



“Free from” claims made for cosmetic products Guidance note from market surveillance authorities

The French National Agency for Medicines and Health Products Safety (ANSM) and the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) have drafted guidance on compliance with the provisions of Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products. The guidance, set out below, refers to “free from” claims made for certain substances.

A number of different “free from” claims are analysed in view of the criteria laid down in the Regulation, supported by examples and questions to help determine the legal compliance of these claims.

The announcement of the simultaneous “entry into effect” on 1 July 2019 of a new version dated 3 July 2017 of the Technical Document on Cosmetic Claims¹ prepared by a sub-working group set up under the European Commission and the latest Cosmetic Products Code of the French Advertising Self-Regulatory Authority² (ARPP) has raised many questions among professionals.

These two documents provide details on the common criteria that apply under Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products, in particular “free from” cosmetic product claims. The market surveillance authorities acknowledge the profession’s self-regulation initiative in response to the European

¹ Technical Document on Cosmetic Claims (version of 3 July 2017).

² ARPP’s Cosmetic Products Code V8.

Commission's calls for action. The fast-growing number of "free from" claims in the sector has caused mistrust and prevented consumers from easily understanding the messages communicated to them.

The Technical Document is not an official European Commission text. It states the position of a working group on best practice and provides guidance for compliance with Article 20 of Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products which refers to common criteria for the justification of claims used in relation to cosmetic products, but is not legally binding³.

To stop any claims, market surveillance authorities have to refer to the common criteria laid down in Regulation (EU) No 655/2013 of 10 July 2013 and the provisions of the French Consumer Code which apply to pre-contractual information for consumers and fairness. Authorities use these regulatory frameworks to make manufacturers withdraw claims that are untruthful, misleading or ambiguous and prevent consumers from making informed purchasing choices.

However, when the information provided to consumers is "useful, understandable and reliable, and [...] it enables them to take informed decisions and to choose the products that best suit their needs and expectations"⁴, claims should not be stopped until they are investigated further. Consumers are highly attentive to messages communicated to them; lists of ingredients in products are not always easily understandable and consumers receive alarmist information about the quality and safety of the products they use every day.

Because claims are required to comply with the fifth criterion – "Fairness" – of Regulation (EU) No 655/2013 which states that claims must be objective and must not denigrate legally compliant products, this does not mean that all "free from" claims should be considered denigrating or misleading. Some "free from" claims provide consumers with information that helps them choose products to address their particular health problems⁵ (allergies or sensitive skin caused by a treatment, an accident or a surgical procedure) or their lifestyles or beliefs. These claims also allow consumers to access products offering innovative technology or specific benefits, thereby contributing fully to the sixth criterion, "Informed decision-making".

It should be noted that market surveillance authorities are constantly taking action in this area. Most of their action involves asking manufacturers to withdraw questionable claims. If a manufacturer is intentionally misleading consumers, authorities may apply penalties, including administrative measures, and even file a report if a breach is found to have occurred.

The examples provided below are for illustrative purposes and reflect the judgment of market surveillance authorities. They do not pre-empt the outcome of any legal proceedings.

> "Free from" prohibited substances claims and other claims stating compliance with regulations

"Free from [substance name]" claims when the substance is prohibited are in breach of criterion 1(3) of Regulation (EU) No 655/2013, "Legal compliance", and are therefore not permitted.

e.g. "free from corticosteroids"

Similarly, claims stating compliance with regulations are not allowed.

e.g. "not tested on animals"

> Unverifiable "free from" claims

Claims that cannot be verified are in breach of the second criterion, "Truthfulness", and the third criterion, "Evidential support", of Regulation (EU) No 655/2013. The "free from endocrine disruptors" claim is a case in point as there is no official definition of an endocrine disruptor. This claim is too inaccurate and vague given the current scientific understanding of the effects, in particular the long-term effects, of these substances. Even the definition of endocrine disruptors is

³ As stated in the foreword to the Technical Document on Cosmetic Claims of 03/07/2017: "This document shall only serve as 'tool' and is a collection of best practice for the case-by-case application of Union Legislation by the Member-States".

⁴ Regulation (EU) No 655/2013 of 10 July 2013.

⁵ Yet these products cannot claim to have therapeutic benefits.

subject to debate. Any form of communication about this issue risks conveying a message that is simplistic and therefore misleading to consumers.

Likewise, the “free from allergens” claim (i.e. the 26 fragrance allergens as listed in regulations) is potentially misleading because it cannot be verified, since every substance is potentially an allergen. However, “hypoallergenic” is allowed, provided the product has been developed to reduce the chance of developing an allergy and evidence is supplied by the responsible person. To make this claim, the product must not contain any known allergens or allergen precursors, as identified by the Scientific Committee on Consumer Safety (SCCS) or other official risk assessment committees, the CLP Regulation, scientific literature or consumer complaints. In addition, the product must not contain substances for which relevant data about their potential to cause skin sensitisation are missing.

> “Free from” regulated substances claims

“Free from [substance name]” claims when the substance is regulated or authorised⁶, but controversial, should be avoided if those substances can be clearly identified and are listed under their INCI names. These claims give a negative perception of the authorised or regulated substance(s) and are considered denigrating, which is in breach of the fifth criterion – “Fairness” – of Regulation (EU) No 655/2013. Consumers who are seeking to avoid these substances have been adequately informed and can check the list of ingredients before making a purchase.

Furthermore, these claims might prompt consumers to buy products that are less suited to their needs and expectations.

e.g. “triclosan-free”, “paraffin-free”, “sodium laureth sulphate-free”, etc. (substances that can be identified under their INCI name).

> “Free from” groups or families of substances claims

Generally speaking, manufacturers are asked to withdraw claims that refer to a family of chemical substances when some substances are banned and others are authorised. This is to ensure that consumers do not experience any unnecessary fears or confusion about products containing authorised substances, in accordance with the fifth criterion, “Fairness”, of Regulation (EU) No 655/2013. The “free from parabens” claim is a case in point: parabens are a family of chemical substances and harmful parabens have been prohibited. Other similar claims are “phthalate-free” and “free from nanomaterials”. Some phthalates and nanomaterials are banned and others are authorised. Authorised substances are listed under their INCI name when they are present in a product.

The “titanium dioxide-free” claim should not be used either because it can cause confusion. Titanium dioxide is either authorised or prohibited depending on its form (nano form or non-nano form) or its purpose (UV filter or colorant). This claim might also prompt consumers to buy other products that are less suited to their needs and expectations or discourage them from buying products that are beneficial for public health (e.g. sunscreen).

The “aluminium-free” claim should not be used on deodorants clearly identified as such because they are not antiperspirants by definition. For antiperspirants, however, this claim may be allowed provided they still have antiperspirant properties.

> “Free from” claims that are allowed because they are informative

Some “free from” claims are allowed if they provide useful information to consumers with particular health problems (allergies or sensitive skin caused by a treatment, an accident or a surgical procedure) or particular lifestyles or beliefs (for reasons that are ethical, environmental, spiritual, etc.) who wish to avoid a substance or category of substances. This information is particularly useful

⁶ Either explicitly as a preservative, colorant or UV filter or implicitly because it is not prohibited for other uses.

for substances that are not easily identifiable under their INCI name. The question of whether consumers are accessing a legitimate source of information is key to deciding on the legal compliance of “free from” claims.

These claims should be examined on a case-by-case basis depending on the target audience and whether they comply with the sixth criterion, “Informed decision-making”, of Regulation (EU) No 655/2013. They may refer to a certain substance or a group of substances based on their function, specific characteristics (e.g. odour, sensitisation to UV light), manufacturing process, type or origin of ingredients used (plant-based, unprocessed, etc.).

Examples of such claims include “free from alcohol” (with “alcohol” referring to ethanol), “GMO-free”, “free from animal-derived ingredients/substances” (i.e. vegan) and “soap-free”, provided no ingredients are derived from the saponification reaction.

In addition, “free from perfume” (provided no fragrance ingredients are present in the product regardless of its other function(s)) and “colorant-free” (or more specifically “free from artificial colorants” or “free from added colorants”) are also considered to provide consumers with useful information, as cited in the Technical Document of 3 July 2017.

“Free from preservatives” is also allowed (as per the Technical Document of 3 July 2017) provided the product does not contain any substances showing a protective effect against micro-organisms, which are not included in Annex V of Regulation (EC) No 1223/2009, e.g. alcohol. This claim could be examined on a case-by-case basis to ensure that consumers have not been misled on the ingredients used in the product as preservatives.

Similarly, “free from sulphate surfactants”, “silicone-free” and “free from mineral oils or synthetic oils” may also be considered to provide consumers with useful information because they highlight the ingredients or manufacturing process of a product that are likely to improve its quality or be innovative in relation to products with the same purpose.

N.B. The guidance provided here on claims used should be taken as a whole and not in any particular order of importance.

Référence regulations

[Regulation \(EC\) No 1223/2009 of 30 November 2009 on cosmetic products](#)

[Regulation \(EU\) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products](#)

Les éléments ci-dessus sont donnés à titre d'information. Ils ne sont pas forcément exhaustifs et ne sauraient se substituer aux textes officiels.

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signal.conso.gouv.fr

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rappel.conso.gouv.fr

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0809 540 550
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34935 Montpellier Cedex

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