

This Draft Guidance Note is provided for the purposes of consultation only for the period 23rd November 2011 to 15th December 2011.

Consultation Draft



Guidance on Best Practice for Nutrition Tolerances for Labelling Declarations

Consultation Draft

Table of Contents

Abbreviations

- 1. Introduction**
- 2. Purpose**
- 3. Scope**
- 4. Recommended Nutrition Tolerances**
- 5. Recommendations for use of Nutrition Tolerances**
- 6. References**
- 7. Glossary**

Consultation Draft

Abbreviations

EC	European Commission
EU	European Union
FSAI	Food Safety Authority of Ireland
MS	Member State(s)
KJ	Kilojoules
Kcal	Kilocalories
UK	United Kingdom
INAB	Irish National Accreditation Board
UKAS	United Kingdom Accreditation Service
ISO	International Standards Organisation

Consultation Draft

1. Introduction

Currently in the European Union (EU) nutrition labelling is voluntary but becomes compulsory if a nutritional claim for a product is made ¹ or when a product is fortified. However, if product labels carry voluntary nutrition information the format must comply with the legislative requirements ².

Recently, the EU has consolidated the existing Directives 2000/13/EC and 90/496/EEC on labelling, presentation and advertising of foodstuffs and nutrition labelling for foodstuffs, respectively into a new Regulation on Food Information to Consumers ³. Among a number of changes provided by the new Regulation ³ will be the mandatory provision of nutrition information on processed foods. The Regulation will also list a number of foods which will be exempt from the obligation to provide nutrition information ³.

Nutrition tolerances are the acceptable variance of nutrition labelling of food in comparison with the actual nutrition content of the food ⁴. Nutrition tolerances are required for nutrition labelling as it's unreasonable to expect foods to always contain the exact nutrition levels labelled, due to natural variations and variations from production and during storage. However, nutrition content of foods should not deviate substantially from labelled values to the extent that consumers are misled ⁵.

Currently, at EU level, mandatory nutrition tolerances for labelling of food have not been set, except in the case of the declaration of fat content in spreadable fats. Some Member States (MS) have developed best practice/national guidelines for nutrition tolerances ⁶. However, Ireland has no equivalent best practice/national guidelines on tolerances for nutrition labelling ⁴. As such the current guidance document is designed to provide a best practice approach for assessing the accuracy of nutrition labelling in Ireland.

2. Purpose

The purpose of the current guidance document is to provide a best practice approach for assessing the accuracy of nutrition labelling in Ireland.

Consultation Draft

3. Scope

The scope of the current guidance document is limited to all food products pre-packed or not, sold directly or indirectly to the final consumer, declaring nutrition information for the following nutrition declarations and making claims such as “typically X%”:

- **Protein**
- **Total Carbohydrate (CHO)**
- **Sugars**
- **Total Fat**
- **Saturates (SFA)**
- **Monounsaturates (MUFA)**
- **Polyunsaturates (PUFA)**
- **Sodium and/or Salt**

The scope of the current guidance document does not cover the following:

- Recommended nutrition tolerances for labelling declarations of other nutrients including dietary fibre, trans fatty acids (TFA), cholesterol, vitamins and minerals. Maximum and minimum values for water and fat soluble vitamins and minerals were set in 2006 ⁷
- Products making specific nutrition claims under Regulation (EC) No 1924/2006 on Nutrition and Health Claims made on Foods ⁸
- Products covered under Directive 2002/46/EC relating to Food Supplements ⁹
- Alcoholic products making a declaration in relation to alcohol content
- Foods covered under Council Directive 89/398/EEC on Foodstuffs Intended for Particular Nutritional Uses ¹⁰
- Infant formulae and follow-on formulae covered under Commission Directive 2006/141/EC ¹¹
- Natural mineral waters, spring waters and other water in bottles or containers ^{12,13}
- The declaration of the fat content of spreadable fats ¹⁴.

4. Recommended Tolerances

Nutrition Tolerances are the acceptable variance of nutrition labelling of food in comparison with the actual nutrition content of the food.

Nutrition tolerances are required for nutrition labelling as it's unreasonable to expect foods to always contain the exact nutrition levels labelled, due to natural variations and variations from production and during storage. However, nutrition content of foods should not deviate substantially from labelled values to the extent that consumers are misled⁴. Table 1 outlines the recommended best practice tolerances for labelling declarations.

Table 1 Recommended Best Practice Tolerances for Labelling Declarations^{a-d}

Labelled Declaration <i>(per/100 g or mls)</i>	Tolerance
Protein, CHO, Sugars & Total Fat	
<i>> 50g</i>	$\pm 7.5g$
<i>10 to 50g</i>	$\pm 15\%$
<i>≤ 10g</i>	$\pm 1.5g$
Fatty Acids (SFA, MUFA & PUFA)	
<i>> 3.5g</i>	$\pm 0.5g$
<i>> 0.5g to 3.5g</i>	$\pm 20\%$
<i>≤ 0.5g</i>	$\pm 0.15g$
Sodium and/or Salt	
<i>> 500 mg/100g</i>	$\pm 100 mg/100g$
<i>≤ 500 mg/100g</i>	$\pm 20\%$

^a Nutrition labelling declarations shall, according to the individual case, be average values based either alone or in any combination on²:

- The manufacturer's analysis of the food;
- A calculation from the known or actual average values of the ingredients used;
- A calculation from generally established and accepted data e.g. *McCance and Widdowsons*¹⁵.

^b The tolerances in Table 1 do not take account of the inherent variability of nutrients in food.

^c The tolerances in Table 1 do not take account of the measurement of uncertainty in respect of the analytical determination of nutrition values *i.e. variability due to equipment, analyst and laboratory conditions*. As such an allowance for uncertainty of measurement should be applied to the tolerances in these instances.

^d The tolerances in Table 1 may not be applicable to all food products.

5. Recommendations for use of Nutrition Tolerances

- 5.1** It is not impossible to produce recommended best practice tolerances for labelling declarations applicable to all types of food under all circumstances. As such the tolerances given in Table 1 may not be equally applicable to all foods. **It is recommended that in circumstances where the given tolerances in Table 1 may not be appropriate, food businesses should document the rationale why this may be the case.**
- 5.2** As nutrition declarations should be based on average values ² the average nutrition content of a food over a number of samples with different batch codes/lot numbers, within a defined period of time will be expected to approximate the declared pack value and not at either extreme of a defined tolerance range. **As such it is recommended that the nutrition tolerances for labelling declarations are not applied to single sample results except where the nutrition content of a food may have public health consequences or significantly mislead the consumer and further investigation and/or sampling is required.**
- 5.3** The relevance of tolerances is different for low and high levels of different nutrients as outlined in Table 1. In some instances where public health is not endangered or consumers are not at risk of being misled, it may be acceptable that specific nutrients are outside the recommended tolerances *e.g. higher protein or lower sodium levels than declared*. **It is recommended that these instances are reviewed on a case by case basis.**
- 5.4** While nutrition labelling declarations shall, according to the individual case, be average values based either alone or in any combination on analysis or calculations of known or actual average values or generally established and accepted data, **the FSAI recommends that nutrition labelling declarations are where possible, based on laboratory analysis of the food.** The FSAI is of the opinion that this is the only accurate means to ensure and verify that a nutrition labelling declaration best represents nutrient content of the food. However, regardless of how nutrition labels are derived, food businesses are responsible for the accuracy of those nutrition declarations.
- 5.5** **It is recommended that food businesses carrying out laboratory analysis use accredited laboratories** *e.g. INAB, UKAS* which have accreditation for each specific nutritional parameter required according to the ISO/IEC 17025:2005 Laboratory Accreditation Standard ¹⁶.
- 5.6** As the key requirement in relation to nutrition labelling is that consumers are not misled, it is prudent for food businesses to ensure the accuracy of their nutrition declaration. **The inclusion of explanatory statements in relation to the nutrition declaration is not recommended**, as it may be used by the food business to negate its responsibilities in ensuring the accuracy of declared nutrition labelling.

6. Reference List

1 Food Safety Authority of Ireland. **The Labelling of Food in Ireland 2007**. 2007.
Ref Type: Report

2 European Commission. Council Directive 90/496/EEC of 24 September 1990 on Nutrition Labelling for Foodstuffs. Amended by Commission Directive 2003/120/EC of 5 December 2003 and Commission Directive 2008/100/EC of 28 October 2008 on Nutrition Labelling for Foodstuffs as Regards Recommended Daily Allowances, Energy Conversion Factors and Definitions. 1990.

Ref Type: Statute

3 European Commission. Statement by Commissioner John Dalli: The Adoption of Food Information Regulation. 2011.

Ref Type: Statute

4 Food Safety Authority of Ireland. **The Accuracy of Nutrition Labelling of Pre-Packaged Food in Ireland**. 2010.

Ref Type: Report

5 European Commission. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying down Procedures in Matters of Food Safety. 2002.

Ref Type: Statute

6 European Commission - Health & Consumer Protection Directorate-General. **Commission Guidance on the Setting of Tolerances for Nutrient Values Declared on a Label - Issues Paper**. 2009.

Ref Type: Report

7 European Commission - Health & Consumer Protection Directorate-General. **Directive 90/496/EEC on Nutrition Labelling for Foodstuffs: Discussion Paper on Revision of Technical Issues**. 2006.

Ref Type: Statute

8 European Union. **Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on Nutrition and Health Claims made on Foods**. 2007.

Ref Type: Statute

9 European Commission. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the Approximation of the Laws of the Member States Relating to Food Supplements. 2002.

Ref Type: Statute

10 European Commission. **Council Directive 89/398/EEC on the Approximation of the Laws of the Member States Relating to Foodstuffs Intended for**

Particular Nutritional Uses. 1989.

Ref Type: Statute

11 European Commission. **Commission Directive 2006/141/EC of 22 December 2006 on Infant Formulae and Follow-on Formulae and amending Directive 1999/21/EC.** 2006.

Ref Type: Statute

12 Irish Government. European Communities (Natural mineral waters, spring waters and other waters in bottles or containers) Regulations, 2007 (S.I. No. 225 of 2007). 2007.

Ref Type: Statute

13 Irish Government. **European Communities (Drinking water)(No. 2) Regulations, 2007 (S.I. No. 278 of 2007).** 2007.

Ref Type: Statute

14 European Union. Commission Regulation (EC) No 445/2007 of 23 April 2007 laying down Certain Detailed Rules for the Application of Council Regulation (EC) No 2991/94 laying down Standards for Spreadable Fats and of Council Regulation (EEC) No 1898/87 on the Protection of Designations used in the Marketing of Milk and Milk Products. 2007.

Ref Type: Statute

15 Food Standards Agency (2002) ***The Composition of Foods, Sixth Summary Edition. McCance and Widdowsons (eds). Cambridge: Royal Society of Chemistry***

16 ISO/IEC. **ISO/IEC 17025:2005 - General Requirements for the Competence of Testing and Calibration Laboratories.** 2005.

Ref Type: Generic

Glossary

Nutrition Tolerances are the acceptable variance of nutrition labelling of food in comparison with the actual nutrition content of the food. Nutrition tolerances are required for nutrition labelling as it's unreasonable to expect foods to always contain the exact nutrition levels labelled, due to natural variations and variations from production and during storage.

Inherent Variability is the variability an ingredient/food has due to its source, type of processing or seasonality. Foods of animal origin such as fresh meat or plant derived foods may have differing nutrition characteristics depending on variety or species.

Measurement of Uncertainty is the doubt that exists about the result of any measurement. Every measurement carries with it a margin of doubt expressed as the measurement of uncertainty.

Consultation Draft