CODEX ALIMENTARIUS COMMISSION

E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/EXEC 12/66/5**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

Sixty-sixth Session

WHO Headquarters, Geneva, 7 – 10 February 2012

APPLICATIONS FOR OBSERVER STATUS IN CODEX

1. The Executive Committee is hereby **invited**, in accordance with Rule IX.6 of the Rules of Procedure and the *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*, to provide advice regarding the applications for observer status from the international non-governmental organizations neither having status with FAO nor official relations with WHO, as included in the Annexes.

2. The representatives of the Legal Counsels of FAO and WHO will provide information at the session, on any further research that may be necessary concerning some of the applicants and any conditions to be included in case of acceptance e.g. for reason of double representation.

3. The Directors-General of FAO and WHO will decide whether the applicant organizations are to be granted observer status, taking into account all relevant information received from the applicant and the advice of the Executive Committee.

4. This document contains the following applications (the additional information referenced in some of the applications will be made available in CRDs at the session in original language only):

Annex	Name	Additional information
Annex 1	ALINA	CRD1
Annex 2	USP	CRD2
Annex 3	ENA	CRD3
Annex 4	FEEDM	CRD4
Annex 5	ICAAS	CRD5
Annex 6	YLFA	CRD6
Annex 7	AIPCE	CRD7

ANNEX 1: ALINA

a. Official name of the organization in different languages (with the corresponding acronyms)

ALINA – THE LATINAMERICAN ASSOCIATION OF THE NATIONAL AGROCHEMICAL INDUSTRIES (Asociación Latinoamericana de la Industria Nacional de Agroquímicos Inc)

b. Complete address, telephone, fax and e-mail, as well as a telex or website address, if possible

Address:

Mr. Renzo Cespedes Vargas
Executive Secretary, San José, Costa Rica.
Lomas de Ayarco Sur, Curridabat,
500 meters south of Colegio Yorkin.

Telephones: (506) 2271-2752, (506) 2271-4184.
Telefaxes: (506) 2271-4184
Mobile: (506) 8319-1909

Legal Address:

ALINA
1500 Miami Center
201 South Biscayne Boulevard
Miami, Florida 33131-9767, USA

Telephones: (305) 3586300.
Telefaxes: (305) 3586300.
Internet: www.alina-latinoamerica.org
E-mail: info@alinainternacional.org

c. Purposes and thematic sectors (mandate) of the organization and operational methods (including statutes, constitution, internal rules, regulations, etc.). Creation date.

Creation date: August 4 2003

Purposes and ambit. ALINA is a union-enterprise development and service entity of the Latin American and Caribbean phytosanitary products industry sector, that through programs, activities, projects, reports, assessments and other acts is oriented to promote and improve the registration activities, manufacturing, formulation, distribution, merchandizing and use of its associates phytosanitary products. ALINA will be able to coordinate its activities with other

natural and legal, public or private persons, of any country, under the principals of respect to its own autonomy, liberty of criteria and subordination to the public order.

Basic Policies: ALINA's finality is to promote the development and continuous improvement of the registration, formulation, distribution, merchandizing, and use of phytosanitary products, of public health, animal health and others, of its associates. Likewise it searches to optimize and harmonize technical criteria and guidelines for the safe and effective use of phytosanitary products, of public health, animal health and others in the different countries of Latin America and Caribbean countries.

Operative Methods: a) exercise representation and intervene in the defense of the common interests of its members before the diverse instances and authorities of each one of the countries of the ALINA associates and international organisms, in compliance with ethical principles commercial loyalty rules; b) carry out analyses, diagnosis and evaluation of the situation and develop action plans in common, on affairs, projects, decisions and action that can affect the current and/or future activities of ALINA associates; c) implementing the broadest communication and exchange between ALINA associates and also with third parties so as to contribute to the development of high quality professional assistance and services to give an adequate answer for the rules and regulations of each country to which the associates pertains; d) promote and support the improvement and innovation initiatives in systems, procedures and manufacturing and

formulating conditions of its associates phytosanitary products taking into account the aspects related to human health, the ecosystem, the manufacturing, agrochemical productivity and business environment.

ATTACHED IS THE ASSOCIATION'S STATUTE.

d. The member organizations (name and address of each national affiliate, affiliation system, number of members, when possible and names of the main officials. If the organization is formed by different members, please indicate the approximate quantity per country). If the organization is of the federal kind and it counts between its members with international non-governmental organizations, please inform if any of those members already possesses the quality of observer before the Codex Alimentarius commission.

TABLE OF COMPANIES REPRESENTED BY ALINA

Fersol S.A.	Brazil	**Michael Haradom**	
Agroquímica Industrial RIMAC, S. A.	Costa Rica	**Roman Macaya**	
CANAPROGE Camara Nacional de Productos Genericos	Costa Rica	**Rodrigo Mora**	**13 Companies**
Interoc S.A.	Ecuador	**Fernando de la Puente**	
Agrocentro S.A.	Guatemala	**Federico Jose Cruz**	
Pharmagro S.A.	Guatemala	**Michael Groos**	
Químicos y Lubricantes, S. A.	Guatemala	**Irving Tejada**	
UMFFAAC -Unión Mexicana de Fabricantes y Formuladores de Agroquímicos A.C	México	**Federico Jose Escalante de la Hidalga**	**23 Companies**
Internacional Química de Cobre IQC	México	**Juan Manuel Ramirez Muro**	
Tecnomyl, S.A.	Paraguay	**Roberto Muñoz**	
Farmex S.A.	Peru	**Oscar Dibos**	
Agrocasa S.A.	Venezuela	**Armando Morera**	
IPESA, S. A.	Argentina	**Hector Di Loreto**	
Agroquimicos Versa, S.A. de C.V	Mexico	**Fernando Vera**	
Phytocare S.R.L.	Colombia	**Lilliana Orejuela**	
Dinagro Agropecuária Ltda.	Brazil	**Luiz Eugenio Pedro de Freitas**	
Cámara de las Industrias Nacionales de los Defensivos Agrícolas-CINDA	Paraguay	**Claudio Pusineri**	**6 Companies**

Regional Councils. The regions, all pertaining to Latin America and Caribbean, are:
North ALINA Region: composed by México, Central America and Caribbean.
Andean ALINA Region: composed by Venezuela, Colombia, Peru, Ecuador and Bolivia.
South ALINA Region: composed by Argentina, Brazil, Paraguay, Uruguay and Chile.
Conformation: The Regional Councils will be formed by two representatives per country chosen by mutual agreement between the active members of that country. Each Regional Council will determine its functioning structure and rules.

e. Structure (assembly or conference; council or other kind of governing body; kind of general secretary; commissions on special issues, if there are; etc.).

DIRECTORY
President: Michael Haradom
Secretary: Roberto Muñoz
Secretary Assistant: Héctor Di Loreto
Treasurer: Federico José Cruz
Coordinator: Fernando Vera
Main Prosecutor: Liliana Orejuela
Substitute Prosecutor: -
Directors:
Román Macaya
Fernando de la Puente
Armando Morera
Víctor Esquivel

f. Financing source (for e.g.: member contributions, direct funding, external contributions or subventions).

ALINA is financed by membership annual fees for its regular functioning, if needed extraordinary contributions can be used

g. Meetings (indicate the frequency and average assistance; send the report of the previous meeting; including the approved resolutions) that are focused on issues that concern all or some activities of the Commission.

ALINA members meet in the Ordinary Annual Assembly, that takes place in the first three months of the year; and the Extraordinary Assemblies also contemplated in its Stature. ALINA's Board, conformed by nine members, three of each region, meets twice a year. The meetings can take place in any Latin America country or in Miami, USA as the founding of ALINA took place in Florida, USA.

h. Relations with other international organizations: a) United Nations and other organs (indicate if they maintain consulting or any other kind of relations; b) Other International Organizations (document essential activities).

ALINA is a member of Agrocare (Asociación Global de Productores de Industria Nacionales de Agroquímicos), with headquarters in Brussels, Belgium. Actively participates as ALINA or as a part of AgroCare in FAO and WHO.

The following documents are attached:

1. Fifth Joint CIPAC/FAO/WHO Open Meeting (52th CIPAC Meeting and 7th JMPS Meeting. Federal Office of Consumer Protection and Food Safety (BVL), Braunschweig, Germany, June 9, 2008
2. Report of the Sixth Meeting of the global collaboration for Development of Pesticides for Public Health. World Health Organization. Geneva, April 24-25, 2008.
3. 1st FAO/WHO Joint Meeting on Pesticide Management and 3rd Session of the FAO Panel of Experts on Pesticide Management. October 22-26, Rome
4. Third Joint CIPAC/FAO/WHO Open Meeting (50th CIPAC Meeting and 5th JMPS Meeting. WHO/HQ, Geneva, June 12, 2006.

i. Foreseen contribution to the joint FAO/OMS program on Food Regulations.

ALINA would contribute with information and technical opinions on the issues treated by the l Committee on Pesticides Residues.

j. Previous activities performed in the name or related to the Codex Alimentarius Commission and the Joint FAO/OMS program on Food Regulations (indicate any relation between the national affiliates and the Regional Coordination Committees and/or the points of contact or Codex national committees during at least the last three years previous to the request).

IPESA S.A., member of ALINA, actively participates in the Argentina CODEX meetings, in the Committee on Pesticides Residues, through the Fertilizers and Agrochemicals Argentine Industry Chamber (CIAFA). Through CIAFA, representatives of the Company have actively

participated in international meetings with CCPR of CODEX, forming part of the Argentine delegation. The following documents are attached:

1. 15th Meeting of the FAO/OMS Coordinating Committee for Latin America and Caribbean, Mar del Plata, Argentina, November 13-17, 2006.
2. 39th Session of the CODEX Committee on Pesticides Residues. Beijing, China, 7-12 May 2007.

k. Sphere of activity in which your participation as an observer is requested (Commission and/or auxiliary organs). If more than one organization with similar interests request the quality of observer in one field of activity, such organizations would be encouraged to join

in a federation or association so as to participate. If the formation of such an organization is not possible, the reasons of this impossibility should be informed in the request.

1) PESTICIDE RESIDUES GENERAL PRINCIPLES

2) LATIN AMERICA AND CARIBBEAN REGIONAL COMMITTEE

l. The candidatures previously presented to request the quality of observer before the Codex Alimentarius Commission, including those presented by member organization of the requesting organization. If the candidature is accepted, when and why a term was set for the quality of observer must be informed. If the candidature was rejected the reasons mentioned for this rejection should be informed.

Formally presented the request as Observer in the year 2007, but the procedure was not continued. For this reason, ALINA is currently trying to regularize the situation.

m. Language in which the documentation must be sent to the international non-governmental organization (Spanish, French or English).

Spanish – English

n. Name, job and address of the person who submits the information

RENZO CÉSPEDES VARGAS, SECRETARIO EJECUTIVO

Executive Director	**Legal Director**
San Jose, Costa Rica.Lomas de Ayarco Sur, Boulevar,	1500 Miami Center, 201 South Biscayne
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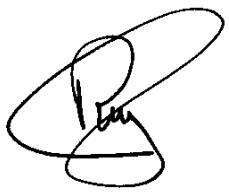
Mobile: (506) 8319-1909

E-mail: renzoonf@racsa.co.cr

Web page: www.alina-latinoamerica.org

o. Signature and address:



ANNEX 2: USP

a. Official name of the organization in different languages (with italics)

United States Pharmacopeial Convention

b. Full postal address, Telephone, Facsimile and Email, as well as Telex and website address as appropriate

USP Headquarters

12601 Twinbrook

Rockville, MD 20852-1790, USA

Telephone: 301-230-6329

Facsimile: 301-998-6798

Email: sdm@usp.org

Website: www.usp.org

c. Aims and subject fields (mandate) of organization, and methods of operation. (Enclose charter, constitution, by-laws, rules of procedures, etc.) Date of establishment

The United States Pharmacopeial Convention (USP) is an independent, science-based, not-for-profit, volunteer-driven standards-setting international organization that was founded in 1820. USP's mission is to improve the health of people around the world through public standards and related programs that help ensure the quality, safety and benefit of medicines, dietary supplements and food ingredients. USP operates on a five-year cycle in which the Convention members meet to elect the Council of Experts (USP's volunteer scientific decision-making body) as well as the Board of Trustees and USP Convention officers (the president and treasurer).

USP publishes the *Food Chemicals Codex (FCC)*, a compendium of standards, which defines the quality of food-grade ingredients in terms of identity and purity. USP recently acquired the *FCC* from the Institute of Medicine (IOM) of the United States (U.S.) National Academies of Science and is now advancing publication of the compendium through 6th and subsequent editions in order to continue the IOM's important work in this area. *FCC* standards are publicly available to all and are comprised of food ingredients legally available in the U.S. market and/or in foreign countries.

FCC standards enjoy certain legal recognition in the U.S. and elsewhere. In the U.S., a limited number of *FCC* standards are incorporated into specific U.S. Food and Drug Administration (FDA) food additive regulations and are legally enforceable. Compliance with *FCC* food ingredient standards not referenced in FDA regulations is not mandatory. However, historically all food ingredients in the U.S. must be of food-grade quality and FDA has recognized *FCC* standards as establishing acceptable "food-grade." Additionally, the FDA recommends that *FCC* standards on identity and purity be included if available, in submissions for direct food additives petitions and food ingredient notifications for substances Generally Recognized as Safe (GRAS). *FCC* standards also have been legally adopted or recognized in Canada, Australia, and New Zealand.

FCC's documentary standards for food ingredients are presented in the form of monographs, which contain the name of the ingredient, recognized synonyms, applicable registration numbers (*e.g.,* Chemical Abstracts Service numbers), a description of the substance, properties, tests, and procedures to qualitatively verify its identity, and tests, procedures, and acceptance criteria intended to ensure purity. In addition, the monograph gives brief packaging and storage requirements and, in some cases, labeling information. The *FCC* also contains standards for food ingredients that are used to manufacture dietary supplement products in the U.S. and abroad. The food ingredient standards in the *FCC* are developed through a transparent, science-based system that invites public participation during the standards-setting process.

As previously stated, the majority of the standards contained in the *FCC* are for food ingredients that are legally approved for use in the U.S. However, some of the *FCC* standards are for food ingredients that have been approved in and are legally marketed in countries other than the U.S. The *FCC* offers the opportunity for the international food industry to develop quality standards for food ingredients that are approved in a particular region of the world and by doing so, helps foster innovation and new technologies currently used in international food markets.

In addition to the *FCC*, USP publishes two internationally recognized compendia concerned with drugs, pharmaceuticals, and dietary supplements—the *United States Pharmacopeia* and *National Formulary (*collectively, *USP-NF)*. Under the Federal Food, Drug and Cosmetic Act, *USP-NF* are official compendia for all prescription drugs, over-the-counter medicines, and dietary supplements manufactured and sold in the U.S. Drugs in the U.S. generally must comply with *USP-NF* standards to avoid being considered adulterated or misbranded. The standards in the *USP-NF* are acknowledged and used in more than 130 countries. These standards have been helping to ensure good quality for consumers and industry throughout the world for more than 185 years.

The *USP-NF* contains a separate section on standards specifically applicable to dietary supplements. Like *FCC* food ingredient standards, the *USP-NF's* standards for dietary supplements are developed through a transparent, participatory process. USP works with the dietary supplement industry to help companies reach these standards and thereby advance public health and facilitate international commerce. The USP standards for dietary supplements contained in the *USP-NF* include tests for identity, purity, potency, packaging, and labeling. Generally, monographs for dietary supplement dosage forms include testing requirements for dissolution or disintegration. *USP-NF* standards for dietary supplements were first established in response to the USP Convention resolutions relating to dietary supplements in 1990 and 1995, which recognized the need for quality standards for these articles.

USP-NF standards for dietary supplements are recognized in the U.S. Dietary Supplement and Health Education Act of 1994, which is incorporated in the U.S. Federal Food, Drug, and Cosmetic Act. Specifically, this U.S. law states that a manufacturer that places "USP" or "NF" on the label of a dietary supplement must meet the specifications in the *USP-NF* or the product may be considered misbranded. Thus, compliance with *USP-NF* standards is required if a dietary supplement manufacturer represents its product as meeting USP standards. In May 2009, USP is publishing the *Dietary Supplement Compendium*, which will contain quality standards exclusively for dietary supplements including tests for purity and content, procedures of analysis and acceptance criteria. In the United States, dietary supplements are regulated as foods, although many are recognizable as traditional medicines in other countries of the world.

USP verifies the identity, potency, purity, and quality of dietary supplement finished products and dietary supplement ingredients thorough its Dietary Supplement Verification Program and Dietary Supplement Ingredient Verification Program. Dietary supplement ingredients that pass all USP verification requirements–including a GMP audit, product and ingredient testing, and manufacturing documentation review–are permitted use of the exclusive "USP Verified" mark. Only those dietary supplement products that meet USP's stringent criteria are permitted to use the "USP Verified Dietary Supplement Mark" to display on their product labels. Finding the "USP Verified" mark on a dietary supplement ingredient label helps manufacturers recognize that they are buying ingredients of consistent quality for use in the supplements they manufacture. Likewise, the "USP Verified Dietary Supplement Mark" on dietary supplement product labels assures consumers that they are buying the expected value as to quality. Participation in both of USP's verification programs is voluntary and they are available to dietary supplement manufacturers worldwide.

In addition to its documentary standards for food ingredients and dietary supplements, which are distributed worldwide to manufacturers, processors, consumers and other users through the *USP-NF* and *FCC*, USP also makes available where needed, reference materials as USP Reference Standards. Reference materials are closely allied through modern principles of metrology to the procedure in a monograph's specification. USP Reference Standards are highly characterized specimens of drug substances, excipients, impurities, degradation products, dietary supplements, compendial reagents and performance calibrators used in testing to assure that articles conform to the documentary standards. USP also offers a Pharmacopeial Education program, a series of training courses designed to help manufacturers and other compendial users understand and implement USP standards.

Appendix I contains copies of USP's Articles of Incorporation, Constitution and By-laws, Rules of Procedures of the 2005-2010 Council of Experts and Rules of Business Practice for the 2005-2010 USP Board of Trustees.

d. Member organizations (name and address of each national affiliate, method of affiliation, giving number of members where possible, and names of principal officers. If the organization has individual members, please indicate approximate number in each country. If the organization is of a federal nature and has international non-governmental organizations as members, please indicate whether any of those members already enjoy observer status with the Codex Alimentarius Commission.

USP membership is composed of organizations that designate a representative or delegate to participate in USP's governance activities. These member organizations consist of 126 U.S. colleges and schools of medicines, 89 U.S. colleges and schools of pharmacy, 54 State medical societies, 52 State pharmacy

associations, 55 national and state professional and scientific organizations, 22 U.S. and non-U.S. governmental agencies, 13 health science and other foreign organizations and pharmacopeias, 9 consumer organizations and individuals representing public interests, and 22 domestic, foreign and international manufacturers, trade and affiliated associations. Some of these USP member organizations such as the International Food Additives Council (IFAC), and Institute of Food Technologists (IFT) currently enjoy observer status with the Codex Alimentarius Commission (CAC) but none of them represent USP's public health interests and standards-setting activities at CAC and subsidiary bodies meetings.

Appendix II is a listing of organizations eligible to appoint delegates to the USP Convention and also contains a membership roster, which contains the name of the colleges and universities, associations and organizations along with their designated representatives or delegates.

e. Structure (assembly or conference; council or other form of governing body; type of general secretariat; commissions on special topics, if any; etc.)

USP has three primary governance and scientific bodies — the Convention membership, Board of Trustees (including Convention officers), and the Council of Experts and its Expert Committees -- all of which are composed entirely of volunteers. As noted above, USP's Convention membership meets every five years to elect the other two bodies – the Board of Trustees and the Council of Experts. At the five year meeting, the membership also approves amendments to USP's Constitution and Bylaws and adopts resolutions that provide strategic direction to the organization during the five-year cycle. An executive team, along with a staff of approximately 600 USP employees in the U.S., Switzerland, India, China and Brazil, supports these volunteers in framing strategies, implementing tactics, and carrying out the day-to-day operations necessary to ensure the quality, safety and benefit of medicines and food.

The USP Convention membership is constituted to ensure diverse representation from those sections of the food industry and health care system that are impacted by, and in turn impact, USP's standards-setting activities. As noted above, the Convention has about 450 members who represent U.S. colleges and state associations of medicine and pharmacy; governments of the U.S. and foreign countries; national and international health professional, scientific, and trade organizations; the pharmaceutical industry; food manufacturers and processors, and consumer organizations. Members guide and facilitate USP's work through conducting deliberations where they address issues of interest to the professions they represent, voting on resolutions that guide USP's public health policies and initiatives, and electing USP's volunteer leadership. Members keep their constituencies informed of USP activities and issues. They gather information and perspectives that are relevant to USP from colleagues and the organizations they represent.

The USP Board of Trustees (Board) makes decisions that guide USP's policies, finances, and strategic direction. The Board has a fiduciary responsibility to USP and approves its budget, and is also responsible for development of the organization's Strategic Plan. The Board comprises two trustees who represent the medical sciences; two trustees who represent the pharmaceutical sciences; three trustees who serve in an at-large capacity; and one trustee who represents the public interest. The officers include a president, treasurer, and past president. The Board chairperson, the president and treasurer of the Convention, and the public trustee make up the Executive Committee of the Board. The trustees elect the Board chairperson annually. The Board selects the USP chief executive officer (CEO), who also serves as an ex-officio, nonvoting member of the Board of Trustees and its Executive Committee.

The Council of Experts (Council) is the body that makes USP's scientific and standards-setting decisions. Members of the Council are elected by the USP Convention membership. Each Council member serves as the chair of an Expert Committee for a 5-year term, and the Council elects the members of the Expert Committees who also serve 5-year terms. The CEO serves as chairperson of the Council of Experts and its Executive Committee. The Council of Experts and its Expert Committees provide the scientific foundation for USP's public health products and programs.

The Expert Committee pertinent to food standards and development of FCC is the Food Ingredient Expert Committee (FIEC). Five separate Dietary Supplement Expert Committees address the following dietary supplements issues: bioavailability, performance standards, botanicals, general chapters, information, and non-botanicals. These Expert Committees are involved in monograph development, quality review, and publication of in-house and peer-reviewed articles relating to food ingredients and dietary supplements.

Appendix III contains a listing of all current USP Council of Experts and Expert Committees and a slide indicating the composition of the 2005-2010 Council of Experts.

f. Indication of source of funding (e.g., membership contributions, direct funding, external contributions, or grants)

USP is predominately self-funded through the sales of its compendial products and services: *USP-NF*, *USP Pharmacists' Pharmacopeia*, and *FCC* compendia, Reference Standards, Verification Programs and Pharmacopeial Education. USP also receives funding from the U.S. Agency for International Development (USAID) over a five year period through a cooperative agreement and grant that runs until September 2010. The cooperative agreement funds USP's Drug Quality and Information Program, which assists developing countries in improving drug quality by addressing gaps in the technical capabilities of quality assurance systems, enhancing drug quality control mechanisms, and building resources for countries to access rational drug information. USP has received a small amount of United States government funding for creation and updating of categories and classes to assure beneficiary access for provision of medicines under the Medicare Part D legislation. Additional grants with other external organizations include John Snow International (in effect from May 2007 until September 2011) and Population Services International (which began in October 2007 and ends in July 2011). In total, sales of USP compendial products and services account for 95% of the organization's revenue and the remaining 5% is derived from grant funding.

g. Meetings (indicate frequency and average attendance; send report of previous meeting, including any resolutions passed) that are concerned with matters covering all or part of the Commission's field of activity

The USP Convention membership meets every five years and 263 delegates attended the 2005 meeting. The proceedings of the 2005 USP Convention meeting including a list of attendees and the resolutions passed are provided in Appendix IV. There are no resolutions from the 2005 USP Convention that are concerned with matters covering all or part of the Commission's field of activity because USP had not yet acquired the *FCC* or begun its involvement in the food ingredients arena. The 2010 USP Convention is currently being planned.

The Board of Trustees convenes on a quarterly basis. The Executive Committee of the Board (the Board chairperson, the president and treasurer of the Convention, the public trustee, and the CEO) meet on an as needed basis. Meetings relating to *FCC* and food ingredients matters are conducted by the FIEC while five separate Dietary Supplements Expert Committees meet as needed on dietary supplements issues. Typically, these Expert Committees meet twice per year.

The USP Food Additives Ad hoc Advisory Panel met on February 22, 2007 and focused primarily on issues regarding finalization of standards for and publication of the 6th Edition of the *FCC*. Also in 2007, USP convened a Food Additives Stakeholders Forum and a Dietary Supplement Stakeholders Forum wherein representatives from national and international trade associations, governmental agencies, and public-interest groups met to share their thoughts and recommendations on the development and implementation of food ingredients and dietary supplements standards. A Food Ingredient Stakeholder Forum, which will focus on food ingredient issues and standards, is scheduled for August 4, 2009 at USP headquarters. On February 21, 2008, October 14, 2008, and February 19-20, 2009, the FIEC met at USP headquarters to discuss the development of food ingredient monographs and review its standard-setting process and procedures. USP also held an International Food Ingredients Issues Workshop on October 15, 2008 wherein speakers from U.S., Canada, Argentina (MERCOSUR), Mexico, the Middle East, Europe, China, Australia/New Zealand and Japan presented and discussed issues confronting the global food market.

Appendix IV contains a copy of the *Proceedings of USP Convention 2005*, the agendas of the February 22, 2007 Food Additives Ad hoc Advisory Panel, February 21, 2008, October 14, 2008, February 19-20, 2009 FIEC meetings and agendas and attendee lists of the 2007 Food Additives and Dietary Supplements Stakeholders Forums. Also included is the agenda and attendee list of the International Food Ingredients Issues Workshop, which took place on October 15, 2008.

h. Relations with other international organizations:

UN and its organs (indicate consultative status or other relationship, if any)

In 2007, USP attended the Thirty-Ninth Session of the Codex Committee on Food Additives (CCFA) as a member of the delegation of the Institute of Food Technologists, which has observer status at CAC meetings. In 2008, USP attended the CCFA meeting as a member of the U.S. Delegation. In 2009, USP will attend, again as a member of the U.S. delegation, the CCFA, Codex Committee on Contaminants in Foods (CCCF), CAC and the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) meetings. USP also plans to attend the Codex Committee on Methods of Analysis and Sampling (CCMAS) meeting in 2010.

USP consistently works closely with many of the same international senior scientific experts in developing food ingredient standards as does the CAC and its various committees. Most significantly, USP has worked with scientific experts that have been involved with the CAC's standards-setting activities, particularly CCCF, CCNFSDU and the Joint Expert Committee on Food Additives (JECFA).

Other international organizations (document substantive activities)

USP interacts with various international non-governmental organizations during the development of food ingredient standards approved for use in the U.S. and foreign countries. USP has worked closely with the International Food Additives Council (IFAC), the International Organization of the Flavor Industry (IOFI), and the International Chewing Gum Association (ICGA) to develop and provide food ingredient standards. IFAC, IOFI, and ICGA enjoy observer status at CCFA meetings.

Also, USP has international laboratory facilities and scientific staff in several countries including India, China, and Brazil. These facilities are being used to provide scientific expertise and state-of-art testing to meet the ever-growing challenges faced by the global food supply relating to intentional adulteration, food additive contaminants, and quality verification of food ingredients through Reference Standards.

i. Expected contribution to the Joint FAO/WHO Food Standards Programme

USP's standard-setting activities regarding pharmaceutical active ingredients, excipients, and final drug dosage forms have been an on-going international activity for almost 200 years. USP's elaboration of food ingredient quality standards through *FCC* and related activities for dietary supplements are complementary to CAC activities, and to the responsibilities of the CCFA, CCCF, CCNFSDU, CCMAS, JECFA and other programs. *FCC* food ingredient standards are vetted through the FIEC in much the same way that JECFA experts contribute to the development of food additive specifications. USP scientific expertise on specifications, analytical test procedures, and contaminants for both food additives and flavoring agents, at the USP professional staff level and through the international experts that serve on USP standard-setting committees, would provide a productive scientific resource on many issues confronting the CAC and its subsidiary bodies. USP also anticipates developing scientific expertise in emerging food ingredient areas such as nanotechnology and biotechnology which may contribute to CAC's efforts in these areas. USP believes that *FCC* can support and supplement the excellent specifications for food additives provided by the CAC through JECFA's *Combined Compendium of Food Additive Specifications*. *FCC* provides a helpful resource to JECFA experts and JECFA experts are known to develop new standards for food additives on the basis of specifications contained in the *FCC*. Likewise, USP with appropriate copyright permission from FAO, has incorporated JECFA food additive specifications during the development of *FCC* monographs. These collaborative efforts save valuable time and resources for both JECFA and USP in developing food additive and food ingredient standards. USP believes that participation as an observer at CAC and its subsidiary bodies will enhance collaboration, information-sharing and harmonization of standards that will benefit consumers and commerce around the world.

j. Past activities on behalf of, or in relation to, the Codex Alimentarius Commission and the Joint FAO/WHO Food Standards Programme (indicate any relationship by national affiliates with the Regional Coordinating Committees and/or the National Codex Contact Points or Committees for at least the last three years preceding the application).

As noted above, in 2007, USP attended the Thirty-Ninth Session of the CCFA as a member of the delegation of the Institute of Food Technologists, which has observer status at CAC meetings. USP's representative was permitted to inform the CCFA with notice that USP had acquired *FCC* from the IOM and would be publishing the 6th edition in 2008.

At the Fortieth Session of the CCFA held in Beijing, China on April 21-25, 2008, USP was part of the U.S. delegation. Unfortunately, because of the size of the delegation, USP was constrained from commenting, particularly during the discussion on specific food additive specifications. Based on its experiences during the last two CCFA meetings, USP emphasizes that obtaining observer status will enable USP to better share its knowledge and scientific expertise with the CAC and its subsidiary bodies particularly on the development and improvement of specifications concerning food additives, contaminants in food, nutrition and foods for special dietary uses and methods of analysis and sampling.

k. Area of activity in which participation as an observer is requested (Commission and/or Subsidiary Bodies). If more than one organization with similar interests is requesting observer status in any field of activity, such organization will be encouraged to form themselves into a federation or association for the purpose of participation. If the formation of such a single organization is not feasible, the application should explain why this is so.

USP is requesting observer status for the following activities:

(1) Codex Alimentarius Commission (CAC)

(2) Codex Committee on Food Additives (CCFA)

(3) Codex Committee on Contaminants in Food (CCCF)

(4) Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

(5) Codex Committee on Methods of Analysis and Sampling (CCMAS)

l. Previous applications for observer status with the Codex Alimentarius Commission, including those made by a member organization of the applicant organization. If unsuccessful, please indicate why and when observer status was terminated. If unsuccessful, please indicate the reasons you were given.

USP has **not** previously applied for observer status with the CAC.

m. Languages (English, French, or Spanish) in which documentation should be sent to the international non-governmental organization

Documentation should be sent to USP in English.

n. Name, Function and address of the Person providing the information

Susan S. de Mars

Chief Legal Officer

United States Pharmacopeia Convention

USP Headquarters

12601 Twinbrook Parkway

Rockville, MD 20852-1790, USA

Email: sdm@usp.org

o. Signature and date

Susan S. de Mars

Chief Legal Officer

April 27, 2009

ANNEX 3: ENA

a. Official name of the organization in different languages (with initials)
Early Nutrition Academy (ENA)

b. Full postal address, Telephone, Facsimile and Email, as well as Telex and website addresses as appropriate
The Early Nutrition Academy is registered at St. Gallen, Switzerland.
All correspondence should be directed to the:
ENA Managing Director
Prof. Dr. Berthold Koletzko
Dr. von Hauner Children's Hospital, Univ. of Munich Medical Centre
Lindwurmstr. 4, D-80337 München, Germany
Tel +49 89 5160 2826, Fax +49 89 5160 7742, office.koletzko@med.uni-muenchen.de
The ENA website address is: www.early-nutrition.org

c. Aims and subject fields (mandate) of organization, and methods of operation. (Enclose charter, constitution, by-laws, rules of procedures, etc.). Date of establishment
The Early Nutrition Academy was founded as a non-profit organization on 14 December 2006 at Fitzwilliam College, Cambridge, UK. The constitution, which also outlines the rules of procedures, is attached (cf. enclosure 1).

d. Member organizations (name and address of each national affiliate, method of affiliation, giving number of members where possible, and names of principal officers. If the organization has individual members, please indicate approximate number in each country. If the organization is of a federal nature and has international non-governmental organizations as members, please indicate whether any of those members already enjoy observer status with the Codex Alimentarius Commission)
The Early Nutrition Academy currently has only individual but no corporate members. The membership consists of highly qualified health care professionals and researchers with an active interest early nutrition and related topics from leading academic institutions in different parts of the world, including *(in alphabetical order)* Erasmus University Medical Center, Rotterdam, The Netherlands, Harvard Medical School, Boston, MA, USA; Kings College London. UK; Leiden University Medical Center, The Netherlands; Medical University of Graz, Austria; Medical University of Warsaw, Poland; Murdoch Children's Research Institute, University of Melbourne, Australia; National and Kapodistrian University of Athens, Greece; Norwegian Institute of Public Health, Oslo, Norway; Ostschweizerisches Kinderspital St Gallen, Schweiz; Statens Serum Institute, Copenhagen, Denmark, Telethon Institute for Child Health Research, University of Western Australia, Perth, Australia; The Children's Memorial Health Institute, Warsaw, Poland; The MetroHealth System, Case Western Reserve University School of Medicine, Cleveland, OH, USA; The Ohio State University Medical Center, Columbus, OH, USA; Université Libre de Bruxelles, Belgium ; University of Amsterdam, The Netherlands; University College Cork, Ireland; University College Dublin, Ireland; University Degli Studi di Milano, Italy; University of Auckland, New Zealand; University of Bristol, UK; University of California, Irvine, CA, USA; University of Cambridge, UK; University of Copenhagen, Denmark; University of Granada, Spain; University of Munich, Germany; University of Murcia, Spain; University of Nottingham, UK; University of Southampton, UK; University of Texas Health Sciences Center, San Antonio, TX, USA: and the University Rovira I Virgili, Tarragona, Spain:

e. Structure (assembly or conference; council or other form of governing body; type of general secretariat; commissions on special topics, if any; etc.)

The **General Assembly** of the ENA meets once a year and is the highest decision making body of the association. The management is executed by the **Council** comprising of the Managing Director (currently Prof. Berthold Koletzko, LMU Munich, Germany), Scientific Director (currently Prof. Michael Symonds, University of Nottingham, UK) and the Secretary (currently Prof. Cristina Campoy, University of Granada, Spain). The council is supported by the **Steering Committee** (currently Prof. Sjurdur Olsen, Copenhagen; Dr. Hans Demmelmair, Munich; Dr. Maria Rodriguez-Palmero, Barcelona; Rhonda Smith, Windermere, UK; Prof. Kurt Bärlocher, St. Gallen, Switzerland; Dr. Margaret Ashwell, Ashwell, UK; Prof. Marjo-Rita Järvellin, London, UK; and Prof. Lucilla Poston, London, UK. The secretariat is located at the office of the Managing Director.

f. Indication of source of funding (e.g., membership contributions, direct funding, external contributions, or grants)

The funding of ENA activity is raised from membership fees, incomes from workshops and training activities, which are often organized in collaboration with other non profit organisations, and from donations.

g. Meetings (indicate frequency and average attendance; send report of previous meeting, including any resolutions passed) that are concerned with matters covering all or part of the Commission?s field of activity

The scienfitic meetings organised or co-organised by the ENA since its foundation in 2006 so far include:

14-16/06/2011, Tutzing, Germany
Scientific workshop "Critical micronutrients in pregnancy, lactation and infancy" (in collaboration with the EU FP7 Project EURRECA)
24/05/2011, Sorrent, Italy (satellite to the 44th annual ESPGHAN conference)
Scientific Workshop on "Quality and safety aspects of infant nutrition" (in collaboration with the Child Health Foundation and ESPGHAN)
28-30/03/2011, Tutzing, Germany
Scientific Workshop on "Documentation of functional effects of infant nutrition" (in collaboration with the Child Health Foundation and ESPGHAN)
22-24/03/2011, Kyiv, Ukraine
ENA co-sponsored Workshop on "Malnutrition in children with disabilities in level 3-4 internats: clinical signs and symptoms, treatment and prevention", "Paediatric Nutrition Update" (in collaboration with the Sight and Life Initiative)
15-18/09/2010, Santander (Cantabria), Spain
Postgraduate school "Early nutrition and physical activity: determinants for metabolic programming" (in collaboration with Nutrivigen)
05/05/2010 Munich, Germany
Workshop on neurological test procedures (in collaboration with the EU FP7 Project NUTRIMENTHE)
06-08/05/2010 Munich, Germany
The Power of Programming. International Conference on Developmental Origins of Health and Disease (in collaboration with the EU FP6 Project EARNEST, EU FP7 Project NUTRIMENTHE, and the scientific societies DOHAD, ESPGHAN, ISSFAL, and IUNS)
October 2009 - July 2010, University of Bristol, UK
Short courses in research methods (in collaboration with the EU FP6 Project EARNEST)
01-04/10/2009, Granada, Spain
Postgraduate School: “Role of nutrition on brain development and behaviour” (in collaboration with the EU FP7 Project NUTRIMENTHE)
24 and 26/09/2009, Cracow, Poland
Workshop "Epidemiology and Statistics for Early life Researchers"
and International PhD training course "How to get your PhD successfully done"
03/04/2009, Warnemünde, Germany
Workshop on assessing brain function and behaviour (in collaboration with the EU FP6 Project EARNEST)
09-13/02/2009, Sierra Nevada, Granada, Spain
International Course "Pregnancy and Programming" (in collaboration with the EU FP6 Project EARNEST and Nutrivigen)
10/10/2008, Glasgow, UK
Workshop 'Current Techniques in Measuring Body Composition' (in collaboration with the EU FP6 Project EARNEST)
25/04/2008, Granada, Spain
Workshop on “Unlocking your potential for fame and fortune: press releases, presentations and proposals - everything you need to know about scientific communication” (in collaboration with the EU FP6 Project EARNEST)
Workshop on “Methodological and practical issues related to compiling and comparing data on maternal dietary intake in European birth cohorts for Joint Analysis of Diet in Pregnancy” (in collaboration with the EU FP6 Project EARNEST)
17/10/2007, Prague, Czech Republic
Workshop “Measurement of the Bioelectrical Impedance Vector; Analysis with the TANITA Scale BC-418 MA; Physical Activity and Lifestyle Questionnaire”
Workshop “Culture Fair Intelligence Tests - Scale 1”

(in collaboration with the EU FP6 Project EARNEST)
08-12/10/2007, Dummerstorf, Germany
Methods for the investigation of energy and substrate metabolism in pigs and mice (in collaboration with the EU FP6 Project EARNEST)
06-08/09/2007 PROBIT Minsk, Belarus
Workshop “PROBIT study III: Glucometry & Blood collection, Consent and data forms” (in collaboration with the EU FP6 Project EARNEST)
20-21/04/2007, Budapest
International Conference on "Early nutrition programming and health outcomes in later life: obesity and beyond" (in collaboration with the EU FP6 Project EARNEST)

h. Relations with other international organizations:

The ENA has established close collaborations with several European Commission supported research networks in the 6th. and 7th. Framework Programmes, including EARNEST, EURRECA, NUTRIMENTHE, PREVENT-CD, TORNADO, TOYBOX, and EarlyNutrition. In addition, collaborations and concerted activities have been established with several international scientific organizations including DOHAD (Developmental Origins of Health and Disease), ESPGHAN (European Society for Paediatric Gastroenterology, Hepatology, and Nutrition), ISSFAL (International Society for the Study of Fatty Acids and Lipids), and IUNS (International Union of Nutritional Sciences).

a. UN and its organs (indicate consultative status or other relationship, if any)

No established collaboration.

b. Other international organizations (document substantive activities)

No established collaborations other than those listed above.

i. Expected contribution to the Joint FAO/WHO Food Standards Programme

The membership of the ENA has in depth scientific and practical knowledge in nutrition and food safety that can help to inform the Codex Alimentarius Commission, and in particular the Codex Committee for Nutrition and Foods for Special Dietary Uses, towards best achieving their goals. Several ENA members have contributed to the work of CCNFSDU over many years as members of national delegations and of NGO observers and thus are familiar with the rules of procedure and the requirements of constructive contribution to the Codex process. We expect to contribute in particular to deliberations in the sensitive areas of nutrition during pregnancy and the breastfeeding period, and nutrition during infancy and early childhood, such as the current deliberations of CCNFSDU on complementary feeding.

j. Past activities on behalf of, or in relation to, the Codex Alimentarius Commission and the Joint FAO/WHO Food Standards Programme (indicate any relationship by national affiliates with the Regional Coordinating Committees and/or the National Codex Contact Points or Committees for at least the last three years preceding the application)

Prof. Berthold Koletzko, Munich and Prof. Hania Szajewska, Warsaw, have extensively contributed to work and sessions of CCNFSDU as members of their national and the ESPGHAN delegations.

k. Area of activity in which participation as an observer is requested (Commission and/or Subsidiary Bodies). If more than one organization with similar interests is requesting observer status in any field of activity, such organizations will be encouraged to form themselves into a federation or association for the purpose of participation. If the formation of such a single organization is not feasible, the application should explain why this is so.

The ENA requests to be granted Observer Status at the Codex Committee for Nutrition and Foods for Special Dietary Uses. To our knowledge no other organisation with a characteristic similar to ENA has Observer Status at CCNFSDU, thus forming a federation of several associations appears not to be a suitable option.

l. Previous applications for observer status with the Codex Alimentarius Commission, including those made by a member organization of the applicant organization. If successful, please indicate why and when observer status was terminated. If unsuccessful, please indicate the reasons you were given.

The ENA has not applied before for Observer Status.

m. Languages (English, French or Spanish) in which documentation should be sent to the international non-governmental organization

We request all communication in the English language, please.

n. Name, Function and address of the person providing the information

Berthold Koletzko, Dr med Dr med habil (MD PhD), Professor of Paediatrics
Managing Director, Early Nutrition Academy
Dr von Hauner Children's Hospital, Univ. of Munich Medical Centre
Lindwurmstr. 4, D-80337 München, Germany
Phone +49 89 5160 2826, Fax +49 89 5160 7742
email: office.koletzko@med.uni-muenchen.de

o. Signature and date
Thank you very much indeed for kindly considering this request.
Sincerely yours
Berthold Koletzko, Dr med Dr med habil, Professor of Paediatrics, Managing, Director, Early Nutrition Academy

ANNEX 4: FEEDM

PART I: Application

a) Official name: F.E.E.D.M.

Fédération Européenne Des Emballeurs Et Distributeurs De Miel

European Federation of Honey Packers and Distributors

b) Contact details:
Grosse Baeckerstrasse 4
20095 Hamburg
Phone: 0049-40-37 47 19-0
Fax: 0049-40-37 47 19-19
E-Mail: feedm@waren-verein.de
Website: www.feedm.com

c) Aims and subject fields: Representing and coordinating the interests of the European honey business.

Date of establishment: 1989

Enclosure: by-laws of our association.

d) Member organizations:

- Austria: Darbo AG
- Belgium: Meli B.V.
- Finland, Hunajainen SAM Oy
- France, Syndicat Français des Miels
- Germany, Honig-Verband e.V.
- Greece, SETSEM
- Hungary, Magyar Mézkereskedök és Csomagolók Egyesülete (Association of Hungarian Honey Distributors + Packers)
- Italy, A.I.I.P.A.
- Netherlands, De Traay B.V.
- Poland, Corpo Gadek Rogalski sp.j.
- Portugal, Apisland LDA
- Slovenia, Medex d.o.o.
- Spain, Asemiel
- United Kingdom and Ireland, British Honey Importers & Packers Association

and as associated EFTA-member:

- Switzerland, Narimpex AG

Please find attached the F.E.E.D.M.'s members list with detailed information on the member associations / single companies.

e) Structure: The association's secretariat is located in Germany, at the above stated address. The members of the association meet bi-annually for the General Assembly which takes place in Spring and Autumn each year at different locations. The main tasks of F.E.E.D.M. are: securing the high quality of honey and representing the interests of the European honey trade at EU and international level.

f) Indication of source of funding: membership contributions

g) Meetings: are held twice every year

h) Relations with other international organizations: FEEDM is member of APIMONDIA. F.E.E.D.M. currently holds the chair at the Advisory Group on Beekeeping at the EU Commission. F.E.E.D.M. is furthermore registered as interested party with the European Medicines Agency, EMA.

i) Expected contribution to the Joint FAO/WHO Food Standards Programme: expertise of anything related to the trade in honey. Particularly we would like to act as expert in the field of veterinary residues in honey and Pyrrolizidine Alkaloids in honey.

j) Past activities: We are registered as Interested Party with EMA in London and as experts at the Advisory Group on Beekeeping at the EU Commission. F.E.E.D.M. maintains contacts to the International Honey Commission, IHC and works closely together with independent laboratories.

k) Area of activity in which participation as observer is requested: Codex Committee Veterinary Drugs and electronic working group for MRLs in honey, as well as Pyrrolizidine Alkaloids.

l) Previous applications for observer status with the Codex Alimentarius Commission: None

m) Languages in which documentation should be sent to the international non-governmental organization: English

n) Name, function and address of the person providing the information:

Dr. Katrin Langner, Secretary General

Grosse Baeckerstrasse 4, 20095 Hamburg, Germany.

o) Date: Signature:

Hamburg, 25 August 2011

Dr. Katrin Langner LL.M.

Secretary General

F.E.E.D.M.

PART II: Clarification on relations with APIMONDIA (existing Codex observer)

Apimondia unites many different associations as international umbrella organization, but with a main focus on beekeeping/apiculture. The structure of Apimondia includes different Scientific Committees but there is no working group existing for the product “honey”. FEEDM has proposed to establish such a working group within Apimondia, but it could not be implemented. Apimondia deals with more technical apiculture related questions.

FEEDM is the European umbrella association for honey importers and traders. Our focus lies more on the product itself. Quality and food safety issues are very important for our association and we are very active in this field. In our understanding FEEDM could contribute to quality safety issues regarding honey and representing the specialized field of interest of the trade in honey, so for this reason we applied for the observer status.

ANNEX 5: ICAAS

PART I: APPLICATION

1. MATTER:

The request by the International Council on Amino Acid Science (ICAAS) to obtain "observer status" with the Codex Alimentarius Commission according to the "*Principles concerning the participation of international non-governmental organizations in the work of the Codex Alimentarius Commission*".

2. OFFICIAL NAME OF THE ORGANIZATION:

English: International Council on Amino Acid Science (ICAAS)
French: Conseil international sur la science des acides aminés

3. FULL POSTAL ADDRESS

International Council on Amino Acid Science (ICAAS)
Avenue Jules Bordet 142
B-1140 Brussels, Belgium
TEL: +32-2-761-1676; FAX: +32-3-761-1699
URL: http://www.icaas-org.com

4. AIMS, SUBJECT FIELDS & METHODS OF OPERATION

Introduction:

ICAAS is an international non-profit association comprised of organizations having interests in amino acid science and incorporated in Belgium since 2008.

ICAAS was established in the year 2000 in Tokyo, Japan. Since then, ICAAS has sponsored a series of international workshops as well as scientific studies on adequate intakes and quality control of amino acids used for nutritional purposes in dietary supplements and foods. In addition, ICAAS has been working on elaborating a new and easy-to-specification method that would enable to identify critically adultered amino acid foods and supplements and it is cooperating with the USP and other governmental bodies, especially in developing countries.

Aims of ICAAS:

1. To explore and resolve scientific concerns related to the safety and quality of amino acids used for nutritional (non-technological) purposes in food and dietary supplements.
2. To establish a framework for assessing and predicting the consequences of differing levels of amino acid intakes in humans.
3. To develop ICAAS quality specifications for amino acid products available on the market in order to ensure consumer safety.

Subject fields:

1. Holding international workshops on the assessment of adequate and safe intakes of dietary amino acids. ICAAS has held a series of international workshops (see **Annex Ia – Ie** for the proceedings) with experts from various research fields from the academic, industrial and government sectors to discuss adequate intakes of amino acids and their safety evaluation methodologies. The next workshop, devoted specifically to upper limits of intake of two amino acids, leucine and tryptophan, is envisioned for November 2011 in Washington DC.
2. Implementing research studies. Via ICAAS Research Funding, ICAAS has provided selected research studies with subsidies to accelerate data-based discussions on determining upper limits of intake for amino acids in foods and supplements.
3. Improving quality control of existing amino acids supplements, including specification control.
4. Presenting scientific information to regulatory authorities and cooperate with the Codex Alimentarius Commission for the furtherance of the objectives of the Joint FAO/WHO Food Standards Program related to the specifications and general safety of nutrients, including amino acids
5. Disseminating to the public scientific information on amino acids.

Methods of operation:

1. ICAAS (see **Annex II** for bylaws in the French language (English translation is also attached) is regulated by the provisions of Title III of the Belgian Law of June 27, 1921 concerning non-profit associations and international non-profit associations.
2. ICAAS is governed by the appointed Board of Directors and General Meeting of the member organizations, and advised by an Scientific Advisory Committee currently consisting from 6 academic scientists, as follows:

- Prof. Dennis M. Bier (Baylor College of Medicine, USA)
- Prof. Sidney M. Morris (Uni. Pittsburgh, College of Medicine, USA)
- Prof. Andrew G. Renwick (Emeritus Professor, Univ. Southampton, UK)
- Prof. Luc A. Cynober (Paris Descartes Univ., France)
- Prof. Yuzo Hayashi (NPO Commission Centre, Food & Health Sciences, Japan)
- Prof. Motoni Kadowaki (Niigata Univ., Japan)

5. MEMBER ORGANIZATIONS:

ICAAS is currently comprised of individual member organizations, as follows:

1. Kyowa Hakko Bio. Co., Ltd., **Japan** (principal officer: Dr. K. Morishita)
2. Evonik Rexim S.A.S., **France** (principal officer: Dr. A. Karau)
3. Ruinian International Ltd., **P. R. China** (principal officer: Mr. H. Tsang)
4. Ajinomoto Co., Inc., **Japan** (principal officer: Dr. R. Yamaguchi)
5. Meiji Diaries Corporation, **Japan** (principal officer: Dr. T. Kaneko)
6. Otsuka Pharmaceuticals Co., Ltd., **Japan** (principal officer: Mr. D. Ikeda)
7. S.A. Ajinomoto Omnichem NV, **Belgium** (principal officer: Mr. H. Hayashi)
8. Suntory Holdings, Ltd., **Japan** (principal officer: Dr. H. Tsujimura)
9. Kyowa Hakko Europe, GmbH, **Germany** (principal officer: Dr. D. Bartschat)
10. Aji Amino Science LLC., **USA** (principal officer: Mr. J. S. Heaton)

Organizations temporarily discontinuing membership (2011):

1. Taiwan Amino Acid Manufacturers Association, **Taiwan ROC**

6. STRUCTURE & MEETINGS:

- ICAAS (association) is a council of member organizations (companies or associations). Each member organization of ICAAS appoints one person as its representative to the association. Each member organization has a voting right and has at least one vote.
- ICAAS activities comply with antitrust laws and any other applicable laws, rules and regulations.
- The association is managed by the Board of Directors (not remunerated) consisting from at least three directors who are appointed by the General Meeting. The Board of Directors has extensive powers for the purposes of management and administration, except those powers attributed to the General Meeting.
- The General Meeting (organized at least once per year) requires an attendance or representation by proxy of more than half of member organizations. Resolutions are adopted by a simple majority of the votes of the present or represented member organizations. Minutes are retained (see **Annex III** for the minutes of the last three General Meetings).
- The Chief Executive Officer is appointed at the Board Meeting (organized at least once per year, see **Annex IV** for the minutes of the last three Board Meetings). The Chief Executive Officer supports the Board of Directors and is responsible for carrying out activities decided at the General and the Board Meetings.
- The President of ICAAS (can be remunerated) is nominated at the Board Meeting and appointed at the General Meeting.
- Member organizations located within a region may establish a chapter and may have a chapter office in the region. Currently, a European and a Japanese chapter are established for the purposes of scientific activities within the concerned region. The association allocates funds to Chapters for their discretional use. Detailed allocation rules are determined at the Board Meeting.
- A Secretariat is established to handle the day-to-day operations of the association. A part of Secretariat work is currently entrusted to a professional organization (Kellen Europe Co., Brussels, Belgium).
- Besides the General and the Board Meetings, ICAAS Research Funding Committee Meetings and ICAAS Scientific Advisory Committee Meetings are called depending on the scientific needs of the association. ICAAS Research Funding Committee Meetings are attended by the appointed scientific members of each member organizations and ICAAS Scientific Advisory Committee Meetings are attended by the academic advisors to ICAAS (see Chapter 4, “Methods of Operation”). Finally, ICAAS workshop organization committee meetings are being organized depending on needs.

7. SOURCE OF FUNDING:

All expenditures of ICAAS, including its research program (IRF), are covered with membership contributions, as governed by the ICAAS bylaws.

8. RELATIONS WITH OTHER INTERNATIONAL ORGANIZATIONS:

United States Pharmacopeia (USP) and Food Ingredients Stakeholder Forum of USP

ICAAS has attended the scientific meetings and given expert comments in respect to amino acid specifications in dietary supplements. Moreover, ICAAS has recently submitted to USP a proposal for

utilizing a novel approach on specifications of amino acids for the Food Chemical Codex (see, **Annex V**, working document) as a simple method to determine the most critically adultered amino acids in food supply. ICAAS proposal is being evaluated by USP experts (1st round of meetings finished in late January 2011).

The International Life Science Institute (ILSI) and ILSI Research Foundation

The 7th Amino Acid Assessment Workshop, sponsored by ICAAS in November 2007 (Tokyo), was co-organized with ILSI Japan as a satellite symposium to the 5th International Conference on Nutrition and Aging (see **Annex Ia**)

The 8th Amino Acid Assessment Workshop scheduled for November 2011 is co-organized with ILRI RF (Wahsington DC).

Japanese Society of Nutrition and Food Science

ICAAS Japan co-organized with the Japanese Society of Nutrition and Food Science the Satellite Symposium (Advances in Amino Acid Research in Human Health and Disease), at the 19th International Congress of Nutrition (Oct. 2009) in Bangkok, Thailand.

Codex Alimentarius Commission

ICAAS statement on the "Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment, 2-6 May 2005" was submitted to the Codex Alimentarius Commission.

9. EXPECTED CONTRIBUTION TO THE JOINT FAO/WHO FOOD STANDARDS PROGRAM

ICAAS activity has an immediate relevance to:

- a Joint WHO/FAO/UNU Expert Consultation on protein and amino acid requirements in human nutrition.
- Codex Committee on Contaminants in Foods & Codex Committee on Nutrition and Foods for Special Dietary Uses, especially in respect to the use of amino acids.
- a Joint FAO/WHO Committee for Establishing Upper Levels of Intake for Nutrients and Related Substances.

Additional comments:

1. Amino acids are extensively used in dietary supplements and fortified foods in the developed countries and their safety in terms of both upper limits and specifications is not being adequately controlled. In addition, in some developing regions, nutritional inadequacy of essential amino acid(s) still represents a significant health care issue. Thus, on a global basis, there are diversified risks of inadequacy, on the one hand, and excess and/or contamination of amino acid supplements/foods, on the other.
2. ICAAS has harnessed an extensive know-how in amino acid sciences, assembled a wide network of academic experts, is sponsoring major research projects on amino acid safety (see **Annex VI** for the latest report of an ICAAS-sponsored research presented at "Experimental Biology", CA in April 2010), so far has organized 7 major international workshops devoted to amino acid safety out of which the last 5 were published as proceedings to the J. Nutrition (see, **Annex Ia - Ie** for the proceedings).

10. PAST ACTIVITIES ON BEHALF OF THE CODEX ALIMENTARIUS COMMISSION

none

11. AREA OF ACTIVITY IN WHICH "OBSERVER STATUS" IS REQUESTED

- Codex Committee on Contaminants in Foods (CX-735)
- Codex Committee on Nutrition and Foods for Special Dietary Uses (CX-720)
- Codex Alimentarius Commission Sessions

12. PREVIOUS APPLICATIONS FOR "OBSERVER STATUS"

none

13. LANGUAGES IN WHICH DOCUMENTATION SHOULD BE SENT

English

14. NAME, FUNCTION AND ADDRESS OF THE CORRESPONDING PERSON

Dr. Miro Smriga, CEO

International Council on Amino Acid Science (ICAAS)

Avenue Jules Bordet 142; B-1140 Brussels, Belgium

Email: ICAAS@kelleneurope.com

15. SIGNATURE & DATE

…… ……..……

Miro Smriga, PhD Date

PART II: Clarification of membership rules

Following our phone call of 25 July 2011 regarding the ICAAS application to obtain observer status at CODEX, I would like to reiterate the membership criteria which apply to become member to the association. The key-requirement to become a member is included in the ICAAS statutes. Art. 6 states in particular that,"*ICAAS welcomes all organizations that have interests in amino acid science, for example, corporations, associations and academic institutions"*. Therefore and in line with the statutes, ICAAS cannot and does not hold any judgment on the data of administrative nature that members submit in their application such as contact details and addresses. I hope that with this letter any query regarding the ICAAS membership application is clarified.

Hans Craen
ICAAS Secretariat.

ANNEX 6: YLFA

Part I: Application

A. NAME OF THE ORGANIZATION:
- English (original denomination): **YLFA International – Association of Yoghurts & Live fermented milks.**
- French **: YLFA International – Association des yaourts & laits fermentés vivants**

B. POSTAL ADDRESS:

Rue de l'Association 32
1000 Brussels
Belgium
Tel: +32 2 210 20 30
Fax : +32 2 210 20 35
E-mail : c.lambert@ylfa.org
Web: www.ylfa.org

C. AIMS AND SUBJECT FIELDS:

1. Mandate: The purpose of the Association is to promote and defend **yoghurts, live fermented milks and other live fermented dairy products.**

To attain its purpose, the Association intends to pursue the following activities:
 Define the concepts of yoghurts and other live fermented milks.
 Act with national and international public authorities, particularly at the legislative level, to promote and ensure the recognition of the definition of yoghurts and other live fermented milks.
 Generate, coordinate and use all studies (scientific, consumer, economic, etc.) intended to show the benefits to consumers provided by "live" products and to promote knowledge about and the image of yoghurt products and other live fermented milks.
 Encourage relations and exchanges with international scientific experts studying yoghurts and other live fermented milks and their health benefits.
 Conduct information exchanges among members in compliance with the purpose of the Association and with competition legislation. To this end, the association shall adopt specific operating rules to help its bodies to comply with competition legislation.

2. Association's fields of study

Association's fields of study: **YLFA** works to safeguard and protect the specificity of (live) yoghurt and live fermented milks and closely monitors all international, regional and national standards and regulations that may impact the yoghurt and live fermented milks industry.

This includes amongst others, standards on definitions and denominations (e.g. the Codex Standard on fermented milk, the FAO definition of probiotics), food safety (e.g. the legal status of living organisms), as well as nutrition and health benefits (e.g. nutrient profile and health claims).

3. Date of establishment:

The association was founded in Paris in January 2005. YLFA moved to Brussels in 2008 and became an international non profit association, according to Belgian Law on 2 December 2009.

Attachment I: bylaws (last version, dated 9/12/2009 – in French, *original language*, and English).

D. MEMBERS

Members
Organisations, companies, or institutions which are directly interested in the development of the yoghurt and other live fermented milk products industry may be members. More precisely, the Association is composed of **active members** and **associate members. Active members** are members that manufacture yoghurts and other live fermented milks. Currently, active members are leading companies such as Danone,

Lactalis-Nestlé produits frais, Yoplait and Yakult. **Associate members** are organisations, companies, institutions and entities that are directly or indirectly interested in the development of the yoghurt and live fermented milks industry, without, however, producing them.
Currently, the Association counts two associate members, both being cultures producers: Chr. Hansen and Danisco. Our members are active in more than **65 countries**.

Attachment II: Member's list.

Procedure and criteria for affiliation:

Organisations, companies, institutions, entities and individuals who wish to join the Association must send their application to the Chairman of the Board of Directors or to the Executive Director of the Association. The application shall be submitted for approval at the next **Extraordinary General Meeting** of the Association.

E. STRUCTURE

YLFA is governed by the General Meeting ('Assemblée Générale') made up of all the active members.
Other governing bodies include:

 The **Board of Directors** which is composed of a minimum of three Members appointed by the General Meeting, including one President and one treasurer.
 The **Secretariat** counts one member of staff dedicated to YLFA International. The Secretariat is in charge of the daily management of the association, as well as the representation of the Association before EU and international institutions, the coordination of the working groups and the general secretarial work.
 The **Working Groups**: Technical & Regulatory Working Group and Communications group. Special ad hoc groups may be appointed to work on specific issues; for instance, ad hoc groups are appointed to work on fermented milks and yoghurt (health benefits, Q&A…), on probiotics (probiotic food category) or on inherent characteristics of fermented milks.

F. FUNDING:

YLFA is financed solely and directly via membership fixed contributions. No external funding or grants are received.

G. MEETINGS:

 General Meeting: meetings at least once a year with an average attendance of 15 people.
 Board of Directors: meetings at least three times a year with an average attendance of 10 people.
 Working Groups: four to six meetings a year with 10 attendees on average. Regarding the Codex Alimentarius activities, we were intensively involved in the discussions and adoption of the Codex standard on fermented milks STAN 243-2003. We expressed our views through some of the Members States of the Codex. In attachment, you will find our position regarding the last modification of the Codex STAN 243-2003.
Currently, regional drafts on fermented milks like the one on Ayran or Doogh are or will be in discussion. This is the reason why we send you our application as observer.

Attachment III: Position paper Codex Standard on Fermented milks

H. RELATIONS WITH OTHER INTERNATIONAL ORGANIZATIONS

YLFA represents the fermented milks industry mainly before European institutions, in particular before the various Directorates General of the European Commission such as Directorate General for Health and Consumers Protection (DG Sanco) and DG Agri with which it maintains frequent contacts. Currently we work mainly on health claims, nutrient profiles or – in collaboration with other associations – on food information or quality standards. YLFA International is the **only** association at European and international level representing yoghurt and fermented milk producers. YLFA is not a Member of any other international (like IDF) or European association representing dairy products. No other association is member of YLFA. Therefore, YLFA has no relationship with associations having the status of observer at Codex level.

Attachment IV: Example of position paper sent to the EU Commission.

I.EXPECTED CONTRIBUTION TO THE JOINT FAO/WHO FOOD STANDARD PROGRAMME

As an expanding association representing the key producers of yoghurt and fermented milks worldwide, YLFA is a highly qualified representative to express industry views and share out experience on fermented milks.

Market

*The yoghurt and fermented milks market represents **€ 55 billion** and **20 million tons** produced per year with North America, Europe and Asia accounting for 50% of the market. Sales of yoghurt and fermented milks also continue to expand worldwide, most noticeably in emerging markets such as China and Russia as well as in countries of the Middle East, North Africa and Latin America. In the span of 5 years, the global sales value increased of about 25 %. The functional fermented milks market grew from € **2, 13 billion** in 2005 to **€ 3, 3 billion** in 2010, which means an increase of 55%. In particular the probiotic drinks have contributed to fermented milks market growth, leading to some of the most innovative new products in the dairy sector today.*

J. PAST ACTIVITIES ON BEHALF OF, OR IN RELATION TO, THE CODEX ALIMENTARIUS COMMISSION AND THE JOINT FAO/WHO FOODS STANDARDS PROGRAMME

As expressed under point G, we were indirectly involved in Codex activities – through our close collaboration with some of the Codex Members or the EU Commission.

K. AREA OF ACTIVITY IN WHICH PARTICIPATION AS AN OBSERVER IS REQUESTED

Observer status is requested in relation to any Codex Commission work likely to affect fermented milks, in particular, works on the Codex Standard on Fermented Milks (STAN 243-2003) or the Regional Standards on Fermented Milks like Ayran or Doogh. We are also interested in the related matters like the works of the Codex Committee on Nutrition and Foods for Special Dietary Uses or Food labelling.

L. PREVIOUS APPLICATIONS FOR OBSERVER STATUS WITH THE CODEX ALIMENTARIUS COMMISSION, INCLUDING THOSE MADE BY A MEMBER ORGANIZATION OF THE APPLICANT ORGANIZATION.

To our knowledge, no application was ever made by any member of YLFA.

M. LANGUAGES:

Working languages during meetings/conference calls: French/English. Documents may be sent to the Secretariat in French, English and Spanish.

N. NAME AND FUNCTION OF THE PERSON PROVIDING THE INFORMATION.

Carine Lambert
Director
Rue de l'Association 32
1000 Brussels
Belgium

O. SIGNATURE AND DATE
17.05.2011

PART II: Clarification on years since establishment (email from Carine Lambert)

YLFA was founded in Paris in 2005. In order to give more "visibility" to the association, YLFA moved to Brussels in 2008. We then had to "convert" our bylaws into new ones, in order to make them aligned to the Belgian Law. Unfortunately the procedure was unexpectedly extended due to the fact that Belgium had no government, and that the executive power couldn't ratify the Decree recognising YLFA as International non profit association. Despite these elements, the name and number of members, the content of the bylaws and the aim of the Association are exactly the same as from 2005… Except for the location, YLFA has existed in its current form for more than 3 years.

ANNEX 7: AIPCE

a. Official name:

AIPCE

In English:
EU Fish Processors Association – AIPCE
In French:
Association des Industries du Poisson de l'U.E. – AIPCE

b. Contact details:

AIPCE c/o AGEP
Boulevard Saint-Michel 77-79
B-1040 Brussels
Tel: +32 2 740 29 61
Fax: +32 2 732 51 02
E-mail: aipce@agep.eu
Website: http://www.aipce-cep.org

c. Aims

Objectives of the association according to our Statutes:

AIPCE's aim is to promote and supply market, scientific, legal, economic and general information together with commercial and statistical studies relating to the fish processing industries. AIPCE also develops and promotes the interest and image of its members and the industry within the EU, representing these interests where it matters.

AIPCE supplies promotional and IT services for its members and organise meetings, conferences and events as required.

The association also works together with other bodies on matters of common interest to achieve these objectives.

The field of activity of AIPCE is defined in detail by decision of the General Assembly.

Date of Establishment: 1959

d. Member organisations: attached

e. Structure:
- General Assembly
- Board of Directors
- Working groups: if necessary to examine technical matters requiring expert opinion
- Permanent Secretariat:

Aurora VICENTE Herrera – Secretary General
Adriana NOSEWICZ – Policy Advisor

f. Indication source of funding:
100% membership contributions

g. Meetings

General Assembly: every year, full attendance

Board of Directors: President and/or Secretary General of the national associations, on average 3-4 times a year
Working groups: 10 times a year

h. Relations with other international organisations

AIPCE cooperate with CEP (EU Fish Traders Association), ACFA and European Commission

i. Expected contribution to the Joint FAO-WHO Food Standards Programme

Codex Committee on Fish and Fishery Products

k. Area of activity

Fishery products, Hygiene, Additives, Labelling, Smoking etc.

m. Languages

English

n. Name, function and address

Aurora VICENTE Herrera
Secretary General AIPCE
Boulevard Saint-Michel 77-79
B-1040 Brussels
Belgium

o. Signature and date

Aurora VICENTE Herrera
16 November 2011