

歐洲共同體執委會 2000 年 1 月 10 日第 50/2000 號

「關於含有基因改造有機體或由基因改造有機體製成之添加物與香料之食品與食品配料之標示」規章

COMMISSION REGULATION (EC) No 50/2000 of 10 January 2000

on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms

歐洲共同體執行委員會，
基於建立歐洲共同體條約，

根據理事會 1978 年 12 月 18 日第 99/112/EEC 號「關於各會員國就食品^①之標示、說明及廣告等相關法規之同化調整」準則（最近一次修正是歐洲議會暨理事會第 97/4/EC 號準則），^②特別是根據第 4 條第 2 項規定，

基於以下理由：

(1) 歐洲共同體歐洲議會暨理事會第 258/97 號「關於新穎食品與新穎食品配料」規章^③，不適用於用於食品之添加物與香料，因為該等添加與香料並無安全上疑慮，因此屬於其他共同體法規的適用範圍，亦即理事會 1988 年 12 月 21 日第 89/107/EEC 號「關於各會員國就用於食品之添加物相關法規之同化調整」準則^④（最近一次修正是歐洲議會暨理事會第 94/34/EEC 號準則^⑤）；以及理事會 1988 年 6 月 22 日「關於各會員國就用於食品之香料及其原料的相關法規之同化調整」準則^⑥（最近一次修正是執委會第 91/71/EEC 號準則^⑦）。

(2) 此處所涉及之食品添加物與香料亦不在歐洲共同體理事會 1998 年 5 月 26 日第 1139/98 號「關於由基因改造有機體所製成之特定食品標示之應說明事項，補充第

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 99/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs^①, as last amended by Directive 97/4/EC of the European Parliament and the Council^②, and in particular Article 4 (2) thereof,

Whereas:

- (1) Regulation (EC) No 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients^③ does not apply to additives and flavourings intended to be used in foodstuffs as, for the purpose of testing these substances for their safety evaluation, they come under other Community provisions, namely Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption^④, as amended by Directive 94/34/EEC of the European Parliament and of the Council^⑤, and Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production^⑥, as amended by Commission Directive 91/71/EEC^⑦;
- (2) these additives and flavourings are also excluded from the scope of Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication, on the labelling of certain foodstuffs

79/112/EEC 號準則之要求」規章⁹的適用範圍之內。

- (3)從而基因改造或由基因改造有機體所製成之作為配料而用於食品之食品添加物與香料，即不適用歐洲共同體第 258/97 號規章第 8 條特殊標示要求之規定，也不適用歐洲共同體第 1139/98 號規章第 2 條標示要求之規定。
- (4)消費者應有權獲知食品添加物與香料是使用基因改造或藉助於生物科技所製成，如同消費者已可獲知含有基因改造有機體或由基因改造有機體所製成之食品配料般。
- (5)若干會員國有意於內國法範疇明定，凡添加物與香料是由基因改造有機體所製成者，必須加以標示，以使消費者可得而知此情事。
- (6)前述法規對於共同體內部貿易有形成新的障礙之虞。
- (7)執委會於其 1998 年 10 月 21 日第 98/613 號「關於奧地利對於標明用來作為食品配料之基因改造添加物及香料的法案」決定中，作成一項會員國也一致同意的結論⁹，共同體之標示規定乃最適切之解決方案。
- (8)有鑑於此，依據與由基因改造有機體所構成、包含基因改造有機體或由基因改造有機體所製成之食品配料

than those provided for in Directive 79/112/EEC⁹,

- (3)a consequence of this exclusion is that additives and flavourings that have been genetically modified or have been produced from genetically modified organisms and are used as ingredients in foodstuffs are not subject to the specific labelling provisions laid down in Article 8 of Regulation (EC) No 258/97 and the labelling provisions laid down in Article 2 of Regulation (EC) No 1139/98;
- (4)it is important that consumers should also be informed of the use of additives or flavourings that have been genetically modified or have been produced through genetic engineering as they are already informed of the presence of other ingredients containing or produced from genetically modified organisms;
- (5)some Member States have served notice of their intention to impose at national level indications on labelling informing consumers of the use of additives and/or flavourings produced from genetically modified organisms;
- (6)such provisions are likely to create new obstacles to intra-Community trade;
- (7)the Commission, in its Decision 98/613/EC of 21 October 1998 concerning a draft decree of the Republic of Austria concerning the identification of genetically modified additives and flavourings⁹, took the view, with the agreement of the Member States, that the most satisfactory solution would be to draw up Community provisions on labelling;
- (8)accordingly, it would be useful to make it obligatory to indicate on the labelling of the foodstuffs concerned that the additives or flavourings used are or contain genetically modified organisms or

之標示相同的原則，對於此處所涉及之食品的標示而言，凡所使用之食品添加物與香料為基因改造有機體、包含了基因改造有機體或由基因改造有機體所製成者，均應就其強制性說明義務予以規定。

- (9) 本規章之條款不適用於非售予終端消費者之添加物與香料。此等添加物與香料應另外規定其標示之要求。
- (10) 依據歐洲共同體第 258/97 號規章第 8 條之規定，終端消費者應有權獲知一項食品之所以不同於既有之食品或食品配料之所有特徵或營養特性，如成分、營養價值或營養效益及使用目的等。基此，與傳統添加物與香料價值不同之基因改造添加物與香料，或由基因改造有機體所製成之添加物與香料，即應確定其相應之標示要求。
- (11) 依據歐洲共同體第 258/97 號規章第 8 條之規定，標示要求須以科學性評估為基礎。
- (12) 對於前述商品，應確定其可讓行政機關得以於可靠的、得複製的、實用的基礎上加以監督的標示要求。
- (13) 此外亦須確保標示之要求雖不至於過度複雜，卻同時包含了使消費者得以獲知所期望之資訊所必要的說明。

have been produced from such organisms, in accordance with the same principles as those laid down for the labelling of ingredients that are, contain, or are produced from genetically modified organisms;

- (9) the provisions of this Regulation do not apply to additives and flavourings sold as such to the final consumer. Separate measures imposing similar obligatory labelling for additives and flavourings should be introduced;
- (10) in particular, in accordance with the approach adopted in Article 8 of Regulation (EC) No 258/97, it is necessary to ensure that the final consumer is informed of any characteristic or food property such as composition, nutritional value or nutritional effects or the intended use of the food, which renders this food or food ingredient no longer equivalent to an existing food or food ingredient. To this end additives and flavourings that have been genetically modified or have been produced from genetically modified organisms that are not equivalent to their traditional counterparts must be subject to labelling requirements;
- (11) in accordance with the approach adopted in Article 8 of Regulation (EC) No 258/97, labelling requirements must be based on scientific assessment;
- (12) clear labelling rules should be formulated for the abovementioned products so as to ensure that official inspections can be carried out on the basis of reliable, reproducible and practicable data;
- (13) care should also be taken to ensure that the labelling requirements are not excessively complex but nevertheless sufficiently detailed to provide consumers with the information they need;

- (14) 歐洲共同體第 1139/98 號規章已確定了該等由基因改造玉米或基因改造黃豆所製成食品之特定的標示要求所須符合的標準。
- (15) 完全符合前述標示要求的標準，在目前是指用來作為食品配料之添加物與香料中存有基因改造蛋白質或去氧核糖核酸。於出現新的科學知識時，得重新審查此一概念。
- (16) 就適用範圍與效力而言，本規章中為達成預設目標所建議之共同體措施，不僅是必要的，而且也是不可或缺的。
- (17) 由於添加物與香料可能受到基因改造蛋白質或去氧核糖核酸之偶發性污染，因此對於是否可透過確定臨界值而得以避免此等污染須有特別之標示的可能性，應加以檢查。
- (18) 本規章中所規定的措施，與食品常設委員會之立場一致。

發布以下規章：

第一條

1. 本規章規定了針對終端消費者以及民間機構，並包含第二項所稱之添加物與香料（以下稱為「系爭添加物與香料」）之食品與食品配料（以下稱為「系爭食品」）之標示的補充性要求。

- (14) Regulation (EC) No 1139/98 specifies the criterion according to which the labelling obligations become operative for food produced from genetically modified maize or soya;
- (15) the presence in additives and flavourings used as ingredients in a foodstuff of protein or DNA resulting from genetic modification is, as matters stand, also the criterion that best meets the abovementioned requirements. Such an approach could be re-examined in the light of new scientific evidence;
- (16) in view of the scope and consequences of the proposed action, the Community measures introduced by this Regulation are not only necessary but indeed essential to achieve the objectives;
- (17) adventitious contamination of additives and flavourings with DNA or protein resulting from genetic modification cannot be excluded; it is useful to examine the possibility of setting up a threshold in order to avoid labelling as a result of such contamination;
- (18) the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

1. This Regulation provides for specific additional labelling requirements for food and food ingredients intended for final consumers and mass caterers hereinafter referred to as 'specified foodstuffs' containing additives and/or flavourings as described in paragraph 2 (hereinafter referred to as 'specified additives and flavourings').

2. 系爭添加物與香料，係指包含理事會第 90/220/EEC 號準則所稱之基因改造有機體、由其所構成或製成^①之：
- 屬於第 89/107/EEC 號準則之適用範圍的添加物，以及/或
 - 第 88/388/EEC 號準則所稱之用於食品之香料。

第二條

在不侵害共同體其他有關食品標示之法規下，系爭食品之標示中應提供終端消費者與民間機構以下資訊：

- (a) 依據第四條第一項之規定，所有導致系爭添加物或香料不同於既有之添加物或香料之特徵或營養特性，如：
 - 成分
 - 營養價值或營養效益
 - 添加物或調味料之使用目的
- (b) 含有於既有之添加物或香料所無之成分，並且可能影響特定人群之健康；
- (c) 含有於既有之添加物或香料所無之成分，並且可

2. The following are specified additives and flavourings:

- additives falling within the scope of Directive 89/107/EEC and/or
- flavourings for use in foodstuffs falling within the scope of Directive 88/388/EEC which are, contain or are produced from genetically modified organisms within the meaning of Council Directive 90/220/EEC^①.

Article 2

Without prejudice to the other requirements of Community legislation on food labelling, the labelling of the specified foodstuffs must inform final consumers and mass caterers of:

- (a) in accordance with Article 4 (1), any characteristic or food property such as:
 - composition
 - nutritional value or nutritional effects
 - intended use of the additives, or flavourings as a result of which the specified additives or flavourings are no longer equivalent to existing additives or flavourings;
- (b) the presence in the specified additives or flavourings of material which is not present in existing equivalent additives or flavourings and which may affect the health of certain sections of the population;
- (c) the presence in the specified additives or flavourings of material which is not present in existing equivalent additives or

能引發倫理上之疑慮；

- (d) 依據第四條第二項之規定，添加物或香料中含有依第 90/220/EEC 號準則之附錄 I A 第一部分非列舉式名單中之基因科技程序為基因改造之有機體，或由此等有機體所構成。

第三條

若於適當分析既有數據之基礎上，經由科學性評估得以證明受檢試之特徵與傳統添加物或香料之特徵有差異時，系爭添加物或香料已非第二條 a 款所稱者。其中應考慮該等特徵受到承認之臨界值自然偏差範圍。若添加物或香料含有經基因改造之蛋白質與（或）去氧核糖核酸時，即屬於此種情形。

第四條

1. 有關第二條 a 款所稱資訊之補充性標示要求，依下列規定為之：

於第 79/112/EEC 號準則第 6 條所定之配料一覽表上，應緊接著系爭添加物或香料之後，以括弧顯示「由基因改造之...所製成」之說明字樣。

上述說明字樣亦得以明顯可見之註腳附於配料一覽表之後；另應加上一個星號（*）以建立與系爭添加物或

flavourings and which gives rise to ethical concerns;

- (d) in accordance with Article 4 (2), the presence of an additive or flavouring that is or contains an organism genetically modified by techniques of genetic modification, the nonexhaustive list of which is laid down in Annex IA, Part 1, of Directive 90/220/EEC.

Article 3

The specified additives or flavourings shall be deemed to be no longer equivalent within the meaning of Article 2(a) if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with traditional additives or flavourings, having regard to the accepted limits of natural variations of such characteristics. This is the case where the specified additives or flavourings contain protein and/or DNA resulting from genetic modification.

Article 4

1. The additional specific labelling requirements with regard to the information referred to in Article 2(a) are as follows:

The words 'produced from genetically modified ...' shall appear in the list of ingredients provided for in Article 6 of Directive 79/112/EEC, in parentheses, immediately after the indication of the additive or flavouring in question.

Alternatively, this wording may appear in a prominently displayed footnote to the list of ingredients, linked to the additive or the flavouring concerned by an asterisk (*). It shall be printed in a font that

香料之關連性。該說明字樣之字體大小，須至少與配料一覽表本文之字體大小相同。

未提列配料一覽表之商品，應將前述說明字樣清楚地標示於系爭食品之標籤上。

2. 有關第二條 d 款所稱資訊之補充性標示要求，依下列規定為之：

於配料一覽表上，應緊接著系爭添加物或香料之後顯示「基因改造」之說明字樣。

上述說明字樣亦得以明顯可見之註腳附於配料一覽表之後；另應加上一個星號 (*) 以建立與系爭添加物或香料之關連性。該說明字樣之字體大小，須至少與配料一覽表本文之字體大小相同。

未提列配料一覽表之系爭食品，應將前述說明字樣清楚地標示於系爭食品之標籤上。

第五條

於本規章生效前已於共同體內合法地製成並標示，或合法地進口至共同體，並於共同體內自由流通之系爭食品，不適用本規章之規定。

第六條

本規章自公告於歐洲共同體公報九十天後生效。

is at least of the same size as that used for the list of ingredients itself.

For specified foodstuffs for which there is no list of ingredients, this wording shall appear clearly on the product's label.

2. The additional specific labelling requirements with regard to the information referred to in Article 2(d) are as follows:

The words 'genetically modified' shall appear in the list of ingredients immediately after the indication of the additive or flavouring in question.

Alternatively, this wording may appear in a prominently displayed footnote to the list of ingredients, linked to the additive or the flavouring concerned by an asterisk (*). It shall be printed in a font that is at least of the same size as that used for the list of ingredients itself.

For specified foodstuffs for which there is no list of ingredients, this wording shall appear clearly on the product's label.

Article 5

This Regulation shall not apply to specified foodstuffs lawfully manufactured and labelled in the Community or lawfully imported into the Community and put into free circulation before the entry into force of this Regulation.

Article 6

This Regulation shall enter into force 90 days following its publication in the Official Journal of the European Communities.

This Regulation shall be binding in its entirety and directly appli-

本規章全文均具有拘束力，並直接適用於所有會員國。

2000年1月10日於布魯塞爾

此致執行委員會

Erkki Liikanen

執行委員會委員

（蔡宗珍譯）

NOTE

- ① OJ L 33, 8.2.1979, p. 1.
- ② OJ L 43, 14.2.1997, p. 21.
- ③ OJ L 43, 14.2.1997, p. 1.
- ④ OJ L 40, 11.2.1989, p. 27.
- ⑤ OJ L 237, 10.9.1994, p. 1.
- ⑥ OJ L 42, 15.2.1991, p. 25.
- ⑦ OJ L 159, 3.6.1998, p. 4.
- ⑧ OJ L 159, 3.6.1998, p. 4.
- ⑨ OJ L 291, 30.10.1998, p. 35.
- ⑩ OJ L 117, 8.5.1990, p. 15.

cable in all Member States.

Done at Brussels, 10 January 2000.

For the Commission

Erkki LIIKANEN

Member of the Commission

註釋

- ① OJ L 33, 8.2.1979, p. 1.
- ② OJ L 43, 14.2.1997, p. 21.
- ③ OJ L 43, 14.2.1997, p. 1.
- ④ OJ L 40, 11.2.1989, p. 27.
- ⑤ OJ L 237, 10.9.1994, p. 1.
- ⑥ OJ L 184, 15.7.1988, p. 61.
- ⑦ OJ L 42, 15.2.1991, p. 25.
- ⑧ OJ L 159, 3.6.1998, p. 4.
- ⑨ OJ L 291, 30.10.1998, p. 35.
- ⑩ OJ L 117, 8.5.1990, p. 15.