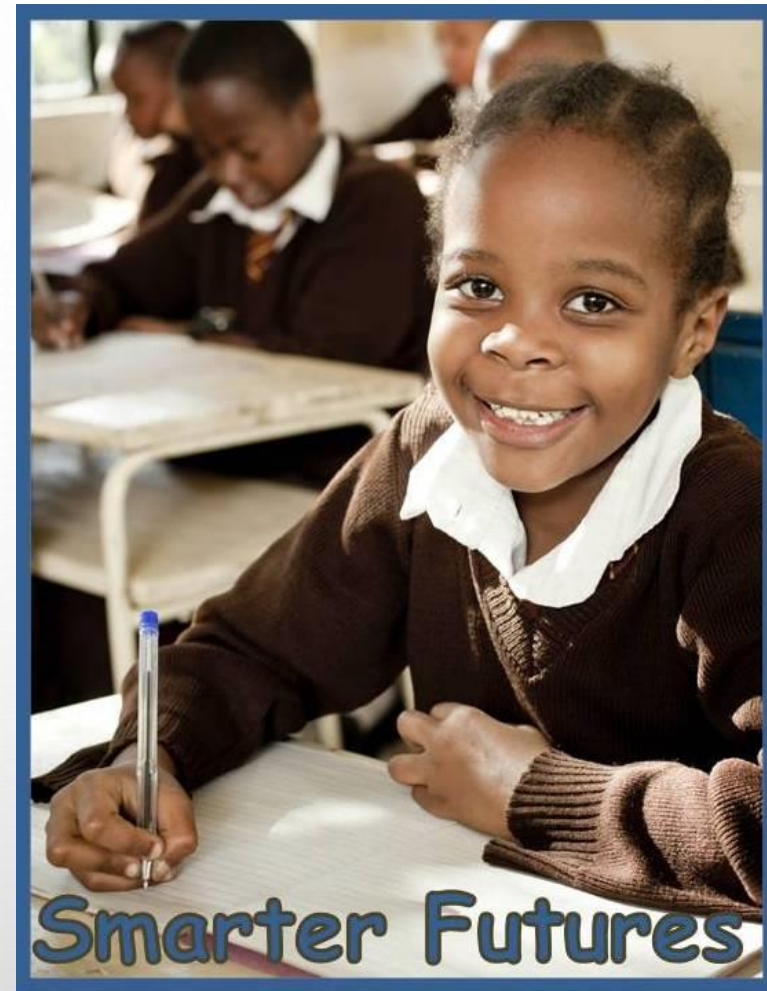


FOOD FORTIFICATION LEGISLATION AND STANDARDS: IN PRACTICE

PHILIP RANDALL
(WITH CONTRIBUTIONS FROM
QUENTIN JOHNSON)





**HOW ARROGANT ARE WE THAT WE DO
NOT EVEN PROBE OR QUESTION OUR
ABILITY TO COMPLY WITH LEGISLATION
OR STANDARDS**

FROM QUENTIN'S SLIDE 2

- **LAWS CREATE THE LEGAL FRAMEWORK FOR BOTH STANDARDS AND REGULATIONS.**
- **REGULATIONS PROVIDE THE FOOD CONTROL AUTHORITIES TO BE ABLE TO INSPECT AND MONITOR THE PRODUCTION OF FORTIFIED FOODS TO A STANDARD**
- **REGULATIONS PROVIDE THE AUTHORITIES WITH THE MECHANISM TO ENFORCE THE STANDARDS THROUGH INSPECTION AND CORRECTIVE ACTIONS**

OVER CONTROL

- WHEAT FLOUR AND OTHER FOODS CURRENTLY BEING FORTIFIED HAVE BEEN PRODUCED IN-COUNTRY FOR MANY YEARS WITHOUT:
 - ✓ BEING INSPECTED BY EVERY AGENCY IN THE COUNTRY
 - ✓ BEING REQUIRED TO COMPLY WITH MULTIPLE PIECES OF LEGISLATION
 - ✓ BEING ANALYSED BY LABORATORIES ILL-DESIGNED FOR THE PURPOSE
 - ✓ BEING TREATED AS A PASS/FAIL SITUATION AS IS THE NORM WITH A PUBLIC SAFETY ISSUE
- SETTING THE STANDARD TOO HIGH
- HIDDEN AGENDAS

OVER CONTROL

- DOES HAVE AN UNEXPECTED 'BENEFIT' AS IT CLEARLY EXPOSES WEAKNESSES IN THE FOOD CONTROL SYSTEM WHICH
- TURNS INTO A MAJOR DRAWBACK AS THE REGULATOR DEMANDS ABILITY TO MONITOR AS A CONDITION OF 'ALLOWING' FORTIFICATION




WHAT IS IN A STANDARD?

IT IS NOT JUST ABOUT FORTIFICATION
AS THE FOLLOWING EXAMPLE
INDICATES




FLOUR COMPOSITION

Parameter	Baker's flour	Home baking flour	Biscuit flour	Cracker flour	Self-raising flour	Standard flour	Atta flour	Whole-meal flour	Method of test
Moisture content, max. %,m/m	13	13	13	13	13	13	13	13	ISO 711 or ISO 712
Crude fibre content, max.	1.0	1.0	1.0	1.0	1.0	1.5	2.0	2.0	ISO 5498
Total ash content, max. %,m/m	0.7	0.7	0.55	0.70	2.0	1.10	2.0	2.0	ISO 2171
Residue on sieving through 180 micron- sieve, max. %	0.8	0.8	0.5	0.5	0.8	30.0	55.0	30.0	
Protein content, min. %, m/m	11.0	9.0	8.0	8.0	8.0	11.0	12.0	12.0	ISO 20483



➤ THE WHEAT FLOUR SHALL BE FORTIFIED WITH ALL THE MICRONUTRIENTS INDICATED USING THE FORTIFICANTS SHOWN IN SUCH A WAY THAT THE PRODUCT CONFORMS TO THE LIMITS SET IN TABLE

➤ FACTORIES SHOULD AIM AT FORTIFYING THE PRODUCTS AT THE RECOMMENDED FACTORY LEVEL TO ENSURE THE PRODUCT CONFORMS TO THE REGULATORY LEVELS THROUGHOUT THE DISTRIBUTION CHAIN



Nutrient	Fortificant compound	Recommended factory level, mg/kg	Regulatory levels, mg/kg	
			Min	Max
Vitamin A ₁	Vitamin A (Retinyl) palmitate	1.0 ± 0.4	0.5	1.4
Vitamin B ₁₁	Thiamin Mononitrate	9.8 ± 4.4	4.6	(14.2)*
Vitamin B ₂₁	Riboflavin	6.6 ± 3	3.3	(9.6) *
Niacin ₁	Niacinamide	60 ± 30	30	(90)*
Vitamin B ₆₁	Pyridoxine	6.5 ± 3.5	3	(10) *
Folate	Folic acid	2.3 ± 1	1.1	3.2
Vitamin B ₁₂	Vitamin B ₁₂ (Water soluble, 0.1%)	0.02 ± 0.009	0.01	(0.029) *
Zinc	Zinc oxide	88 ± 28	60	116
Total iron	Total iron	30 ± 10	20	(60) *
Added Iron	NaFeEDTA ₂	30 ± 10	20	40
	Ferrous fumarate ₂	40 ± 10	30	50

¹The addition of these micronutrients is optional in XXXXX.

* The maximum limits for these nutrients may not be necessary because the upper tolerance limits of these nutrients are very high.

² The use of one of these would be considered.

STABILITY REQUIREMENT

- THE VITAMIN FORTIFICANTS AND PREMIXES SHALL HAVE STORAGE STABILITY SUCH THAT NO MORE THAN 20 % OF ITS ORIGINAL ACTIVITY WILL BE LOST WHEN STORED FOR 21 DAYS AT 45°C IN A WELL CLOSED CONTAINER AT A LEVEL 2.5G PER KG IN WHEAT FLOUR HAVING MOISTURE CONTENT IN THE RANGE OF 13.5 % TO 14.5 %.
- THE SUPPLIER OF THE PREMIX SHALL PROVIDE THE STABILITY DATA FOR THE FORTIFICANTS AND PREMIXES.

ALSO ADD IN – OR REFER TO CODEX

- MICROBIOLOGICAL LIMITS
- HEAVY METAL LIMITS
- PESTICIDE RESIDUES
- MYCOTOXINS

USING THE WRONG METHODOLOGY

- WHEAT FLOUR SHALL COMPLY WITH THOSE MAXIMUM MYCOTOXIN LIMITS ESTABLISHED BY THE CODEX ALIMENTARIUS COMMISSION FOR THIS COMMODITY. IN PARTICULAR, TOTAL AFLATOXIN LEVELS IN WHEAT FLOUR FOR HUMAN CONSUMPTION SHALL NOT EXCEED 10 MCG/KG (PPB) WITH B₁ NOT EXCEEDING 5 MCG/KG (PPB) WHEN TESTED ACCORDING TO ISO 16050.
- ISO 16050:2003 SPECIFIES A REVERSE-PHASE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHIC METHOD, WITH IMMUNOAFFINITY COLUMN CLEAN-UP AND POST-COLUMN DERIVATIZATION, FOR THE DETERMINATION OF AFLATOXINS IN CEREALS, NUTS AND DERIVED PRODUCTS. THE LIMIT OF QUANTIFICATION FOR AFLATOXIN B₁, AND FOR THE SUM OF AFLATOXINS B₁, B₂, G₁ AND G₂, IS 8 MCG/KG .

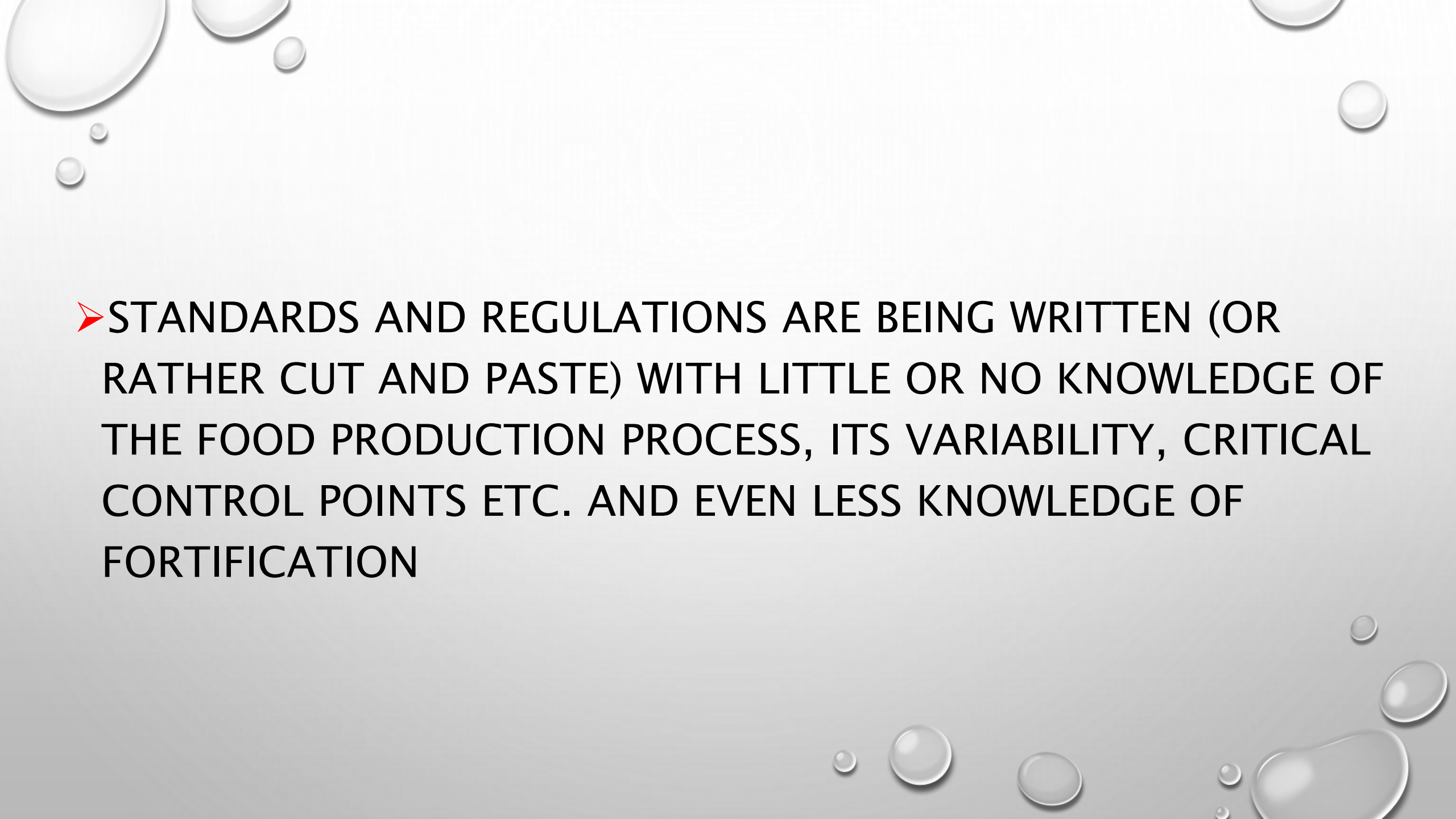
The image features a light gray gradient background with several realistic water droplets of various sizes scattered in the corners. The droplets have highlights and shadows, giving them a three-dimensional appearance. The text is centered in the middle of the frame.

SO WHAT'S THE PROBLEM?

IT'S EASY – WE HAVE BEEN ADDING BAKERY IMPROVERS ETC. FOR DECADES !!

- AS WE HAVE BEEN ADDING IMPROVERS WE ARE FULLY CONVERSANT WITH MICRO-FEEDERS
- IMPROVERS ARE USUALLY SPECIFIED AS “WITHIN GMP” LIMITS
- IMPROVERS ARE NOT A SAFETY RISK

- NO ONE HAS BEEN CHECKING ADDITION RATE OF BAKERY IMPROVERS



➤ **STANDARDS AND REGULATIONS ARE BEING WRITTEN (OR RATHER CUT AND PASTE) WITH LITTLE OR NO KNOWLEDGE OF THE FOOD PRODUCTION PROCESS, ITS VARIABILITY, CRITICAL CONTROL POINTS ETC. AND EVEN LESS KNOWLEDGE OF FORTIFICATION**

WHAT THE LAW SAYS AND WHAT IT MEANS

- LAW SAYS MILLERS MUST ADD A SPECIFIC QUANTITY OF FORTIFICATION PREMIX SAY 200G/MT BUT MAY BE AS HIGH AS 600G/MT
- LAW SAYS MILLERS MUST INDICATE THEIR PRODUCT IS FORTIFIED AND THE LEVEL OF THAT FORTIFICATION
- LAW SAYS THAT THE PRODUCT MUST BE COMPLIANT AT POINT OF SALE BUT HAS, OR DOES NOT CONCERN ITSELF WITH THE DISTRIBUTION CHAIN
- LAW MEANS EVERY 0.5 TO 1 G THE LABORATORY ANALYSES MUST COMPLY

WHAT THE LAW DOES NOT SAY OR TAKE INTO ACCOUNT

- HOW WELL CAN MILLS MIX FORTIFICANTS
- WHAT THE INTRINSIC NUTRIENT CONTENT IS
- HOW THE LABORATORY IS SUPPOSED TO DISTINGUISH BETWEEN ADDED AND INTRINSIC CONTENT WHEN IT ACTUALLY MEASURES TOTAL CONTENT
- HOW MUCH UNCERTAINTY AT 95% CONFIDENCE IN LABORATORY ANALYSIS

WHAT THE LAW DOES NOT TELL US

- HOW THE REGULATORY MINIMUM AND MAXIMUMS WERE CALCULATED (SOMETIMES WHY WE EVEN HAVE A MAXIMUM)
- HOW THEY DETERMINED THAT THE RECOMMENDED FACTORY LEVEL DO ENSURE THE PRODUCT CONFORMS TO THE REGULATORY LEVELS THROUGHOUT THE DISTRIBUTION CHAIN
- HOW A SAMPLE IS TO BE TAKEN – OR IF THEY DO THE METHODOLOGY DOES NOT MEET INTERNATIONAL STANDARDS

The background features a light gray gradient with several realistic water droplets of various sizes scattered in the corners. The droplets have highlights and shadows, giving them a three-dimensional appearance. The text is centered in the middle of the page.

THE MAJOR WEAKNESS

WHAT THE REGULATOR HAS FAILED TO DO

➤ RISK ANALYSIS

- ✓ RISK ASSESSMENT

- ✓ RISK MANAGEMENT

- ✓ RISK COMMUNICATION

➤ ASCERTAIN WHO HAS THE CAPACITY TO

- ✓ CONDUCT INSPECTIONS

- ✓ CONDUCT ANALYSIS

➤ ADVISE ALL PARTIES ON HOW THE ESTIMATES OF UNCERTAINTY ARE TO BE ACTED UPON

INSTRUCTIONS ON CODEX SAMPLING PROCEDURES CX/MAS 1 – 1987

- *“IN PARTICULAR, THE ESTIMATE OF THE VALUE MAY BE DEPENDENT UPON THE METHOD OF ANALYSIS USED, BUT IT IS ALWAYS DEPENDENT ON THE TYPE OF SAMPLING PLAN AND THE LOT ACCEPTANCE PROCEDURE USED”*

EURACHEM – MEASUREMENT UNCERTAINTY FROM SAMPLING

[HTTPS://WWW.EURACHEM.ORG/IMAGES/STORIES/GUIDES/PDF/UFS_2007.PDF](https://www.eurachem.org/images/stories/guides/pdf/ufs_2007.pdf)

- IF THE OBJECTIVE OF THE MEASUREMENT IS TO ESTIMATE THE VALUE OF THE ANALYTE CONCENTRATION IN A SAMPLING TARGET, THEN THE UNCERTAINTY ASSOCIATED WITH THE SAMPLING PROCESS MUST INEVITABLY CONTRIBUTE TO THE UNCERTAINTY ASSOCIATED WITH THE REPORTED RESULT
- ALL PARTIES NEED GUIDANCE FROM THE APPROPRIATE REGULATOR ON HOW THESE ESTIMATES OF UNCERTAINTY ARE TO BE ACTED UPON, TO ENSURE THE RELIABILITY OF THE DECISIONS BASED UPON THE MEASUREMENTS
- THE RESPONSIBILITY FOR THE QUALITY OF THE WHOLE MEASUREMENT PROCESS SHOULD ULTIMATELY REST WITH ONE ORGANISATION. AND

SCIENTIFIC EVIDENCE ON ANALYSIS

- USE OF A STANDARD LEVEL OF FORTIFICATION AND THE TOLERANCES THAT THE CANADIAN FOOD INSPECTION AGENCY (CFIA) APPLY TO DETERMINE IF FORTIFIED FLOUR (NATIONAL PRODUCTION AND IMPORTS) IS ADEQUATELY FORTIFIED IS **80% TO 175%**

✓ [HTTP://WWW.INSPECTION.GC.CA/FOOD/NON-FEDERALLY-REGISTERED/PRODUCT-INSPECTION/FLOUR-SAMPLES/ENG/1383837268150/1383837269041](http://www.inspection.gc.ca/food/non-federally-registered/product-inspection/flour-samples/eng/1383837268150/1383837269041)

SCIENTIFIC EVIDENCE ON ANALYSIS

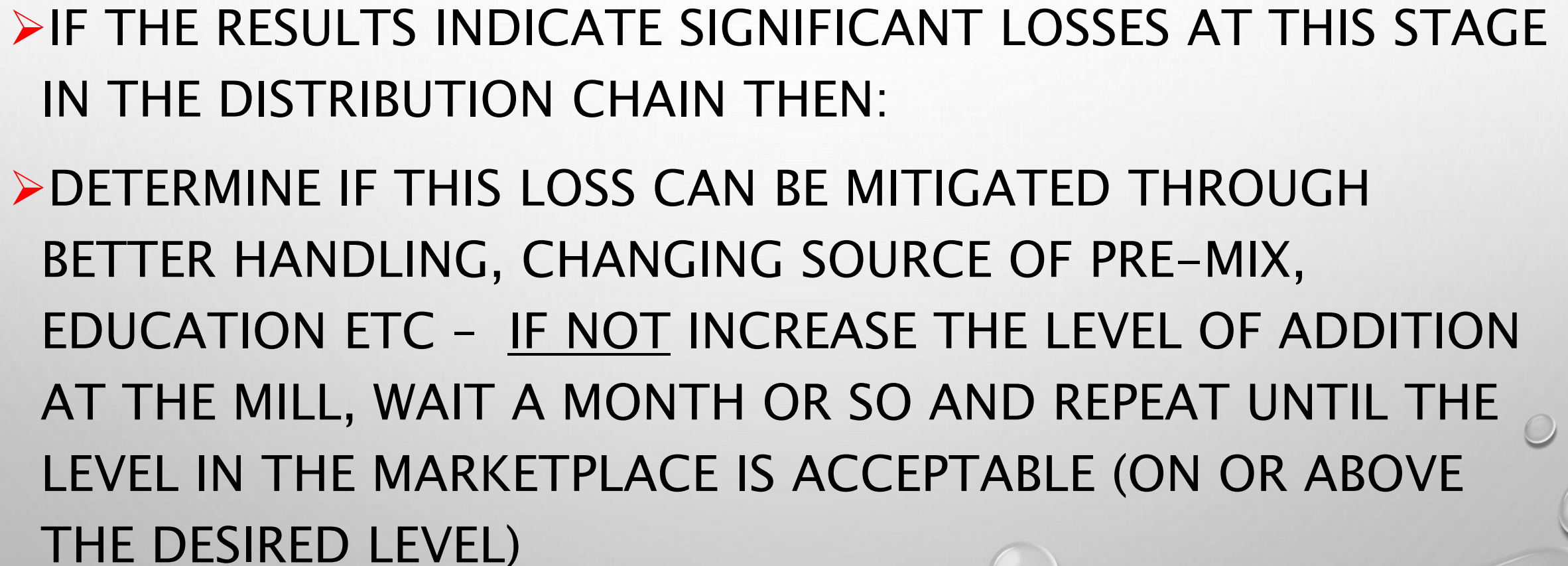
- THE MILLS PROVIDED ABOUT 3000 ANALYSES WHEAT FLOUR SAMPLES (CIRCA **15,000 ANALYTICAL RESULTS**) IN AN EXERCISE BETWEEN THE CANADIAN MILLERS ASSOCIATION AND THE CANADIAN FOOD INSPECTION AGENCY
- THIS CLEARLY BRINGS INTO QUESTION ANY EXISTING FORTIFICATION STANDARD WHERE THE TOLERANCE RANGE HAS BEEN DETERMINED WITHOUT ANY DUE ATTENTION TO ACTUAL PRACTICE
 - ✓ CANADIAN EXAMPLE WAS A PAPER BASED SURVEY AND ASSESSMENT USING THE RESULTS FROM ALL THE MILLS RATHER THAN THE CFIA TESTING ALL THE SAMPLES OF FLOUR

The image features a light gray background with a subtle gradient. In the top-left and bottom-right corners, there are several realistic water droplets of various sizes, rendered with soft shadows and highlights to give them a three-dimensional appearance. The text "PART OF THE SOLUTION" is centered in the middle of the page in a bold, black, sans-serif font.

PART OF THE SOLUTION

FILL CRITICAL INFORMATION GAPS

- GET INDUSTRY FORTIFYING AND BEING CONFIDENT IN THEIR SKILLS. INDUSTRY AND STANDARDS INSTITUTES TESTING AT MILL LEVEL AND MUTUALLY ESTABLISHING WHAT IS ACCEPTABLE VARIATION IN TERMS OF ADDITION AND IN TERMS OF MILL VARIABILITY AND IN ANALYTICAL CAPABILITY.
- TEST FORTIFIED WHEAT FLOUR IN THE MARKETPLACE TAKING INTO ACCOUNT THE VARIOUS METHODS BY WHICH THE FLOUR IS SOLD I.E. OPEN MARKET, SMALL RETAILER, LARGE RETAILER, “WALKMANS” ETC.

- 
- IF THE RESULTS INDICATE SIGNIFICANT LOSSES AT THIS STAGE IN THE DISTRIBUTION CHAIN THEN:
 - DETERMINE IF THIS LOSS CAN BE MITIGATED THROUGH BETTER HANDLING, CHANGING SOURCE OF PRE-MIX, EDUCATION ETC - IF NOT INCREASE THE LEVEL OF ADDITION AT THE MILL, WAIT A MONTH OR SO AND REPEAT UNTIL THE LEVEL IN THE MARKETPLACE IS ACCEPTABLE (ON OR ABOVE THE DESIRED LEVEL)

The background of the slide is a light gray gradient with several realistic water droplets of various sizes scattered across it. The droplets have highlights and shadows, giving them a three-dimensional appearance.

NOW YOU CAN THINK ABOUT DEVELOPING A FORTIFICATION TECHNICAL REGULATION

**INDUSTRY MUST BE PART OF THE PROCESS OF
BOTH THE TECHNICAL REGULATION AND THE
NATIONAL STANDARD**

The image features a light gray gradient background with several realistic water droplets of various sizes scattered in the corners. The droplets have highlights and shadows, giving them a three-dimensional appearance. The text 'AN ALTERNATIVE' is centered in the middle of the page.

AN ALTERNATIVE

SYSTEMS APPROACH

➤ AUTO-CONTROL IS A SYSTEM BASED ON THE OFFICIAL USE OF RESULTS OF SELF-MONITORING OBTAINED BY A PRODUCTION FACILITY. PROVIDED THAT THE VALIDITY OF THESE FACTORY RESULTS CAN BE VERIFIED THEY COULD REPLACE THE OFFICIAL CONTROL LABORATORY RESULTS TO DECIDE IF THE PRODUCT MEETS QUALITY SPECIFICATIONS.

[HTTP://WWW.MONIQA.ORG/WEBFM_SEND/225](http://www.moniqua.org/webfm_send/225)