COMPLIANCE

Order of analyses for cosmetic products

Ensuring safety and compliance in the EU market

GUIDE

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A glossary of biotrade terms can be found at www.abs-biotrade.info/resources

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Glossary

- **CPNP** - Cosmetic Product Notification **Portal**
- **CMR** - EU cosmetics legislation contains provisions for the use of substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR substances) in cosmetic products. The use of CMR substances is prohibited, except in exceptional cases.
- **ECHA** - The European Chemicals Agency is an agency of the European Union which manages the technical and administrative aspects of the implementation of EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- **Frame formulation** - Formulation which details the category/function and maximum concentration of each ingredient
- **GLP** - Good Laboratory Practice
- **IUPAC** - International Union of Pure and Applied Chemistry
- **Leach tests** - Should be conducted according to *Appendix XIX C. Plastic Containers and Closures (Pharmacopoeia, 2020)*.
- **Member state** - A country that is a member of the European Union
- **Packaging contaminant** - Any avoidable or unavoidable substance which is present in a raw material, packaging or final cosmetic product. Refer to *EU food contaminant legislation i.e. COUNCIL REGULATION (EEC) No 315/93 ((EEC) No 315/93, 1993)*
- **PIF** - Product Information File
- **SCCS** - EU Scientific Committee on Consumer Safety
- **Technically avoidable contaminants** - Impurities or contaminates that can be avoided by following Good Manufacturing Practices
- **Technically unavoidable contaminants** - Substances originating from impurities of natural or synthetic ingredients, manufacturing processes, storage and/or migration from packaging, which is technically unavoidable in Good Manufacturing Practices (EC, 2009)

Introduction

This ABioSA best practice guide focuses on the process and sequence that should be followed in order to place a cosmetic product on the EU market compliant with EU market regulations.

It is based on the findings of a product dossier gap analysis study among South African SMEs seeking EU market access for indigenous ingredients and cosmetic products, the EU Cosmetics regulation *EC 1223/2003*, and the *SCCS* ***Notes of Guidance*** *for the Testing of Cosmetic Ingredients and their Safety Evaluation*.

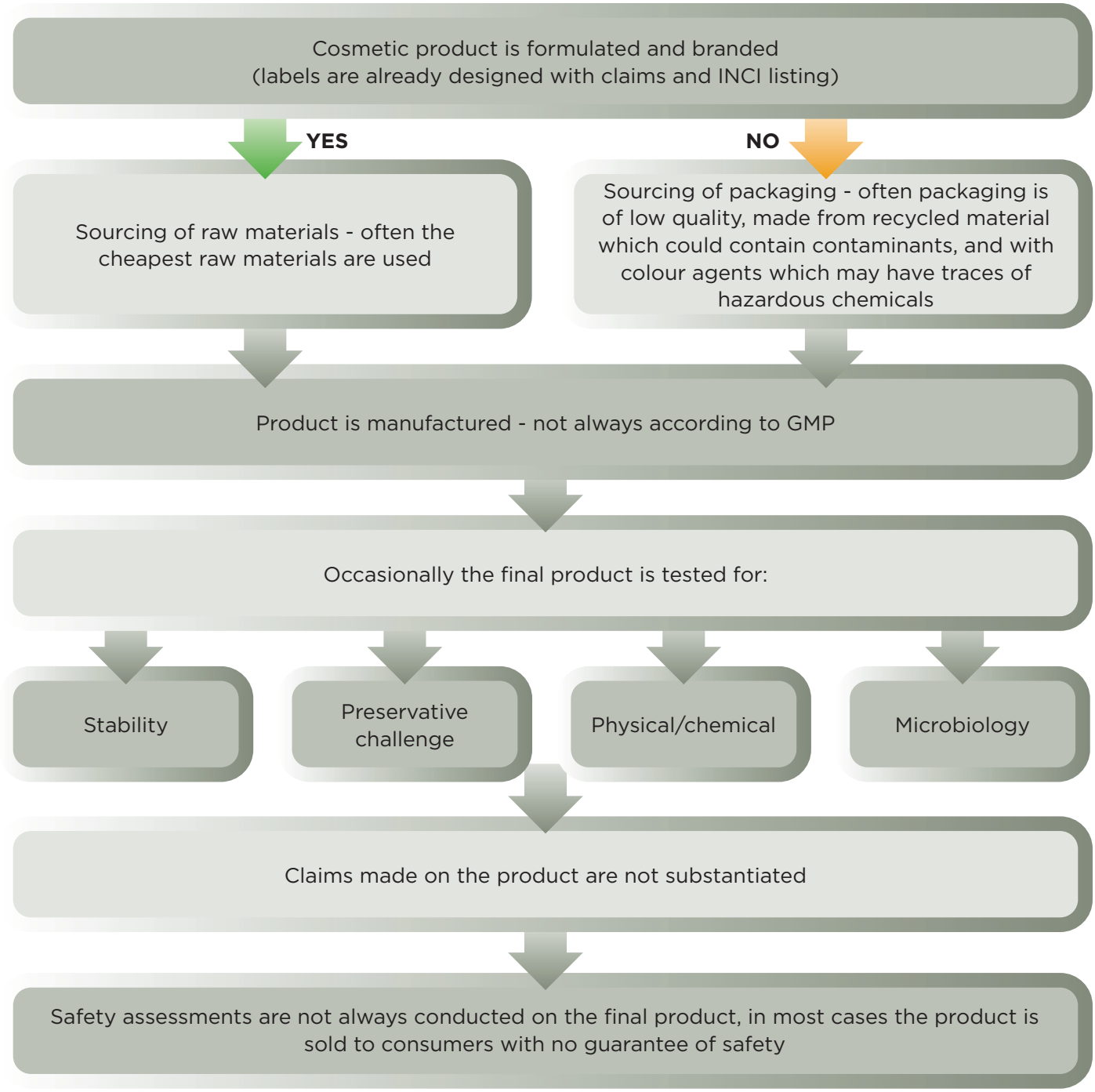
The aim of this document is to assist SMEs producing cosmetic products to benefit from best practice, save time and costs, and ensure their final product is safe for consumer use.

Common current practice

A common practice amongst SMEs in the South African and Southern African cosmetics industry is the validation of a cosmetic product formulation before safety assessments or a calculation of raw material safe use levels are conducted.

This is illustrated in the flow chart below, showing significant gaps in current processes which may lead to failure to comply with regulations, lack of market access, risk to consumers and loss of confidence in Southern African products and materials.

Current common practice by SME cosmetics companies



By following best practice, SMEs can create a cosmetic product that is safe and compliant with EU market regulations. This is illustrated in the process and decision logic represented below.

SMEs are encouraged to assess the natural and chemical raw materials in a product in order to determine what compliance documents are required.

Once the documentation is in place, they need to assess product safety and levels of safe use, including the safety of the packaging. A final round of testing includes product stability, challenge testing and efficacy. After a final safety assessment, the product should be manufactured according to Good Manufacturing Practice and registered on the CPNP Notification Portal.

Recommended process flow for creating safe and compliant cosmetic products.

Basic cosmetic formula (in R&D phase)

Assess the type of raw materials in your product and determine the supporting documents needed

Natural

General:
- Safety data Sheet (SDS)
- Certificate of Analysis (COA)
- Technical data sheet (TDS)
- Complete composition including preservatives, additives and impurities/by-products
- Microbiological quality
- Physical/Chemical data (pH, viscosity, density, physical state, molecular size, etc.)
- Manufacturing process
- Non-animal testing statement
- Heavy metal analysis
- Pesticide analysis
- Fragrance - Allergen report

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 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, possible purification, and preservation procedures.

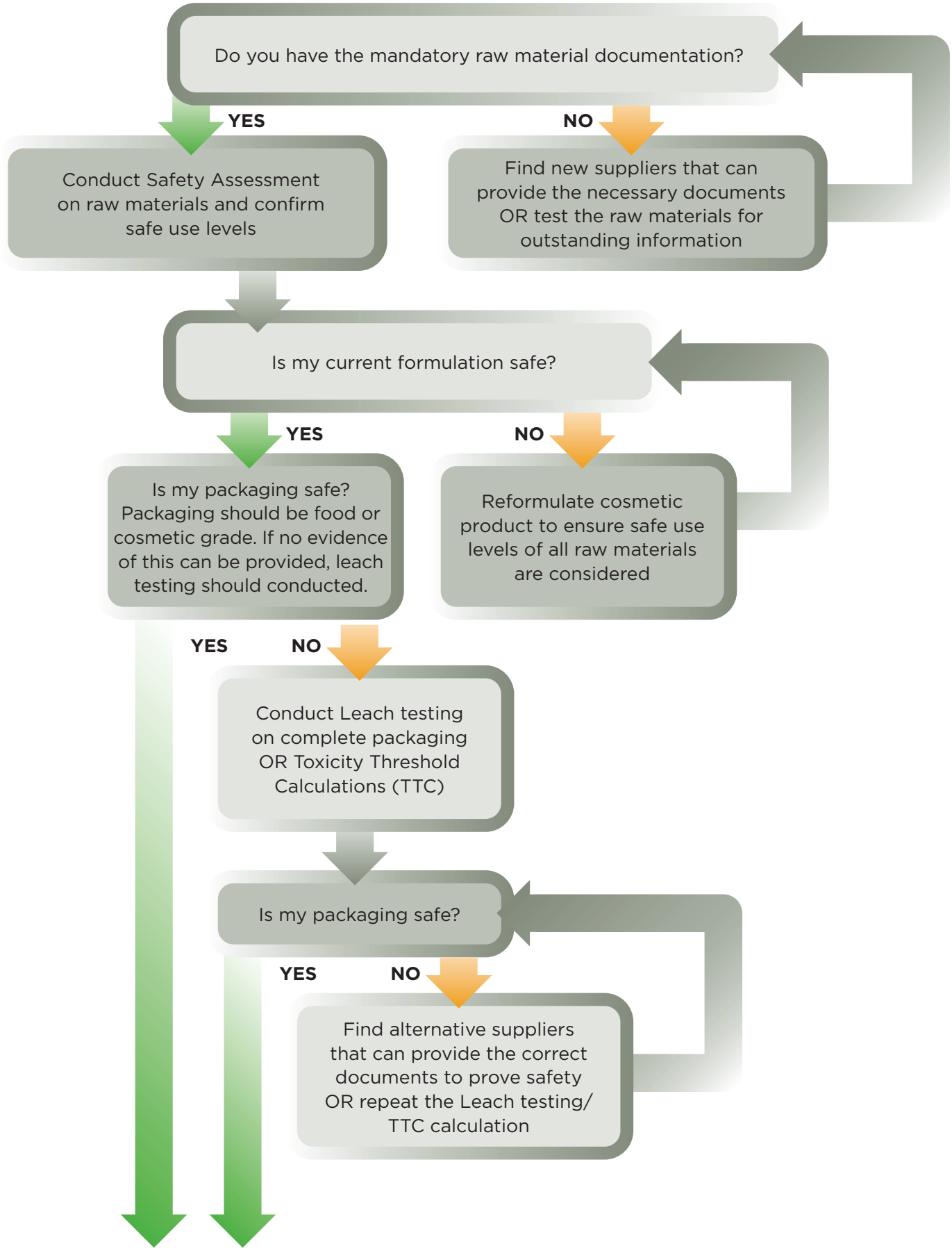
Chemically Processed

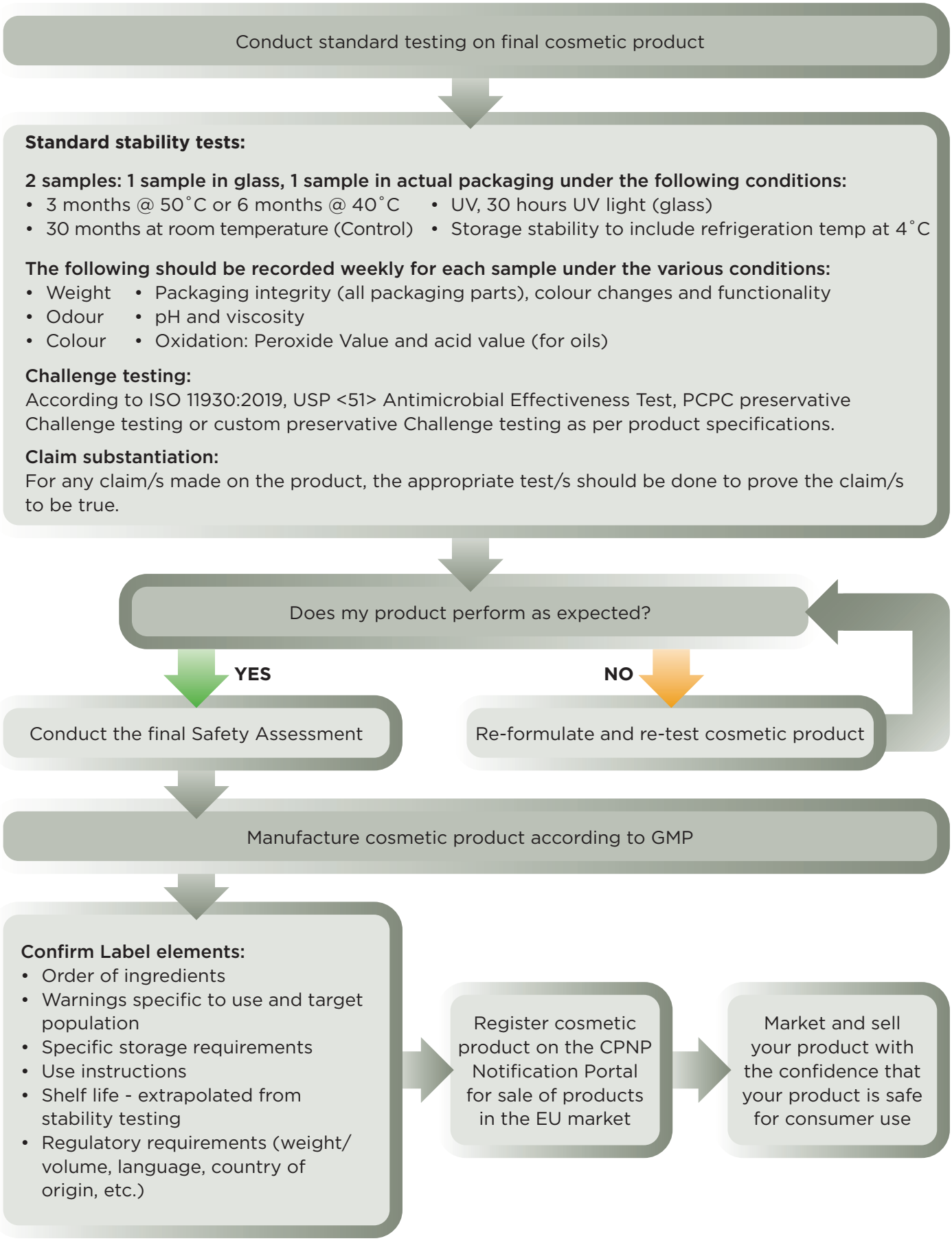
General:
- Safety data Sheet (SDS)
- Certificate of Analysis (COA)
- Technical data sheet (TDS)
- Complete composition including preservatives, additives and impurities/by-products
- Microbiological quality
- Physical/Chemical data (pH, viscosity, density, physical state, molecular size, etc.)
- Manufacturing process
- Non-animal testing statement
- Heavy metal analysis
- Pesticide analysis
- Fragrance - Allergen report

Botanical:
- 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
- GC analysis: Clear indication of all min-max ranges (semi-quantitative % of all components must be indicated)
- Peroxide Values in mmol/batch specific for oils

Animal:
- The preparation process: conditions of extraction (solvent, pH, temperature)
- Type of hydrolysis (enzymatic etc.); other chemical modifications; possible purification
- Commercial form: powder, solution, suspension, free-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

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


Do you have the mandatory raw material documentation?
YES
NO
Conduct Safety Assessment on raw materials and confirm safe use levels
Find new suppliers that can provide the necessary documents OR test the raw materials for outstanding information
Is my current formulation safe?
YES
NO
Is my packaging safe? Packaging should be food or cosmetic grade. If no evidence of this can be provided, leach testing should conducted.
Reformulate cosmetic product to ensure safe use levels of all raw materials are considered
YES
NO
Conduct Leach testing on complete packaging OR Toxicity Threshold Calculations (TTC)
Is my packaging safe?
YES
NO
Find alternative suppliers that can provide the correct documents to prove safety OR repeat the Leach testing/ TTC calculation


Conduct standard testing on final cosmetic product
Standard stability tests:
2 samples: 1 sample in glass, 1 sample in actual packaging under the following conditions:
• 3 months @ 50˚C or 6 months @ 40˚C
• 30 months at room temperature (Control)
• UV, 30 hours UV light (glass)
• Storage stability to include refrigeration temp at 4˚C
The following should be recorded weekly for each sample under the various conditions:
• Weight
• Odour
• Colour
• Packaging integrity (all packaging parts), colour changes and functionality
• pH and viscosity
• Oxidation: Peroxide Value and acid value (for oils)
Challenge testing:
According to ISO 11930:2019, USP <51> Antimicrobial Effectiveness Test, PCPC preservative Challenge testing or custom preservative Challenge testing as per product specifications.
Claim substantiation:
For any claim/s made on the product, the appropriate test/s should be done to prove the claim/s to be true.
Does my product perform as expected?
YES
NO
Conduct the final Safety Assessment
Re-formulate and re-test cosmetic product
Manufacture cosmetic product according to GMP
Confirm Label elements:
• Order of ingredients
• Warnings specific to use and target population
• Specific storage requirements
• Use instructions
• Shelf life - extrapolated from stability testing
• Regulatory requirements (weight/ volume, language, country of origin, etc.)
Register cosmetic product on the CPNP Notification Portal for sale of products in the EU market
Market and sell your product with the confidence that your product is safe for consumer use

Mandatory regulatory requirements for cosmetic products sold in the EU

Good Laboratory Practice (GLP)
According to Article 10.3 of *Regulation (EC) No 1223/2009*, all non-clinical tests referred to in a safety assessment should comply with relevant legislation on the principles of GLP or with equivalent international standards recognised by the European Commission or ECHA (EC, 2009).

Good Manufacturing Practice (GMP)
According to Article 8 of *(EC) No 1223/2009* of the European Parliament and the Council on Cosmetic products regulation, cosmetic product manufacturers should comply with Good Manufacturing Practice.

Responsible Person (RP)
According to Article 4 of *(EC) No 1223/2009* of the European Parliament and of the Council on Cosmetic products regulation, the Responsible Person (RP) shall ensure that the cosmetic product complies with all relevant regulations. The person who places the product on the market, i.e. the EU manufacturer or the EU importer, and under some circumstances the distributor, shall be the default RP for that product, unless there is a written and signed mandate between the default RP and the alternate RP indicating the nomination of the alternate RP (EC, 2009). The EU manufacturer/ importer can appoint an alternate RP by a written and signed mandate, appointing the legal person as the RP of the cosmetic product within the EU.

The legal obligation of the RP is to ensure that a cosmetic product complies with EU cosmetic regulatory requirements. There are some articles as set out in the EU Cosmetic Regulation *EC 1223/2009* that in particular should be noted with reference to analytical requirements, PIF and safety assessment for cosmetic products:

- Article 3 – Safety
- Article 8 – GMP
- Article 10 – Safety assessment
- Article 11 – PIF
- Article 12 – Sampling and Analysis
- Article 13 – Notification
- Article 14 – Restriction of substances listed in the Annexures
- Article 15 – Substances classified as CMR substances
- Article 16 – Nanomaterials
- Article 17 – Traces of prohibited substances
- Article 18 – Animal testing
- Article 19 – Labelling
- Article 20 – Product claims
- Article 21 – Access of information for the public
- Article 23 – Communication of serious undesirable effects
- Article 24 – Information on substances

Safety Assessments
According to Article 10 of *(EC) No 1223/2009* of the European Parliament and of the Council on Cosmetic Products Regulation, it is the responsibility of the RP to ensure that a safety assessment has been conducted on the cosmetic product prior to placement in the EU market (EC, 2009).

A safety assessment must ensure:

a. Intended use of the product and users' systemic exposure to all individual ingredients are accounted for

b. Weight of evidence is used when reviewing data

c. The safety report is kept up to date with additional relevant information, even after the product is placed on the market

d. The safety assessment is signed by a qualified safety assessor for the EU

Safety assessor
A safety assessor conducting the assessment on a finished cosmetic product should have the appropriate university qualifications and practical experience in pharmacy, toxicology, medicine, or a similar discipline, or a relevant course recognized by the EU member state/s (EC, 2009).

France requires specific qualifications as per ***Arrêté*** *du 25 février 2015 relatif à la qualification professionnelle des évaluateurs de la sécurité des produits cosmétiques pour la santé humain:* which requires somebody with a diploma in toxicology or a *French* qualification as specified (Francaise, 2019).

Notification - Cosmetic Products Notification Portal (CPNP)

Prior to placing a product in the EU market, the Responsible Person must register the product on the CPNP.

The following information must be submitted:

a. Product category and name/s

b. Name and address of the RP

c. Country of origin (for imports)

d. Member state/s in which the product will be sold

e. Contact details of emergency/essential personnel

f. For nanomaterials:

- Identification (chemical/IUPAC name) and other descriptions
- Foreseeable exposure routes – how users or consumers may be exposed to the product, e.g. ingestion, inhalation, dermal etc.
- CAS/EC numbers for CMR (category 1A/1B) substances
- Frame formulation

Additional information on these topics can be found in the *(EC) No 1223/2009* regulation.

Animal Testing

Article 18 of *(EC) No 1223/2009* of the European Parliament and of the Council on Cosmetic products regulation, prohibits animal testing on cosmetic products or their ingredients and raw materials. Producers and manufacturers should provide written confirmation that no animal testing was conducted on their raw material or finished product after 11 March 2009 and 11 March 2013 for the purposes of cosmetics, as per the European Cosmetic Regulation *(EC 1223/2009)*.

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