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## **Labelling foodstuffs made with the enzyme Transglutaminase**

Bearing in mind the deadline of December 13<sup>th</sup>, 2014, set with Article 55 Regulation (EU) No 1169/2011 on the provisions of food information to consumer (Food Information to Consumer Regulation, FIR), changeover period is drawing near. This raises the question whether or not the labelling for foodstuffs made with the enzyme Transglutaminase has to be adapted to upcoming law and if so, how this has to be done.

Transglutaminase itself is used in the production of the most different kinds of foodstuffs. Such foodstuffs reach from meat and fish products to bakery products to milk products. Transglutaminase is suitable for manifold purposes, be it the improvement of physical properties and texture, decrease of salt content or combining meat or fish parts.

The enzyme Transglutaminase is used in the production process of food because of its ability to cross-link proteins. By cross-linking proteins it acts as a catalyst. As such it does not create new protein bonds on its own but supports the cross-linking of proteins.

As soon as the substrate used during production is depleted, the enzyme will be inactive and does not function in a technological manner in the finished foodstuff even though it may still be present. Provided a pasteurisation or other heat treatment takes place during the production process the enzyme will become destructed and thereby inactive. Under no circumstances Transglutaminase neither serves a technological function nor a functional effect in the finished foodstuff.

For a better understanding of the new labelling requirements under upcoming Food Information to Consumer Regulation (FIR) the current law has to be recappeded.

### **1) Labelling under current law**

Finished foodstuffs, including such during its production process food enzymes are used, had and still have to be labelled in accordance with Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29) as last amended by Council Directive 2013/20/EU of 13 May 2013. In Germany this Directive is implemented by Verordnung über die Kennzeichnung von Lebensmitteln (LMKV) of 22.12.1981 as last amended by Verordnung of 25.02.2014.

Corresponding to Article 6 para 4 (a) Directive 2000/13/EC German § 5 para 1 LMKV qualifies such substance as ingredient “used in the manufacture or preparation of a foodstuff and – even in altered form – being present in the finished product” (“der bei der Herstellung oder Zubereitung eines Lebensmittels verwendet wird und – wenn auch möglicherweise in veränderter Form – im Enderzeugnis vorhanden bleibt”). In general also the enzyme Transglutaminase may be an ingredient in this sense. Inter alia, “enzymes which are used as processing aids” are excluded from the legal definition of “ingredient” as they shall not be regarded as ingredients, Article 6 para 4 (c) ii) indent 2 Directive 2000/13/EC, § 5 para 2 No. 3 LMKV.

The legal definition of processing aid (German: technologischer Hilfsstoff or Verarbeitungshilfsstoff) is laid down in Article 3 para 2 (b) Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16). Therefore processing aid shall mean any such substance which

*“(i) is not consumed as a food by itself; (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and (iii) 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”.*

Transglutaminase is not consumed as a food by itself. Instead it is used in the processing of the food or its raw materials for technological purposes. These are the purposes named above like improvement of physical properties and texture, decrease of salt content or combining meat or fish parts. The effect is merely technological by catalysing  $\epsilon$ -( $\gamma$ -glutamyl)-lysine cross-links in liquidised proteins. This mechanism is brought to an end by depletion of the substrate or thermal denaturation. The denatured enzymes or the for lack of substrate inactive enzymes cannot be separated by technical means from the final product, the foodstuff. They will be present as unintentional but technically unavoidable residues. They do not have any effect on the final product, in other words they do not serve any technological function. In health terms the enzyme – even in denatured state – is safe.

Therefore the enzyme Transglutaminase is a processing aid in a legal sense. As a processing aid Transglutaminase is not an ingredient and under current law must not be labelled in the list of ingredients.

Under Arrête du 19 octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires (retrieved 22.6.2011) Transglutaminase has the legal status as a processing aid in France. This directive as the subsequent directives has undergone Community notification procedure without any objections from European Commission regarding its legal qualification. This opinion is shared by German state laboratories (Islam, Bewig, Landeslabor Berlin-Brandenburg, Klebeschinken – Verfälschung von Rohschinken durch Einsatz von Enzymen?!, <http://www.landeslabor.berlin-brandenburg.de/sixcms/detail.php/bb1.c.225507.de>).

Because of its legal status as processing aid the enzyme Transglutaminase has not to be labelled pursuant § 6 para 4 No. 3 LMKV, laying down the rule that enzymes shall be designated by the name of their category followed by their specific name. This rule does

only apply to enzymes that are ingredients. This results from the reference to Article 6 para 6 indent 5 Directive 2000/13/EC, stating that only enzymes other than those named in Article 6 para 4 (c) ii) Directive 2000/13/EC have to be labelled. But Transglutaminase as a processing aid is an enzyme within the scope of Article 6 para 4 (c) ii) Directive 2000/13/EC.

## **2) Labelling under future Food Information to Consumer Regulation**

Food Information to Consumer Regulation (FIR) entered into force on December, 12<sup>th</sup>, 2011 and will be applicable from December 13<sup>th</sup>, 2014, with respect to the general labelling requirements and from December 13<sup>th</sup>, 2016, regarding the mandatory nutrition labelling. From 13 December 2014 on it will replace current Directive 2000/13/EC.

Pursuant Article 20 (b) ii) FIR “food enzymes, which are used as processing aids” are not required to be included in the list of ingredients. Other as under current law food enzymes, which are used as processing aids, are not explicitly excluded from the legal definition of “ingredient”. Whereas Article 6 para 4 (c) ii) indent 2 Directive 2000/13/EC stated that they are not regarded as ingredients, Article 20 FIR only releases from the requirement to include them in the list of ingredients. Therefore one may conclude that they may be named in the list of ingredients voluntarily. And as the designation by the name of their category followed by their specific name does not apply for enzymes named in Article 20 (b) FIR, i.e. for processing aids, Annex VII Part C FIR, just naming the enzyme as such would be appropriate.

But as residues are not considered as ingredients under FIR, in other words are excluded from the legal definition of the term “ingredients”, and processing aids by legal means can only be present in a final product as residues (Article 3 para 2 (b) Regulation (EC) 1333/2008) the before mentioned conclusion may be disputed. According to Article 18 para 1 FIR the list of ingredients comprises ingredients only. Therefore a substance that is not an ingredient, like a residue, must not be named in the list of ingredients. From this perspective Article 20 (b) ii) FIR referring to the use of food enzymes as processing aids is redundant and lacks the necessary clarity.

Insofar future law will not change the situation that the enzyme Transglutaminase has not to and must not be labelled in the list of ingredients.

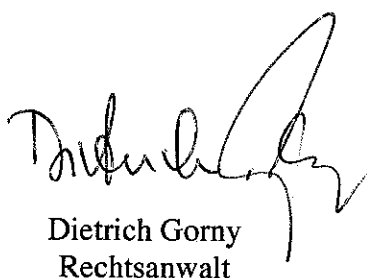
If the enzyme Transglutaminase is used at production of meat products, meat preparations and fishery products which may give the impression that they are made of a whole piece of meat or fish, but actually consist of different pieces, it is necessary to refer to this fact, Annex VI Part A No. 7 FIR. In this case the indication “formed meat” or “formed fish” is mandatory. Only the terms listed in Annex VI Part A No. 7 FIR in the languages of each Member State may be used. This labelling obligation applies from 13 December 2014 to all kinds of products aforementioned made of combined parts, regardless of the technology used to combine those parts. This shall ward off the false impression of whole cuts. It does not result that the substance providing or just supporting such connection has to be labelled.

This is systematic as only substances being more or less functional in the finished product have to be listed in the list of ingredients. But if a substance without any function in the finished product is listed the false impression of a purpose or an effect may arise and mislead the consumer.

The educational information obligatory in future is equivalent to French law in force since January 2011 and to the labelling advise given by Ajinomoto Foods Europe SAS for years.

### 3) Conclusion

As a processing aid the enzyme Transglutaminase is no ingredient under both current law and future law. It has not to be included in the list of ingredients. From 13 December 2014 on all meat products, meat preparations and fishery products which may give the impression that they are made of a whole piece of meat or fish, but actually consist of different pieces, have to bear the mandatory labelling “formed meat” or “formed fish”.



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