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ETA Policy Statement **in Reaction to Concerns Regarding** **Japan's Fukushima Nuclear Plant Radiation**

In response to the growing public health concern over radiological contamination following the earthquake and tsunami that damaged the Fukushima nuclear power plants on March 11, 2011, the Enzyme Technical Association (ETA) is issuing the following policy statement regarding enzymes and enzyme preparations imported to the United States from Japan.

In response to the public health concern associated with radiation and nuclear contamination, the U.S. Food and Drug Administration (FDA) issued an Import Alert (#99-33), available at http://www.accessdata.fda.gov/cms_ia/ialist.html. In the Import Alert, FDA states that certain categories of product from Fukushima, Ibaraki, and Tochigi are subject to detention, without physical examination, at U.S. ports of entry.

In addition to the Import Alert (#99-33), FDA is augmenting its screening procedures with screening of all shipments from Japan, and in particular, FDA has established special procedures to evaluate products from the ten prefectures in closest proximity to the Fukushima Daiichi nuclear plant. FDA's screening is intended to assure that nothing enters the U.S. that contains actionable levels of concern. While FDA may elect to conduct additional testing, FDA is not requiring additional testing of products being offered for import by companies.

Enzymes and carriers used in enzyme mixtures are not products of concern cited in Import Alert (#99-33). ETA does not have any reason to believe that enzymes or enzyme preparations produced in Japan and imported for use in the U.S. pose a risk of radiological contamination. Therefore, ETA concludes that there is currently no concern regarding enzyme products imported from Japan. In addition, barring production in one of the prefectures listed in FDA's Import Alert, ETA takes the position that testing of enzyme product for radionuclide contamination is not necessary.

ETA will continue to monitor the U.S. FDA and Japanese Government's positions.

June 10, 2011

**The above ETA Policy Statement was provided to FDA on June 10, 2011
and to date, ETA has received no comments.**