

Plant Food Supplements; Composition, Benefits, and Adverse Effects, Results and Sustainable Outputs

Jenny Plumb

Paul Finglas

on behalf of PlantLIBRA project partners

Food Databanks National Capability, Food and Health Institute of Food Research, Norwich, UK

Natural Product Biotechnology Conference

Inverness 20th November 2014



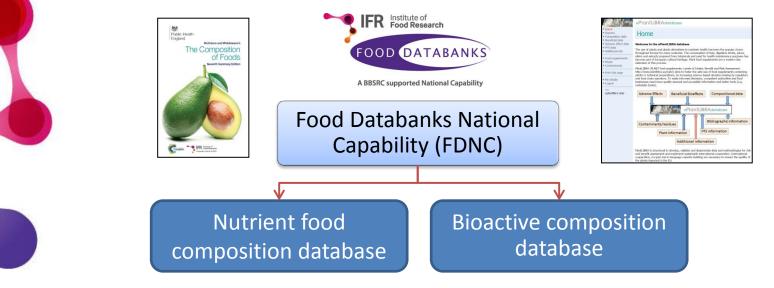








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Plant Food Supplements History and Traditional Use

"Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect whose purpose is to supplement the normal diet."





'Stop drinking nothing but water; take a little wine for your digestion, for your frequent ailments' Timothy 5:23







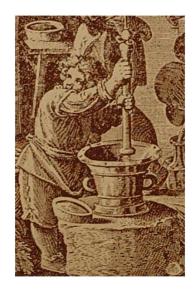




Plant Food Supplements to the present time













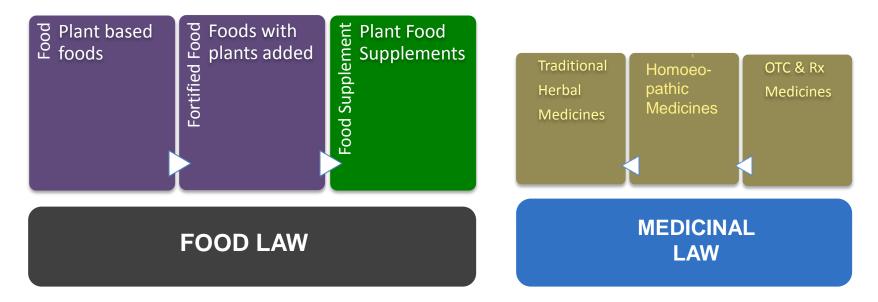








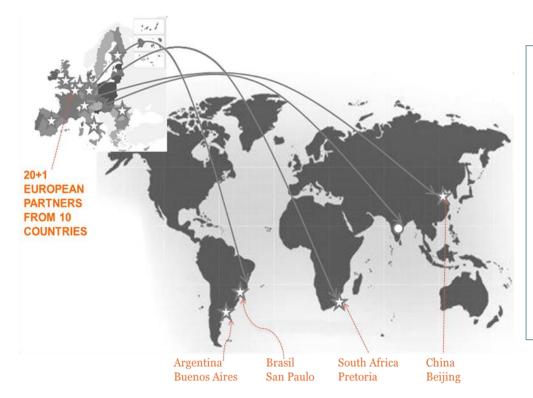
Food Supplement Directive 2002/46





Need for science based decisions & clear definitions & structured, searchable, reliable information on quality, safety and efficacy on botanicals





Main targets:

- To promote the safe use of PFS
- To increase science-based decision-making
- To create new data and methods
- To implement international cooperation

EC FP7 project: 2010-2014, 25 partners, 14 countries



FOOD DATABANKS

DPlantLIBRA

EC project number 245199



Patrizia Restani Uni of Milan patrizia.restani@unimi.it





Main PlantLIBRA outputs

- Consumer survey, Consumer perception
- Risk benefit studies
- Analytical methods
- Regulatory aspects
- ePlantlibra database

	ePlantLIBRAc	database	
Home Reports Composition data	You are now logged in.		
Beneficial data Adverse effect data PES data	Home		
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http://www.eurofir.org/plantlibra









Consumer survey

Intake estimation of Plant Food Supplements

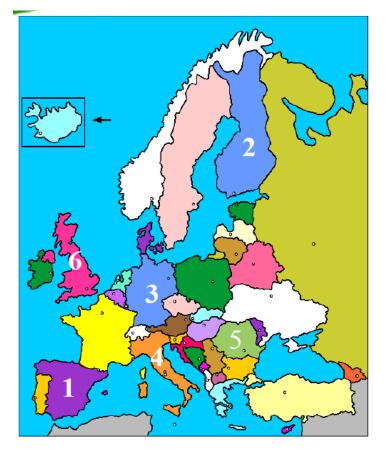
• Six EU countries, n=2359 Spain, Finland, Germany, Italy, Romania, UK

Consumers

- Demographic information
- Socio-economic data
- Lifestyle factors

Products and botanicals

- Product information
- Consumption patterns







Alicia Garcia-Alvarez fin@fin.pcb.ub.es





Most commonly used botanicals in PFS

Ginkgo biloba Oenothera biennis Cynara scolymus Panax ginseng Aloe vera *Foeniculum vulgare* Valeriana officinalis Glycine max Melissa officinalis Echinacea purpurea Vaccinium myrtillus

ginkgo evening primrose artichoke ginseng aloe fennel valerian soybean lemon balm echinacea blueberry







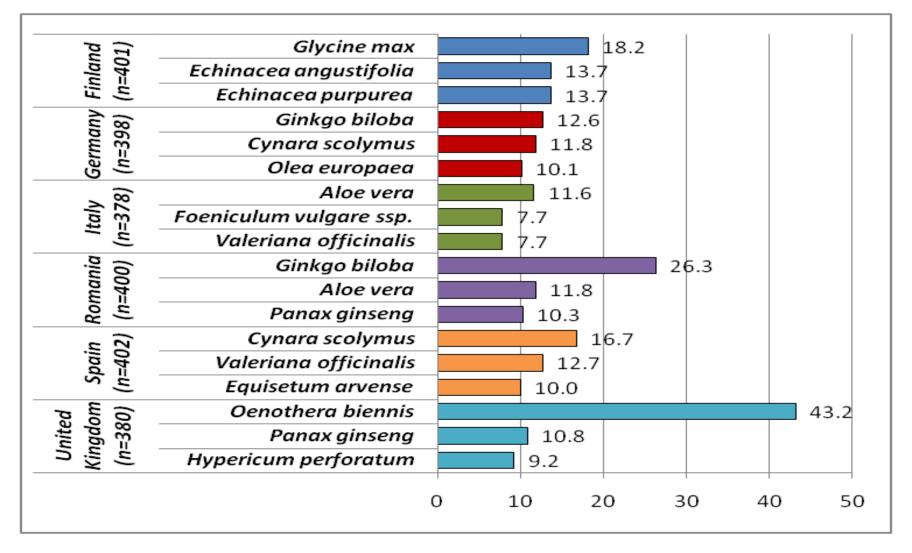


S. de Klein simone.deklein@phytolab.de





ABBSRC supported National Capabilithree most used PFS-contained botanicals (%), per country







Alicia Garcia-Alvarez *fin@fin.pcb.ub.es*





Ten most reported sources of recommendation of PFS consumption

	Total	Finland	Germany	Italy	Romania	Spain	United Kingdom
	%	%	%	%	%	%	%
Friend/relative	38.2	41.1	44.9	30.7	39.7	33.1	38.1
Nobody/myself	23.2	42.7	22.3	15.6	16.4	14.3	18.3
Herbal shop assistant	15.6	17.2	6.2	34.2	10.3	15.2	10.4
Doctor/General Physician	10.7	4.7	12.2	12.3	22.6	9.7	4.6
Pharmacist	10.0	2.9	20.1	12.7	18.5	6.9	1.4
Nutritionist/dietitian	8.2	2.7	2.0	1.4	4.1	20.4	21.0
Magazine/newspaper	8.1	18.0	10.4	1.7	6.0	0.4	7.5
Internet/social group	6.5	7.9	12.2	3.1	6.5	4.0	4.8
Homeopath	5.1	2.3	10.2	3.3	2.6	9.3	4.1
TV/radio	2.2	3.8	3.1	0.9	3.0	1.1	0.2





Alicia Garcia-Alvarez *fin@fin.pcb.ub.es*





Consumer Perception: benefits sought

- Defence /immunity (33%)
- **Energy (15%)**
- Digestive function (14%)
- □ Sleeping (10%)
- □ Flu/cold (10%)
- Hair/skin (9%)
- Body weight (9%)
- □ Relaxation (8%)
- Joints and bones (8%)





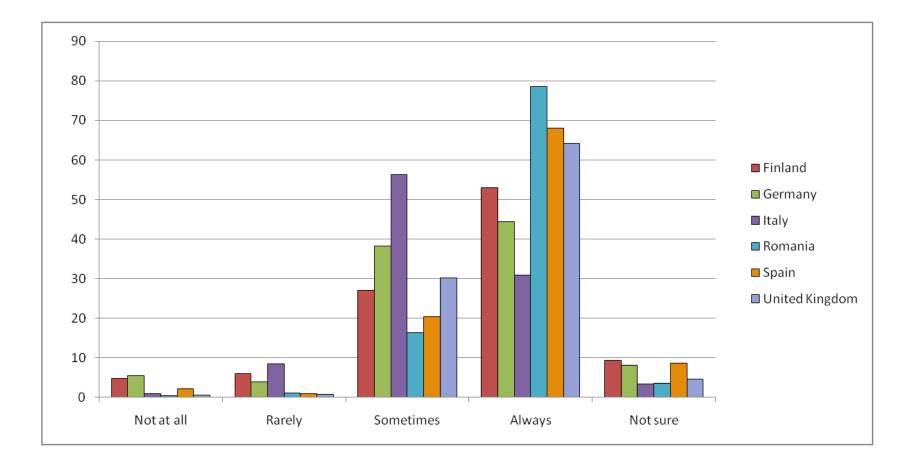


Bernadette Egan m.egan@surrey.ac.uk





A BESRC supported National Capability Level of confidence: "Do you think the product helps you?"







Alicia Garcia-Alvarez fin@fin.pcb.ub.es





Beneficial properties

- **Systematic reviews:** epidemiological, clinical and human intervention studies
 - cardiovascular health; post-menopausal bone health; menopausal symptoms; gastrointestinal health; inflammation.
- The **biomarkers of intake** of PFS reviewed and validated in human studies.
- **Biomarkers of exposure methods:** Human intervention studies with a single dose of PFS to determine biomarkers in urine

* Ginkgo biloba, Panax ginseng, Camellia sinensis, Vitis vinifera

 Development of a consensus for "best practice" for future human intervention studies on PFS.



Publications at http://www.eurofir.org/plantlibra



Gary Williamson G.Williamson@leeds.ac.uk





Adverse effects

- Systematic literature review on 67 botanicals
- Adverse effects and poisonings in humans
- Assessed according to WHO classification for causality (association between exposure and effects)
 - Certain
 - Probable
 - Possible
 - Unlikely/unclassifiable



- Consideration of **misidentification** of botanicals
- A study with **European Poisons Centres** on adverse effects or poisoning due to consumption of, misidentification of or interactions with conventional drugs
- A network was created between PlantLIBRA partners and European Poisons Centres, establishing alerting system based on the websites of PlantLIBRA (<u>www.plantlibra.eu</u>) and the EAPCCT (www.eapcct.org)





Patrizia Restani patrizia.restani@unimi.it





Risks and benefits of PFSs

- Identification and chemical characterization of the botanical preparation of interest
- Parallel evaluation of adverse and positive effects 1 botanical preparation and single compounds

Risk assessment:

- Identification of adverse effect
- Characterization of the adverse effect
- Estimate of product intake
- Evaluation of the quality of scientific evidence

Benefit assessment:

- Identification of the beneficial effect
- Characterization of the positive effect
- Estimate of product intake
- Evaluation of the quality of scientific evidence

Comparison between risks and benefits and evaluation of their health impact







Antonella Guzzon





RBA - The product

- Online tool for estimating concentrations and intakes of compounds in a PFS product
- Exposure assessment: possible to estimate mean, median, percentiles of intake of compound
- Integrated approach to risk-benefit assessment of PFS
- Assessments structured in different pages corresponding to the steps of the RBA methodology
- Data integration with e-plantilibra to be used in the tool for risk assessment. Compound intake estimator
- http:// en.opasnet.org/compound_intake_estimator
- User can add own data for calculations













Analysis and Safety concerns

- Natural presence of toxic compounds and substances having a pharmacological action
- Mis-identification of botanical
- Substitution of non-harmful plants with harmful ones
- Contamination with different plants
- Presence of environmental contaminants
- Biological contamination
- Microbiological contamination



 Addition of synthetic drugs to enhance the efficacy of the product





Brunella Carratu brunella.carratu@iss.it





ABBSRC SUPPOrted National Capable Example of adulteration with alternative species

Adulteration of Star Anise, Illicium verum Adulterants I. anisatum and other I. species toxic compound Anisatin



Illicium verum Hooker

Star anise

Illicium anisatum L. (religiosum Sieb.)

H. Sievers, PlantLIBRA Conference 12/14 May 2014









Creation of Network of Laboratories

- Establishment of an **international network of laboratories** expertise in analysis of plants/extracts/PFS to both public and private sector
- Capable of performing reliable high quality analytical data on plants and botanical preparations and to detect contaminants and irradiation treatments
- Provide analytical tools to the European Poison Centres for rapid identification of adverse effects to plant ingredients

http://www.eurofir.org/plantlibra/science/networks-of-labs



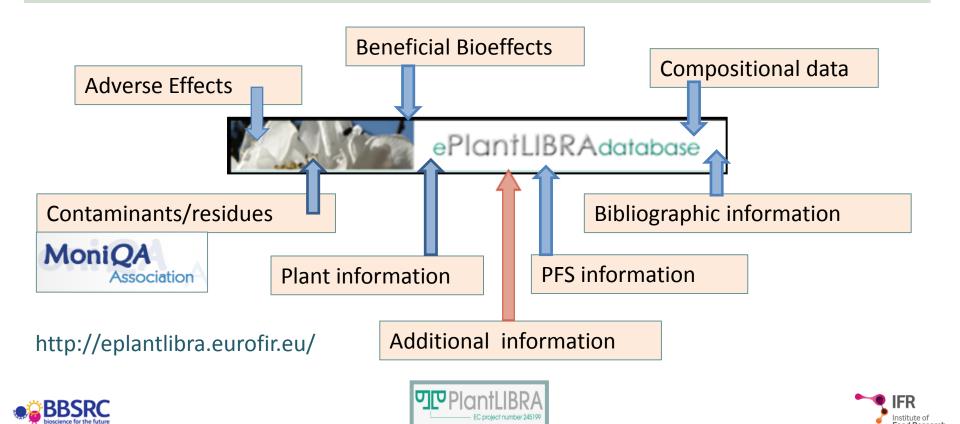






ePlantLIBRA: A sustainable integrated meta-database of biologically active compounds, residues and contaminants

ePlantLIBRA: A sustainable, reliable, flexible and fit-for-purpose internet-deployed database, providing a unique comprehensive resource on PFS for researchers, health professionals, health educators, the food industry and policy makers





"Inherent non-nutrient constituents in plant foods with putative health-promoting and/or toxic effects"



Beneficial: May help to promote optimal health and to reduce the risk of chronic disease





- Plant-based bioactive compound classes including:
 - Anthroquinones (e.g Aloe)
 - Ginkgolides (e.g Ginkgo)
 - Flavonoids (e.g. grapes, berries, onions, tea)
 - Glucosinolates (e.g. Brussels sprouts, cabbage, broccoli)





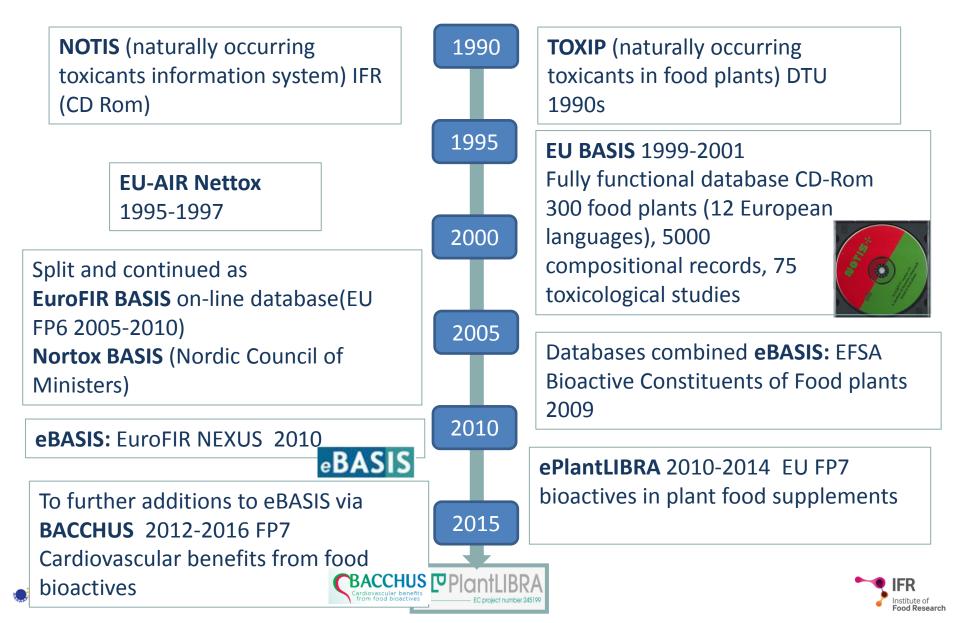






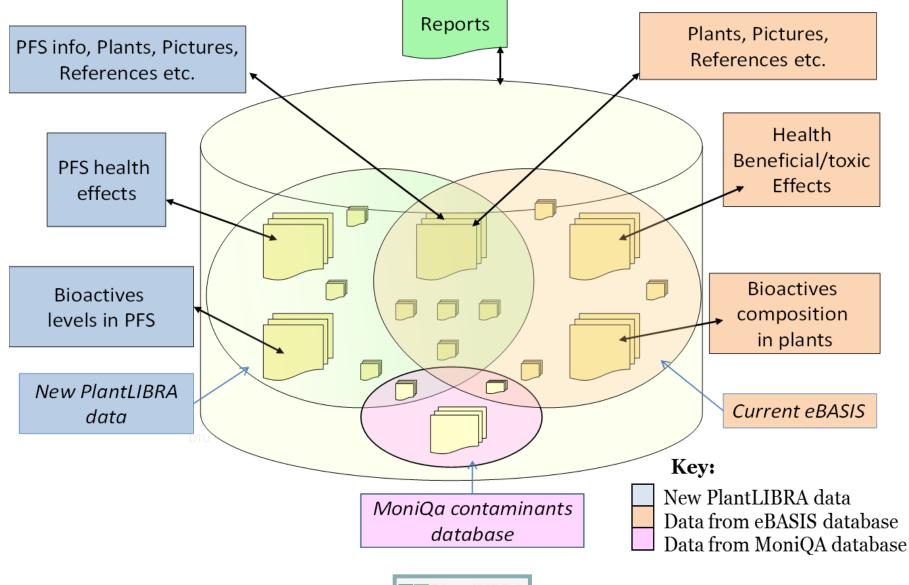
eBASIS/ePlantLIBRA History:

Bioactive Substances Information System





ePlantLIBRA Structure











Reports

· Composition dat

• Beneficial data Additional info

· Food plants

• Updates

· Print this name

Bug reports

My details

Logout

Evaluator

ePlantLIBRA functions

PlantLIBRA Technical Hor



Via 5 online systems

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

Data reporting:

user led data retrieval software system, searchable by:

compound, food, biological effect:

- Composition
- Bio-effects
- •PFS info
- Plant details
- Contaminants

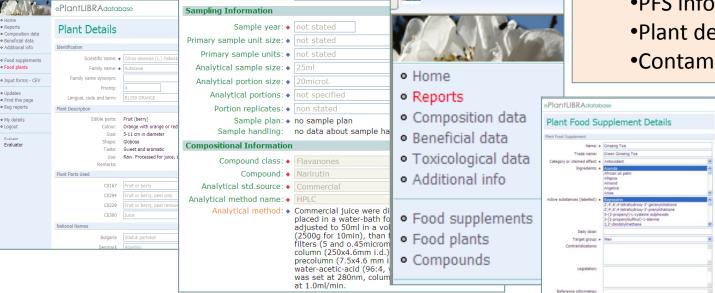
PlantLIBRA

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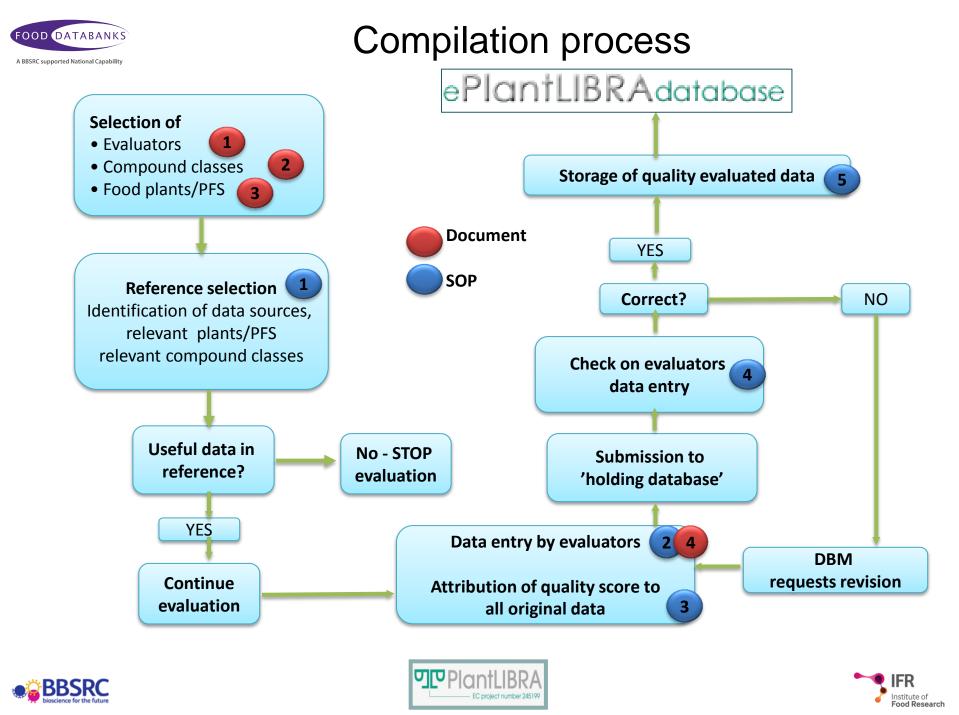
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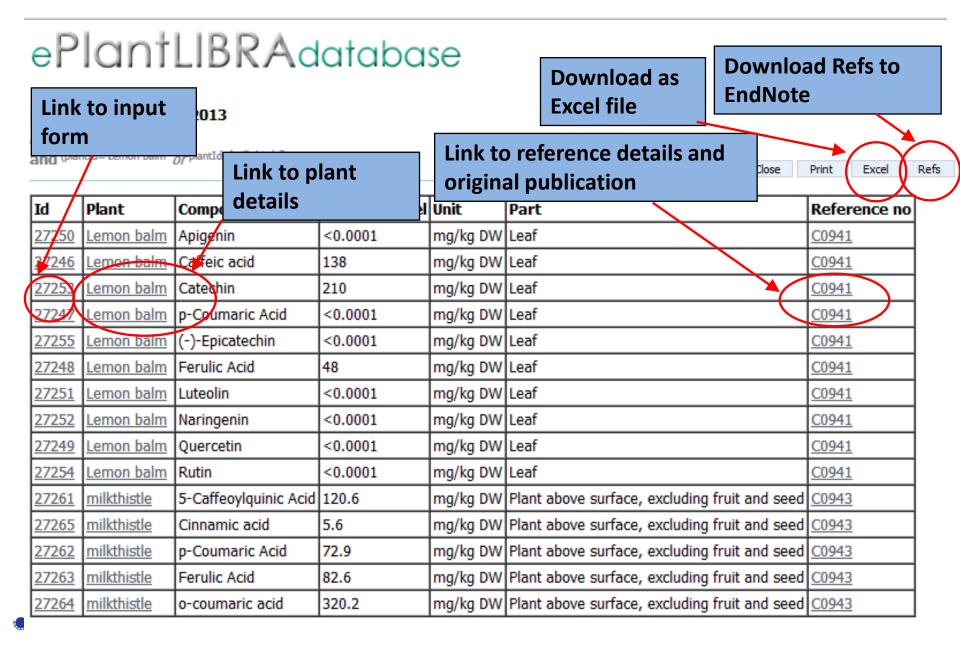


Reporting: Composition data

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Reporting: Composition data





Beneficial Biological effects

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Parameter Plant Food Supplement	Selected Search Criteria Black cohosh product	▶ 5	ality Assessment Study design ?
	窗 Ginkgo product 窗 Milk-thistle product 窗 Red clover supplement 窗 Soy supplement	۶T	Subject ? Test material ? Conduction of study ?
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<u>1569</u>		<u>Not</u>	Isoflavone glucosides	Red clover supplement	Human clinical study	80mg red clover derived isoflavones per day	-Total HADS (anxiety and depression domain scores also) an more significantly after isoflavone treatment compared to pla significant differences observed between study groups for ba	acebo (p < 0.001) - No
<u>1571</u>	<u>L0008</u>	<u>Not</u> specified	Isoflavone glucosides	Soy supplement	Human clinical study	80mg or 120mg total isoflavones per day	-No overall bone-sparing effect of soy isoflavones in nonoste either the intent-to-treat or compliant analysis -Modest but p decline in femoral neck bone mineral density observed (p = factors had been taken into account in the compliant analysis	rotective effect on the 0.024) once covariate
<u>1570</u>	<u>L0009</u>	<u>Not</u> specified	Mixed isoflavones	Soy supplement	Human clinical study	Powder twice u	ardiovascular health ost-menopausal bone health lenopausal symptoms	hal dryness due to bo - Significant e MRS subscales after kcept on the urogenita in the HT and soy groups
<u>1576</u>	<u>L0022</u>	<u>Not</u> <u>specified</u>	Mixed isoflavones	Red clover supplement	Human clinical study	378 mg (2 capsu d × 12 mo G	astrointestinal health flammation showed a significant improvement over time on the anxiety s	intervention were: nly CEE/MPA differing uce the frequency of vas safe as ns - red clover score (p 0.04)
1586	<u>L0027</u>	<u>Not</u> <u>specified</u>	Mixture	Ginkgo product	Human clinical study	120mg G.biloba extract twice daily	 no significant difference in CHD/CVD mortality between G.b groups - no significant difference in hospitalisations for cardi between groups (among those with no self-reported history significant reduction in peripheral vascular disease (PVD) even G.biloba supplement compared with placebo 	ovascular events of CVD at baseline) -
<u>1573</u>	<u>L0022</u>	<u>Not</u> specified	Mixture	Black cohosh product	Human clinical study	128 mg (2 capsules) / d × 12 mo	Reductions in number of vasomotor symptoms after 12-mon black cohosh (34%), placebo (63%), and CEE/MPA (94%), w differing significantly from placebo Black cohosh did not sig frequency of vasomotor symptoms as compared with placeb safe as administered - no improvements in other menopaus	vith only CEE/MPA gnificantly reduce the o - Black cohosh was



Adverse effects reporting

ePlantLIBRAdatabase

DPlantLIBRA

Print

Excel

Refs

Close

[New search] 06/02/2013

Criteria: (Form status='Approved')

and (pfsId='Ginkgo product' or pfsId='Ginseng product' or pfsId='St. Johns wort products')

Id	Reference no	Diant	Compound	Plant Food Supplement	Diant	Main clinical effects	Doco ingostad	Outcome	Caucality accordment	Conclusion
⊢									Causality assessment	
556	<u>K0013</u>	<u>Not</u> specified	not specified	Ginkgo product	<u>Not</u> <u>specified</u>	Spontaneous intracerebral haemorrhage	40 mg three times a day	The patient remained with a left inferior quadrantanopia	Possible/suspected	Auhors state there are grounds to suspect an association between Ginkgo biloba and intracranial haemorrhage
<u>557</u>	<u>K0014</u>	<u>Not</u> specified	not specified	Ginkgo product	<u>Not</u> <u>specified</u>	Nose bleeds, ecchymosis on hands and arms after minor trauma	75 mg per day	The patient discontinued ginkgo and had no further bleeding episodes.	Probable (evaluator - according to WHO classification)	None
559	<u>K0027</u>	<u>Not</u> <u>specified</u>	not specified	Ginkgo product	<u>Not</u> specified	Headache, back pain, nausea and sleepiness	40 mg of Ginkgo biloba tablets 3-4 times a day	The patients recovered uneventfully	the subarachnoid hemorrage was caused by	authors suggest that doses of herbal compounds must
560	<u>K0026</u>	<u>Not</u> <u>specified</u>	not specified	Ginkgo product	<u>Not</u> <u>specified</u>	Bilateral subdural hematomas	60 mg Ginkgo biloba twice/day	Thirthy-five days after discontinuation of Ginkgo biloba. bleeding time was 6.5 min (normal). On follow-up, 15 months	In absence of other risk factors or trauma, the authors postulated that the bilateral subdural hematomas may have occurred, at least in part, due to the presence of abnormal platelet aggregability associated	The authors suggest a significant anti-platelet effect of Ginkgo biloba products, which could be responsible for the adverse effects described. They hope for further investigations in this field.

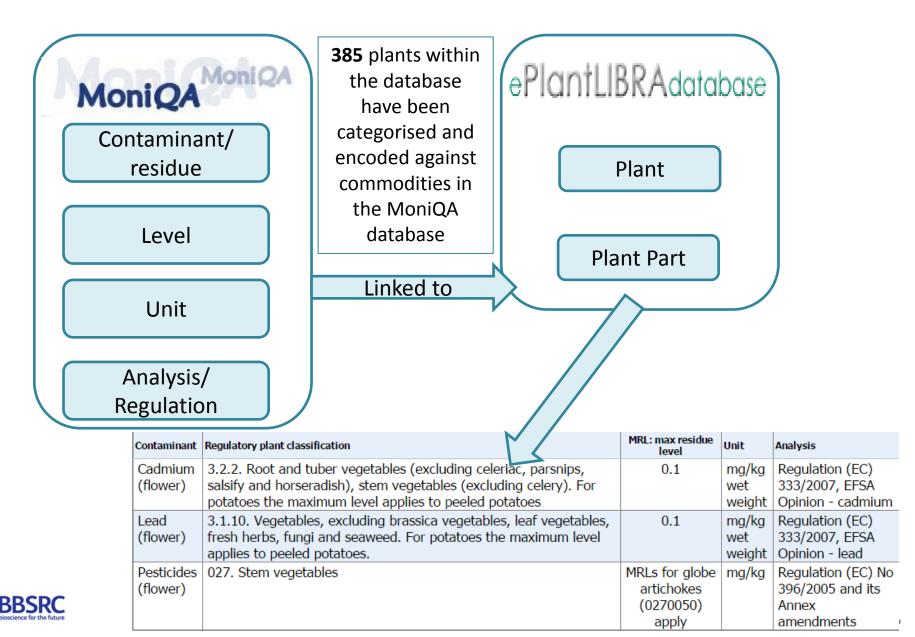








Contaminant information





Additional information

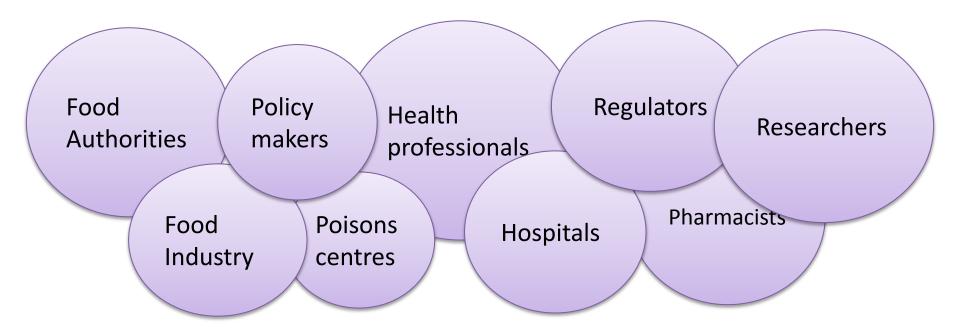
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ePlantLIBRA content

	Plants covered	PFS covered	Compounds	References	Datapoints		
Composition	78	40	350	260	6500		
	(260)		(600)	(460)	(31,500)		
Beneficial	33	32	161	82	82		
Bioeffects	(70)			(563)	(894)		
Adverse Bioeffects	67	23	-	210	243		
Contaminants	374						
Signature C project number 245199							

Users and Uses of eplantlibra



- Regulatory issues,
- Science based decision making,
- Preparation of health claim dossiers
- Benefit/risk assessments

- Estimating exposure levels,
- Epidemiological studies,
- Supporting submissions to research

- New product development
- User friendly info on botanicals
- Easily accessible info on adverse effects



Example of PFS review

PlantLIBRA EC project number 245199

ePlantLIBRA Plant Food Supplement Report:

Ginkgo biloba/common ginkgo

What is Ginkgo biloba?

Ginkgo biloba or common ginkgo is one of the oldest types of trees in the world. Ginkgo is been cultivated all over the world but only can be found in the wild in China. (Royer) According to Charles Darwin Ginkgo is a living fossil. It is the oldest living tree species in the world. After the ice age it was thought that it hadn't survived. In 1691 Englebert Kaempfer, a German Physician and Botanist, discovered in China a ginkgo biloba tree. It was not the same tree as its ancient ancestors due to environmental changes. (Nelson)



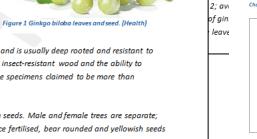
The tree normally reaches a height of 20–35 m, some specimens in China are known being over 50 m. The tree has

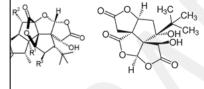
an angular shaped crown and long, somewhat erratic branches, and is usually deep rooted and resistant to wind and snow damage. A combination of resistance to disease, insect-resistant wood and the ability to form aerial roots and sprouts makes ginkgo long-lived, with some specimens claimed to be more than 2,500 years old. (Royer).

Ginkgo's are also popular subjects for growing as bonsai.

It takes 20-35 years for trees to reach maturity and start bearing seeds. Male and female trees are separate; male trees have pollen-producing catkins while female trees, once fertilised, bear rounded and yellowish seeds with a fleshy outer coat. (Simmonds)

Prepared by Tom Segers





and in plant food supplements obtained from scientific publications.

Figure 4 Structure of ginkgolide

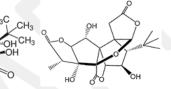


Figure 5 structure of terpene trilactones

The following tables and charts report the amount of the above described compounds in Ginkgo biloba plant

Bilobalide in Ginkgo biloba leaves

3 structure of bilobalide

Bilobalide in Ginkgo biloba leaves

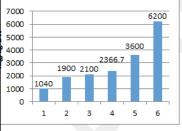
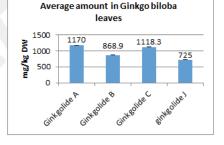


Chart 2 Ginkgo compounds in Ginkgo biloba leaves



shows that the documented quantity of hildhalide in leaves varies between 1040 and 6200 marky DW.

Causality assessment 2; avi Definition leave Chart 5 Causality assessment adverse effect data Chart 5 shows the amount of possible and probable interactions of Ginkgo biloba in the observed adverse effects. In 4 papers no classification was given due to lack of information or that no good judgement could be made. Causality assessment



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PlantLIBRA project outcomes: Policy

- Creation and establishment of a Policy Advisory Board, consisting of EU regulators and international agencies from Argentina, China and United States
- Policy implications at the international level were analysed and reported
- The policy report:
 - policy context and an update on the legal situation of botanicals in the EU and in selected regions outside the EU;
 - the potential policy implications on the basis of the project's outcomes and presents conclusions and recommendations.









PlantLIBRA outcomes : Microsite

benefit of laboratories tugged benefit of laboratories tugged

PlantLIBRA

About the project ePlantLIBRA Science

According to one estimate, 18.8% of consumers in a sample of European Union countries have used a plant food supplement in the past year. Food supplements are concentrated source of nutrients or other substances, plant food supplements (PF3) are supplements with one or more plant-derived substances (botanicals). Though very oppular and other with a long tradition of use, scientific knowledge on PF3 and botanicals is sill supprintly limited.

The PlantLIBRA EC-funded project has resulted in significant advances in the field of PFS. Some of the project's results have been published or otherwise made available to the wider public. The project has also resulted in the development of tools, databases, and skills that, through EuroFIR AISBL and associated organisations, are available to takeholders, NGS, industry, governmental agencies and other interested parties.

Check below what the tools, the databases and skills of PlantLIBRA can still do for you:



About ePlantLIBR/

The PlantLIBRA consortium has completed the work funded by the European Commission and is making available several outputs and activities that are available to solicymakers and other stakeholders. This microsite helps you understand what PlantLIBRA can do for you, through ePlantLIBRA and other tools and services.

News

Welcome to the ePlantLIBRA Microsite !

EuroPE ASSLI: ipleased to externing you on this new ePlantLBRA microsite. You will have a direct access to the ePlantLBRA which is a comprehensive database on bobancias), with guidely a-susteri differentiation on composition. Adverse effects, potentiati beneffs and contaments on engreprisentia beneffs and and contamismism. PerfundLBRA will help you understand estabilised and new totancials you are evaluating, with more and new data, identify potential beneffs and out effects, and potentiar indis, in the context product development, dosser preparation or safety asserted.

ePfantLIBRA development was based on three existing database; e26435 (Bloacthre Substances in Food Information System), developed by EuroFIR (http://ebasis.eurofir.eu); the MonQA contaminants database; EU FP6 funded MonQA (Monitoring and Quality Assurance in the total food supply chain) database (www.monique.eu/); the MonQA contaminants database; EU FP6 funded MonQA (Monitoring and Quality Assurance in the total food supply chain) database

What information is available in the database ?

For all plants within ePlant(IBRA scientific name, plant family, synonyms, common name in 15 European languages, colour photograph identification and links to the Germplasm Resources information Network (GRN, http://www.ars.gmov) have been included, LanguaL code for food description and term http://www.languaLorg/ is included, together with details on edible parts, colour, is and shape.

How to access the database ?

Log in is by individual user name and password contact Carlos Ramos at EuroFIR secretariat(@)eurofir.org for log in.

For queries on structure, function and content please contact Jenny Plumb (enny.plumb(@))fr.ac.uk.





Networks of Labs

Analysing botanicals for beneficial compounds, for contaminants, for identity markers, to detect irradiation, for harmful compounds or other markers is often challenging. A network of labs is available to perform quality-controlled testing of most botanicals used in the EU.

Preparations for ring-tests are ongoing.

Labs interested in joining the network should contact.... For further information, on ring test please contact xx

Case study

The problem: a single company claimed that one botanical contained a compound that had beer so far considered only man made. Most experts disagreed with the claim, but there was no final proof.

Our work: we set up a large sampling effort, with plants of verified origin and standardised extraction, to prove that the substance was not naturally present in the

Click here to view the list of laboraties.

http://www.eurofir.org/plantlibra







Acknowledgements

PlantLIBRA members and 3rd Parties

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jenny.plumb@ifr.ac.uk

www.ifr.ac.uk/fooddatabanks

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