Libertad y Orden

Social Protection Ministry
Republic of Colombia

Code 13100
Bogotá, D.C.

Doctor
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Reference: Comments related with the modification of Decree 3249 of 2006
WTO Notifications – G/TBT/N/COL/65/Add, 3 and G/SPS/N/COL/98/Add.3
Proceeding from The Trade Institute, Standards, and Sustainable Development, ITSSD
Dear Doctor Madriñan:

Regarding to the observations realized by Mr Lawrence A. Kogan, president of the Institute for Trade , Standards and Sustainable Development (ITS), the Ministry of Social Protection, considers convenient to express to the requesting party before giving the explanations of the observations to the modifications of Decree 3249 of 2006: The following:

1. As a preview of Decree 3249 of 2006, it's a fact that the National Government issued the Decree 337, "By which are established the dispositions about the

natural resources used in pharmaceutical preparations and widens the term established in the article 1st of Decree 341 of 1997, ”Norm that serves as a general framework for the pharmaceutical products based in natural resources, but that do not establish the specific requirements for registration, vigilance, sanitary control and advertisement of the phytotherapeutic products, therefore the national government issued the Decree 2266 of 2004, modified afterwards by Decree 3553 of 2044.

NORM	**SUBJECT**
Decree 2266 of 2004	By which the sanitary vigilance, sanitary control and advertisement registration of the phytotherapeutic products are regulated
Decree 3553 of 2004	By which Decree 2266 of 2004 is modified

2. the products that in the country are called “Dietary supplements”, were products that some were classified as phytotherapeutic products, others as food, and others that for their composition they were not subject to any vigilance, or control by the state and it’s its obligation to watch over and control them, according to the Colombian political constitution, in its article 78 that states: “The law will regulate the quality control of the goods and services offered to the community, as well as the information that should be offered to the public…”

3. The Decree that in Colombia regulates the products called “Dietary upplement’s is Decree 3249 of 2006 and which request of the National Institute of Food and on Medicines “INVIMA”, according to communication sent to the health and welfare’s vice minister’s office Dr. Blanca Elvira Cajigas de Acosta, with registration No. 82610 of April 29th 2007, which requests the social Protection’s

Ministry, the modification of Decree 3249 of 2006, due to the difficulties the this institute (INVIMA) found in the application of the norm.

4. In order to proceed with the transaction of the request mentioned before, the social Protection Ministry started a process of discussion with the INVIMA and with the sector's guilds.

Due to this, it's understood that the modification of Decree 3249 of 2006, obeys to the necessity to count with more elements by the state in order to endow the sanitary registrations and to exercise a sanitary watch over the products called dietary supplements, as human consumption products.

As far as to the Answer to the ministry's observations, the position about that, is presented next, describing first the comment that ITSSD makes and them the Social Protection's Ministry's technical position about the comments:

1- ITSSD's comments: The Decree 3249 of 2006, shouldn't be adjusted and it should have that the products presented in pharmaceutical forms accepted by the revision committee without therapeutic indications should be classified as food products and they should be subject to the regulations for these products.

Technical position: Such as it was mentioned in the statements preceding this answer, the Decree 3249 of 2006, came up as the obligation that the state has to protect the goods and services offered to the community and the necessity to establish clear rules for the registration of the products called dietary supplements, as well as its watch over and control.

If in the international ambit the "Dietary Supplement products" are considered as food; through Decree 3249 of 2006 Colombia has defined that, within the requirements for the manufacturing and marketing of the Dietary supplements is

found “that these products do not adjust to the definitions established for foods, medicines, phytotherapeutic products or pharmaceutical preparations based of natural resources, nor alcoholic beverages in the current sanitary legislation”, in another words they belong to a different category.

2- ITSSD comment: The project of article 1, modifies decree 3249, article 3, number 2.

“The maximum vitamin, minerals and oligo-elements permitted for Dietary Supplements… …. For daily consumption will be the maximum consumption level indicated in annex 1 of the present decree……”
The ITSSD wishes to remind the Social Protection Ministry that the established criteria in the Codex Alimentarius, which are applied for dietary supplements and the ingredients of the products regulated as “Food” supposing that the project of reform of the Colombian Decree 3249 is really attempting to treat certain dietary supplements and ingredients of products as “Foods” and not as “medicines”, therefore the Codex Directives recommended that the “maximum vitamins and minerals’ safety levels should be established by the scientific risk evaluation based in scientific data generally accepted, taking in to consideration, according to the procedure, the different degrees of sensibility of the different consumer groups”.

Also, they recommend that the “Maximum quantities of vitamins and minerals in the vitamin supplements and minerals that will be established…, … taking into consideration the daily ingest of vitamins and minerals from other food sources”.

The problem is based that in the prescriptive language of the amendment to the Decree 3249’s project, as well as the Decree 3249, it simply refers to a predetermined list of the maximum levels established in the modification of Annex 1 of Decree 3249 which derogates annex 1 of the original decree 3249.

Therefore, it's incompatible with the quantity and quality standards that figure in the International directives of the Codex Alimentarious, according to which the maximum daily levels will be determined based on tested scientific processes and methods.

Technical position about the comment: Colombia as a member country of the Codex Alimentarious can adopt or adapt the norms, codes, directives or suggestions made by the Codex, since these serve a guide or reference for the countries, but its application is never obligatory ".

The list that the country pretends to adopt with Anex 1 of the modified Decree 3249 of 2006,, was made based in bibliographic researches and revisions of regulatory revisions of countries such as the United Kingdom.

In addition, to calculate the vitamin and, mineral levels in the table that is proposed as Anex 1, considers that the ingestion of vitamins and minerals should come from food sources and they should not come from the dietary supplement products only.

The ITSSD wishes to remind the Social Protection Ministry that, although the food supplements generally fall under the U.S.' jurisdiction, the Food and Drugs' Administration (FDA) which is the U.S. main responsible of the administration and enforcement of the Federal Food, Drug and Cosmetic Act (FD&C Act) and the FDA does not have to establish, or prove or in any other way make statements about food supplements or their ingredients. If well is possible to get an export certificate or verification from the FDA's Drugs Investigation and Evaluation Center (CDER) the products supplements for which this type of certification and verification is requested must pass through the complete approval process by the drugs' FDA,which is not required by the U.S. legislation., unless under certain conditions. For example; a dietary supplement should be considered: a) Posing an imminent danger for public health or security, b) and ingredient that makes it a fake, or c)

contain a new diet ingredient that doesn't have enough safety information, in virtue of section 402 of FD&C's Law, in its modified version by the U.S.A. Health diet supplement and 1944's Education Law ("DSHEA").

Besides these conditions, and besides an ingredient of the diet that figures in the dietary supplement product, as it's established in section 201 (ff) (1) of the FD&C Law, in its modified version for the DSHEA, other thing is that they are considered <<Food>>, in the meaning of section 201 (ff) of the FD&C Law. Therefore, it's not treated as a "food additive" in virtue of section 201(s) (6) of the FD&C Law added as part of the food additives 1958 amendment to the FD&C Law, therefore, is not object of FDA's regulation – in other words , that is not established or approved by the FDA.

Besides, still is recognized that "some diet ingredients that can be used in dietary supplement, can escape the FDA's regulation and be considered GRAS (Generally Recognized as Safe) for its use in an conventional food (for example, vitamin C; (calcium carbonate), in virtue of section 201 (s) (4) of FD&C Law. This regulation exclusion (of the food complements as GRAS) is separated and different from the regulator before the exclusion of the diet ingredients (of the food additive definition of the food supplements) under section 201(s) of the FD&C Law.

Therefore, the ITSSD suggests that the project of article 1, that modifies the Decree 3249 article 3 point 3, be modified in the following way:

" The ingredients, additives or substances expressly restricted by the current Colombian legislation in this matter, or in the Codex Alimentarius, will not be accepted, but all ingredients, additives or mixtures, classification, labelling, containers and claims will be accepted as long as they appear in the FDA in all the normative system that foresees the protection to public health for the elaboration an manufacturing of products (included the Dietary supplements; public law

DSHEA 103-417) and/or from the European Community, 2002 – 46 – CE of the European Parliament and/or by the Codex Alimentarius regulated by the CAC/ GL 55 – 2005 act".

Technical position about the comment: One of the problems that the INVIMA had in the enforcement of the Decree 3249 of 2006, was the limited listing of the substances that can be accepted in the composition of the dietary supplements, therefore with annex 3 of the modification proposal, that appear in the FDA 's ingredients list Codex Alimentarius, European Commission (The Act which you refer to, European Community 2002 – 46 its cited) and other sources that make part of annex 1 of this communication, so that you can verify the amplification of the source in reference.

On the other hand, following are stated the motives that the Invima has had to propose that they be taken as reference sources, the center for the Food Safety an Applied Nutrition known as CFSAN and the reference lists of the European Commission:

"In the United State Department of Health and human Services in their labour of Protection of consumer and safety control of the products that are sold to the American residents it backs up in the Food and Drug Administration (FDA).

The FDA is a scientific normative entity responsible of the safety of food, cosmetics, medicines, biological products, medical devices and radiology products produce in the country as well as the imported ones. The FDA has international recognition as the leader regulatory agency of Food and Medicines in the world. Many foreign nations request and receive help from the FDA in order to control and better the safety of their products.

In order to meet the laws on food safety that rule National and imported foods, the FDA realize among other activities:

*Proves the safety of the food additives and colour before they go out for sale.

*Develops codes and order models, rules and interpretations.

*Establishes the good food production practices and other production norms, such as sanitation at factories, bottling and packing requirements and critical control point and risk analysis.

*Works with foreign governments to ensure the inoquosness of certain imported food products.

*Requests that the manufactures retire from the market food products.

*Takes the appropriate measures to enforce the laws

*Carries out research work about food safety. (1)

The FDA counts with the contribution of six government centers to do its work.

The Center for the Food Safety and Applied Nutrition know as CFSAN, is one of the six centers oriented to the product, besides a national field force, that carries out the FDA's chores.

The CFSAN, along with the agency's field personnel, is responsible of the fomentation and the protection of the public health guaranteeing that the Nation's Food supply is safe, sanitary, healthy and is correctly labelled, and that the cosmetic products are safe and correctly labelled.

The Center is primary responsibilities include:

*The safety of the substances added to the food IE., **Additives** (including the ionizing radiation) and the **colorants.**

*The food safety and the ingredients development through biotechnology norms about danger analysis and the critical control point of fish (HACCP).

*Normative and investigation programs to confront the sanitary risks with the chemical and biological pollutants carried by foods.

*Norms and activities related to the correct labelling of the foods (I.E. **Ingredients, Nutritional Health declarations**) and the cosmetics.
*Norms and policies that rule the **Dietary Supplements Safety,** child formulas and medicinal food.
*Supervision and fulfilment after commercialization by the food industry.
*To educate the consumer and reach industry
*Cooperation programs with local and state governments.
*Safety harmonisation efforts and the International food standards. (2).

According to the work realized by the (SFSAN), the INVIMA takes as reference the different concepts issued in food additive safety matters, ingredients used in the manufacture of these products and substances generally recognized as safe (GRAS) according to the safety, of the food, complements or food supplements (dietary supplements).

These conclusions are put in the lists taken as reference by this institute, most of which belong to the work done by CFSAN, for example the list of food additives.

In the case of the list called “Module 19 botanicals generally recognized as safe” which is a summary of the botanical species that appear in the FDA’s GRASS list, a list of Food additives which are generally recognized as safe according to a scientific opinion consensus (3), it was considered that once the safety of these species is determined, it could be a useful reference list in order to meet what’s stipulated in Decree 3249 of 2006, in article 3rd this same procedure was followed to define the lists of the European Commission reference. In this case, is the EFSA as a sanitary entity who has to issue acts of the parlament in which are included substances that can be used in the fabrication of food supplements, that for our classification is for the dietary supplements.

The interest of the institute in pursuit of its mission (for the collective and individual health protection of Colombians through the application of the sanitary norms related with the products of its domains), is to count with the safety, and innocuousness, for the case, of the ingredients used in the manufacturing of the dietary supplements.

(1)= http://www.cfsan.fda.gov/~lrd/foodteam.html

(2)= http://www.cfsan.fda.gov/~lrd/cfsan4.html

(3)= http://www.ars-grin.gov/duque/syllabus/gras.html

4. ITSSD Comment: The norm project that modifies decree 3249 of 2006 in article 1 number 4 “The substances not included in the previous lists will be considered new dietary supplements ingredients……”).

The ITSSD, once more wishes to make emphasis to the social Protection Ministry that in the United States, the FDA does not regulate and it’s not necessary “to approve” the food before the manufacture or the sale of substances if any of the previously described exclusions apply

The ITSSD, therefore, suggest that the project of modification of article 1 modification of decree 3249, in the number 4 to be modified in the following way:

“A substance used in a dietary supplements as an ingredient of the diet”, in the sense of 21 USC 321 (ff) (1) with the purpose of the supplementation, is out of the GRASS food additive ambit dispositions of the law (by 21 USC 321). The Colombian, legislation shouldn’t demand, that the dietary ingredients, must be GRAS”

On the other hand, although the FDA is not obliged to regulate GRAS, that supervises and holds several GRAS substances or use the notification lists. The

ITSSD wishes to out stand never the less, that these lists do not include all the parts, since the notification procedure has not been finished by the FDA and therefore, continues being volunteer given that the use of a GRAS substance is not subject to the FDA before the market's revision and approval, is not viable for the FDA that the list of all GRASS substances are the ones to be really used in the food. This means that the use of a substance can be GRAS even if it doesn't appear in the list by the FDA as GRAS.

As a consequence, if the **PROJECT OF ARTICLE 1, DECREE BY WHICH ARTICLE 3 IS MODIFIED, POINT # 4**, is approved such as is redacted in such a way that is treated as "New ingredient in a supplement", in order for the sanitary registration and authorizations previous to the commercialization that all GRAS substances require, with uses not included in a <<positive>> list FDA GRAS, the Decree 3249 would have the practical effect of prohibition of the markets in Colombia for many American GRAS ingredients. In other words, the purpose of this modification project to Decree 3249 is the creation of new technical obstacles to the commerce.

Technical position: As it was mentioned in the previous answer, the proposed annex has as objective to increase the quantity of substances (ingredients additives), that have an approval in the international ambit, to be approved in the dietary supplements that are commercialized in Colombia, in such a way that they are safe. In case of not finding a substance in some of the lists mentioned in the annex 3, the project of modification of Decree 3249 of 2006, creates the mechanism for the new substances to be evaluated by the Specialized Board of Natural Products of the review committee of the Invima, according to article 11 in the modifying project of Decree 3249 of 2006.

It emphasizes that decree 3249 of 2006 by which the manufacture, bottling,

labelling or tagging, sanitary registration regimen, quality control sanitary watch over and sanitary control of the dietary supplements are regulated, derogates decree 3636 of 2005, it has the clear purpose to make easy to get the sanitary registration and with the adjustment that is proposed, it pretends to make easy the commerce of this type of products wether they are national or imported, taking in to consideration that they meet with safety conditions, since they are products for human consumption.

5. ITSSD comment: The article project that modifies decree 3249, in the article 7 and the parts 2 and 3: “to the dietary supplements that are produced in the country or imported, it will be accepted the certificate of meeting the good manufacturing practices for medicaments, and in the case that they make phytotherapeutic products it will be accepted the certificate of meeting the good manufacturing practices or the certificate of production ability in the terms provided in the decree 2266 of 2004.

Prior to the sanitary registration request, the interested party should contribute to the sub direction of medicaments and biological products of the national institute of medicines and food surveillance INVIMA the validation and cleanness supports.

The project demands that the dietary supplements imported to Colombia should satisfy requirements, like for medicaments instead of good manufacturing practices for foods, as well as inspections. This can create difficulties due to the multiple differences between the dietary supplements and the pharmaceutical products. Curiously, this modification project to decree 3249, different to article 7 of the original decree 3249, it refereed to a certificate of Good Practices Food Manufacturing, issued by the INVIMA or an equivalent document issued by the competent authority in the country of origin” – for example, the U.S.A.

The ITSSD wishes to remind the Social Protection Ministry that the FDA in its most

recent publication “to establish a definite norm on current regulations that the Good Practices of Manufacturing demand (cGMP) for the dietary supplements, it could be said it’s considered as a “process equivalent for the effects of getting a certificate of Good Manufacturing Practices of Food Products, as is established in article 7 of the original Decree 3249, or obtaining a certificate of meeting the Good Manufacturing Practices of Dietary Supplements in article 7, third paragraph of the amendment project of decree 3249.

The new FDA’s norm ensures that the dietary supplements that are produced in a uniform form to attend quality, do not have pollutants or impureness, and this condition is placed in the label.

The GMPc it’s applied “to all the national and foreign companies that manufacture bottle or label dietary supplements, including the ones that participate in the verification, quality control, bottling and lebeling activities and their distribution in the U.S.A.

The state has scaled to three years in a transition phase for the small companies in order not to interrupt the manufacturing of the dietary supplements produced. The final GMPc’s term is effective in June 2008 for the large companies.
The companies with less than 500 employees have until June 2009 and the companies with less than 20 employees have until June 2010 to meet with such regulations.

The request that is made, is that the manufacturer be able to request the exception of 100 percent of the proof of identify requirements for the ingredients that are used in the manufacture of dietary supplements.

The provisional norm is effective as of June 2008 where the GMPc makes the final

norm effective. These more specific complementary norms should be considered seriously by the Social Protection Ministry before approving the amendment project of article 7 of decree 3249"

Position and Concept: The Decree's project contemplates that the Good Manufacturing Practices Certificate or its equivalent be accepted, when it refers to Decree 549 of 2001 and to Decree 162 of 2004.

As for the exemption in one hundred percent, the identify requirements for the Dietary Supplements, this Ministry does not accept such request, since the norm's project foresees that if the National Institute of Medicament and Food's Surveillance, INVIMA, in the process of getting the sanitary registration, considerers it permanent, to take samples or verify aspects that considers necessary, it can do it and in case that the product presents any ingredient or additive whose presence could not be verified, it could request an analysis certificate issued by the country of origin's authority from a recognized laboratory.

With the explanations previously mentioned, this ministry hopes to have answered the observations presented and wishes also to emphasize that Decree 3249 of 2006 and its modification, have the clear purpose of establishing requirements for the registration and commercialization of what in Colombia is classified as Dietary Supplements in order to meet the state's obligation of protecting the population of users

Cordially,

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Anex of Minute to the OMC,
ITSSS Observations

ANNEX 3
REFERENCES FOR ALLOED SUBSTANCES IN DIETARY SUPPLEMENTS

CODEX ALIMENTARIUS

OFFICIAL CODEX ALIMENTARIUS NORMS

http://www.codexalimentarius.net/web/standard.list.do?lang=es

FOOD ADDITIVES CODES

http://www.codexalimentarius.net/gsfaonline/additives/index.html

FDA
EAFUS: A FOOD ADDITIVE DATABASE, GRAS LIST

http://www.cfsan.fda.gov/~ldms/eafus.html

FOOD ADDITIVE STATUS LIST

http://www.cfsan.fda.gov/~dms/opa-appa.html#ftnC

BOTANICAL GRAS

http://www.ars-grin.gov/dike/syllabus/gras.htm

TITLE 21 -- FOOD AND DRUGS

PART 172 -- FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION
Subpart D--Special Dietary and Nutritional Additives

http://www.accessdata.fda.gov/scrips/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=172&showFr=1&subpartNode=21:3.0.1.1.3.4

PART 182 -- SUBSTANCES GENERALLY RECOGNIZED AS SAFE

http://www.cfsan.fda.gov/~lrd/fcf182.html

PART 184 – DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

http://www.accessdata.fda.gov/scrips/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=184&showFr=1

PARTIAL LIST OF ENZYME PREPARATIONS THAT ARE USED IN FOODS

http://www.cfsan.fda.gov/~dms/opa-ENZY.HTML

FDA SEAFOOD LIST

http://www.cfsan.fda.gov/~frf/seaintro.html

Carrera 13 No. 32 -76 PBX. 3305000Ext: 1735 a 1739 – 1400 – 1415 FAX: 3305050

Additionally to the GRAS lists, previously mentioned, the following references could be consulted

http://www.cfsan.fda.gov/~rdb/opa-gras.html

http://www.cfsan.fda.gov/~dms/opascogd.html

They contain GRAS modifications received since 1998, with their respective answer by the FDA, besides it should go at the end of the GRAS lists previously mentioned.

EUROPEAN COMIMSSION

Directives on "foods for particular nutritional uses", " dietetic foods" or

" dietary foods", *in which lists of the nutritional substances that can be added to this type of supplements are included.*

Commission Directive 2001/15/EC

Commission Directive 2004/5/EC

Commission Directive 2004/6/EC

Commission Directive 2006/34/EC

http://ec.europa.eu/food/labellingnutrition/nutritional/index.en.htm

Also could be consulted a summary in Spanish in which links for direct consultations for the directives above mentioned are found

http://ec.europa.eu/scadplus/leg/es/lvb/121102.htm

Directive 2002/46/CE of the European Parliament of the June 10th 2002 Council. Relative to the approximation of the State members' legislations in the matter of food complements, in which are included the substances that can be replaced in the manufacturing of food supplements.

http://ec.europa.eu/scadplus/leg/es/lvb/121102.htm

LEGISLACION COLOMBIANA

Foods not processed included in the table of Colombian food composition of the Colombian Family Welfare Institution (ICBF)

http://www.icbf.gov.co/espanol/planes/plan.nal.de.alimentacion/glosarioicbf.xls

List of medicinal plants approved with therapeutic purposes included in the number 23.1 and the list of natural resources approved with therapeutic purposes included in number 23.2 of the Manual or Pharmacological Norms 2006 or its actualizations, in concentrations that don't go over the therapeutic levels.

2006 Pharmaceutical Norms

23. Natural Resources accepted with therapeutic purposes

23.1 List of Medicinal plants approved with therapeutic purposes

23.2 Other Natural resources approved with therapeutic purposes.
http:www.invima.gov.co/Invima//consultas/docs.normas.farmacologicas/normasfarmacologicas%202006.pdf