

**Contract between the RTFP PMU and PhytoTrade Africa
RTFP II/68
Quarterly Progress Report**

REVIEW OF ACTIVITIES

PHASE 1 - Regulatory Approval

The following deliverables are in the contract under regulatory approval activities:

1. Three Gap Analysis reports for GRAS notification for Baobab fruit pulp, Depectinised Baobab fruit pulp, and Baobab fruit fibre.
2. Strategic analysis for NDI notification for Baobab fruit pulp
3. GRAS notification dossier for Baobab Fruit Pulp, with proof of submission
4. Either GRAS notification dossier for Depectinised Baobab fruit pulp, or Baobab fruit fibre, or NDI notification dossier for Baobab fruit pulp, with proof of submission. PhytoTrade undertakes to notify the RTFP PMU which of these products will be selected for notification, in advance of implementation.

Gap Analysis for Baobab Pulp, Depectinised Baobab Pulp and Baobab Fibres, and strategic analysis for NDI notification for Baobab Pulp

PhytoTrade Africa contracted Herbal Sciences International (HSI) to perform the GAP Analysis for submitting a GRAS dossier for Baobab Pulp, Depectinised Baobab Pulp, and Baobab Fibers. The contract also included a strategic analysis as to whether PhytoTrade Africa should consider submitting an application to approve Baobab Pulp as a New Dietary Ingredient.

The first report back provided good detail and information on Baobab Pulp and a strategic assessment for NDI notification, but there was too much information that HSI still required before a full response of the gap analysis on Depectinised Baobab Pulp and Baobab Fibres could be fulfilled. In consequence a long delay was experienced between sourcing the information in partnership with HSI and completing the gap analysis for these two products.

In the first report, the completion of the gap analysis for Baobab Pulp was clear and precise, and since it was already approved to submit a GRAS dossier for Baobab Pulp, PhytoTrade awarded HSI the contract to compile the GRAS Dossier for Baobab Pulp.

In the first report, the strategic analysis of the NDI notification concluded that an NDI application should only be considered once Baobab Pulp has demonstrated market success and experiences growing demand within the USA.

The second report with the gap analysis for depectinised baobab pulp and baobab fibres was only completed on the 22nd May. Based on this report a decision is meant to be made as to whether the second GRAS Dossier should be completed for Depectinised Baobab Pulp or Baobab Fibers. Please refer below to the section on the second GRAS Dossier.

Deliverable and payments for the GRAS gap analysis and NDI strategic analysis

The first report with the GRAS gap analysis for Baobab Pulp, and the NDI notification for Baobab Pulp is attached. The second report with more detail on the GRAS gap analysis for depectinised baobab pulp and baobab fibres is also attached.

1st GRAS dossier for Baobab Pulp

HSI completed the compilation of the GRAS dossier for Baobab Pulp at the end of April. The next stage in the process of completing the dossier is to send the final draft to an expert committee for their independent opinion prior to sending it forward to the regulatory authorities.

PhytoTrade delayed sending the GRAS dossier for Baobab Pulp to an expert panel as it was intended to add the second GRAS Dossier in order to keep the cost of review to a minimum. Furthermore it was important to know which second product would be approved for the compilation of a GRAS Dossier to ensure the expertise of the panel was relevant to the product. Now that there will be a delay in producing a second dossier, PhytoTrade will now proceed to send the GRAS dossier for Baobab Pulp to the expert panel.

PhytoTrade Africa has contacted the southern Africa US Trade Hub to assist in identifying experts in the US and has requested funding to cover the costs of the expert panel. PhytoTrade will also promote the response of the Advisory Committee on Novel Foods and Processes in the UK that is a professional and technically competent committee that has given its evaluation and approval of Baobab Pulp for the EU. Details of their approval will appear in the 2007 annual report that should be published by July 2008.

The gap analysis did identify some research that was not available for the GRAS dossier. However HSI has stated that the recommendations for this additional analytical work were more optional than recommended. HSI has said that the dossier as it stands makes a strong case for approval, and so did not advise that the additional research was necessary. However PhytoTrade will ask the expert panel for their opinion as to whether it is essential to do this research.

The final draft of the GRAS Dossier that will be sent to the expert panel is long and has 19 annexes. If the RTFP would like a copy of this version PhytoTrade will of course

provide it. However it has not been attached at this stage since the draft that takes into account the expert panel's comments and which will be submitted to the regulatory authorities in the US will be the version that will be sent to RTFP.

2nd GRAS Dossier

The completion of the gap analysis for submitting a second GRAS Dossier for Depectinised Baobab Pulp and Baobab Fibres has indicated a cost for research and compilation of the dossier much higher than was expected by PhytoTrade. The implication is that the budget of GBP 6,000 to complete the second GRAS Dossier will not be sufficient to cover even the compilation costs, and the budget for research is considerably higher. PhytoTrade had hoped that following their success in combining Baobab Pulp and Depectinised Baobab Pulp in their EU Novel Foods application, that a similar approach or one which did not require considerable further research could be possible for GRAS. It was also hoped that a simple approach for Baobab Fibres to be passed as a tea was possible. However the gap analysis has indicated that significant extra research and new information will be required for both products.

PhytoTrade therefore needs to reassess the process of obtaining GRAS approval for either Depectinised Baobab Pulp or Baobab Fibres. PhytoTrade will arrange meetings with the private sector and will look for a commercial partner to cover the costs of research and GRAS approval. PhytoTrade intends to unpack the costs in the gap analysis and will look for opportunities where costs can be reduced, and will also look at finding a commercial partner to leverage funds to cover the costs beyond the budgeted GBP 6,000.

Until PhytoTrade has a viable approach for the second dossier, the proposal is that PhytoTrade continues with the process of approval for the 1st GRAS Dossier for Baobab Pulp, and that the budget of GBP 6,000 for the 2nd GRAS Dossier remains uncommitted until PhytoTrade informs RTFP of a viable route forward.

PHASE 2 – Preparations for market launch and Trade Fair participation

Phase 2 activities are dependent upon completion of the gap analysis, and the subsequent submission of the 1st and 2nd GRAS Dossier. PhytoTrade Africa requests the RTFP PMU to approve Phase 2 activities to start upon submission of the 1st GRAS Dossier for Baobab Pulp. There are 3 main reasons for this:

- The 1st GRAS Dossier for Baobab Pulp will have the most significant impact on opening trade for Baobab Pulp to be used as an ingredient in products to be marketed in the US market
- The 2nd GRAS Dossier of either depectinised baobab pulp or baobab fibres are important niche markets but require investment from the private sector to cover research costs and this will take time to arrange

- Support has been given to attend 2 trade events, and it is hoped that progress with the 2nd GRAS dossier will be relevant to the second trade event, and also that PhytoTrade should be able to leverage investment from the private sector partner into also covering a percentage of costs of the second trade event

The following proposed activities are based on the RTFP PMU approving PhytoTrade Africa to start Phase 2 activities upon submission of the 1st GRAS Dossier for Baobab Pulp.

Preparations for market launch

The following deliverables are listed in the contract:

1. Market review of the food and beverage industry in the USA identifying companies that could be interested in using Baobab fruit pulp for developing new products
2. Articles and Press releases for the US industry about GRAS notification for Baobab fruit pulp
3. Progress report prior to first Trade Fair outlining number of companies contacted, interest shown, and follow-up actions to be taken.

Activities 1 and 3 have started with PhytoTrade Africa compiling details of companies that could be interested in Baobab Pulp as an ingredient in new products.

Trade Fair Participation

PhytoTrade Africa had a stand at Natural Products Expo West held in Anaheim during March 2008. At the trade fair PhytoTrade was promoting all of the focal species including Baobab Pulp, and their approach of supporting sustainable, fairly traded natural products from southern Africa which benefit rural communities.

There was positive feedback from the US companies that were met, especially on the desire to have a welcome change from Latin American products. However being the first time that PhytoTrade Africa presented their member's natural products to the 30,000 participants at the trade fair, the result was much more one of information provision than making business leads. Furthermore the majority of participants that visited the trade fair appeared to be retailers, wholesalers, distributors, and consumers rather than manufacturers and brand owners. This was supported by the fact that the supply side section of the trade show was very quiet, and from discussions with exhibitors who explained that the best trade fair for promoting new ingredients is Supply Side West. In comparison to European trade shows where PhytoTrade obtains around 200 business leads for further investigation, at the Natural Products Expo West only 40 of the contacts were worth further investigation.

As per the proposal, PhytoTrade Africa had planned to have a stand at Natural Products Expo East which will be held in Boston between 15th and 18th October 2008. PhytoTrade has already paid on the 12th February a 40% deposit to reserve a stand at the trade fair, for an amount of USD 1,680.

However following their experience at Natural Products Expo West, PhytoTrade is concerned that Natural Products Expo East is not the right venue to promote Baobab Pulp as a new ingredient.

PhytoTrade Africa believes that Supply Side West would be the best industry trade event most suitable to launching a new ingredient such as Baobab to manufacturers and brand owners. Supply Side West is held in Las Vegas between 22nd and 24th October 2008, and PhytoTrade is confident that the GRAS Dossier for Baobab Pulp will have been submitted to the FSA by then.

PhytoTrade therefore proposes that they should cancel the stand at Natural Products Expo East. This will mean that the deposit will be forfeited, and PhytoTrade requests the RTFP PMU to confirm whether the deposit amount of USD 1,680 should be deducted from PhytoTrade's budget or whether it can be allocated to the project budget.

PhytoTrade has looked at booth fees (USD 4,000) and at available booths. Additional to the booth fee are set up costs and at least 3 staff to man the stand. The stands that are available are on the periphery of the exhibition hall floor and are not well placed. However PhytoTrade has been offered the opportunity to share part of a stand that has been reserved by the largest importer of Rooibos into the US. This would allow PhytoTrade to reduce the cost of the booth, and the number of staff manning the stand to 2.

PhytoTrade proposes to look into holding a side event at Supply Side West and to invite industry to attend to learn more about Baobab Pulp and other natural ingredients from southern Africa. Another alternative is combine attendance at Supply Side West with a trade mission approach to visit around 6 key industry clients (such as Coca Cola) to promote Baobab Pulp, as well as visiting the FDA that will be in the process of reviewing the GRAS Dossier for Baobab Pulp to ensure it is moving ahead smoothly and to inquire about the approach for the 2nd GRAS Dossier.

PhytoTrade Africa requests the RTFP PMU to kindly consider whether the above activities could replace the intended participation at Natural Products Expo East. The budget to cover booth costs, publicity material and direct participation costs at 2 trade shows is GBP 10,000, and a budget of GBP 4,000 is allocated to staff time in organizing and attending the 2 trade fairs. PhytoTrade proposes to use 50% of the trade fair budget to cover the above proposed activities, and the balance would be committed to attendance at a second trade fair as originally intended.

CONCLUSION

Whilst the project has been delayed due to the considerable time it has taken to complete the gap analysis for depectinised baobab pulp and baobab fibres, the full gap analysis has been crucial in establishing the best strategy to achieve regulatory approval for baobab pulp, depectinised baobab pulp and baobab fibres. PhytoTrade can now confidently adopt a two pronged approach – supporting the final expert review of the GRAS dossier for Baobab Pulp and its submission to the FDA, and working on finding a commercial partner and to leverage funds to complete the necessary research on either depectinised baobab pulp or baobab fibres and continue the GRAS approval process.

PhytoTrade has also benefited the project from its experience of attending Natural Products Expo West. Instead of waiting for the first trade show to be funded by the project, PhytoTrade used its own funds to attend NP Expo West in March 2008. The result is that PhytoTrade believes that continuing with the planned stand at Natural Products Expo East would not be the best use of project funds. PhytoTrade has slightly changed track by proposing sharing a stand at Supply Side West and taking a more trade mission orientated view than simply trade fair participation.

The need to adapt the project as it progresses is a reflection of the dynamic and variable market conditions that exist in the US and in comparison with other global markets. The project has already been of great value in furthering access of Baobab Pulp into the US market and the future planed activities and targeted outcomes are still on track to deliver US market interest and new demand for Baobab Pulp that is sourced from rural communities in southern Africa.