



## Day 2: Regional biotrade collaboration – Marula value chain

10:30 – 13:30, 19 September, 2025

Growing Southern Africa's Marula Industry through regional collaboration, sector development planning, geographical indication advancements, and market access with EU Novel Food application



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Federal Department of Economic Affairs,  
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EU Novel food application and food business operator update

Mr Cyril Lombard



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## Milestone 1 update: SoC - Alkaloids

### Research Article

#### Nutritional and Phytochemical Variation of Marula (*Sclerocarya birrea*) (Subspecies *caffra* and *birrea*) Fruit among Nine International Provenances Tested in Malawi

Mussa Kamanula<sup>1</sup>, Chimuleke Yagontha Munthali,<sup>1</sup> and John Finias Kamanula<sup>2</sup>

<sup>1</sup>Mzuzu University, Department of Forestry, Private bag 201, Luwingu, Mzuzu, Malawi

<sup>2</sup>Mzuzu University, Department of Chemistry, Private bag 201, Luwingu, Mzuzu, Malawi

Correspondence should be addressed to Mussa Kamanula; kamanulamussa@yahoo.com

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TABLE 5: Phytochemical composition of *S. birrea* (subspecies *caffra* and *birrea*) seed kernel between provenances.

Provenance	Subspecies	Alkaloids	Saponins	Phytochemical Tannins	Terpenoids
Chikhwawa	<i>caffra</i>	+	+	++	-
Marracuene	<i>caffra</i>	+	+	+	-
Magunde	<i>caffra</i>	+	+	+	-
Moamba	<i>caffra</i>	+	+	++	-
Matebeleland	<i>caffra</i>	+	+	+	-
Ngundu	<i>caffra</i>	+	+	+	-
Magamba-Turiani	<i>caffra</i>	+	++	+	-
Kalimbeza	<i>caffra</i>	+	++	+	+
Missira	<i>birrea</i>	+	+	++	+

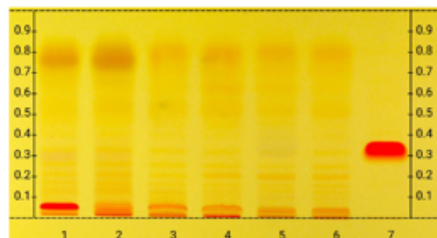
\*Concentrations (+++=high, ++=moderate, +=weak, and -=absent).

### Recommendation:

- Refine the analytical approach to more definitively clarify presence or absence

➤ Underway now

TUT studies: higher concentrations show bands but these include amino acids but could also be some alkaloids



- Contract: April 2025
- Contract extended with additional analyses: July 2025
- Final report: September 2025
- Confirmed and quantified 2 substances of (potential) concern
- Low levels, but requires articulation of safety for dossier
- Caused some delays, underway

### Purpose of the additional analyses:

- Seek to obtain better resolution of the compounds identified
- Quantify the identified compounds to the extent possible with available standards

The EU's **3Rs principle** refers to a cornerstone of animal welfare in research, testing, and safety assessment. It stands for:

- **Replacement** – Use alternative methods that avoid or replace the use of animals where possible (e.g., in vitro tests, in silico models like QSAR).
- **Reduction** – Minimize the number of animals used while still obtaining scientifically robust data (e.g., shared data, tiered testing strategies).
- **Refinement** – Modify procedures to reduce pain, suffering, or distress and improve animal welfare when animal testing is unavoidable.

Enabling Marula fruit to have the option of an Article 10 application (Full Novel Foods with 5 years of data protection / confidentiality for the FBO) ***whilst avoid the need for animal testing***

Approach	Description	Regulatory Use (EU Food & Feed Safety)
Read-across	A data-gap filling strategy where information (e.g., toxicity data) from one or more structurally similar “source” substances is used to predict the properties of a “target” substance. It relies on scientific justification of similarity in structure, metabolism, or mode of action.	Accepted under EFSA and ECHA frameworks for hazard and risk assessment (e.g., pesticides, additives, contaminants) to reduce animal testing; assessed using ECHA’s <b>Read-Across Assessment Framework (RAAF)</b> .
QSAR (Quantitative Structure–Activity Relationship)	A computational modelling method that predicts a biological activity or property of a chemical from its molecular structure or descriptors. It provides a quantitative or qualitative prediction without direct experimental data.	Used to predict endpoints like genotoxicity, mutagenicity, or bioaccumulation. Regulators apply the <b>OECD QSAR validation principles</b> to evaluate reliability and relevance before acceptance.
In silico	A broad term for computer-based approaches used in toxicology and risk assessment, including QSAR, molecular docking, and other computational models. It encompasses QSAR and can be part of read-across justifications.	Encouraged as part of the EU’s move towards <b>New Approach Methodologies (NAMs)</b> and the <b>3Rs principle</b> (Replace, Reduce, Refine) to <b>minimize animal testing</b> in regulatory submissions.



# Towards Global Market Access Through Compliance with EU Novel Food Regulations

Dossier Element	EU (Article 10, Reg 2015/2283)	USA (GRAS)	China (NHC Novel Food)	Brazil (ANVISA RDC 839/2023)	India (FSSAI)
<b>Identity &amp; Characterisation</b>	Required (composition, production, specifications)	Required (identity, intended use)	Required (nomenclature, source, specifications)	Required (raw materials, production, specifications)	Required (identity, specs, safety)
<b>Production Process / Manufacturing</b>	Required	Expected, but not explicitly regulated	Required (traceability, process)	Required (flowcharts, R&D background)	Required for safety evaluation
<b>History of Use / Traditional Use</b>	Required or addressed in risk assessment	Supports GRAS (common use evidence)	Important; history aids justification	Relevant in defining 'new'; safe consumption evidence	Considered during safety assessment
<b>Chemical Composition &amp; Analysis</b>	Detailed compositional and analytical data required	Robust analyses required	Required to meet quality standards	Required (specs, analyses)	Required for risk assessment
<b>Toxicological &amp; Safety Data</b>	Required (toxicology, ADME, nutritional, allergenicity)	Required (equivalent to food additive safety)	Required in safety assessment	Required (toxicological/clinical data)	Required (scientific safety assessment)
<b>Intended Uses / Conditions of Use</b>	Required to define scope and risk	Essential for GRAS determination	Required for Catalogue inclusion	Required (labelling, use instructions)	Required for approval and labelling
<b>Labelling / Use Instructions</b>	Required	Not part of GRAS dossier	Considered in safety/tracing	Required (labels, instructions)	Considered in approval
<b>Post-market monitoring / Transparency</b>	EFSA transparency rules; public register	GRAS notices inventoried	Catalogue published by NHC	ANVISA may recognise foreign dossiers	Not transparent; limited public record

# Marula Fruit Products Association

## Progress



The following progress has been made:

- Approximately 30 *Potential* members, some companies identified but still to contact.
- First draft constitution / articles of association.
- First draft prospectus especially membership benefits, fees and rights (coherent with constitution/articles).
- First draft of repository of all confidential information (will form part of the valorisation of all previous ABioSA studies and reports from the Marula Fruit EU NFR project).
- Identification of administrative aspects and requirements for a legally constituted Food Business Operator.

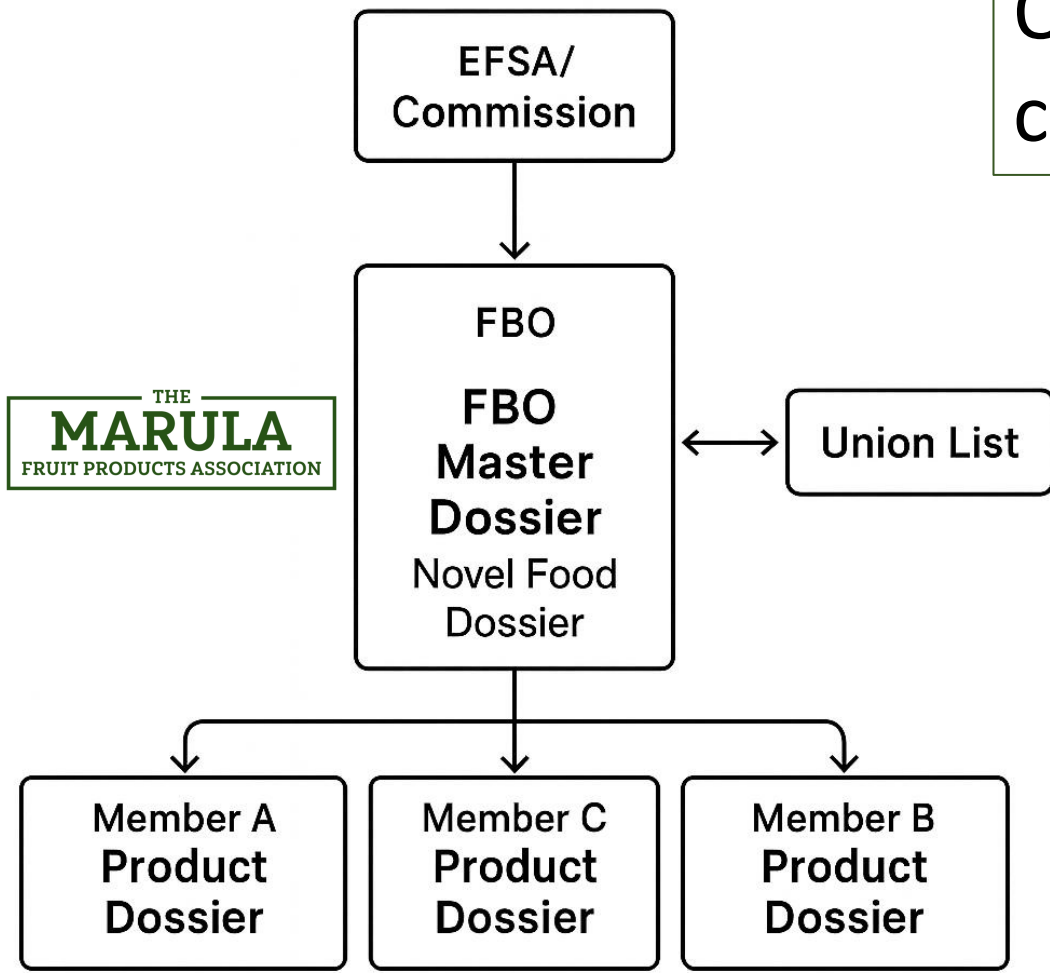


**MFPA membership categories, benefits and costs:**

Membership category & fees	Type of business / organisation	Voting rights	Other benefits
Full Member (Percentage of relevant turnover per year – R5,000 – R20,000 per year)	<ul style="list-style-type: none"> <li>Manufacturers of products derived from or incorporating Marula fruit and registered in Southern Africa and able to comply with relevant product standards</li> </ul>	Yes (full)	<ul style="list-style-type: none"> <li>Food Business Operator status for EU compliance purposes</li> <li>Can contribute to sector development plan (SDP) and related projects</li> <li>Access to Marula fruit regulatory database</li> <li>Access to Marula fruit research library</li> <li>MFPA members newsletter</li> </ul>
Associate member (R2,000 per year)	<ul style="list-style-type: none"> <li>Organised farmers &amp; harvesters including registered Communal Property Associations, conservancies, cooperatives, businesses etc</li> <li>Manufacturers of Marula fruit products registered in Southern Africa not yet able or willing to comply with relevant product standards</li> <li>Organisations including universities, incubators, business support organisations working on the development of the Marula fruit sector in Southern Africa</li> </ul>	Yes (advisory)	<ul style="list-style-type: none"> <li>Participate in sector development projects</li> <li>Access to Marula fruit research library</li> <li>Standard newsletter</li> </ul>
Individual member (R1,000 per year)	<ul style="list-style-type: none"> <li>Individual academics and researchers working on Marula fruit in Southern Africa</li> </ul>	No	<ul style="list-style-type: none"> <li>Access to Marula fruit research library</li> <li>Participate in sector development projects subject to collaboration with other members</li> <li>Standard newsletter</li> </ul>
Friends of the MFPA (R1,000 per year)	<ul style="list-style-type: none"> <li>Product researchers, developers, innovators, manufacturers and marketers with a potential interest in Marula fruit products and registered in Southern Africa and/or internationally</li> <li>Sponsors and supporters</li> </ul>	No	<ul style="list-style-type: none"> <li>Participate in SDP projects subject to collaboration with other members</li> <li>Standard newsletter</li> </ul>

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One master dossier supports multiple companies with their own dossier

Principle	Pharmaceutical DMF	Potential in Novel Food dossier
<b>Centralised confidential data</b>	DMF holds proprietary manufacturing & safety data	FBO holds the core toxicology, production process, specs, stability & compositional data
<b>Multiple downstream users</b>	Many MA holders rely on one DMF	Many association members can rely on the dossier & Union List entry
<b>Letter of Access / cross-reference</b>	Applicant provides <u>LoA</u> to FDA/EMA	FBO could issue internal licences to members; members then prepare own <i>simplified notifications</i> or <i>post-market files</i> citing FBO data
<b>Version control</b>	DMF updates ripple to all MA holders	FBO manages dossier updates (e.g. spec change, new uses) and notifies members

Based on similar commercial arrangements in pharmaceuticals with Drug Master File and REACH common dossiers in consortia



**DRAFT**

**Marula Fruit Sector Development Plan - Current Ideas for 1 to 3-year Plan**



Pillar	Notes of selected activities	Selected costs
Market Development & Promotion	<ul style="list-style-type: none"> <li>Establish partnerships, collaboration between local, regional and international companies</li> <li>Cooperation with SIPPO, IPD</li> </ul>	R1 million [€50K]
Sustainable Supply Chain Development	<ul style="list-style-type: none"> <li>Developing innovative solutions for ABS permits (including primary producers, farmers, harvesters, landowners as TK holders)</li> <li>Resource assessments considering issues specific to Marula fruit selection, varieties, emerging quality requirements</li> <li>Support to farmer groups to establish quality and reliable supply, scaling through agriculture</li> <li>Conservation practices</li> </ul>	R6 million [€300K]
Product Innovation & Development	<ul style="list-style-type: none"> <li>Collaboration between universities, incubators, SMMEs and industry to address current product challenges and develop potential as a superfruit, food and beverage ingredient, local products</li> <li>Curation of latest science, IP information (BioMoT)</li> </ul>	R5 million [€250K]
Quality, Standards & Regulatory Compliance	<ul style="list-style-type: none"> <li>Finalisation of EU NFR “master dossier” as basis for global market access and compliance for FBO members</li> <li>Technical support to develop and operate Master Dossier model, ongoing compliance management</li> <li>Establish and manage industry standards</li> </ul>	R9 million [€450K]
Coordination, Governance & Investment	<ul style="list-style-type: none"> <li>Complete proposal with rationale for the “Food Business Operator” as an association, operating model</li> <li>Launch FBO with board of directors</li> <li>Raise funds to implement SDP and manage process</li> <li>Establish M&amp;E system linking to conservation, SDGs and KMGBF goals and targets, UNFCCC, jobs and other targets</li> </ul>	R1 million [€50K]

**Draft** based on first round of discussion with stakeholders

This will be tidied up with narrative and shared with parties wishing to join the association

After feedback and refinement, it will form the basis of a proposal for 2026 onwards

Rand 22 million  
Euro 1.1 million



# What next?

## ABioSA II Marula fruit EU Novel Foods Regulation project Milestones 2024 and 2025

Milestone	Timeframe
<b>Milestone 1:</b> SoC study completed, reviewed and recommendations prepared	By end of October 2024
<b>Milestone 2:</b> Industry communication plan prepared, 1 <sup>st</sup> publication drafted, FBO and key stakeholders updated	Ongoing to end of December 2024 (with ongoing communication with sector through to end of June 2025)
<b>Milestone 3:</b> Pre-submission advice obtained from EC, EFSA or relevant National Competent Authority	Ongoing to end of March 2025
<b>Milestone 4:</b> Comprehensive proposal to complete Marula fruit EU NFR application / notification completed and presented to industry and potential funders	Ongoing to end of June 2025
<b>Milestone 5:</b> Close-out of ABioSA II and Marula fruit EU NFR component	By end of December 2025

- Some delays due to SoC findings
- Need to revisit milestones and prioritise (team meeting 14<sup>th</sup> October 2025)
- Another round of bilateral meetings and discussions with interested parties
- Develop the business model of the FBO and finalise prospectus
- Receive and review report by regulatory consultants
- Engage with EU regulators/EFSA
- SDP with narrative to become basis for proposal for 2026 onward
- When to trigger the association / FBO constantly under consideration



Thank you for your attention



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