

## **Conference**

# **Botanical Products as Food, Herbal Remedies and Drugs: Safety Aspects**

**Thursday, November 20 2008**

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**Centro Congressi Cariplo**  
Via Romagnosi, 6  
**Milan**

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Botanical products are used as food, drugs and herbal remedies; these products fall, therefore, under different legal classifications and regulations.

This conference, promoted by NFI- Nutrition Foundation of Italy, together with ASSOERBE, Italian Association for Regulatory Activities – SIAR and Società Italiana delle Scienze e delle Tecniche Erboristiche-SISTE, aims at providing an in-depth analysis of the current regulatory situation of botanical products from a global perspective, within the context of the European market, and the legal requirements that define their classification.

Moreover, current approaches relevant to evaluation of the safety of such products in their pertinent regulatory frameworks will be discussed and clarified.

State of the art activities of EFSA and EMEA in this field will be presented, to provide an updated insight. Recognised experts from academia, industry, and institutions will offer a range of viewpoints and will contribute, through interactive discussions, to highlight the future of this rapidly evolving sector.

# Program

h. 8,45 **Registration of participants**

9,30 **Introductory remarks**

*Rodolfo PAOLETTI*

*Vittorio SILANO*

9,40 **I session**

**The regulatory framework**

*Chair: Giuseppe RUOCCO*

**European and national regulations relevant to botanical products**

*Barbara KLAUS*

10,00 **II session**

**Activities of EFSA and EMEA**

*Chair: Agostino MACRI*

**Activities of EFSA**

*Bernard BOTTEX*

**Activities of HMPC/EMEA**

*Lucia D'APOTE*

*Discussant: Gioacchino CALAPAI*

10,50 *Coffee Break*

11.10 **III session**

**Analysis of the implementation of regulations on food supplements and traditional herbal medicines in the UE member states**

*Chair: Alessandro TORSELLO*

***Viewpoints of industry associations***

**Food supplements**

*Patrick COPPENS*

**Traditional Herbal Medicines**

*Hubertus CRANZ*



***Viewpoints of the institutions***

**The food sector**  
***Bruno SCARPA***

**The pharmaceutical sector**  
***Marisa DELBO'***

**The herbal remedies sector**  
***Paola MINGHETTI***

*Discussant: Giuseppe RUOCCO*

12.35 *Lunch*

13,30 **IV session**  
**Round Table: The way forward**

*Chair: Vittorio SILANO*

*Participants:*

***Bernard BOTTEX***

***Hubertus CRANZ***

***Lucia D'APOTE***

***Marisa DELBO'***

***Agostino MACRI'***

***Luisella MAJORI***

***Valentino MERCATI***

***Anna PAONESSA***

***Bruno SCARPA***

***Hartwig SIEVERS***

***Marinella TROVATO***

15,30 **Final Discussion**

16,00 *Coffee Break*

16,15 **V session**  
**Issues related to traditional Chinese Medicine**

*Chair: Alvaro VACCARELLA*

**New herbal compound against Alzheimer's disease from traditional medicine: Huberzine**

***Maria Laura COLOMBO***

**Medicinal plant and immunomodulation in Chinese traditional medicine**

***Ario CONTI***

**Traditional Chinese medicine herbal drug monographs in European pharmacopoeia**

***Franco VINCIERI***

17,30 *End of the Conference*



## **SPEAKERS AND CHAIRMEN**

**Bernard BOTTEX** - Scientific Officer, Scientific Committee & Advisory Forum, European Food Safety Authority - EFSA (Parma, Italy)

**Gioacchino CALAPAI** - Department of Clinical and Experimental Medicine and Pharmacology, University of Messina (Messina, Italy)

**Maria Laura COLOMBO** – Medicinal Plant Biology, School of Pharmacy, University of Turin (Turin, Italy)

**Ario CONTI** - Alpine Institute of Chemistry and Toxicology, Alpine Foundation for Life Sciences (Olivone, Switzerland)

**Patrick COPPENS** - Secretary General, Botanical Forum (Bruxelles, Belgium)

**Hubertus CRANZ** - Director General, Association of the European Self-Medication Industry - AESGP (Bruxelles, Belgium)

**Lucia D'APOTE** - Post-Authorisation Evaluation of Medicines for Human Use Unit, Regulatory Affairs and Organisational Support (RAOS) Sector, European Medicines Agency - EMEA (London, UK)

**Marisa DELBO'** - GMP Senior Inspector, Manufacturing and Control Department – GMP Inspection Unit, Italian Medicines Agency - AIFA (Rome, Italy)

**Barbara KLAUS** - Lawyer, meyer//meisterernst (Milan, Italy); Lecturer in food law (University of Munich and European Centre for Judges and Lawyers in Luxemburg)

**Agostino MACRI'** - Director, Animal Welfare and Food Safety Department, Italian National Institute of Health (Rome, Italy)

**Luisella MAJORI** – Board of Directors, Italian Association for Regulatory Activities - SIAR (Milan, Italy)

**Valentino MERCATI** - Vice President, ASSOERBE (Milan, Italy)

**Paola MINGHETTI** - Institute of Pharmaceutical Chemistry and Toxicology University of Milan (Milan, Italy)

**Rodolfo PAOLETTI** - President, Nutrition Foundation of Italy (Milan, Italy)

**Anna PAONESSA** – Italian Association of Food Product Industries (Milan, Italy)

**Giuseppe RUOCCO** – Head, Directorate General of Drugs and Medical Devices, Italian Ministry of Labour, Health and Social Policies (Rome, Italy)

**Bruno SCARPA** - Veterinary Health, Food and Nutrition Directorate, Italian Ministry of Labour, Health and Social Policies (Rome, Italy)

**Hartwig SIEVERS** - PhytoLab GmbH & Co KG (Vestenbergsreuth, Germany)

**Vittorio SILANO** - President, Scientific Committee, European Food Safety Authority – EFSA (Parma, Italy)

**Alessandro TORSELLO** - Vice President, Italian Association for Regulatory Activities - SIAR (Milan, Italy)

**Marinella TROVATO** - President, Società Italiana delle Scienze e delle Tecniche Erboristiche - SISTE (Milan, Italy)

**Alvaro VACCARELLA** - Scientific and Medical Office, China-Italy Foundation (Milan, Italy)

**Franco VINCIERI** – Department of Pharmaceutical Sciences, University of Florence (Florence, Italy)

## GENERAL INFORMATION

**Venue of the Conference** - the meeting will take place on **November 20, 2008** at **Centro Congressi Cariplo** in **Via Romagnosi, 6 – Milan**. The venue is in the city centre of Milan, at 5 minutes walking distance to the Dome.

**Simultaneous Translation** – the official language of the meeting will be Italian. A simultaneous translation from Italian into English (and *viceversa*) will be provided to participants.

**Registration and Fees** – Participants are entitled to: - attend the scientific sessions - receive the conference material; - nr. 1 lunch; - Nr. 2 Coffee breaks; - CD rom of the speakers' slides (to be delivered after the Conference)

### **Registration Fee for members of the Italian Associations ASSOERBE - SIAR – SISTE**

- |                              |   |                                   |
|------------------------------|---|-----------------------------------|
| • <b>By October 10, 2008</b> | € | <b>300,00</b> (€ 250,00+ VAT 20%) |
| • <b>By November 5, 2008</b> | € | <b>360,00</b> (€ 300,00+ VAT 20%) |

### **Registration fee for non members**

- |                              |   |                                   |
|------------------------------|---|-----------------------------------|
| • <b>By October 10, 2008</b> | € | <b>360,00</b> (€ 300,00+ VAT 20%) |
| • <b>By November 5, 2008</b> | € | <b>420,00</b> (€ 350,00+ VAT 20%) |

To register **after November 5, 2008** please contact the Scientific-Organizing Secretariat. **Participants must send both the Registration form** (filled in all its parts) **and a copy of the bank transfer to the Scientific Organizing Secretariat (NFI - Centro Studi dell'Alimentazione - Nutrition Foundation of Italy, Viale Tunisia 38 - 20124 MILAN- Italy; Phone: +39 02 76006271 - +39 02 76399532, Fax: +39 02 76003514; E-mail: [meeting@nutrition-foundation.it](mailto:meeting@nutrition-foundation.it)).**

Written notice of cancellation must be sent to the Secretariat not later than **November 7 2008**. If cancellation notice is received by this date, the registration fee will be refunded, less 30%. Cancellations received after November 7, 2008 will not be refunded.

**Method of Payment** – Please transfer the payment to:  
**CENTRO STUDI DELL'ALIMENTAZIONE.**

*Bank details: Credito Artigiano – Agency n. 13, Via Lazzaretto, 19 - Milan, Italy*

*Account number: 000000007889- IBAN: IT49Q0351201618000000007889-*

*SWIFT CODE/BIC: ARTI IT M2- CIN: Q - CAB: 01618 - ABI: 03512*

*For further information, please contact:*

**NFI – Centro Studi dell'Alimentazione - Nutrition Foundation of Italy**

**Viale Tunisia 38 - 20124 Milan, Italy – Phone: +39 02 76006271- 76399532**

**Fax: 02 76003514 - E-mail: [meeting@nutrition-foundation.it](mailto:meeting@nutrition-foundation.it)**

**Website: [www.nutrition-foundation.it](http://www.nutrition-foundation.it)**

# REGISTRATION FORM

## Conference

### **Botanical Products as Food, Herbal Remedies and Drugs: Safety Aspects**

**Milan, November 20, 2008**

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Nutrition Foundation of Italy**

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**Phone: +39 02 76006271 - +39 02 76399532, Fax: +39 02 76003514;**

**E-mail: [meeting@nutrition-foundation.it](mailto:meeting@nutrition-foundation.it)**

#### **PERSONAL DETAILS**

Family name/ Surname

First Name and middle initial(s)

Position

Department

Institution/Organization/Company

Address

City

Postal code/Zip

Country

Telephone

Fax

E-mail

#### **INVOICE DETAILS (*Compulsory*)**

Family name and First Name/ Company	
Address	
City	Postal code/Zip
Country	
VAT Code (compulsory for EC company)	

## **PAYMENT**

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The personal data will be handled exclusively by Centro Studi dell'Alimentazione according to the law 675/96 and D.L. 196/2003.

Date \_\_\_\_\_

Signature \_\_\_\_\_

