

# HEALTH INFORMATION ON BOTANICALS: PLANT EXTRACTS, PILLS, CAPSULES AND HERBAL SUPPLEMENTS

PlantLIBRA analyses and assesses  
'green substances' in food



## The project: Food safety research and product development

Are there health benefits to taking Ginkgo biloba capsules? Can cinnamon tablets have any adverse effects?

The PlantLIBRA project aims to provide new science-based data and an integrated approach to better evaluate these questions. Moreover, it focuses on the safe use of plant food supplements (PFS) made from plants or botanical preparations, referred to as botanicals.

PFS and food compounds of plant origin are closely examined in the project. These are defined as concentrated sources of nutrients (or other substances with a nutritional or physiological effect) whose purpose is to supplement the normal diet and which are marketed in dose form as pills, tablets, capsules, or liquids in measured doses.

As yet undetermined number of plant species can currently be used legally in the EU, mainly based on their history of use and differences in national permission lists. So far, EU legislation distinguishes between plant food supplements and traditional herbal medicinal products, but this categorisation can vary between countries, and the boundaries are fuzzy. This can lead to consumer confusion and regulatory inconsistency across Europe. To respond to the increasing demand of decision makers for quality data on botanicals, adequate methodologies, including vast, sustainable, immediately accessible databanks, need to be made available.

PLantLIBRA has also investigated the intake and consumption patterns of botanicals in six European countries, delivering data

in support of food risk management and food marketing. After the project's four-year lifespan, one major final deliverable will be a multipurpose internet metadatabase. PLantLIBRA closely cooperates with the EuroFIR project, which has developed the edatabase structure for standardised plant food data.

## The product: Validated health information, quality data and etools

An internet-deployed database, ePlantLIBRA, has been developed for use by researchers and health professionals, the food industry, regulators and policy makers.

Users can access data on the composition of produce, botanical information, inherent active compounds, bioeffects data (beneficial and adverse), contaminants and residues, as well as PFS-specific information on claimed effect, ingredients, active substances, target groups, and contraindications.

Risk assessment know-how: Due to the variety of products and consumer habits, lack of shared definitions and harmonised methodology, data on the intake and consumption patterns of PFS in Europe are largely unknown. Such data would be extremely useful for conducting risk and benefit assessments. Regulations and controls required for PFS vary at the European and international level and pose barriers for market development.

PlantLIBRA set out to provide harmonised approaches, validated methodologies and new data. The array of features includes a combined database of quality-assessed data on plant composition and compounds, extracts, analytical methods, case-reports of adverse events, literature on benefits and risks, and the beneficial and adverse effects of component compounds.

## The end users: Lawmakers, supply chain, pharmacists, consumers

Lawmakers and regulators: Because of the many sensitive health effects of PFS and botanical preparations, including food safety issues, PlantLIBRA's data are of high interest to lawmakers. They currently form the biggest stakeholder group for the product. The active involvement of stakeholders through PlantLIBRA's Policy Advisory Board (PAB) has provided the opportunity to address problems and receive input on regulatory bottlenecks, priority plants, Member State (MS)



differences, and limitations in the sector from government officials dealing with the regulation of botanicals. At present, the PAB includes delegates of 25 countries from 21 EU MS, non-EU countries and Norway, and international representatives from China, the USA, and Argentina. Such broad membership extends the impact of the project's outputs, like ePlantLIBRA, to countries with large plant food supplement markets.

**Supply-chain:** Food manufacturers, pharma firms, food marketers and retailers are increasingly interested in user-friendly data on botanicals for quality control and traceability for plant authentication, cases of adulteration, and related contaminants and residues.

**Health professionals:** Poison emergency centres, hospitals, medical doctors, pharmacists, and nurses should have easy access to information on beneficial or adverse effects of PFS and botanical preparations, which the database provides.

**Education and consumers:** In order to help the public make informed choices and learn the use of health databases, a user-friendly version of the database will be provided.

### **The inventors: Academia, SMEs and associations**

The EuroFIR Network of Excellence, coordinated by the Institute of Food Research (UK), has built on 25 years of collaboration and sustained activity in food composition research in Europe. This expertise has been used by the PlantLIBRA project. Overall coordination of the PlantLIBRA project is provided by the coordinator, Patrizia Restani of UMIL, (Università degli Studi di Milano, Italy). The consortium comprises leading academics, public research institutions, SMEs, industry and non-profit organisations.

The added value of the ePlantLIBRA database is not only the targeted expansion of existing databases and its food composition data, but also the inclusion of the methodology and data being generated by the PlantLIBRA work packages which started in 2010 under the EU-FP7. Its holistic approach includes the interface and links to other databases like the transfer of relevant data from the MoniQA database information on residues and contaminants into ePlantLIBRA.

### **Development stage: Piloting and test phases**

The ePlantLIBRA web platform has already gone through the first phase of system and reporting revisions resulting from the first usability testing during September 2012 which consisted of remote, unsupervised access to the database for 2-3 weeks by project stakeholders: partners, experts, policy and special interest advisory groups.

The second cycle of usability testing will start soon, and once again the project partners, potential users from the PlantLIBRA Policy Advisory Board (mainly national regulators) and other experts from industry will be invited to test and provide feedback on the database. For this second cycle, poisons emergency centres are also being invited to access the database and test a dedicated section to search for adverse effects of botanicals.

With regards to the potential benefits for industry, manufacturers, associations, consumer groups, pharmacists, retailers and stakeholders, the second round of usability testing of ePlantLIBRA will take place in September 2013, displaying the database's features and giving you the opportunity to share your expert opinion in order to improve its functionality and usability for your special needs.

Please contact Carlos Ramos at [cr@eurofir.org](mailto:cr@eurofir.org) if you would like to be involved.

### **Policy impact: Better regulation**

While research on the biological effects of plants is carried out worldwide, only a small proportion is specific to PFS, and takes place mostly as a national effort in the USA. Without pre-existing cooperation with stakeholders and local intelligence, it is difficult to identify, prevent and control food safety crises, including those involving PFS. PlantLIBRA forms an international research community, contributing to international law-making and harmonisation of standards, and ultimately helps increase science-based decision-making by regulatory authorities and players of the PFS supply chain in the EU and in exporting countries.

The PlantLIBRA consortium is made up of 25 beneficiaries, spanning four continents: 20 are from EU Member States (Austria, Belgium, Finland, Germany, Italy, the Netherlands, Romania, Spain, and UK); one is from Switzerland, an Associated Country; and four are from International Cooperation Partner Countries (ICPC): Argentina, Brazil, China and South Africa, where botanicals are widely used and exported.

To potentially influence future PFS legislation, the usability testing gives stakeholders an opportunity to have their say.

### **Next steps: Updates, launch and IP rights**

Testing, improving and enlarging the database and its dissemination.

After the project's end, the continuity and sustainability of the ePlantLIBRA is a key issue. To address it, a sustainability task force has been formed to:

- Promote and deliver training, e.g., webinars to target stakeholders and key users;
- Meet users' needs and requirements;
- Involve experts in continuous updates of new data;
- Conduct appropriate dissemination and promotion, including launch and IP protection;
- Develop membership model, pay-per-access and income.



#### **PlantLIBRA**

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