Final Report Summary - GO4STEVIA (Stevia rebaudiana as a diversification alternative for European Tobacco Farmers to strengthen the European Competitiveness)

Executive Summary:

The reform of the Common Agricultural Policy (CAP) for the tobacco farm sector (EG Nr. 864/2004 from April 29, 2004, effective on January 1, 2006) has the aim to phase out the subsidy payment for tobacco cultivation. When the subsidy payment is finished Tobacco can not be further cultivated in the EU due to economical feasibility. This will have a great impact on the tobacco growers in terms of income and employment, in particular in Greece, Italy, Spain and Portugal where 90% of the Tobacco was cultivated in the EU-15 before the enlargement.

About 96% of all tobacco farms are family farms with 1 to 3 hectares of Tobacco production per farm. About 92% of all farms have a total farm land of less than 10 hectares (EU-FP6 Project DIVTOB-SSPE-022739). All the Tobacco farms are SMEs according to the EU definition. They are organized in SME Associations and are facing the same problem of subsidy cultivation and need cultivation alternatives to keep employees and stay economical competitive. In all EU countries they formed Associations (Farmers Cooperatives or Associations) specialized in technical advice and economical support and services for their SME members. The CAP reform for Tobacco forces the Tobacco farmers into new business opportunities by diversification alternatives for their farms.

The Go4STEVIA project proposal has the strategic objective to solve the problem of livelihood for EU tobacco farmers a new business opportunity of Tobacco farmers in order to maintain their income, employment and farms. The outcome of DIVTOB project showed that only the development of high added value products will allow the small Tobacco farmers will survive. The Go4STEVIA is designed to demonstrate the safety of a sweet low calorie Novel Food based on Stevia rebaudiana. It should be understood that this proposal goes beyond the needs of only a crop introduction. The experience of the Tobacco growers with the Tobacco industry is that never a fair price was paid for the Tobacco leaf. And the same will happen, if the Tobacco farmers will only produce Stevia leaves.

The Go4STEVIA proposal will bring the Tobacco SME Associations into the position to set up a full production chain, which allows the marketing of a high value added low calorie sweet food based on Stevia rebaudiana. For this attempt it is necessary to prepare a safety dossier for EFSA. The necessary data will be provided by the Go4STEVIA project. The results of the Go4STEVIA project will transfer tobacco producers growing unhealthy plants to a new stage – the protection of human health.

The project aims to develop a new business alternative for European Tobacco farmers by exploring the possibilities to replace partially the tobacco production by the diversification alternative Stevia rebaudiana and by the development of products thereof. By this the project supports the CAP Reform for Tobacco of the Council and the Commission. In particular, the Go4STEVIA project aims to develop a new European standard in the area of human consumption by developing Stevia rebaudiana as a Novel Food. By execution of the project all relevant requirements
of the Opinion of the Scientific Committee of Food (CS/NF/STEV/3 Final June 17, 1999) will be addressed in order to meet the regulatory norms of the EU. As a consequence the proposal aims also to support policy objectives in the area of health (fight against obesity) and food safety. The whole project aims to develop a high value-added Novel Food production chain, giving to the Tobacco farmers a new economic opportunity and to European Consumers and Food Industry a new safe Novel Food with sweetening properties.

In order to achieve the objectives of this project the following work programme shall be executed:

- The complete colon metabolism of steviol and its derivates will be assessed by the application of an in-vitro digestion model to identify and to characterize the steviol metabolites of the possible metabolic changes by chronic long-term ingestion of a Novel Food derived from Stevia rebaudiana. (WP2).
- The evaluation of the influence of the Novel Food derived from Stevia rebaudiana on the absorption of macro- and micro nutrients, on antioxidant potential, vitamin status and gut micro-flora in the rat (WP3).
- To establish the long-term safety of a novel food developed from Stevia rebaudiana Bertoni by the execution of a two years study in rats (WP4).
- To develop an integrated production system for Stevia rebaudiana as an important research effort of the SME Associations (WP5).
- The dissemination of the results will be an important tool for the success of the project (WP6).
- Training (WP7) shall ensure that the SME Associations and their staff personal will absorb the developed technologies and products in order to provide new market opportunities as a solution for the problem of livelihood of the tobacco farmers by switch over partially to the alternative crop Stevia rebaudiana.

The involvement of the SME Associations focuses on an implementation of an integrated agricultural production system of Stevia rebaudiana in their regions (WP5), dissemination and exploitation of the results (WP6) and training (WP7) in order to develop the new business opportunity and to train and absorb the knowledge for the production chain.

Project Context and Objectives:
The Go4STEVIA project proposal has the strategic objective to solve the problem of livelihood for EU tobacco farmers a new business opportunity of Tobacco farmers in order to maintain their income, employment and farms. The outcome of DIVTOB project showed that only the development of high added value products will allow the small Tobacco farmers will survive. The Go4STEVIA is designed to demonstrate the safety of a sweet low calorie Novel Food based on Stevia rebaudiana. It should be understood that this proposal goes beyond the needs of only a crop introduction. The experience of the Tobacco growers with the Tobacco industry is that never a fair price was paid for the Tobacco leaf. And the same will happen, if the Tobacco farmers will only produce Stevia leaves. The Go4STEVIA proposal will bring the Tobacco SME Associations into the position to set up a full production chain, which allows the marketing of a high value added low calorie sweet food based on Stevia rebaudiana. For this attempt it is necessary to prepare a safety dossier for EFSA. The necessary data will be pro-vided by the Go4STEVIA project. The results of the Go4STEVIA project will transfer tobacco pro-ducers growing unhealthy plants to a new stage – the protection of human health.

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The dissemination of the results will be an important tool for the success of the project (WP6). For SME Associations the important dissemination and use of the achieved results shall be supported by a WIPO patent application and the preparation of a dossier for the Novel Food application as outcome from WP2-WP4. Secondly, the dissemination shall be directed to the European Food Industry companies which are the end-users of the developed products.

Training (WP7) shall ensure that the SME Associations, their staff personal and the SME Association members (the farmers) will absorb the developed technologies and products in order to provide new market opportunities as a solution for the problem of livelihood of the tobacco farmers by switch over partially to the alternative crop Stevia rebaudiana. The involvement of the SME Associations focuses on an implementation of an integrated agricultural production system of Stevia rebaudiana in their regions (WP5), dissemination and exploitation of the results (WP6) and training (WP7) in order to develop the new business opportunity and to train and absorb the knowledge for the production chain.

Project Results:
The objective of the Go4Stevia project was to develop a natural low calorie sweet food ingredient based on the leaves of the plant Stevia rebaudiana. For this product a Novel Food approval will be prepared by submission of an application to the EU Commission once the new Novel Food Regulation is in force (January 1, 2018).

By the use of only physical and mechanical means, a natural low calorie food ingredient was produced from the leaves of Stevia rebaudiana Bertoni (SNF). The product (SNF) is specified and it is standardized. This product (SNF) was used for toxicological and nutritional studies in rats. The used rat feed was analyzed by a certificated laboratory and the homogeneity and stability of the rat feed was confirmed by a GLP laboratory as well as the correct dose-depend presence of bio-markers. In all four rat studies, six animal groups where used (control, 0,1%, 1%, 2,5%, 5% and 10%).

Main results:
1. Subchronic 90 day study to establish the maximum tolerable dose (according the guidelines of OECD408 under Good Laboratory Practise) with 120 animals: The study showed that even the highest dose (10% of the feed) was tolerated by the rats without any negative results.
2. Combined Chronic/Carcinogenicity study over 104 weeks (according the guidelines of OECD453 under Good Laboratory Practise) with a total of 1180 animals to increase statistical power: The result showed that no chronic toxicity and no carcinogenicity even at highest dose level (10% of the feed) which corresponds to 8 gram/day/kg rat bodyweight. 30.000 slides on histopathology have been evaluated. At high doses a significant decrease of liver fatty degeneration was observed in males and females compared to controls. Moreover cholesterol and triglycerides blood concentrations tended to decrease among treated groups compared to controls, particularly in males
3. Subchronic 90 day study on nutritional effects with 168 animals: No statistical differences on nutritional indices, blood hematological and biochemical parameters in rats between control and the dose groups. No statistical differences in blood antioxidant biomarkers and vitamin status in rats between control and dose groups. Stevia Novel Food can modulate rat gastrointestinal microbiome without significant changes in pH of digesta. Increases Lactococcus population significantly in 0.1% dose (= dietary level of human food). The potentially beneficial lactic acid bacteria population was not affected and no statistical difference observed between control and dose groups. Stevia Novel Food reduces antibiotic resistant pathogenic microbiota in 0.1% and 1% dose.
4. Life-time exposure over 102 weeks on nutritional effects with 248 animals: There was no significant difference between control and dose groups (0.1-10% diet) in the mineral status (Ca, Mg, Fe, Zn, Cu) in male and female rats.
5. Genotoxicity: Not genotoxic in AMES-Test in TA98 and TA100.

The objective was further to develop an integrated weed control:
During the project mechanical and chemical weed control measures have been developed which are ready for application.

Six herbicides have been selected for residue control. Application according to conditions of use show that either no residues
remain in the leaves of the Stevia plant or are below of maximum levels applied for herb or tea infusion crops.

After a homologation of the proposed herbicides for the use of Stevia the SME associations may start with cultivation.

For an effective treatment in Stevia rebaudiana two ways the following recommendations have been worked out:

Chemical means: Best is to start with the control of the perennial grasses already the year before to plant Stevia rebaudiana. This means that after the harvest of the rotation crop again irrigation should be applied to increase weed germination and to spray glyphosate + urea

2 – 3 treatments kill nearly all perennial grasses

Mechanical means: During the vegetation period of Stevia

Cut very early after appearance (April, average temperature > 15°C)
Continue to cut 3 – 4 times always after emerge of Cyperus
Storage organs deplete = perennial grass dies

By this method the use of herbicides in Stevia can be lowered drastically. However, a prototype for a row-mower must be built and tested.

Integrated weed control can be done by following means:

a) Combat Perennial grasses in the year before planting Stevia
b) Before planting use of pre-emerge herbicides
c) During the season if possible only mechanical control or chemical weed control under specific conditions
d) Problem remains in the row: Before harvest control by hand

Potential Impact:
The Go4STEVIA consortium will demonstrate that partial re-conversion of tobacco farms by Stevia rebaudiana will be one of the most potential tools for European tobacco farmers. As an example for the potential of Stevia rebaudiana figures from artificial sweeteners are demonstrated: Worldwide about 120.000 tons of artificial sweeteners are consumed yearly. This demand can be substituted by the cultivation of about 400.000 hectares of Stevia (as double as much as tobacco cultivation area within EU). In the EU the yearly demand of artificial sweeteners is about 18.000 tons which can be substituted with 36.000 hectares of Stevia. It can be estimated that Stevia rebaudiana can be grown in a scale 1.000 to 5.000 hectares (without EU Food approval) and up to 10.000 to 15.000 hectares in EU (with EU Food approval). With a full application of all Stevia features the growing of Stevia can still be increased. For the farms which will decide for the Stevia diversification alternative, the income can maintained like tobacco according to results of the FAIR-project on Stevia. Therefore the cost-effectiveness of the Go4Stevia project can be judged:

• Investments in the Stevia production chain have a leverage of 1: 46 to 1:74. This means that one invested Euro brings back 46 to 74 € per year as gross income.
• The leverage for labour in Stevia rebaudiana is 1:4. This means that one hectare of Stevia rebaudiana generates 4 jobs, mainly as temporary like Tobacco cultivation.
• The industrial transformation can be done near by the farms in the cultivation areas by the developed Green Crop Dressing Technology (FAIR-3751).
• The break-even for investment of the EU-Commission is the conversion of 860 hectares of Tobacco to Stevia rebaudiana.

Fight against obesity (Quality of Life): In humans, sweet taste exerts a profound influence on
behaviour. Generally spoken, the more intense the sweet taste, the greater the pleasure response. The pleasure response to sweetness is assumed to serve a physiological need. A hungry organism is reputed to find sweetness attractive, while a satiated organism does not. A hungry organism may also select foods that provide a maximum number of calories per unit weight. Energy density of the diet is often perceived through the sensation of taste. Sweetness, the traditional sensory indicator of both nutrients and calories, adds to the sensory appeal of a given food. According to recent reports, under ad libitum conditions people tend to consume a fixed weight or volume of food. When foods or diets differ in energy density, so do also daily energy intakes. But as a fact, as energy density for foods goes down, so does also palatability. However, only few consumers are willing to sacrifice palatability in the pursuit of an energy dilute diet. The development of intense sweeteners represents a deliberate – and costly – strategy to separate the palatability from energy density in foods. Intense sweeteners cleanly separate sweet taste and calories. Therefore, the development of a natural low calorie sweet food ingredient (Novel Food) supports the fight of the Commission against obesity and also the goals of the ETP “Food for life” and the “European Platform on Diet, Physical Activity and Health”. Go4STEVIA contributes by providing a low calorie sweet food ingredient which maintains all valuable plant ingredients as oligosaccharides, polyphenols and minerals as a natural sweet food.

Blood pressure and antioxidant status: In a recent published study about the effects of fruit and vegetable consumption on plasma antioxidant concentrations and blood pressure small effects have been observed (blood pressure fall 4.0 mm Hg systolic and 1.5 mm Hg diastolic). The authors concluded that these results produce only small clinical effects, but would substantially reduce cardiovascular disease at the population level. A reduction of 2mm Hg in diastolic blood pressure results in a decrease of about 17% in the incidence of hypertension, 6% in the risk of coronary heart disease and 15% in the risk of stroke and transient ischaemic attack. It was shown during the DIVAS and Go4Stevia project that Stevia rebaudiana develops a high anti-oxidative potential at all the locations the cultivations trials have been executed. It is like Green tea.

For the European citizen: As high intense sweetener consumption is increasing dramatically in risk groups (diabetic people, children, elderly population), the development of an alternative will need research on European level. Stevia as a renewable source will contribute a solution in this respect. Steviol glycosides have a very low numerical ADI (4 mg/kg bodyweight expressed as Steviol equivalents). Such a value is much too low for modern industrial societies like in the EU. This is the reason why the EU Commission limited the use of Steviol glycosides as well in the number of food categories and the maximum applicable dose. Therefore Steviol glycosides bring only a limited benefit for the consumer. The minimum ADI must be 40 – 50 mg/kg bodyweight like Aspartame in order to give a broad benefit for consumers and the food industry. The Go4STEVIA project overcomes this gap of the Steviol glycosides. Go4STEVIA project will develop a sweet Novel Food based on Stevia rebaudiana with an ADI of 50 mg/kg bodyweight.

List of Websites:
www.go4stevia.eu

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