STANDARD FOR FOODS FOR SPECIAL DIETARY USE FOR PERSONS INTOLERANT TO GLUTEN

(CXS 118-1979)

(Prepared by Canada)

Background:

The 43rd Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) agreed that the Codex Secretariat would consider approaches to review all texts under the purview of CCNFSDU to assess if they were still fit for purpose and noted the willingness of FAO and WHO to assist in this task.

The *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CXS 118-1979), also known at the time as the *Standard for "Gluten-Free" Foods*, was first adopted in 1979. In 1983, editorial amendments were adopted following a request from the Commission to review the wording of the provisions on date-marking and storage instructions to align with the revised text of the *Guidelines on Date Marking for Use by Codex Committees* (Vol. VI of the Codex Alimentarius) that had just been adopted at CAC 14.

In 1987, at CCNFSDU 15, the standard was first proposed to be revised as a result of (a) a preference to use gliadin as an indicator of the acceptability of gluten-free foods; (b) the increased tendency to use gluten as a food additive; and that (c) several foods contained this toxic factor naturally. At CCNFSDU 16, the Committee agreed not to proceed with the amendment of the Standard as no collaboratively tested method was available for gliadins. However, it agreed to discuss amendments to Codex Standards and Guidelines for Gluten-Free Foods at its next session, if the required information became available.

At CCNFSDU 18, a new work proposal was presented to the Committee to revise CXS 118-1979. The Committee agreed that the level of gluten and the methods for its determination are the crucial points in the revision of the standard. However, it was also aware of important developments in gluten methodology but did not want to delay the revision of the entire standard because of lack of validated methods. Therefore, the Committee agreed to initiate work on a proposed revised draft *Standard for Gluten-Free Foods*. Several aspects of the standard were revised over a period of 15 years and at CCNFSDU 29, the Committee agreed to send a renamed, revised standard, *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten*, to CAC 31 for adoption.

The last amendment to the standard was adopted in 2015. CCNFSDU 36 was asked to consider amending the standard to add the term “khorasan wheat”. The Committee agreed with this change and the addition of the term “Khorasan wheat” that appears as the phrase “khorasan wheat, which is also marketed under different trademarks such as KAMUT” in the standard under sections 2.1.1 and 2.1.2 was adopted by CAC 38.

Discussion:

Part I: Overview

People with celiac disease (CD) and other gluten-related disorders react adversely if they consume gluten, which is the storage group of proteins found in certain cereal grains, namely wheat, rye and barley. The only available treatment for CD is a gluten-free diet (GFD), which consists of the dietary exclusion of grains containing gluten and an individual’s intake of gluten should not exceed 10 mg per day (La Vieille et al., 2016; Wieser et al., 2021). Studies have demonstrated that both natural and certified gluten-free foods can be contaminated with gluten well above the commonly accepted safe threshold of 20 mg/kg (Koerner et al., 2013; Wieser et al., 2021). Most countries define gluten-free foods as those with gluten level that do not exceed 20 mg/kg (20 ppm) in total, based on the food as sold or distributed to the consumer.

This review aims to ensure that the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CXS 118-1979) continues to provide appropriate guidance related to the formulation, composition, labelling and methods of analysis for foods for special dietary use (FSDU) for persons intolerant to gluten, supporting both consumer health and international trade. Historically, some countries, such as the United States, Australia, and New Zealand, have regulated gluten-free foods within their general food frameworks, rather than as FSDU. More recently, jurisdictions, including the European Union, have also moved the regulation of gluten-free foods within their general food frameworks, rather than as FSDU. Canada is currently working on a regulatory modernization initiative for FSDU and is proposing to regulate gluten-free

foods under their general food framework (Refer to Appendix 1 for details on the regulatory frameworks for gluten-free foods in these jurisdictions).

The primary reason many jurisdictions are reconsidering the classification of gluten-free foods as FSDU is to provide clarity and consistency for consumers. Ultimately, from a consumer point of view, whether a food is specially processed or formulated to be gluten-free, or if it is inherently gluten-free and manufactured in a gluten-free facility, the food label should be permitted to make a gluten-free claim as long as the requirements are met (i.e., less than 20 ppm gluten). This enhances consumer safety by offering reliable information for individuals with CD and other gluten-related disorders.

Moreover, one can argue that gluten-free foods do not meet the requirements of an FSDU. The *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses* (CXS 146-1985) defines FSDU as "those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist." While some gluten-free foods may meet this definition, not all do, even those specially processed in a gluten-free facility to restrict cross-contamination with gluten, since they do not "differ significantly from the composition of ordinary foods of comparable nature."

Another point to consider is the inconsistency in how foods specially processed to be free of certain allergens are classified compared to gluten-free foods. Currently, gluten-free foods are considered FSDU, while foods specially processed to be free of allergens are not. This discrepancy suggests a need for a uniform approach in addressing them. Although celiac disease is an autoimmune disease, not an allergy, other gluten-related disorders do exist, and the conventional treatment—a gluten-free diet—is similar to the dietary management of food allergens. Consequently, several jurisdictions have reclassified gluten-free foods as conventional foods within allergen-free food regulations. Adopting a uniform approach where all allergen-free foods are treated as conventional foods with additional labelling and manufacturing requirements would simplify regulations and ensure consistency. This shift would help standardize requirements for all allergen-free foods, providing clarity and consistency to consumers and supporting the global trade of gluten-free foods.

Therefore, the Committee may want to consider the reclassification of gluten free foods from FSDU to general foods to improve alignment with the current regulatory frameworks in many international jurisdictions. This shift would help standardize requirements for all allergen-free foods, providing clarity and consistency to consumers and help the global trade of gluten-free foods. This would, however, necessitate several amendments to the Standard (e.g. title, scope, labelling sections, etc.). Moreover, if consideration is given to remove the FSDU designation for gluten-free foods, it may also be worth considering moving the relevant provisions from the standard to *the General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985). The Committee could consider the inclusion of provisions for gluten-free foods under the allergen labelling provisions in the *General Standard for the Labelling of Prepackaged Foods (*GSLPF), currently under review by the Codex Committee on Food Labelling, as the draft provisions include a proposed definition for celiac disease and lists cereals containing gluten as foods and ingredients known to trigger food allergy or celiac disease. While coeliac disease is not an allergy, the conventional treatment is a gluten-free diet, which is a consistent approach for food allergy and other gluten-related disorders. Another option is to create a standalone section on gluten-free claims within the GSLFP, similar to the approach for allergen labelling, but distinct from it.

Part II: Provisions in Standard

TITLE and SCOPE

Proposal: Further to the consideration raised above regarding the classification foods for persons intolerant to gluten as an FSDU, the Committee may want to consider amending the name of the standard by changing **"***Persons Intolerant To Gluten" to "Persons with Gluten-Related Disorders"* to accurately capture all conditions related to gluten.

Rationale: There is a general consensus based on the Oslo definitions for celiac disease and related terms (Ludvigsson JF et al. 2013), that gluten-related disorders, is the preferred term to use in order to describe

all conditions related to gluten. This may include disorders such as gluten ataxia, dermatitis herpetiformis (DH), non-celiac gluten sensitivity (NCGS) and CD.

DESCRIPTION

2.1 Definitions

Section 2.1.1 Gluten-free foods

In this standard, oat is included as a source of gluten, and is included within the definition for gluten-free foods with a footnote indicating that, **"***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*".

Proposal: Based on current recommendations and under specific conditions, the Committee may want to consider removing oats from the list of sources of gluten.

Rationale: The protein fractions considered to be the constituents of most concern in patients with CD include the alcohol-soluble fractions (prolamins) of wheat (gliadins), rye (secalins), and barley (hordeins) (Benoit et al., 2017). The prolamin fraction in oats (avenins) is structurally different from other prolamin fractions (lowest contents of proline and glutamine) and represents only a small proportion of total oats protein (10-20% of total protein in oats compared to 40-50% in wheat) (Comino et al., 2015; Pinto-Sanchez et al., 2017). Considering that oats can be heavily contaminated with gluten from the other sources, the role of gluten derived from oats in the pathogenesis of CD has been considered as uncertain for many years and oats was added to the Codex list of products containing gluten.

However, several studies have suggested that the consumption of "pure" oats (i.e., uncontaminated by other gluten sources) is safe in the vast majority of patients (adults and children) with CD (La Vieille et al., 2015; Lionetti et al., 2017; Hoffmanova et al., 2019; McDermid et al., 2023). Nonetheless, some concerns persist regarding the tolerance and the safety of oats for all patients with celiac disease and it is still recognized that some CD patients can be sensitive to pure oats (i.e., uncontaminated by gluten from other cereals) (Lundin et al., 2003; Peraaho et al., 2004; Spector Cohen et al., 2019). In addition, some oats varieties showed toxicity in vitro, suggesting that there are differences between oat varieties in relation to their safety or toxicity for people with celiac disease (Arentz-Hansen et al., 2004; Comino et al., 2015) explaining why many studies (but not all) found no evidence that the addition of oats to a gluten-free diet affects symptoms or the activity of celiac disease. For some authors, it is not excluded that the inconsistent study outcomes are explained by the differences in study oats rather than the differences in study subjects (Fritz and Chen, 2020). However, the current consensus is that the introduction of oats to a gluten-free diet should be monitored to confirm no adverse effects occur (Hoffmanova et al., 2019; Pinto-Sanchez et al., 2017).

The latest Academy of Nutrition and Dietetics Evidence-Based Nutrition Practice Guideline published in 2023 (McDermid et al., 2023) affirm that all individuals with celiac disease should follow a GFD (Level 1C/Imperative) that may include gluten-free oats in adults (Rating: Level 2D/Conditional) and children should follow a nutritionally adequate GFD that supports healthy growth and development and does not unnecessarily restrict gluten-free oats (Rating: Consensus/ Conditional). However, the strength of guideline recommendation for the safety of oats in adults is considered as weak (level 2) and the certainty of evidence from systematic review as very low (D). For children, this recommendation is only based on clinical expertise and experience with client values (consensus).

Therefore, the Committee may want to consider removing oats and the associated footnote of the gluten free foods definition in section 2.1.1:

Gluten-free foods should be defined as "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 khorasan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley~~, oats[1]~~ 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 khorasan wheat, which is also marketed under different trademarks such as KAMUT), rye, barley~~, oats[1]~~ 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.

However, the Committee may want to consider retaining the content of the footnote page or to include it in a specific section. It may also want to revise the current footnote to reflect the preferred nomenclature of gluten-related disorders as well as to clarify the type of oats that can be tolerated, as follows: "*Pure/uncontaminated* oats can be tolerated by most but not all people who *have CD and other gluten-related disorders"*.

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

Proposal: The Committee could reconsider the need of this section.

Rationale: The standard includes a provision for the labelling of products specially processed to reduce gluten content to a level above 20 up to 100 mg/kg as sold or distributed to the consumer. However, the safe gluten threshold for people with CD and other gluten-related disorders is below 20 ppm. It is unclear whether this provision is widely used in jurisdictions that permit its use, and if it is well understood consumers. According to a 2018 publication by the International Special Dietary Foods Industries (ISDI), this statement is seldom used by Food Business Operators to the extent that the tolerance to gluten in individuals is difficult to quantify.

The United Kingdon Food Standards Agency conducted qualitative research with consumers and health professionals in 2009 in order to explore reactions towards the updates to the European Union labelling legislation with regard to labelling on products marketed to individuals who follow a gluten-free diet, that is 'gluten-free' for foods which contain less than 20 parts per million gluten and 'Very Low Gluten' for foods containing cereal ingredients that have been treated to reduce their gluten content and which will contain more than 20 ppm but less than 100 parts per million gluten. The report, entitled, "Consumer understanding of new labelling terms for foods markets for people with gluten intolerance" indicated that consumers found the "very low gluten" claim concerning and confusing, as it was seen as requiring a judgment as to whether a product displaying this claim was suitable or not for them or their child. This caused anxiety amongst most of the sample who felt that rather than take the risk, they would avoid these products. For most respondents with celiac disease, gluten avoidance was seen an indispensable requirement to manage their condition. In their approach to making food choices, most aimed to exclude gluten absolutely from their diet rather than consuming a minimal amount of gluten. Consequently, many questioned and rejected the suitability of products labelled 'very low gluten' for people with celiac disease.

Noting the potential for consumer confusion, some jurisdictions, such as Canada, prohibit the use of "low gluten" or "reduced gluten" claims, including in relation to foods containing less than 20 ppm of gluten. These claims are considered to be misleading, as consumers with celiac disease may be led to believe that these foods are safe to consume, while medical advice recommends a gluten-free diet. Therefore, the Committee may want to reconsider the necessity of this section to ensure consumer safety and understanding.

1.2 Subsidiary Definitions

Section 2.2.2 Prolamins

Proposal: The Committee may want to consider the removal of two sentences, "*It is however an established custom to speak of gluten sensitivity. The prolamin content of gluten is generally taken as 50%"* from this section.

Rationale: The term, "gluten sensitivity" is used ambiguously in scientific literature; some scientific articles use the term synonymously with coeliac disease (CD), while others use the term to describe a condition in which symptoms are triggered by gluten ingestion, in the absence of CD. In this latter case, the term non-celiac gluten sensitivity (NCGS) is more appropriate. NCGS refers to one or more of a variety of immunological, morphological or symptomatic manifestations that are precipitated by the ingestion of gluten

in people without CD (Ludvigsson et al., 2013). To provide clarity and avoid confusion, the Committee may want to consider discontinuing the use of the term, “gluten sensitivity.”

With respect to the proposal to remove the statement, “*The prolamin content of gluten is generally taken as 50%*”, it should be noted that prolamin content varies significantly between grains. The sentence preceding this statement indicates that “*the prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats avenin.*” However, the prolamin content from oats, as avenin, is actually 10-20% of total protein in oats compared to 40-50% in wheat, as gliadin). Noting that the avenin content from oats is included within this section, it’s not accurate to state that “The prolamin content of gluten is generally taken as 50%” should be removed.

5. METHODS OF ANALYSIS AND SAMPLING

Section 5.1: General outlines of the methods

Proposal: The Standard notes that, **“**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 Committee should consider whether this limit is too high and could be lowered.

Rationale: The current limit of detection for gluten is 1 ppm, while the limit of quantification is 5 ppm. Therefore, a maximum detection limit of 10 mg gluten/ kg may be too high.

Recommendation:

To ensure the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CXS 118-1979) remains relevant and effective, the Committee may want to consider several updates. Globally, regulatory frameworks for gluten-free foods have evolved, with many jurisdictions now regulating these foods within their general food frameworks rather than as FSDU. The Committee should consider aligning the standard with these global practices, which could involve removing gluten-free foods from FSDU framework and potentially integrating relevant provisions into broader food labelling standards, such as the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985). Alignment with food allergens (since gluten from wheat may be dangerous for wheat allergic individuals) may be warranted to improve consistency and clarity in the accurate labelling and quantification of gluten content in all foods, not just those that are FSDU.

The Committee may want to consider the need to update this standard to reflect the advances related to gluten detection and the evolving representation of gluten-free foods as FSDU, or as general foods with certain labelling and associated requirements for accurate quantitative determination of gluten in foods. Additionally, the Committee may want to update terminology in the standard to reflect current understanding and preferences, such as using "Persons with Gluten-Related Disorders" instead of "Persons Intolerant to Gluten." The inclusion of oats in the list of gluten sources may also need reconsideration, given recent evidence suggesting that pure, uncontaminated oats are generally safe for most individuals with celiac disease. Finally, the necessity of provisions for foods with reduced gluten content may warrant re-evaluation, as such claims can confuse consumers and are not widely used. Updating methods of analysis to reflect advances in gluten detection technology may also be considered.

Overall, these recommendations aim to enhance the standard's alignment with current scientific knowledge and international regulatory practices, ultimately supporting consumer safety and facilitating the global trade of gluten-free foods.

APPENDIX I: Regulation of Gluten-Free Foods in Some International Jurisdictions

European Union (EU)

In the EU, gluten-free foods were previously regulated under the special dietary food framework known as foods for particular nutritional uses (PARNUTS). However, in 2013, gluten-free foods were moved from the PARNUTS framework to the general foods framework. This transition occurred when the EU repealed the Directive on foods for particular nutritional uses (EC Regulation No 41/2009) and adopted the new Regulation on Foods for Special Groups, which did not include gluten-free foods (EU Regulation No 609/2013; Specialised Nutrition Europe, 2018).

To ensure clarity and consistency, it was decided that all the rules applying to gluten should be consolidated under the same piece of legislation. Regulation (EU) No 1169/2011 sets rules requiring the mandatory labelling of substances causing allergies or intolerances, including gluten-containing ingredients. Additionally, Commission Regulation (EU) 828/2014, effective from 20 July 2016, sets harmonized requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (EC Regulation No 828/2014). All the foods containing no more than 20 mg/kg of gluten can make a gluten-free claim.

Regulation (EU) No 828/2014 did not change the substantial rules for using the "gluten free" and "very low gluten" statements which were previously laid down in Regulation (EC) No 41/2009. However, the new rules also apply to non-pre-packaged foods such as those served in restaurants (out of the scope of the old rules). In addition, the new Regulation clarifies how operators can inform gluten-intolerant consumers of the difference between foods that are naturally free of gluten and products that are specially formulated for them.

United States of America (USA)

In the US, gluten-free foods are regulated under the general labelling framework under 21 CFR 101.915. All foods that meet the definition and conditions established for making a ‘gluten-free' claim can be labelled as such. Foods that are inherently gluten-free (for example bottled spring water, fruits and vegetables, and eggs) can also be labelled “gluten-free” provided any gluten that came in contact with the food is less than 20 ppm (US FDA 21 CFR 101.915; US FDA update, 2023).

Australia and New Zealand (ANZ)

Australia and New Zealand regulate gluten-free foods as conventional foods under the Australia New Zealand Food Standards Code (the Code). Gluten-free claims are regulated under Standard 1.2.7 which sets the general rules on nutrition, health and related claims. For a food to be labelled as gluten free, it must not contain detectable gluten; or oats or their products or cereals containing gluten that may have been malted, or their products. All foods that meet the conditions for making a gluten-free claim can be labelled as such. The most widely used and accepted test for gluten in NZ and Australia is the RIDASCREEN ELISA Gliadin kit. This kit has a Limit of Detection (LOD) of 0.5 ppm gliadin (corresponding to 1 ppm gluten) and a Limit of Quantification (LOQ) of 2.5 ppm gliadin (corresponding to 5 ppm gluten). Often a limit of less than 3 parts per million (<3 ppm) is referred to as the accepted limit in NZ & Australia. This can be taken to be the 'middle ground' for the LOD and LOQ of the above-testing kit. However, current legislation does not refer to any quantifiable limit (Coeliac New Zealand).

In February 2021, the Code was amended to introduce new requirements for the labelling of allergens in food, including “contains statement” for gluten (, FSANZ-Codex; Coeliac New Zealand, Allergen labelling; FSANZ Code, Standard 1.2.7). These requirements include that the allergen information is to be declared in a specific format and location on food labels, and using simple, plain English terms in bold font. The changes are intended to help people find allergen information on food labels more quickly and easily, so they can make informed and safe food choices.

Canada

In Canada, gluten-free foods are currently regulated as Foods for Special Dietary Use (FSDU) under Division 24 of the *Food and Drug Regulations* (FDR). This means that only gluten-free foods that have been specially processed or formulated to be gluten-free, can make gluten-free claims on their labels. This is an issue for people with celiac disease who rely on food labels to select all gluten-free foods, not just gluten-

free foods that are FSDU. Regulating gluten-free foods outside a framework for specially processed or formulated foods would allow gluten-free claims to appear on more foods. This would ensure that consumers have access to a wider range of gluten-free foods. This is why, as part of its regulatory modernization, Canada is now proposing to regulate GF foods under their general foods framework (see consultation on a proposed modernized regulatory framework for foods for special dietary use (Health Canada, 2024)). Like other allergen-free foods, gluten-free foods regulated under the general food framework would still be subject to rigorous regulatory oversight including the enhanced labelling regulations for food allergens which also apply to gluten cross-contamination.

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