THE ORGANIC BODY CARE INDUSTRY

A TECHNICAL GUIDE

Sonia Peter, Ph.D.

CONTENTS – THE ORGANIC PERSONAL CARE INDUSTRY TECHNICAL GUIDE

EXECUTIVE SUMMARY

The publication offers technical assistance for small enterprises in the organic body care industry. Emphasis has been placed on the parameters for organic production and the importance of standards. The current dilemma of no harmonisation among global standard agencies regarding the organic brand is highlighted and the lack of a Caribbean perspective. Guidelines are offered for production from acquisition and handling of raw materials, selection of appropriate chemical ingredients, processing and packaging of the final product. The importance of the green underlying principle is stressed throughout the publication.

The pertinence of management of the manufacturing plant in relation to quality assurance strategy and quality control activities has been delineated. Flow charting and tables are used to encapsulate ideas and information. Technical support is provided for common processing methods including access to suppliers of essential pieces of equipment. The publication does not outline specific recipes but gives focus to the necessary constraints of formulation as requisite for the organic classification. Additional features include listing of suppliers of organic ingredients and green packaging, and a glossary of technical terms.

The small enterprise The Coal Pot located in Grand Bay, Dominica, has been overviewed as a case study. The structure of the manufacturing unit and range of products has been examined and the efforts made by the plant to ensure natural product integrity. An assessment of the value of the publication to such enterprises is provided by The Coal Pot management.

ACKNOWLEDGEMENTS

The executive members of the Dominica Herbal Business Association and the Director of The Coal Pot, Ms Avril James, are acknowledged for their accommodation during the field visit. The DHDA extended an invitation to a workshop for members which proved informative. Ms James willingly accommodated a tour of her facility and volunteered to participate in the case study and assessment. Chairman of the Board of Public Works, Dominica, Ms Gloroa Tavernier and Manager of West Indies Oil Co. Ltd, Mr Joe Tavernier are also appreciated for offering assistance during the field visit,

1.0 INTRODUCTION

The organic body/personal care industry is growing at a significant rate on a global scale.[1,2] Heightened concern regarding exposure to synthetic chemicals with potential toxic effects is driving the resurging interest in natural or organic products. Many issues remain unresolved in the industry, however, including acceptable ingredients, methods of processing and labelling. In the USA and Europe a number of organisations and standard bodies have been striving to develop guidelines for the industry and set limits for the organic classification. No such consensus has been engaged in the Caribbean region and hence international standards and methods must be adopted to ensure that products are within acceptable margins of quality.

1.1 Organic body care products - definition and scope

The term 'organic' as used in the labelling of personal/body care products is defined as being free from synthetic fertilisers, pesticides, ingredients and not being exposed to radiation. Currently the guidelines on the classification of manufactured items as organic are still being defined. Some notable agencies including the United States Department of Agriculture, USDA, Organic and Sustainable Industry Inc, OASIS, National Standards Foundation, NSF, and Certech Registration Inc. have made an effort to clarify the usage of the term 'organic' as it pertains to consumer items including foods and body care items. The USDA, through the National Organic Program, has organic standards for food products but the organisation provides certification for personal care products if evidence of the use of organic materials is provided. In most instances limits are set for specific classifications in terms of organic content.

In Europe the wrangling over what can be rightfully declared as an organic product has led to two recent standards being released. The European Cosmetics Standard Working Group informed of the publication of the Cosmos standard in July 2009. This standard was collaborated on by major entities in the body care industry across Europe including **BDIH** (Germany), **BIOFORUM** (Belgium), **COSMEBIO & ECOCERT** (France), **ICEA** (Italy) and **SOIL ASSOCIATION** (UK) and they announced the publication of the **COSMOS-standard** as the new harmonised and most challenging European cosmetics organic and natural Standard. The European competitor to the Cosmos standard, NaTrue, was launched to provide organic production and labelling guidelines for natural and organic cosmetics. It provides guidelines for three grades depending on the formulation of the organic personal care products and proposes limits for acceptable ingredients.

The Organic Monitor Ltd., January 2008, stated that ,the natural and organic sector is the fastest growing in the United States personal care industry.[3] In addition it was assessed that healthy market growth rates are projected to raise the market share of natural & organic products to 15% of total cosmetic & toiletry sales in the coming years. The monitor predicts that global revenue in natural personal care products should exceed 10 billion worldwide by 2010. The First Research Industry Overview for the US market identifies the popular range of personal care products as

cosmetics, hair products, creams and lotions.[4] It is stated that revenue is composed of cosmetics (makeup, deodorant and nail products) – 33%, hair products – 25%, creams and lotions – 21%, perfume – 10%, mouthwashes – 2%, shaving preparations – 2%. The Datamonitor, an independent market research analyst publication, reports that current trends show that consumers are moving away from personal care products with traditional ingredients and towards products bearing the natural or organic classification.[5]

Market analysis for the Caribbean region is not extensive but the establishment of the Caribbean Herbal Business Asociation is a reflection of the increase in entrepreneurial activity in plant based or natural products.[6] This is a response to the regional shift in preference to personal care products formulated with natural ingredients which are typically plant derived.

1.2 Current Standards for Organic Products

An appreciation of the international standards for formulation and labelling of organic products is essential for the stake holders in the personal care industry. Though there is no global harmonised standard the USA and Europe have established a number of standards under which organic products can receive certification. There are common elements in all of the standards especially in terms of the selection of ingredients employed in formulation. Currently there are no standards for organic personal care products or a certification body in the Caribbean. Therefore, manufacturers closely follow the guidelines offered by the international standards as outlined below.[7,8,9,10,11]

OASIS - Organic and Sustainable Industry Standards (Updated March 2008)

100% Organic – product should contain 100 % organically produced ingredients.

Any processing aids, catalysts, reagents, or other materials to come in contact with this product must also be certified to the 100% organic level and must be plant derived.

Organic – product should contain not less than 85 % organically produced raw or processed agricultural products intended for use in personal care products. This percentage will move to 90 % in 2010 when improvements in ability to meet the organic requirements will allow for the higher level. Any remaining product ingredients shall be organically produced, unless not commercially available in organic form. Any processing aids, catalysts, reagents, or other materials to come in contact with this product must also be in conformance with standards.

Made with Organic – product should contain not less than 70 % organically produced, raw or processed agricultural products. Any remaining product ingredients shall be organically produced, unless not commercially available in organic form.

Soap and other products that, by their inherent nature will always be below 95% organic content, shall be placed in the "made with" category. In all of the above classifications salt and water are allowable inorganic ingredients (*www.oasisseal.org*)

USDA – National Organic Products Program 2008

Once certified, cosmetics, personal care products, and body care products are eligible for four organic labelling categories as are all other agricultural products, based on their organic content and other factors:

100 percent organic - product must contain only organically produced ingredients.

Organic - product must contain at least 95 % organically produced ingredients.

Made with organic ingredients - products contain at least 70 % organic ingredients and product label can list up to three of the organic ingredients or "food" groups on the principal display panel. For example, body lotion made with at least 70 % organic ingredients (excluding water and salt) and only organic herbs may be labelled either "body lotion made with organic lavender, rosemary, and chamomile," or "body lotion made with organic herbs." (*www.ams.usda.gov/nop)*

Certech Registration Inc. 2008

Natural - a minimum of 95 % of product must be of natural origin.

Certified organic - product must consist of ingredients that have been grown, cultivated and stored without the use of chemical fertilisers, herbicides, pesticides and toxins. Chemicals (used to promote chemical change) and harmful substances cannot be used during the manufacturing process, and packaging must be recyclable. Additionally, the end product and ingredients cannot be tested on animals, must be free of synthetic ingredients and most not contain pesticides, harmful preservatives, artificial colours and fragrances. (*www.certechregistration.com)*

Cosmos Standard – Cosmetics Organic and Natural Standard September 2009

Organic - At least 95% of the physically processed agro-ingredients must be organically produced. Products that have less than 95 % organic ingredients can list organically derived ingredients on the label e.g ' contains organic eucalyptus oil'

Natural - There is no requirement to use organic ingredients. Processing must be natural, under the regulations of the standard, as it relates to minimal chemical interference. (*www.cosmos-standard.org*)

NSF's New 'Made with organic ingredients' Standard for Personal Care products 2009

This standard was adopted as the American National Standard for personal care products made with organic ingredients. It allows the 'Contains Organic Ingredients' certification for products containing 70 % of or higher organic ingredients. In addition it allows some chemical processing for the generation of components required to impart characteristic notes in formulations. Processes include esterification, hydrolysis and transesterfication, which are typically involved in generating fragrances. (*www. nsf.org*)

1.3 Certification of Organic Products

The European Cosmos Standard and the establishment of the NSF standard as an American standard pave the way for the development of a Global Natural and Organic Personal Care Standard. In the Caribbean no standards have been developed for the organic personal care industry. However, it is essential that good manufacturing practices be employed in production and careful consideration given to the guidelines as indicated by the international standards regarding ingredients and processing.

Appendix 5.2 provides information for the calculation of organic percentages.

2.0 FORMULATION

The formulation of organic personal care products requires careful attention to the nature of the ingredients and methods of processing. The use of synthetic agents as base materials, colourants, fragrance or preservatives must be limited as well as the degree of chemical processing. Suppliers are conscious of the demand for organic products and increasingly offer 'natural' ingredients many of which are plant extracts including essential oils. The use of natural ingredients provides challenges in terms of aesthetic appearance of products and extension of shelf life. Some of the ingredients that are excluded form organic products formulation are listed in **Table 1.**[1]

TABLE 1 – Some ingredients excluded from organic products formulation

Ingredient	**Application**	**Reason for exclusion**
Propylene glycol (PG), butylene glycol (BG)	Humectants	Can act as attractants for other potentially harmful chemicals in the blood stream, can cause skin irritation
Polyethylene glycol (PEG)	Thickening agent	Though considered safe when pure, can contain traces of 1,4-dioxane which is carcinogenic
Triclosan	Preservative (antimicrobial)	Registered pesticide with many potential health effects if absorbed through the skin
Sodium Lauryl Sulphate	Strong cleansing agent	Can damage lipid skin layer and act as irritant
Monoethanolamine, diethanolamine, triethanolamine	Foam and viscosity boosting agents	Can form carcinogens on reacting with other ingredients
Parabens	Preservative	Possible endocrine disruptor and being examined for link to breast cancer from presence in underarm deodorants
Mineral oil	Petroleum by-product used as base oil	Could contain organic contaminants
FD&C colour pigments	Colouring agents	Can cause allergic responses
Phthalates	Fragrance	Potential toxins

2.1 Common ingredients for personal care products

The ingredients listed in **Table 2** below are commonly used in personal/body care products including soaps, lotions, shampoos and creams. (*http://www.insidecosmeceuticals.com*).[1,15] In order to meet the requirements for organic products, ingredients must be organic certified and sourced from suppliers that provide such ingredients. The biggest challenge for the selection of allowed organic ingredients is in the choice of preservatives. There are many preservatives which, though naturally derived, are considered as petrochemical in nature and not considered acceptable in 'organic' products. Some concern has been raised by consumer associations and researchers regarding the use of triclosan and triclocarban in personal care products.[12,13,14] However, experimental assessment indicates that there is low toxicity related to the use of these preservatives at incorporated levels up to 0.3 % (*European Commission Scientific Committee on Cosmetics*).[16] **Table 3** lists ingredients classes of alternative ingredients.

Table 2 - Common ingredients used in personal/body care products

Ingredient	Description
Botanical material	Originates from plants (herbs, roots, flowers, fruits, leaves or seeds)
Fragrance	Any natural or synthetic substance or substances used solely to impart an odour to a product.
Palm kernel oil	Used as skin conditioning agent – occlusive, or viscosity agent in skin care formulations and cosmetics.
Mineral oil	A mixture of liquid hydrocarbons produced from the distillation of petroleum. Functions as a hair conditioning agent, skin conditioning agent – emollient, skin conditioning agent – occlusive, skin protectant and as a solvent.
Preservative ingredients	A natural or synthetic ingredient that is added to a product to inhibit microbial growth or chemical change.
Colourant	Any ingredient which functions alone or in combination with other ingredients to impart colour to, or modify the colour of, a product.
Glycerol	An alcohol found in both animal and vegetable oils. It is used as a humectant which slows moisture loss from products.
Lanolin	A lubricant obtained from sheep's wool.
Titanium dioxide	A substance derived from minerals and is used as an opacifying agent, a sunscreen agent and a colourant in products.
Triclosan	A broad-spectrum antimicrobial used as an active agent in skin care products and as a preservative in water based products.
Triclocarban	An antibacterial agent used in personal care products to retard spoilage and prevent the formation of odours.

2.2 Table 3 - Natural Additives with General Applications for Organic Personal Care Products

Additive	Description	Recommended for organic products
Absorbents	Absorbents add holding capacity for moisture or oils.	• Arrowroot starch • Bentonite • Baking soda • Oat bran powder
Antioxidants	Antioxidants are agents that act to capture free radicals which can contribute to aging of the skin. Antioxidants also possess preservative properties by hindering atmospheric oxidation.	• Ascorbic acid • Glycolic acid • Citric acid • Olive oil • Oregano oil • Papaya enzyme extract • Pomegranate juice/extract • Vitamin E – tocopheryl acetate • Wheat germ oil • Niacinamide (vitamin B3) • Beta carotene
Astringent	An astringent is an active agent that tightens the pores of the skin thereby limiting the release of oils.	• Witch hazel
Base oils/butters	These oils/butters are used to dilute essential oils or to function as the base in soap making.	• Olive oil • Coconut oil • Palm oil • Castor oil • Shea butter • Cocoa butter • Mango butter

Additive	Description	Recommended for organic products
Colouring agents	These agents impart their natural colouring during formulation.	• Annatto • Beets • Carrot powder • Grape juice • Paprika • Red cabbage • Saffron • Spinach powder • Tomato powder • Turmeric
Emulsifiers	Emulsifiers are used in combining oil with water and water with oil (O/W and W/O) formulations. An **emulsion** is a mixture of two immiscible (unblendable) substances. One substance (the dispersed phase) is dispersed in the other (the continuous phase). An **emulsifier** (also known as an **emulgent** or **surfactant**) is a substance which stabilises an emulsion.	• Lecithin • Cetyl alcohol • Beeswax
Fragrant essential oils	Essential oils are the aromatic essences extracted from leaves, roots or seeds. They impart pleasing aromas used in single form or as blends.	• Bay leaf • Cinnamon leaf • Clove • Eucalyptus • Geranium • Ginger • Lavender • Lemon • Lime • Orange • Peppermint • Rosemary • Vanilla
Humectants	Humectants are used in cosmetic preparations to hinder loss of moisture from the surface of the skin. They also aid in moisturisation. Products for dry skin care should always contain a humectant.	• *Aloe vera* gel • Glycerin • Panthenol • Lecithin

Additive	Description	Recommended for organic products
Mechanical exfoliants	An exfoliant is used to improve the skin's appearance by removing dead skin cells from the surface. Exfoliation can be achieved by either mechanical or chemical methods. Mechanical exfoliants include micro-bead facial scrubs, crushed shells, sugar or salt crystals, pumice, and other abrasive media. (Chemical exfoliants include chemical peels containing salicylic acid, glycolic acid, fruit enzymes, citric acid, or malic acid which should only be applied in low concentrations in over-the-counter products).	• Corn meal • Coffee • Lemon peel • Coconut shell • Sea salt • Sugar • Pumpkin seeds • Almond meal • Pumice
Moisturisers	A moisturiser is a compound that traps moisture when applied to the skin.	• Almond butter • Almond oil • Aloes (*Aloe vera*) extract • Apricot kernel oil • Avocado oil • Jojoba oil • Glycerin • Pumpkin seed oil • Shea butter • Sunflower oil • Wheat germ oil • Cetyl alcohol (derived from palm oil)
Preservatives	A preservative is a natural or synthetic chemical that is added to products including foods, skin care products, and pharmaceuticals to retard or inhibit spoilage, whether from microbial growth or oxidative chemical changes. Various herbal and plant compositions are already recognised for their antimicrobial benefits by institutions such as the Chemical Abstracts Service (CAS) and European Inventory of Existing Commercial/ Chemical Substances (EINECS)	• Cinnamon (*Cinnamomum zeylancium*) bark extract • Lavender (*Lavandula angust*ifolia) flower extract • Lemon (*Citrus medica limonum)* peel extract • Oregano (*Origanum vulgare)* leaf extract • Peppermint (*Mentha piperita)* leaf extract • Rosemary (*Rosmarinus officinalis)* leaf extract • Thyme (*Thymus vulgaris*) extract

Additive	Description	Recommended for organic products
Repellants	These active agents offer a protective repelling barrier from insects.	• Citronella oil • Lemon grass oil
Thickeners	Thickening agents, or thickeners, are substances which, when added to a mixture, increase its viscosity without substantially modifying its other properties. They provide body, increase stability, and improve suspending action. Thickening agents are often food additives that can also be used in cosmetic preparations.	• Arrowroot powder • Corn starch • Stearic acid

2.3 Good Manufacturing Practices

The key objective is product safety and hence consumer protection. The GMP Concept is based on

- product quality
- consistency of manufacturing methods
- conformation to standards
- identification of critical steps in processing
- traceability of critical steps in processing

Product Quality

In the development of new products attention must be given to all details of processing. The flow diagram in **Fig. 1** outlines the stages through which product development should be taken to ensure that the final product meets the required quality standards for consumers. In the formulation of organic products special care must be taken to incorporate ingredients which are considered acceptable according to the labelling guidelines. Quality assurance and quality control must be practiced to guarantee maintenance of product standards.

Consistency of Manufacturing Methods

Formulations for each product must be standardised and documented. This is essential for consistency in batches of product and also to offer standard guidelines for workers in the manufacturing process.

Conformation to Standards

The manufacture of organic products requires that there is strict adherence to guidelines relating to the nature of ingredients to be incorporated at formulation. Guidelines should be followed according to the categories for labelling of products.

Identification and Traceability of Critical Steps in Processing

Steps which can lead to product contamination must be carefully guarded. The use of plant material in formulation requires that steps be taken to ensure that the correct plant material is used and not related species. Adulteration of plant material can lead to unwanted properties being transferred to the product which could have adverse effects for the consumer. Strategies must be put in place to guarantee plant identification and plants should be sourced from a natural pesticide free environment. Sterile conditions are essential to avoid microbial contamination. Equipment must be kept sterilised and plant conditions should prevent build-up of moisture which promotes growth of fungal spores. Periodic testing of equipment, materials and end-product is recommended for quality control purposes. Packaging and labelling are also critical steps. Product batches should be coded on packaging for traceability purposes. This is essential for customer services and also shelf life testing. Packaging materials should be carefully selected to

maintain product integrity. The use of environmentally friendly packaging materials is an asset to the organic product classification. Labelling must follow acceptable standards for listing of ingredients and in accordance with the organic product classification. See Section 4.0.

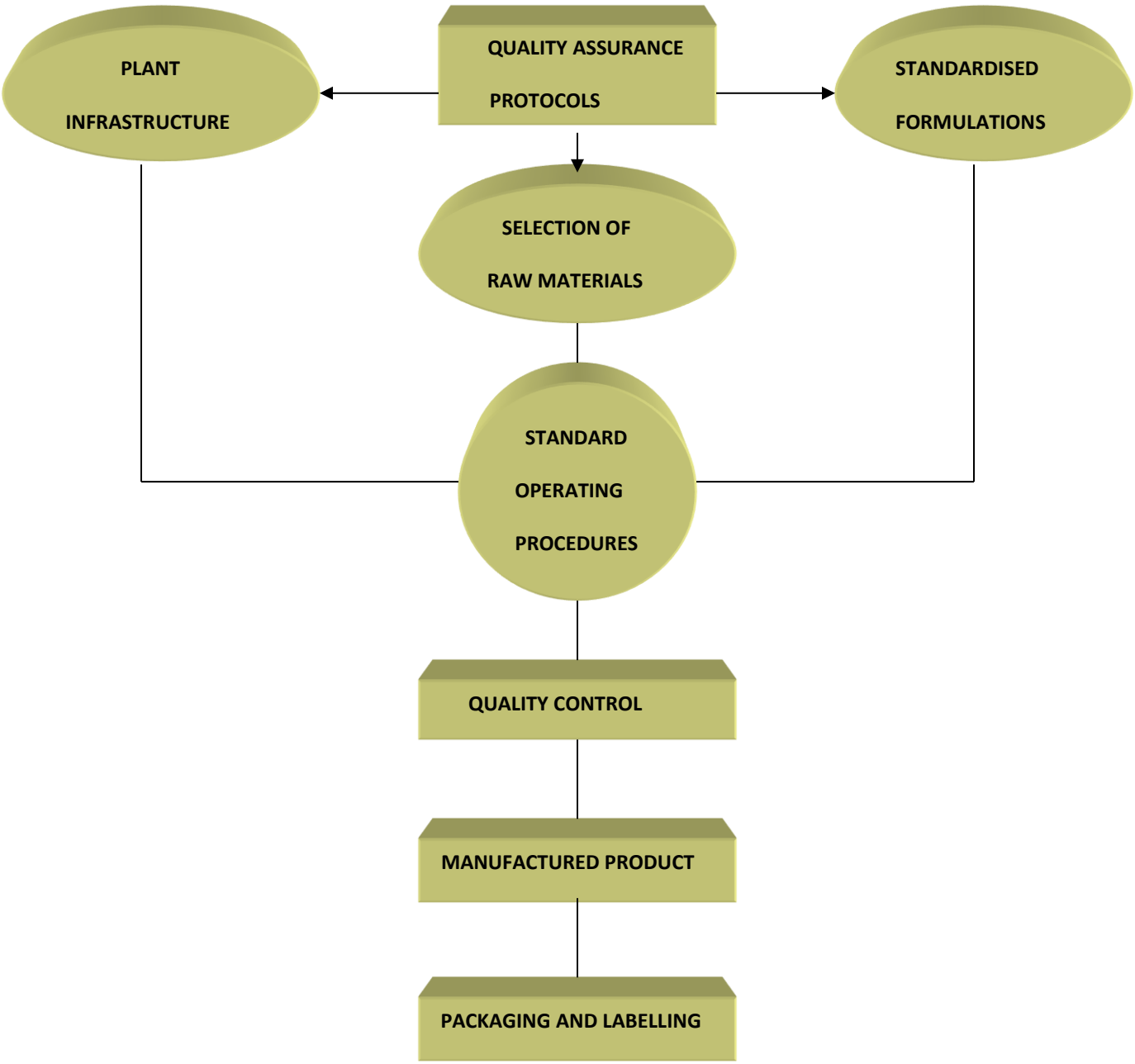


Fig. 1 – Flow Diagram for Best Manufacturing Practices

2.4 Standard Operating Procedures (SOPs)

Product development requires documentation of every step in the manufacturing process in order to maintain product integrity. All aspects of organisation in the plant must be clearly defined so that all actions are standardised. Standard operating procedures should be defined in the areas of

- cleaning and sanitizing of equipment
- occupational health and safety
- selection of raw materials
- handling of raw materials
- formulations
- processing steps for each product
- quality control checks
- handling of products
- production logs

Definition of these procedures eliminates uncertainty within the plant, minimises impact of mishaps and generally enhances productivity. SOPs must be updated as operations at the plant are modified due to changes in product line or applied technologies.

Cleaning and Sanitising of Equipment

The manufacture of organic products requires that cleansing agents also meet organic standards. This is of special concern as traces of these agents could be incorporated in the final products. Cleansing agents should therefore be non-petroleum based and made from naturally derived substances. Some manufacturing plants recycle their waste product from soap manufacture for cleansing. Acceptable cleansing agents include washing soda, baking soda, vinegar and lemon juice. The use of alcohol as a sanitising agent is within acceptable standards. Water based mixtures of some essential oils also provide antimicrobial protection to surfaces including lavender, clove tea tree oil and grapefruit seed extract.

Occupational Health and Safety

It is essential that operating procedures that relate to health and safety be regularised and documented for continuity and quality assurance. Strategies should include:

- Dress code for staff in terms of protective wear and minimisation of contamination of product.
- Separation of general staff activities from production.
- Hygienic guidelines

Selection and Handling of Raw Materials

Particular attention must be paid to the sourcing of raw materials. In organic production raw materials should be sourced from suppliers that provide certified organic materials. In situations where organically **certified** material is not accessible an effort should be made to ascertain the conditions under which the raw material was obtained and handled as it relates to the requirements for organic production. The incorporation of plant material requires that growth and harvesting be under conditions free from synthetic fertilisers, pesticides and exposure to restricted substances. Wild harvested plant material is also acceptable but the area of harvesting must be likewise free from contamination and removed from sites of potential pollution such as roadsides. Plant materials should be stored under conditions that would conserve their integrity as sourced.

Processing Steps

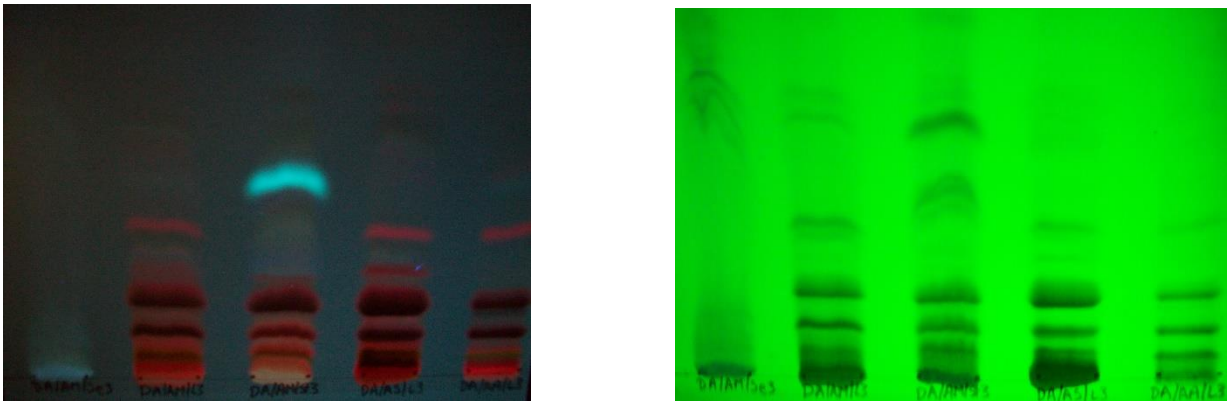
Organic production requires that raw materials be not subjected to harsh chemical processing. This is to avoid the destruction of the active organic ingredients. Conditions required for handling of ingredients must be clearly defined for consistency. Quality control checks made at critical stages must be embodied in the processing steps.

3.0 PRODUCTION

The formulation of organic body care products requires diligence in adhering to set standards at all levels of production. Special focus has to be given to the exclusion of materials considered unacceptable. The use of plant material including extracts poses special concerns for product integrity. Product preservation is a challenge in the production of organic body care products because most of the established preservatives are of synthetic origin. The maintenance of sterile working conditions is key to limiting product contamination.

3.1 Handling of Plant Material

Adulteration of plant material has been a major hurdle in the use of natural material in the formulation of organic products. Products have been faced with recall because of problems experienced by consumers due to the inclusion of misidentified plant material. It is therefore essential that steps are put in place to guarantee that the correct plant material is sourced. This can be achieved by the execution of quality control fingerprinting of the plant material. An established laboratory could be contacted to provide this service or the use of a prepared testing kit. The plant has a signature based on the natural compounds it produces and this signature is seen in the fingerprint. The plant material is subjected to testing for development of the fingerprint and this can be used as a quality control guide. Differences in the fingerprint will indicate adulteration of the plant material which should then be discarded in order to maintain product integrity.



Finger printing of plant extracts

The images show fingerprints obtained for different plant extracts. Each plant extract has a signature as indicated by the pattern obtained. Each of the coloured lines in the fingerprint represents characteristic compounds produced by the plant. This fingerprint is similar to that obtained on DNA testing. The identical pattern should be obtained every time the plant material is tested. Changes in pattern would indicate a change in the type of natural compounds present and this would alter the integrity of the product if the plant material is included in formulation.

When the material is obtained in the dry state care must be taken to ensure that the drying procedure was complete and that the raw material is free from mould which can form due to the presence of moisture. In addition, the dried material should be free from extraneous matter and insects. This is important especially if the plant material is used to make extracts as the extract would contain the agents from the extraneous matter as well as the plant material. Plant material can also be air dried on site if harvested green. Oven drying should be avoided as natural agents in the plant material may be destroyed at the elevated temperatures.

Plant material harvested green and dried

Air drying of plant material is preferred in order to preserve the active agents. The plant material is spread on a sterile surface and exposed to the air at ambient temperature. The material should be turned daily to achieve even exposure. The drying process is complete when the plant material is crisp and disintegrates without resistance on applying pressure.

3.2 Methods of Plant Extraction

The inclusion of plant material may require the use of a plant extract. Plant extracts can be obtained by blending the plant material with water or alcohol. This blending process allows the water or alcohol to extract the natural active agents from the plant material. Alcohol will generally extract more of the natural agents than water so knowledge of the plant material and its application is essential when used in formulations. The extracting power of water can be increased if used at a temperature above room temperature. However, a temperature above 60 ºC should be avoided in order to avoid destruction of the natural agents. Plant material can also be infused in base oils used in the formulations for creams, lotions or soaps. In this case the oil needs to be warmed to a temperature not above 60 ºC to enhance the extracting power and increase the potency of the extract. If the plant material is not meant to be included in the finished product a filtering system must be employed after extraction. The filtering medium must be of a mesh size to eliminate the smallest particles from the maceration of the plant material.

Essential oils are often important ingredients in personal care products. These can be obtained from retailers or obtained from in-house processing. Common techniques used to extract essential

oils from plant material include steam distillation and the use of plant presses. Several distillation units that fit small and medium size enterprises are available. See suppliers in **Appendix 5.3**.

Plant presses are less readily available and require the use of more plant material per unit of essential oil expressed. Essential oils can be applied in the pure form or as hydrosols. A hydrosol is the water based essential oil extract obtained directly from steam distillation. Essential oils vary in their viscosity. The lighter oils are more difficult to separate from the water and can therefore be applied directly as the hydrosol.[18] In the organic market hydrosols are made intentionally to be included in skin cleansers, facial toners or body splashes. There is some concern related to the standards for the use of hydrosols as it relates to the concentration of the hydrosol that can be effective in the personal care product.[19] It is felt that some manufacturers can claim the use of a specific hydrosol but the actual concentration embodied in the product can be so low that it may be considered an inactive agent and not contributing to the properties of the product.

3.3 Soap making

Soap is manufactured by the process of saponification of oils or fat with alkali solutions of sodium hydroxide or potassium hydroxide, lye. Soap can be made using hot processing or cold processing. Hot processing involves heating a mixture of the oil or fat with the sodium hydroxide solution until the soap is produced. Cold processing involves no added heat but the heat produced on mixing the sodium hydroxide solution is used to promote the slower process of soap formation. The type of soap formed depends on the oil base and these should be chosen wisely depending on the desired properties of the soap. In addition, the alkali used will determine the texture of the soap.[17]

Dry plant material may be included in the processed soap. This is best added with the oil base whether in free form or as an oil infused plant extract. Water based extracts should be added with the alkali solution. It must be noted that the hot processing method may lead to destruction of the active ingredients in the plant material if added during the heating process. Dry plant material should be added at the beginning of tracing to minimise heat damage.

3.4 Using emulsifying agents in making lotions and creams

Emulsifying agents are essential additives to body care formulations involving the blending of two phases, e.g oil and water phases. The emulsifying agent acts to produce a homogenous product which does not separate on standing. This adds to the quality and appearance of the product. Natural emulsifying agents are available for organic products. See **Table 2** in section 2.2.

Creams and lotions are based on oil/water emulsions. A cream has a higher proportion of oil than water. Emulsifiers are needed to bring the two phases together to guarantee uniformity in product appearance.

4.0 QUALITY ASSURANCE

The adoption of quality assurance practices within a manufacturing plant provides the manufacturer with the ability to track efficiency of the production stages and hence product quality.

4.1 IN-HOUSE QUALITY ASSURANCE

Quality assurance steps that should be implemented in small to medium size operations include:

- Training of staff
- Documentation of formulations
- Standardisation of procedures
- Maintenance of equipment
- Implementation of product quality checks
- Use of product codes for traceability

These steps ensure sustainability of product quality according to the standards built into the production process. There is often some confusion when distinguishing between quality control and quality assurance. According to the **International Organisation for Standardisation**, **ISO (9000)**, ***quality control*** (QC) is defined as 'the operational techniques and activities that are used to fulfill the requirements for quality' and ***quality assurance*** (QA) is defined as 'all those planned and systematic activities implemented to provide adequate confidence that an entity will fulfill requirements for quality'. Put simply this means that quality assurance entails the factory strategy for guaranteeing quality while quality control entails the steps to monitor that quality.

Quality control activity in the manufacturing plant should focus on:

- documentation of the QC processes to ensure continuity
- implementation of strategic checks on the production process from raw material acquisition to packaged product
- detection and mitigation of problems in production to inform the process

Quality control and assurance must be carefully defined for any manufacturing company. However, in the era of organic products the issue is especially pressing. Manufacturing entities must make a decision, before embarking on production, on the categorisation of their organic product with respect to the percentage of organic ingredients or application of organic processing. This is important as it relates to the standards as covered in section 1.2. This decision will then have an impact on the selection of raw materials, methods of processing and ultimately QA/QC in-house strategy. Small to medium size enterprises may need to set goals in terms of the standards to be achieved and work gradually towards attaining those standards.

Quality control testing that should be practiced in the running of the manufacturing plant include

- bacterial testing of equipment, water, raw materials and end product
- verification of the authenticity of plant material

- monitoring of product parameters during processing e.g pH, colour, fragrance, texture, homogeneity
- testing of product for standards e.g pH, shelf life, secure packaging

4.2 Environmentally Friendly Packaging

The underpinning principle of organic production requires that it be extended to the type of packaging used. Materials selected for organic products should be recyclable and biodegradable with minimum impact on the environment and resources. The images below represent examples of environmentally friendly packaging made from natural fibres. Newspaper is also being recycled into environmentally friendly packaging. The pulp is moulded into packaging similar to that used in making egg cartons. Recycled plastics are also considered acceptable as packaging for organic personal care products. Packaging should also be selected to minimise impact of the environment on the product and guarantee that the integrity of the product is maintained during storage, shipping and shelf life.[20] Exposure to light, air and moisture can degrade products and this should be taken into consideration. Opaque or coloured containers are readily available on the market. Recent additions include airless containers which minimise the potential for atmospheric oxidation of active agents in products. A list of suppliers of green packaging is provided in **Appendix 5.3**.

Soap product packaged in moulded pulp packaging (http://www.molded-pulp.com)

ABACA International Natural Reusable Packaging Solutions – made form natural fibres and recycled material (http://www.packageit.net)

Hubschercorp - Industry leader in fabric pouches and bags (http://www.hubschercorp.com)

4.3 Labelling Standards

There is great debate regarding the accurate labelling of organic personal care products. In most instances there is ambiguity between the labelling and actual contents of the product as it relates to the organic nature of the ingredients used and hence the product. Many product lines are being branded as fraudulent because of their claims to the organic classification. Guidelines to labelling of product lines are indicated in section 1.2. In addition to the classification of the product line, in terms of percentage organic nature, organic ingredients should be listed in order of decreasing percentage. See **Appendix 5.2** for guidelines for calculating percentages.

Some organic product manufacturers employ biodegradable inks for labelling in keeping with the underlying environmentally friendly principle. Vegetable based inks are more favoured because they release less volatile organic compounds (VOCs) into the atmosphere than petroleum based inks.

5.0 APPENDIX

5.1 CASE STUDY – THE COAL POT

http://www.coalpot-soaps.com/home

E-mail: thecoalpotsoaps@yahoo.com

Mission Statement

The company's mission, as stated, is to provide the best quality all natural handmade herbal products using locally grown additives and pure essential oils.

The Coal Pot manufacturing plant

The Coal Pot is a cottage industry located in Geneva, Grand Bay, Dominica. The small enterprise has been in operation for eight years. A range of products are manufactured including soaps, creams, massage oils, bath salts and facial products. The company has an underlying organic philosophy and embodies operating procedures that minimise the cottage industry's impact on the environment.

Product Range

- **Soaps –** Eleven varieties including Garden fresh, Oatmeal delight, Lemon sunrise, Ginger bay, Peppermint passion and Sulphur.
- **Creams** – Four varieties, Wild tiger, Luxurious cocoa butter, Silk Caress and Shea angel
- **Massage oils** – Seven varieties including Exotic mint, Sweet basil, Zesty ginger and Juniper rose.
- **Ointments** – Eczelite for eczema and Sulphex for skin conditions including ring worms and liver spots.
- **Bath Salts** – Seven varieties including Floral rose, Lavender field, Mango peach and Vanilla cream.
- **Facial Products –** Five varieties, Patchouli mud mask, Rose mud mask, Feminine touch facial toner, Rugged splash and Bay rum.

- **Raw Materials**

The company sources the raw materials from local farmers and also from external suppliers. Herbs are self grown under organic conditions and non-petroleum based oils are used in production including coconut and castor oils.

Aloes – organically grown for production

Processing

Standard operating procedures are provided for the small staff including dress code, hygiene and cleansing routine. All equipment is sterilised before production and a complete cleaning routine is exercised between batches to avoid cross contamination of product. Extensive chemical processing of the raw materials is avoided. Soaps are made via the cold process method. Herbs are air dried or used in the fresh state.

Dried herbs for processing

Dress code for staff during production of cold process and moulding of soap

Quality Assurance

The Staff of four has been trained by the OECS Bureau of Standards and Invest Dominica. All formulation guidelines are documented in order to maintain continuity in product standard. Soaps are cured for a standard time of two weeks to guarantee the appropriate reduction in alkalinity. Each batch of product is given a batch number for ease of tracing.

Quality Control

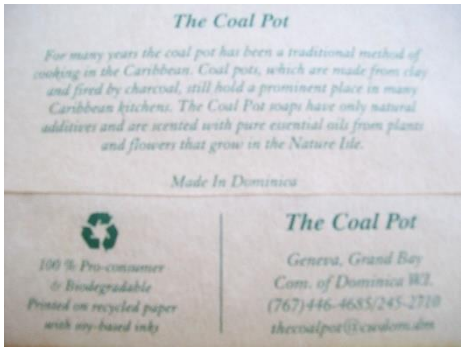
Tests are conducted on essential oils to assess purity. During manufacturing organoleptic properties of products are assessed including, colours, fragrance level and texture.

Packaging

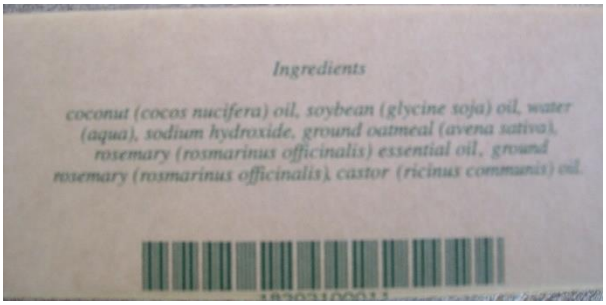
Environmentally friendly packaging is used for the line of soaps. Soap boxes are made of recycled card and paper and sourced from a regional territory, Trinidad.

Labelling

The biodegradable packaging is printed with environmentally friendly soy based ink which releases less volatile organic compounds into the atmosphere. The soaps are labelled as 'All Natural Handmade' instead of being classified according to percentage organic content. The company is working towards attaining this level of classification but at the current status their products are eligible for the 'Made with organic ingredients' labelling. This would require, however, specific listing of the selected organic ingredients. Ingredients are listed with scientific names given for all plant material as an indication of authenticity. Each item is labelled with a bar code and/or batch number. Batch numbers are essential for traceability.



Printing on recycled paper with soy based ink - biodegradable and 100 % pro-consumer



Listing of ingredients with scientific identification of plant species used in production

Coal Pot's Assessment of the Technical Guide

The management of the Coal Pot felt that the information provided in the technical guide is very useful for organic product development. The Director indicated that the contents provided new viewpoints and insights related to management of the manufacturing plant. It was expressed that an extended workshop on the technical guide would prove useful to practitioners in the organic personal care industry or those about to enter the field. The Coal Pot felt that the technical guide is complete in that it offers full guidelines and information for the industry and provides the baseline information for adaptation to individual needs.

5.2 CALCULATING ORGANIC PERCENTAGES

In accordance with standards proposed by the Organic Food Federation, Non-food Certification Company Division (April 2007)

The percentage of all organically produced ingredients in an agricultural product sold, labelled, or represented as "100 percent organic," "organic," or "made with organic [specified ingredients]," or as including organic ingredients shall be calculated by:

– Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product;

– Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation shall be made on the basis of single-strength concentrations of the ingredients and finished product; or

– For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

The percentage of all organically produced ingredients in a product shall be rounded down to the nearest whole number.

5.3 SUPPLIERS

Raw materials

- **Earth Supplies Limited –** Suppliers of certified organic ingredients and alternative agents **http://www.espllc.us**
- **Scienceuticals -** Leading contract and private label manufacturing company, laboratory, and supplier of wholesale beauty products, personal care products **http://www.scienceuticals.com**
- **http://www.soap-making-essentials.com/soap-making-suppliers**
- **http://www.essentialwholesale.com**
- **The Caribbean Herbal Product Catalogue http:// www.caribbeanherbs.org**

Packaging

- **Green packaging http://www.greenpackaginginc.com**
- **Green packaging and custom design packaging http://www.greenpackagingdesign.com**
- **Natural Reusable Packaging Solutions http://www.packageit.net**
- **Moulded pulp packaging made from recycled newspaper print http://www.enviropak.com**
- **Custom packaging http://www.hubschercorp.com**
- **Cardboard custom design boxes http://www.anyboxtoday.com**
- **Gift boxes and custom design boxes http://www.magicpaperbox.com**
- **Biodegradable packaging solutions http://www.bananapackaging.com**
- **Moulded pulp packaging http://www.molded-pulp.com**

Equipment

- **Distillation equipment for essential oil production http://www.essentialoil.com/distiller**
- **Hydraulic press http://www.edenlabs.org/press**
- **Distillation systems http://www.floragenics.com/products**
- **Complete steam distillation unit for essential oils http://www.heartmagic.com/EssentialDistiller**

5.4 QUESTIONNAIRE

A Technical Guide for the Organic Body Care Industry

Assessment Questionnaire

Please respond to the following questions by shading the appropriate circle.

Your participation is appreciated.

1. How would you describe your role in the herbal business/natural products sector?
   - ○ Research
   - ○ Product development
   - ○ Quality assurance
   - ○ Management
   - ○ Production assistant
2. How useful is the information provided in the Technical Guide for the Organic Body Care Industry?
   - ◉ Very useful
   - ○ Somewhat useful
   - ○ Uncertain
   - ○ Minimally useful
   - O Not very useful
3. Would you find this manual useful in the line of work indicated in Q1?
   - ○ Very useful
   - ○ Somewhat useful
   - ○ Uncertain
   - ○ Minimally useful
   - ○ Not useful

4. Has the presentation of the manual contents given you new viewpoints and insights as it relates to managing your manufacturing plant?
   - To a great degree
   - To a moderate degree
   - Somewhat
   - To a minimal degree
   - Hardly at all

5. Would an extended workshop on the contents of the manual be useful?
   - Very useful
   - Somewhat useful
   - Uncertain
   - Minimally useful
   - Not useful

6. What did you find to be most useful in the contents of the manual?

7. What was least useful in the manual?

8. Is there any other material related to the organic products industry that you would like to see in the manual?

5.5 GLOSSARY OF TERMS

Adulterant – an ingredient that is incorrectly substituted for active agent

Alkali – a compound that produces a solution when dissolved in water which can neutralise acids and breakdown fats.

Antioxidant – a compound that acts to hinder or prevent reaction of active agents or tissue with oxygen.

Baking soda – sodium hydrogen carbonate used as a raising agent but also possessing cleansing properties.

Biodegradable – capable of being degraded by natural environmental processes

Esterification – a chemical process for synthesising fragrant compounds called esters by reacting alcohols with organic acids

Fertiliser – an agent that adds nutrients to the soil

Fingerprint – a pattern obtained from the separation of the characteristic complex mixture of natural compounds made by a plant

Hydrolysis – a chemical process involving water as the degrading agent

Hydrosol – an intimate mixture of essential oil and water obtained as a distillate from steam distillation of plant material

Petroleum – based – derived from, or natural substances found in, crude oil

Plant extraction – the process of using a liquid to remove natural agents from plant material by maceration and steeping

Recyclable – capable of degrading and reconstituting into a new product

Saponification – the chemical process of converting a fat or oil into its constituent components with the use of an alkali

Transesterification – the chemical process of exchanging the alcohol present in an ester with a another alcohol

Volatile Organic Compounds (VOCs) – odorous compounds that are released into the atmosphere from petroleum or petroleum-based products

Washing soda – sodium carbonate used as a water softener and cleansing agent

6.0 REFERENCES

1. www.naturalproductsassoc.org
2. High Beam Research: http://www.highbeam.com/doc/1P1-153990990.html
3. Organic Monitor Ltd., January 1, 2008, 170 Pages - Pub ID: OM1806878
4. www.firstresearch.com/Industry-Research/Personal-Care-Products-Manufacturing
5. High Beam Research: http://www.highbeam.com/doc/1G1-86745595.html
6. www.caribbeanherbs.org
7. www.oasisseal.org
8. www.ams.usda.gov/nop
9. www.certechregistration.com
10. www.cosmos-standard.org
11. www.nsf.org
12. Babich H., Babich J. P.; Toxicology Letters 91 (3), pg 189- 196 **(1997)**
13. Patil S.M., Singh P., Maibach H.I.; International Journal of Pharmaceutics, 110 (2), pgs 147-154 **(1994)**
14. Williams R-M; Triclosan a Controversial Antibacterial, Townsend Letter for Doctors and Patients (**May 2006**)
15. www.insidecosmeceuticals.com
16. http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_166.pdf
17. www.soapguild.org
18. www.go2oils.com
19. Tannous P., Juliani R., Wang M, Simon J.; Case Study using Lavandin (*Lavandula* x *intermedia*) - Water balance in Hydrosol Production Via Steam Distillation; NUANPP and ASNAPP Programs, Department of Plant Biology and Plant Pathology, Rutgers **(2004)**
20. www.cpcpkg.com/magazine/03_03_insidedesign.php