



Amano Enzyme Europe Ltd.

Roundway House, Cromwell Park, Chipping Norton
Oxfordshire OX7 5SR
United Kingdom

DIVISION OF CHEMISTRY
AND FOOD QUALITY

24.01.2013

Protease P "Amano" 6SD-K/ Acceptance

Ruling

The enzyme preparation Protease P "Amano" 6SD-K also called Protease P "Amano" 6SD is accepted for use in protein hydrolysis of meat and vegetables, in cheese production as well as for production of meat- and yeast extracts.

For production of hydrolyzed proteins and extracts the enzyme preparation Protease P "Amano" 6SD-K can be used at a dosage up to 0,2-0,4 %. These proteins and extracts can be used in food products at a dosage up to 10 %. Hereby the maximal amount of enzyme preparation in the final food product will not exceed 0,02 %.

The production organism for this enzyme preparation is a non-GM strain of *Aspergillus mel-leus*.

The conditions for the acceptance are given in the following.

Background

The company has by letter of July 12th 2012 notified the enzyme preparation Protease P "Amano" 6SD-K. The notification is made in accordance with §12 in the Danish regulation on food additives¹.

The Danish Veterinary and Food Administration asked for supplemental information a couple of times and the company replied to these inquiries. The latest reply was given on January 23rd 2013. The notification was then considered satisfactory.

Conditions

The acceptance from the Danish Veterinary and Food Administration imply that the enzyme product is continuously produced according to the provided information including the requests regarding purity that are specified in the Danish regulation on food additives¹.

It is a prerequisite that the additives used in the production of - or in the enzyme product are in accordance with the requests of identity and purified described in Positivlisten² if the compounds are included in this list.

¹ Bekendtgørelse nr. 1114 af 28. november 2012 om tilsætninger mv. til fødevarer

It is also a prerequisite that the use of the enzyme product is in accordance with the information given by the notifying company, i.e. only the mentioned products, and with good manufacturing practice.

The Danish Veterinary and Food Administration points out that the continued use of the enzyme product can be dependent on new data and reserves the right to obtain information about the product at any time. The acceptance can be withdrawn if the conditions have changed in such a way, that the Danish Veterinary and Food Administration find a withdrawal necessary.

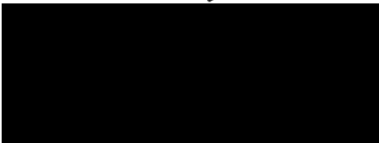
The company is obliged to follow and obey changes in regulations that may be implemented post acceptance.

If the method of production of the enzyme products changes or the production is closed down, the Danish Veterinary and Food Administration must be informed. Since the company is the producer of the given product, it is at resale, imposed to inform the Danish wholesale dealers or producers of food that the product used in accordance with the conditions appointed in the present acceptance, including the limits of use. If the user wishes to use the product at different conditions than described in this acceptance, it has to be reported to the Danish Veterinary and Food Administration.

Marketing

The product has to be marked according to the regulation on marketing of foodstuffs³.

Yours faithfully



MSc. Eng. Biotechnology

The Danish Veterinary and Food Administration
Department of Chemistry and Food Quality



² Appendix 6 of Bekendtgørelse nr. 1114 af 28. november 2012 om tilsætninger mv. til fødevarer

³ Bekendtgørelse nr. 1308 af 14. december 2005 om mærkning m.v. af fødevarer