New EU Labeling Law: Omission of Food Additives and Enzymes from the List of Ingredients under Regulation (EC) No. 1169/2011

*Sonja Schulz**

Food additives and food enzymes were not regarded as ingredients under the Labeling Directive 2000/13/EC if they were a carry-over substance or used as processing aids and were therefore not allowed to be included in the list of ingredients. With the new EU labeling law, that has been introduced by the Food Information Regulation (EU) No. 1169/2011, this rule has been changed. Since 13 December 2014, it is generally admitted to inform the consumer about the presence of such substances – at least if it is not misleading in the specific circumstances of the case. Also, the traditional difficulty of the delimitation of food enzymes and food additives from processing aids has developed. A Guidance Document tackles the categorization of food enzymes and allows conclusions for the delimitation of food additives and processing aids, as well. At least with regard to degraded or denatured substances, the Guidance Document contributes to more legal certainty.

I. Introduction

Today, the core of mandatory food labeling law can be found in Food Information Regulation (EC) No. 1169/2011[1] which has been generally applicable since 13 December 2014. This act has changed the legal form[2] and introduced numerous material amendments to food labeling law. As a European Regulation it is directly applicable in all EU Member States. Former deviations between different EU legislations, which were caused by non-uniform national acts implementing the prior legal act, Labeling Directive 2000/13/EC[3], have consequently been abolished.

One specific aspect of food labeling which has undergone formal changes as well as a material development is the omission of food additives and enzymes from the ingredient list. Just like the previous Labeling Directive, the new Food Information Regulation governs the labeling of food additives and enzymes that are ingredients and also provides for exemption clauses. While additives were not regarded as ingredients and were therefore not allowed to be listed in the list of ingredients under the Labeling Directive, the Food Information Regulation introduces an optional inclusion of food additives and enzymes in the list of ingredients in two situations: either if these substances end up in the final product by carry-over or if they are used as processing aids. Thus, formally and materially the rules for labeling of carry-over substances and processing aids have been changed. This article discusses the new omis-

* Sonja Schulz, LL.M. is partner at ZENK Rechtsanwälte in Hamburg, Germany, a law firm specialised in food industry. She advises in all areas of national and European food and competition law. E-mail: schulz@zenk.com.

1 Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004.

2 As the prior act was a European Directive, cf. next footnote.

3 Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

sion rule and sheds light on the interpretation of this rule.

II. Where do we come from?

Until 13 December 2014, the national acts that implemented Article 6 of the Labeling Directive applied. Article 6 Section 1 stated that "Ingredients shall be listed in accordance with this Article ((...))". Section 2 of this rule provided that "Ingredients need not be listed in the case of: ((...))" which applied to fresh produce, cheese and a number of other foodstuffs which traditionally do not carry a list of ingredients. Aorticle 6 Section 4 ocontained a definition of the term "ingredient" adding a legal fiction: "Ingredient shall mean any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form." While additives were expressly named to be ingredients in this definition, in the very section of this rule, it is established that additives shall not be regarded as ingredients if one of two conditions is met. If the additive was used as a processing aid or if its presence in the finished foodstuff was solely due to the fact that it was contained in one or more ingredients of that foodstuff, provided that it served no technological function in the finished product, the "ingredient" was not regarded to be one.

From these provisions, one can deduce that for most foodstuffs a complete list of ingredients was mandatory and that additives generally constituted "ingredients". However, under specific conditions, additives were not treated as ingredients. As a consequence, because the list of ingredients exclusively comprises ingredients, the inclusion of additives was not admitted if one of the above-mentioned exemptions applied. This interpretation was confirmed by the judgment of the European Court (first chamber) in case C-144/93 ("Diphosphate"). The European Court explains in grounds 17 and 18 that an additive that is not needed in the finished product for its technological function, does not serve a technological effect in that finished product in the sense of the processing aid definition[4]. From this, the Court concluded that the respective additive should not be included in the list of ingredients to avoid misleading the consumer.

III. New situation as of 13 December 2014

The European legislator held up the general principle of listing all ingredients on finished consumer products. In the Food Information Regulation it can be found in Article 18 Section 1: "The list of ingredients [...] shall include all the ingredients of the food". Article 20 lists exemptions to this rule under the title "Omission of constituents of food from the list of ingredients" and therewith constitutes the successor rule to Article 6 of the Labeling Directive.

1. General structure of Article 20

The provision states that "without prejudice to Article 21", i.e. irrespective of the necessity to always list substances causing allergies or intolerances, "the following constituents of a food shall not be required to be included in the list of ingredients". Following this introductory sentence, the article lists a group of exemptions. One of those can be found in Section b) and refers to "food additives and food enzymes". Both categories are not required to be included in the list of ingredients if they either come under the carry-over doctrine or if they are used as processing aids. Thus, in contrast with the prior situation (described under "B"), food additives and food enzymes are not excluded from the group of "ingredients" anymore. They keep their character of being ingredients, even if they are used as a processing aid, resulting in a finished product that, for example, contains virtually no residue of the ingredient. As a consequence, the former situation in which an inclusion in the list of ingredients was not admitted for the "non-ingredients" carry-over substance and processing aid has changed. However, it is not mandatory to list these substances as ingredients as the law clearly states.[5]

From the wording of Article 20 one can clearly construe that it is neither mandatory nor forbidden to list these additives and enzymes. However, as both alternatives under Section b) include the condition that the respective substance does not have any technological function in the finished product, and the

4 Cf. Section C.4 below for the definition and its interpretation.

5 Cf. wording of Article 20 "shall not be required to be included in the list of ingredients".

use as a processing aid additionally requires only residues to be leftover in the finished product, a line has to be drawn to prevent misleading the consumer. In cases where only traces of the additive or enzyme remain or the use of a substance exclusively leaves reaction products in the finished food, it would clearly be misleading to include the additive or enzyme in the list of ingredients pretending that this substance is present in the finished product to a relevant extent.

2. Equal treatment of additives and enzymes

The omission rule of Article 20 evenly names additives and enzymes to determine its scope of application. The prior rule[6], in contrast, had solely referred to additives. Here, food enzymes were treated as food additives and therefore came under this rule as well.

In this context, the transition in the rules governing enzymes has to be regarded. In 2008, a package of regulations in the field of food additives and similar substances was issued.[7] Regulation (EC) No. 1332/2008 deals with enzymes. Since one focus of this Regulation was the adoption of a Community list of food enzymes – which did not exist before – there was a need for transitional rules until the list could be applied. Consequently, the Community temporarily continued to treat enzymes as food additives. Article 2 Section 3 of Regulation (EC) No. 1333/2008, which generally governs food additives, states that that the Regulation shall not apply to food enzymes falling within the scope of the Enzymes Regulation[8] with effect from the date of adoption of the Community list of food enzymes[9]. Additionally, the Regulation states that the valid enzyme authorisations[10] shall be repealed with effect from the date of application of the Community list of food enzymes. Thus, once the Community list of enzymes exists[11], enzymes form a seperate legal group of substances. Consequently, if they are supposed to be subject to the same rule as food additives, this has to be stipulated explicitly. For this reason, the omission rule in Article 20 of the Food Information Regulation names both additives and enzymes without causing material changes with regard to the even treatment of additives and enzymes in the context of the list of ingredients.

3. Carry-over exemption

The first alternative for an omission of additives and enzymes from the list of ingredients ties in with the so-called carry-over principle.[12] There are three conditions to be met by the respective substances.

First, the presence of the additive or enzyme in the food is solely due to the fact that it was contained in one or more ingredients of that food, i.e. it has not been added directly and seperately to the finished food. An example would be an antifoam agent used in the production of a fruit preparation that is later mixed with yoghurt.

Secondly, the carry-over result has to be in accordance with Article 18 Section 1 (a) and (b) of the Additives Regulation[13]. This means that the additive or

6 Article 6 Section 4 Labeling Directive 2000/13/EC.

7 So-called Food Improvement Agents Package (FIAP) of 16 December 2008, including Regulation (EC) No. 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings), Regulation (EC) No. 1332/2008 on food enzymes, Regulation (EC) No. 1333/2008 on food additives and Regulation (EC) No. 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods.

8 Regulation (EC) No. 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No. 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No. 258/97.

9 In accordance with Article 17 of Regulation (EC) No. 1332/2008.

10 Invertase and lysozyme, cf. Directive 95/22/EC.

11 Cf. Article 17 of the Enzymes Regulation regulating that the Community list will be adopted after a lengthy procedure which we are in the middle of at the moment. It includes the establishment of a Register of all enzymes considered for inclusion in the Community list, a publication thereof and an evaluation by EFSA as a basis for the decision of adoption by the Commission.

12 Article 20 (b)(i) is applicable to "food additives and food enzymes whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food, in accordance with the carry-over principle referred to in points (a) and (b) of Article 18(1) of Regulation (EC) No. 1333/2008, provided that they serve no technological function in the finished product".

13 This rule of Regulation (EC) 1333/2008 reads: "The presence of a food additive shall be permitted:
(a) in a compound food other than as referred to in Annex II, where the food additive is permitted in one of the ingredients of the compound food;
(b) in a food to which a food additive, food enzyme or food flavouring has been added, where the food additive:
(i) is permitted in the food additive, food enzyme or food flavouring in accordance with this Regulation; and
(ii) has been carried over to the food via the food additive, food enzyme or food flavouring; and
(iii) has no technological function in the final food".

enzyme has to be admitted for the specific use, including the carry-over result.

Thirdly, the additive or enzyme must not serve any technological function in the finished product. This condition differentiates a foodstuff that contains an active enzyme or an additive that still performs its technological task like preserving, colouring, flavour-enhancing or other, from such foodstuff which merely contains enzymes or additives because the technological function was needed in an ingredient.

a. Application to food additives

Regarding additives, there are clear examples for the lack of technological function in the finished product such as silicon dioxide (E 551) that is used as an anti-caking agent for salt. After the salt becomes an ingredient of a soup, for example, its technological function disappears.[14]

A second type of example is food additives, which do not have a technological function in the finished product due to dilution. This is typically the case if a preservative is used in an ingredient that forms a very small part of the finished product. The concentration of the preservative in that foodstuff is too low to cause a preserving effect.

Another example for an application of this rule is the case that came before the European Court regarding potato puree flakes. During processing, diphosphate (E 450a) was added to counteract the grey discoloration caused by enzymes in the potato pulp. Further steps in the process were heating and dehydration. The latter steps inactivated the enzymes with the consequence that the diphosphate is not needed to counteract a discoloration in the finished product. The European Court ruled that "accordingly, the additive at issue no longer serves a technological function in the finished product". Thus, it is not relevant that the technological result of the use of an enzyme or additive in an ingredient is carried through into the finished product as long as the technological function is not carried out at this stage anymore.

b. Application to food enzymes

Looking at enzymes, there are various examples in which there have been discussions whether the enzyme still fulfills a technological function in the finished product. It is part of the definition of "food enzyme"[15] that it is a product containing one or more enzymes capable of catalyzing a specific biochemical reaction. This effect depends on a number of conditions such as temperature and the characteristics of the foodstuff the enzyme is added to. If these conditions are not sufficient, the finished food could contain an enzyme in a significant amount that is nevertheless not active and does not perform its technological function – however, it could do so (again) if conditions change. Furthermore, being proteins, many enzymes can be denatured or degraded by heating. As heating is a typical step in processing food, enzymes are in many cases present in the finished food in an irreversibly denatured or degraded form. In this case, they cannot be activated again by changing the composition of the finished foodstuff or other conditions such as temperature.

In both cases, when enzymes are present but not active due to unfavourable conditions or when they are present but not active due to denaturation or degredation, the question arises if they (still) perform a technological function in the finished product within the meaning of Article 20 b) of the Food Information Regulation. Depending on the answer, either the ingredient has to be indicated in the list of ingredients of the finished food or there is no such obligation (provided all other conditions of Article 20 are met, s.a.). However, the law itself does not provide a clear answer.

Because of this lack in legal certainty, the Standing Committee on the Food Chain and Animal Health has adopted a Guidance Document[16] to help food business operators and competent authorities. Unfortunately, because the Guidance Document focuses on the identification of food enzymes used as ingredients in contrast to such used as processing aids[17], it does not give specific guidance in view of the question of technological effect in the finished food in carry-over situations.

However, since the Guidance Document states that enzymes that have been irreversibly denatured or degraded during processing[18] should be considered as a processing aid, at least for these situations, the Guidance is clear. As processing aids differ from food ad-

14 Markus Weck, Lebensmittelrecht, 2011, at p. 47, Rn. 155.

15 Cf. Article 3 Section 2 Enzyme Regulation (EC) No. 1332/2008.

16 Guidance Document on Criteria for Categorisation of Food Enzymes, 24 February 2014.

17 See below section 4.

18 Cf. Principle 3.1, page 10 of the Guidance Document; for further discussion of this principle, see below in this article.

ditives with regard to the technological function of the substance in the finished product, it can be deduced from this statement in the Guidance Document that legally, there does not exist any technological function in the final product if the enzyme is irreversibly denatured or degraded. Thus, also in carry-over situations, no labeling is required if the enzyme only exists in this state.

Despite the Guidance Document, the question remains of how to interpret the meaning of "no technological function" in those cases where an enzyme is inactive but not degraded or denatured. From the wording "no technological function", one has to assume that none of the functions an enzyme has got in a foodstuff must be present. The term "in the finished product" both comprises the moment the product is marketed and the time in which the product is prepared and consumed by the consumer. Since Article 20 of the Food Information Regulation is an exemption rule, it should be interpreted in a rather narrow scope of application to give the rule[19] a broad scope.[20] Therefore, "no technological function in the finished product" should be understood as to mean that the substance does not have any technological effect at the time the finished product is marketed or at the time it is opened, prepared, or consumed.

4. Processing aid exemption

The second alternative for an omission of additives and enzymes from the list of ingredients takes effect if these substances are used as processing aids. The concept of "processing aid" is defined in Article 3 Section 2 b) of the Additives Regulation[21] as "any substance which 1. is not consumed as a food by itself; 2. is intentionally used in the processing of raw materials, foods or their ingredients, to fulfill a certain technological purpose during treatment or processing; and 3. may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product".

In practice, the first test of this definition is regularly met as neither additives nor enzymes are typically consumed by themselves. Also, the second condition usually does not disqualify a lot of enzymes or additives because intentionally using these substances is exactly what a food producer regularly does to fulfill a technological purpose. Almost every discussion and difficulty arises from the definition's third test. Both the concept of "technically unavoidable residues" as well as the condition "not any technological effect on the final product" are sometimes difficult to apply in practice.

a. Application to food enzymes

As described above, specifically for this reason, the Standing Committee has issued the Guidance Document on Criteria for Categorization of Food Enzymes.[22] The Standing Committee describes that, if a food enzyme is no longer functioning after food processing but the effect remains on the food as marketed, the categorization of the food enzyme as an ingredient or as a processing aid should follow a certain decision tree. Here, for food enzymes that are present in the final food, the relevant question is if the enzyme has irreversibly been denatured or degraded in the manufacture, processing or treatment. If this is the case, the Standing Committee categorizes the enzyme as a processing aid. This guidance means that, irrespective of the reason for the enzyme being degraded or denatured and irrespective of the quantity of such inactive enzyme left over in the finished product, all tests of the processing aid definition are fulfilled. Consequently, the denatured or degraded enzymes are considered to be technically unavoidable residues and, at the same time, do not have any technological effect on the final product. Although the Guidance Document lacks a detailed discussion of the legal deduction of this conclusion, the result is surely very useful for food business operators and competent authorities. Also, it is in line with the principles of food law that the consumer should be informed clearly and comprehensively. If the consumer read the indication of a functional ingredient such as an enzyme in the list of ingredients, he would reasonably expect this ingredient to be in the finished product in an active and working state. For enzymes, this surely means that the enzyme is not denatured or degraded and most probably not inactive either.

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19 I.e. the obligation to list all ingredients on the finished product.

20 Otherwise, the legislators' decision on the balance between rule and exemption could be overturned.

21 Regulation (EC) 1333/2008 of the European Parliament and of the Counsel of 16 December 2008 on food additives.

22 Cf. section 3 above, footnote 16.

b. Application to food additives

For food additives that are used as processing aids, no such guidance exists. However, the critical points are the same as discussed above in the context of enzymes. Here, again, both the questions of technically unavoidable residues and the condition of no technological effect on the final product are the decisive aspects when trying to identify food additives used as ingredients and as processing aids.

Enzymes and food additives have got a lot in common with regard to their use in foods. It has not been by accident that enzymes have been part of the concept of "food additive" for a long time and regulated as such.[23] This suggests that the general principles of the Guidance Document on Criteria for Categorisation of Food Enzymes can be transferred to the differentiation of food additives from processing aids. Just like enzymes, additives should be considered as processing aids if – after the manufacture, processing or treatment – the residues are in a state in which they cannot possibly resume their technological function. Just as for enzymes, it would not be in line with basic principles of food law with regard to consumer information to indicate such a substance in any case in the list of ingredients and thereby possibly mislead the consumer. For example, if a food additive is almost completely removed from the finished product or has undergone a chemical reaction leaving nothing of the original substance but only reaction products, it would be clearly misleading to indicate the used substance in the list of ingredients.

IV. Conclusion

The Food Information Regulation brings about numerous small but also fundamental changes in the area of mandatory food labeling law in the European Union. Most modifications limit the opportunities of food business operators. In Article 20, however, one finds one of the scarce examples in which the European legislator created a little more freedom: the choice to inform the consumer about certain residues in the finished food if this seems adequate. At the same time, some difficulties of how to construe the exemption rules are tackled by the Guidance Document regarding food enzymes – which also delivers indications for the interpretation with regard to food additives. However, too many questions remain unanswered to call the current status under the Food Information Regulation legal certainty.

23 Cf. Section 3.