export certificate or a kind of verification from FDA's Center for Drug Evaluation and Research (CDER), the supplement product for which such certification/verification is sought must first go through the complete drug approval process. This takes a long time, costs a lot of money and requires a lot of clinical testing. Consequently, the failure of a U.S. exporter of finished dietary supplement products to provide a Colombian importer with a U.S. sanitary registration would likely subject the importer to costly testing and verification procedures in Colombia which are likely to cause the imported product to lose its price competitiveness in the Colombian domestic market.

According to the U.S. Department of Commerce, "U.S. companies retailing nutritional supplements in Colombia [have] continue[d] to experience problems [since at least 2003,] due to the lack of legislation that establishes clear parameters for sanitary registration. Colombia does not have a specific classification for nutritional supplements, causing nutritional supplements to be registered as nourishing products or medicines. In those categories, the products must meet certain requirements that nutritional supplements don't have to."[29]

; Discussion Paper on the Setting of Maximum and Minimum Amounts for Vitamins and Minerals in Foodstuffs, European Commission, Health and Consumer Protection Directorate-General (June 2006) at: http://ec.europa.eu/food/food/labellingnutrition/supplements/discus_paper_amount_vitamins.pdf ; Framework Council Directive 89/398/EEC (May 3, 1989) at: http://ec.europa.eu/food/food/labellingnutrition/nutritional/d89-398-ec.pdf .

[28] The 'Certificate of Free Sale' is for food, including dietary supplements, and cosmetic products that may be legally marketed in the United States. A Certificate of Free Sale is insufficient to substantiate safety of the product. It just states that the FDA regulates the manufacturer, who is operating in compliance with the law, but gives no assurances about the product per se.

[29] *See* "Doing Business in Colombia: A Country Commercial Guide for U.S. Companies", U.S. & FOREIGN COMMERCIAL SERVICE AND U.S. DEPARTMENT OF STATE, 2004, at p. 15, at: http://www.export.gov/docs/x_7368283.pdf . *See* also

In light of all the complexities characterizing the opaque and prescriptive regulatory regime established by the Colombian government, including the continuous and frequent amendments to the relevant laws (e.g., Decrees 3636, 3249, 915, etc.) reasonable persons may conclude that such regime was actually designed other than to ensure against genuine public health risks and to provide protection from consumer fraud. Rather, it is arguable that such regime was primarily intended to function as a disguised technical trade barrier that protects the economic interests of entrenched domestic dietary supplement companies and foreign and domestic pharmaceutical companies operating within Colombia from lower priced and more efficient foreign dietary supplement competitors.

The dynamic of the Colombian market for medicinal plants and pharmaceutical products seems to bear this out. Market data confirm that, "In Colombia, the use of medicinal plants is linked to cultural traditions [and]...conventional (synthetic) medicines tend to be very expensive or inaccessible to lower social classes or rural communities." As a result, "medicinal plants and natural products [offer] a very interesting alternative."[30] In addition, "[m]ost Colombian companies [have been] focused on the production of finished products (cosmetic, nutritional supplements, phytopharmaceuticals) for consumers in local markets. There is not much export of these products; almost every laboratory produces its own ingredients for its own finished products." In the absence of a viable export market for Colombian manufactured dietary supplement products,[31] it is not surprising that the domestic companies have remained especially covetous of their local market position and have lobbied to preserve it. This could be achieved through imposition of complex and opaque regulations that would serve to block American dietary supplement company access to the Colombian market and to prevent the penetration of lower-priced and more competitive U.S. products.[32]

Market data also reveal that Colombia has a robust and highly competitive pharmaceutical industry consisting not only of indigenous manufacturers,[33] but also comprised of foreign companies and their

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National Foreign Trade Estimates 2007 at p. 151, at: http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_NTE_Report/asset_upload_file855_10945.pdf .

[30] *See* Jose Andres Diaz Merchán, BioTrade National Programme in Colombia, Alexander von Humboldt Institute and Lina Maria Ibañez (Proexport Colombia), "SECTOR ASSESSMENT: Natural Ingredients for Cosmetics and Pharmaceuticals in Colombia", UNCTAD /DITC/TED/2004/2 (Sept. 2004) at p. 8, at: http://www.biotrade.org/National/Colombia/Colombia-docs/colombia-assessment-naturalingredients.pdf .

[31] "Although the country has a substantial medicinal flora, current legislation permits the use of only a few plants (around 96, most of them being non-native)...due to the non- existence of guarantees regarding the toxicity and effectiveness of the plants...This context only allows for the development of products with the permitted plants, disregarding possibilities for research and development with new and native plants. The result is that although there are many interesting plants to work with, there is little scientific research to make industrial developments possible. The main challenge of the sector, therefore, is to achieve export development by using Colombian endemic plants in a sustainable way." *Ibid*.

[32] "That is why BIOTRADE Colombia has two areas of action: a) to support the consolidation of companies in local markets, and b) to access international markets with the natural ingredients." *Ibid*. *See also* Lawrence A. Kogan, "Trade Protectionism: Ducking the Truth About Europe's GMO Policy", International Herald Tribune (Nov. 27, 2004) at: http://www.iht.com/articles/2004/11/27/edkogan_ed3_.php .

[33] "The domestic [pharmaceutical] industry is dominated by multinationals. Major indigenous manufacturers include Bussie, Genfar, Lafrancol, La Sant, Procaps and Tecnoqumicas" [but] is heavily dependent on imports of raw materials." *See* "The

local /domestic subsidiaries which have invested significantly in their local operations and in developing their local markets. Indeed, "between 2005 and 2006, imports of the pharmaceutical sector increased 33.7% from US$ 549 million to US$ 735 million. Approximately 80% of imports were in finished goods, and the remaining 20% were raw materials."[34] These imports largely originated from the United States (US$ 133.4 million – 18% of all imports), Germany (US$ 72.4 million – 10% of all imports), Brazil (US$ 61.7 million – 8% of all imports), Mexico (US$ 55.7 million – 8 % of all imports) and France (US$ 52.7 million – 7% of all imports). In fact, these five countries sourced 51% of all Colombian imports of pharma products.[35] The main import products were medications for oncological and HIV treatment, which grew 38.8%, and therapeutic medications, which grew 32.1%" (36% of all pharma imports).[36] By company, the "largest importers in 2006 were Productos Roche S.A (Swiss-based), Abbott (US-based), Laboratorios de Colombia S.A (domestic-based), Schering Colombiana S.A (German-based) and Laboratorios Wyeth INC (US-based), each with a similar share of total imports, and none of them above 8% of the total." [37]

Unlike the domestically focused dietary supplements manufacturers which lack a viable export market for their products, however, Colombian pharmaceutical product exports grew 10.5%, from US$ 272 million to US$ 300 million...[b]etween 2005 and 2006. The great majority of the exports [were] finished products (98% in 2004)." During 2006, exports of therapeutic medications accounted for 50% of total pharmaceutical exports (US$ 152.4 million), and vitamins accounted for 7% of total pharmaceutical exports (US $21 million).[38]

Thus, it would appear more than likely, as in the case of Germany, described above in Section 1, that Colombia's relatively strong pharmaceutical industry would be inclined to favor a more restrictive regulatory regime on vitamin and mineral products the requirements of which they could easily satisfy. Both the Colombian pharmaceutical companies and the Colombian government would therefore find it difficult to deny that they have remained concerned that the lower priced foreign (e.g., American) dietary supplement products and ingredients, which have grown in popularity among price conscious Colombian consumers who also seem to favor natural and herbal medicine-based alternatives, could seriously undermine the profit margins on Colombian-manufactured pharmaceutical drugs, and hence the Colombian economy at large.

Indeed, informed persons could credibly argue that such a result is consistent with the activities typically undertaken by "a wide variety of economic associations (gremios) [that have] existed in the Colombian agriculture, banking, commerce, construction and insurance industries. They seldom initiated policy changes, but they often tried to amend or defeat legislation proposed by the executive; they also resorted to court challenges to delay or impede implementation. The largest *gremios* exercised significant influence on governmental leaders and had elaborate, well-staffed organizations with departmental and

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Pharmaceutical Market: Colombia", Strategic Report Summary (Epsicom Publishers Aug. 2006), reported on Piribo Business Intelligence website at: http://www.piribo.com/publications/country/latin_america/pharmaceutical_market_colombia.html .

[34] *See* "THE PHARMACEUTICAL SECTOR IN COLOMBIA", ProExport Colombia (2006) at p. 7, at: http://www.proexport.com.co/VBeContent/library/documents/DocNewsNo5452DocumentNo7399.PDF

[35] *Ibid*., at p. 8.

[36] *Ibid*.

[37] *Ibid*.

[38] *Ibid*., at pp. 6-7.

local affiliates."[39] It is probable that members of at least one of these associations were in favor of the recent draft amendments to Decree 3249.[40]

Lastly, the Colombian government must seriously evaluate the likely socio-economic fallout from their creation of but another disguised protectionist regulatory regime. Have the Colombian regulators even thought about how unnecessarily opaque and complex rules can serve to reduce indispensable U.S. and EU knowledge-based trade and investment flows to Colombia? Do not the Colombian regulators appreciate how such foreign trade and investment flows could diminish if foreign businesses and investors begin to lack confidence in Colombian government officials and institutions due to their inability or failure to enforce the rule of law? Have the Colombian authorities taken into account how these regulations could adversely affect the further development and advancement of native Colombian crops of medicinal plants which are integrally linked to Colombia's cultural traditions and economic future? Have the Colombian government and business communities calculated what it will truly cost American taxpayers and Colombian businesses and citizens in the future, in terms of foregone or reallocated U.S. investment dollars, if Americans are forced to pay more now in order to eradicate these illegal Colombian crops? Have Colombia's economic associations studied how, as a consequence of their gamesmanship, the opportunity to create new, higher paying, and thus more desirable jobs for Colombia's lower and middle classes – value-added jobs which could serve as a viable and profitable long-term alternative to the short-term expediency of cultivating more and more cocoa leaves crops - could be squandered? And, have the Colombian authorities and economic associations thoughtfully considered whether and to what extent these technical regulations might harm ongoing Colombia-US Free Trade Agreement negotiations, if U.S. government officials, congressional representatives and businesses believe they were designed, adopted and/or employed as disguised protectionist barriers to market access?

[39] *See* "Economic Associations" in *Colombia: A Country Study*, Federal Research Division of the Library of Congress, Dennis M. Hanratty and Sandra W. Meditz, Eds. (1988) at http://countrystudies.us/colombia/93.htm ; http://countrystudies.us/colombia. "[T]hese associations included the National Association of Manufacturers (Asociación Nacional de Industriales--ANDI), the National Federation of Merchants (Federación Nacional de Comerciantes--Fenalco), the National Federation of Colombian Coffee Growers (Federación Nacional de Cafeteros de Colombia--Fedecafe), and the Colombian Popular Association of Small Manufacturers (Asociación Colombiana Popular de Industriales--Acopi)." *Ibid.*

[40] ANDI, with its pharmaceutical members, was most likely in favor of the recent amendment to Decree 3249. "A strong advocate of free enterprise, ANDI was composed of more than 500 of the largest industrial enterprises; its members were high in social and economic status, exercising influence not only on the economy but on politics and education as well. Fenalco supported much the same policies as ANDI and, like ANDI, was wealthy and well organized. Fedecafe, a nonprofit organization dedicated to improving Colombia's coffee cultivation and raising the living standards of its coffee growers, was particularly influential in setting and administering the nation's official coffee policy. The government delegated Fedecafe total responsibility for coffee policy, including quality control of exports and all other matters related to the coffee sector. ANDI, Fenalco, and Fedecafe were effective not only because they were able to influence the initiation and outcome of legislation and executive decrees affecting the economy but also had close ties to most of the government's finance and development ministers and both major parties" (emphasis added). *Ibid.*