

APPENDIX III

**DRAFT REVISED CODEX STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR
PERSONS INTOLERANT TO GLUTEN****(At Step 8 of the Procedure)****1. SCOPE**

1.1 This standard applies to foods for special dietary uses that have been formulated, processed or prepared to meet the special dietary needs of people intolerant to gluten.

1.2 Foods for general consumption which by their nature are suitable for use by people with gluten intolerance may indicate such suitability in accordance with the provisions of section 4.3.

2. DESCRIPTION**2.1 Definitions**

The products covered by this standard are described as follows:

2.1.1 Gluten-free foods

Gluten-free foods are dietary foods

a) consisting of or made only from one or more ingredients which do not contain wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats¹ or their crossbred varieties, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer, and/or

b) consisting of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats¹ or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20 mg/kg in total, based on the food as sold or distributed to the consumer.

2.1.2 Foods specially processed to reduce gluten content to a level above 20 up to 100 mg/kg

These foods consist of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats¹ or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100 mg/kg in total, based on the food as sold or distributed to the consumer.

Decisions on the marketing of products described in this section may be determined at the national level.

2.2 Subsidiary Definitions**2.2.1 Gluten**

For the purpose of this standard, "gluten" is defined as a protein fraction from wheat, rye, barley, oats¹ or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl.

2.2.2 Prolamins

Prolamins are defined as the fraction from gluten that can be extracted by 40 - 70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats¹ avenin.

It is however an established custom to speak of gluten sensitivity. The prolamin content of gluten is generally taken as 50%.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 For products referred to in 2.1.1 a) and b), the gluten content shall not exceed 20 mg/kg in the food as sold or distributed to the consumer.

¹ Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level.

3.2 For products referred to in 2.1.2 the gluten content shall not exceed 100 mg/kg in the food as sold or distributed to the consumer.

3.3. Products covered by this standard substituting important basic foods, should supply approximately the same amount of vitamins and minerals as the original foods they replace.

3.4 The products covered by this standard shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with gluten.

4. LABELLING

In addition to the general labelling provisions contained in the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) and the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985), and any specific labelling provisions set out in a Codex standard applying to the particular food concerned, the following provisions for the labelling of “gluten-free foods” shall apply:

4.1 The term "gluten-free" shall be printed in the immediate proximity of the name of the product in the case of products described in section 2.1.1.

4.2 The labelling of products described in section 2.1.2 should be determined at the national level. However these products must not be called gluten-free. The labelling terms for such products should indicate the true nature of the food, and shall be printed in the immediate proximity of the name of the product.

4.3 A food which, by its nature, is suitable for use as part of a gluten-free diet, shall not be designated “special dietary”, “special dietetic” or any other equivalent term. However, such a food may bear a statement on the label that “this food is by its nature gluten-free” provided that it complies with the essential composition provisions for gluten-free as set out in section 3.1 and provided that such a statement does not mislead the consumer. More detailed rules in order to ensure that the consumer is not misled may be determined at the national level.

5. METHODS OF ANALYSIS AND SAMPLING

5.1 General outline of the methods

- The quantitative determination of gluten in foods and ingredients shall be based on an immunologic method or other method providing at least equal sensitivity and specificity.
- The antibody used should react with the cereal protein fractions that are toxic for persons intolerant to gluten and should not cross-react with other cereal proteins or other constituents of the foods or ingredients.
- Methods used for determination should be validated and calibrated against a certified reference material, if available.
- The detection limit has to be appropriate according to the state of the art and the technical standard. It should be 10 mg gluten/kg or below.
- The qualitative analysis that indicates the presence of gluten shall be based on relevant methods (e.g. ELISA-based methods, DNA methods).

5.2 Method for determination of gluten

Enzyme-linked Immunoassay (ELISA) R5 Mendez Method.