DECISION RULE POLICY

1. Definitions:

Decision rule – a rule that describes how measurement uncertainty (see section 7.6) is accounted for when stating conformity with a specified requirement. The decision rule will be agreed with the customer as part of the contract agreement process.

Predefined requirement - a value set by regulation, a value set from opinion based on a non-regulatory document or a value supplied by the customer.

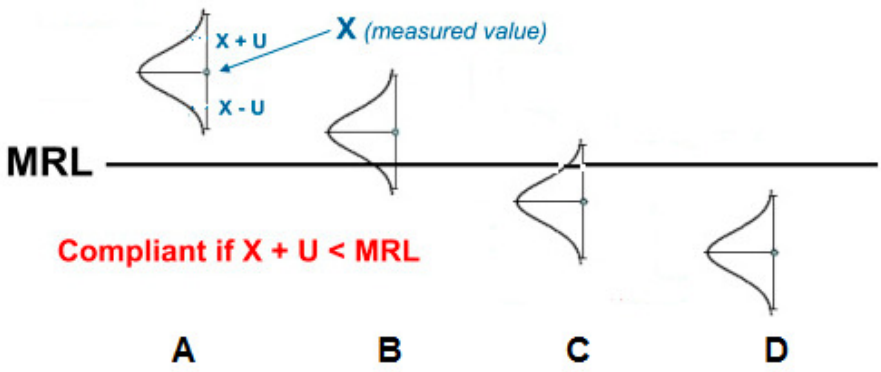
2. Principle:

Where the laboratory states on a test report a comment that a test sample has satisfied, or not satisfied, a predefined requirement it will have documented the decision rule it has used to reach that decision.

The decision rule will consider the level of risk, associated with the decision rule used, when it has not been set from a predefined requirement. It is considered unlikely that the laboratory will be assessing test samples without there being a predefined requirement already set.

3. Decision Rules Applied

Consider the following pictorial representation of test results with associated measurement uncertainty:



The MRL is the maximum residue limit i.e. the maximum acceptable value set by regulation. (This value could come from a differing source but must be agreed with the customer). X is the measured value[#4] found from testing or examination. U is the expanded measurement uncertainty.

[#4] Note that certain regulations require the amendment of the measured value, for example by correction for recovery, prior to assessment of the results.

In case A – the sample is not compliant ('fails') even when measurement uncertainty is taken into consideration;

In case D – the sample is compliant ('passes') even when measurement uncertainty is taken into consideration.

In cases B and C - there is potential that the sample 'passes' or 'fails' when measurement uncertainty is taken into consideration. Where the risk to the consumers is high the result (such as Cl. botulinum controls, peanut protein etc.) will be interpreted to protect the consumer and the sample will be 'failed'. This will be referred to as 'Decision Rule C' having been applied. In all other cases the sample will be deemed to 'pass'. This will be referred to as 'Decision Rule B' having been applied.

It is accepted that in the use of Decision Rule B that there is a risk of false acceptance of non- compliant test samples, or in the use of Decision Rule C that there is a risk of false rejection` of compliant test samples. The measurement uncertainty will be reported with the results in these cases along with the confidence interval being applied (normally 95%, k=2).

The table below [Table 1] lists the commonly used regulations and other guidance documents used to form opinion. A flow chart is also provided below to provide guidance on the steps to be taken when using the decision rules whilst reporting results. The decision rule the laboratory will apply, in the format explained above, will be listed against the relevant regulation or guidance document. The customer may propose a differing decision rule from that offered by the laboratory.

Certain regulations and guidance documents require test sample results to be treated in a specific manner. The laboratory will adhere to any such regulatory requirement[#5]. Examples of these include:

(a) 'The Contaminants in Food (Scotland) Regulations 2013' which require that the measured value is corrected for analytical recovery prior to considering measurement uncertainty for samples which are found to have a level of at least 0.5 times the MRL;

(b) 'The Animal Feed (Scotland) Regulations 2010' provides acceptable tolerances for certain analytical constituents in varying groupings of declared amounts which incorporate technical and analytical deviations and thus measurement uncertainty does not need to be considered;

(c) The Animal Feed (Scotland) Regulations 2010' provides acceptable tolerances for certain feed additives in varying groupings of declared amounts which incorporate technical deviations only and thus measurement uncertainty does need to be considered. The tolerances also only apply to samples which on testing have been found to have a measured value below that of the declared amount;

(d) The Water Intended for Human Consumption (Private Supplies) (Scotland) Regulations 2017 and The Public Water Supplies (Scotland) Regulations 2014 requires that the uncertainty of measurement is not used as an additional tolerance to the prescribed concentration or value for the parameter. Consequently, the prescribed concentration or value shall be used for all assessments with measurement uncertainty not taken into consideration. This ruling shall also be applied to samples taken for testing under The Private Water Supplies (Scotland) Regulations 2006.

[#5] Results assessed against 'European Commission Guidance Document on the Setting of Tolerances for Nutrient Values Declared on a Label: December 2012' are assessed unrounded at TSS.

Table 1

Document	Decision Rule
Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007	B
Bread and Flour Regulations 1998	B
Cocoa and Chocolate Products (Scotland) Regulations 2003	B
Coffee Extracts and Chicory Extracts (Scotland) Regulations 2001	B
Condensed Milk and Dried Milk (Scotland) Regulations 2003	B
Contaminants in Food (Scotland) Regulations 2013	B
Drinking Milk (Scotland) Regulations 2011	B
Erucic Acid in Food (Scotland) Regulations 1977	B
Fish Labelling (Scotland) Regulations 2013	N/A
Food Additives, Flavourings, Enzymes and Extraction Solvents (Scotland) Regulations 2013	B

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2009	B
Food Hygiene (Scotland) Regulations 2006	B, C (for all micro-organisms/their toxins, metabolites covered by EC Regulation 2073/2005 except histamine)
Food Information (Scotland) Regulations 2014	B, C (for allergens)
Food intended for Use in Energy Restricted Diets for Weight Reduction (Scotland) Regulations 1997	B
Food Supplements (Scotland) Regulations 2003	B
Fruit Juices and Fruit Nectars (Scotland) Regulations 2013	B
Honey (Scotland) Regulations 2015	B
Infant Formula and Follow-on Formula (Scotland) Regulations 2007	B
Jam and Similar Products (Scotland) Regulations 2004	B
Materials and Articles in Contact with Food (Scotland) Regulations 2012	B
Natural Mineral Water, Spring Water and Bottled Drinking Water (Scotland) (No.2) Regulations 2007	B
Novel Foods (Scotland) Regulations 2017	B
Nutrition and Health Claims (Scotland) Regulations 2007	B
Processed Cereal Based Foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004	B
Products Containing Meat etc. (Scotland) Regulations 2014	B
Specified Sugar Products (Scotland) Regulations 2003	B
Spirit Drinks Regulations 2008	B
Spreadable Fats, Milk and Milk Products (Scotland) Regulations 2008	B
Wine Regulations 2011	B
Commission Recommendation 2013/647/EU - acrylamide	B
Food Standards Scotland guidance on the safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic Clostridium botulinum	C
European Commission Guidance Document on the Setting of Tolerances for Nutrient Values Declared on a Label: December 2012	B
Code for Edible Ices (2013) published by Euroglaces (European Ice Cream Association)	B
The Scottish Food Enforcement Liaison Committee report on the Survey of Fat Content and Sulphur Dioxide in Lean Beef Mince and Steak Mince (January 2010)	B
The Animal Feed (Scotland) Regulations 2010	B
The Feed (Hygiene and Enforcement) and Animal Feed (Scotland) Amendment Regulations 2013	B
Commission Recommendation 2006/576/EC	B
The Approved Code of Practice & Guidance on the control of Legionella bacteria in water systems issued by Health & Safety Executive (2013)	C

International Journal of Environmental Health Research (2009 Dec;19(6):431-43)	C
Health Protection Agency Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Food(s) (November 2009)	C
The Institute of Food Science and Technologies Guidance on The Microbiological Criteria for Foods (1999)	C

Flow Chart: