

The Netherlands

Health Claims for Botanicals: 'On Hold', yet Forbidden?

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I. Introduction

In our last country report (EFFL 6/2015), we stressed that the Dutch Advertising Code Committee (ACC) is a force to reckon with in Dutch food law. Apart from applying rules on misleading and comparative advertising, the ACC also applies specific statutory food regulations, such as provisions on food information (FIC Regulation) and on nutrition and health claims (Claims Regulation). The ACC also decides over product packaging – even though it is not advertising in its strict meaning. As we will show in this country report, the ACC also has an outspoken view on health claims for botanicals. While health claims for botanicals are 'on hold' at the European level, the ACC treats the presentation of botanicals very critically, effectively marginalising the possibilities to market their health benefits.

II. Health Claims for Botanicals: 'On Hold'

On the basis of the European Claims Regulation (1924/2006), the use of health claims is subject to strict conditions. A producer is only allowed to make a health claim, e.g. "*contributes to the normal functioning of the immune system*", if such a claim is on the list of approved health claims as appended to the Claims Regulation.

So far, one group of products falls outside the strict regime of the Claims Regulation: botanicals. Botanicals are food supplements consisting of herbs, such as nettle and echinacea. Many botanicals have been on the market for decades. The EU was not yet ready to take a decision on the assessment of (traditional) proof where botanicals are concerned. They are 'on hold': health claims for herbs for which an EFSA approval application was filed are allowed for the time being, despite the fact that furnished proof of the claim has not yet been assessed.

III. Botanicals in the Netherlands: Monitoring by KOAG/KAG

Generally, the Netherlands also stick to this 'on hold' practice. KOAG/KAG, the Dutch council for the monitoring of health products, approves the marketing of botanicals with health claims for which an EFSA application is pending, as long as the product meets some basic conditions. The packaging should clearly state which herb is responsible for what effect. In addition, the dosage should fit the claim as filed with EFSA, and medical claims are not allowed.

Although notification of food supplements is not mandatory in the Netherlands, companies can voluntarily ask KOAG/KAG to approve the marketing of their products, e.g. product labels, but also advertising materials and website content. KOAG/KAG is non-governmental, but it works in close cooperation with the Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel- en Warenautoriteit*, hereafter NVWA). Having clearance from KOAG/KAG provides a significant advantage since, in principle, NVWA does not take enforcement measures against labels or advertising materials that have been cleared by KOAG/KAG. As a consequence, health claims for botanicals are very unlikely to be challenged by NVWA as long as they meet the basic conditions of KOAG/KAG. This may change as soon as the EU fulfils its task of assessing the various health claims for botanicals, but for now botanicals get the benefit of the doubt.

IV. Approach of the ACC: 'On Hold', yet Forbidden

The approach of the ACC is surprisingly different. In its decisions, the ACC requires hard scientific evi-

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dence, regardless of the question whether the claims are on hold. For example, the ACC recently decided that the claim “enhances concentration and memory” on the packaging of a product called “Bacopa Arkocaps” was misleading.¹ Each of the Bacopa Arkocaps capsules contained 200 mg bacopa manniera extract, a South Asian botanical that has a reputation for enhancing concentration and memory. Proof for the claim has been filed at EFSA, but EFSA has not yet assessed the claim as a result of the ‘on hold’ policy. In the proceedings at the ACC, KOAG/KAG – which is asked for its opinion by the ACC as a standard procedure – did not see any objection to using the claim since it is ‘on hold’ and because the product met KOAG/KAG’s basic conditions. However, the ACC ignores the special status of botanicals, arguing that the claim is not proven. In two other recent decisions on ‘green coffee’, the ACC also disregarded the special status of botanicals.²

1 ACC, 4 August 2015, 2015/00733, Bacopa Arkocaps.

2 See ACC, 11 June 2015, 2015/00276, Green Coffee, in: ACC, 7 August 2015, 2015/00589, De Tuinen Groene Koffie.

V. Conclusion

From a misleading advertising perspective, it is not strange to require hard evidence for any serious claim that is made, be it for mobile phone subscriptions, vacuum cleaners or food supplements. However, botanicals – at least for the time being – have a special status at the EU level. The fundamental question as to what type of evidence is sufficient to support health claims is undecided. Until the European Commission answers this question, health claims for botanicals are allowed.

Taking into consideration the ‘on hold’ status of botanicals in the specific context of health claims, it seems strange to require hard evidence in relation to misleading advertising. The special status of botanicals is recognized by KOAG/KAG and the NVWA, but the ACC remains exceptionally strict. By doing so, the ACC ignores European policy and obscures the legal and economic playing field for botanicals. The ACC should feel free to strictly assess any health claims for botanicals for which no application has been filed at EFSA, or which does not meet the basic conditions. However, requiring hard evidence for claims made in accordance with pending EFSA applications goes against the European current.