

Annex 3

Further information required

Thickening agent

Curdlan

The following information is required for evaluation in 2001:

- information on the use of curdlan, including the maximum and typical levels expected to occur in the food categories proposed in the draft General Standard for Food Additives being developed by the Codex Committee on Food Additives and Contaminants;
- data on the consumption of foodstuffs that might contain curdlan in different regions of the world, to permit assessment of the intake.

Miscellaneous substance

Sodium sulfate

Information on the functional effect and actual uses of sodium sulfate in food is required for evaluation in 2001.

Substances evaluated using the Procedure for the Safety Evaluation of Flavouring Agents

Information on those flavouring agents for which the specifications are designated as “tentative” is required for evaluation in 2000.

Contaminant

Methylmercury

The results of the 96-month evaluation of the cohort of children in the Seychelles exposed pre- and postnatally to methylmercury in fish, and other relevant data that have become available, are required for evaluation in 2002.

Annex 4

Report of an ad hoc Panel on Food Allergens

An ad hoc Panel on Food Allergens met in Geneva, Switzerland, from 18 to 19 February 1999 to provide advice to the Joint FAO/WHO Expert Committee on Food Additives about criteria for labelling. The following scientists participated:

Members

Dr J. Greig, Joint Food Safety and Standards Group, Department of Health, London, England

Dr M. Lovik, Department of Environmental Medicine, National Institute of Public Health, Oslo, Norway

Dr C. Madsen, Institute of Food Safety and Toxicology, Danish Veterinary and Food Administration, Ministry of Food, Agriculture and Fisheries, Søborg, Denmark

Professor S.L. Taylor, Department of Food Science and Toxicology, University of Nebraska, Lincoln, NE, USA

Secretariat

Dr J.L. Herrman, International Programme on Chemical Safety, WHO, Geneva, Switzerland

Dr E. Smith, International Programme on Chemical Safety, WHO, Geneva, Switzerland

Introduction

Allergens in food have been considered by the Codex Committee on Food Labelling on a number of occasions since 1993, when a working paper on the consideration of potential allergens in foods was prepared by Norway, in cooperation with Finland, Iceland and Sweden (1).

An FAO Technical Consultation on Food Allergies was held in Rome from 13 to 14 November 1995, which was asked inter alia to “provide guidance on the development of science-based criteria to determine which foods or food products should be placed on a list of those foods or food products whose presence should always be declared in the list of ingredients on a food label, because of their allergenic properties”. The Consultation confirmed that the listing of foods and ingredients known to cause allergies and intolerance that had been developed by the Codex Committee on Food Labelling was appropriate, with some modifications (2).

The revised list of those foods and ingredients known to cause food allergies and intolerance and whose presence should always be declared was identified as the following:

- cereals containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and their products;

- crustacea and their products;
- eggs and egg products;
- fish and fish products;
- peanuts, soya beans and their products;
- milk and milk products (including lactose);
- tree nuts and nut products; and
- sulfite at concentrations ≥ 10 mg/kg.

After debate in the Codex Committee on Food Labelling, this list was forwarded at step 8 for adoption by the Codex Alimentarius Commission. During the debate, further questions arose which required advice from the Joint FAO/WHO Expert Committee on Food Additives, the Committee that provides scientific recommendations to the Codex Alimentarius Commission relating to food additives and ingredients in food.

The Panel was convened to consider the issues forwarded by the Codex Committee and to provide guidance on them to the Expert Committee. The issues included:

- identifying criteria for adding foodstuffs to the list of common allergenic foods forwarded by the Codex Committee on Food Labelling, if found to be necessary;
- developing criteria for identifying products of foodstuffs on the list of the Codex Committee for which labelling of the food source is unnecessary; and
- considering ways in which FAO and WHO could provide continuous guidance in this area to the Expert Committee.

The literature on food allergies

The Panel noted that the scientific literature contains numerous recent authoritative reviews on food allergy, its manifestations and its causes. It considered that a selection of articles (1–6), complemented by this report, would provide the information that the Expert Committee required.

Terminology

The Panel noted some inconsistency in the use of certain terms in various documents. It therefore agreed on the following definitions of terms. The Panel recognized that individual heightened responses to foods and food ingredients can occur through a variety of mechanisms. “Food allergies” involve abnormal responses of the immune system to food components, which are usually naturally-occurring proteins. They can be classified as either immunoglobulin E (IgE)-mediated reactions (e.g. allergies to peanuts or eggs) or cell-mediated

reactions (e.g. coeliac disease). "Food intolerance" is an abnormal response to food components that occurs through a non-immunological mechanism. Food intolerance may include metabolic food disorders, anaphylactoid reactions and idiosyncratic illnesses. "Metabolic food disorders" are enzymatic deficiencies such as lactose intolerance. "Anaphylactoid reactions" involve the release of histamine and other mediators from mast cells without the intervention of IgE. Although anaphylactoid reactions to specific drugs have been well documented, the involvement of this mechanism in adverse food reactions remains unproven. "Idiosyncratic reactions" are those that occur through unknown mechanisms in susceptible individuals. Although the cause-and-effect relationship between the ingestion of a specific food and the onset of symptoms of idiosyncratic illnesses is a subject of some debate, sulfite-induced asthma is an example of an idiosyncratic illness in which the cause-and-effect relationship is unequivocally established but the mechanism of the reaction remains unknown. Food additive intolerances are usually considered as idiosyncratic illnesses.

The Panel further recognized that certain types of food intoxication such as with histamine-containing toxins (e.g. scombrottoxins) involve allergy-like reactions, but in contrast to the situation with food allergies and intolerance, all consumers are susceptible.

Criteria for the addition of foodstuffs to the list of the Codex Committee on Food Labelling

In determining whether a foodstuff should be added to the list of common allergenic foods drawn up by the Codex Committee on Food Labelling, the Panel recommended that all of the following criteria be met:

- (i) The existence of a credible cause-and-effect relationship, based on a positive reaction to a double-blind placebo-controlled food challenge or unequivocal reports of a reaction with the typical features of a severe allergic or intolerance reaction.
- (ii) The existence of reports of systemic reactions after exposure to the foodstuff, the reactions including atopic dermatitis, urticaria, angio-oedema, laryngeal oedema, asthma, rhinitis, abdominal pain, diarrhoea, vomiting, anaphylactic shock and chronic severe malabsorption syndrome.
- (iii) Data on the prevalence of food allergies in children and adults, supported by appropriate clinical studies (i.e. double-blind placebo-controlled food challenges) in the general population of several countries. However, the Panel noted that such information is available only for infants, from certain countries and for certain foodstuffs. The Panel therefore agreed that any available

data, such as the comparative prevalence of a specific food allergy in groups of patients in several countries, could be used as an alternative, preferably backed up by the results of a double-blind placebo-controlled food challenge.

The list adopted by the Codex Committee on Food Labelling includes not only allergenic foods but also products of such foods. Because allergens are naturally-occurring proteins, the Panel considered whether the definition is too broad in that it may include products that are not allergenic because they do not contain sufficient protein to elicit an allergic reaction. The available data do not, however, permit definition of the amount of allergenic protein necessary to elicit an allergic reaction.

The Panel therefore recommended that products of the allergenic foods on the list of the Codex Committee on Food Labelling should always be labelled as such, unless they are on the list of products that are excluded from the requirement for labelling of the food source.

The criteria for inclusion of a product on the latter list are:

- (i) evidence that a clinical study with a double-blind placebo-controlled food challenge has confirmed that the specific product does not elicit allergic reactions in a group of patients with clinical allergy to the parent foodstuff;
- (ii) submission of specifications for the product and its manufacturing process which demonstrate that the process yields a consistently safe product; and
- (iii) for products implicated in coeliac disease:
 - (a) products of rye, barley and oats would not be required to meet the criteria set out in (i) and (ii) above because IgE-mediated allergic reactions to these cereal grains are uncommon;
 - (b) products of wheat, spelt and their hybridized strains would be required to meet the criteria set out in (i) and (ii) above; and
 - (c) products of wheat, rye, barley, oats and spelt and their hybridized strains would be required to adhere to existing specifications for gluten-free products.

To the knowledge of the Panel, only two products may currently fulfil these criteria: highly refined peanut oil and soya bean oil. The Panel recommended that these two products be reviewed at the next meeting of the Joint FAO/WHO Expert Committee on Food Additives to consider food additives and contaminants.

The Panel recognized that application of all the criteria set out above would rely heavily on expert advice. It considered that such advice would best be provided by a body which, because of geographical variation in food allergy and in diets, should be constituted so as to have representation from a variety of disciplines and global regions.

References

1. Codex Committee on Food Labelling. *Consideration of potential allergens in foods. Paper prepared for the Twenty-second Session of the Codex Committee on Food Labelling, Ottawa, Canada, 26–30 April 1993*. Rome, Food and Agriculture Organization of the United Nations, 1993 (unpublished document CX/FL 93/5).
2. *Report of the Technical Consultation on Food Allergies, Rome, Italy, 13–14 November 1995*. Rome, Food and Agriculture Organization of the United Nations, 1995 (unpublished document).
3. Løvik M et al., eds. Chemical exposure and food allergy/intolerance. Proceedings of an IPCS/NIPH scientific symposium on chemical exposure and food allergy/intolerance. *Environmental Toxicology and Pharmacology*, 1997, 4:1–186.
4. Metcalfe DD, Sampson HA, Simon RA, eds. *Food allergy: adverse reactions to foods and food additives*, 2nd ed. Cambridge, MA, Blackwell Science, 1997.
5. Bousquet J et al. Scientific criteria and the selection of allergenic foods for product labelling. *Allergy*, 1998, 53 (Suppl. 47):3–21.
6. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment. *Peanut allergy*. London, Department of Health, 1998.