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THE ABS CAPACITY DEVELOPMENT INITIATIVE
L'INITIATIVE DE RENFORCEMENT DES CAPACITES POUR L'APA

Schweizerische Eidgenossenschaft
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Federal Department of Economic Affairs,
Education and Research EAER
State Secretariat for Economic Affairs SECO

ABioSA ABS Compliant Biotrade in South(ern) Africa

Product dossier gap analysis study

By: Lisam South Africa in collaboration with the GIZ and SAEOPA

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Summary

The ABioSA programme is funded by the Swiss State Secretariat for Economic Affairs (SECO) and implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) office in South Africa. The programme aims to create a high growth, jobs-rich and innovative bio-trade that complies to the domestic and international ABS regulations. It supports sustainable development goals and contributes to the livelihoods of rural people and the productive use of South(ern) Africa's plant biodiversity. It aims to create permanent and seasonal jobs in bio-trade value chains, while substantially boosting the value generated from bio-trade products from the region.

Lisam South Africa was appointed to conduct a GAP analysis for the ABioSA programme in order to identify regulatory GAPs for 5 essential and 8 seed oils produced for various applications and in particular, used by the Southern African Cosmetic and Personal Product sector to facilitate trade of the oils and value-added products with the European Union and the European Economic Area. The aim of the project was to move Southern African indigenous oil stakeholders towards greater sector compliance with EU cosmetic and chemical regulations to facilitate EU market access. In this study a total of ±58 SME's from South Africa and surrounding SADC countries were invited to participate in the project. After a pre-selection phase 30 SME's were invited to participate in the final phase of the project and were given a RMIF to complete. The RMIF was used to conduct the Gap analysis study. In this study it was found that there were major gaps in REACH/CLP compliance in terms of lack of regulatory compliance documents (SDS, PIF's, COA's etc), analytical data, physicochemical data and toxicological/ecotoxicological data which is imperative for REACH registration and joint REACH registrations. The major gaps identified for cosmetic products were that indications are that at initial formulation stage, most potential exporters had clearly not taken the EU regulatory requirements into account when formulating, selecting raw materials, obtaining all the documentation required from suppliers, even in terms of the basic requirement of ensuring compliance with the Annexures for the Cosmetic Regulation. In particular; PIFs and Cosmetic Product Safety Reports (CPSR) have not been done by SME's for their products. The lack of correct and compliant regulatory compliance documents and information available for the indigenous seed and essential oils will need to be overcome prior to the successful launch of such products into the EU market.

Table of Contents

LIST OF FIGURES

GLOSSARY

ABioSA	ABS Compliant Biotrade in South(ern) Africa
ABS	Access to Benefit Sharing
Additive	A substance that has been intentionally added to stabilise the substance
Article	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition
BABS	Bioprospecting Access and Benefit Sharing
BSE	Bovine Spongiform Encephalopathy
BSOs	Business Support Organisations
CAS	Chemical Abstract Service
Chromatographic fingerprint	Representation of the composition of a substance from the characteristic distribution of constituents in an analytical chromatogram
CI	Colour index
CLP	Classification, labelling and packaging of substances and mixtures Regulation EC 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures
Colorants	means substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants [c]
Component	Substance intentionally added to form a mixture
Cosmetic product	Cosmetic product in terms of EC 1223/2009: Article 2 1(a): means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours and Article 2(2): a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product - Nutro cosmetics are NOT cosmetics - the primary function of the cosmetic must be as per the allowable definition for cosmetics [c]
CPSR	Cosmetic Product Safety Report as required by EC 1223/2009. An assessment report based on exposure and foreseeable use of the cosmetic product in humans, the potential human health effects and whether the cosmetic product can be regarded as safe. A risk-benefit justification cannot justify a risk to human health [c]

CPNP	Cosmetic Product Notification Portal https://ec.europa.eu/growth/sectors/cosmetics/cpnp_en
DEA	Department of Environmental Affairs
Dissolution with water	Only solvent that can be used is water. Any other solvents mixed with water disqualifies the substance as natural occurring
ECHA	European chemicals agency
EC Inventory	Although not legally defined in the REACH Regulation, the EC Inventory is a combination of three independent and legally approved European lists of substances from the previous EU chemicals regulatory frameworks: EINECS, ELINCS and the NLP-list (no-longer polymers). The entries in the EC Inventory consist of a chemical name and a number (EC name and EC number), a CAS number, molecular formula (if available) and description (for certain types of substances)
EC number	The EC number is the numerical identifier for substances in the EC
EFEO	European Federation of Essential Oils
EFFA	The European Flavour Association
End user	means either a consumer or professional using the cosmetic product [c]
EU/EEC	European Union/The European Economic Community
EEA	European Economic Area
End user	means either a consumer or professional using the cosmetic product [c]
Exposure scenario	The set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its lifecycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate
EINECS	European Inventory of Existing Commercial Substances
Essential oil	An essential oil is defined as a volatile part of a natural product, which can be obtained by distillation, steam distillation or expression in the case of citrus fruits. It contains mostly volatile hydrocarbons. Essential oils are derived from various sections of plants. The oil is "essential" in the sense that it carries a distinctive scent, or essence of the plant
Extracted from air by any means	substances which occur naturally in air, extracted by applying any methods and solvents as far as no chemical reaction occurs
Extraction with water	Separation process which is based on the different distribution of a certain constituent or constituents from a material by using water with or without conditioners (flocculants, emulsifiers, etc) that only exploit differences in physical behaviour of the constituents in water without chemical reaction

Flotation	Physical separation process taking place in water or in a liquid such as oil without chemical reaction
GC	Gas chromatography
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
GLP	Good laboratory Practices
GMP	Good Manufacturing Practices
GQSP	Global Quality and Standards Programme
Harmonised standard	means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services on the basis of a request made by the Commission in accordance with Article 6 of that Directive [c]
Heating solely to remove water	Purification or concentration of a substance by removing water by heat while no chemical reaction occurs
HPLC	High Performance Liquid Chromatography
INCI	The International Nomenclature of Cosmetic Ingredients
IFEAT	The International Federation of Essential Oils and Aroma Trades
IFRA	The International Fragrance Association
IPLCs	Indigenous People and Local Communities
IUCLID	International Uniform Chemical Information Database. IUCLID is a database and management system for the administration of data on chemical substances
IUPAC	International Union of Pure and Applied Chemistry
List number	Automatically allocated number assigned by REACH-IT. Applies to all incoming and valid submissions (e.g. pre-registrations, PPORD, inquiries, registrations, classification, and labelling notifications). A list number has no legal relevance and is only used as a technical identifier for managing submissions within ECHA
Making available on the market	means any supply of a cosmetic product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge [c]
Manufacturing	means production or extraction of substances in the natural state
Manufacturer	means any natural or legal person established within the EEA who manufactures a substance within the EEA
Mixture	means a mixture or solution composed of two or more substances [c]
Mono-constituent substances	Substances in which one constituent is present at a concentration of at least 80% (w/w)

Multi-constituent substances	Substances consisting of several main constituents present at concentrations generally above or equal to 10% and below 80% (w/w)
MS	Mass spectrometry
Nanomaterial	means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm [c]
Naturally occurring substances	Plants, Animals, micro-organisms or parts thereof, inorganic material (minerals, ores), crude oil, coal and natural gas as it presents in nature, are excluded from REACH
Naturally occurring substances unprocessed	no treatment at all of the substance takes place
NEMBA	National Environmental Management: Biodiversity Act 10 of 2004
Not chemically modified substance	A substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities
OECD	Organization for Economic Cooperation and development
PBT/vPvB	persistent, bioaccumulative and toxic (PBT)/ very persistent and very bioaccumulative (vPvB)
Phase-in substance	A substance which meets at least one of the following criteria: (a) It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS); (b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this; (c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, by the manufacturer or importer before the entry into force of this Regulation and it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this, including proof that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive
Preservatives	means substances which are exclusively or mainly intended to inhibit the development of microorganisms in the cosmetic product [c]

Processed only by manual, mechanical or gravitational means	Parts of the substance removed by hand or machine (centrifugation), Minerals processed mechanically (grinding, sieving, centrifugation, flotation, etc)
Placing on the market	means the first making available of a cosmetic product on the Community market [c]
QSAR	Quantitative structure-activity relationship
Reasonable Foreseeable use	Normal use, storage and exposure conditions [c]
Registrant	The EEA manufacturer or the EEA importer of a substance or the EEA producer or EEA importer of an article submitting a registration for a substance into the EEA
REACH	Registration, evaluation, authorisation, and restriction of chemicals. *Regulation EC 1907/2006 of the European Parliament and of the Council of 18 December 2006 for the Registration, Evaluation, Authorisation and Restriction of Chemicals*
Registrant's own use	means an industrial or professional use by the registrant
RMIF	Raw Materials Information Form
SAEOPA	Southern African Essential Oil Producers Association
SCCS	Scientific Committee on Consumer Safety (EU)
SECO	Swiss State Secretariat for Economic Affairs
SIEF	Substance Information Exchange Forum
SMEs	Small and Medium Enterprises
SIP	Substance identity profile
Steam distillation	Distillation of naturally occurring substances with water vapour as carrier for the separation of certain constituent(s) without chemical reaction.
Substance	Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition
Substance which occurs in nature	A naturally occurring substance as such, unprocessed or processed only by manual, mechanical gravitational means; by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means
Supplier	means any EEA manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture
SDS	Safety data sheet

SME	means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises
UV-filters	means substances which are exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation [c].
TDS	Technical data sheet
TSE	'Transmissible spongiform encephalopathies (TSEs)' means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation (EC) No 999/2001
UNIDO	United Nations Industrial Development Organisation
Use	means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation
UV/VIS	Ultra violet /visible
UVCB substances	Substances of Unknown or Variable composition, Complex reaction products or Biological materials
Vegetable oil	Vegetable fats and oils are substances that are generally obtained from the seeds of oil seed plants (rape, flax, sunflower etc), although some other parts of the plants may also yield oils. Vegetable oils and fats are mainly composed of triglycerides, which contain a range of fatty acids of different chain lengths; for example, they can be rich in palmitic, oleic or linoleic acid.
w/w	Weight by weight

Definitions were obtained from the following sources:

[a] REACH: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006. Off. J. of the European Union L396/1 of 30-12-2006 as amended by L 136 of 29-5-2007. http://eurlex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf

[b] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)

[c] Cosmetics Regulation (EC) N° 1223/2009

[d] ECHA 2012. Guidance for Annex V Exemptions from the obligation to register November 2012 ed. Finland: European Chemicals Agency

[e] EFEO/IFRA 2015. Guidelines on substance identification and sameness of Natural complex substances (NCS) under REACH and CLP.

1 BACKGROUND

Currently, the presence of South African natural products in international markets remains low. According to the latest essential oils market report presented at the 2019 IFEAT conference some of the main oils being exported from South Africa included eucalyptus smithii oil, tagette oil, tea tree oil, grapefruit oil and orange oil. However, indigenous oils did not even feature on the list in South Africa due to the low volume of indigenous oil products being exported (Ultra International B.V., 2019). Globally the major producers of essential oils are China and India, followed by Indonesia, Sri Lanka, and Vietnam. In Africa, the major producers of essential oil include Morocco, Tunisia, Egypt, and Algeria; the Ivory Coast, South Africa, Ghana, Kenya, Tanzania, Uganda, and Ethiopia play minor roles. In 2017, worldwide essential oil production was estimated at 150,000 tonnes valued at $6B USD(Barbieri and Borsotto, 2018).

The EU is the biggest importer of essential oils, with France, Germany and the UK representing the major importers. In a study by Borsotto *et al*., (2018), it was reported that between 2012 and 2016, essential oil imports grew in the EU considerably with imports reaching 60,000 tonnes in 2016 at a value of €1.2B. The French market may be very appealing to South African oil producers as speciality oils used in the cosmetics sector are sort-after and France acts as a chemical and cosmetic hub for industry across Europe. In contrast, some European countries act mainly as re-exporters and import essential oils for the express purpose of re-selling the oils to countries outside the EU. This may be a useful way of getting a producer's essential oils into the European market. European cosmetic manufacturers are interested in new ingredients and new sources for established ingredients, especially those with an attractive marketing story or traceable, natural and sustainable value chain. South Africa has rich biodiversity, a variety of climates, strong human resources and technological base and can offer these [1]. In recent years the demand for seed oils as ingredients for food, cosmetics and biofuel has increased due to industry's need to find natural alternatives. It has been reported that the global supply of seed oil is obtained only from 15 plant species out of nearly half a million known to man, highlighting the greater potential.High-value vegetable oils are predominantly used in cosmetics as many are rich in fatty acids and have been found to be beneficial to the skin[2]. Countries that import a relatively large portion of high-value vegetable oils include Germany and the UK. When it comes to imports from developing countries, France and Germany purchase the largest proportion of high-value vegetable oils. It is in these European countries that South Africa has great potential in Europe by providing vegetable and essential oils of high quality, regulatory compliant, that are indigenous to the region and may have specific stories around ethnicity, idigenous knowledge or organic production [3,4,5,].

However, South Africa plays a small role, accounting for only 0.3% of EU import volume. In 2014, total supplies to the EU by South Africa amounted to 1,192 tonnes at €4.1 million. Imports fluctuated considerably, with a peak in 2008 and, more recently, in 2014. The Netherlands and France are the leading destinations, each accounting for 40% of EU imports from South Africa. South African suppliers face challenges in entering the European market for cosmetics ingredients. One of the major challenges is market access [1,5]. The market for cosmetic raw materials is predominantly driven by consistency of supply, quality guarantees, regulatory compliance and the assurance that the contents of the oil is safe for human use.

In order to access the European market, there are certain regulations that must be adhered to. The EU has two relevant bodies for chemical legislation: REACH and CLP [1]. Ingredients used in cosmetics are chemical substances are also bound by REACH (Registration Evaluation Authorisation and Restriction of Chemicals) and CLP (Classification, labelling and packaging of substances and mixtures) legislation and must be registered and/or comply accordingly. There are certain exemptions, such as non-chemically modified, natural substances that are not dangerous (as defined by CLP). Moreover, registration is not required for companies that import less than 1 tonne of a chemical substance annually. In all cases, the burden of proof lies with the EU manufacturer/importer that wishes to use this exemption. Common ingredients are often already registered. However, if the importer/manufacturer is not part of an existing registration, they must still register if required. For those that are not registered, it is the responsibility of the EU manufacturer, importer or an Only Representative of a non-EU supplier to comply with requirements. As compiling the dossier for registration is an extensive and expensive procedure, EU partners often expect information from suppliers of the new ingredient. Some buyers are willing to form an alliance with SME exporters seeking market entry assistance for a new ingredient, provided it offers them the possibility of being first to market. Furthermore, the EU has adopted GHS in its own classification, labelling and packaging legislation, CLP. CLP classifies chemicals according to their hazardous properties (physical, human and environmental hazards) and defines the pictograms and other notices which must appear on the label. Importers will require a Safety Data Sheet (SDS) that complies with EU requirements (REACH and CLP) (South Africa currently applies GHS through SANS 10234 and there are distinct differences and requirements between EU and SA GHS requirements), regardless of the volumes exported to an individual importer. The SDS provides information on possible dangerous characteristics of chemical substances. An SDS includes information such as physical data (melting point, boiling point, flash point, etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment and spill-

handling procedures. Derived from the legislation mentioned above, EU buyers need well-structured product and company documentation [1].

For cosmetics, the Cosmetics Regulation (EC) N° 1223/2009 applies to cosmetic products which is the main regulatory framework for finished cosmetic products when placed on the EU market. It strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector, but in order for this to be accomplished the Cosmetics Regulation (EC 1223/2009) sets restrictions and prohibitions on which substances must be restricted (dependant on application) or may not be used at all in cosmetics and which information on physico-chemical, microbiological & toxicological characteristics of ingredients has to be included in the Product Information File (PIF) and its key components, the Cosmetic Product Safety Report. Although applicable to finished products, the PIF requires documentation and data on all the ingredients used in the product in terms of safety (e.g. formulation and the function of each ingredient, physical and chemical characteristics of the raw materials and final cosmetic product, stability, microbiology including challenge testing, raw material component detail including contaminant information, substance toxicity, packaging components and details, label details, declaration on animal testing, GMP declaration, GLP declarations, market and clinical trials (efficacy according to regulation 655/2013), label details, market surveillance reports and any foreseeable adverse effects and precautions.Cosmetic ingredient buyers expect good standards of manufacture for the ingredients, ensuring consistent quality according to specifications as well as product safety.

Most EU buyers expect suppliers to at least follow Hazard Analysis & Critical Control Points (HACCP) principles; at least in terms of processes documented as per Standard Operating Procedures (SOPs). Handling according to Good Manufacturing Practice of the European Federation for Cosmetic Ingredients is also referred to. Furthermore, for farming and wild collection it is common to follow Good Agricultural and Collection Practices (GACP) prior to processing. According to European industry sources, there are large differences in terms of how well South African suppliers comply with documentation and buyer requirements. Companies who work closely with European buyers are more aware of the requirements in terms of processing, sampling, documentation, certifications, labelling, packaging etc. It is noted by buyers that South African suppliers are more aware that they need to conform to international requirements and legislation in order to supply global markets, but that the required documentation is still often lacking[1]. The GIZ in collaboration with Lisam and SAEOPA conducted a “Gap analysis study” with the aim of identifying the regulatory GAPs for a group of selected oils in terms of REACH, CLP and the Cosmetic Regulation EC

1223/2009 in order to facilitate trade of the oils according to European cosmetic and chemical legislative requirements. The six seed/vegetable and five essential oils selected for the gap analysis study (as seen in Table 1), have been identified based on criteria including traditional knowledge, ecological sustainability, market demand, potential for value-adding and job creation, and the participation of Indigenous People and Local Communities (IPLCs) and Small Medium Enterprises (SMEs).

Table 1: High-impact value chains consisting of a cluster of six seed oils and five essential oils

OIL	BOTANICAL NAME	USE
SEED OIL		
Marula oil	*Sclerocarya birrea*	cosmetics
Baobab oil	*Adansonia digitata*	cosmetics, food industry
Mongongo oil	*Schinziophyton rautanenii*	cosmetics and hair products
Kalahari melon oil	*Citrillus lanatus*	cosmetics, food and pharmaceuticals
Sour Plum oil	*Ximenia Americana* *Ximenia var.* *Ximenia caffra/* *Ximenia natalensis*	cosmetics
Mafura oil	*Trichilia emetica*	cosmetics
Mafura butter	*Trichilia emetica*	cosmetics and hair products
ESSENTIAL OIL		
Lippia oil	*Lippia javanica* *Lippia rehmani* *Lippia scaberrima*	insect repellent, tea, pharmaceutical, research for insecticides and fungicides
Rose geranium oil	Cultivated from two or three of the following: *Pelargonium graveolens* *Pelargonium radens* *Pelargonium capitatum* resulting in the hybrid Pelargonium var rose	Perfumery, flavouring, aromatherapy and pharmaceutical industries
Helichrysum oil	*Helichrysum splendidum/* *Helichrysum odoratissimum etc*	Mood enhancemant plant and perfumery
Buchu oil	*Agathosma betulina* *Agathosma crenulata*	Flavouring, fragrance and pharmaceutical
Cape camomile oil	*Eriocephalus species* *Eriocephalus punctulatus* *Eriocephalus africanus* *Eriocephalus comosum* *Eriocephalus racemosus*	Perfumery, flavoruing, aromatherapy and pharmaceutical industries

2 INTRODUCTION

2.1 REACH requirements

REACH Regulation concerns the **R**egistration, **e**valuation, **a**uthorisation and restriction of **ch**emicals EC1907/2006 (or "substances") and explicitly references the "Sustainable Development Implementation plan" (Johannesburg World summit 2002) where it was agreed that by 2020, chemicals would be used in ways that lead to the minimization of significant adverse effects on human health and the environment. It was also agreed that GHS would be implemented globally by 2008. The REACH regulation was adopted in June 2007 and because REACH is a regulation and not a directive, it applies directly to the European economic area (EEA), that is, all EU member states, including Iceland, Liechtenstein and Norway. The main aims of REACH are:

1) Protection of human health;
2) Protection of the environment;
3) Reduce the number of tests conducted on animals;
4) while still enhancing the competitiveness of the EU chemical industry;

CLP [Classification, Labelling and Packaging of substances and mixtures] (EC 1272/2008) is also legally binding across the Member States and is directly applicable to all industrial sectors. CLP is based on the United Nations' Globally Harmonised System (GHS). Its purpose is to ensure:

1) a high level of protection of human health
2) protection of the environment
3) Free movement of substances, mixtures and articles

- The obligation to meet the requirements for both EU regulations REACH and CLP, lies with the importers established in the European Union, or for REACH obligations, with the only representative of a non-EU manufacturer established in the European Union. The Only Representative (OR) is:
- A natural person or legal entity established physically in the EEA
- Equipped with sufficient knowledge in the practical handling of the substances and information related to them
- Appointed by a mutual agreement with a manufacturer, formulator or article producer, established outside the EEA
- Responsible for complying with the legal requirements for importers under REACH

The non-EU manufacturer has an obligation to confirming the appointment of their only representative (OR) in writing, as the OR must have this letter available in the event of an inspection by the relevant Member State's enforcement authority. Some of the main responsibilities of the OR are to:

- submit an inquiry for a substance for registration;
- submission of a registration dossier for the substance imported into the EU to the European Chemicals Agency (ECHA)

- keep the information available in the dossier updated;
- provide information to the importer regarding the hazards of the chemical,
- keep information on the EEA supply chain
- track volumes imported
- provide information to the Authorities as and when required to do so

It is therefore important to appoint an OR that is knowledgeable about the product you produce. The non-EEA manufacturer must provide the ORs details to the EEA importer/s

2.2 Substances under REACH

REACH registration applies to substances. REACH by article 3 and CLP by article 2 defines a substance as "*a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition*". This term refers to both substances obtained by a manufacturing process and in their natural state.

For both REACH and CLP purposes a substance may contain:

- One or more constituents: those are constituents that make up the majority of the substance and contribute to the naming of the substance and its identification
- Impurities: these include accidental constituents arising from the manufacturing process or starting materials
- Additives: all the constituents used to stabilise the substance and only for this purpose

REACH applies to all individual chemical substances on their own, in mixtures or in articles. A mixture means "*a mixture or solution composed of two or more substances".* When attempting to identify a substance under REACH and CLP, one basic rule should be followed which is to define as far as possible by its chemical composition (the content of each constituent, the main impurities and any additives) and its chemical identity (name, numerical identifiers, molecular information)(ECHA, 2017).

The ECHA SID guidance divides substances into two groups:

1) **Well defined substances**: Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters

listed in REACH Annex VI section 2 which requires to provide information that is "sufficient to enable each substance to be identified".

Below is a list of information that must be submitted:

- The name or other identifier of the substance
- Name(s) in the IUPAC nomenclature or other international chemical name(s)
- Other names (usual name, trade name, abbreviations)
- EINECS or ELINCS number (if available and appropriate)
- CAS name and CAS number (if available)
- Other identity code (if available)

Well defined substances can be further divided into two groups:

- Mono-constituent substances: are substances that contain one constituent at a concentration of at least 80% (w/w)
- Multi-constituent substances: are substances that consist of several major constituents at concentrations generally above or equal to 10% and below 80% (w/w)

2) UVCB substances

These are substances of **U**nknown or **V**ariable composition, **C**omplex reaction products or **B**iological materials. These substances cannot be sufficiently identified by the above parameters (see example of a UVCB substance below).

Figure 1.1: Example of a UVCB substance Botanical name: *Helichrysum odaratissimum* essential oil under REACH (pictures courtesy of Highland essential oils*)*

Borderline cases between the above categories are acknowledged in the ECHA SID Guidance and it states that it is the responsibility of the registrant to identify a substance in the most appropriate way.

The **registration obligations under REACH** are also dependant on the point in time when the substance was manufactured, imported or placed on the EU market for the first time. Thus, substances can be distinguished into phase-in and non-phase-in substances. A substance has phase-in status if it meets the following criteria:

1) the substance is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)
2) the substance was manufactured in the EU at least once between 1992 and 1 June 2007 but not placed on the market by the manufacturer or importer
3) the substance was placed on the market before June 2007 and was considered as having been notified under the previous legislation (Directive 67/548/EEC), but does not meet the definition of a polymer as set out in the REACH Regulation ("no-longer-polymer").

. In contrast a substance has Non-phase-in status when:

1) A substance that does not fulfil any of the criteria of a phase-in substance
2) A substance requiring registration which does not benefit from the transitional regime provided for phase-in substances under REACH

Non-phase-in substances must be registered immediately once the yearly volume imported reaches one tonne.

The difference between phase-in and non-phase-in substances is about to become obsolete due to the recent adoption of an implementation regulation. On the 10th of October 2019, the commission set the 31st of December 2019 as a cut-off date after which certain conditions under phase-in substances will no longer be accepted. After the cut- off date:

1) Companies will need to calculate their manufactured or imported volume per calendar year for their individual substances
2) Companies that are planning on registering a substance will need to submit and inquiry to ECHA to get information on other registrants in order to begin data-sharing negotiations, and will no longer be permitted to rely on their pre-registrations
3) If there are data-sharing disputes within a substance information exchange forum (SIEF), data sharing disputes can be submitted according to Article 30(3) of REACH but following this date, all data will be handled according to Article 27

4) Some phase-in substances will continue to benefit from less stringent information requirements but only if they are registered at the lowest tonnage band, between 1 and 10 tonnes per annum and also do not meet the criteria listed in Annex III to REACH. https://echa.europa.eu/-/rules-for-registration-of-phase-in-substances-clarified

2.3 REACH Exemptions and tonnage band

Before embarking on REACH registration, it is important to identify if a product needs to be registered under REACH. For instance, if a substance is manufactured or imported in the EU in amounts less than one tonne per annum, the substance does not need to be registered. However, if this threshold is reached or exceeded the tonnage band will determine the registration fee as well as the informaiton needed to complete a REACH registration. Under REACH the total volume of a substance manufactured or imported must be determined in tonnes per calendar year. It must be noted that the total volume per calendar year takes into account the combined volume of a substance on its own, in a mixture and in an article to be released.

There are four tonnage bands for standard registrations:

1-10 tonnes a year,
10-100 tonnes a year,
100-1 000 tonnes a year, and
more than 1 000 tonnes a year.

Note:

(If your volume reaches the lower limit of a tonnage band, this will be your tonnage band for registration)(ECHA, 2018).

SME's should be made aware that an exemption from REACH registration does not equal an exemption from REACH regulation and are required to still keep a dossier proving their exemption. Before embarking of the REACH registration process, it is important for SME's to determine if their products fall under one of the following categories as outlined below to determiine if their products may be exempted from all or certain REACH obligations.

1) Substances subject to customs supervision in the European Union
2) Substances used in medicinal products
3) Substances used in food and feeding stuffs, including use as a food additive in food stuffs
4) Substances listed in Annex IV

5) Substances listed in Annex V (see exemption of vegetable oils below in section 2.4)
6) Substances re-imported into the EU
7) Substances in plant protection and biocidal products

2.4 Exemption of Vegetable oils from REACH

Vegetable fats and oils are substances that are generally obtained from the seeds of oil seed plants (rape, flax, sunflower etc.), although some other parts of the plants may also yield oils. Vegetable oils and fats are mainly composed of triglycerides, which contain a range of fatty acids of different chain lengths; for example they can be rich in palmitic, oleic or linoleic acid (ECHA, 2012).

Article 2(7)(b) of the Regulation (EC) No 1907/2006 (REACH) and its amendment by Regulation (EC) No 987/2008 of 8 October 2008 sets out criteria for exempting substances covered by Annex V from the registration, downstream user and evaluation requirements.

"*substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC13 with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f):*

Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts; glycerol".

In short, this exemption from REACH applies directly to vegetable oils and fats. However, the following must be considered:

- In this exemption 'obtained from natural sources' means that the original source must be a natural material (plants);
- "Not chemically modified" means that the substances covered by this exemption, once obtained from a natural source, are not further chemically modified. However, If the oil
  - is classified as hazardous according to CLP then it **MUST be registered** (if the oil is only classified as Flammable 3, Skin Irrt 2 and Eye Irrt 2 then it is exempt).
  - meets criteria for PBTs and vPvBs then it must be registered;

-substance is of high concern or on the candidate lists then it must be registered.

- "fatty acids from **C6 to C24**", and their potassium, sodium, calcium and magnesium salts' are listed in Annex V- This means that the chemical structure of the 'fatty acids from C6 to C24, and their potassium, sodium, calcium and magnesium salts' substance cannot be changed. It is commonly known that oils and fats derived from natural sources e.g. plants are composed mainly of triglycerides (up 97% triglyceride (i.e., triesters of glycerol with fatty acids); up to 3 % diglycerides and up to 1 % monoglycerides). The triglycerides of naturally occurring fats and oils contain saturated and unsaturated fatty acids;
- The following exemption mentioned above does not apply to synthetic materials
- Hydrogenated fats and hydrogenated oils are not considered as vegetable or animal fats and oils but substances, which have undergone a chemical modification of the original fats and oils and are therefore not covered by this entry;

According to the ECHA Annex V guidance on exemptions from the obligations to register, it clearly outlines that in all cases, the burden of proof rests with the manufacturer/importer that wishes to use this exemption for his substance. Therefore, the absence of information on the properties of a substance cannot justify to the absence of hazardous properties (ECHA, 2012).

2.5 Natural complex substances under REACH

Natural Complex Substances (NCS) of botanical origin are a very diverse family of substances that are notably used as ingredients in fragrance formulations and [directly or indirectly] added to cosmetic and other consumer products. The identification and characterization of NCSs is described in the Guidance for the Identification and Naming of Substances under REACH (see http://guidance.echa.europa.eu/guidance_en.htm). The most common NCS's are **essential oils** and volatile solvent extracts that are utilised mainly by the fragrance industry. Essential oils also known as volatile oils/ aetherolea /ethereal oils, are derived from leaves, stems, flowers, bark, roots, or other parts of the plant. Essential oil is obtained from various herbs and plants, such as orange, eucalyptus, corn mint, peppermint, citronella, lemon, lime, clover leaf and spearmint by steam distillation of plants, cold pressing of fruit peels (citrus) and by dry distillation of certain plant materials.

Other NCSs are also derived from botanical sources by processes such as deterpenation, rectification, folding and the raw extracts extracted from plants via volatile solvent extraction. When the starting material is fresh plant material the extract obtained is referred to as a concrete. However, when an extract is obtained from starting material that is a dried plant or

an exudate, then the extract is referred to as a resinoid. Concretes and resinoids are both treated with ethanol to remove vegetable waxes which results in what is referred to as the absolute. Extracts can also be derived using super-critical CO_2. NCSs are commonly used in everyday consumer products such as fragrance materials for cosmetics, cleaners and household products as well as in foods. Generally, the EU imports NCSs that originate from tropical or other regions.

The most common NCSs are:

1) Essential oils (as mentioned)
2) Concretes and absolutes
3) Oleoresins and resinoids
4) CO_2 extracts
5) Infusions and alcoholic extracts

NCSs have distinguishing characteristics that make them a unique class of UVCBs with regards REACH:

a) NCSs are botanical products and thus have variations in their chemical composition due to:
- the region of growth
- the annual variations in climate within a region
- the variations that exist naturally between species of the same family
- the part of the plant
- the use of different methodologies for processing: drying, cutting, expression, extraction, distillation, fractionation, concentration, precipitation, etc;

b) Their composition varies extensively in complexity ranging from the simple (a few constituents) to highly complex (over 100 constituents).
c) The bulk of NCSs have been used for centuries as ingredients of flavours and of fragrances
d) A considerable number of constituents identified in NCSs have similar uses and will be registered for REACH as substances used in fragrances generally at higher volumes than the NCSs from which they are derived.
e) NCSs are made up of a combination of major and minor constituents which are inherent to the NCS and is essential for its sensory properties. Therefore, minor constituents are not regarded as "impurities".

f) Exemptions from the obligation to register of Annex V, point 8 and 9 (revision October 8, 2008) is not applicable to most NCSs because they are processed and even though they may contain well defined constituents, they are often classified as hazardous.

2.5.1 Substance identification of NCSs

Historically NCSs have been listed on EINECS under a generic heading and considered as a UVCB. Currently, the ECHA SID Guidance considers that NCS fit the sub-category of "UVCB sub-type 3", which are named and identified by their botanical source and process. However, some NCSs can also be characterised as "well defined substances" and may be registered as mono-constituent or multi-constituent substances depending upon their composition.
In principle, the main parameters to characterise NCSs are:

1) the botanical source
2) the manufacturing process
3) the chemical composition

Of the parameters listed, the chemical composition is the most important as it is used to determine if an NCS qualifies as a UVCB and / or as a mono- or multi-constituent substance. Composition is crucial as it also has bearing on the hazard identification and classification of the substance under CLP.

2.5.2 Registration of NCSs

The first step to registering an NCS under REACH, is characterising the NCS first as a UVCB/mono-constituent/ multi-constituent substance as this will affect the:

1) “qualities” of NCS that can be registered in a single registration dossier
2) the data that is required for such registration

The conditions under which NCSs can be registered together in a single dossier can be found in the question and answer section of the EFEO/IFRA Guidelines on substance identification and sameness of natural complex substances (NCS) under REACH and CLP.

REACH registration separates NCS’s into two types:
Type 1: “Well-defined NCSs” which are NCSs which are analytically characterised to at least 90%.
Type 2: “Incompletely defined NCSs” are NCSs which are analytically characterised for less than 90%.

A REACH compliant registration for NCS of type 1 or 2 requires the following:

- Data from tests conducted with a representative quality of the NCS
- Data directly obtained on the identified constituents
- Data indirectly obtained by read-across from data on substances related to the constituents and other non-test methods

Industry Guidance on the data requirements and methods of data collection for registration of NCS used as fragrance ingredients can be found in the "Protocol for REACH Registration of Natural Complex Substances" (revision 2, January 7, 2009).

2.5.3 **Strategy for Data Collection**

In section 5 of the "Protocol for REACH Registration of Natural Complex Substances" (revision 2, January 7, 2009) a strategy for data collection is included. It presents a strategy for data gathering, which NCS-registrants can optionally use.

In the strategy for data collection it states that for a registration all the endpoints should be addressed by:

- Data for the NCS
- Data for the constituents
- Data on the related NCSs or constituents justified by read-across
- Justifications for the applied specific rules for adaptation of the standard requirements
- Justifications for applied general rules for adaptation of the standard testing regime

The strategy is based on the concept of double grouping:

- the identified constituents of the NCS are grouped by the characteristics of their chemical structure (e.g. C10-C15 aliphatic alcohols, aldehydes and related esters or cinnamate structures)
- the NCSs are grouped based on the dominating chemical group(s) of their constituents

Double grouping optimizes the possibilities for read-across of data on constituents and NCSs. The Road Map for registration of Natural complex substances by EFEO of November 2008 can be referenced for further details on the grouping of the NCSs.

2.5.4 **Naming of NCSs**

The characterisation of an NCS as a UVCB/mono-constituent/ multi-constituent substance influences the naming of the NCS for REACH registration.
The information that needs to be submitted include:

- The name or other identifier of the substance
- Name(s) in the IUPAC nomenclature or other international chemical name(s)
- Other names (usual name, trade name, abbreviations)
- EINECS or ELINCS number (if available and appropriate)
- CAS name and CAS number (if available)
- Other identity code (if available)

The following names should be used for registration purposes:
- Mono-constituent substance: The name of the main constituent, present at or above 80%
- Multi-constituent substance: The words "Reaction mass of ..." followed by the chemical names of the constituents present at or above 10%
- UVCB: The name should use a combination of the source and the process, starting with the source

A summary to determine if an NCS should be registered and the correct EINECS number to consider is provided in Figure 2 below.

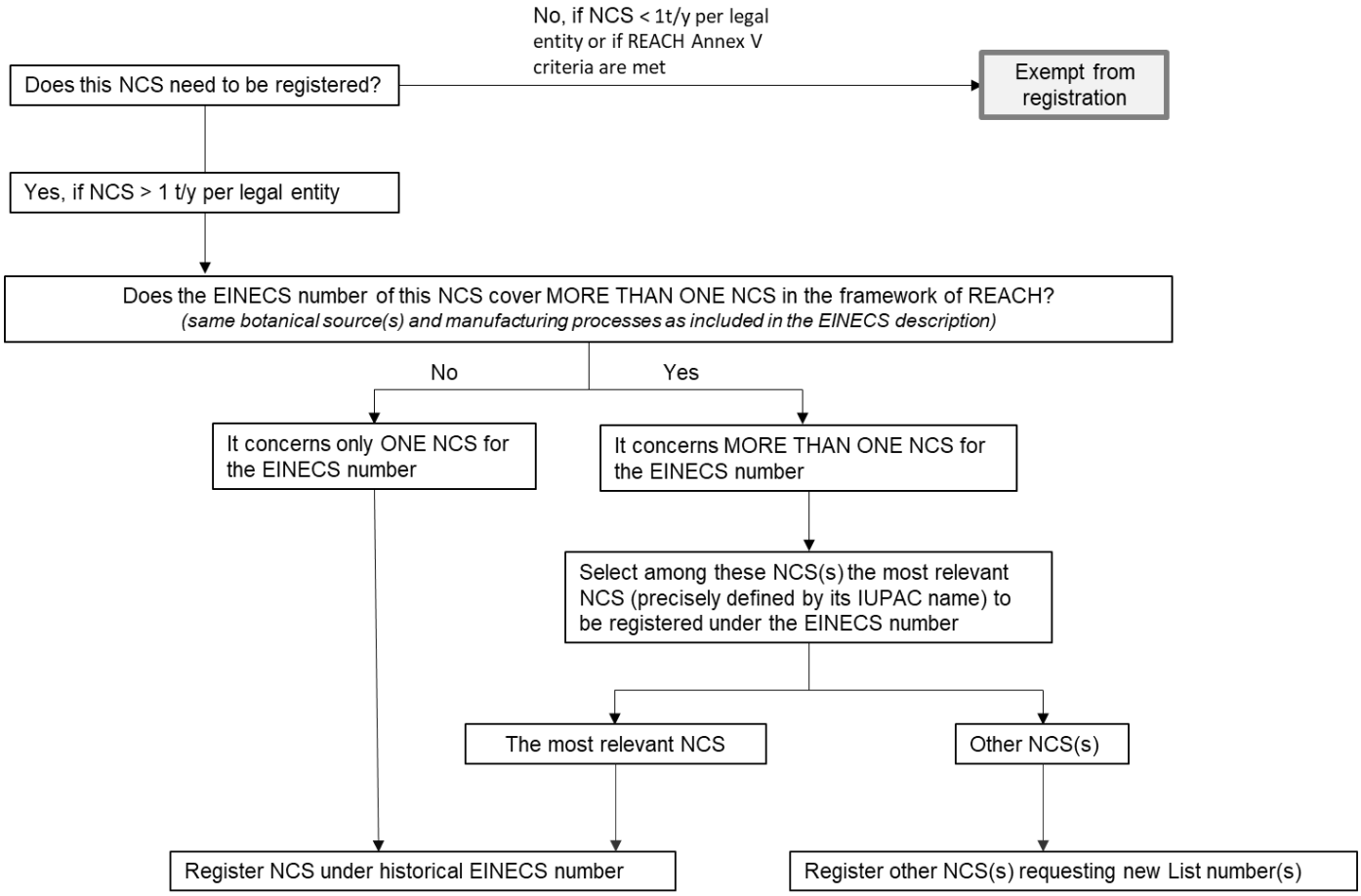


Figure 1.2: Decision tree for registration of NCS and EINECS numbers (re-drawn from EFEO/IFRA Guidelines on substance identification and sameness of natural complex substances (NCS) under REACH and CLP)

2.6 Essential oils and how lavender farms are affected by REACH- a case study

The challenges and concerns faced by indigenous oil stakeholders to meet EU REACH requirements is not unique to South Africa. In a fairly recent 2013 case study in France(E.F.E.O, 2016), producers of lavender ran a very successful campaign against the requirement to register essential oils in the framework of the European chemical regulations, REACH and CLP. French farmers were initially incensed by the regulations as they believed their traditional, artisanal sector was being unfairly categorised by a complex EU law designed for the multi-national chemicals industry. Escalation of the campaign forced the EU commission to call on IFRA to facilitate a dialogue between the 'supply' chain (mainly farmers and essential oil producers) and EU institutions in order to facilitate a resolution. From 2014, IFRA (the International Fragrance Industry Association) and EFEO (the European Federation of Essential Oils) engaged in a dialogue through the entire value chain and EU institutions. The essential oil sector was clear that they wanted to comply but wanted the French government to understand that nature is complex and the substances the farmers produced did not fit into the REACH requirements. Over two years a series of five round-tables and workshops were held to identify the needs, develop roadmaps of actions and deliver on sector-specific guidelines. It was through this process that guidelines on the identification of essential oils, as **natural complex substances (NCS)** was developed. It also yielded agreed guidelines for the environmental assessment of essential oils. These guidelines and protocols are available on the ECHA website and the websites of the respective associations in 8 different languages. They have been designed specifically to aid small and medium sized enterprises in the essential oils sector to comply with REACH registration.

Figure 1.3 : Protest signs of French Lavender farmers against the requirement to register essential oils under REACH and CLP regulations(E.F.E.O, 2016)

2.7 Brief Regulatory comparison of two developing countries that are major exporters of essential oils into Europe

2.7.1 Brazil

- In Brazil the Health Regulatory Agency (ANVISA) is an autarchy linked to the Ministry of Health, part of the Brazilian National Health system (SUS) acts as the coordinator of the Brazilian Health Regulatory System (SNVS), which covers the entire national territory. The role of Anvisa is to promote the protection of the population's health by implementing sanitary control of the production, marketing and use of products and services subject to:

- Health regulation
- Processes
- Ingredients and technologies
- Control in ports
- Control in airports
- Control at borders

- Before placing a product on the market in Brazil, "Pre-market approval" is required.
- The pre-market approval is the legal act that recognizes the suitability of a product to the Brazilian sanitary regulation, and it is issued by ANIVISA

- Pre-market approval is a control measure only for the categories of products that are considered to be of greatest health risk. It should be noted that some categories of products subject to health regulation are exempt from the need of obtaining pre-market approvals, because they represent a lower health risk, as established in Article 41 of Law 9.882/1999.
- Pre-market approvals are published in the Official Gazette
- Once pre-market approval is published in the official gazette for a product, this publication can be used as proof from ANVISA, as an exemption from having to submit further documentation such as certificates and declarations and the product can be freely marketed in the Brazilian territory.
- Like the REACH regulation in the EU, in Brazil foreign companies cannot make administrative arrangements for issuing of pre-market approvals directly from ANIVISA. Foreign companies must have partner companies legally constituted in Brazil that will be legally responsible for the products imported to and distributed in the Brazilian territory, very similar to the role of the Only representative in the EU.
- In 2015, the controls performed by ANVISA for pharmaceutical ingredients were recognised as equivalent to those of the European community and Brazil became a member of the International Cooperation on Cosmetics Regulation (ICCR)

http://portal.anvisa.gov.br/english

http://portal.anvisa.gov.br/regulation

2.7.2 India

- The regulations and legislations for chemicals management in India are not at the level of European regulations such as REACH
- In terms of REACH, companies exporting to Europe do meet European requirements but do not have similar domestic regulations or even equivalents to REACH. Compliance to REACH, RoHS (Regulation of Hazardous substances) and CLP, is mainly for Exports especially Europe
- Both the formal and informal chemical industry is very strong in India, which drives the market. To some extent the fragmented nature of the Chemical industry in India (as shown below in Figure 1.4), is what also influences the legislation in their favour
- In India the chemicals industry is divided into:

Figure 1.4: India's fragmented Chemical Industry (redrawn from…..)

- The Federation of Finnish Technology Industries warned Finish companies that efforts by central government to implement and enforce regulations could be met with resistance from industry bodies, making the process slow

2.7.3 A comparison of Brazil's and India's international regulatory position

- Brazil and India are major producers and suppliers of essential oils into Europe. Brazil is a major exporter of Orange oil and it is estimated that in 2018/2019 494 million boxes (1 box= 40.8 kg) of oranges will be processed for the production of orange oil. India are major producers of peppermint oil and spearmint oil. India holds the second position (after the USA) among the *M. piperita* mint producing countries with an annual production of 500-750 MT. There is a high demand for peppermint oil from Europe, China and other key markets (Ultra International B.V., 2019). However, both countries have two different international regulatory positions (see Table 2 below). As described above Brazil, has a centralised body (ANVISA) which since 2010 has

complied with all the necessary criteria to be recognised as a Regulatory Authority of Regional Reference (NRArr) by the Pan American Health Organization (PAHO). Brazil's regulations are in line with those set out by Europe. In 2015, controls performed by ANVISA for pharmaceutical ingredients were recognised as equivalent to those of the European community and Brazil became a member of the International Cooperation on Cosmetics Regulation (ICCR). In contrast, India does not participate in most international treaties and takes the stance that developing countries should be treated differently. Although India does not have a centralised body like ANVISA in Brazil, India values the export market and the Ministry of Commerce supports the REACH-compliance needs of Indian Chemical companies through CHEMEXCIL REACH-Help desk. Chemexcil is Basic Chemicals, Pharmaceuticals & Cosmetics Export Promotion Council. The Confederation of Indian Industry (CII) along with SSS Europe also provides REACH Support through their Help desk, for Indian companies

Table 2: Summary of Brazil and India's International position

Brazil	India
• 2016: Became a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) • 2015: The controls performed by ANVISA for pharmaceutical ingredients are recognised as equivalent to those of the European community. Brazil became a member of the International Cooperation on Cosmetics Regulation (ICCR) • 2012: Co-founds the International Medical Device Regulators Forum (IMDRF) • 2010: Brazil complied with all the necessary criteria to be recognised as a Regulatory Authority of Regional Reference (NRArr) by the Pan American Health Organization (PAHO)	• India is reluctant to participant in most international treaties • In international forums India is of the firm belief that there is no such thing as a "one size fits all policy is not fair", and developing countries should be treated differently • Locally India's chemical industry operates outside of global standards • There is no centralised REACH body to monitor REACH preparedness, instead have many ministries such as Ministries of Chemicals and Fertilizers, Ministry of Commerce and Ministry of Environment & Forests issues guidelines related to environment, etc • Ministry of Commerce supports the REACH-compliance needs of Indian Chemical companies through CHEMEXCIL REACH-Help desk. Chemexcil is Basic Chemicals,

	Pharmaceuticals & Cosmetics Export Promotion Council • Confederation of Indian Industry (CII) along with SSS Europe also provides REACH Support through their Help desk, for Indian companies

2.8 CLP requirements

2.8.1 Definition of CLP for the EU

- Regulatory reference for the EU: EC 1272/2008
- CLP stands for **C**lassification, **L**abelling and **P**ackaging of substances and mixtures
- It is based on the United Nations' Globally Harmonised System (GHS).
- It requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemical products appropriately before placing them on the market.

2.8.2 Obligations under the CLP Regulation for non-EU manufacturers

- The obligation to ensure that a product is classified, labelled and packaged in accordance with the CLP Regulation lies with the EU-importer
- However, the non-EU manufacturer of a substance or a mixture should cooperate with their importer to check the relevant requirements regarding the packaging and labelling of their product
- They should also cooperate to ensure **proper hazard classification of the product**
- One of the main aims of CLP is to determine whether a substance or mixture displays properties that lead to a hazardous classification

2.8.3 Harmonised classification and labelling

When a substance /chemical classifies as hazardous under CLP, the hazards are identified by assigning a hazard class or category

The hazard classes in CLP cover:

1. Physical
2. Health
3. Environmental
4. And additional hazards

Once a substance or mixture is classified, the identified hazards must be communicated to other actors in the supply chain, including consumers through a Safety Data Sheet and GHS label. Hazard labelling allows the hazard classification, with labels and safety data sheets, to be communicated to the user of a substance or mixture, to alert them about the presence of a hazard and the need to manage the associated risks.Once a substance or mixture is classified, the identified hazards must be communicated to other actors in the supply chain, including consumers.

Hazard labelling allows the hazard classification, with labels and safety data sheets, to be communicated to the user of a substance or mixture, to alert them about the presence of a hazard and the need to manage the associated risks.

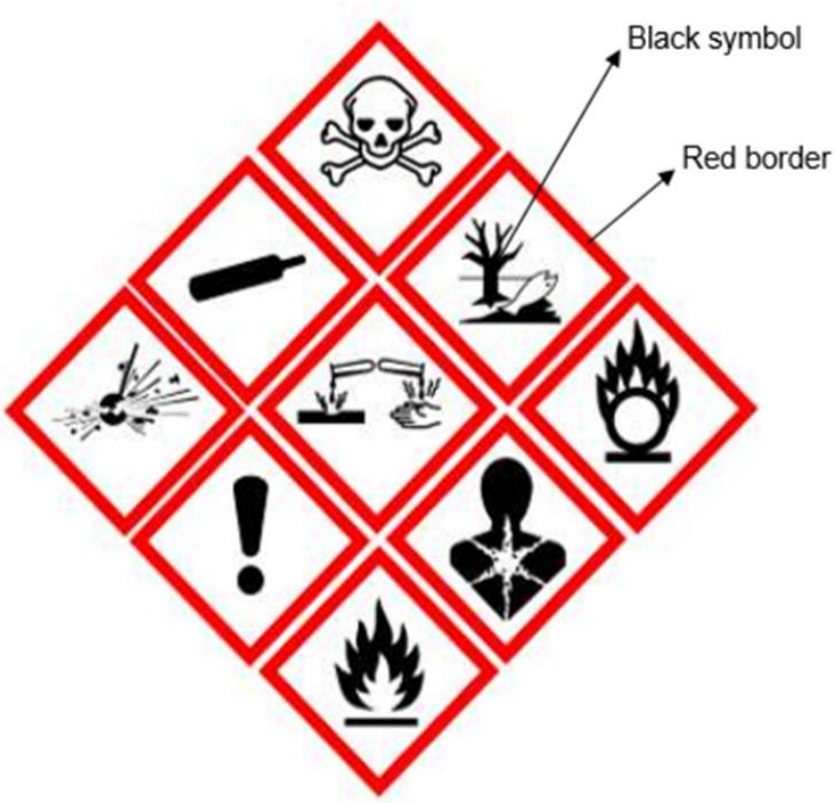


Figure 1.5 Examples of GHS pictograms containing a red border and black symbol

2.8 CHECKLIST of requirements and INTRODUCTION TO Product Information File (PIF) and Cosmetic Safety Report (CPSR) for the European Union (EU)

2.8.1 Definition of a Cosmetic Product for the EU:

- Regulatory Reference for Cosmetics in the EU: EC 1223/2009
- Definition of a cosmetic: Article 2 1(a): means “any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly for:
    - Cleaning them
    - perfuming them,
    - changing their appearance,
    - protecting them,
    - keeping them in good condition
    - correcting body odours
- a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product
- Nutro cosmetics are NOT cosmetics - the primary function of the cosmetic must be as per the allowable definition for cosmetics
- Biocidal Products are not cosmetics
- Cosmetics cannot take the form or shape of a toy

2.8.2 DEFINTION of RESPONSIBLE PERSON (RP) in the EU:

- The Responsible Person (RP) is the LEGALLY responsible entity in the EU for the SAFETY and COMPLIANCE of the cosmetic product;
- The responsibility of the RP is to ensure that a cosmetic product that is placed on the EU market is safe under normal, foreseeable use;
- Each cosmetic product sold or distributed in the EU must be linked to an RP;
- The RP must be a natural or legal person within the EU community;
- The RP details must appear on the label of the cosmetic product;
- Consumers may request certain information on the product from the RP;
- The RP is responsible for market surveillance and all serious undesirable effects (SUEs) must be notified to the authorities by the RP;
- Default RP is either:
    - EU Manufacturer
    - EU Importer

    - Distributor if product is changed in any way e.g. re-packed
- Alternatively, a company selling cosmetics in the EU may legally appoint an INDEPENDENT RP;
- The RP must cooperate wit the authorities in the EU on request;
- The responsible person must ensure that a cosmetic product has undergone a safety assessment as per the regulatory and technical guidelines set by the EU prior to the cosmetic product being placed on the market;
- The RP must keep the product information file up-to-date and must ensure that it is available to the Authorities on request;

2.8.3 INFORMATION required for the PIF AND CPSR

1) GENERAL INFORMATION

a) Details of Brand owner (Name, address, contact details)
b) Details of EU Importer (Name, address, contact details)
c) Details of EU distributor or re-packer (Name, address, contact details)
d) Details of Original Manufacturer (Name, address, contact details)
e) Details of Responsible Person in the EU (Name, address, contact details)
f) Countries that product will be sold in the EU
g) Details of Safety Assessor for the EU- qualified in terms of Cosmetic Safety requirements for the EU (Qualifications to be provided). Certain countries have additional regulated requirements for the safety assessor e.g. France

2) COSMETIC PRODUCT INGREDIENTS/RAW MATERIAL INFORMATION -PHYSICAL AND CHEMICAL IDENTITY OF ALL COMPONENTS IN A COSMETICS PRODUCT:

a) The identity of all components/substances of all the raw materials down to CAS number level/ International Nomenclature of Cosmetic Ingredients (INCI) name or Common Ingredient Nomenclature (CIN) name and the EC number (see Appendix 2 for more details) should be provided. This must include isomer details.
b) Frame formulation (% of each raw material and the intended use in the formulation e.g. preservative, humectant, perfuming, solvent, bulking, viscosity control, pH buffering etc) etc
c) Exact % of each chemical in the cosmetic product (Formulation) including preservatives, additives and impurities (e.g. pesticides, heavy metals).
d) Molecular weight of each substance (to be supplied by supplier if the chemical component is confidential, otherwise this information is readily available for common chemicals used in cosmetics).

e) Physical form of each substance forming part of a raw material

f) For components that cannot be identified, enough information regarding the process used to obtain the substance in order to determine the characteristics of the chemical substance.

g) Stability of raw material and preservative used including storage stability

h) Physical/Chemical information where applicable or available of raw materials/individual components:

   i) Solubility
   ii) Hydrophilic/Hydrophobic properties
   iii) Log P_{ow} defined by pH
   iv) Boiling Point, Flash point
   v) pH
   vi) density
   vii) Gases: Auto ignition temperature
   viii) If there is a UV absorbing component: UV spectrum
   ix) If Nano material used i.e. >50% of particle distribution <100 um, then additional information will be required. This will be advised on request.
   x) Proprietary chemicals- information to be supplied will be advised on request

i) Documentation required to support the composition, physical and chemical data of the components/raw materials of the cosmetic product:

   i) Supplier SDS's
   ii) Technical Data sheets or Certificates of Analyses:
      (1) GLP analyses – reference to batch certificate of analyses must made on the COA and batch reference/date.
      (2) A reference to the test procedure used, including the acceptance criteria/standards (limits).
      (3) The results of all tests performed on the batch for which the certificate is issued (in numerical form, where applicable) and a comparison with the established acceptance criteria (limits/standards), including information on appearance, identity (IR, NMR, MS), purity, solubility, impurities (% content), heavy metals. The date(s) on which the test(s) was (were) performed. The signature of the head of the laboratory or an authorized person. A declaration that the lab is GLP accredited or applies GLP principles within its operation and the test procedures used (test procedures must be
      (4) If the supplier does not want to provide all the test results, the supplier must at least warrant that this information is available and conforms with the above and has been adhered to e.g. in conformance with all EU regulatory

requirements including GLP requirements as well as a statement indicating whether the results were found to comply with the requirements.

(5) IFRA certificate for fragrances and essential oils

(6) Any additional test results obtained on samples from the batch as part of a periodic statistically based testing program

iii) A statement for the raw material of the expected conditions of shipping, packaging, storage and distribution, deviation from which would invalidate the certificate.

iv) Source of raw material (organic/natural, inorganic, chemically, biotechnology).

j) Source of Raw Material must be defined, and additional information required if the source is:

i) **Botanical** (common or usual names of the plant, alga or macroscopic fungus, name of variety, species, genus, and family (if more than one variety used, specify), specify organoleptic, macroscopic and microscopic evaluation, morphological and anatomical description (including gender, if applicable) and a photograph of the plant or plant part, alga, or macroscopic fungus used, Source of botanical: cultivated or harvested from the wild; description of natural habitat and geographical distribution of the plant, alga, or macroscopic fungus; description of preparation process: collection, washing, drying, extraction, distillation, destructive distillation, possible purification, preservation procedures; description of handling, transportation, storage; description of commercial form; description of characteristic elements of the composition: identification of characteristic components, known toxic components (%); description of physical and chemical specifications including Peroxide value where applicable as required by the regulation; description of microbiological quality including relevant fungi; description of additional external contamination; description of preservatives and/or other additives added; Clear indication of all the components of a multi-constituent raw material and min-max ranges (semi-quantitative % of all components must be indicated); Peroxide values in mmol/l batch specific for oils;

ii) **Animal** (the preparation process: conditions of extraction (solvent, pH, temperature); type of hydrolysis (acidic, enzymatic etc); other chemical modifications; possible purification; commercial form: powder, solution, suspension, freeze-dried etc); characteristic elements of the composition: characteristic amino acids, total nitrogen, proteins, polysaccharides, molecular mass and any other relevant information; physical and chemical specifications;

microbiological quality including relevant viral contamination; additional external contamination; preservatives and/or other additives added.

iii) **Mineral** (description of the preparation process: physical processing, chemical modifications, possible purification, semi quantitative analyses, mineralogy, particle size distribution, description of physical and chemical specifications, description of microbiological quality, description of preservatives and/or other additives added)

iv) **Biotechnology process**, a detailed description of process, description of organisms involved: donor organisms, recipient organisms, modified microorganisms; host pathogenicity toxicity and identification of metabolites, any toxins produced by the organisms; fate of viable organisms in the environment-survival-potential for transfer of characteristics to e.g. natural bacteria; physical and chemical specifications; microbiological quality; additional external contamination; preservatives and/or other additives added;

k) Microbiology test results and testing regime for raw materials on an ongoing basis (including anaerobic, aerobic bacteria and fungi). Microbiological testing protocol for raw materials must be provided;

l) Allergen report for all fragrances and essential oils and any raw material that contains any of the 27 Allergens as specified in Annex V of EC 1223/2009)

m) Quality assurance protocol or declaration for raw materials to be provided by the supplier;

3) Cosmetic Product Information – General

a) Brand;

b) Product Name;

c) Product Code;

d) Formula code and Name;

e) Use instructions;

f) User group/s: Adult, Baby, Children (Age range), elderly

g) Foreseeable uses;

h) Recommended warnings;

i) User group – consumer, professional, industrial;

4) Cosmetic Product -physical and chemical characteristics and product testing:

a) Physical form (Solid, emulsion, aerosol, liquid, liquid with different phases, gas);

b) Homogeneity and stability;

c) pH of final formulation;

d) Viscosity;

e) UVA, UVB tests results if sun protection formula;

f) If solid powder, particle size distribution, inhalable fraction;
g) If a sprayed formulation, a description of the droplet size, density;
h) Any further physical and chemical properties if relevant for safety evaluation;
i) Complete Challenge tests for formula;
j) Complete stability testing or in process with interim report suggesting self-life period based on testing regime;
k) Microbiology testing protocol for final product must be provided

5) Cosmetic Product – Good Manufacturing Process

a) The manufacture of a cosmetic product must comply with GMP to ensure safety.
b) The manufacturer must supply a certificate of accreditation or a statement that the product has been manufactured according to the principles of GMP as per EU regulated requirements for GMP standards.
c) Manufacturing and sanitization process description;

6) Cosmetic Product -Packaging information

a) Food grade certificate for each component of the packaging – if not available, leach test for each component as per a recognised food packaging standard method;
b) Complete stability tests for using exact formula in the exact packaging to be placed on the EU market; Any changes to formula require a new stability test;
c) Exact excerpt/description/photos of all labels and wording (PDF);
d) Photos of all packaging parts;
e) Net Weight/volume as defined by EU regulation and E-mark if applicable complying with EC:76/21,
f) Volume of packaging (empty)

7) No-Animal testing declaration

a) A declaration that neither the cosmetic nor any of the ingredients contained in the cosmetic product have been tested on animals in order to meet the requirements of EC 1223/2009;

8) Cosmetic Product- Product Advertising/presentation/labelling/Claims

a) All test results for claims supported by market information, scientifically sound tests or clinical trials must be provided for the PIF and Safety Report (CPSR) and must have been conducted according to best practice guidelines and standards as required by the EU.

b) Note that the following guidelines must be taken into account for wording of claims on Cosmetics Products:

i) Any reference to healing must be accompanied by a medico-clinical trial;

ii) Any claims must be accompanied by the necessary test reports to substantiate the claim

iii) Legal claims e.g. this product complies with EU regulations is not allowed.

iv) Claim must be truthful;

v) Relevant evidential support required for claims;

vi) Claims should be honest – example if a claimed is based on a combined use with another product in the range this should be specified;

vii) No claim can be made that a sunscreen 100 % protection from UV radiation (such as ‘sunblock’, ‘sunblocker’ or ‘total protection’;

viii) Sun protection level must be determined using standardised, reproducible test methods;

ix) Claims should be fair – should be objective and should not unfairly criticize ingredients e.g. does not contain parabens;

x) Claims should be clear and understandable;

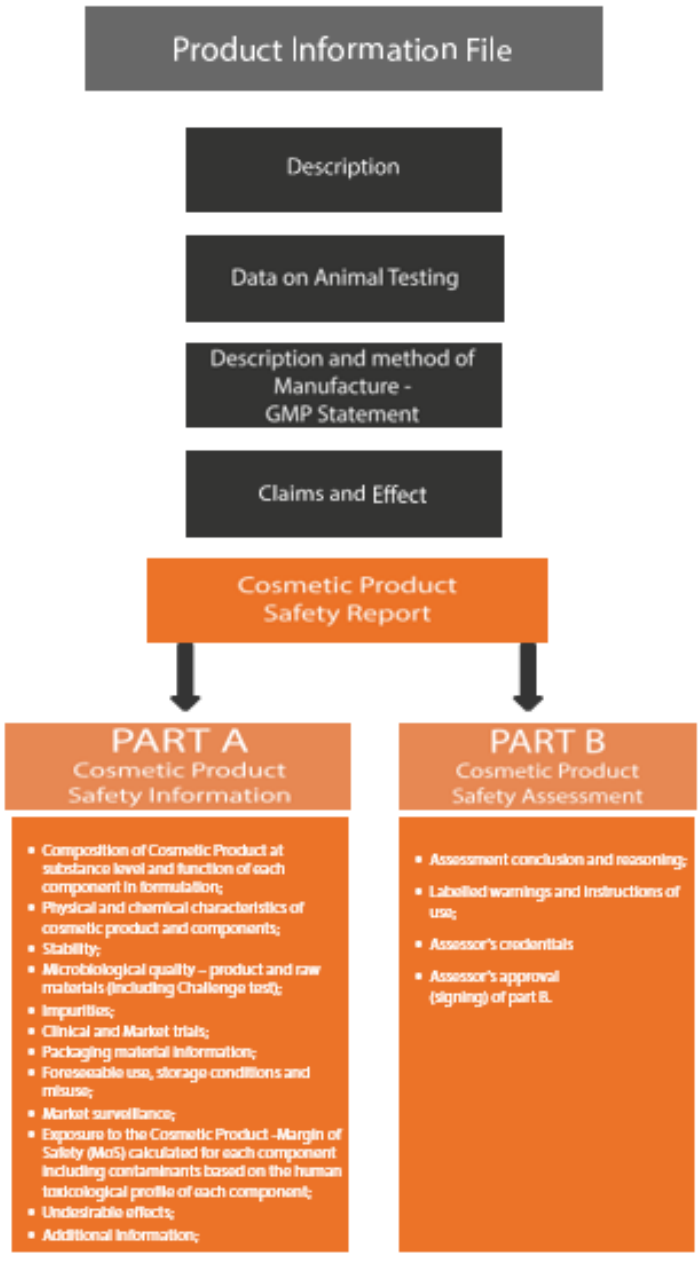
xi) Market data may be a legitimate source in order to substantiate a claim (e.g. “best seller in France” – must be substantiated by sales data for the are specified).

xii) Validity of consumer questionnaires must be demonstrated in terms of being clear and well understood by participants must be. A report should be made available that clearly identifies the product that was surveyed.

xiii) The term hypoallergenic must be substantiated with robust statistically, reliable, scientific user information and the product may not contain any allergens that have been identified in legislation, classified under GHS/CLP, reported as allergens/sensitizers by the SCCS or any other official risk assessment committee, generally recognised;

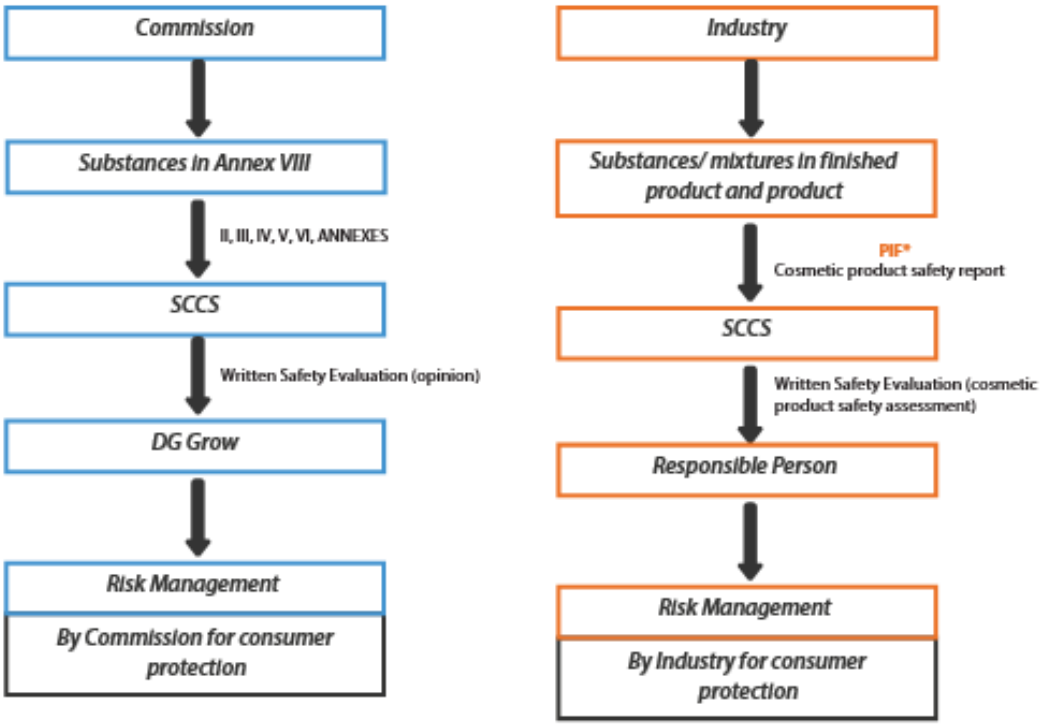
c) Keep a market surveillance report and report any severe undesirable incidences and report the incident to the Authorities immediately;

2.8.4 SUMMARY OF PRODUCT INFORMATION FILE DEVELOPMENT/INFORMATION REQUIREMENTS



2.8.5 Summary of the roles and Responsibilities of Cosmetics Safety in the EU

Two channels (regulatory and Industry) are required in the Safety Assessment Process



PIF*: *Product Information File*

Figure1: Human health safety evaluation of cosmetic ingredients in the EU

Reference: SCCS NoG rev 10 2018

3 PROJECT METHODOLOGY

Stakeholders in the indigenous oil industry in South(ern) Africa affiliated to the following organisations were invited to participate in the ABioSA "Gap analysis" project:

Table 3 Industry associations:

Industry associations	Approximate No. Of members
Cosmetic Export Council of South Africa (CECOSA)	105*
Society of Cosmetic Chemists South Africa (Coschem)	420*
South African Essential Oils Producers' Association (SAEOPA)	54*

*Note: there may be overlap between members in these organisations

3.1 Phase 1: Pre-selection

Initial information (see Annex I) was requested from a list of 58 SME's, the names of which were provided by the organisations and that had indicated their willingness to participate. The SMEs were invited to participate in the study as part of the first phase of the pre-selection process. This was done to ensure SMEs selected to continue to the next phase of the project involved in identifying the GAPs in the regulatory requirements for trade with the European Union (EU) and the European Economic Area (EEA) sufficiently met the following criteria outlined below:

a) Existing/possible trade relations with the EU;
b) Product readiness;
c) Existing/in the process of acquiring regulatory compliance documents;
d) Working according to standards e.g. ISO guideline, GLP/GMP;
e) Produced/distributed the relevant oils in the project scope;
f) Existing data acquired through previous analyses of relevant products/oils;
g) And lastly provided value add to the relevant oils

Of the 58 SME's that were invited 41 completed questionnaires were returned.

Table 4 Pre-selection SME submissions

Regulatory Gap analysis	Vegetable oils	Essential oils
REACH and CLP		
Cosmetics		

3.2 Selection outcome

SME's were grouped into three tiers:

Tier 1: SME's who obtained 70-100%

Tier 2: SME's who obtained 50-70%

Tier 3: SME's who obtained 0- 50%

The 28 SME's that obtained over 70% (Tier1) according to the project scorecard (see Annex II) were invited to continue to the final phase of the project. SME's that fell into Tier 2 were reviewed and two SME's were selected by the project team to continue to the final phase of the project. A total of 30 SME's from Tiers 1 and 2 were selected at the end of the Pre-selection phase.

3.3 Raw Material Information form (RMIF)

In the final phase of the project selected SME's were given a RMIF (reconstructed by Lisam South Africa and Lisam Telegis) to complete (see Annex III). In total 19 SME's responded by completing their RMIF by the required deadline. All 19 RMIF's were used to conduct the regulatory "gap analysis". The RMIF was based on the following regulations outlined below:
REGULATION EC 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH); and Product readiness;
REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP); and
REGULATION (EC) NO 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products

4 RESULTS

4.1 REACH GAPS

In the final phase of the project SME's did not provide all the information for the various indigenous oils they produced (see Excel Project file).

4.1.1 Vegetable seed oils

Vegetable oils as mentioned earlier according to Article 2(7)(b) of the Regulation (EC) No 1907/2006 (REACH) and its amendment by Regulation (EC) No 987/2008 of 8 October 2008 sets out criteria for exempting substances covered by Annex V from the registration, downstream user and evaluation requirements.

"*substances obtained from natural sources, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC13 with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f)"*

Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts; glycerol

Based on the information provided, the tentative results indicate that all the vegetable seed oils within the scope of the "Gap analysis study are exempt from REACH. However, more information is required to further support this as discussed below.

In this study it was found that all oils were obtained from natural sources and were not chemically modified. The manufacturing process for extracting the oil from the seeds generally involved a physical process such as cold-pressing and filtering. One of the important parameters in the identification of a vegetable oil over an essential oil is its fatty acid profile. Earlier it was explained under the Annex V guidelines that "fatty acids from **C6 to C24**", and their potassium, sodium, calcium and magnesium salts' are listed in Annex V- This means that the chemical structure of the 'fatty acids from C6 to C24, and their potassium, sodium, calcium and magnesium salts' substance cannot be changed". One of the major gaps identified in the study was missing data for the fatty acid composition/profile (C6: C24) as required by REACH

to determine if oils are a vegetable oil. Most SME's only had a partial fatty acid profile and none had a complete fatty acid profile from C6:C24. The majority of oils were found to be non-hazardous (some oils could not be classified due to insufficient information provided).

In the study it was found that many SME's did not have enough regulatory documents/test data to confirm that their oils were exempt from REACH registration. SME's must be made aware that an exemption from REACH registration does not equal an exemption from the EU REACH regulation.

"According to the ECHA Annex V guidance on exemptions from the obligations to register, it clearly outlines that in all cases, the burden of proof rests with the manufacturer/importer that wishes to use this exemption for his substance. Therefore, the absence of information on the properties of a substance cannot be equated to the absence of hazardous properties" (ECHA, 2012). Therefore manufacturers/ formulators of vegetable oils must still keep a dossier proving exemption from REACH registration if they are exporting to the EU over 1 tonne.

4.1.2 **Essential oils**

The exemption from the obligation to register of Annex V, does not apply to most NCSs like essential oils as they are processed and generally contain well-defined constituents, which classify as hazardous. Despite the various qualities of NCSs as detailed above, NCSs are best registered for REACH with one dossier as intended by Recital 45 of RECAH. Due to the complexity of REACH and the variability in composition of NCSs the "Protocol for REACH Registration of Natural Complex Substances" (revision 2, January 7, 2009) should be followed for their registration in a compliant manner. One of the major gaps identified in this study was that there was insufficient information supplied by the SME's to Lisam in order to establish which SME's producing an essential oil of "similar composition" could be grouped together in a joint REACH registration. Different "qualities" of one NCS can be covered in one UVCB registration dossier provided that come from the same botanical source (family, genus, species) and are obtained from the same generic process (e.g. cold pressing, extraction and/or distillation, or a specific combination of them) and have a similar composition

In the Gap analysis study:

- Gap 1: Several SME's failed to identify the family, genus and species that they work with.
- Gap 2: The botanical source refers to the family, genus and species of the organism from which the substance has been derived. It is important that SME's also take into account and document the part of the plant used for the extraction of the substance as

this may be relevant for the purpose of identification especially if there is a difference in composition of the extract obtained from different parts of the plant.

- Gap 3: It is understandable that SME's may have trouble identifying the botanical source as there are different botanical systems of classification (ex: Citrus genus), It is suggested in the EFEO/IFRA guidelines on substance identification and sameness of Natural complex substances (NCS) under REACH and CLP that it might be useful to check the right name ("Accepted Latin name") and look for synonyms by which the species has been identified.
- Gap 4: The full manufacturing methods were not submitted which is imperative in determining if the essential oils are obtained from the same generic process.
- Gap 5: SME's did not do a full GC analysis of their oils or supplied laboratory reports that did not belong to them (tests were carried out on SME's own oils) which is needed in order to determine if essential oils produced by different SME's have the same or "similar composition"

Unfortunately, the term "similar composition" is not defined under REACH nor the ECHA SID Guidance. There are tools to determine if two NCSs have a "similar composition"

- The International Standards Organisation (ISO) has developed standards for the characterisation of essential oils. Therefore, if an essential oil is described in ISO standard then the composition ranges mentioned in the standard may be used for purposes of substance identification and generally if the NCS complies with the composition ranges then the NCS could be regarded as similar for registration under REACH.
- In the event that no standard exists or if the existing standard does not fit with the qualities that are currently placed on the market, other tools addressing the concept of "composition similarity", though not designed for substances, may be used by analogy for NCS. The JRC Guidance on Assessment of Mixtures14 could be used which incorporates the definition of "similar mixture" of the US Agency for Toxic Substances and Disease Registry (ATSDR)15, as follows: "similar mixtures are mixtures having the same chemicals but in slightly different proportions or having most but not all chemicals in common and in highly similar proportions."
- It is ultimately up to the registrant to decide the appropriate methodology to demonstrate similarity in composition.

SME's should be aware that a single UVCB registration can be made for two or more NCSs with a similar composition but obtained from different botanical sources. Below is an example

of Spearmint essential oil taken directly from EFEO/IFRA guidelines on substance identification and sameness of Natural complex substances (NCS) under REACH and CLP

Example: Spearmint essential oil

Spearmint essential oil is produced by distillation treatment of two mentha species: *Mentha spicata/gracilis* (EC # 283-656-2) and *Mentha cardiaca/gracilis* (EC # 294-809-8). The source concerns the same areal parts of the plants, which are processed in the same way (cutting and field drying followed by steam distillation) to obtain Spearmint oil. All qualities of the oils share the same classification and are very similar in composition as shown in the below table:

COMPOSITION OF SPEARMINT OILS	CAS no	Spearmint oil (Mentha spicata/ gracialis)		Spearmint oil (Mentha cardiaca/gracilis)	
CONSTITUENT % v/v		Typical % w/w	Range % w/w	Typical % w/w	Range % w/w
L-Carvone	6485-40-1	68	62-80	68	49-85
Limonene (1L)	5989-54-8	11	5-16	17	2-20
Other 8 identified constituents ≤ 2,5 and ≥ 1.0% present in both NCS*		11		6	
Other 23 identified constituents < 1.0%		7		7	
Not identified		3		2	
Total		100		100	
*myrcene-beta, terpinen-4-ol, Cineol 1, 8, beta-bourbonene, trans-dihydrocarvone germacrene D, sabinene hydrate, 3-octanol					

Spearmint oils from *Mentha spicata/gracilis* and *Mentha cardiaca/gracilis* as obtained by the above described process consist of the same constituents in typically the same concentrations with minor variations in the concentration ranges.

A single UVCB registration for spearmint oil would thus be possible in this case. The substance would be identified in the registration dossier according to the rules for UVCBs sub-type 3, i.e.: "Essential oil of Spearmint obtained from the aerial part of *Mentha spicata/gracilis* and *Mentha cardiaca/gracilis* by distillation".

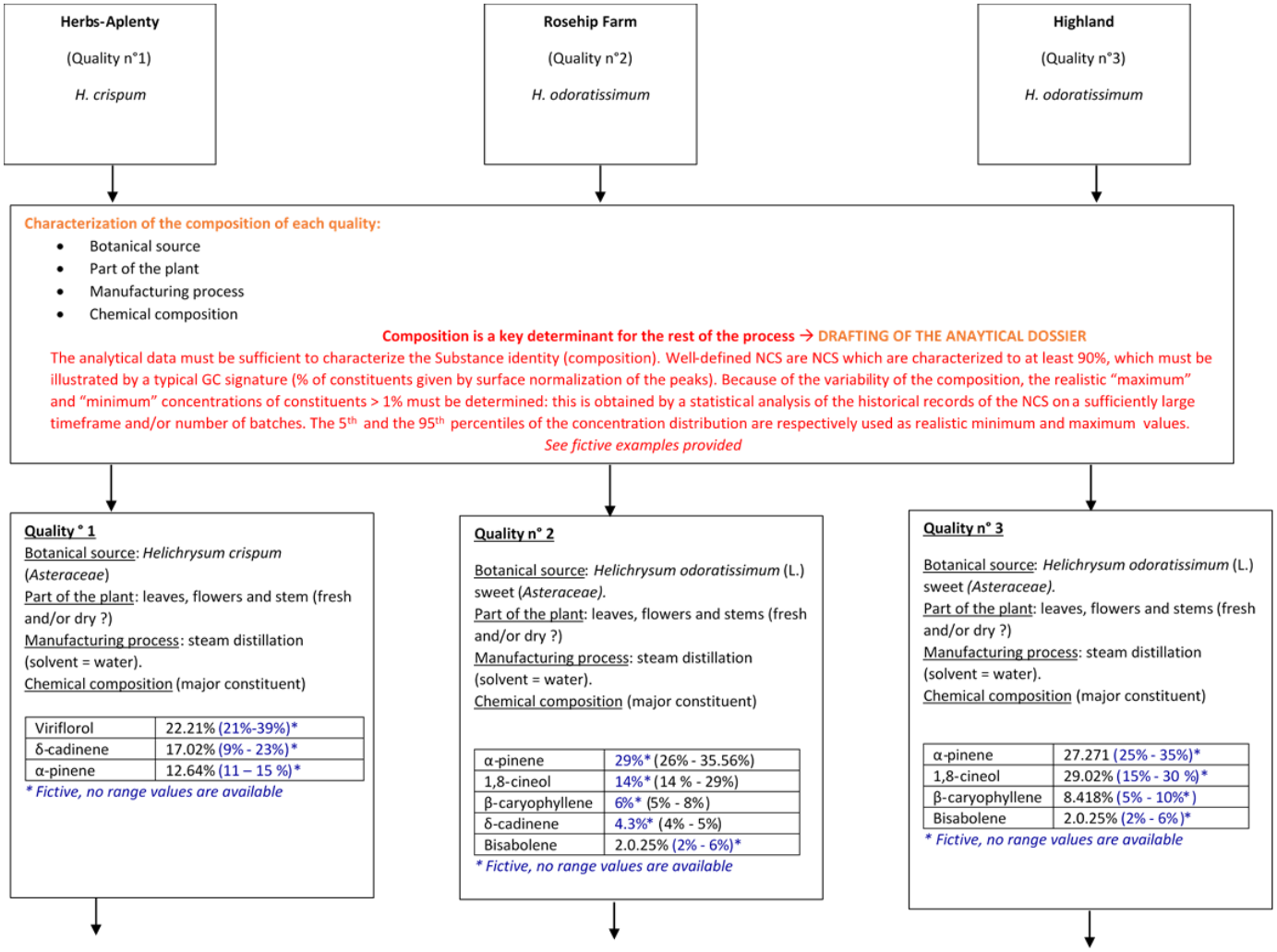
The multi-constituent approach may also be considered in this case because of the typical concentration and ranges of the main constituents (see chapter 3.2.).

Figure 1.6 example of spearmint essential oil obtained from the same botanical source and have similar composition

[(On the contrary, EFEO/IFRA guidelines on substance identification and sameness of Natural complex substances (NCS) under REACH and CLP an example of the essential oils of *Citrus aurantium* (Rutaceae) (Orange bitter and Petitgrain oil) addresses the issue of a single UVCB registration for an NCS from the same botanical source, but with different composition due to the use of different parts of the same plant (e.g. the peel and the leaves and twigs of the same botanical species)]. Although SME's did not provide enough information to enable them to be grouped into possible joint registrations, Lisam Telegis have devised a fictive workflow (as shown below) and fictive analytical reports (see Annex IV) to demonstrate the REACH process. The fictive analytical reports were created using data submitted by three SME's namely, Herbsaplenty, Highland essential oils and Rosehip farm. Some data included in the

analytical report are from the manufacturer but where data was missing fictive examples have been included.

Figure 1.7: Fictive Workflow for Helichrysum essential oil


Herbs-Aplenty
(Quality n°1)
H. crispum
Rosehip Farm
(Quality n°2)
H. odoratissimum
Highland
(Quality n°3)
H. odoratissimum
Characterization of the composition of each quality:
Botanical source
Part of the plant
Manufacturing process
Chemical composition
Composition is a key determinant for the rest of the process → DRAFTING OF THE ANAYTICAL DOSSIER
The analytical data must be sufficient to characterize the Substance identity (composition). Well-defined NCS are NCS which are characterized to at least 90%, which must be illustrated by a typical GC signature (% of constituents given by surface normalization of the peaks). Because of the variability of the composition, the realistic "maximum" and "minimum" concentrations of constituents > 1% must be determined: this is obtained by a statistical analysis of the historical records of the NCS on a sufficiently large timeframe and/or number of batches. The 5th and the 95th percentiles of the concentration distribution are respectively used as realistic minimum and maximum values.
See fictive examples provided
Quality ° 1
Botanical source: Helichrysum crispum (Asteraceae)
Part of the plant: leaves, flowers and stem (fresh and/or dry ?)
Manufacturing process: steam distillation (solvent = water).
Chemical composition (major constituent)
Viriflorol 22.21% (21%-39%)*
δ-cadinene 17.02% (9% - 23%)*
α-pinene 12.64% (11 – 15 %)*
* Fictive, no range values are available
Quality n° 2
Botanical source: Helichrysum odoratissimum (L.) sweet (Asteraceae).
Part of the plant: leaves, flowers and stems (fresh and/or dry ?)
Manufacturing process: steam distillation (solvent = water).
Chemical composition (major constituent)
α-pinene 29%* (26% - 35.56%)
1,8-cineol 14%* (14 % - 29%)
β-caryophyllene 6%* (5% - 8%)
δ-cadinene 4.3%* (4% - 5%)
Bisabolene 2.0.25% (2% - 6%)*
* Fictive, no range values are available
Quality n° 3
Botanical source: Helichrysum odoratissimum (L.) sweet (Asteraceae).
Part of the plant: leaves, flowers and stems (fresh and/or dry ?)
Manufacturing process: steam distillation (solvent = water).
Chemical composition (major constituent)
α-pinene 27.271 (25% - 35%)*
1,8-cineol 29.02% (15% - 30 %)*
β-caryophyllene 8.418% (5% - 10%*)
Bisabolene 2.0.25% (2% - 6%)*
* Fictive, no range values are available

ANALYSIS OF THE SAMENESS OF THE 3 QUALITIES

(see EFEO/IFRA guidance on sameness criteria and the impact on the REACH registration)

Remark: ISO standard : if an essential oil is described in an ISO standard (or other standards), NCSs which comply with the composition range of the corresponding ISO Standard could be regarded as similar for registration under REACH.

Quality ° 1 – 1 REACH dossier

Search on ECHA if a potential registration dossier is available:
https://echa.europa.eu/fr/information-on-chemicals

Quality ° 2 and 3 – 1 REACH dossier

Search on ECHA if a potential registration dossier is available:
https://echa.europa.eu/fr/information-on-chemicals

Search performed with the botanical name, chemical identifiers available…

CAUTION: NCSs have historically been listed on EINECS **under a generic heading** and considered as UVCBs. More specifically, at the time of listing on EINECS, NCSs were reported under a generic heading as follows: "*Plant extracts and their physically modified derivatives are listed in EINECS under generic heading, covering all products extracted from the same plant irrespective of the part of the plant or physical process used. Each plant extract identified with genus and species has its own EINECS entry. They are named with common names on the genus and species*". This naming convention agreed at the time of the listing on EINECS is important as it has been used to name NCSs in product labels and SDSs for over 30 years.

Therefore, plant oils which derive from the same genus and species are covered by the same entry in EINECS or by the same CAS number, while for the registration purposes, there is a need to better define the identity. This is why, several CAS numbers can be applicable to the same substance, and that under REACH, a substance initially covered by a historical EINCES entry can be registered under another EC/List N°.

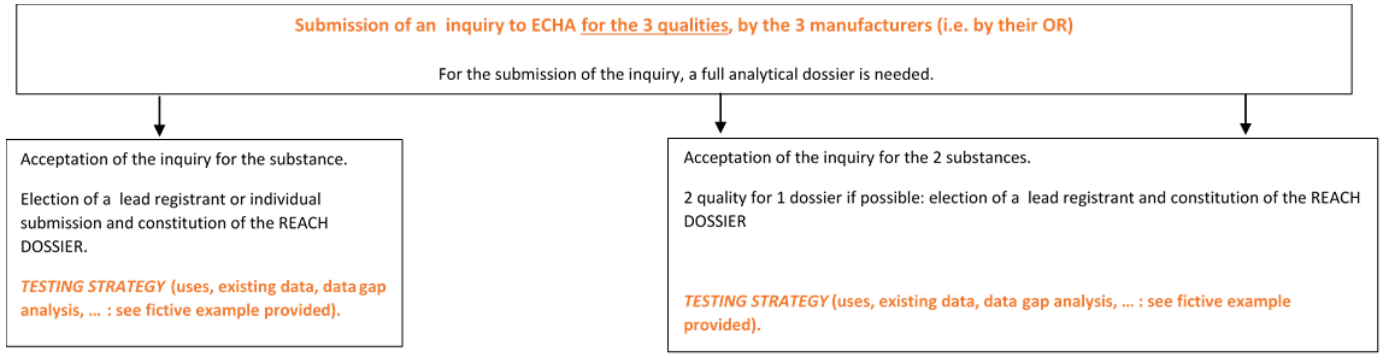
Quality ° 1 – 1 REACH dossier

No results: the substance does not seem to be registered under REACH, nor preregistered

Quality ° 2 and 3 – 1 REACH dossier

Substance identified under 2 list numbers, but no registration dossier available: the Substance does not seem to be registered under REACH. But there are existing pre-registrations.

Helichrysum Odoratissimum	923-526-0	-
Helichrysum Odoratissimum, ext.	917-953-1	-


Submission of an inquiry to ECHA for the 3 qualities, by the 3 manufacturers (i.e. by their OR)
For the submission of the inquiry, a full analytical dossier is needed.
Acceptation of the inquiry for the substance.
Election of a lead registrant or individual submission and constitution of the REACH DOSSIER.
TESTING STRATEGY (uses, existing data, data gap analysis, … : see fictive example provided).
Acceptation of the inquiry for the 2 substances.
2 quality for 1 dossier if possible: election of a lead registrant and constitution of the REACH DOSSIER
TESTING STRATEGY (uses, existing data, data gap analysis, … : see fictive example provided).

4.1.3 General REACH Gaps

- Tests results submitted (e.g. GC-analysis) to Lisam were not carried on SME's own oils
- Laboratory reports could not be submitted to confirm physical chemical property data/toxicological/ecotoxicological provided on the SDS
- Laboratory reports and certificate of analyses (COA's) were supplied but omitted the name of the laboratory that conducted the tests and their accreditation
- Lack of understanding of what GMP or GLP, many SMEs could not provide GMP/GLP statements
    - In brief Good laboratory practice (GLP) refers to "a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. Its purpose is to ensure the quality and integrity of the safety data submitted to regulatory authorities ('GLP receiving authorities')".
    - The principles of GLP "are applied to the non-clinical safety testing of test items contained in a range of products. The application of GLP is required by a variety of different product-specific legislation. This document lists all the EU legislation containing GLP provisions".
    - EU legislation that has GLP provisions:

      1) Article 1(1) of the Directive requires that "Member States shall take all measures necessary to ensure that laboratories carrying out tests on chemical products, in accordance with Directive 67/548/EEC, comply with the principles of good laboratory practice (GLP)". Directive 67/548/EEC is the Dangerous Substances Directive, which is repealed by the CLP Regulation (listed below) from 1 June 2015.

      2) Article 1(2) specifies that this requirement "shall apply also where other Community provisions provide for the application of the principles of GLP in respect of tests on chemical products to evaluate their safety for man and/or the environment." These other provisions are listed in this document.

      3) Article 13.4 of REACH Regulation (EC) No 1907/2006 requires that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in

Directive 2004/10/EC or other international standards recognized as being equivalent by the Commission or the Agency.

4) Article 8.5 of Regulation (EC) No 1272/2008 (CLP) requires that where new tests for physical hazards are carried out for the purposes of this Regulation, they shall be carried out, at the latest from 1 January 2014, in compliance with a relevant recognized quality system or by laboratories complying with a relevant recognized standard. The ECHA guidance on the Application of the CLP criteria (November 2013) further explains that Article 8.5 can be interpreted as compliance with the principles of good laboratory practice (GLP) (as formerly required by the DSD), application of EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories as amended as a relevant recognised standard, lastly other internationally recognised standards of comparable scope

- Therefore, it is important that SME's use accredited laboratories or laboratories working according to GLP

- Incorrect hazard classification e.g. oil classified as non-hazardous was found to be hazardous from GC analysis
- Missing full GC analysis of oils as required by REACH
- Missing full fatty acid composition/profile (C6: C24) as required by REACH for vegetable oil
- Missing full-manufacturing method
- Unsure of volume of oil that they are producing (hectares of land or kg of leaves etc)
- None of the SME's who submitted their information were found to be compliant with REACH

4.2 CLP GAPS

- Labels provided minimal information
- Many labels provided did not have GHS pictograms
- Some SME's did not supply pictures of their labels.
- Classification of oils as hazardous in terms of CLP and exemptions to REACH was not possible for all SMEs' as many did not provide SDS and full GC.
- Regulatory GAPS in terms of SDSs (CLP):
- Information on SDS was found to be incorrect e.g. SDS supplied by one SME was for the incorrect specie

- Sections were missing on the and contained old outdated DSD classification risk and safety phrases
- SDS's in the old format/layout contained section 2 and 3 were in the incorrect order
- Some SDS's had no regulation stated
- Some SDS's supplied did not contain any company details on the SDS
- Some SDS's did not have any emergency numbers supplied (PCN Notification –consumer use 2020 deadline)
- The EC numbers on some SDS's did not correspond to the CAS number on the SDS but to a different CAS number for the same oil
- Major components listed on the TDS/COA/SDS did not match the major components listed on the GC
- SDS's provided to us were from other suppliers and not SME's own SDS
- No SME was found to be compliant with CLP
- An incorrect SDS and label and a correct label and SDS authored for South Africa and the EU have been included (see Annex IV)

4.3 COSMETIC REGULATION EC 1223/2009 GAPS

A total of three out of the seven companies who participated in the study provided feedback that they have completed safety assessments and have complete PIFs with their appointed RPs (Responsible person) in the EU. They were not prepared to provide the project with any further information as the PIF is a confidential document. The following EU regulatory GAPs were identified for the SME cosmetic producers that use indigenous oils in their product formulations with the intention to export to the EEA:

1) No evidence that the EU cosmetic regulatory requirements were taken into account prior to the formulation and during the planning process. This is an imperative 1st step in terms of ensuring compliance for the EU i.e. to assess the compliance and level of detail available for the raw materials and packaging to be used, up-front before finalising formulation and commencing with stability, challenge, microbiology.
2) Very limited information was provided in order to enable the assessment of systemic toxicity during the Safety Assessment process which will be required prior to export i.e. very limited raw material information and in some cases information supplied did not match the ingredient/s. Records of constituents/components of raw materials, of oils, valid safety data sheets that are representative of the raw materials used, chemical and physical data of the finished cosmetic product, detailed formulation data, analyses of contaminants/ trace elements in raw materials, details of packaging, details of microbiological analyses (raw materials and finished cosmetic

product) including challenge tests, stability testing (to determine shelf life and stability of product over time and in relation to the packaging under variable storage conditions)

3) Detailed use instructions on labels were not available;
4) Detailed description of the application (where the product is to be applied, how it is to be applied, what sector of the population is it intended for (babies, children, adults, aged-adults) and possible foreseeable uses were not supplied or limited information provided.
5) Non-animal testing data not supplied for raw materials or products;
6) Description and Method of manufacturing according to GMP not supplied;
7) Detailed precautions were not supplied on labels;
8) Details of allergens in ingredient list not provided on the labels that were provided;
9) Correct INCI names in correct order for the labels were in most cases incorrect (either name, order or both);
10) Net weight/volume and correct spacing not correct on the labels that were provided;
11) Evidence of ongoing market surveillance reports – complaints, compliments, adverse effects, medical report regarding adverse effects were not provided
12) No evidence of the use of REACH registered raw materials in products or evidence that the raw materials are exempt. If any of the ingredients exceed 1 tonne per annum at any point in the product's life cycle imported into the EU, REACH requirements apply. This may not be an issue to start with as volumes of products may be small, but as the product demand grows, this requirement should rather be taken into account from the start of formulating the product with the intention to export to the EEA.
13) Claims on labels are made as part of the description of the product/s with no supporting clinical/market trials. Claims are made by using names that border on medicinal claims.
14) A large proportion of Raw Material Analyses were copied and summarised on supplier COA's with no reference to the performing laboratory, no refence to a qualified signatory, no reference to accreditation.
15) Raw Material detailed information as required by the EU Cosmetic Regulation was mostly not available for the oils (within the scope) used in the cosmetic formulations. It is imperative that the information required is supplied in detail in order for an EU safety assessor to sign product safety. The process to determine safety is to understand all the components and concentrations of a raw material which includes the potential contaminants. Pesticide and heavy metal statements were not provided. In certain cases, the word "organic" was used liberally without any proof of organic certification.
16) Limited details of conditions provided for shipping, packaging, storage and distribution, deviation from which would invalidate the certificate for the Raw Materials was not supplied for the Raw Materials (oils within the scope of the proposal).
17) Very limited technical details vs specifications (standardised) was provided for the raw materials. It is important to understand the expected range in terms of the REACH registration/exemption in order to understand the quality of the product.

18) Non-compliant SDSs for raw materials supplied (only limited SDSs provided)

In summary, a very limited level of detailed information required to meet EU regulatory requirements for the assessment of cosmetic safety and registration on the CPNP was observed. In most cases, no PIFs nor any level of safety assessment had been conducted on the cosmetic product. The lack of information available for the indigenous seed and essential oils will need to be overcome and provided prior to the successful launch of such products into the EU market.

5 RECOMMENDATIONS TO INDUSTRY

5.1 REACH and CLP

1) As a more cost-effective approach it is recommended that not more than 10 tonnes of essential oil be exported to Europe. This includes parties that form part of a joint registration (collectively must not exceed 10 tonnes for any particular oil).
2) Testing required should be done on a range (example to acquire physical chemical data) and at an accredited laboratory that follows GLP
3) There is a requirement for Safety data sheets that are GHS compliant for Europe and South Africa. SDS's received from SME's were of very poor quality.
4) There is a need for fatty acid analysis (C6-C24) to be carried out on all vegetable oils
5) There is a need for a full GC analysis to carried out on all essential oils at an accredited laboratory that follows GLP.
6) A platform should be created to allow collaboration between co-registrants to deal with new registrants and requests for more information from authorities
7) Webinars/seminars to educate SME's on REACH, CLP, GMP and GLP
8) SME's use SANAS accredited laboratories or laboratories working according to GLP. Please see list below
    a) Precision oil laboratories
    b) Intertek
    c) Microchem
    d) Laboratory and biological services
    e) SWIFT
    f) Local Universities (it is important to confirm they are working according to GLP)
9) A plan for keeping up to date with registrations needs to be in place. Keeping track of new data, potential new users for a substance, and volumes produced or imported is essential
10) SME's should consider a joint registration of their respective oils. The various types and qualities of NCSs originating from the same botanical source can be combined in one registration dossier. However, their volumes will have to be taken together. If the NCS composition of the constituents differs to the extent that another hazard classification must be assigned, then these NCS types and qualities shall be separately reported in one dossier. Therefore, broad specification ranges per type and quality can

be chosen as long as the hazard classification remains the same. Because one dossier covering all qualities is submitted, the registration fee must be paid also just once.

5.2 Cosmetics

1) Develop an action plan to provide Industry with a set of guideline documents for the regulatory requirements for the EU.
2) Provide a “knowledge database” to industry of available expertise in South Africa i.e. Safety Assessors, toxicologists, scientists who have confirmed knowledge/qualified sufficiently in EU cosmetic regulatory requirements (possibly through an online expert registration portal specific for Cosmetic Safety which would need to be verified) and contact points as ORs for the EU so that the SMEs do not loose product value by having to appoint an EU importer as their RP and loosing value through the RP offering to provide the PIF and registration at a cost in margin-loss to the South African SME.
3) Provide industry with guideline documents for the safe use levels of indigenous oils in cosmetic products as per the product types listed by the SCCS notes of guidance (NoG) for the testing of cosmetic ingredients and their safety evaluation -10th revision.
4) It is extremely important and cannot be stressed enough that cosmetic product brand owners/manufacturers intending to export to the EU must take the following into account from stage of planning and formulation:
    - The use of REACH registered raw materials. If not right from the start, plan to do this in the future;
    - Ensuring that suppliers of raw materials are able to provide the level of information that will be required for the Safety assessment process prior to purchasing the raw material;
    - Availability of an animal testing declaration for all raw materials and final product - A declaration that neither the cosmetic nor any of the ingredients contained in the cosmetic product have been tested on animals in order to meet the requirements of EC 1223/2009;
    - All analyses are declared to have been conducted according to EU regulatory requirements and were conducted according to GLP;
    - All necessary physical and chemical test have been conducted or are available for the final product;
    - Microbiological testing including challenge tests available for the final product formulation;

- Stability tests available under variable conditions to determine shelf life as per EU requirements has been conducted for the exact formulation (no substitution of raw materials, if so, then test must be repeated. This applies to all testing conducted on the final product);
- Sourcing of food grade packaging (all components);
- Manufacture of product according to the principles of GMP;
- Define additional regulatory requirements for all countries that product will be sold in the EU;
- Appoint a Safety Assessor for the EU- qualified in terms of Cosmetic Safety requirements for the EU (Qualifications to be provided) as soon as possible in the process.
- Identify all components/substances for all the raw materials (CAS number level/ International Nomenclature of Cosmetic Ingredients (INCI) name or Common Ingredient Nomenclature (CIN) name and the EC number, including preservatives, additives and impurities (e.g. pesticides, heavy metals);
- Microbiological testing of raw materials is available;
- All additional information required for natural ingredients is available;
- Ensure the availability of a frame formulation (% of each raw material and the intended use in the)
- Exact % of each chemical in the cosmetic product (Formulation)
- All claims are supported by either clinical or market data. Clinical data must comply with EU regulatory requirements (EU) No 655/2013 of 10 July 2013 Laying down common criteria for the justification of claims used in relation to cosmetic products
- All test results for claims supported by market information, scientifically sound tests or clinical trials must be provided for the PIF and Safety Report (CPSR) and must have been conducted according to best practice guidelines and standards as required by the EU.
    - Any reference to healing must be accompanied by a medico-clinical trial;
    - Any claims must be accompanied by the necessary test reports to substantiate the claim
    - Legal claims are not allowed.
    - Claim must be truthful, honest, fair, clear and understandable
    - Market data may be a legitimate source in order to substantiate a claim (e.g. “best seller in France” – must be substantiated by sales data for the are specified).

- Validity of consumer questionnaires must be demonstrated in terms of being clear and well understood by participants must be. A report should be made available that clearly identifies the product that was surveyed.
- The term hypoallergenic must be substantiated with robust statistically, reliable, scientific user information and the product may not contain any allergens that have been identified in legislation, classified under GHS/CLP, reported as allergens/sensitizers by the SCCS or any other official risk assessment committee, generally recognised;

- Keep an ongoing market surveillance report

6 REFERENCES

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2.8.6 References

1) The approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC, 20 December 1979, (80/ 181 /EEC);
2) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products;
3) The harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (87/18/EEC) 18 December 1986
4) EU No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products;
5) Scientific Committee on Consumer Safety (SCCS). The SCCS notes of guidance (NoG) for the testing of cosmetic ingredients and their safety evaluation 10th revision;
6) 25 June 1987 on the approximation of the laws of the Member States concerning products
   which, appearing to be other than they are, endanger the health or safety of consumers (87/357/EEC)

Annex I: ABioSA gap analysis: Explanatory letter and questionnaire

Questionnaire

COMPANY DETAILS	
Company Name:	
Registration Number of Company:	
CONTACT DETAILS	
Name:	
Registered Address (Physical):	
Email:	
Tel:	
Website:	
DETAILS OF OIL/S	
Name of Oil/s produced or used by your company (only list oils that are on the project scope list)	
Description of how your Company produces the oils and/or adds value to the oils by producing secondary products using the listed oil/s (Note: do not disclose any proprietary information). Attach brief description of process and photos of products produced	
List of countries that your company currently sells the product/s containing the oil – please be "Oil specific" when listing the Countries	
Provide a high-level summary of the regulatory compliance achieved for the oil/s and/or products for the EU to date	
Provide an estimation of the revenue/annually generated in the EU/EEA with the products	
Signed by Authorised Signatory on behalf of the Company:	
Date Signed and Place:	

Deadline for Submission: 16th August 2019

Confidentiality

Lisam South Africa (Pty)Ltd, SAEOPA and the GIZ (hereinafter referred to as the "Project Team") undertake not to disclose the content of any information provided by the Participating Company (hereinafter referred to as the "Participant") on a voluntary basis in the questionnaire and as provided by the Participant, to any third party without the written permission of the Participant. The Participant, by submitting the information to the Project Team provides the Project Team with permission to use the information solely for the purposes of the pre-selection process and for further communication with the Participant.

Annex II

Scorecard

Tiers	No.	Tick	Name of SME	Oils	Trading with the EU	Ready for Trade	Regulatory compliance documents	Standards	Number of relevant oils	Analyses	Add Value	Total	(%)
Tier1: ±70%-100%	1	X	HERBS-APLENTY(PTY)LTD	Marula seed oil crude;, Baobab Seed Oil crude;, Kalahari melon seed oil crude;, Lippia javanica essential oil; , Rose geranium essential oil; , Helichrysum essential oil;, Buchu essential oil; , Cape camomile essential oil	2	2	2	2	4	2	2	16	100
	2	X	DPS investment	Kalahari melon seed oil crude;, Kalahari melon seed oil refined;, Marula seed oil crude;, Marula seed oil refined;, Lippia javanica essential oil; , Mongongo seed oil crude;, Mongongo seed oil refined;, Ximenia seed oil X. Americana crude;, Ximenia seed oil X. Americana refined;, Ximenia seed oil X. Caffra crude;, Ximenia seed oil X. Caffra refined;, Mafura seed oil Butter (Trichilia emetica) crude;, Mafura seed oil Butter (Trichilia emetica) refined;, Mafura seed oil crude (Trichilia emetica);, Mafura seed oil (Trichilia emteica) refined;	2	2	2	2	4	2	2	16	100
	3	X	Natural and Organic Formulations	Marula seed oil refined;, Mongongo seed oil refined;, Kalahari melon seed oil refined;, Ximenia seed oil X. Americana refined;, Helichrysum essential oil;, Cape camomile essential oil	2	2	2	2	4	2	2	16	100
	4	X	Afrinatural	Marula seed oil refined;, Kalahari melon seed oil refined;, Baobab Seed Oil refined;, Mongongo seed oil refined;, Mafura seed oil Butter (Trichilia emetica) refined;	2	2	2	2	2	2	2	14	87.5
	5	X	Rosehip Farm (Pty) Ltd	Helichrysum essential oil;	2	2	2	2	2	2	2	14	87.5
	6	X	EcoProducts	Baobab Seed Oil refined;, Baobab Seed Oil crude;	2	2	2	2	2	2	2	14	87.5
	7	X	AFRICAN ORIGINS FARMINS (PTY) LTD	Kalahari melon seed oil crude;, Kalahari melon seed oil refined;	2	2	2	2	2	2	2	14	87.5
	8	X	Botanica Natural Products (Pty) Ltd	Marula seed oil crude;, Marula seed oil refined;, Baobab Seed Oil crude;, Baobab Seed Oil refined;, Mongongo seed oil crude;, Mongongo seed oil refined;, Kalahari melon seed oil crude;, Kalahari melon seed oil refined;	2	2	2	2	2	2	2	14	87.5
	9	X	Vlakbult Plaas Boerdery CC t/a HIGHLAND ESSENTIAL OILS	Kalahari melon seed oil crude;, Kalahari melon seed oil refined;, Helichrysum essential oil;	2	2	2	2	2	2	2	14	87.5
	10	X	Pure Beginnings (Pty) Ltd	Marula seed oil crude;, Marula seed oil refined;, Kalahari melon seed oil crude;, Kalahari melon seed oil refined;, Rose geranium essential oil; , Lippia javanica essential oil;	2	2	2	2	2	2	2	14	87.5
	11	X	Veld Botanicals (Pty) Ltd	Rose geranium essential oil; , Baobab Seed Oil crude;, Baobab Seed Oil refined;, Kalahari melon seed oil crude;, Marula seed oil crude;, Kalahari melon seed oil refined;, Marula seed oil refined;	2	2	2	2	2	2	2	14	87.5
	12	X	Skimmelberg Fynbos Oils (Pty) Ltd	Buchu essential oil; , Cape camomile essential oil	2	2	2	2	2	2	2	14	87.5
	13	X	K.Paulsen Botanicals	Baobab Seed Oil crude;, Baobab Seed Oil refined;	2	2	2	2	2	2	2	14	87.5
	14	X	Green Zone Irrigation Services and Projects (Pty) Ltd	Buchu essential oil; , Marula seed oil crude;, Marula seed oil refined;, Baobab Seed Oil refined;, Kalahari melon seed oil refined;, Mafura seed oil (Trichilia emteica) refined;	2	2	2	2	2	2	2	14	87.5
	15	X	New Growth SA	Baobab Seed Oil crude;, Baobab Seed Oil refined;, Marula seed oil refined;, Marula seed oil crude;, Kalahari melon seed oil crude;, Kalahari melon seed oil refined;, Lippia javanica essential oil; , Rose geranium essential oil;	2	2	2	2	2	2	2	14	87.5

Scorecard

Tiers	No.	Tick	Name of SME	Oils	Trading with the EU	Ready for Trade	Regulatory compliance documents	Standards	Number of relevant oils	Analyses	Add Value	Total	(%)
Tier1: ±70%-100%	16	X	GREATER SEKHUKHUNE REGION SECONDARY CO-OPERATIVE LTD	Marula seed oil refined;	2	2	2	2	2	2	2	14	87.5
	17	X	Intiki t/a Hanneo (Pty) Ltd	Marula seed oil crude;, Ximenia seed oil X. Americana crude;, Kalahari melon seed oil crude;, Mongongo seed oil crude;	2	2	2	2	2	2	2	14	87.5
	18	X	The Marula Guys	Kalahari melon seed oil crude;, Marula seed oil crude;	1	2	2	2	2	2	2	13	81.25
	19	X	ULUMA Entrepreneurship & Community Empowerment (NPC)	Rose geranium essential oil; , Helichrysum essential oil;, Lippia javanica essential oil;	1	2	2	2	2	2	2	13	81.25
	20	X	Escentia Products	Marula seed oil crude;, Marula seed oil refined;, Baobab Seed Oil crude;, Baobab Seed Oil refined;, Kalahari melon seed oil crude;, Kalahari melon seed oil refined;, Mafura seed oil Butter (Trichilia emetica) crude;, Mafura seed oil Butter (Trichilia emetica) refined;, Mafura seed oil crude (Trichilia emetica);, Mafura seed oil (Trichilia emteica) refined;, Lippia javanica essential oil; , Rose geranium essential oil; , Helichrysum essential oil;, Buchu essential oil; , Cape camomile essential oil	0	2	1	2	4	2	2	13	81.25
	21	X	Wild Food's (Pty) Ltd	Marula seed oil crude;, Kalahari melon seed oil crude;, Ximenia seed oil X. Americana crude;, Ximenia seed oil X. Caffra crude;	2	2	1	2	2	2	2	13	81.25
	22	X	PHEPISA NATURAL RESOURCES INSTITUTE (Pty) Ltd	Marula seed oil crude;, Ximenia seed oil X. Americana crude;, Mafura seed oil crude (Trichilia emetica);, Kalahari melon seed oil crude;	1	2	2	2	2	2	2	13	81.25
	23	X	Melo Bless Trading (Pty) Ltd	Rose geranium essential oil; , Lippia javanica essential oil;	1	2	1	2	2	2	2	12	75
	24	X	Lavenderlane Essential Oils cc	Cape camomile essential oil , Rose geranium essential oil; , Kalahari melon seed oil crude;, Kalahari melon seed oil refined;	0	2	2	2	2	2	2	12	75
	25	X	Ayanda African Oils	Rose geranium essential oil;	2	2	2	2	2	2	0	12	75
	26	X	Botanica Essenza	Lippia javanica essential oil; , Rose geranium essential oil; , Helichrysum essential oil;, Cape camomile essential oil , Marula seed oil crude;, Baobab Seed Oil crude;, Mongongo seed oil crude;, Kalahari melon seed oil refined;	1	2	1	0	4	2	2	12	75
	27	X	Ethanolsa (Pty) Ltd	Kalahari melon seed oil crude;, Baobab Seed Oil crude;, Marula seed oil crude;, Rose geranium essential oil; , Cape camomile essential oil	0	2	1	2	2	2	2	11	68.75
	28	X	Temothuo Farms Cooperative	Rose geranium essential oil; , Lippia javanica essential oil;	1	2	1	1	2	2	2	11	68.75

Scorecard														
Tiers	No.	Tick	Name of SME	Oils	Trading with the EU	Ready for Trade	Regulatory compliance documents	Standards	Number of relevant oils	Analyses	Add Value	Total	(%)
Tier 2: ±50%-70%	29	X	B'Ayoba (Pvt) Ltd t/a Kaza Natural Oils	Marula seed oil crude, Baobab Seed Oil crude, Kalahari melon seed oil crude, Mafura seed oil Butter (Trichilia emetica) crude, Ximenia seed oil X. Americana crude;	2	2	1	1	2	0	2	10	62.5
	30		Rosemary Hill	Rose geranium essential oil;	0	2	1	1	2	2	2	10	62.5
	31	X	Nalane Group (Pty) Ltd	Marula seed oil crude;, Marula seed oil refined;, Baobab Seed Oil crude;, Baobab Seed Oil refined;, Mongongo seed oil crude;, Mongongo seed oil refined;, Kalahari melon seed oil crude;, Kalahari melon seed oil refined;, Mafura seed oil Butter (Trichilia emetica) crude;	0	2	1	2	2	0	2	9	56.25
	32		Essential Skincare	Marula seed oil crude, Rose geranium essential oil, Cape camomile essential oil	2	2	1	0	2	0	2	9	56.25
	33		Hi Hanyile Essential Oils	Lippia javanica essential oil, Rose geranium essential oil;	0	0	1	2	2	2	2	9	56.25
Tier 3:± 0%-50%	34		Mamoa Trading Enterprise	Kalahari melon seed oil refined, Rose geranium essential oil, Marula seed oil refined, Baobab Seed Oil refined, Mongongo seed oil refined;	0	2	0	1	2	0	2	7	43.75
	35		QOBO QOBO Essential Oils Incubator	Rose geranium essential oil, Helichrysum essential oil, Cape camomile essential oil	1	2	1	1	2	0	0	7	43.75
	36		Precision Oil laboratories	Laboratory	0	0	2	2	0	2	0	6	37.5
	37		SENZUBUHLE FARMING AND PROJECTS COOP	Start-up company that is still struggling to get support to expand and distillation unit	0	0	0	0	2	0	2	4	25
	38		Oblivion	Rose geranium essential oil;	0	0	0	0	2	0	0	2	12.5
	39		Gowar Enterprises	Do not produce oils, only Aloe ferox	0	0	0	0	0	0	0	0	0
	40		Pabalelo Trust	In research	0	0	0	0	0	0	0	0	0
	41		Kasselhoft Trading Pty Ltd	Producers of Lavandin "Abrialli" , Rosemary oil , not in the scope of the project	0	0	0	0	0	0	0	0	0

Annex III

16 September 2019

Dear Indigenous Oil Stakeholder,

Congratulations, you have been selected to take part as a contributor in the next phase of the ABS Compliant bio-trade in South(ern) Africa (ABioSA) project. Thank you for your initial contribution by providing the LISAM South Africa Project team, in collaboration with SAEOPA (Southern African Essential Oils Producers' Association) and the GIZ South Africa (Deutsche Gesellschaft für Internationale Zusammenarbeit) with the information supplied as part of a pre-selection process. Through a rigorous selection process your company was selected to further engage with the selected parties to assist with identifying the GAPs in the regulatory requirements for trade with the European Union (EU) and the European Economic Area (EEA). The selection process was based on the following criteria:

h) Existing trade relations with the EU
i) Product readiness
j) Existing regulatory compliance documents
k) Working according to standards e.g. ISO guideline, GLP/GMP
l) Number of relevant oils
m) Existing data acquired through previous analyses of relevant products/oils
n) And lastly value add to the relevant oils

Please find attached below, a detailed questionnaire based on the requirements as set out in REGULATION (EC) No 1907/2006) (REACH), REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP), and the cosmetic products REGULATION (EC) No 1223/2009. If you require further assistance with completing the questionnaire or have any additional questions, please do not hesitate to contact the Lisam South Africa team who would be happy to assist. You can contact either Letesha Moodley (on+27(0) 8449-33-277) /letesha.moodley@lisam.com) or Anushka Govindsamy (on +27(0) 8289-68-164/Anushka.govindsamy@lisam.com). We will contact you during the course of the following week to take you through the requirements of the questionnaire in order to facilitate completion within the project timeline.

Your further contribution to the ABioSA project will be invaluable in ensuring greater sector compliance; assisting the Southern African essential oil producers in taking active ownership of REACH dossiers, CLP regulatory requirements and/or the Cosmetic regulatory and safety requirements for the EU and help reduce existing barriers to exportation into the EU/EEA. Once the study has been completed, we would like to invite you to a presentation of the findings and way forward (date to be advised ~end October 2019).

We look forward to your submission by **no later than Monday the 16th September 2019**

Kind regards,
Dr Anushka Govindsamy
Sales and Product Consultant
Mobile: +27 8289-68-164
Email: anushkagovindsamy@lisam.com

Questionnaire

QUESTIONNAIRE	
SME Company details	
Name:	
Registration number:	
SME Contact details	
Name	
Registered Address (Physical):	
Email:	
Tel:	
Website:	
Section 1: General Form	
According to the following: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ***Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)***	
Information required for REACH (EC 1907/2006)/CLP- SME to complete for each substance	**Date Completed:**
Please note the following terms and conditions:	
This questionnaire is intended to help in the technical approval and qualification of potential suppliers of Southern African indigenous oils as raw materials or used in final cosmetic products. As such, your prompt and accurate completion of all sections will facilitate this process and the data on the form will be treated as critical base data for safety and regulatory work and the identification of the regulatory GAPs for further attention. • All information supplied to the Project Team will be treated as confidential. • All information contained in this document is confidential. No third party is entitled to action any of the inf ormation and detail supplied in this document without the authorisation of the Project Team. - If the information being requested is either unavailable or not applicable, please indicate and provide a n explanation.	
Glossary	
Term	**Definitions and abbreviations**
CAS	Chemical Abstract Service
CI	Colour index
CLP	Classification, labelling and packaging of substances and mixtures
Cosmetic product	COSMETIC product in terms of EC 1223/2009: Article 2 1(a): means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the

	teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours and Article 2(2): a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product - Nutro cosmetics are NOT cosmetics - the primary function of the cosmetic must be as per the allowable definition for cosmetics.
EFFA	The European Flavour Association
EU/EEC	European Union/The European Economic Community
EEA	European Economic Area
Exposure scenario	The set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its lifecycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate
EINECS	European Inventory of Existing Commercial Substances
GLP	Good laboratory practises
GMP	Good Manufacturing practises
INCI	The International Nomenclature of Cosmetic Ingredients
IFRA	The International Fragrance Association
Manufacturing	means production or extraction of substances in the natural state
Manufacturer	means any natural or legal person established within the EEA who manufactures a substance within the EEA
OECD	Organization for Economic Cooperation and development
PBT/vPvB	persistent, bioaccumulative and toxic (PBT)/ very persistent and very bioaccumulative (vPvB)
QSAR	Quantitative structure-activity relationship
Registrant	The EEA manufacturer or the EEA importer of a substance or the EEA producer or EEA importer of an article submitting a registration for a substance into the EEA
REACH	Registration, evaluation, authorisation, and restriction of chemicals
Registrant's own use	means an industrial or professional use by the registrant

Substance	Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition
Supplier	means any EEA manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture
SDS	Safety data sheet
SME	means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises
TDS	Technical data sheet
TSE	'Transmissible spongiform encephalopathies (TSEs)' means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation (EC) No 999/2001
BSE	Bovine Spongiform Encephalopathy
Use	means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation

A. Registrant Identification: (if substance is registered under REACH)
Name *(Non-EEA company e.g. SA manufacturer):*
Address:
Telephone number:
Fax number:
Email address:
Website:
Contact person:
If Importer or appointed REACH Only Representative (OR), the following details are required below:
Name:
Status (for example Only Representative):

Address:
Telephone number:
Fax number:
Email address:
Website:
Contact person:

B. Substance Identification and existing information available

(Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition)

i. Analytical data	**Value/Results attached (Yes/No)**
Please supply the following analytical data below or provide test results as an attachment	
Chemical Name(s):	
Common names:	
EINECS or ELINCS number:	
CAS name:	
CAS number:	
Other identification code: e.g INCI, CI	
Information on optical activity:	
Typical ratio of (stereo isomers):	
Molecular formula:	
Molecular structure:	
Molecular weight or weight rate:	
Type of substance:	
Purity (%):	
Impurities (isomers, by-products, residual solvent, monomers…):	
Additives:	
Spectroscopic data (IR, UV, mass or nuclear magnetic resonance spectrum):	
High pressure liquid chromatogram (HPLC), gas chromatogram (GC)	
Description of the analytical methods	
Technological process for the manufacture	

ii. Physiochemical Properties:	**Value**	**Guideline employed**	**Laboratory ISO 17025 Registered or GLP compliant Yes/No**
Melting point/ Melting range:			
Boiling point:			
Relative density:			
Vapour pressure:			
Surface tension:			
Water solubility:			
Partition coefficient n-octanol/water:			
Flash point:			
Flammability			
Explosive properties:			
Self-ignition temperature:			
Oxidising properties:			
Granulometry/Particle size distribution:			
iii. Toxicological data: Required for: 1-10 tonnes (Annex VII) and 10-100 tonnes (Annex VIII)	**Report attached Yes/No**	**Guideline employed**	**Laboratory ISO 17025 Registered or GLP compliant Yes/No**
IRRITATION AND CORROSION *IN VITRO*			
EYE IRRITATION OR EYE CORROSION *IN VITRO*			
SKIN SENSITISATION *IN VITRO* (required only for 1-10 tonnes, Annex VII)			
SKIN SENSITISATION *IN VIVO*			
MUTAGENICITY: *in vitro* gene mutation study in bacteria			
ACUTE TOXICITY BY ORAL ROUTE			
iv. Toxicological data: Required for: 10-100 tonnes (Annex VIII) Only	**Report attached Yes/No**	**Guideline employed**	**Laboratory ISO 17025 Registered or GLP compliant Yes/No**
IRRITATION AND CORROSION *IN VIVO*			

EYE IRRITATION OR EYE CORROSION *IN VIVO*			
MUTAGENICITY: *In vitro* cytogenicity study in mammalian cells or in vitro micronucleus study			
MUTAGENICITY: *In vitro* Mammalian Cell Gene Mutation Test, if both *in vitro* gene mutation study in bacteria and/or *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study are negative			
ACUTE TOXICITY BY INHALATION ROUTE The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route needs to be provided.			
ACUTE TOXICITY BY DERMAL ROUTE The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route needs to be provided.			
REPEATED DOSE TOXICITY: Short-term repeated dose toxicity study (28 days), by oral, inhalation and/or dermal route.			
REPRODUCTIVE TOXICITY: Screening for reproductive/ developmental toxicity, if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from in vitro methods that the substance may be a developmental toxicant			
TOXICOKINETICS			
v. Ecotoxicological information: Required for: 1-10 tonnes (Annex VII) and 10-100 tonnes (Annex VIII)	**Report attached Yes/No**	**Guideline employed**	**Laboratory ISO 17025 Registered or GLP compliant Yes/No**
Short-term toxicity testing on invertebrates			
Growth inhibition study aquatic plant			

Ready biodegradability			
vi. Ecotoxicological information: Required for: 10-100 tonnes (Annex VI) Only	**Report attached Yes/No**	**Guideline employed**	**Laboratory ISO 17025 Registered or GLP compliant Yes/No**
Short-term toxicity testing on fish			
Activated sludge respiration inhibition testing			
Hydrolysis as a function of ph.			
Fate and behaviour in the environment: Adsorption/ desorption screening			
C. Additional Assessments: Required for 10-100 tonnes (Annex VIII) ONLY	**Assessment attached Yes/No**	**Guideline employed**	**Laboratory ISO 17025 Registered or GLP compliant Yes/No**
i. Chemical Safety assessment Please note: The CSA must cover the entire chain of supply of the substance (from the point of manufacture and/or import to the final users)			
ii. PBT/vPvB assessment			
D. Manufacture and uses Please supply the following information required for: 1-10 tonnes (Annex VII) and 10-100 tonnes (Annex VIII)	**Value/Results attached (Yes/No)**		
Quantities (per year)			
Indication of the tonnage used for own use(s)			
Substance/mixture/article to downstream users			
Concentration in the final product			
Technological process for the manufacture			
Uses			
Waste quantities			
Uses advised against			

E. Classification and Labelling according to Regulation (EC) No 1272/2008 (CLP)	**Value/s/Results attached (Yes/No)**
Hazard classification of the substance(s)	
Hazard label	
Specific concentration limits	
F. Guidance on safe use/environ mental and safety information	**Information provided/attached (Yes/No)**
First-aid measures/Health Emergency procedures	
Environmental emergency procedures	
Fire-fighting measures	
Accidental released measured	
Handling and storage	
Transport information	
Exposure controls/personal protection	
Stability and reactivity	
Disposal considerations	
Recycling and methods of disposal for industry	
Recycling and methods of disposal for the public	
G. Additional supporting documents	**Document/s attached (Yes/No)**
SDS	
TDS	
Certificate of analysis	
GMP Certificate	
Full Manufacturing method	

Information required for Cosmetic Products ONLY- SME to complete for each product	
Note the definition of COSMETIC product in terms of EC 1223/2009: Article 2 1(a): means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours and Article 2(2): a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product - Nutro cosmetics are NOT cosmetics - the primary function of the cosmetic must be as per the allowable definition for cosmetics.	
PLEASE PROVIDE THE FOLLOWING INFORMATION WHERE POSSIBLE:	**Value/report attached**
Name of Product	
Quantities (per year)	
Description of uses of product e.g. Face cream (intended uses)	
Do you have a Product Information File and Safety Assessment according to EU regulation for the product?	
Do you currently export the product to the EU? If so, please advise if registration has been completed on the Cosmetics Product Notification Portal?	
If the product is marketed in the EU do you have a Responsible Person. Please supply details	
Any Claims on your product? Please describe and provide clinical testing reports	
Do you have any marketing material for your product? If so, please attach	
Do you have any marketing survey reports or consumer perception reports for the cosmetic product?	
GMP certificate, Manufacturing method for the specific product and any other certificate relevant to production e.g. ISO certification	
GMP issue date	
Specify cleaning and sanitisation methods/procedures during Manufacturing of product	
Stability test of cosmetic product-provide test reports with methods	
Have you conducted a Challenge test on your Cosmetic Product- if so please attach? If not please give reasons why	
<u>MICRO TESTING:</u> *E.coli* Total coliform count Total plate count Yeast Count Mould Count *S.Aureus* *P.Aeruginosa* Aerobic spore count Anaerobic Spore Count (depending on ingredients)	

Formula - exact % of components required (all raw materials at CAS level)	
Please provide the cosmetic function of each component in your formulation	
Please provide all use instructions for your product	
Foreseeable misuse?	
Recommended warnings?	
Storage Instruction/Requirements	
Provide specification sheets and drawings for each component of the packaging used for the product	
Food safety certificates for each component of packaging. If food safety not available, provide leach analyses for each packaging component	
Provide photographs of the packaging	
Provide photographs of the products label (all)	
Do you keep Consumer Surveillance records? Please provide a record/template	
Raw Material Contaminants (Pesticides, unavoidable process contaminants, heavy metals.) - Provide certificate of analyses either for all raw materials or for the final product	
Known uses in cosmetics (only applies to pure oils being marked as a cosmetic)	
Provide the following information for the final cosmetic product	
Non-Animal Testing Statement	
Biodegradability Tests - product	
Certificate of Analyses	
Composition Information	
EC 648/2004 information	
Ecotoxicity for final product	
Please attach exposure Scenarios for Raw Materials registered under REACH	
GMO statement for raw materials	
Heavy Metal Analyses for raw materials where applicable	
IFRA/EFFA certificate for fragrances and essential oils	
Microbiological Analyses	

Nano analyses and Statement for raw materials where applicable	
Pesticide analyses/Statement for raw materials where applicable	
Product Data Sheet for raw materials	
REACH Registration number for each component of each raw material if available	
Specifications for final product	
Toxicological Profile/testing of raw materials or final product?	
BSE TSE-free Statement	
Provide a GHS compliant SDS for each raw materials and the final product	
Is your product a sunscreen? Any UV and SPF claims? Please provide test reports	
Does your Cosmetic product contain Natural Products if so please provide the following information:	
Botanical Origin	
Common or usual names of the plant, alga or macroscopic fungus	
Name of variety, species, genus, and family (if more than one variety used, specify)	
Specify organoleptic, macroscopic and microscopic evaluation	
Morphological and anatomical description (including gender, if applicable) and a photograph of the plant or plant part, alga, or macroscopic fungus used	
Source of botanical: cultivated or harvested from the wild. Description of natural habitat and geographical distribution of the plant, alga, or macroscopic fungus	
Description of preparation process: collection, washing, drying, extraction, distillation, destructive distillation, possible purification, preservation procedures	
Description of handling, transportation, storage	
Description of commercial form: powder, solution, suspension,…	
Description of characteristic elements of the composition: identification of characteristic components, known toxic components (%);	
Description of physical and chemical specifications including Peroxide value where applicable as required by the regulation	
Description of microbiological quality including relevant fungi	
Description of additional external contamination	
Description of preservatives and/or other additives added	

Clear indication of all the components of a multi-constituent raw material and min-max ranges (semi-quantitative % of all components must be indicated)	
Peroxide values in mmol/l batch specific for oils	
Mineral Origin	
Starting material	
Description of the preparation process: physical processing, chemical modifications, possible purification,	
Semi quantitative analyses, mineralogy, particle size distribution	
Description of physical and chemical specifications	
Description of microbiological quality	
Description of preservatives and/or other additives added	
Animal Origin	
Species	
Type of organs, tissues, biological liquids	
Country of origin	
Description of:	
• the preparation process: conditions of extraction (solvent, pH, temperature,…); type of hydrolysis (acidic, enzymatic,…); other chemical modifications; possible purification;	
• Commercial form: powder, solution, suspension, freeze-dried,…	
• Characteristic elements of the composition: characteristic amino acids, total nitrogen, proteins, polysaccharides, molecular mass,…	
Physical and chemical specifications	
Microbiological quality including relevant viral contamination	
Additional external contamination	
Preservatives and/or other additives added	
Biotechnology derived	
Description of organisms involved: donor organisms, recipient organisms, modified microorganisms	
Host pathogenicity	
Toxicity, and when possible, identity of metabolites, toxins produced by the organisms	
Fate of viable organisms in the environment-survival-potential for transfer of characteristics to e.g. Natural bacteria	
Physical and chemical specifications	
Microbiological quality	
Additional external contamination	
Preservatives and/or other additives added	

not to disclose the content of any information provided by the Participating Company (hereinafter referred to as the “Participant”) on a voluntary basis in the questionnaire and as provided by the Participant, to any third party without the written permission of the Participant. The Participant, by submitting the information to the Project Team provides the Project Team with permission to use the information solely for the purposes of the pre-selection process and for further communication with the Participant.