



BULLETIN INTENDED FOR INTERESTED PARTIES

16 April 2014

Article 13(1) 'on hold' health claims spreadsheet

As you are aware, the only Article 13(1) health claims permitted now are those listed as 'authorised' in the [EU Register of claims](#); and those put 'on hold' by the European Commission (EC). A list of all the 'on hold' claim ID numbers can be found on the [EC website](#).

Claims 'on hold' may be used while they are still under consideration, subject to the transition measures in Article (28)(5) of the Nutrition & Health Claims Regulation (EC) 1924/2006. Our interpretation is that this means that they must comply with Articles 3,5,6,7 & 10 of the Regulation as well as other relevant national legislation. Claims must be scientifically substantiated and an individual using a claim must be able to justify its use.

However, the Department has often been asked by enforcement officers and businesses for help in trying to find which Article 13(1) health claims for botanicals and non-botanicals (e.g. caffeine, lactose, very low calorie diet) are considered as 'on hold'. We refer people to the ['on hold' list published by the EC on the Europa website](#); [the European Food Safety Authority's \(EFSA\) Access database of Article 13\(1\) health claims](#) (zipped file), submitted for assessment; [the EFSA Register of Questions database](#); and the [EU Register of Claims](#). However we realise searching everything can be a difficult task, hence we have created the attached spreadsheet of Article 13(1) 'on hold' health claims which we hope is more straight forward to use.

We have extracted some information specifically relating to 'on hold' claims from the EFSA Access database of Article 13(1) health claims submitted for assessment (i.e. [the zipped file](#)) and transferred this information into the attached spreadsheet. Claims are listed by substance name, health relationship originally proposed; claim wording originally proposed and ID number. The majority of the claims relate to botanical substances but there are a few related to caffeine, foods with reduced lactose content and a very low calorie diets.

Please consider the following points when using the information in the spreadsheet:

1. An Article 13(1) general function health claim relating to a botanical substance used now should only be considered to be an 'on hold' claim if it relates to the same plant part(s) as a claim in the spread sheet and the wording(s), health relationship and if applicable any proposed conditions of use (e.g. the dose) are the same. [The Access database of all Article 13\(1\) submitted to EFSA](#) (zipped file) *may* provide further details on any proposed conditions of use. The attached spreadsheet does not provide this level of information.
2. Some claims, similar to claims in the attached spreadsheet, are listed in the [EU Register](#) as 'non-authorised' (e.g. certain claims on caffeine and antioxidants). These can no

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longer be used so you should check in the Register as well as the spreadsheet when considering whether a claim can be used.

3. Some 'on hold' claims were submitted to EFSA in a language other than English and these should not be translated into English as the wording could be misleading.
4. Many of the proposed claim wordings may not be acceptable under the general provisions of Regulation (EC) 1924/2006 or general food labelling rules.
5. If it is not clear whether a product containing botanical substances should be regulated as a food supplement or as a medicinal product, please contact the Medicines Borderline Section at the Medicines & Healthcare products Regulatory Agency (MHRA) in the first instance: borderline_medicine@mhra.gsi.gov.uk
6. Some of the proposed health relationships and claim wordings may be construed as medicinal claims and must not be made on foods. The Borderline section at the MHRA can advise.
7. Some of the substances listed may be unauthorised novel substances. The Food Standards Agency will be able to advise: novelfoods@foodstandards.gsi.gov.uk

We intend to update and circulate the spreadsheet as soon as any of the claims listed are no longer considered as 'on hold'.

We hope the spreadsheet is helpful.

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