



The Intricate Regulatory Framework of Aromatherapy: Today & Tomorrow

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What is Aromatherapy ?



PRANARŌM
AROMATHÉRAPIE
SCIENTIFIQUE

DEFINITION

Aromatherapy can be defined as a discipline that contributes to Health and Well-being, where essential oils are active substances

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where essential oils are active substances

The product supports body functions

Physiological impact of essential oils

Not a « Marketing Concept » but a Fact based on Scientific evidences

What is Aromatherapy ?



If we take d-Limonene...

You probably think of...

- A common monoterpene
- Found in most essential oils
- Present in many Fragrances and Aromas

...while we think of...

- A physiologically active molecule
- Extensively studied for its beneficial effects
- Such as Metabolic support

[1] Victor Antony Santiago J, Jayachitra J, Shenbagam M, Nalini N. (2012) – “Dietary d-limonene alleviates insulin resistance and oxidative stress-induced liver injury in high-fat diet and L-NAME-treated rats.” Eur J Nutr. 2012 Feb;51(1):57-68. doi: 10.1007/s00394-011-0182-7.

[2] Jing L, Zhang Y, Fan S, Gu M, Guan Y, Lu X, Huang C, Zhou Z. (2013) – “Preventive and ameliorating effects of citrus D-limonene on dyslipidemia and hyperglycemia in mice with high-fat diet-induced obesity.” Eur J Pharmacol. 2013 Sep 5;715(1-3):46-55. doi: 10.1016/j.ejphar.2013.06.022.

[3] Murali R, Karthikeyan A, Saravanan R. (2013) – “Protective effects of D-limonene on lipid peroxidation and antioxidant enzymes in streptozotocin-induced diabetic rats.” Basic Clin Pharmacol Toxicol. 2013 Mar;112(3):175-81. doi: 10.1111/bcpt.12010.

[4] Tan XC, Chua KH, Ravishankar Ram M, Kuppusamy UR. (2016) – “Monoterpenes: Novel insights into their biological effects and roles on glucose uptake and lipid metabolism in 3T3-L1 adipocytes.” Food Chem. 2016 Apr 1;196:242-50. doi: 10.1016/j.foodchem.2015.09.042. Epub 2015 Sep 12.

[5] Bacanlı M, Anlar HG, Aydın S, Çal T, Arı N, Ündeğer Bucurgat Ü, Başaran AA, Başaran N. (2017) – “d-limonene ameliorates diabetes and its complications in streptozotocin-induced diabetic rats.” Food Chem Toxicol. 2017 Dec;110:434-442. doi: 10.1016/j.fct.2017.09.020.

How does Aromatherapy fit in the current Regulation framework ?




Herbal Medicine

Medical Device

Food Supplement

Cosmetic


Definition

Botanic  (s) with therapeutical
purpose & pharmacological action

Safety
Requirements

Based on  recognised traditionnal use
and safety Assessment

Proof of
Efficacy

Based on  recognised traditionnal use
and Scientific Plausibility

Quality
Requirements

GACP for  & GMP-API for Essential
Manufacturing

How does Aromatherapy fit in the current Regulation framework ?



	Herbal Medicine	Medical Device	Food Supplement	Cosmetic
Definition		The botanical product with mechanical action »		
Safety Requirements		In vitro Clinical study		
Proof of Efficacy		In vitro Clinical study		
Quality Requirements		Conformance to ISO13485		

How does Aromatherapy fit in the current Regulation framework ?



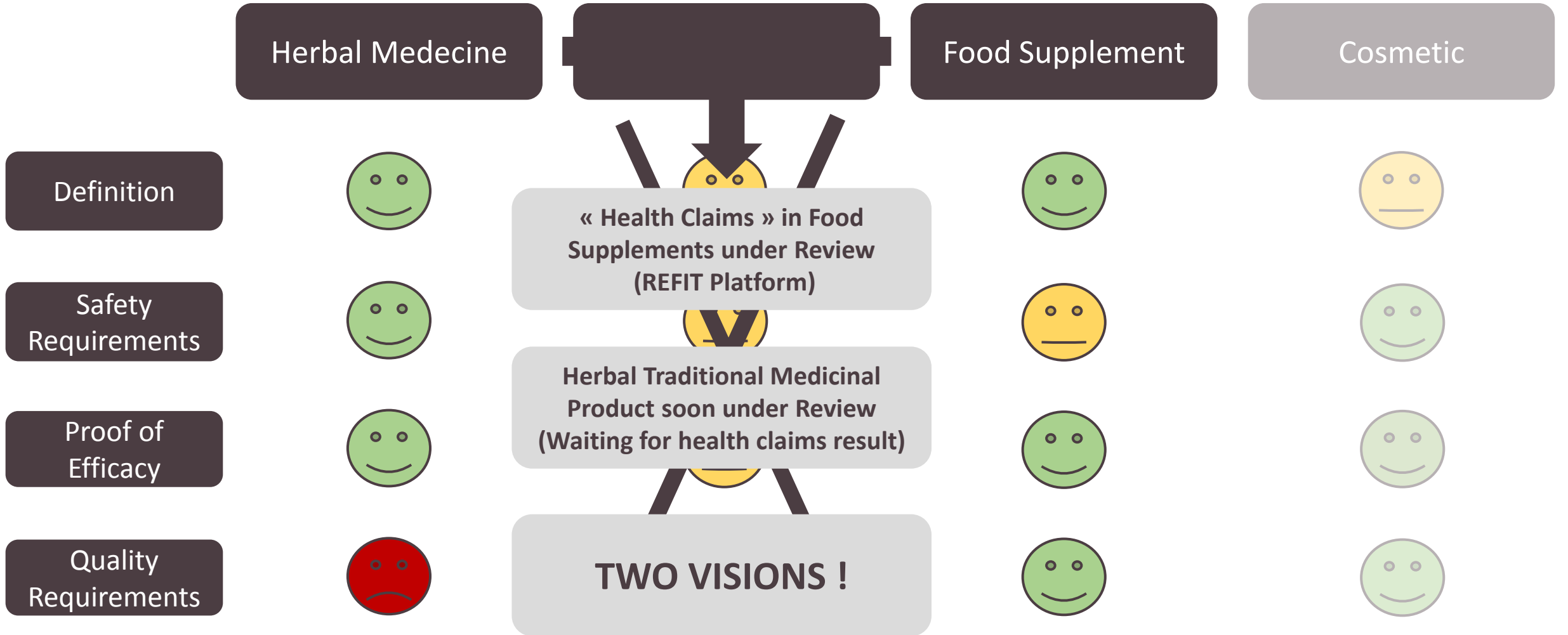
	Herbal Medicine	Medical Device	Food Supplement	Cosmetic
Definition			Foodst health related » but non-therapeutical	
Safety Requirements			Safety A ent & Restrictive Plant List	
Proof of Efficacy			Bota health Claims (on hold)	
Quality Requirements			Food- raw materials & HACCP procedures	

How does Aromatherapy fit in the current Regulation framework ?



	Herbal Medicine	Medical Device	Food Supplement	Cosmetic
Definition				Supereffect & Non-related
Safety Requirements				Compliance Regulation & Safety Assessment
Proof of Efficacy				Experimental Data
Quality Requirements				Compliance ISO 22716

How does Aromatherapy fit in the current Regulation framework ?



What is the future of Aromatherapy from a regulatory stand point ?



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Pharmaceutical version of Aromatherapy



What is the future of Aromatherapy from a regulatory stand point ?



Creation of a Phytotherapy Category

Definition

Product that contributes to Health & well-being and use Botanicals as active substances

Authorised Claims

Specific Health claims that are Scientifically plausible



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Safety Requirements

Complete Safety Assessment based on molecules & Vigilance program



A growing market based on claims that are substantiated by Science

To contribute to Health & well-being without encroaching on drugs field

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Quality Requirements

Upgraded compared to food supplement regulation but REALISTIC

Oil composition & necessary perspective to evaluate the « sustainability » of it.

We have toxicological data of main aromatic molecules present in essential oils

We can implement « Aromavigilance Program »

Not capable of investing in 200 Clinical Studies to ensure the safety of our essential oils portfolio

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Need for Quality Improvement !

We already have high quality standards

What is the future of Aromatherapy?



For the good of all stakeholders, the fast growing market of Aromatherapy should be...

**...a New Science-based field of
« Health & Well-being »**

**... seeking Continuous
Quality Improvement**

**... based on sustainable
Partnerships**

« we should let no room for cow-boys in our industry and on the contrary help those willing to do it better to join our club of ethical and quality-conscious professionals. »

Michel Horn, President of EHPM

THANK YOU FOR YOUR ATTENTION

If you have any question ?



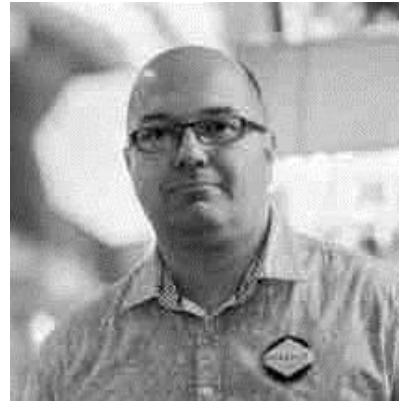
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