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EU Buyer Requirements

Ensuring compliance to make use of business opportunities for health, cosmetics and food

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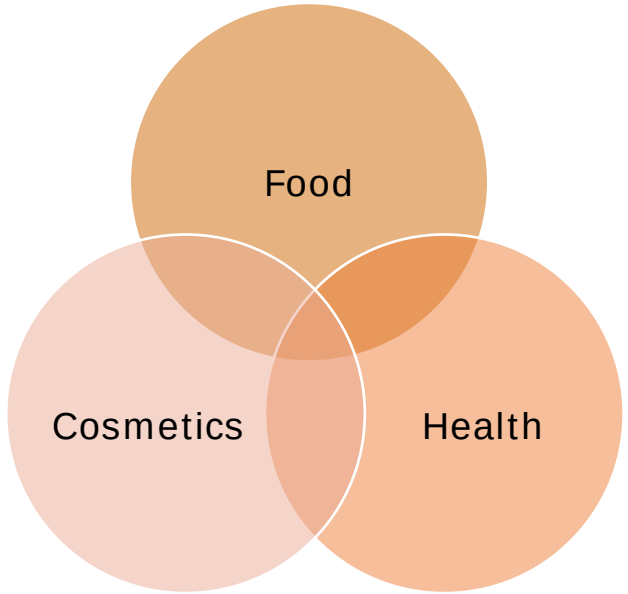
Business opportunities for natural ingredients

1. Different value addition propositions
   - Sustainability
     - Certification
     - Marketing stories
   - Quality and traceability, with right documentation
   - Further processing, with right documentation
2. New market segments
3. Proprietary ingredients with proven efficacy relevant to segment



Providing the right ingredient

- **Established** ingredients, offering a better alternative in terms of:
  - ✓ Better price/quality ratio
  - ✓ Better service
  - ✓ Traceability & Supply security
  - ✓ Certification and documentation
  - ✓ An added-value story

- **New** ingredients
  - ✓ Prove efficacy and safety
  - ✓ Filling a gap – USP?
  - ✓ User friendly, stable
  - ✓ Price (vs. % in formulation)
  - ✓ Low Quantities – Fluctuation - Uncertainty

Rules to use plant resources

Convention on Biological Diversity – Nagoya protocol on ABS

Regulation 511/2014

BABS

Convention on International Trade in Endangered Species of Wild Fauna and Flora

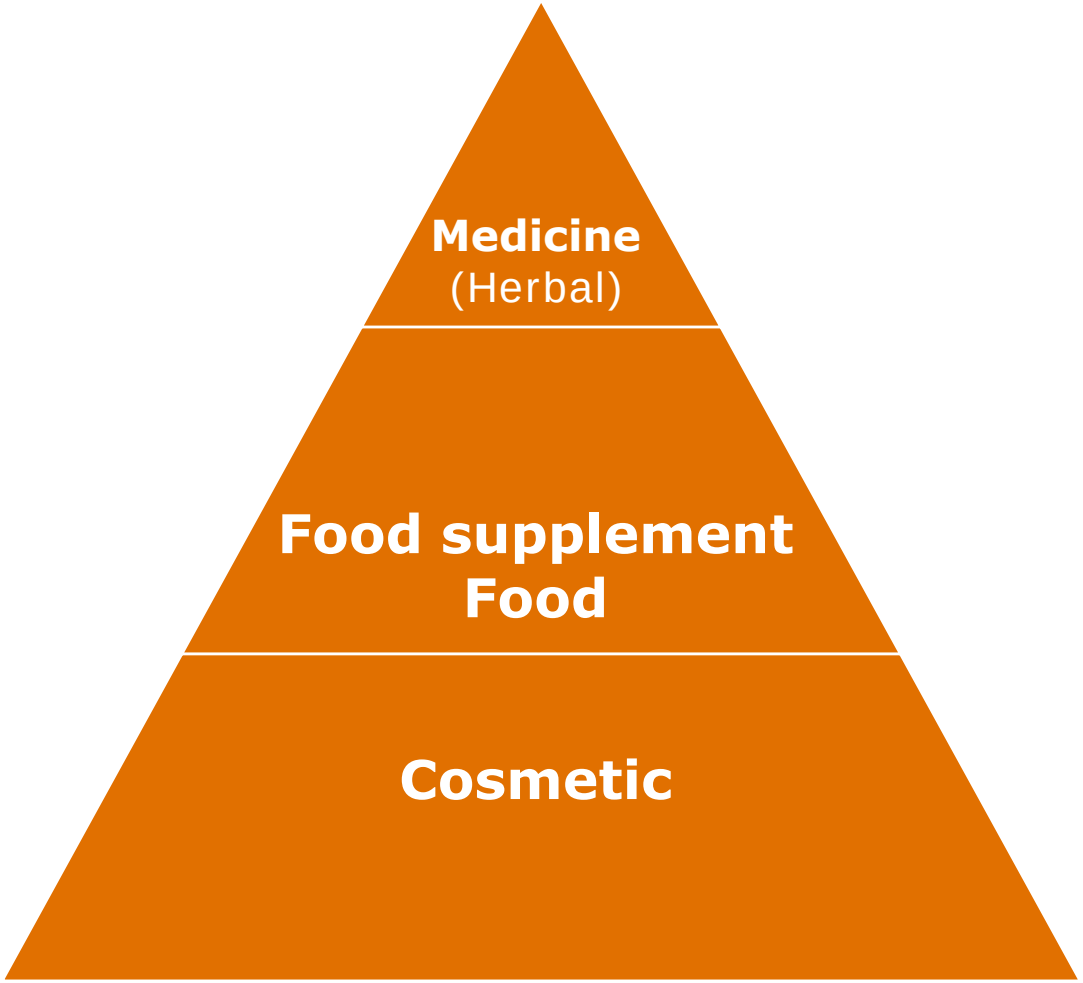
Regulation 338/97

National Environmental Management: Biodiversity Act

- Terms and conditions of access and use of **genetic resources and traditional knowledge**
- ABS due diligence needed
- **EU demands compliance**
- **Implementation** different

- Trade in **protected** species
- **Prohibited** species
- Cost – benefit analysis when working with listed species

Compliance – Cosmetics vs. Health



Increasing demands on:

- Authorisation / registration
- Safety
- Efficacy vs. power of the claim
- Documentation & Certification

Cosmetics	Medicine	Food (supplements)
GHS ISO standards	WHO Guidelines	CODEX
Cosmetic Reg. **REACH** CLP	Pharma Reg. GACP/GMP **THMPD**	Food Law **Food Suppl. Law** **Novel Food**
CTFA Compendium GHS Claims on Cosmetics	Pharma Reg. **Complement.** **Medicine** GACP/GMP	Foodstuffs, Cosmetics and Disinfectants Act Food Labeling Legislation

- **Safety** of ingredient and production – documented
- **Efficacy/claims** of the product – documented

- Regulators catch-up to close **grey areas**
- Ensure you meet standards

Safety – ingredients for food (supplements)

Two guiding policies

1. ***EU Directive for food supplements***
   - Safety in concentrated levels
   - Authorizations in ***national positive lists***
2. ***General Food law:***
   - Hygiene/HACCP/ISO22000/BRC
   - Contaminants
   - Residue levels
   - Extraction solvents
   - ***Novel food***

Upcoming changes!

New Novel Food legislation

Altering the playing field

1. ***Leveraging traditional knowledge***
   - Considered safe if documented safety is available @ origin
   - Consumption only allowed in traditional form
2. ***Generic authorization***
3. ***Transparency and speed***

What is the South African response

Legislation

What is the current Novel Food legislation?

As of 1 January 2018, the new Regulation (EU) 2015/2283 on novel foods (the new Regulation) is applicable. It repeals and replaces Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 which were in force until 31 December 2017.

The new Regulation improves conditions so that food businesses can easily bring new and innovative foods to the EU market, while maintaining a high level of food safety for European consumers.

The **main features and improvements** of the new Regulation are the following:

1. **Expanded categories of Novel Foods:** The Novel Food definition describes the various situations of foods originating from plants, animals, microorganisms, cell cultures, minerals, etc., specific categories of foods (insects, vitamins, minerals, food supplements, etc.), foods resulting from production processes and practices, and state of the art technologies (e.g. intentionally modified or new molecular structure, nanomaterials), which were not produced or used before 1997 and thus may be considered to be as novel foods.
2. **Generic authorisations of Novel Foods:** Under the new Regulation, all authorisations (new and old) are generic as opposed to the applicant-specific, restricted novel food authorisations under the old Novel Food regime. This means that any food business operator can place an authorised Novel Food on the European Union market, provided the authorised conditions of use, labelling requirements, and specifications are respected.
3. **Establishment of a Union list of authorised Novel Foods:** This is a positive list containing all authorised novel foods. Novel Foods which will be authorised in the future will be added to the Union list by means of Commission Implementing Regulations. Once a novel food is added to the Union list, then it is automatically considered as being authorised and it can be placed in the European Union market.
4. **A simplified, centralised authorisation procedure** manged by the European Commission using an online application submission system.
5. **Centralised, safety evaluation of the Novel Foods** will be carried out by the European Food Safety Authority (EFSA). The European Commission consults EFSA on the applications and bases its authorisation decisions on the outcome of the EFSA's evaluation.
6. **Efficiency and transparency** will be improved by establishing deadlines for the safety evaluation and authorisation procedure, thus reducing the overall time spent on approvals.
7. **A faster and structured notification** system **for traditional foods from third countries** on the basis of a history of safe food use. To facilitate the marketing of traditional foods from countries outside the EU, which are considered novel foods in the EU, the new Regulation introduces a simplified assessment procedure for foods new to the EU. If the safety of the traditional food in question can be established on the basis of evidence of a history of consumption in the third country, and there are no safety

Safety – ingredients for medical products

Table illustrating the application of Good Practices to the manufacture of herbal medicinal products[3].

Activity	Good Agricultural and Collection Practice (GACP)[4]	Part II of the GMP Guide†	Part I of the GMP Guide†
Cultivation, collection and harvesting of plants, algae, fungi and lichens, and collection of exudates	■		
Cutting, and drying of plants, algae, fungi, lichens and exudates *	■	■	■
Expression from plants and distillation **		■	■
Comminution, processing of exudates, extraction from plants, fractionation, purification, concentration or fermentation of herbal substances		■	■
Further processing into a dosage form including packaging as a medicinal product			■

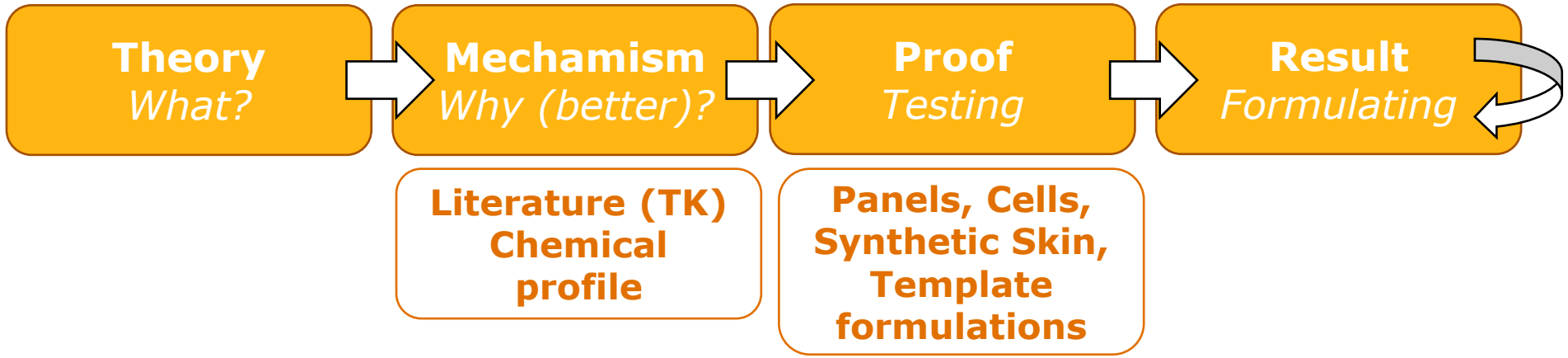
Safety– ingredients for cosmetics

1) REACH registration

2) Safety for cosmetic ingredients: Related to information requirements in **P**roduct **I**nformation **F**ile

- Product composition
- Chemical and microbiological **specifications of raw materials** and finished product
- **Safety assessment** (for each ingredient) by safety analyst, based on:
  - Toxicological profile
  - Chemical structure – purity
  - Level of exposure
  - Specific exposure characteristics of areas where product will be applied!
  - **Data on undesirable effects, proof of claimed effects**
  - Data on **Animal Testing**

Efficacy – Cosmetic ingredients



- The further in product development, the more valuable the offer
- With testing intellectual property (with potential for patent) is created
- Most **SMEs operate on "Mechanism level"**

Efficacy/authorisation for medicinal products

Reference in EU/National Pharmacopoeia

- Limited claims in marketing to **Herbal monographs** and the **Community list**

Simplified registration procedure for herbal medicine

- **Proven use** 30 years, including 15 in Europe

- **Mostly contain well/known, temperate species!**
- **EU Pharmacopoeia contains wider range of species**
- **Very expensive to register outside of these systems**

Efficacy for ingredients for food supplements

Two guiding policies

- EU Directive for food supplements
- Health Claims – for now restricted to vitamins and minerals
- Up to national authorities
- General Food law:
- Nutritional Claims?
- Permitted claims: energy/nutrients

Environmental and social standards

1. Environmental certifications: FairWild, Organic etc. **Not just about environment but also <u>sustainability of supply</u>**

2. Social: especially since introduction of **Fairtrade cosmetics**
   - **<u>Fair treatment</u>**

     Fairtrade, SA 8000, OHSAS 18001, ISO 26000
   - **<u>Fair sharing of benefits</u>**

     UEBT, FairWild, BioTrade Principles and Criteria

Buyer requirements - Corporate Social Responsibility

CSR increasingly important

- Company specific policy (e.g. Unilever, P&G)
- Supplier questionnaires contain more CSR information
- International initiatives (e.g. BSCI)
- Publish a code of conduct to define your social and environmental policies
- Be up front in personal selling and marketing tools

BSCI
Business Social Compliance Initiative

Sedex®

SEDEX: online database to share CSR practices - industry specific

Questions

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