

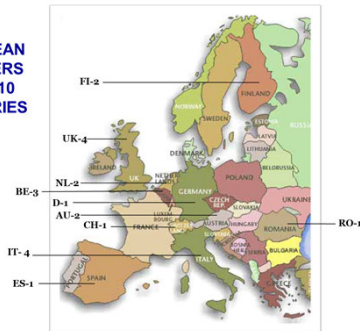
PlantLIBRA – useful overview and international tool for science-based decision-making by regulators and food chain operators

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PlantLIBRA (acronym of **Plant Food Supplements: Levels of Intake, Benefit and Risk Assessment**) is a project co-financed within the context of the 7th EU Framework Program (EC Project 245199). PlantLIBRA aims to foster the safe use of food supplements containing plants or botanical preparations, by increasing science-based decision-making by regulators and food chain operators.

21
EUROPEAN
PARTNERS
FROM 10
COUNTRIES



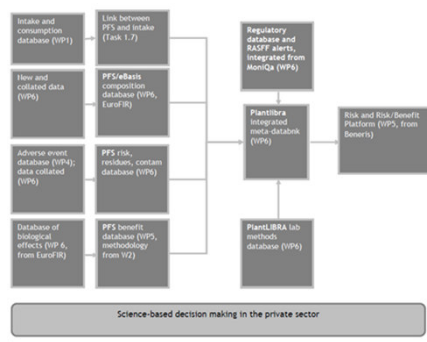
4 ICPC Partners



ICPC (coordinator)	Università degli Studi di Milano	ICPC	Country
2	BioDetection Systems B.V.	BDS	The Netherlands
3	Council for Scientific and Industrial Research	CSIR	South Africa
4	European Advisory Services	EAS	Belgium
5	European Botanical Forum	EBF	Belgium
6	Euro	Euro	Finland
7	Fundación para la Investigación Nutricional	FIN	Spain
8	Hycoates Consulting Srl	HYLO	Italy
9	International Association for Cereal Science and Technology	ICC	Austria
10	Institute of Food Research	IFR	United Kingdom
11	Institute of Medicinal Plant Development	IMPAD	China
12	Isola, Sussone di Savoia	ISL	Italy
13	PhytoLab GmbH & Co. KG	PLFN	Germany
14	Società Italiana Scienze e Tecniche Erboristiche	SISTE	Italy
15	Swiss Toxicological Information Center	STIC	Switzerland
16	Kansanterveyslaitos	TSL	Finland
17	Hospital de Clínicas "José de San Martín", University of Buenos Aires	UBA	Argentina
18	University of Surrey	UNIS	United Kingdom
19	University of Leeds	UOL	United Kingdom
20	Universidade de São Paulo	USP	Brazil
21	Universitatea Transilvania din Brasov	UTBV	Romania
22	Universitatilíder	UIRiB	Austria
23	Wageningen University	WUR	The Netherlands
24	European Food Information Resource Network ASBL	EuroFIR	Belgium
25	Department for Environment, Food and Rural Affairs	Defra	United Kingdom

PlantLIBRA Work Packages

- WP1: Intake estimation of Plant Food Supplements (PFS)
- WP2: Methodology of benefit assessment for PFS, application and validation
- WP3: New concepts for the risk assessment of PFS, application and validation
- WP4: Investigation on adverse effects to botanicals and PFS: methods, biological markers, network of Poison Centers
- WP5: Integration of risk and benefit assessment models, risk benefit assessment and validation
- WP6: Meta-database of composition, biologically active compounds, safety information, residues and contaminants
- WP7: Investigation on botanical ingredients and PFS: plant identity, methods, new compounds, network of laboratories
- WP8: Consumer and stakeholder perceptions of PFS
- WP9: Dissemination, international cooperation and stakeholders
- WP10: Policy implications
- WP11: Management



Brochure for PFS consumers – Questions- Recommendations

- Why the plants in food supplements?
- Do the PFS contribute to my total diet?
- What are the benefits of PFS?
- Should I check with my doctor or healthcare provider before using a PFS?
- Some supplements may interact with prescription and over-the-counter medicines
- Can PFS as natural products be considered safe?
- Who is responsible for ensuring the safety and efficacy of PFS?

<http://www.plantlibra.eu>

Transilvania University of Brasov - partner of PlantLIBRA project

WP1 – Definitions + concepts/Survey in Romania

- Key informant data
- Survey – preparation of questionnaires + implementation + Data analysis
- Lists of PFS in Romania – Company, PFS, Names of the plants, Forms of presentation
- Data analysis - articles

WP2 – Benefits of PFS

- Review of evidence for PFS benefit from epidemiological studies

WP6 – PlantLIBRA database

- Data collection – analytical methods

WP7 – Analytical methods

- Contaminants detection
- Develop of network of laboratories in order to perform different analysis

WP8 – Consumers and stakeholder perception of PFS

WP9 – Dissemination activities

- Brochure of the project – also in Romanian - www.plantlibra.eu
- International Conference HNPB 2011 – Healthy Nutrition and Public Health –presentation- Italy, Romania, South Africa, China
- Round Table - Botanical food supplement regulatory and scientific framework in EU: open questions and possible solutions, Brasov May 16, 2011 – for local and national authorities and universities
- Conference - Botanical food supplements: from regulatory aspects to technical and scientific rules, May 17, 2011 – for SME's, universities, doctors, pharmacists, students
- Press conference – Brasov – May 18, 2011
- Project meeting – 17-20 May 2011, Brasov

Level of Intake

To collect data on PFS intake patterns in different European and extra-European countries several points must be considered

- Different terminologies and classifications of PFS: necessity to harmonize the partners' action
- Definition of intake (PFS, food, etc.)
- Definition of consumer (period of intake)
- Collection of data on PFS market from operators (producers, importers, shops, etc.)
- PFS intake survey among consumers
- Objective: Identification of top ten for the most important categories (body weight control, antioxidant, menopause, etc.)

Consumer and stakeholder perception

To collect data on PFS perception – UK, Italy, Romania

- Key informant interviews - 10 interviews in each of 3 countries – experts from pharmaceutical industry, retailers, interest groups, regulators, consumer associations
- Information for consumers - leaflets, magazine articles (women magazine, health magazine...), package labels
- Understanding stakeholder and consumer perceptions of PFS - create "mental model"

ePlantLIBRA functions

Data inputting: Via 5 online systems

- Chemical data
- Biological data
- Adverse effects
- PFS information
- Plant information

Data supporting: sophisticated covered data retrieval software system, searchable by compound, food, biological effect

- Chemical
- Bio-effects
- PFS info
- Plant details
- Metadata

Benefits

To collect data on PFS benefits: Systematic revision of the literature according to PlantLIBRA guidelines

Collection of data for plants included in the Annex 1 of the project (36 plants suggested by PlantLIBRA partners and stakeholders)

Definition of benefit and biomarker

Collection of experimental approaches for benefit assessment (in vitro tests, omics, etc.)

Some areas have been identified (UMIL → metabolic syndrome, CVD and diabetes)

Objective: Identification of main gaps for future PlantLIBRA activities

Adverse effects - Poisonings

To collect data on PFS adverse effects in humans:

- Revision of the literature according to PlantLIBRA guidelines
- Collection of cases from Poison Centers and National surveillance systems
- Groups at risk
- Identification of markers of exposure
- Set up of methods of analysis
- Studies on new cases – network of PC
- Objective: Protocols for PC survey (case collection), retrospective PC case study (focusing on misidentification), prospective case study

Risk-benefit assessment

Development of risk-assessment approaches:

- Review of existing approaches to risk assessment for food and similar products (some documents are at disposal – EFSA and other EU projects)
- Total intake is a critical point
- Specific points must be considered: benefit for someone could be risk for other groups, overconsumption, interaction with drugs

Dissemination

Logo:

WWW.PLANTLIBRA.EU

PlantLIBRA activities in different languages (English, Italian, Spanish, Portuguese, Romanian, Chinese)

Newsletter: bi-monthly newsletter distributed by e-mail

PlantLIBRA Brochure: edited in English, Portuguese, Romanian and Chinese

Conclusions

The project will directly achieve the following objectives:

- Meta-Database containing data on consumption and biological activity of constituents and contaminants;
- Accessible risk, benefit and risk-benefit models for Plant Food Supplements;
- Dissemination of data and models relevant to risk-benefit for PFS to stakeholders in order to assist science-based decision making and enhance international cooperation and harmonization