14 July 2017

Food Standards Australia New Zealand
PO Box 5423 PO Box 10559
KINGSTON ACT 2604

A1130 – Triacylglycerol Lipase as a Processing Aid (Enzyme)

I wish to make comment on elements of the Proposed Draft Revision on behalf of the Food Intolerance Network (FIN), which has 13,249 current members and so is probably the largest consumer organisation focused on food in Australia.

The first comment is from the point of view of consumers. While we do not oppose the use of the enzyme *per se* we object strongly to it being classified as a processing aid. As consumers, we want to know what changes have been made in our food. To hide the cause of the the change as a 'processing aid' is deliberately misleading.

There is a world-wide trend by the food industry to reduce additives shown on the Ingredients Panel because up to 80% of consumers are concerned about what is in their food (Ref 1). One strategy is to have current additives classified or reclassified as 'processing aids' so that they do not appear on the panel.

However as consumers we want to know if these additives have been used in the food because they alter the composition of the food in ways that may affect certain people.

A practical example of the problem is that some existing permitted proteases increase the levels of free glutamates to levels that affect sensitive individuals. At present the use of these proteases must be declared because they are additives, so consumers can make an educated guess about free glutamates and avoid foods containing them if necessary.

If they are deleted as permitted additives or reclassified as processing aids but are still used in foods, consumers are denied this information and choice.

Second, there is also some evidence of harm from enzymes that has been presented to CODEX, as attached in Annex A. We are concerned at this scientific evidence given in CX/FA 17/49/12 so again we request that if these enzymes are used in food their presence continues to be shown on the Ingredients Panel and they are not hidden as processing aids so that consumers can make a choice. In other words, if they are deleted from the list of additives but their use continues 'in accordance with GMP' or in any other way, we consumers want to know about this use.

The Australian Food Standards Code currently lists the following enzymes and we would resist any attempt to remove them from the Food Standards Code and hide them as processing aids:

- 1100 a-Amylase
- 1101 Proteases (papain, bromelain, ficin)
- 1102 Glucose oxidase
- 1104 Lipases
- 1105 Lysozyme

Third, we wish to draw to your attention to very recent scientific evidence of harm from enzymes, showing that they are not always the benign proteins which many scientists assume.

Occup Environ Med. 2017 Jan;74(1):39-45. doi: 10.1136/oemed-2015-103442. Epub 2016 Sep 21.
Sensitising effects of genetically modified enzymes used in flavour, fragrance, detergence and pharmaceutical production: cross-sectional study.
Budnik LT1,2, Scheer E3, Burge PS2,4, Baur X2,5. https://www.ncbi.nlm.nih.gov/pubmed/27655774

Abstract

OBJECTIVES:

The use of genetically engineered enzymes in the synthesis of flavourings, fragrances and other applications has increased tremendously. There is, however, a paucity of data on sensitisation and/or allergy to the finished products. We aimed to review the use of genetically modified enzymes and the enormous challenges in human biomonitoring studies with suitable assays of specific IgE to a variety of modified enzyme proteins in occupational settings and measure specific IgE to modified enzymes in exposed workers.

METHODS:

Specific IgE antibodies against workplace-specific individual enzymes were measured by the specific fluorescence enzyme-labelled immunoassay in 813 exposed workers seen in cross-sectional surveys.

RESULTS:

Twenty-three per cent of all exposed workers showed type I sensitisation with IgE antibodies directed against respective workplace-specific enzymes. The highest sensitisation frequencies observed were for workers exposed enzymes derived from a-amylase (44%), followed by stainzyme (41%), pancreatinin (35%), savinase (31%), papain (31%), ovozyme (28%), phytase (16%), trypsin (15%) and lipase (4%). The highest individual antibody levels (up to 110 kU/L) were detected in workers exposed to phytase, xylanase and glucanase. In a subgroup comprising 134 workers, detailed clinical diagnostics confirmed work-related symptoms. There was a strong correlation ($r=0.75$, $p<0.0001$) between the symptoms and antibody levels. Workers with work-related respiratory symptoms showed a higher prevalence for the presence of specific IgE antibodies against workplace-specific enzymes than asymptomatic exposed workers (likelihood ratio 2.32, sensitivity 0.92, specificity 0.6).

CONCLUSIONS:

Our data confirm the previous findings showing that genetically engineered enzymes are potent allergens eliciting immediate-type sensitisation. Owing to lack of commercial diagnostic tests, few of those exposed receive regular surveillance including biomonitoring with relevant specific IgE assays.

We look forward to a favourable response to this reasonable request that consumers are informed what is in their food, as your Act requires.

Regards

Howard Dengate BSc PhD
www.fedup.com.au
02 6654 7500
PO Box 718 WOOLGOOLGA NSW 2456 Australia

Ref 1: http://www.fedup.com.au/images/stories/TheRealFoodtrend.pdf

ANNEX A

EXERPT FROM: **JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES Forty-Ninth Session Macao SAR, China, 20-24 March 2017**

PROPOSED DRAFT REVISION TO THE INTERNATIONAL NUMBERING SYSTEM (INS) FOR FOOD ADDITIVES (CAC/GL 36-1989)

Deletion of amylases(INS 1100 i, ii, iii, iv, v, vi), proteases(INS 1101 i, ii, iii, iv, v, vi)and lipases(INS 1104)

10. Amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi), lipases (INS 1104) are not justified for use as food additives since they fall outside the scope of the definition for food additives. These substances have no activity in final food (flour and bakery products) because the production process typically includes heat inactivation of the enzyme in order to terminate the process when the desired effect is obtained.

11. In compliance with table 3 of GSFA, amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi) and lipases (INS 1104) could be used in broad food categories in accordance with GMP. In some of these FC activity enzymes could be manifested.

12. Amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi) and lipases (INS 1104) are digestive enzymes. They have been broadly used in therapy of digestive tract diseases. However in case of systematic use of digestive enzymes with food there could be imbalance in digestive process:

- Decrease production of endogenic digestive enzyme
- Change of Michaelis constant, from which depend of enzymatic reaction rate in the digestion of food
- Violation allosteric control of enzyme activity
- Hormone imbalance which are for supervising production of digestive enzyme responsible in the human organism.

13. For example, changing quantity of lipase and amylase could lead to imbalance of endocrine function of pancreas and lowering organism tolerance into glucose. It should be noted that:

- As producers of these food additives permitted microorganisms with modified DNA
- Volumes of enzymes production and food produced with help of enzymes are constantly increased.

14. Produced by GM microorganisms enzymes could have different characteristics from enzymes elaborated in digestive tract:

- Another optimum of temperature and pH for enzyme activity
- Different enantiomers could have different type of enzyme activity.

15. For example, the possibility of negative influence of food additive lipase (in case its use in a higher concentration) showed in:

- WHO Food Additives Series: 71, World Health Organization, Geneva, 2015, p.27-37;

- Safety evaluation of certain food additives World Health Organization, Geneva, 2012.-p.39-51;
- Safety evaluation of certain food additives World Health Organization, Geneva, 2012.-p. 51-63;
- Sixty-first report of the Joint FAO/WHO Expert Committee on Food Additives, WHO 2004, 15-20.