



BORDERLINE CLAIMS AND CLAIM SUBSTANTIATION FROM THE VIEW OF AN OFFICIAL COSMETIC CONTROL LABORATORY

ANTI-AGEING SKIN CARE CONFERENCE

Our Chemical & Veterinary Surveillance Institute cvua Karlsruhe



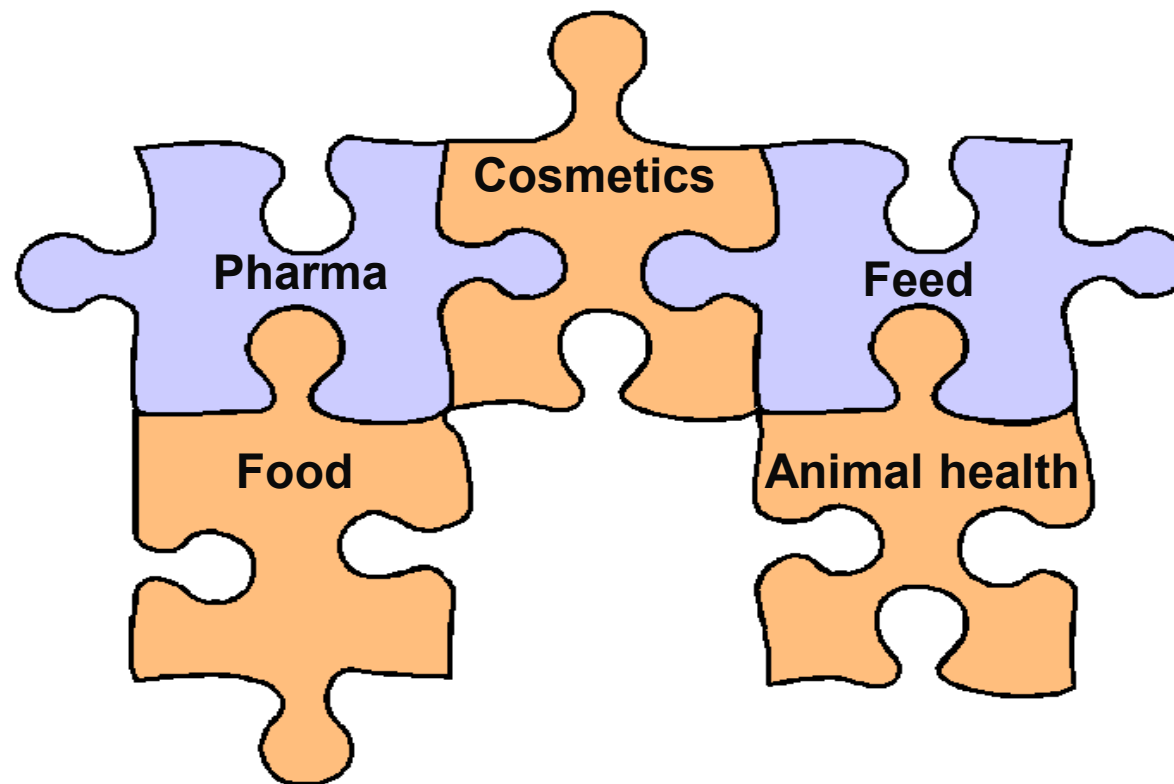
Our Tasks:

Analysis/Assessment of Official Samples

Check of Safety Assessments

Claims Conformity

Consultant for Competent Authorities



Cosmetics Variety Including Tattoo/ Pmu-Inks



Overview : legal regulation with focus on claims for cosmetics and classification in Europe

**EU Cosmetic Regulation
(EC) N° 1223/2009, Art. 20**

**COM Regulation (EU) N°
655/2013 Common Criteria
for Claims**

**Technical Document on
Cosmetic Claims (July 2017)**

**Borderline Manual –Version
2020-09
Guidance Document on the
Demarcation between
Cosmetics and Medicinal
Products**

„tool“, collection of best
practice, not legally binding,
work in progress

Article 20 EC/1223/09

□ EC/1223/09 Article 20 Product claims:

In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.

□ Recital 51 EC/1223/09 (=additional comment):

The consumer should be protected from misleading claims concerning efficacy and other characteristics of cosmetic products...

Common criteria for the justification of claims

According to Commission Regulation (EU) No 655/2013 claims on cosmetic products shall conform to the following common criteria:

- 1. Legal compliance**
- 2. Truthfulness**
- 3. Evidential support**
- 4. Honesty**
- 5. Fairness**
- 6. Informed decision-making**

Technical document on cosmetic claims

- Different types of evidential support can be used to substantiate claims
- Either experimental studies or consumer perceptions tests and/or published informations or combinations of these
- **The aim of the document is to describe best practices specifically related to the type of support used.**

Proof of the effect claimed

- **Documents with proof of the effect claimed for the cosmetic product are part of the product information file (Art. 11 Abs. 2 cosmetic regulation)**
- **These documents have to be readily accessible to the competent authority of the Member State in which the file is kept.**

The acceptability of an advertising claim is based on

- **“the perception of the average end-user of a cosmetic product, who is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors on the market in question“**

Claims substantiation

- **Claims shall be scientifically proven**
- **Concrete requirements can not be defined in general.**
- **It's a case by case decision according the labelled effect**
- **Essential is the relevance of the claim to consumer perception**

Examples for graded claims an their evidence

<ul style="list-style-type: none">• Wrinkles disappear	Evidence not possible
<ul style="list-style-type: none">• Depth of wrinkles reduced by 50 %	Evidence difficult 50 % reduction has to be proved scientifically by adequate and statistical methods
<ul style="list-style-type: none">• Small wrinkles are reduced detectably	Evidence possible by detection of wrinkle depth (adequate scientific method)
<ul style="list-style-type: none">• Small wrinkle look reduced	Evidence proof by better visual appearance

Examples for graded claims an their evidence

- **We often notice, that manufacturers give evidence to their claims only by general (advertising) informations from their suppliers.**
- **These information may not be appropriate to the concrete formulation, for example the product type is another one, the concentration of the active ingredient is lower etc.**
- **We accept only claim substantiation that is adjusted to the product.**

Anti ageing claims

- **Anti ageing claims are not really an issue for surveillance in these days.**
- **Therefore I want to turn to other presently trendy claims, even if they do not mainly deal with anti ageing effect.**

„free from“ claims - examples

- free from preservatives
- free from parabens
- free from silicone
- free from emulsifiers
- free from alcohol
- free from perfumes
- free from allergenic substances

Claims for decision making ?

- **We pose the questions:**
 - in which cases are the claims misleading (and therefore not allowed),
 - in which cases are the claims valuable for consumer regarding decision making (and therefore allowed)
 - Answer is a decision on a by case basis, basically difficult and differently seen from authority to authority
 - Support by technical document

Comments to the *free from* examples

free from preservatives

- Should not be used when the product contains ingredients with protective effect against microorganisms, which are not included in the regulation, for example alcohol etc.
- If the responsible person can prove that this ingredient is not necessary for the microbial stability, the claim can be accepted.

□

Comments to the free from examples

free from parabens

- claims (or claims with similar meaning) should not be allowed when they imply a denigrating message,
- notably when they are mainly based on a presumed negative perception on the safety of the ingredient
- certain parabens are safe when used in accordance to Regulation (EC) No 1223/2009.
- considering the fact that all cosmetic products must be safe, the claim 'free from parabens' should not be accepted.

Until now we have not objected this claim, because from our point of view it can be valuable to allow an informed choice to consumers.

Comments to the free from examples

free from alcohol or free from animal derives ingredients

- should be permitted, if this is a valuable information for certain groups of end users.
- For example: mouth wash products
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Comments to the free from examples

free from perfume

should not be used when a product contains an ingredient which exerts an perfuming function, regardless of it`s other possible functions in the product

free from allergens

can not be permitted, because the absense of an allergic reaction cannot be guaranteed and the product should not give the impression that it does.

Concrete examples: Hair care products (here hair oils)

- Hair oils on silicon basis have actually a bad image because of being synthetic and because they are said to make hair heavier
- Positive image: argan oil or other natural oils in hair care
- There are products on the market with eye catching claims like Arganoil from Marocco , together with well known positive effects (nourish and protects hair, no heaviness on hair)

But: main ingredient is silicon, which can only be noticed by check of the ingredients list , natural oils very very low concentration (which can not be realised by consumer).

Cannabidiol (CBD) aromatherapy

- **Cannabis derivative – currently a hot cosmetic ingredient**
- **label: CBD aromatherapy care oil for external application**
- **striking label applies to joints**
- **recommendation: application on affected parts of body and solar plexus**
- **pictograms indicates to pain release at affected parts**
- **Soft massage shall nourish skin ????**
- **No primary cosmetic purpose**

Organic cosmetic- green washing- cosmetic near to nature



- Broad field with plenty potential for misleading
- Cosmetic ***near to nature***- what is it? Until now no acceptable definition.
- Something between conventional and organic cosmetic, a combination between organic and synthetic ingredients
- Currently we notice: manufacturer explain cosmetic as ***near to nature*** with the absence of substances, for example certain chelating agents.
- From our point of view, ***near to nature*** has to be substantiated with substances present not absent.

Organic cosmetic- green washing- cosmetic near to nature



trend: claim of the sum of substances with natural origin- including water

- **Calculation according the rules written down in ISO_16128**
- **From the technical point of view these figures may be correct**
- **But these figures may easily simulate more naturalness than actually is the case**

Organic cosmetic- green washing- cosmetic near to nature

The following facts have to be considered:

- Water is calculated as natural ingredients- water is the main ingredient of the most cosmetics, so the sum is mostly high and the product seems to be almost natural
- Substances with natural origin, but chemical modified are as well partly calculated as natural (for example the often used amphoteric surfactant cocamidopropylbetain)
- If the product has additionally a *green washed* design, consumer may be misled

It has to be noted, that substances unwanted for natural cosmetics can be present in products in such low concentrations, that they hardly influence the calculated sum of substances of natural origin, for example preservatives like isothiazolinone (allowed limit: 15 mg / kg)

□ |

Free from animal testing

In almost all cases this claim is misleading.

The claim is allowed, if the following requirements are fulfilled:

- **Neither manufacturer of the finished product nor all suppliers have tested their products on animals- at any time or any place (or gave the order to other parties) for the purpose of developing new cosmetic products and can prove it.**

Free from animal testing

- **Only tests for other purposes than development of cosmetics are possible (medicines, food additives)**
- **In practise: it is nearly impossible for the responsible persons to supply evidence**
- **In consequence there cannot be used toxicological data based on animal testing in safety reports**

Alcoholic hand gels

- **Due to corona pandemic a very hot topic**
- **Borderline question: do alcoholic hand gels, which are put on the hands and not washed or wiped off and which *clean* only by removing microorganisms fulfill the cosmetic purpose of cleaning?**
- **That means: Is the removal of microorganisms a cleaning procedure in the sense of the cosmetic regulation?**
- **Or are these products to be classified as biocides?**
- **This point is a urgent topic for the borderline working group of the EU commission**

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Alcoholic hand gels

- **the opinions of the members are very different**
- **Soon a position paper will be published**
- **The current proposal gives recommendations for labelling elements that would not support a main cosmetic function (not to be used in cosmetic products)**
- **Examples: antibacterial, antimicrobial, disinfecting...**
- **For cosmetic products unless the alcoholic hand gels (soaps, washing gels) we accept claims like antibacterial, antimicrobial, if these purposes are secondary and the main function is a cosmetic function.**

Claim substantiation

- **I hope the examples show that claim substantiation is mostly a case by case issue and requires a responsible handling either from manufacturer side as well from official control side.**
- **Thank you for your attention.**