Supplementing risk assessment

Professor Patrizia Restani, project manager Luca Bucchini and project partner Patrick Coppens explain how the PlantLIBRA initiative can help to improve the safety of Europe’s plant food supplement industry.

Can you begin by offering an insight into the objectives of the ‘Plant food supplements: Levels of Intake, Benefit and Risk Assessment’ (PlantLIBRA) project?

PR: The safe use of plant food supplements by Europe’s consumers is our overarching goal. We strongly believe this requires evidence-based decisions by policy makers and industry. PlantLIBRA aims to fill the most fundamental gaps that limit the ability to make science-based decisions in this field, including assessment, management and communication.

How do you rate the current use of food supplements containing plants or botanical preparations? Are there any areas where safety could be dramatically improved, and how can PlantLIBRA make a difference?

PR: There is enormous diversity in the current use of food supplements containing plants or botanical preparations. These range from well-known plants in a simple form – from reputed, quality-controlled sources – to very complex products of uncertain origin, and whose safety and efficacy are not up to standard. Official controls and industry responsibility will need to play a role, but more evidence and scientific standards are needed.

The screening and scoring of analytical methods is the second area where I expect PlantLIBRA to immediately improve quality and safety. I should add that evaluating safety without information about exposure, or about intake, is impossible. PlantLIBRA is going to produce the first data on consumption of botanicals in Europe produced according to scientific standards.

Could you provide an outline of the origins of the project?

LB: When Patrizia started to discuss the possibility of working towards the research call which eventually gave rise to PlantLIBRA, it was really a matter of deciding whether we needed all the experts on botanicals around Europe, or whether we also needed leading experts who could provide new insights in this field, for example from FP6 Networks of Excellence, like MoniQA or EuroFIR.

Who are the primary partners involved in your studies? Furthermore, how important is collaboration to the overall success of this project?

PR: Collaboration is the cornerstone of PlantLIBRA, and all our partners are pivotal to our success. We need to work together daily within work packages and during project meetings to put together a shared, comprehensive understanding, and bring out the results stakeholders expect from us. As a consequence, the e-mail traffic, as well the number of online meetings PlantLIBRA generates, is impressive, and our younger scientists are growing up within this climate of international and transdisciplinary collaboration. This is an achievement in itself.

Have you witnessed any disparity in facilities, knowledge and technical capacities between your partners and the four continents they cover? Can you elaborate on this, and explain how PlantLIBRA helps to reduce this inequality?

PR: We have seen disparities that came as no surprise. That is the reason for our close
Maintaining the quality of plant products that are imported into the European Union and used in plant food supplements is a challenging and ongoing task. A novel EU Seventh Framework (FP7) research programme seeks to develop tools and methodologies to help fulfil this mission.

**PLANT FOOD SUPPLEMENTS** provide the paradox of being both a very traditional and highly innovative field. Whether everyday foodstuffs such as coffee or tea are taken for pleasure or in mind of their therapeutic properties, we consume plant food supplements on a daily basis, often without considering the compounds they contain, or the potential risks that they may pose to our health. In fact, very little is known about the underlying mechanisms by which these products deliver benefits or health risks, and there is a considerable disparity in how supplements are risk-benefit assessed when compared to other products. This is a pertinent issue which needs to be addressed, and it provides the focus of a new EU Seventh Framework Programme (FP7) research project, ‘Plant food supplements: Levels of Intake, Benefit and Risk Assessment’ (PlantLIBRA).

The PlantLIBRA initiative seeks to promote the safe use of food supplements containing plants or botanical materials by providing a scientifically informed platform for policy makers and food chain operators, to better understand the potential risks involved in these products, and how best to address them. This will be achieved through developing and validating data and methodologies for risk and benefit assessment to provide the companies and regulators with the tools to improve consumer safety.

**ESTIMATING INTAKE**

Due to the wide range of products available under the umbrella of plant food supplements – and the lack of information regarding the risks-benefit assessment of plant food supplements in Europe – it is almost impossible to determine the possible benefits or negative effects of products...
INTELLIGENCE

PLANTLIBRA

PLANT FOOD SUPPLEMENTS: LEVELS OF INTAKE, BENEFIT AND RISK ASSESSMENT (PLANTLIBRA)

OBJECTIVES

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.

PlantLIBRA is structured to develop, validate and disseminate data and methodologies for risk and benefit assessment, and implement sustainable international cooperation to ensure the quality of the plants imported to the EU.

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PATRIZIA RESTANI is Associate Professor in Food Chemistry at the University of Milan; she has a degree in Pharmaceutical Chemistry and Technology and a postdoc specialisation in Toxicology. The study of food supplement quality and of adverse effects associated with botanicals has become one of her major topics of research.

PATRICK COPPENS has been employed by EAS since 2005 to lead ERNA and EBF. He holds a degree in Dietetics and Nutrition (Chert and Louvain), and has been active in many food and food supplement federations.

LUCA BUCCHINI is a food risk scientist and a food information consultant. As managing director of Hylobates Consulting srl, an SME, he has participated in FP6 and FP7 research projects. He is PlantLIBRA’s project manager.

that are consumed on a daily basis. This is a considerable cause for concern for both regulators and knowledgeable citizens alike, and is also an urgent focus for PlantLIBRA, as Professor Patrizia Restani of the University of Milan stresses: “It is possible that some plant food supplements are effectively helping European consumers stay healthy with significant benefits for them and with reduced healthcare costs for society as a whole, while other plant food supplements are not helping so much, or may even be harming some people.” She continues: “The methods we use to discriminate among those possibilities are still rudimentary; we need some specific data and new tools, and that’s where PlantLIBRA comes in”. Through their initial work package (WP), they hope to harmonise the terminology and classification of plant food supplements, while identifying important parameters for their consumption, such as population groups and cultural factors.

This information will be gathered through a number of sources, including open access repositories, grey literature, market surveys and industry data on pharmaceutical expenditure from healthcare corporations and public agencies. Perhaps the most valuable tool at PlantLIBRA’s disposal in understanding plant food supplement consumption is a European-wide survey to determine intake related factors (eg. lifestyle habits such as smoking, alcohol and use of other medications, socioeconomic status, health status, etc.), adherence to product usage recommendations, and determinants of usage and place of purchase. This information provides a platform for the ongoing work of PlantLIBRA.

RISK-BENEFIT ASSESSMENT

Drawing on the data gathered in the first WP, the team will investigate the application and validation of methodologies to determine the benefits of consumption of plant food supplements using in vitro models. These will be used to establish consensus for best practice for future human intervention, epidemiological and clinical studies on plant food supplements and related substances, providing decision makers with accessible, standardised information on related substances, providing decision makers with accessible, standardised information on the risk and benefit of plant food supplements. The standardisation and continuity of these tests is a particular strength of PlantLIBRA, as Restani illustrates: “They will be able to verify that the methods used for testing are those recommended by scientists. Such a platform does not currently exist, and it will prove useful for policy makers and industry, since they are often confronted with the same questions: is this plant safe at the recommended use level? What are the confirmed and suspected risks? And as for the benefits?”.

INCREASED RAPIDITY, IMPROVED SAFETY

The data platform produced by PlantLIBRA will not only provide insight into the effects of plant food supplements and offer reassurance of the quality of research, but should also help to speed the currently lengthy process of validating plant-based products. According to Restani, this is something that has been lacking for some time: “We still are not ’21st Century ready’, I would say, both for safety and benefit validation. Official controls and industry responsibility will need to play a role, but scientific standards and more evidence are needed”.

THE POWER OF PARTNERS

While PlantLIBRA has been structured to improve data validation and dissemination, it also aims to improve international collaboration through standardising methodologies, and develop communication to ensure uniformity in the quality of imported plants across the EU. To meet these demands, PlantLIBRA has developed an extensive network of 25 partners over four continents, comprised of leading academics, SMEs, industry and non-profit organisations, thereby providing a cross-section of those involved in the import of plants into the EU, and those involved in maintaining plant food supplement safety standards.

Furthermore, through its partners, PlantLIBRA has also been able to assess important databases, such as the Meta-database, and has also had the support of two Networks of Excellence, EuroFIR and MoniQA. This has played a fundamental role in the validation of available data and in maximising the methodologies employed in the project.

FOOD FOR THOUGHT

With PlantLIBRA approaching a year since its launch, and still three years away from completion, there is still much work to be done. Restani is excited by the progress made thus far and believes that it is an indication of the importance of the initiative: “The world of botanicals is moving very fast, and we need to deliver our results so that they can inform decision-making in the coming 2-4 years”. She summarises: “We are laying the foundations, and in this sense, I am very glad to have the first survey of plant food supplements ready to start, having captured the most significant findings on benefits and settling upon the structure of the database. But I would say the very favourable response from policy makers has been our most successful outcome to date”. 