Plant Food Supplements: Level of Intake, Benefit and Risk Assessment

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on behalf of SISTE (WP9 leader)

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Plant Food Supplements: Level of Intake, Benefit and Risk Assessment

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Seventh Framework Programme
Theme 2
Food, Agriculture and Fisheries, and Biotechnology

Large-scale integrating project for specific cooperation actions dedicated to international cooperation partner countries (SICA)
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21 EUROPEAN PARTNERS FROM 10 COUNTRIES
4 ICPC Partners

- Argentina Buenos Aires
- Brasil San Paulo
- South Africa Pretoria
- China Beijing
## 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
Meta-Database on PFS

- **Aim:** To develop, test and apply a sustainable integrated meta-database of biologically active compounds
- Compositional data; inherent compounds and contaminants/ residues
- Bioeffects data; both beneficial and adverse
- PFS information; claimed effect, ingredients, active substances, target group, contraindications
- Plant information; photos, scientific name, 16 languages, part used

- **Workshop in Barcelona – September 2010**
  Guidelines for a Systematic Literature Search (SLS)
Safe use of food supplements

Science-based decision-making

Risk, benefit and risk-benefit assessment

Extended Methodology

Intake and consumption patterns

Expansion and generation of knowledge

Accessible metadata

Collation and production of data

Consumer and Policy Research
ePlantLIBRA functions

Data inputting:
Via 5 online systems
- Composition data
- Beneficial data
- Adverse effects
- PFS information
- Plant information:

Data reporting:
sophisticated user led data retrieval software system, searchable by compound, food, biological effect:
- Composition
- Bio-effects
- PFS info
- Plant details
- MoniQA

Interface linking composition, RASFF reports validated methods on residues and contaminants from the MoniQA database to PlantLIBRA database.
Level of Intake

To collect data on PSF 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.)
Benefits

To collect data on PSF 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 PSF 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
Consumer and stakeholder perception

To collect data on PSF perception

- 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”
Dissemination

✓ Logo: PlantLIBRA

✓ WWW.PLANTLIBRA.EU
  Project objectives and activities in different languages (English, Italian, Spanish, Portuguese, etc.) from 1st October

✓ Newsletter n.1 December 2011 distributed by Web and e-mail

✓ PlantLIBRA Brochure edited in English, Spanish, Italian, Portuguese, Romanian and Chinese
Dissemination events

- **Brasov, 17-20 May 2011**
  - 2nd PlantLIBRA Project meeting
- **Berlin, 8-9 December 2011**
  - Conference: *The regulation of food supplements in Europe*
- **Beijing (China), December 2011**
  - PL presentation by Paul Finglas (IFR)
- **Utrecht, February 2012**
  - PFS related projects initiatives for cooperation (Nat-Test, GP-TCM): Patrizia Restani (PL presentation Nat-Tes)
- **Strassburg, 4th July 2012**
  - Conference: Scientific and Regulatory questions on plant food supplements: discussion on practical approaches
    Université de Strasbourg
- **Rome, 21 September 2012**
  - Conference: efficacy and safety of botanicals food supplements: scientific approaches
    Italian Minister of Health
    Simultaneously with 10th anniversary of the EFSA
- **Rome, 19-21 September 2012**
  - 3rd PlantLIBRA Project Meeting