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The Need and Scientific Approaches for Regional Harmonization of Food Fortification Standards

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Regional Expert Group on Harmonization of Wheat Flour Fortification Standards

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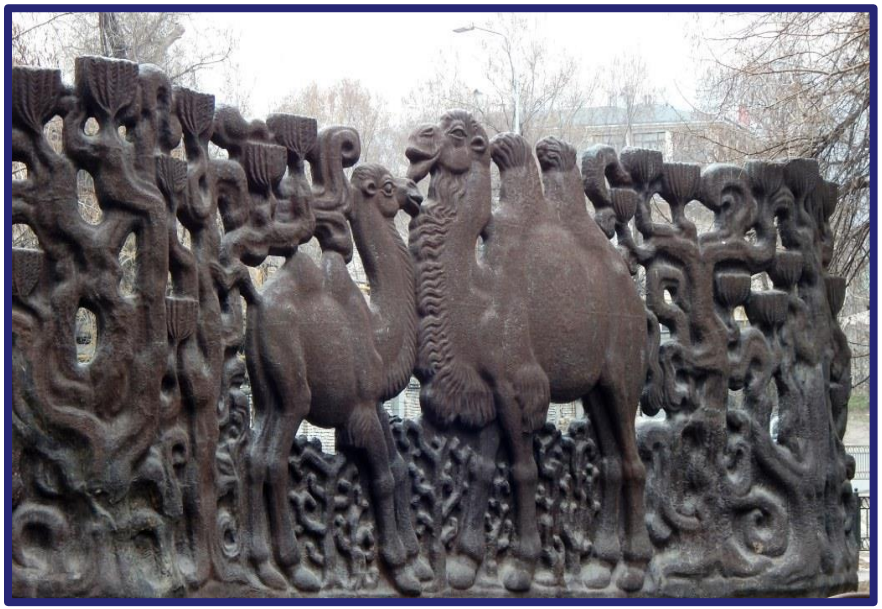

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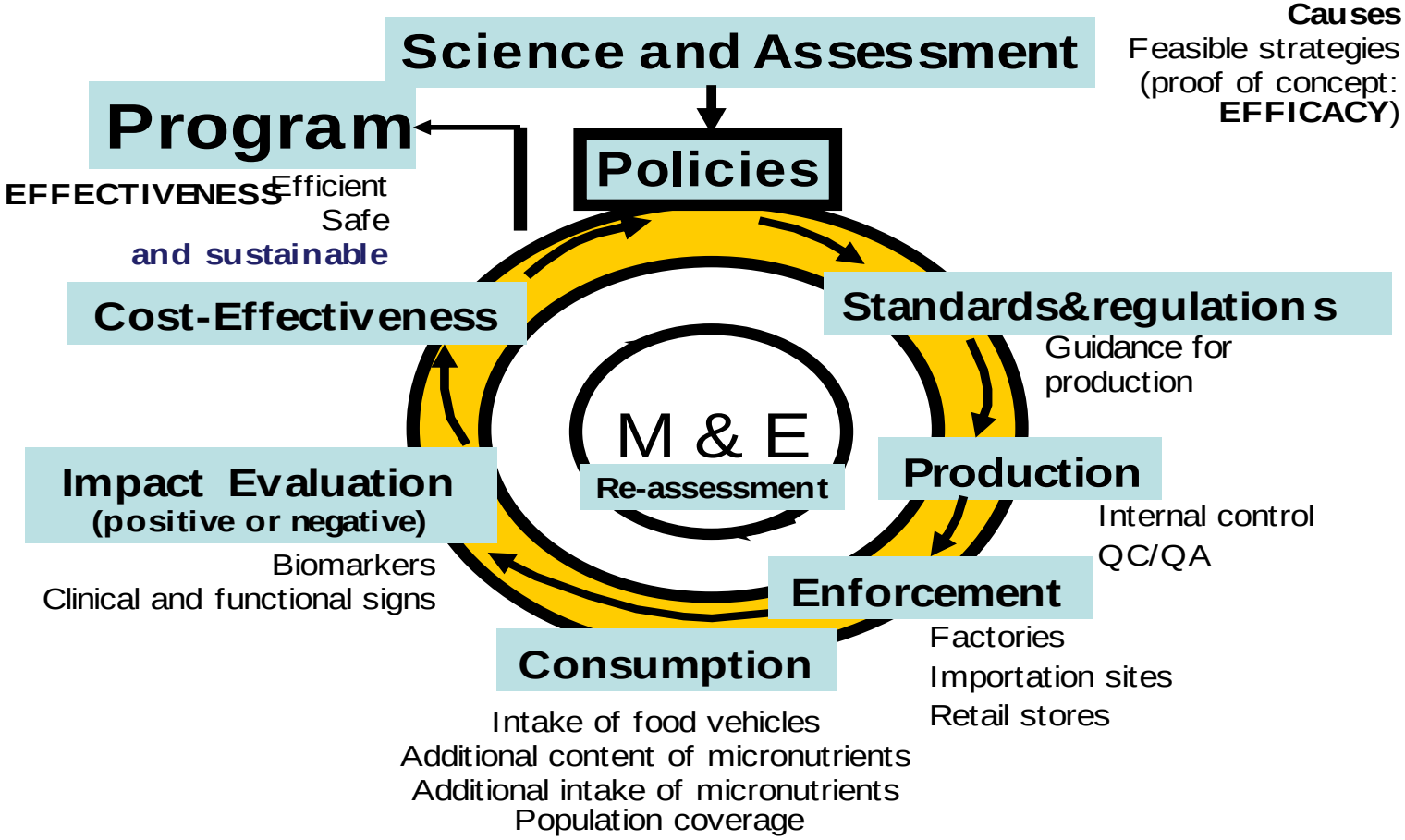
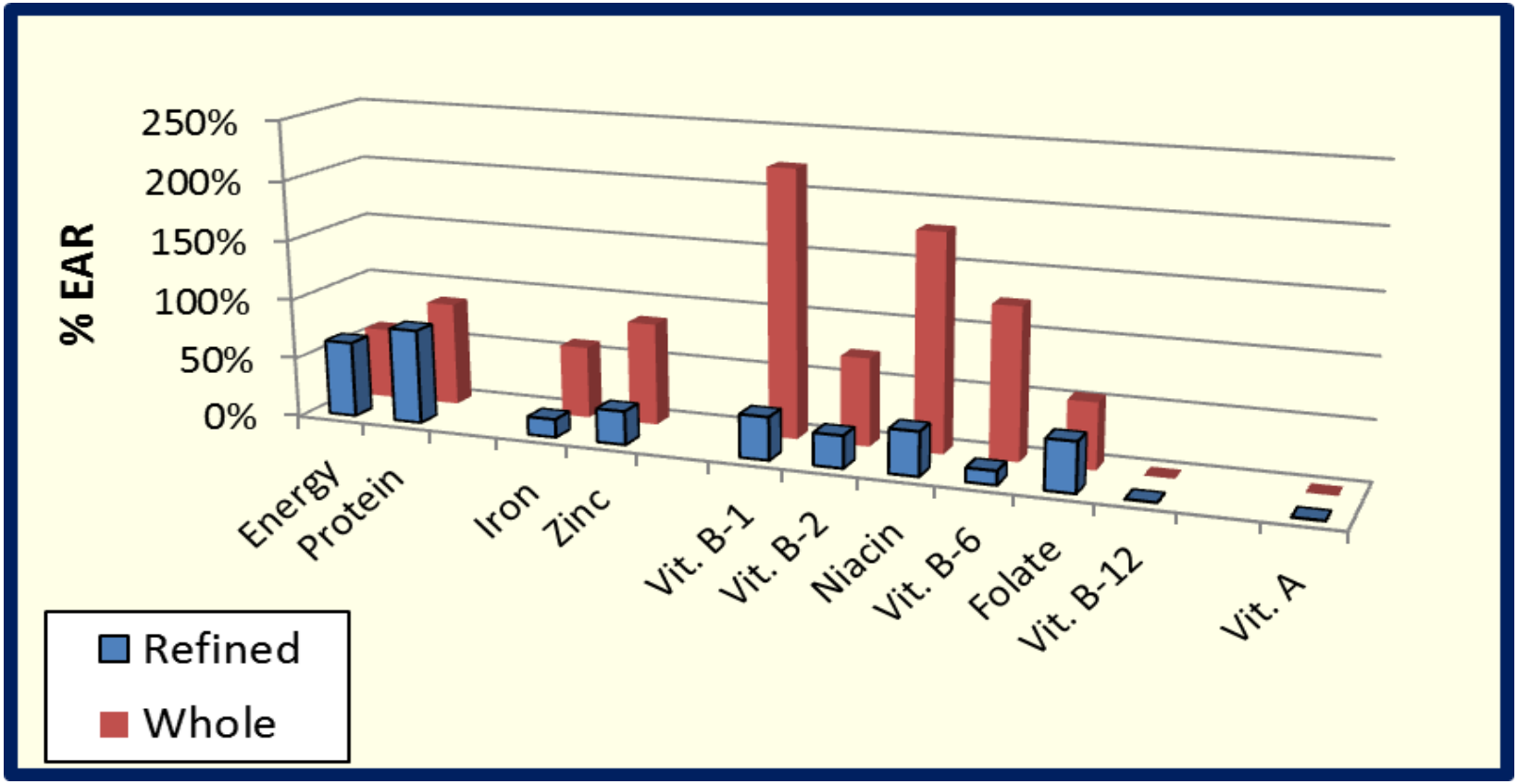
Remembering the steps of a food fortification program



Deduction: Agreement on the standards is important as the first step; but it is only one of the many steps that we should pay attention.

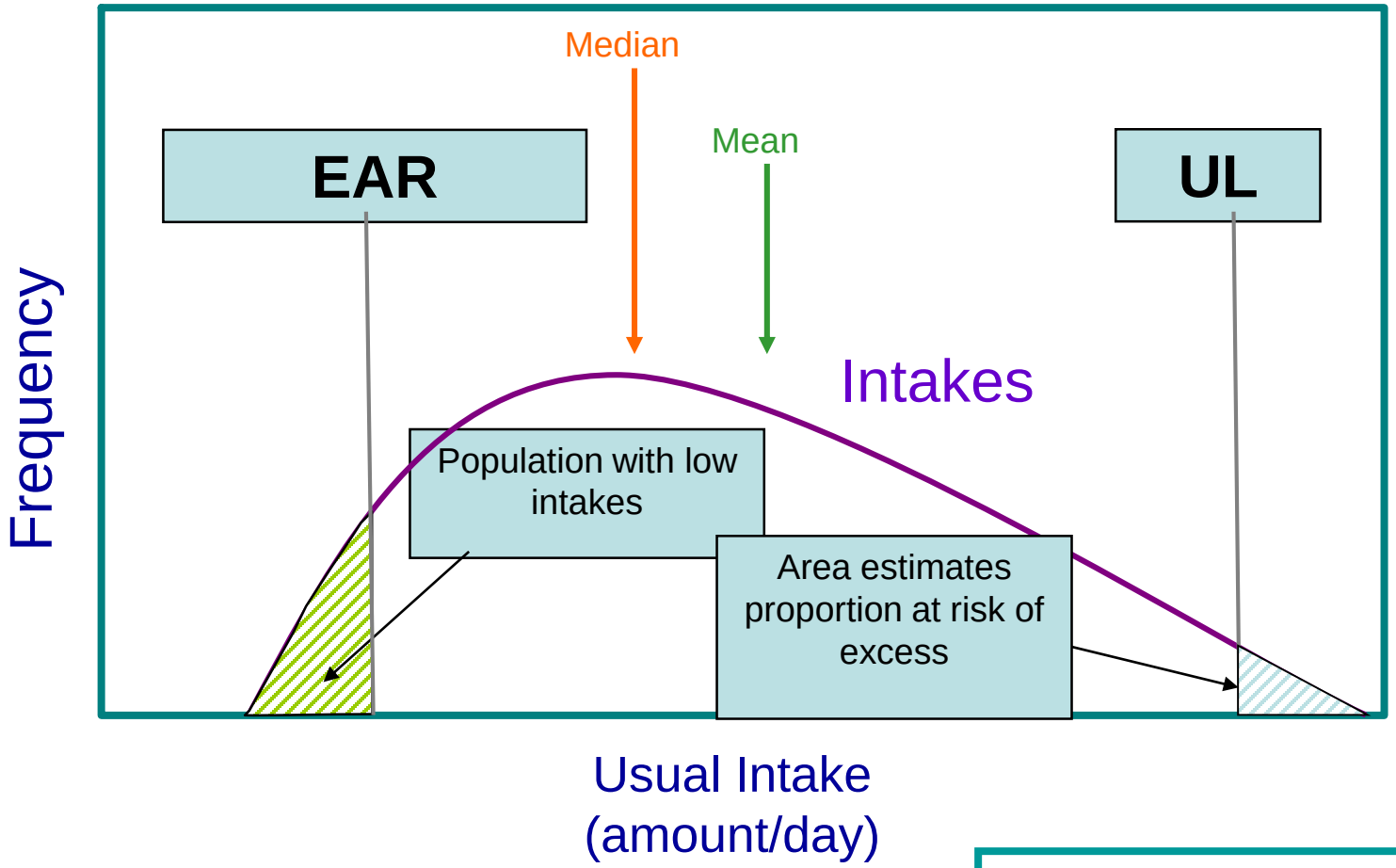
Nutrient contribution (% EAR) of 400 g/day of wheat flour for women of child-bearing age



Source of nutrient content of w.flour : USDA Food Composition Table (http://ndb.nal.usda.gov/)

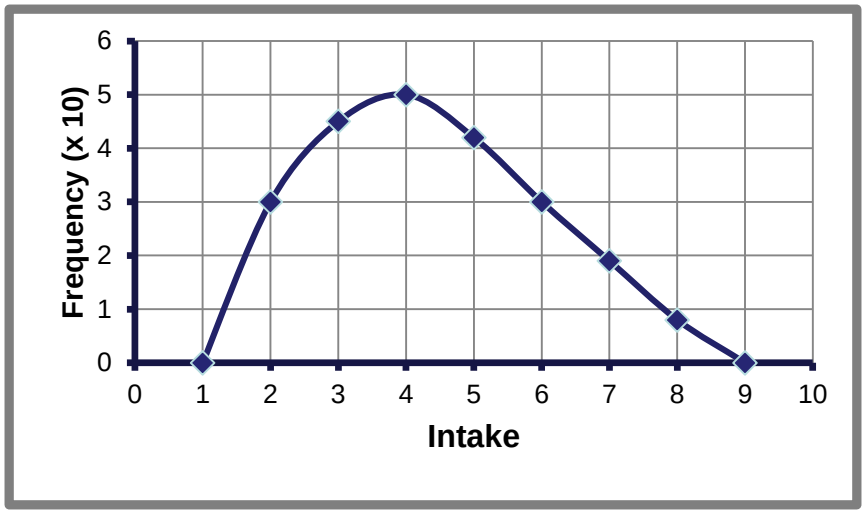
Note: Absorption of iron and zinc for whole wheat flour may be half or lower.

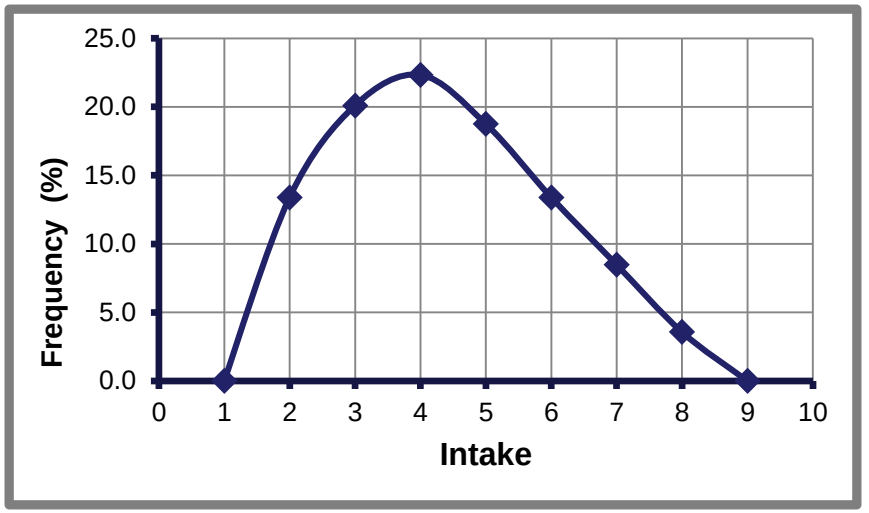
Dietary Recommended Intakes for efficacy and safety

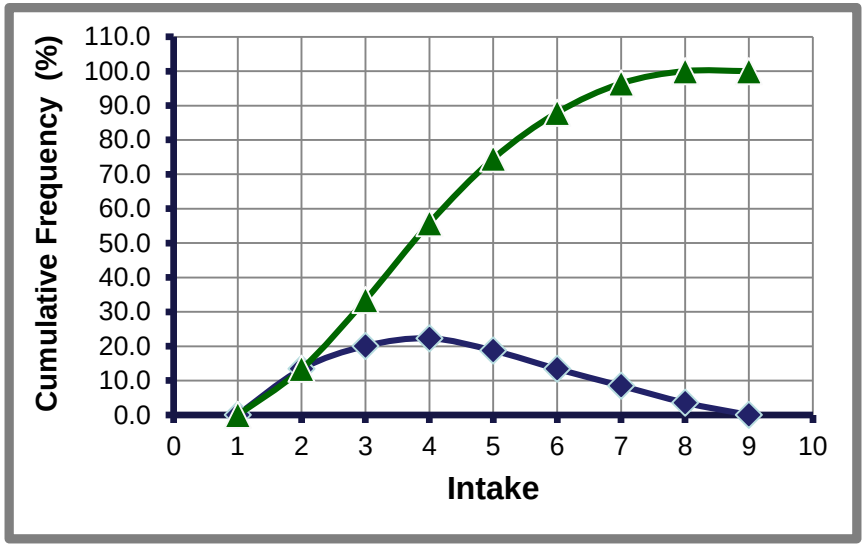


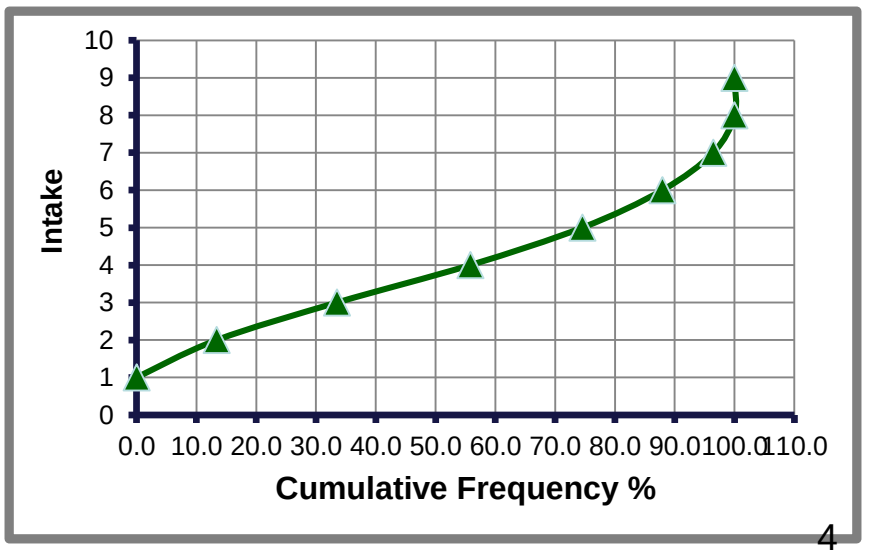
Modified from Suzanne Murphy

Four forms to present the results

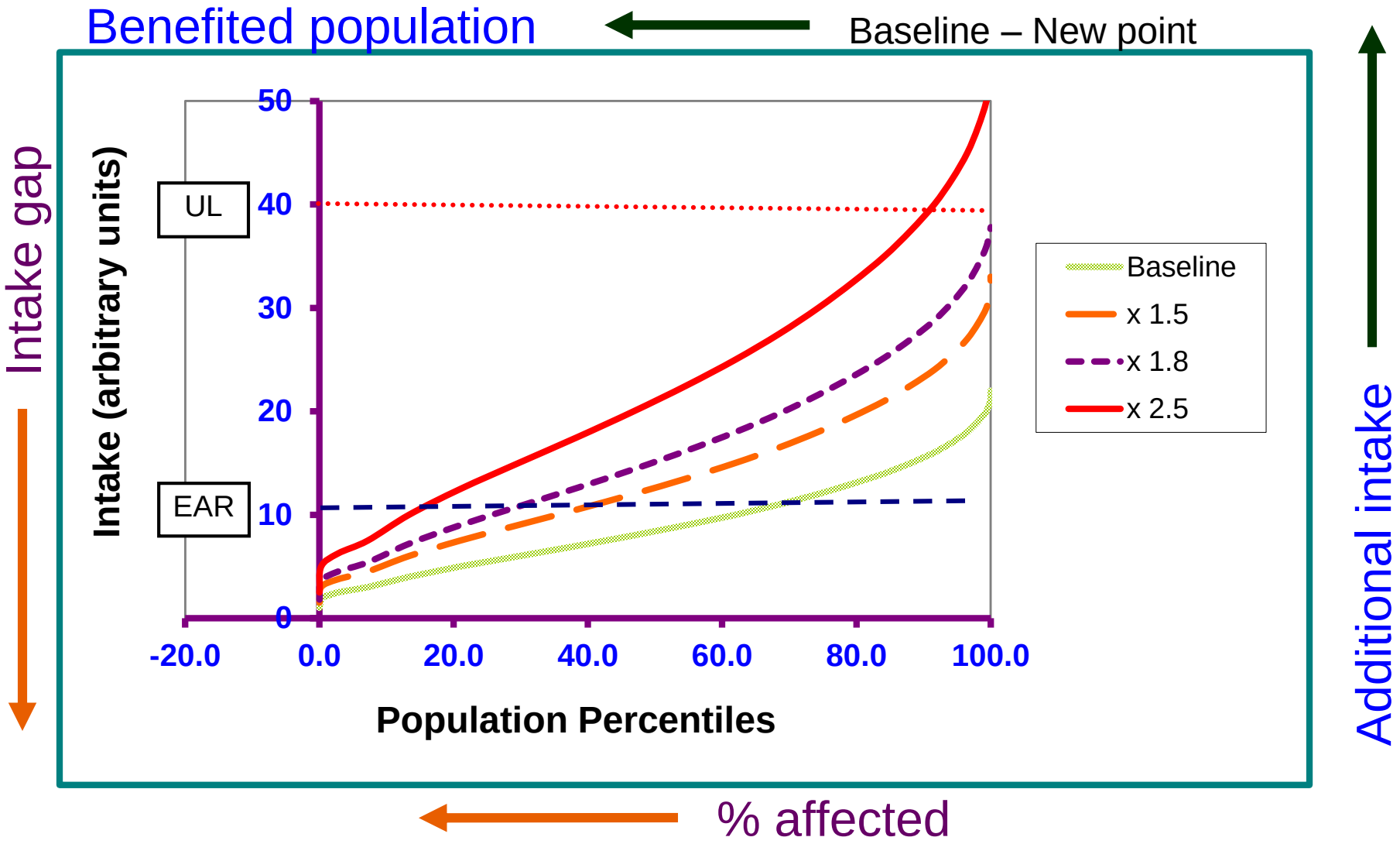








Estimating efficacious and safe fortification contents



Efficacious content: EAR – P_{10} nutrient intake

Micronutrient	EAR	P_{10} Intake	Efficacious intake
Vitamin A RE (µg)	357	229	128
Thiamine (mg)	0.9	0.8	0.1
Riboflavin (mg)	0.9	0.6	0.3
Niacin (mg)	10.8	5.2	5.6
Vitamin B6 (mg)	1.1	0.7	0.4
Folate (µg DFE); FA/1.7	320	90	135
Vit. B12 (ug)	2.0	0.9	1.1
Vitamin C (mg)	34.6	24	10.6
Iron (mg); ÷ 1.5 if NaFeEDTA	26.5	6.4	20.1 (13.4)
Zn (mg)	8.2	5.2	3.0
Calcium (mg)	800	229	571

Modified for women of child bearing age in Mexico; from: Guamuch *et al*., Anna N Y Acad Sci 2014. doi:1-.1111/nyas.12350

Maximum allowable additional intake: UL – P_{90} nutrient intake

Micronutrient	UL	P_{90} Intake	Allowable additional intake
Vitamin A RE (µg) - Retinol	3,000	1,085	1,915
Niacin (mg) (Nicotinic acid)	35	15	35
Vitamin B6 (mg)	100	2	98
Folic acid (µg) – No folate	1,000	0	1,000
Vitamin C (mg)	2,000	244	1,756
Iron (mg);~24 from NaFeEDTA	45	18	27 (24)
Zn (mg)	45	14	31
Calcium (mg)	2,500	990	1,510

Modified for women of child bearing age in Mexico; from: Guamuch *et al*., Anna N Y Acad Sci 2014. doi:1-.1111/nyas.12350

AEC-additional efficacious content; MAC-maximum allowable content

Micronutrient	Efficacious intake	Allowable additional intake	Contents (mg/kg)		
			AEC (167 g)	MAC (350 g)	Propose to select
Vitamin A RE (µg)	128	1,915	0.78	5.5	0.8
Thiamine (mg)	0.1	-	0.6	-	0.6
Riboflavin (mg)	0.3	-	1.8	-	1.8
Niacin (mg)-nicotinic acid	5.6	35	34	100	34
Vitamin B6 (mg)	0.4	98	2.4	280	2.4
Folate (µg DFE); FA	135	1,000	0.8	2.9	0.8
Vit. B12 (ug)	1.1	-	0.007	-	0.007
Vitamin C (mg)	10.6	1,756	63	5,017	NA*
Iron (mg); if NaFeEDTA	20.1 (13.4)	27 (24)	120 (80)	77 (68)	45 (30)*
Zn (mg)	3.0	31	18	88	20
Calcium (mg)	571	1,510	3,419	4,314	NA*

* Because technical incompatibility

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Comparison of fortification formulations (mg/kg)

Micronutrient	Propose to select in Mex. (167-350 g)	WHO* Statement (150-300 g)	WHO* Statement (> 300 g)	CAR refined	CAR whole
Vitamin A RE (µg)	0.8	1.5	1.0	-	-
Thiamine (mg)	0.6	If needed	If needed	**2.0**	-
Riboflavin (mg)	1.8	If needed	If needed	**3.0**	-
Niacin (mg	34	If needed	If needed	**10**	-
Vitamin B6 (mg)	2.4	If needed	If needed	-	-
Folate (µg DFE); FA	0.8	1.3	1.0	**1.0**	**1.0**
Vit. B12 (ug)	0.007	0.010	0.008	**0.008**	**0.008**
Vitamin C (mg)	NA	NA	NA	**NA**	**NA**
Iron (mg); if NaFeEDTA	45 (30)	30 (20)	20 (15)	**10+15**	**15**
Zn (mg)(high extraction)	20	40 (80)	30 (70)	**30**	**30**
Calcium (mg)	NA	NA	NA	**NA**	**NA**

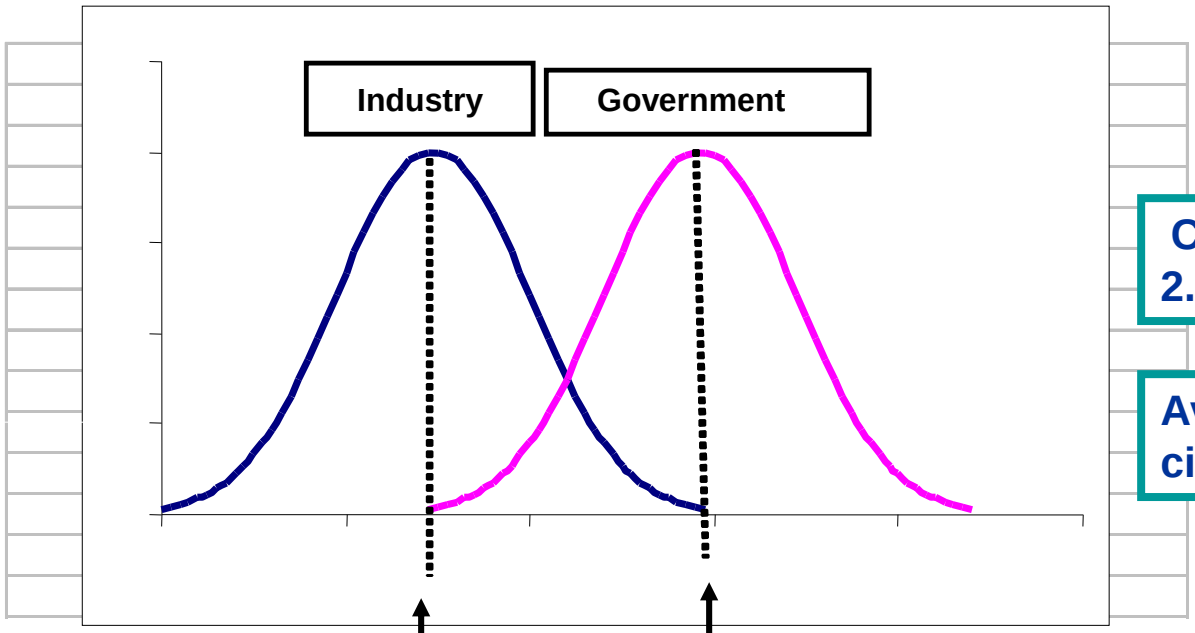
* Assuming that the fortified food is the only source of the micronutrients.

Estimated costs of micronutrient addition to refined wheat flour in the CAR formula

Nutrient	Added content (mg/kg)	Cost (US$/MT)	%EAR Women (300 g/d)	Cost to supply 100% EAR
Vitamin B-1	2.0	$0.06	44 %	US$ 0.14/MT
Vitamin B-2	3.0	$0.18	83 %	US$ 0.22/MT
B-3 (Niacin)	10	$0.10	24 %	US$ 0.42/MT
Folic acid (B-9)	1.0	$0.12	131 %	US$ 0.09/MT
Vitamin B-12	0.008	$0.32	102 %	US$ 0.31/MT
Iron (as $FeSO_4$)	10	$0.10	23 %*	US$ 0.44/MT*
Iron (as NaFeDTA)	15	$0.75	51 %*	US$ 1.47/MT*
Zinc (ZnO)	30	$0.22	220 %*	US$ 0.10/MT*
Total	-	$1.85	-	-
Total plus other costs		~ $2.66/MT	250 g premix per MT	~ $9.50/kg

*In whole wheat flour , the provision would be half for FeSO4 and ZnO, and 0.67 for NaFeEDTA; costs to supply 100% EAR would be increased in the same magnitudes.

A specific recommendation: Pay close attention to the content called the "minimum": Conflict in Chile between government and industry -2007



Regulation : 2.0-2.4 mg/kg.

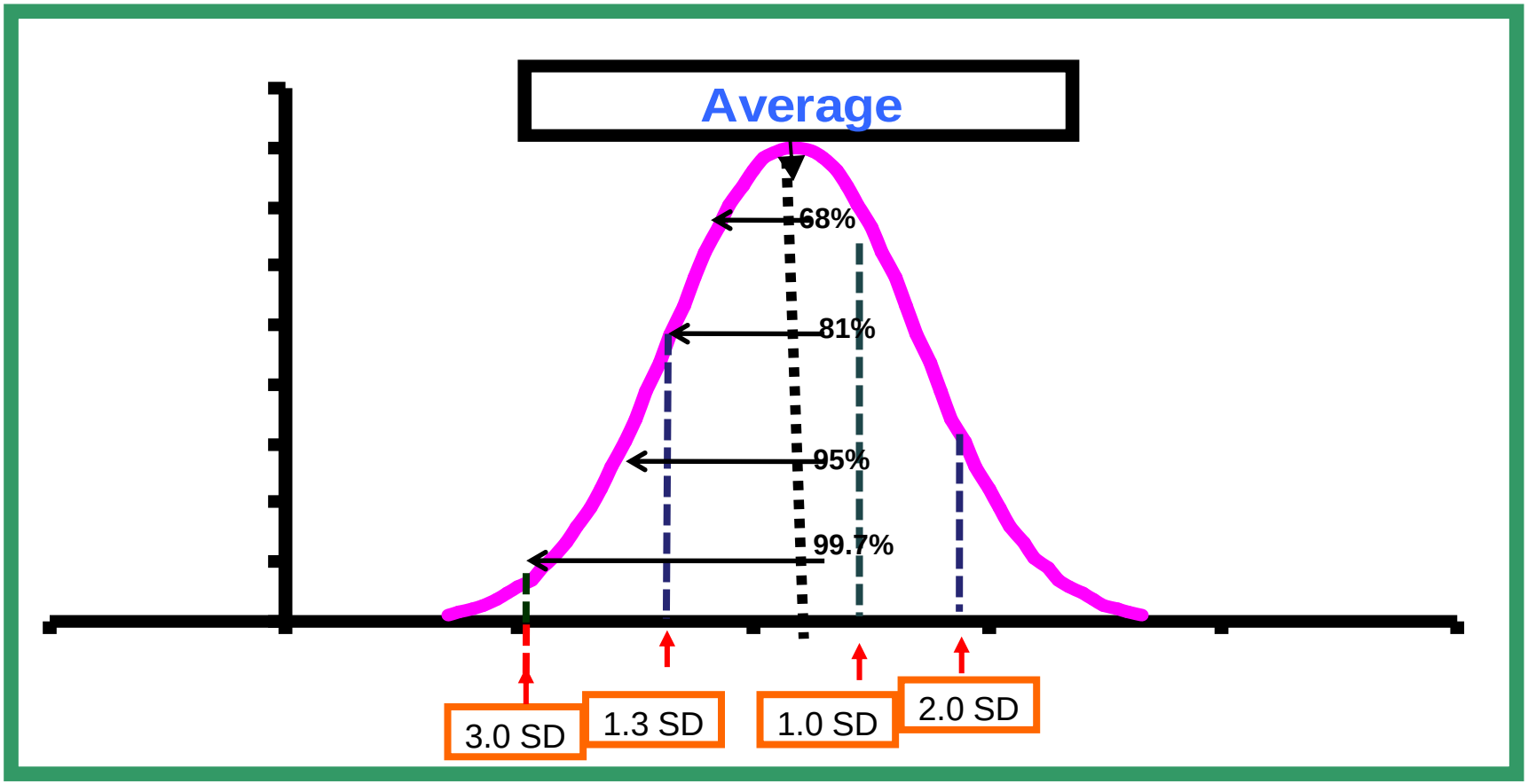
Country average: 2.0 mg/kg

Average in capital city: 7.1 mg/kg

Industry: Mean
Govrnmt: **Mínimum**

Govrnmt: **Mean**

Remembering the normal distribution



CV = DS/μ x 100

DS = (CV x μ)/ 100

Look also at the analytical ranges under different conditions

Condition	C.V.	SD *	Analytical Range **
Analytical assay	5 %	2.25	41.1 – 47.9
Same batch	10 %	4.50	39.2 – 50.8
Same factory	20 %	9.00	33.5 – 56.5
“Good” factories	30 %	13.50	27.7 – 62.3
Retail samples	50 %	22.50	16.4 – 73.6
“1-g home” samples	80 %	36.00	0.0 – 91.0***

* Iodized Salt: Assuming average of 45 mg I/kg; and ** 80% compliance

*** Even for the same average, and samples produced in the same program:

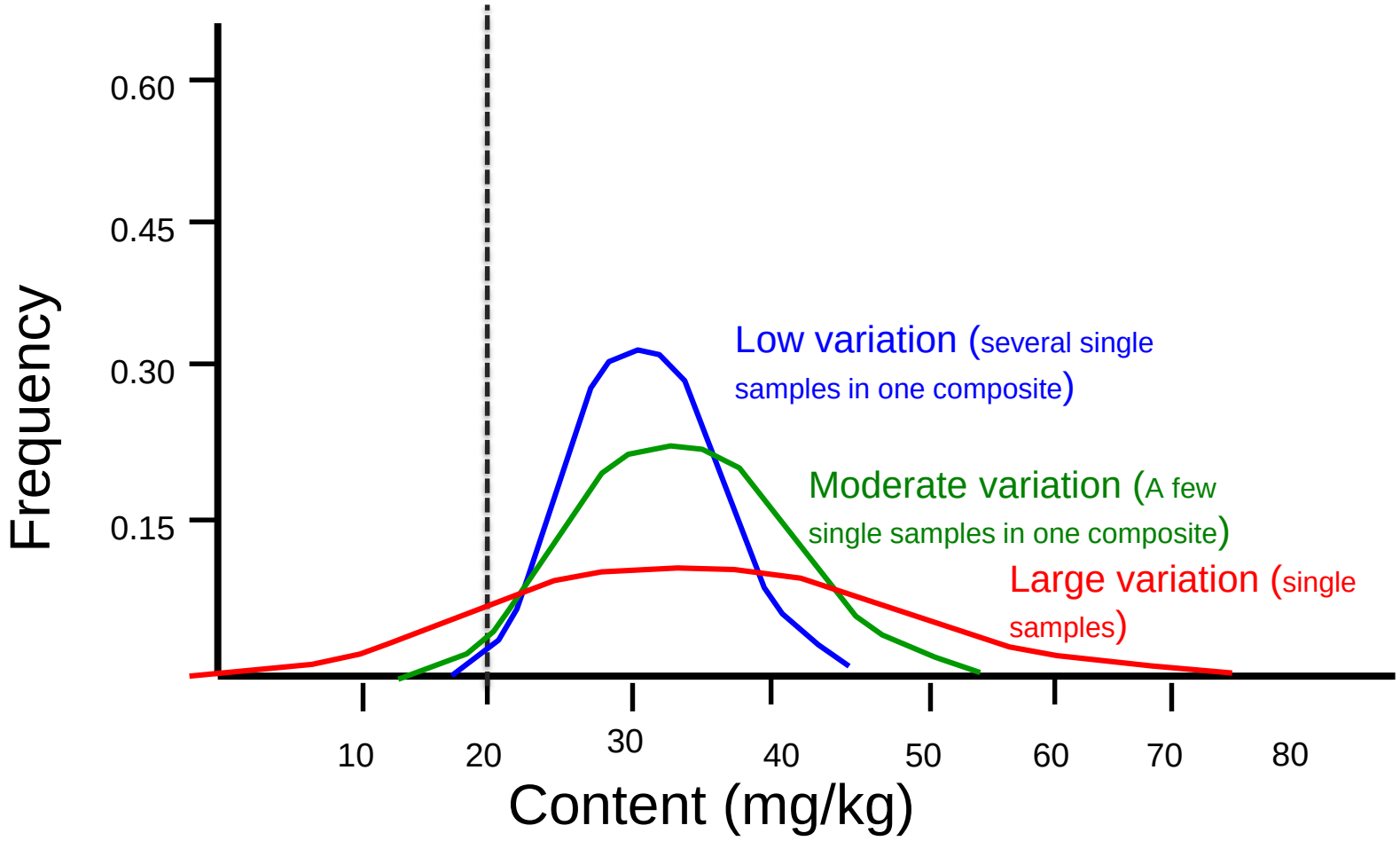
20% samples < 15 mg/kg; 16% < 10 m/kg; and 10% as lacking of iodine.

Real example: Iodine content in washed salt in México-2013 (Regulation: 30 ± 10 mg/kg)

Parameter	Single	2 combined	4 combined
n	8	8 x 2	8 x 4
Median (mg/kg)	30.1	31.5	30.2
Mean (mg I/kg)	35.0	33.2	30.0
S.D. (mg I/kg)	14.1	7.2	5.5
C.V. (%)	40.3 %	21.7 %	18.4 %
% samples < 20 mg I/kg	14.4 %	3.3 %	3.4 %
% samples < 15 mg I/kg	7.8 %	1.0 %	0.3 %

Source: Unpublished results from Government Food Control (COFEPRIS), México, 2013.

Variation under different scenarios; Average 31 ± 10 mg I/kg



Source: Unpublished results from Government Food Control (COFEPRIS), México, 2013.

Composite samples provide same averages as the arithmetic average

Samp.type	[Iodine] (mg/kg) Salt from Cambodia				
Single Samples	8.2	2.2	2.4	2.9	3.6
	1.6	1.5	2.8	1.8	3.0
	6.7	15.2	4.7	1.8	3.8
	15.6	13.6	17.4	7.1	3.1
	23.9	3.5	2.3	5.0	5.4
Average	11.2	7.2	5.9	3.7	3.8
Composite Samples	11.7	7.7	5.9	3.7	5.5

50 g of each salt were analyzed by the titrimetric method for iodine

Conclusions

1. Standards are important, but they are only the first step of many others, and all of which should receive equal attention.
2. Fortification formulas are designed in a way that inadequacies are corrected but at the same time safety is ensured. Average intakes above 100% of the EAR are normal and expected in a population.
3. Selection of appropriate micronutrient contents require of food intake surveys, but programs might start following international guidance and examples from similar countries.
4. In order to make the fortification process easier and reduce cost of premixes, the use of similar formulas is encouraged; it requires technical and economic compromises among countries.
5. Standards should emphasis the mean added content, and include a variation around the mean for promoting homogeneity; but the main parameter of enforcement should be the mean.
6. Composite samples (combination of single samples) allow to estimate the mean with a minimum amount of analytical work.