



envirocare labs pvt. Ltd.
Analysis and Beyond...

ANALYTICAL REPORTS FAILURE & RISK

Dr Nilesh S Amritkar
Managing Director



Good Business



*Quality Testing is the key to **good business***

ANALYSIS – A Key Player ?



**Are Analytical Reports
a critical step in deciding the fate of the FBO ???**



Standardized & Proprietary Foods



326 standardized products

Non-standardized foods for which no identity standards have been prescribed in regulations excluding Novel foods, food for special dietary uses, functional foods , nutraceuticals & health supplements – **Proprietary Foods**

Any deviation in specific quality parameters (such as TSS, ash content etc.) of a standardized food shall not qualify as proprietary food”.



**Test Parameters for
Proprietary food products ??**

Standardized & Proprietary Foods



Proprietary foods shall comply with contaminants (Chemical & Microbiological) specifications prescribed for its **ingredients**.

FSSR	Food Product (FSSR category)	Parameter	FSSR Quality Test Limit	Observed Values in certain cases/ The Issue
2.3.24	Synthetic Syrups/ Sharbat	TSS	Not less than 65 %	40-45 Mocktail Syrups
2.3.29	Soya Sauce	TSS (Salt free basis)	Not less than 25 %	18-20 Gourmet Sauce
2.3.44	Black Olives in Brine	Salt	Not less than 7 %	4-5%
2.3.19	Fruit Bar/ Toffee	TSS	Not less than 75%	?? Cereal Fruit Bar

Sample Fail !!!



- Is it Safe / Pass / Fail
- Validated method w.r.t particular matrix

FSSR	Parameter	FSSR Specification	Product
Appendix A, Table 10	Acetic Acid	GMP	Tomato Ketchup
Appendix A , Table 13	Ascorbic Acid	GMP	Chocolates
Appendix A , Table 9	Calcium alginate	GMP	Squashes

Is it Real Compliance ?



FSSR	Parameter	FSSR specification	Product	Issue
3.1.8	Antifoaming agent -DMPS	In edible oils and fats max 10 ppm	Solid Food	Estimated & reported as Silica and not as "DMPS"
3.1.12	Buffering agent Phosphoric Acid	In beverages & soft drinks max 600 ppm	Solid Food	Estimated & reported as elemental Phosphorus – Cumulative value obtained
3.1.5	Antioxidants	Around 11 antioxidants can be added to edible oils & fats	Solid Food	Request for antioxidants testing even if they are not specified for the product
2.2.1	Aflatoxin M1	0.5 ppb for Milk	Shrikhand, Cheese	EU 0.05 ppb in milk and milk products
3.1.2 (4)	Allura Red	Earlier : Not listed under allowed synthetic colours	Ice Creams Confectionary	Now Allura red values included in regulations for these products (Also allowed in other countries)

Rampant Issuance of Test reports by Labs

Is it killing Innovation ?



2.1.12 Yogurt / Low Fat Fruit Yogurt

FSSR	Parameter	FSSR Specification	Product	Results
Yogurt	Milk fat	NLT 3.0%	Low Fat Fruit Yogurt	0.12% Fat 2.6% Protein
	Milk Protein	NLT 3.2%		
Skimmed Yogurt	Milk fat	NMT 0.5 %		
	Milk Protein	NLT 3.2 %		
Fruit Yogurt	Milk fat	NLT 1.5 %		
	Milk Protein	NLT 2.6 %		

Methods



FSSR	Parameter	Issue
3.1.11	MSG	AOAC 970.37, MSG which detects glutamic acid and calculates to MSG
Appendix A Table 8	Alginates Xanthan gum	No standard method available
2.7.4	Vegetable fat in chocolates	No standard method available
Tomato Powder	Ash Content	Std Method AOAC at 550 C, however, DGHS gives reference to Ash Content for Vinegar !!!

Methods...



Product	Parameter	FSSR requirement	Method	Result interpretation
Cocoa Powder	Alkalinity	Alkalinity of total ash not more than 6 % as K ₂ O on moisture fat free basis	IS 1164- Specification for cocoa powder	Alkalinity of total ash as K ₂ O – Result obtained are less or more than 6 % (Sample passes or fails)
			FSSAI manual method – For roasted coffee	Alkalinity of soluble ash – Result always less than 6 % - Sample passes
Mawa	Citric acid	Not more 0.1% by weight	Titration method	Acidity expressed as citric acid, other acids e.g. Lactic acid also contributes.
			Ion Chromatography	Differentiates between citric acid and other acids.
			Microbiology parameters !!!	

Clarity...



FSSR	Product	FSSR Specification	Issue
3.5.2 / 4.4.3	Wines & Beer	Free from Pathogens	!!!
Appendix B, Table 1 B	Fish & Fish Products	Unit for E.coli cfu/g and MPN/g Absence of botulinum toxin	Only BAM method specified 2 Class and 3 Class Plan for manufacturing & retail not defined
2.3.3 / 2.3.8	Canned Tomatoes & Tomato Juice	Free from microorganisms capable of development under normal conditions of storage. Not contain substances originating from microorganisms which may represent a hazard to health	!!!
Appendix B Table 5 B,	Meat & Meat Products	Listeria monocytogenes , Method of Analysis mentioned is IS14988 Part 2	Part 2 is enumeration, Part 1 is present / absent
Appendix B Table 2A/2B	Milk & Milk Products	<i>E.coli</i> Absent/0.1 g	Insignificant sample quantity, IS / BAM specifies 25 g

Ms Interpret



FSSR	Parameter	Product	FSSR Specification	Risk
2.3.8	Mould Count	Tomato Juice	Max, 45 % +ve fields	Very difficult to distinguish mycelial growth from fibres instead use standard plate
Appendix B , Table 4 (12)	a)Flat sour organisms	a) All Fruits and Vegetable products and ready – to – serve Beverages including Fruit Beverages and Synthetic products covered Regulation 2.3.	(i) Not more than 10,000 cfu / gm for Those products which have pH less than 5.2 (ii) Nil for those products which have pH more than 5.2	Applicability of the limits – product parameter wise or otherwise ?
	b) <i>S. aureus</i>	b)Table olives	Absent in 25 gm / ml	
	c) <i>Salmonella</i>	c) Raisins	Absent in 25 gm / ml	
	d) <i>Shigella</i>	d) Pistachio nuts	Absent in 25 gm/ ml	
	e) <i>C. botulinum</i>	e) Dates	Absent in 25 gm/ ml	
	f) <i>E. coli</i>	f) Dry fruits and nuts	Absent in 1 gm / ml	
	g) <i>V. cholera</i>	g) Vinegars	Absent in 25 gm/ ml	

Clarity...



FSSR CTR	Parameter	FSSR Specification	Product	Issue
2.1.1	Cadmium	0.2 ppm	Wheat	Limit not specified for all food products
		1.5 ppm	Other foods	
2.1.1	Lead	0.1 ppm	Olive oil, refined	crude as well as refined oils have same limits
		0.1 ppm	Olive oil, virgin	
		0.1 ppm	Olive oil, residual oil	
		0.1 ppm	Vegetable oil, Crude oils	
		0.1 ppm	Vegetable oil , edible oils	

Clarity



FSSR	Parameter	FSSR Specification	Product	Need of ICP MS !!!
2.1.1	Mercury	0.1 ppm	Salt, food grade	ICP - 0.1 ppm ICP MS - 0.025 ppm
2.1.1	Arsenic	0.1 ppm	Olive Oil, Refined	ICP - 0.05 ppm ICP MS - 0.01 ppm
2.1.1	Cadmium	0.1 ppm	Legume vegetables	ICP - 0.1 ppm ICP MS - 0.025 ppm
2.1.1 (1)	Lead	0.02 ppm	Milk	ICP - 0.1 ppm ICP MS - 0.025 ppm
2.1.1	Zinc	50 ppm	Cocoa powder	Naturally Occurring Zn : 60 - 70 ppm

Clarity...



FSSR	Parameter	FSSR Specification	Product	Clarity
2.3	Fenthion	0.5 ppm	Tomatoes	For Tomato Juice ?
2.3	Malathion	4 ppm	Food grains	Reduced MRL !!!
		1 ppm	Milled Food grains	
2.3	Any pesticide	Not specified	Masala Oats	Mixture of ingredients ???
			Herbal Tea	
			Garlic & Herbs butter	

Is it Really Safe ???



- FSSR MRLs lenient as compared to EU and codex
- Lack of uniformity in limits for many pesticides

Pesticide	Product	FSSR (ppm)	Codex (ppm)	EU (ppm)
Dicofol	Fruits & Veggies	5	0.1	0.02
Propargite	Tea	10	5	0.05
Phosalone	Pears	2	0.01	NS
Imidacloprid	Tomato	1	0.5	0.5

Ms Interpret



Cake mix (with natural colour beet root)

Regulatory lab will do DGHS – paper chromatography followed by spectrometry

False positive for Carmoisine, **SAMPLE FAILS**

Understanding of the Food & Food Ingredient vital

FSS Shining...



Earlier		Now		
NOT's	Limits	NOT's	Food Category	Limits
Agaric acid	100 ppm	Agaric acid	Food containing mushrooms	100 ppm
			Alcoholic beverages	100 ppm
Hydrocyanic acid	5 ppm	Hydrocyanic acid	Nougat, marzipan or its substitutes	5 ppm
			Canned stone fruits	5 ppm
			Alcoholic beverages	5 ppm
			Confectionery	5 ppm
			Stone fruit juices	5 ppm
Hypericine	1 ppm	Hypericine	Alcoholic beverages	1 ppm
Saffrole	10 ppm	Saffrole	Meat preparations and meat products, including poultry and game	10 ppm
			Fish preparations and fish products	10 ppm
			Soups and sauces	10 ppm
			Non-alcoholic beverages & others	10 ppm

Nutritional Labelling



FSSR	Australia NZ	EU	USA	UK
Energy (kcal) Protein (g) Fat (g) Carbohydrates (g) Sugars (g)	Energy (KJ/Kcal) Protein (g) Fat (g) Carbohydrates (g) Sugars (g)	Energy (kcal/g or kJ/g) Protein (g) Fat (g) Carbohydrates (g) Sugars (g)	Energy (Cal) Protein (g) Carbohydrate (mg) Dietary Fibre Sugar (g)	Energy (kJ/lcal) Protein (g) Fat(g) Carbohydrate (g)
	Sodium (mg/mmol)	Sodium (g)	Sodium (mg)	Sodium (g)
Fatty Acids (g) MUFA(g) PUFA (g) Cholesterol (mg) Trans Fat (g)	Sat Fat (g) PUFA (g) MUFA (g)	Saturates (g) <i>MUFA (g)</i> <i>PUFA (g)</i> <i>Cholesterol (mg)</i>	Fat (g) Saturates (g) Trans Fat Cholesterol (mg)	Sugar (g) Fibre (g) Saturates (g)
		Vitamins & Minerals - 15% RDA in general foods & 7.5% in beverages	Energy from Fat Vitamin A & C Calcium Iron	
Detection Limits: Protein : 0.1 g Fat : 0.1 g Sugar : 0.5 g	No use of symbols (< >) Less Than			For trace - 0 g may be used Less Than

What the World says...



If the food is sold uncooked but requires cooking before consumption, the nutrition information panel should be provided for the uncooked food

Where foods should be reconstituted with water or drained before consumption, the quantities in the nutrition information panel should reflect the food as reconstituted or drained

Where a food business intends that the food be prepared or consumed with at least one other food, the nutrition information panel should contain a 'per serve' and a 'per 100 g' (or per 100 mL) column that reflects the contents of the package of the food to be prepared or consumed with the other food as usual

Nutritional Labelling should be reviewed periodically

Nutritional Information



Laboratory
Analysis

Nutritional
Content

Nutritional
Panel
Calculator

Food
Composition
Table /
Databases

Regardless of how nutrition declarations are derived, food business operators **should act in good faith** to ensure a high degree of accuracy of those nutrition declarations. In particular, declared values should approximate to the **average values across multiple batches of food**

Tolerance



Standard/ Guideline	Specifications	Nutrients	Compliance criteria
US FDA	Three nutrient classes		
	Class I	Added in fortified food / fabricated foods	Should be atleast min 100 % of the declared label
	Class II	Vitamins, minerals, proteins, Carbohydrates, Dietary Fibres & other carbs, MUFA,PUFA and K	Must be present at 80 % or more of the declared label
	Third Group	Calories, sugars, Total fat, Sat fat, Cholesterol & Na	Must be 120 % or less
CFIA		For all nutrients	10 % Tolerance limit
FSSR			± Tolerance not specified

Tolerance...



Product	Tolerance limits Regulation No 1169/2011		Tolerance in %
Vitamins			+ 50 % - 35 %
Minerals			+ 45 % - 35 %
Carbohydrates	< 10g per 100g	± 2g	± 20%
Sugars	10 – 40 per 100g	± 20 %	± 20 %
Protein			
Fibre	> 40 per 100g	± 8g	± 20 %
Fat	< 10g per 100g	± 1.5 g	± 15 %
	10 – 40 per 100g	± 20%	± 20 %
	> 40 per 100g	± 8g	± 20%
Saturates	< 4g per 100g	± 0.8 g	± 20 %
Monounsaturates, Polysaturates	≥ 4g per 100g	± 20 %	± 20 %
Sodium	< 0.5 g per 100g	± 0.15 g	± 30%
	≥ 0.5 g per 100g	± 20 %	± 20%
Salt	< 1.5 g per 100g	± 0.375 g	± 25%
	≥ 1.5 g per 100g	± 20 %	± 20 %

Tolerance...



If the value measured is outside the tolerance for the declared

- a) the nutrient in question
- b) the extent of the deviation
- c) the nature of the deviation (overestimation or underestimation) in relation to the nutrient concerned
- d) natural high variation of the nutrient, including seasonality
- e) particular high degradation rates of nutrients in some food matrices
- f) particular high analytical variability of nutrients in a specific food matrix
- g) particular low homogeneity of a product leading to particular high variation of nutrient content in a product that is not offset by the sampling procedure
- h) compliance of the majority of samples from the lot with the tolerance range, if such data is available
- i) validity of the manufacturer's process for establishing the declared nutrient value
- j) how the self-monitoring of the company functions in general
- k) previous problems or previous sanctions against the company

Degree of sanctions - extended guidelines, warnings, enforcement notice or fines.

Manufacturers may be asked to provide the rationale justifying deviation

Labelling Failures



- Misleading pictures : Fruit juices with added flavouring agents, but portraying to be derived from natural fruits (Picture on the packaging)
- Name of the product cannot falsely portray health claim (Trademark Required)
- Regulator / NGO may at times check for Ingredients / Contaminants that are not found on the label or are supposed to be absent



Quality Tested in India

THANK YOU



TEST WITH TRUST

nilesh.a@envirocare.co.in

9167232003



envirocare labs pvt. ltd.
Analysis and Beyond...

