

# BARRY CALLEBAUT GUIDANCE ON THE USE OF THE COCOA FLAVANOL HEALTH CLAIM IN THE EUROPEAN UNION<sup>1</sup>

## Introduction

The legal requirements when making a health claim regarding cocoa flavanols in a commercial context - whether in labelling, presentation or advertising and in whatever medium including websites, radio and television - are defined in:

- EU Regulation 1924/2006 on nutrition and health claims made on foods<sup>2</sup>
- EU Commission Implementing Decision 2013/63 adopting guidelines concerning Article 10 of EU Regulation 1924/2006<sup>3</sup>
- EU Regulation 851/2013<sup>4</sup> authorising certain health claims made on foods and amending Regulation (EU) No 432/2012<sup>5</sup>

Further guidance is provided by the EU Commission and Member States in among others:

- EU Guidance of 14 December 2007 on the implementation of EU Regulation 1924/2006<sup>6</sup>
- UK summary of 19 June 2012 on the general principles on flexibility of wording for health claims as discussed by experts of 17 EU Member States<sup>7</sup>

The present Barry Callebaut Guidance aims to summarise the legal requirements when making a health claim on cocoa flavanols in order to help you to comply with the legislation.

It goes without saying that all legal requirements as defined in the above regulations must be met, which includes not being false, ambiguous or misleading, not encouraging or condoning excess consumption of a food, not implying that a balanced diet cannot provide necessary nutrients and not referring to recommendations of individual doctors or health professionals on the food.

It has to be kept in mind that, although the Regulation on nutrition and health claims has been defined at EU levels and thus applies directly in each EU Member State, it is the National Authorities that control the use of the claims in the different EU Member States.

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<sup>1</sup> This guidance may not be interpreted as an acceptance by Barry Callebaut of any adapted wording of the authorized claim. The operator under whose name or business name the food is marketed or, if that operator is not established in the Union, the importer into the Union market is solely responsible for the presentation, communication and/or labelling of the final product.

<sup>2</sup>[http://eur-lex.europa.eu/search.html?instInvStatus=ALL&or0=DTS%3D3,DTS%3D0&or1=DTT%3DR&DTN=1924&DTA=2006&qid=1413463444699&DTC=false&DTS\\_DOM=ALL&type=advanced&SUBDOM\\_INIT=ALL\\_ALL&DTS\\_SUBDOM=ALL\\_ALL](http://eur-lex.europa.eu/search.html?instInvStatus=ALL&or0=DTS%3D3,DTS%3D0&or1=DTT%3DR&DTN=1924&DTA=2006&qid=1413463444699&DTC=false&DTS_DOM=ALL&type=advanced&SUBDOM_INIT=ALL_ALL&DTS_SUBDOM=ALL_ALL)

<sup>3</sup> <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013D0063>

<sup>4</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0851&rid=1>

<sup>5</sup><http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1416932706346&uri=CELEX:02012R0432-20140513>

<sup>6</sup> [http://ec.europa.eu/food/food/labellingnutrition/claims/guidance\\_claim\\_14-12-07.pdf](http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf)

<sup>7</sup> <https://www.gov.uk/government/publications/update-on-flexibility-of-wording-for-health-claims>

Differences in interpretations of the nutrition and health claims Regulation can therefore occur between these countries. Therefore it is recommended to take into account national guidance where needed.

#### The approved health claim

The EU Regulation 851/2013 authorises the health claim:

**Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow**

The following conditions of use apply:

**The claim can be used only for cocoa beverages (with cocoa powder) or for dark chocolate which provide at least a daily intake of 200 mg of cocoa flavanols degree of polymerisation 1-10.**

#### Authorised use of the approved health claim

The approved health claim has been authorised on 24.9.2013 on the basis of proprietary data. This means that the health claim is restricted to the use of Barry Callebaut Belgium NV, Aalstersestraat 122, B-9280 Lebbeke-Wieze, Belgium, for a period of five years and to any customer who has been granted authorisation by Barry Callebaut by signing the licensing agreement.

The health claim can only be made for dark chocolate as such and for cocoa beverages with cocoa powder.

#### Rewording of the approved Health Claim into a more commercial wording

The following principles need to be taken into account when using other wording for the health claim:

- It is recommend to stick as closely as possible to the authorised wording of health claims
- Some flexibility of wording of the claim is possible provided its aim is to help consumer understanding, taking into account factors such as linguistic and cultural variations and the target population. Adapted wording must have the same meaning for the consumer as the authorised claim in the EU Register and therefore must demonstrate the same relationship between the substance and the claimed beneficial effect.
- The claim may not be made “stronger”, e.g. by using wording like “stimulates” instead of “contributes”. Moreover, the claim may not be misleading.
- The cocoa flavanol health claim has been authorised under the article 18 procedure as a health claims describing or referring to the role of a substance in the functions of the body. Hence, it is not authorised to refer to any disease risk factor or to children’s development or health. Using the claim on products specifically designed for children can therefore not bear the cocoa flavanol health claim.

- It is allowed to focus on selective parts of the approved health claim on the label under the condition that reference is made to the full health claim.
- Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being in the form of an attractive statement (e.g. good for your health) may be made if
  - a specific authorised health claim is made 'next to' or 'following' such a statement and
  - the specific authorised health claim has to bear some relevance to the general reference. It is the responsibility of the food business operators making the general, non-specific claim to demonstrate the link between the statement and the accompanying specific health claim.
- The health claims can only be made for the substance for which they have been authorised (cocoa flavanols), and not for the food product that contains them (chocolate, cocoa beverage).

Based on the above principles it is our understanding that the following non-exhaustive examples of other wordings for the health claim:

- Are compliant with the legal requirements:
  - o Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood circulation
  - o Cocoa flavanols help maintain the elasticity of blood vessels, which supports a normal blood flow
  - o Cocoa flavanols (as) (naturally) present in cocoa/chocolate help maintain the elasticity of blood vessels, which contributes to normal blood flow
  - o Chocolate contains cocoa flavanols. Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow
  - o Cocoa flavanols help support vascular health by helping to maintain blood vessel elasticity, which contributes to a normal blood flow.
  - o Cocoa flavanols plays a role in the cardiovascular system. Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow
  - o Flavanols belong to a larger group of polyphenols. Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow.
  - o Good for your blood flow (this is a general non specific claim, an asterisk to the full specific wording of the authorised health claim must be added)
  - o Helps to maintain cardiovascular health (this is a general non specific claim, an asterisk to the full specific wording of the authorised health claim must be added)

- Are compliant with the legal requirements in some EU Member States (to be checked with National Authorities)
  - o Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to maintaining/the maintenance of a healthy/good/proper blood flow
  - o Cocoa flavanols helps maintain the elasticity of blood vessels, which optimises a normal blood flow
  
- Are not compliant with the legal requirements
  - o Cocoa/chocolate helps maintain the elasticity of blood vessels, which contributes to the maintenance of a normal blood flow
  - o Cocoa/chocolate with cocoa flavanols helps maintain the elasticity of blood vessels, which contributes to the maintenance of a normal blood flow
  - o Polyphenols help maintain the elasticity of blood vessels, which contributes to normal blood flow.
  - o Cocoa flavanols helps maintain the elasticity of blood vessels, which stimulates a normal blood flow
  - o Cocoa flavanols are good for your heart as they help maintain the elasticity of blood vessels, which contributes to the maintenance of a normal blood flow

#### Additional labelling requirements when making the health claim

When making a health claim on a food product about the cocoa flavanols and blood flow, the following pieces of information are mandatory on the label in addition to the standard labelling requirements as defined in the EU Regulation 1169/2011 on food information to consumers<sup>8</sup>:

- the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect  
E.g. Enjoy 10 g of this dark chocolate a day to help maintain the elasticity of blood vessels, which contributes to normal blood flow.
- A statement on the importance of a varied and balanced diet and a healthy lifestyle.  
Both informations can be combined.  
E.g.: 10 g a day of this dark chocolate as part of a varied and balanced diet and a healthy lifestyle help maintain the elasticity of blood vessels, which contributes to normal blood flow.
- The amount of the cocoa flavanols present in 100g. This information must be given in the same field of vision as the nutrition information table (but not in the nutrition

<sup>8</sup>[http://eur-lex.europa.eu/search.html?instInvStatus=ALL&or0=DTS%3D3.DTS%3D0&or1=DTT%3DR&DTN=1169&DTA=2011&qid=1413533757661&DTC=false&DTS\\_DOM=ALL&type=advanced&SUBDOM\\_INIT=ALL\\_ALL&DTS\\_SUBDOM=ALL\\_ALL](http://eur-lex.europa.eu/search.html?instInvStatus=ALL&or0=DTS%3D3.DTS%3D0&or1=DTT%3DR&DTN=1169&DTA=2011&qid=1413533757661&DTC=false&DTS_DOM=ALL&type=advanced&SUBDOM_INIT=ALL_ALL&DTS_SUBDOM=ALL_ALL)

information table itself). Additionally the amount of flavanols may also be given for the portion or serving size.

E.g: Flavanols: 2000 mg per 100g dark chocolate

### Nutrition claims

Nutrition claims on cocoa flavanols, as stand alone or additionally to the cocoa flavanols health claim, can also be made.

Products other than dark chocolate as such or cocoa beverages that contain dark chocolate and/or cocoa powder (e.g. greek yoghurt with dark chocolate pieces or nutrition bars with cocoa powder) are currently only allowed to carry a nutrition claim on cocoa flavanols.

The following principles must be followed:

- only “contains” nutrition claims on flavanols or cocoa flavanols or any claim likely to have the same meaning for the consumer, e.g. “source of” are allowed. It is not allowed to use claims like “high flavanol” or any claim likely to have the same meaning for the consumer.
- nutrition claims on polyphenols (e.g. contains polyphenols, contains x% of polyphenols) are not allowed, but reference to polyphenols can be made in the nutrition claim on cocoa flavanols.
- Comparative claims are not allowed for substances like cocoa flavanols.

Based on the above principles and to the best of our knowledge the following examples of nutrition claims

- Are possible:
  - o contains/source of (cocoa) flavanols
  - o contains x% (cocoa) flavanols
  - o with naturally present cocoa flavanols
  - o with x% naturally present cocoa flavanols
  - o contains cocoa flavanols. Cocoa flavanols are part of a larger group of polyphenols
  - o contains x mg of (cocoa) flavanols per portion of x gr
  - o guaranteed 200 mg of cocoa flavanols per portion of x gr
- Are not possible:
  - o rich in (cocoa) flavanols
  - o increased (cocoa) flavanols
  - o with extra flavanols
  - o contains more flavanols than ...
  - o contains x times as much as ...
  - o contains “as much flavanols as” ...
  - o contains polyphenols

In the case only a nutrition claim is made on the product, the following labelling requirement, additionally to the labelling requirements as defined in the EU Regulation 1169/2011 on food information to consumers<sup>9</sup>, applies:

- The amount of the cocoa flavanols present in 100g must be labelled. This information must be given in the same field of vision as the nutrition information table (but not in the nutrition information table itself). Additionally the amount of flavanols may also be given for the portion or serving size.  
E.g: Flavanols: 2000 mg per 100g dark chocolate

In the case an additional health claim is made, the above labelling requirements as detailed under the title “Additional labelling requirements when making the health claim” apply.

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<sup>9</sup>[http://eur-lex.europa.eu/search.html?instInvStatus=ALL&or0=DTS%3D3,DTS%3D0&or1=DTT%3DR&DTN=1169&DTA=2011&qid=1413533757661&DTC=false&DTS\\_DOM=ALL&type=advanced&SUBDOM\\_INIT=ALL\\_ALL&DTS\\_SUBDOM=ALL\\_ALL](http://eur-lex.europa.eu/search.html?instInvStatus=ALL&or0=DTS%3D3,DTS%3D0&or1=DTT%3DR&DTN=1169&DTA=2011&qid=1413533757661&DTC=false&DTS_DOM=ALL&type=advanced&SUBDOM_INIT=ALL_ALL&DTS_SUBDOM=ALL_ALL)