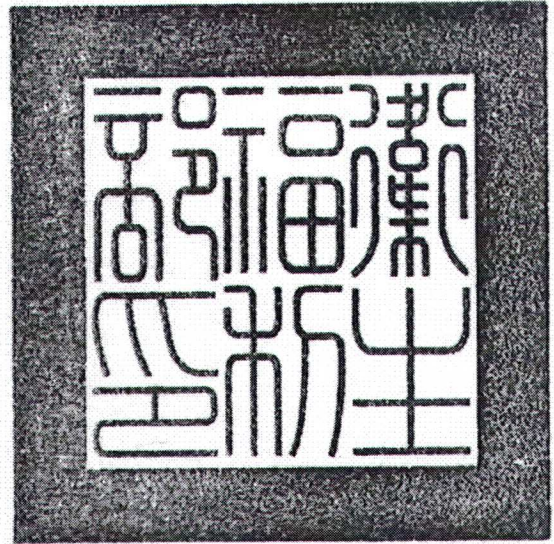


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## 衛生福利部 公告

發文日期：中華民國111年11月8日  
發文字號：衛授食字第1111302625號  
附件：修正規定之總說明及對照表各1份



主旨：修正「健康食品應加標示事項」，並自中華民國一百十三年一月一日生效。

依據：健康食品管理法第十三條第一項第十一款。

公告事項：修正「健康食品應加標示事項」。

部長 薛瑞元

## 健康食品應加標示事項修正總說明

衛生福利部前依據健康食品管理法第十三條第一項第十一款規定，於一百零八年一月十七日以衛授食字第一〇七一三〇三八二〇號公告訂定「健康食品應加標示事項」；為整併有關健康食品之相關標示規定，將一百零八年一月十七日衛授食字第一〇七一三〇三八三二號公告「健康食品應於產品容器或外包裝明顯標示保健功效之相關成分含量」，及一百零六年七月十七日衛授食字第一〇六一三〇〇五九〇號函修正「健康食品查驗登記審查原則」涉健康食品標示部分規定，以及含魚油及紅麴原料警語標示，納入健康食品應加標示事項，全文共九點，其修正要點如下：

- 一、法源依據。(修正規定第一點)
- 二、健康食品應標示保健功效或品管指標之成分及其含量。(修正規定第二點)
- 三、健康食品保健功效敘述之標示規定。(修正規定第三點)
- 四、健康食品之注意事項標示規定。(修正規定第四點)
- 五、健康食品含外加精緻糖之注意事項標示規定。(修正規定第五點)
- 六、健康食品含魚油原料之警語標示規定。(修正規定第六點)
- 七、健康食品含紅麴原料之警語標示規定。(修正規定第七點)
- 八、健康食品之注意事項及警語標示格式規定。(修正規定第八點)
- 九、國產產品及輸入產品之緩衝規定。(修正規定第九點)



## 健康食品應加標示事項修正規定

- 一、本規定依健康食品管理法(以下簡稱本法)第十三條第一項第十一款規定訂定之。
- 二、健康食品應於容器或外包裝，標示保健功效成分及其含量；未核有保健功效成分者，應標示其品管指標成分及其含量。
- 三、健康食品之容器或外包裝標示之保健功效敘述，應為下列之刊載：
  - (一) 符合本法第三條第一項第二款規定取得許可證者：於保健功效敘述之文字後，加載「功效由學理得知，非由實驗確認。」或等同字義之文字。
  - (二) 以動物實驗進行保健功效評估者：載明「經動物實驗結果，有助於該特定保健功效敘述」或等同字義之文字。
- 四、健康食品之容器或外包裝標示之注意事項，應包括下列內容：
  - (一) 膠囊及錠狀型態者：
    1. 本產品非藥品，供保健用，罹病者仍需就醫。
    2. 請依建議攝取量食用，勿過量。
  - (二) 膠囊及錠狀以外型態者：本產品供保健用，請依建議攝取量食用。
- 五、健康食品之每日建議攝取量，其所含外加精緻糖十七公克以上者，應標示「本品依每日建議攝取量〇〇公克/毫升，所含外加精緻糖量達〇〇公克，請注意熱量攝取。」或等同字義之文字。
- 六、健康食品含魚油原料者，其警語標示之內容，應包括「嬰幼兒、孕婦、糖尿病患者或正在服用抗凝血劑之凝血功能不全者，食用前請先徵詢醫師意見。」或等同字義之文字。
- 七、健康食品含紅麴原料者，其警語標示之內容，應包括「本品與降血脂藥 (statin 及 fibrate 類藥物)、葡萄柚合併使用，恐會造成肝、腎損傷、橫紋肌溶解症。」或等同字義之文字。
- 八、依前四點規定標示之內容，其字體顏色應與底色區別。
- 九、國產產品之製造日期或輸入產品之進口日期於本規定生效日前者，可繼續販賣至其有效日期屆至為止。

## **Regulations governing the labeling of health food**

1. The Regulations are set forth pursuant to the subparagraph 11 of paragraph 1 of Article 13 of the Health Food Control Act (hereinafter referred to as "Act").
2. The containers or packages of health food shall be labeled with the related ingredients with health care effect and its content, but it shall be labeled by ingredients with quality control criteria if the related ingredients with health care effect are unapproved.
3. The containers or packages of health food shall be labeled the approved description of health care claims to meet the following requirements:
  - (1) The product conforming to the subparagraph 2 of paragraph 1 of Article 3 of the Act shall be stated "the health care effects of the product is known from academic theory but not approved by product experiments" or other similar statements with the same meaning in the behind of the description of "health care claims".
  - (2) The experiments using animal model to assess the health care effect of the health food shall be stated "Based on the testing results from animal model, the product can help to..." or other similar statements with the same meaning in the front of the description of health care claims.
4. The containers or packages of health food shall be labeled the following precautions at least:
  - (1) Health food in capsule and tablet form
    - i. This product is not a drug, for health care only. Patients still need medical treatment.
    - ii. Please eat according to the recommended intake, excessive intake does not benefit health.



(2) Health food in other than capsule and tablet form

This product is for health care only, without therapeutic efficacy.

5. Health food with additional refined sugar over 17 grams of the recommended daily intake shall be labeled “The additional refined sugar will reach 00 grams when eating the product in accordance with the recommended daily intake 00 grams (g)/ milliliter (mL) and be care of the caloric intake.” or other similar statements with the same meaning.
6. Health food with fish oil shall be labeled “Infants, pregnant women, patients with diabetes mellitus or the people with abnormal blood coagulation taking anticoagulant are suggested to ask doctor’s recommendations before eating.” or other similar statements with the same meaning in the warnings on containers or packages.
7. Health food with red yeast rice shall be labeled “Eating this product combined with statin- and fibrate-derived hypolipidemic agents or grapefruit may result in liver and kidney hurt or rhabdomyolysis.” or other similar statements with the same meaning in the warnings on containers or packages.
8. The above four points that related the precautions and statements in the warnings on containers or packages of health food shall be displayed distinct color from the background color.
9. The domestic and foreign products based on their manufacturing and import date before the promulgation date, respectively, can still sell continuously until their expiry date.