



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



**Seventh Framework Programme**

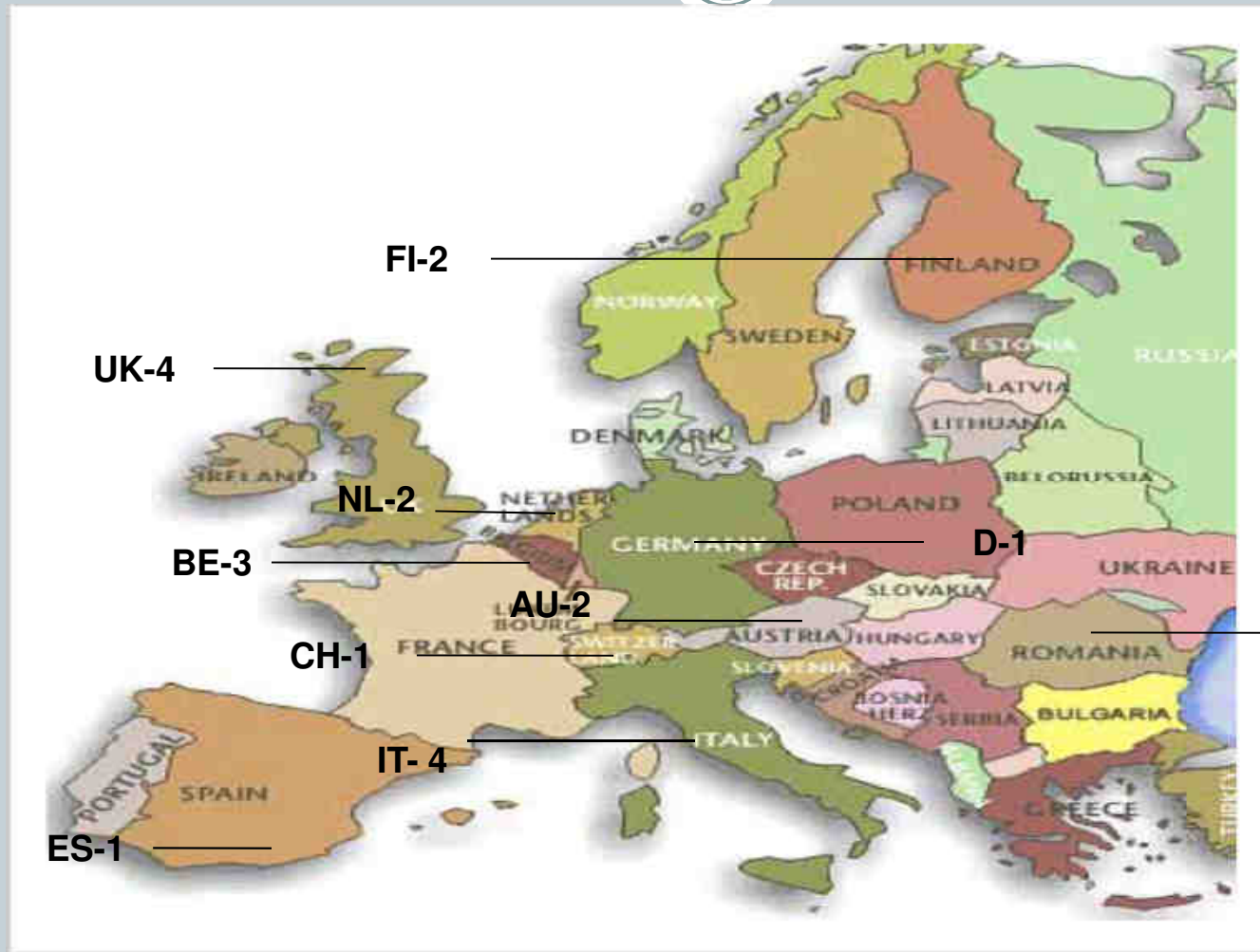
**Theme 2**

**Food, Agriculture and Fisheries, and Biotechnology**

**Large**-scale integrating project for specific cooperation actions dedicated to international cooperation partner countries (**SICA**)

1 (coordinator)	Università degli Studi di Milano	UMIL	Italy
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	Evira	Evira	Finland
7	Fundación para la Investigación Nutricional	FIN	Spain
8	Hylobates 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	IMPLAD	China
12	Istituto Superiore di Sanità	ISS	Italy
13	Phytolab GmbH & Co. KG	PLFIN	Germany
14	Società Italiana Scienze e Tecniche Erboristiche	SISTE	Italy
15	Swiss Toxicological Information Center	STIC	Switzerland
16	Kansanterveyslaitos	THL	Finland
17	Hospital de Clinicas "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	Universität Wien	VUW-Bot	Austria
23	Wageningen University	WUR	The Netherlands
24	European Food Information Resource Network AISBL	EuroFIR	Belgium
25	Department for Environment, Food and Rural Affairs	Defra	United Kingdom

# 21 EUROPEAN PARTNERS FROM 10 COUNTRIES



# 4 ICPC Partners



Political Map of the World, April 2006



Argentina  
Buenos Aires

Brasil  
San Paulo

South Africa  
Pretoria

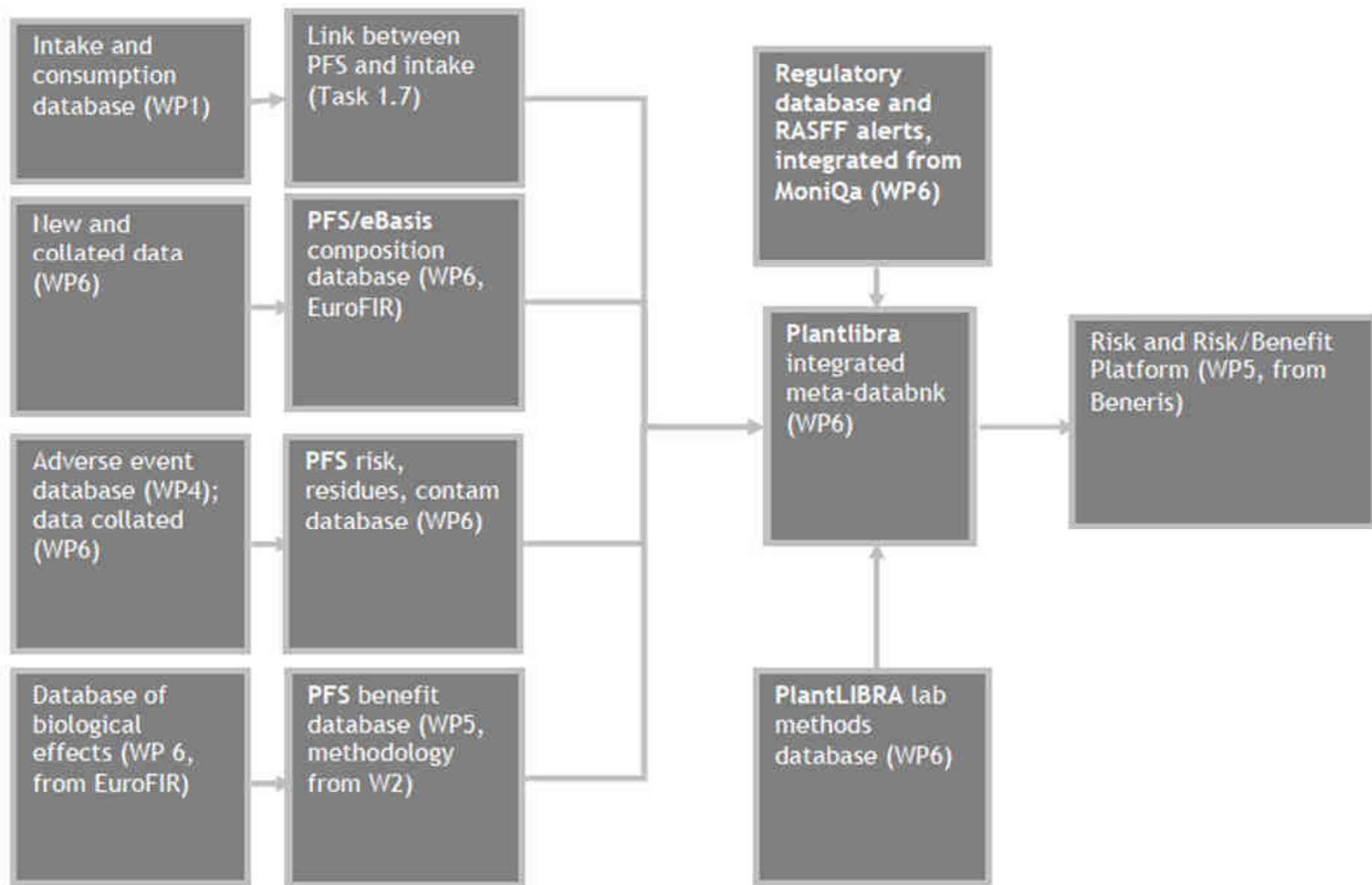
China  
Beijing

# 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





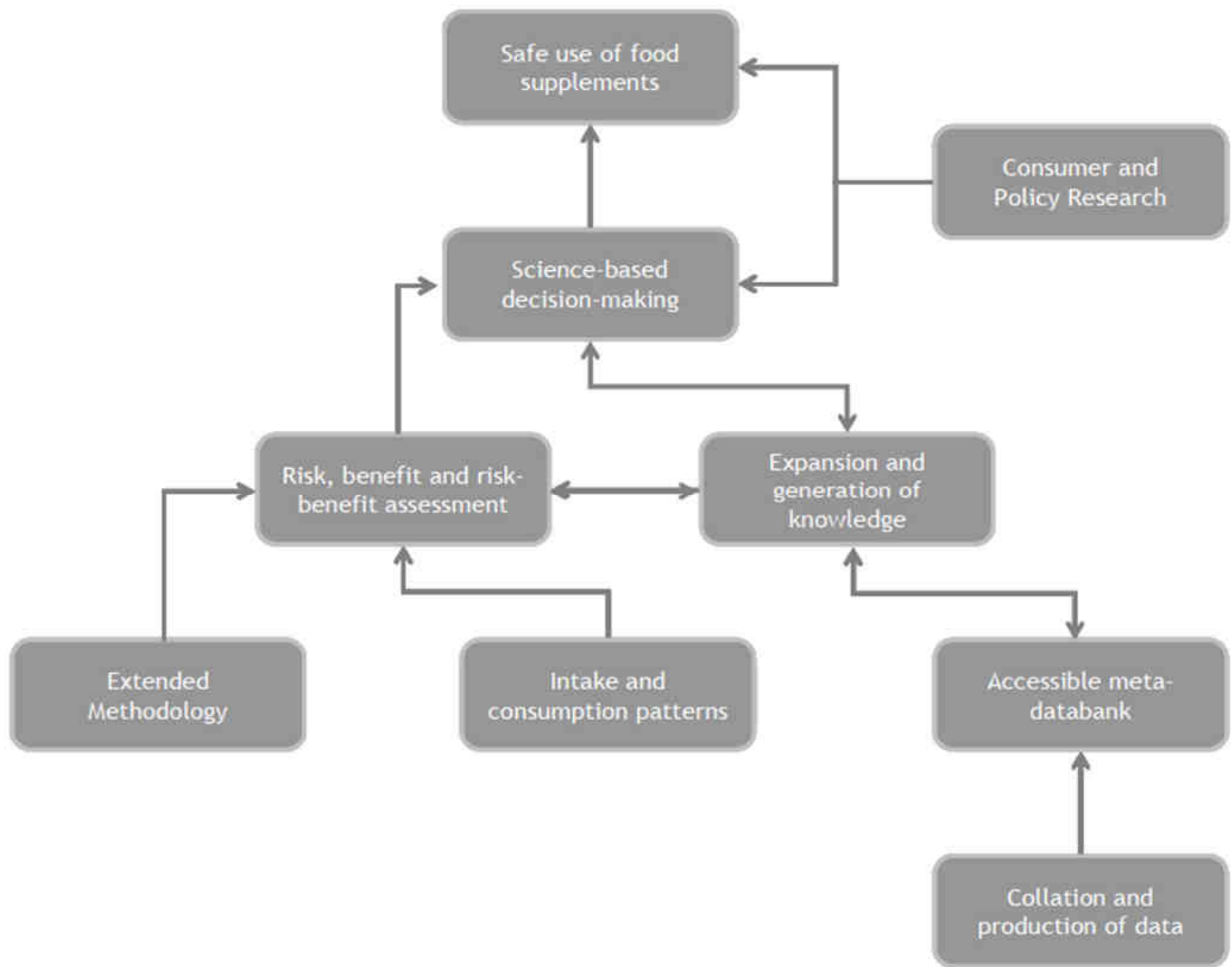
Science-based decision making in the private sector

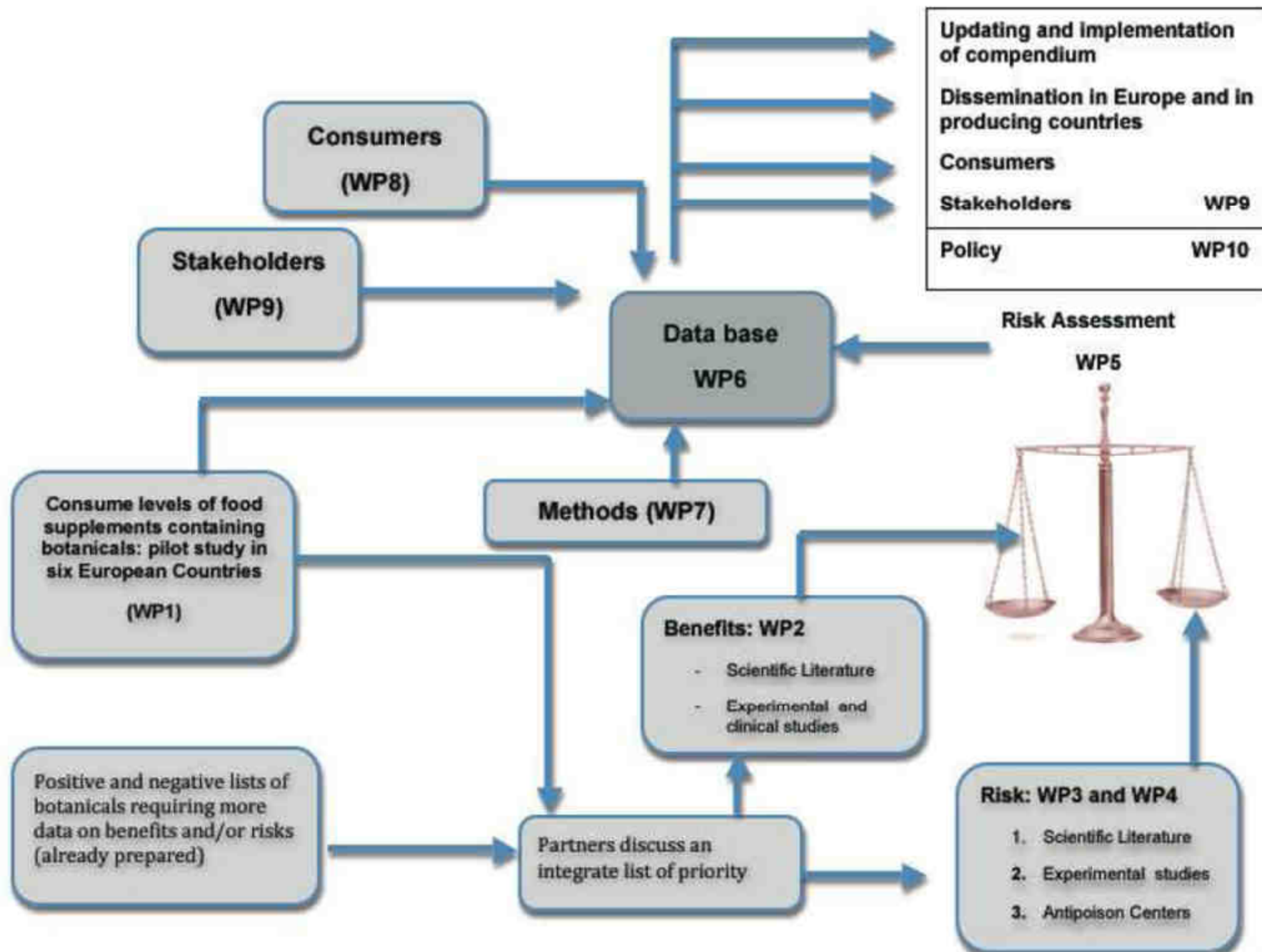


# Meta-Database on PFS



- **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)*





# ePlantLIBRA functions

## Data inputting:

Via 5 online systems

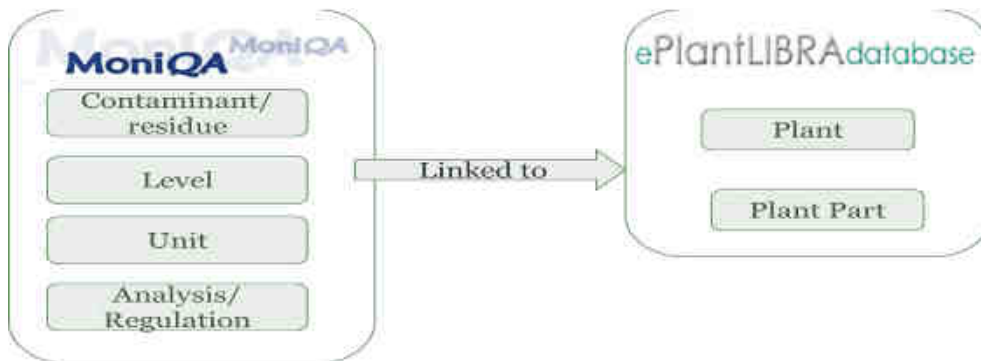
- Composition data
- Beneficial data
- Adverse effects
- PFS information
- Plant information:

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

## Data reporting:

sophisticated user led data retrieval software system, searchable by compound, food, biological effect:

- Composition
- Bio-effects
- PFS info
- Plant details
- MoniQA



Compositional	Level	Unit	Analysis
Calcium	0.1	mg/kg wet weight	Regulation 2002/31/EC
Calcium	1.25	mg/kg wet weight	Regulation 2002/31/EC

# Level of Intake

Food supplements  
Herbals  
Botanicals  
Nutraceuticals....

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”

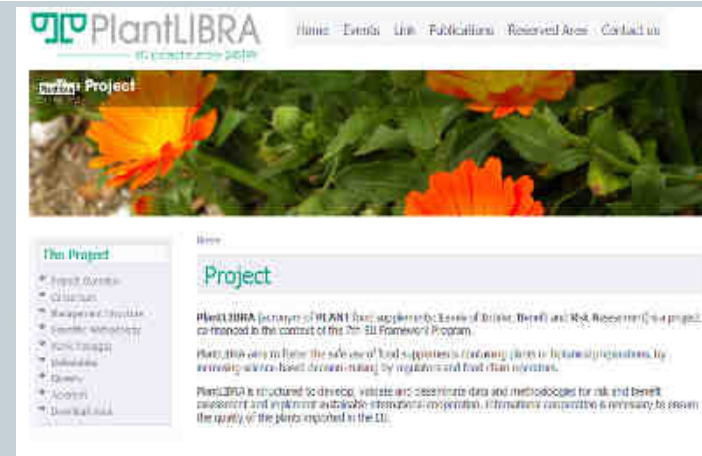
# Dissemination

- ✓ **Logo :**



- ✓ **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**
  - **2<sup>nd</sup> 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 4<sup>o</sup> 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**





*The PlantLIBRA  
team*