1111 Pennsylvania Avenue, N.W. Washington, DC 20004

Telephone 202.739.5612 Fax 202.739.3001 www.enzymetechnicalassoc.org

BIOTECHNOLOGY, ENZYMES AND ALLERGIES

What are enzymes?

Enzymes are special kinds of proteins that are found in all living matter. Man, animals, plants – all living cells produce and need enzymes to live and grow. However, enzymes themselves are not living organisms. Enzymes are catalysts: substances which speed up chemical reactions by being present in very small amounts and without being changed in the reaction.

What is an allergy?

The purpose of the immune system is to protect the organism from foreign substances such as infectious agents and tumors. An allergy is a hypersensitivity reaction of the immune system. There are several types of allergies. Taken together, allergies occur among 20-30% of all humans. Proteins, and therefore enzymes as well, can in some cases cause a so-called Type I allergy which requires the development of allergic antibodies. Type I allergy symptoms can include watery eyes, runny noses, sneezing (hay fever), wheezing (asthma), hives (urticaria) and several reactions to food, including vomiting and diarrhea.

Routes of exposure to allergens

Allergens can trigger the immune system through several routes of exposure, via food, via skin contact or via inhalation. Enzymes can cause allergies through repeated exposure via inhalation in sufficient high doses and possibly by contact with mucosal surfaces (eyes, nose). There is limited evidence for enzyme allergy development from contact with eyes. In addition, only susceptible individuals will develop allergies. Exposure via food and skin contact has not been documented to be associated with enzyme allergy.

AMFEP (Association of Manufacturers of Fermentation Enzyme Products) established an Expert Group to evaluate whether residual enzymes in foods are an allergy risk for consumers. The Expert Group concluded that there are no scientific indications that the small amount of enzymes in bread and other food can sensitize or induce allergy reactions in consumers ("Consumer Allergy Risk for Enzyme Residues in Food," AMFEP 1998).

AISE (Association Internationale de la Savonnerie et de la Detergence) evaluated the possible association between contact allergy (Type IV, delayed hypersensitivity) and skin contact with enzyme products. This evaluation including results of predictive testing in man demonstrated that enzymes do not have a significant skin sensitization potential. ("Enzymes: Lack of Skin Sensitization Potential," AISE 1995.)

1

DB1/759727761

1111 Pennsylvania Avenue, N.W. Washington, DC 20004

Telephone 202.739.5612 Fax 202.739.3001 www.enzymetechnicalassoc.org

Modern biotechnology and enzyme allergies

Modern biotechnology techniques are utilized to improve microbial production strains to increase the enzyme yields and to make minor amino acid changes that improve the functionality of the enzyme. These changes are not known to increase the ability of enzymes to cause allergies.

What does the enzyme industry do to prevent allergies from occurring?

In the 1960's dusty, powder enzymes in detergent manufacturing plants induced respiratory allergies among workers (Findt 1969, Pepys et al., 1969). Since this time, solid enzymes have been encapsulated (prilled, granulated) to reduce the dustiness of the material markedly. In addition, a significant improvement of manufacturing sites and industrial hygiene practices and procedures has taken place. With the introduction of encapsulated enzymes, the incidence of adverse respiratory symptoms has virtually disappeared in detergent workers (Hendricks and Carter, 1970; Bolam et al., 1971; Zachariae et al., 1981). Retrospective data furthermore provides compelling evidence that consumer use of current enzyme containing detergents does not lead to respiratory allergies to enzymes (Pepys et al., 1973 and 1985). The enzyme industry has undertaken several studies (of which some are quoted in the AMFEP and AISE references mentioned above) to study whether enzymes used in laundry and food products cause allergies and the data to date has not suggested a need for concern.

23 April 2001

DB1/759727761