



ELISA Technologies, Inc.

www.elisa-tek.com

December 20, 2002

Walter Ranzau
MAYACAMAS
1206 E. MacArthur
Sonoma, CA 95476

Re: Gluten Testing

Dear Walter,

I am writing to follow up on our conversations regarding testing foods for the presence of gluten. As of this date, the FDA and other US agencies have not, to my knowledge, published guidelines for defining a threshold level for "gluten-free foods".

However, the Joint FAO/WHO Food Standards Program Codex Committee on Nutrition and Foods for Special Dietary Uses at their twenty first session in Berlin, Germany in September 1998 drafted a revised standard for gluten-free foods. This statement has served as the guideline defining which foods may be declared "gluten-free"

Their report states in section 1.1: "This standard applies to foodstuffs and ingredients which have been especially processed or prepared to meet the dietary needs of persons intolerant to gluten".

It goes on in section 2.1 to state that "Gluten-Free" foods are food stuffs so described:

- a) consisting of or made only from ingredients which do not contain any prolamins from wheat or all Triticum species such as spelt, kamut, or durum, wheat, barley, oats, spelt or their crossbred varieties with a gluten level not exceeding 20ppm: or
- b) consisting of ingredients from wheat, rye, barley, oats, spelt or their crossbred varieties, which have been rendered "gluten-free"; with a gluten level not exceeding 200ppm: or
- c) any mixture of the two ingredients as in a) and b) with a gluten level not exceeding 200ppm.

In section 3.1 of the report it states:

"For the purpose of this standard 'gluten-free' means that the total content of gluten in products defined in 2.1a) shall not exceed 20ppm, that the total content of gluten from wheat, rye, barley, oats or crossbred varieties of these does not exceed 200ppm in these food stuffs or ingredients defined in 2.1b) and c) on a dry matter basis. The prolamin content of liquid food products is in the same way expressed in ppm of the original product.

The GLUTEN ELISA ASSAY used to test your samples is a sensitive and specific assay utilizing antibodies originally developed at the Wheat Research Unit, Division of Plant Industry of C.S.I.R.O. in Australia. These antibodies are specific for detection of omega-gliadin, which is used to indicate the gluten content of foods.

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The Gluten ELISA, which is available commercially as the BioKits and ELISA-TEK Gluten Assays, was tested in an AOAC approved collaborative trial published in the JAOAC (Skerritt & Hill, JAOAC, Vol. 74, No. 2, 1991). It has since been designated AOAC Official Method 991.19 and is described in The AOAC Official Methods of Analysis (2000), Chapter 32, pages 15-17. The official method is intended to be used for the detection of gluten at levels of >200ppm (>100ppm gliadin) in a wide range of uncooked and cooked foods.

A "high sensitivity" protocol for the Gluten Assay, designed to detect gluten at levels of >20ppm (>10ppm gliadin), is offered for customers who wish to test for very low levels of gluten contamination, e.g. in non-wheat derived foods in order to meet the >20ppm standard for "gluten-free" as described in the WHO/FAO committee guidelines.

In testing your products, we utilized the high sensitivity protocol for the Gluten ELISA to allow us to report if your product samples contain less than 20ppm gluten. Samples containing less than 20ppm gluten meet the strictest interpretation of the WHO/FAO codex alimentarius statement which defines "gluten-free" foods as those containing less than 20ppm gluten. This is also the level currently utilized for determining "gluten-free" foods by most agencies monitoring gluten content of foods.

Please note that we cannot declare that samples contain "zero" gluten. Although that may be the case, all tests have a detection limit and therefore there is always an element of uncertainty about "negative" samples that fall below the detection limit.

We appreciate the opportunity to serve your analytical needs. If you have any questions, or if I can be of any further assistance, please feel free to contact me.

Sincerely,

Bruce Ritter
President

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