New Labelling Requirements for Food Additives, Enzymes and Flavourings*

An overview of the labelling provisions of the "Food Improvement Agents Package"

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The core of the so called "Food Improvement Agents Package", namely Regulations (EC) No. 1332-1334/2008, contains substantial labelling provisions for food additives, food enzymes and flavourings for use in and on foods. Some of the relevant rules are completely new, some of them remain unchanged and some of them have been more or less modified. All three regulations essentially distinguish between the labelling of products intended and not intended for sale to the final consumer. The package has also consequences for the ingredients-labelling of foodstuffs containing the substances in question. Furthermore, specific requirements become applicable for the use of the term "natural" to describe a flavouring. A closer examination of the relevant rules reveals that, although the agents concerned may improve the quality of food, the labelling provisions themselves cannot truly be called an "improvement".

I. Introduction

Labelling of food is certainly not a new invention. The same applies to the labelling of food ingredients sold as such, be it to food businesses or consumers. However, with the advent of what has been labelled by the Commission itself as the "Package on Food Improvement Agents"[1] in December 2008, new labelling provisions have been implemented all over the European Union. The package itself includes comprehensive provisions on food additives, food enzymes as well as flavourings and food ingredients with flavouring properties[2]. The main emphasis of all these harmonising statutes is on general prohibitions of non-compliant substances and the parallel establishment of Community lists together with conditions of use for approved substances. Special labelling rules are enacted in Art. 10-13 of Regulation (EC) No. 1332/2008 on food enzymes[3], Art. 21-25 of Regulation (EC) No. 1333/2008 on food additives[4] and Art. 14-18 of Regulation (EC) No. 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods[5].

Anyone who has been labelling ingredients before the new law was enacted knows that there are predecessors in Europe, some of which have served as models for their immediate successors. The labelling of food additives in particular has so far been regulated by Art. 7-8 of Directive 89/107/EEC concerning food additives authorised for use in foodstuffs intended for human consumption[6]. The labelling of flavourings has even got a slightly older source, namely Art. 9-9a of Directive 88/388/EEC relating to flavourings for use in foodstuffs and to

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1 http://ec.europa.eu/food/food/chemicalsafety/additives/new_regul_en.htm.

2 For a diligent and critical overview of the whole package cf. Barwig, StoffR 2008, p. 269.

3 OJ L 354/7 of 31.12.2008.

4 OJ L 354/16 of 31.12.2008.

5 OJ L 354/34 of 31.12.2008.

6 OJ L 40/27 of 11.2.1989, last amended by Regulation (EC) No. 1882/2003, OJ L 284/1 of 31.10.2003.

source materials for their production[7]. Only food enzymes (so far as they are not classified as additives themselves) have not yet been regulated in a harmonised way at Community level. As a consequence there are only few changes in principle for food business operators labelling food additives and flavourings, whilst members of the enzymes industry will have to acquaint themselves with a complete set of new labelling rules for products to be marketed in the European Union.

Systematically, the three regulations distinguish between the labelling of substances intended for sale and not intended for sale to the final consumer. In all cases the definition of "final consumer" pursuant to Art. 3 no. 18 of Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law applies[8]. Since that definition determines the "final consumer" as "the ultimate consumer who will not use the food as part of any food business operation or activity", it can be concluded that anyone not amounting to a final consumer must necessarily be a "food business" within the meaning of Art. 3 no. 2 of Regulation (EC) No. 178/2002. Accordingly, all relevant substances offered to "any undertaking ... carrying out any of the activities related to the stage of production, processing and distribution of food" are covered by the labelling rules for substances intended not for sale to the final consumer. It is of course the responsibility of each food business operator to ensure that the correct labelling provisions are observed[9]. As will be seen, however, there is not much difference between the two separate sets of rules. Let us take a look at them in turn.

II. Substances intended for food businesses

1. General labelling requirements

All three pertinent regulations of the package envisage essential general labelling requirements. Pursuant to Art. 10 para. 1 of Regulation (EC) No. 1332/2008, Art. 21 para. 1 of Regulation (EC) No. 1333/2008 and Art. 14 para. 1 of Regulation (EC) No. 1334/2008, the labelling of the respective substances must be labelled "easily visible, clearly legible and indelible". Furthermore, the compulsory information "shall be in a language easily understandable". These provisions essentially correspond with the requirements entrenched since 1979 in what are now Art. 13 para. 2 and 16 para. 1 of Directive 2000/13/EC on labelling, presentation and advertising of foodstuffs[10]. The first three criteria are not known to have been in issue before the European Court of Justice. In principle they should be self-explanatory: Invisible, illegible or deleted labelling elements cannot serve their essential purpose, namely to inform potential purchasers of the contents of the packaging. Only with respect to the language of the labelling the Court has decided that a particular language cannot be prescribed by the legislator[11]. This of course does not clarify which language can meet the requirement of being easily understandable. Hence it may well become the subject matter of future disputes whether e.g. merely English labelling would suffice for a product offered in several member states or whether multilanguage labelling will remain necessary in such a case.

2. Information details of all substances

Food additives, food enzymes as well as flavourings and food ingredients with flavouring properties share the majority of labelling elements. Pursuant to Art. 11 para. 1 of Regulation (EC) No. 1332/2008, Art. 22 para. 1 of Regulation (EC) No. 1333/2008 and Art. 15 para. 1 of Regulation (EC) No. 1334/2008, a number of details must generally be given in all categories; these are (in the order of their listing in the relevant provisions)

b) "the statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use";
c) "if necessary, the special conditions of storage and/or use";
d) "a mark identifying the batch or lot";

7 OJ L 184/61 of 15.7.1988, last amended by Regulation (EC) No. 1882/2003, OJ L 284/1 of 31.10.2003.

8 OJ L 31/1 of 1.2.2002, last amended by Regulation (EC) No. 596/2009, OJ L 188/14 of 18.7.2009.

9 As to the responsibility cf. the decision of the ECJ, C-315/05 – "Lidl Italia", reported in EFFL 2007, p. 33, as well as the pertaining article by Klaus/Meyer, EFFL 2008, p. 407.

10 OJ L 109/29 of 6.5.2000, last amended by Regulation (EC) No. 596/2009, OJ L 188/14 of 18.7.2009.

11 ECJ, C-366/98 – "Geffroy" and C-385/96 – "Goerres".

e) "instructions for use, if the omission thereof would preclude appropriate use of" the substance (this does not apply to flavourings);
f) "the name or business name and address of the manufacturer, packager or seller";
g) "an indication of the maximum quantity of each component or group of components subject to quantitative limitation in food";
h) "the net quantity";
i/j) "the date of minimum durability or use-by-date" and
j/k) "where relevant, information on" a substance "listed in Annex IIIa to Directive 2000/13/EC" (i.e. substances which can be "the cause of allergies or intolerances in consumers" as set out in Recital 3 of Detective 2003/89/EC[12]).

It should be noted that in some of these instances (b, f and i/j) it is possible to choose one of several options, although with respect to the durability (i/j) it remains unclear whether the operator's choice is pre-determined by the special characteristics of the product in question in accordance with the criteria of Art. 10 para. 1 of Directive 2000/13/EC which prescribes a use-by-date for "foodstuffs which, from the microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health". Other items (c, e and j/k) are conditional, i.e. they only need to be labelled if the pertaining criteria are met – otherwise they can be omitted from the label. Maximum quantities (g) should be understood to include "quantum satis" authorisations where applicable.

Furthermore, Art. 11 para. 4-5 of Regulation (EC) No. 1332/2008, Art. 22 para. 4-5 of Regulation (EC) No. 1333/2008 and Art. 15 para. 2-3 of Regulation (EC) No. 1334/2008 provide for two different kinds of express exemptions from the general labelling obligation. Some information details may thus be confined to "the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication 'not for retail sale' appears on an easily visible part of the packaging or container of the product in question"; in this case, however, there is no choice as to which indication the operator may use on the label (like pursuant to the rules mentioned above). And all details can be restricted to "accompanying documents relating to the consignment which are to be supplied with the delivery", if the substances concerned "are supplied in tankers". Regrettably, there is no definition of tankers in the regulations!

3. Peculiarities regarding food additives

Food additives must of course be labelled with their "name and/or E-number" pursuant to Art. 22 para. 1 lit. a) of Regulation (EC) No. 1333/2008. Accordingly, the proper name or E-number must be the one "laid down in this Regulation". It can be assumed that these names will most certainly be those which are already regulated under present additives law. Alternatively, the new provision allows "a sales description which includes the name and/or E-number". In case several additives are sold mixed with one another, the relevant indication must comprise "each food additive".

Additionally, Art. 22 para. 2 of Regulation (EC) No. 1333/2008 prescribes the indication of "a list of all ingredients" including potential other food ingredients "in descending order of their percentage by weight of the total". This is a modernised version of the parallel rule contained in Art. 6 para. 5 of Directive 2000/13/EC, albeit – for reasons unknown – without the obligation to precede the list with a suitable heading including the word "ingredients".

Finally, Art. 22 para. 3 of Regulation (EC) No. 1333/2008 demands that substances "added to food additives to facilitate their storage, sale, standardisation, dilution or dissolution" must also be labelled "in descending order of their percentage by weight of the total". Since this obligation is stipulated separately from the ingredients list, it must be concluded that the relevant "list of all such substances" shall be an independent labelling element.

4. Peculiarities regarding food enzymes

Food enzymes are subject to similar rules. Pursuant to Art. 11 para. 1 lit. a) of Regulation (EC) No. 1332/2008 their packaging or containers generally need to bear their prescribed "name laid down under this Regulation in respect of each food enzyme or a sales description which includes the name of each food enzyme". Should such a name not exist and as long as no names have been laid

12 OJ L 308/15 of 25.11.2003.

down, the provision alternatively envisages "the accepted name laid down in the nomenclature of the International Union of Biochemistry and Molecular Biology (IUBMB)". This is the relevant scientific association – affiliated to the International Council of Science (ICSU) – which has been dedicated to the worldwide research and nomenclature in the areas of biochemistry and molecular biology since 1955[13]. The IUBMB's competent Nomenclature Committee has already established a comprehensive Enzyme Nomenclature[14] which can now be referred to for labelling purposes as provided by the new law.

Because of their special characteristics, food enzymes also require an additional labelling element, namely "the activity of the food enzyme(s)", according to Art. 11 para. 1 lit. i) of Regulation (EC) No. 1332/2008. As no special way of indicating that activity is mentioned in the stipulation, it is recommendable to label it in scientifically acknowledged units of the enzyme's activity level and to quote at least the minimum amount of a range or the lowest specification value.

Finally, Art. 11 paras. 2 and 3 of Regulation (EC) No. 1332/2008 prescribe the indication of "a list of all ingredients" or "a list of all components", respectively, including potential other food ingredients "in descending order of their percentage by weight of the total". It is completely unclear from the regulation itself as well as otherwise what difference the legislator has had in mind regarding "ingredients" and "components". Whilst the term "ingredients" has long been defined in Art. 6 para. 4 lit. a) of Directive 2000/13/EC (and shall now also include enzymes pursuant to the amendment provided for in Art. 21 of Regulation (EC) No. 1332/2008, cf. No. IV. below), there is no such definition of the term "components". Moreover, it is difficult to imagine what a component should be other than an ingredient. For practical purposes it is thus suggested that the duplication of labelling obligations must be an error and both provisions in fact regulate one and the same obligation, namely the indication of an ingredients list.

5. Peculiarities regarding flavourings for use in and on foods

Flavourings of course also require a product name or "sales description"; this shall be "either the word 'flavouring' or a more specific name or description of the flavouring" according to Art. 15 para. 1 lit. a) of Regulation (EC) No. 1334/2008. And as in the case of additives and enzymes there is an obligation to label an ingredients list pursuant to Art. 15 para 1 lit. e) of Regulation (EC) No. 1334/2008.

III. Substances intended for consumers

1. Food additives

Art. 23 para. 1 of Regulation (EC) No. 1333/2008 essentially equates food additives with foodstuffs which have to be labelled as prescribed by Art. 3 of Directive 2000/13/EC, by Directive 89/396/EEC on indications or marks identifying the lot to which a foodstuff belongs[15] and GMO labelling provisions, if applicable. Additionally, items a) and b) of Art. 22 para. 1 of Regulation (EC) No. 1333/2008 are repeated (cf. No. II. 2. and 3. above), so that a mandatory name and the indication "for food" together with its lawful alternatives are made compulsory as in the case of additives intended for sale to food businesses. As in that case, these indications have to be labelled in accordance with Art. 13 para. 2 of Directive 2000/13/EC pursuant to Art. 23 para. 5 of Regulation (EC) No. 1333/2008; i.e. they, too, must be "easily visible, clearly legible and indelible" and in addition to that they must not be "hidden, obscured or interrupted by other written or pictorial matter".

With respect to table top sweeteners the well known labelling rules of Art. 5 of Directive 904/53/EEC on sweeteners[16] are augmented and transferred to Art. 23 paras. 2-4 of Regulation (EC) No. 1333/2008. Accordingly the sales description of such a product "shall include the term '...-based table top sweetener', using the name(s) of the sweetener(s) used in its composition", the presently prescribed warnings "excessive consumption may induce laxative effects" for sweeteners containing polyols and "contains a source of phenylalanine" for

13 http://www.iubmb.org/index.php?id=8.

14 Published in Enzyme Nomenclature 1992 with Supplement 1 (1993), Supplement 2 (1994), Supplement 3 (1995), Supplement 4 (1997) and Supplement 5 (in Eur. J. Biochem. 1994, 223, 1–5; Eur. J. Biochem. 1995, 232, 1–6; Eur. J. Biochem. 1996, 237, 1–5; Eur. J. Biochem. 1997, 250; 1–6, and Eur. J. Biochem. 1999, 264, 610–650; respectively); cf. also http://www.chem.qmul.ac.uk/iubmb/enzyme/.

15 OJ L 186/21 of 30.6.1989.

16 OJ L 237/3 of 10.9.1994, last amended by Directive 2006/52/EC, OJ L 204/10 of 26.7.2006.

sweeteners containing aspartame or aspartame-acesulfame remain in force and manufacturers of the relevant sweeteners "shall make available by appropriate means the necessary information to allow their safe use". The latter obligation may be supplemented with an official guidance document. However, it is unclear what other appropriate means of communicating details on the safe use of a foodstuff there can be apart from labelling the relevant information, be it by way of words, symbols or pictures.

2. Food enzymes

Art. 12 para. 1 of Regulation (EC) No. 1332/2008 equates food enzymes with foodstuffs in the same way as Art. 23 para. 1 of Regulation (EC) No. 1333/2008 equates food additives (cf. No. 1 above). Here items a) and b) of Art. 11 para. 1 of Regulation (EC) No. 1332/2008 are repeated (cf. No. II. 2. and 4. above), so that a scientific name and the indication "for food" together with its lawful alternatives are made compulsory as in the case of enzymes intended for sale to food businesses. Pursuant to Art. 12 para. 2 of Regulation (EC) No. 1332/2008 these indications also have to be labelled in accordance with Art. 13 para. 2 of Directive 2000/13/EC (cf. No. 1 above).

3. Flavourings for use in and on foods

Art. 17 para. 1 of Regulation (EC) No. 1334/2008 equates flavourings with foodstuffs in the same way as Art. 23 para. 1 of Regulation (EC) No. 1333/2008 equates food additives (cf. No. 1 above). However, only the indication "for food" together with its lawful alternatives is made compulsory as in the case of flavourings intended for sale to food businesses (cf. No. II. 2. above). Furthermore, the provision directly prescribes that this indication must be "easily visible, clearly legible and indelible". In addition Art. 17 para. 2 of Regulation (EC) No. 1334/2008 refers to Art. 16 of Regulation (EC) No. 1334/2008 "if the term 'natural' is used to describe a flavouring" (cf. No. V. below).

IV. Ingredients labelling

1. Food colours

A completely new – and scientifically extremely questionable[17] – labelling obligation for certain food colours is imposed by Art. 24 para. 1 of Regulation (EC) No. 1333/2008. This provision demands that "the labelling of food containing the food colours listed in Annex V to this Regulation shall include the additional information set out in that Annex". The relevant Annex currently lists six food colours, namely: Sunset yellow (E 110), Quionline yellow (E 104), Carminosine (E 122), Allura red (E 129), Tartrazine (E 102) and Ponceau 4R (E 124). If only one of them is contained in a food, the following warning must be labelled separately: "'name or E number of the colour(s)': may have an adverse effect on activity and attention in children". Whether the product compulsorily ear-marked with this indication can actually – i.e. in a scientifically proven way – have such an effect and what quantities would need to be consumed (daily?) in order to suffer from it, is completely irrelevant. Criteria as required in accordance with Recital 17 of Regulation (EC) No. 1924/2006 on nutrition and health claims[18] for the scientific substantiation of such claims, especially "taking into account the totality of the available scientific data" and "weighing the evidence" do not seem to have guided the legislator when enacting the obligation to label the warning. Needless to say that Art. 24 para. 2 of Regulation (EC) No. 1333/2008 once again refers to Art. 13 para. 2 of Directive 2000/13/EC which makes it mandatory to label the additional indication "easily visible, clearly legible and indelible" and not "hidden, obscured or interrupted by other written or pictorial matter" (cf. No. III. 1. above).

2. Food enzymes

With respect to enzymes the most important novelty is their inclusion in the definition of ingredients. This change of the law is effected through Art. 21 of Regulation (EC) No. 1332/2008 which amends Art. 6 para 4 of Directive 2000/13/EC in such a way

17 Cf. EFSA scientific opinion of 7 March 2008, EFSA Journal 2008, 660, 1–54; http://www.efsa.europa.eu/en/scdocs/doc/afc_ej660_McCann_study_op_en.pdf.

18 OJ L 12/3 of 18.1.2007, last amended by Regulation (EC) No. 109/2008, OJ L 39/14 of 13.2.2008.

as to insert "enzymes" in the ingredients definition which now reads as follows: "'Ingredient' shall mean any substance, including additives and enzymes ...". The main consequence of this inclusion appears to concern the labelling of ingredients lists of products containing enzymes. This is regulated through an additional amendment of Art. 6 para. 6 of Directive 2000/13/EC which provides that enzymes "shall be designated by the name of one of the categories of ingredients listed in Annex II, followed by their specific name". At a second glance this is somewhat confusing, because with respect to other ingredients the same obligation only exists concerning "ingredients belonging to one of the categories listed in Annex II", so that additives not belonging to a listed category, for example sequestrants, do not require a category name. Moreover, the category "enzymes" is not currently listed in Annex II of Directive 2000/13/EC either. In practice, however, these problems will hardly ever materialise, because enzymes are currently used predominantly in fruit juice production and in bakeries. In both instances they are employed as "processing aids" within the meaning of the new definition in Art. 3 para 2 lit. b) of Regulation (EC) No. 1333/2008 and are therefore exempted from the ingredients definition pursuant to Art. 6 para. 6 of Directive 2000/13/EC. As a consequence they do not need to be labelled as ingredients, in fact they must not be labelled as such[19], because they are merely present in juices or bakery products in technically unavoidable residues, if at all.

3. Flavourings

With respect to flavourings there is little change as regards ingredients labelling. Art. 29 of Regulation (EC) No. 1334/2008 also amends Directive 2000/13/EC, namely its Annex III which is captioned "Designation of flavourings in the list of ingredients". However, these changes mainly serve to integrate the new terminology covering the different types of flavouring substances defined in Art. 3 para. 2 lit. b)-h) of Regulation (EC) No. 1334/2008 and particularly "smoke flavouring(s)" into current food labelling law as far as ingredients lists are concerned. In addition the use of "the term 'natural' for the description of flavourings" in the list of ingredients shall also be in accordance with the new Art. 16 of Regulation (EC) No. 1334/2008 (cf. No. V. below).

V. "Natural" flavourings

Nature, by definition the original source of anything non-artificial, i.e. not created by mankind, remains a powerful icon especially in food advertising and marketing. Hence there have been statutory provisions regulating the use of the word "natural" ever since flavourings were first regulated on a European level in Art. 9 para. 2 and 9a para. 2 of Directive 88/388/EEC. These have now been lifted onto a new level of complication in Art. 16 paras. 2-6 of Regulation (EC) No. 1334/2008. Their main purpose is rather simple and apparent from Recitals 25 and 26 of Regulation (EC) No. 1334/2008: They shall "ensure that consumers are not misled". One might argue that misleading food labelling and advertising has already been banned all over the European Community since 1979 in what is now Art. 2 paras. 1 and 3 of Directive 2000/13/EC. However, experience shows that no European food law is so unclear that the legislator cannot muddy it further – especially under the pretence of clarity and efficiency, as mentioned in Recital 1 of Regulation (EC) No. 1334/2008. With the revision of the legal categories of flavouring substances it was apparently felt that new dimensions of nature could be fathomed. This is what they look like at a brief glance[20]:

The main principle of claiming "natural" flavourings remains unscathed: Art. 16 para. 2 of Regulation (EC) No. 1334/2008 determines that "the term 'natural' for the description of a flavouring may only be used if the flavouring component comprises only flavouring preparations and/or natural flavouring substances". With respect to these two categories the definitions of Art. 3 para. 2 lit) c) and d) Regulation (EC) No. 1334/2008 apply. A first variation of this topic with respect to the term "natural flavouring substance(s)", which "may only be used for flavourings in which the flavouring component contains exclusively natural flavouring substances",

19 Cf. also ECJ, C-144/93 – "Pfanni", reported in EFLR 1995, p. 197.

20 For a detailed analysis of the „natural" labelling rules with many practical examples cf. the EFFA Guidance Document on the EC Regulation on Flavourings of 19 February 2009, http://www.effa.be/guidance/EFFA%20Guidance%20Document%20on%20the%20new%20EC%20Flavouring%20Regulation.pdf; CAUTION: No liability can be accepted by the author of this article for the perusal of the Guidance; its "Disclaimer – Important Legal Notice" contains an obvious typing error as well as other misconceptions which strongly support the suspicion that the EFFA Guidance itself may be inaccurate otherwise, too.

can be found in Art. 16 para. 3 of Regulation (EC) No. 1334/2008. Another variation concerns the description "natural 'food(s) or food category or source(s)' flavouring", which may only be used "if the flavouring component has been obtained exclusively or at least 95% by w/w from the source material referred to", is laid down in Art. 16 para. 4 of Regulation (EC) No. 1334/2008[21]. According to Recital 26 of Regulation (EC) No. 1334/2008 the other 5% "can only be used for standardisation or to give a, for example, more fresh, pungent, ripe or green note to the flavouring"[22].

As a kind of catch-all-category, Art. 16 para. 6 of Regulation (EC) No. 1334/2008 provides for the use of the term "natural flavouring", which allows that "the flavouring component is derived from different source materials and where a reference to the source materials would not reflect their flavour or taste". To make matter even more complicated, a legislatory highlight is hidden in Art. 16 para. 5 of Regulation (EC) No. 1334/2008 which establishes criteria for the use of the somewhat bizarre term "natural 'food(s) or food category or source(s)' flavouring with other natural flavouring", namely that "the flavouring component is partially derived from the source material referred to, the flavour of which can easily be recognised". With respect to this particular, albeit rather unattractive category, an example can be found in Recital 26 of Regulation (EC) No. 1334/2008: "cocoa extract in which other natural flavourings have been added to impart a banana note". At this stage, however, one is inclined to stop for the sake of the reader and to admit that nothing else should be added – neither by the legislator nor by the author.

21 The rather cryptic abbreviation „w/w" is purportedly meant to signify „weight per weight".

22 Cf. e.g. Ziegler, Flavourings, 1998, 362–363.