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How to Design and Implement Food Fortification?

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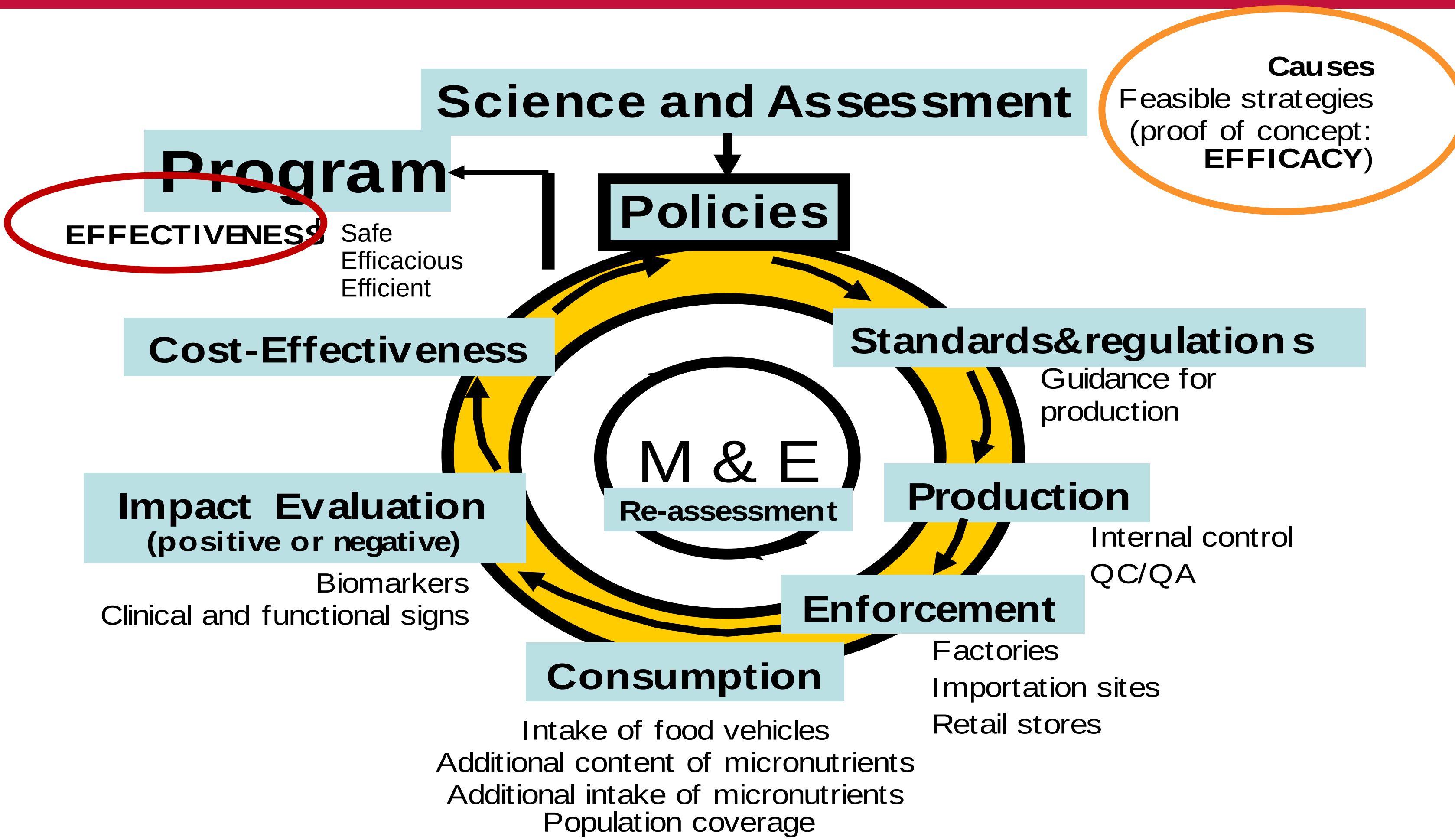
Outline

1. **Components of a food fortification program**
2. **Assessment and science:** proof-of-concept; efficacy
3. **Design:** ensuring safe, efficacious, and efficient impact
4. **Standards/regulations:** Mean and a variation around the mean; sampling and handling
5. **Production and enforcement**
6. **Monitoring consumption:** program performance
7. **Evaluating impact:** programmatic effectiveness

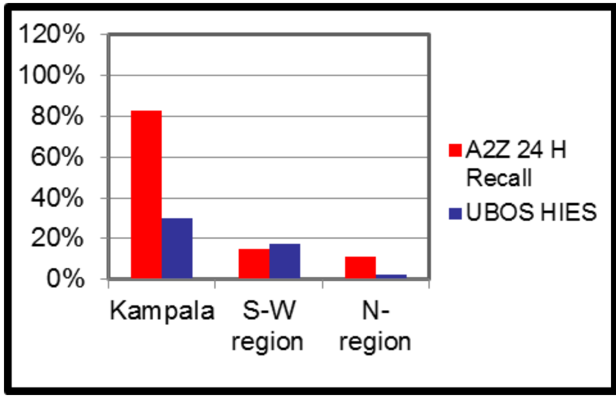
Components of a food fortification program



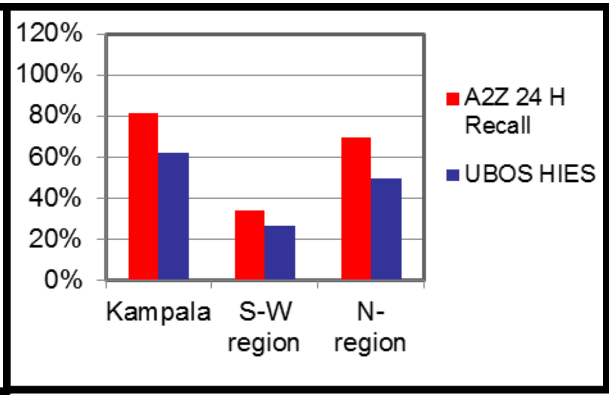
Deduction: In food fortification, many stakeholders are essential: bureau of standards, industry, food control authorities, statistic offices, epidemiologist, nutritionists, others.

Science 1: Selecting the appropriate fortification vehicles for attaining good population coverage

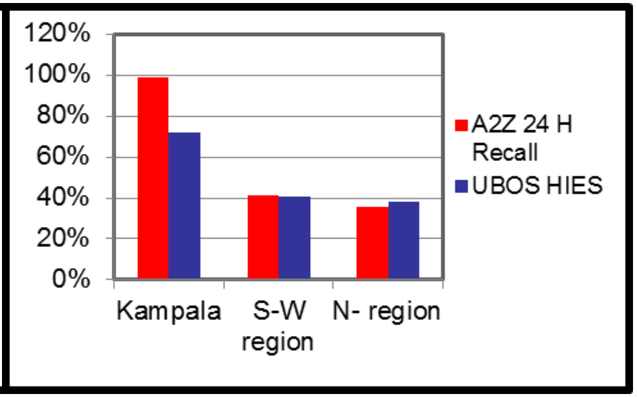
Percent of household use of fortification vehicles (industry-manufactured foods) in three regions of Uganda - 2010



Wheat flour



Oil



Sugar

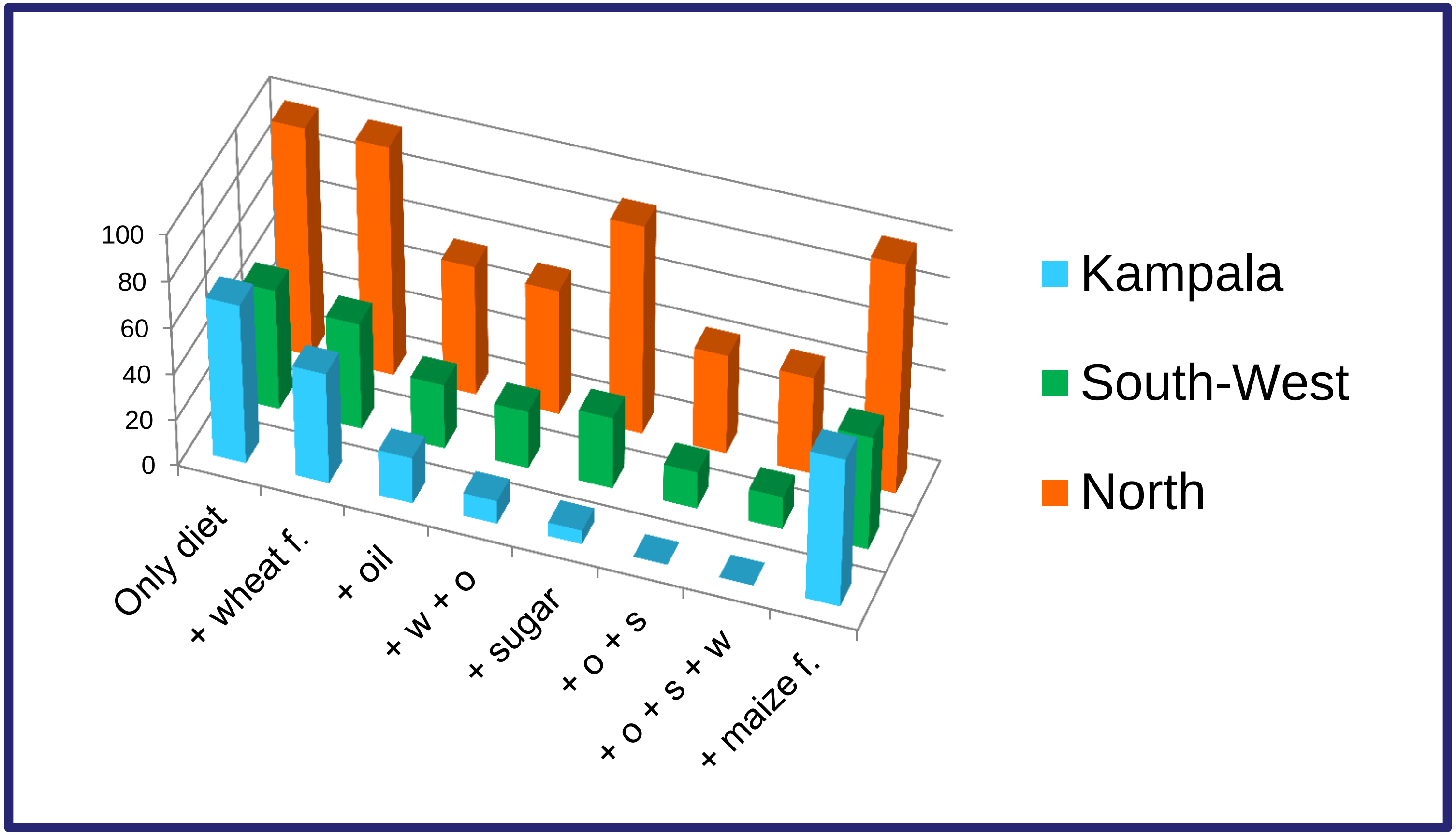
Source: Rambeloson *et al*., 2011.

Deduction: Population impact depends –in part- on coverage, which in turn depends on the penetration, access, and utilization of the fortification vehicle.

Food fortification favors mainly urban populations.

Science 2: Determining the better combination of fortification vehicles (individual impact x population coverage)

% Children (24-59 months) with intakes below the EAR values for vitamin A in Uganda - 2008



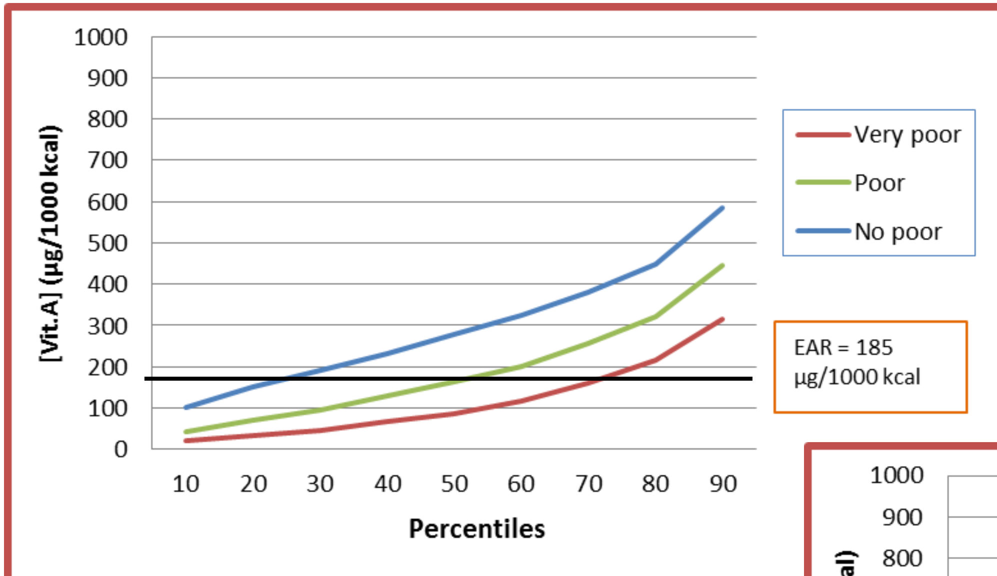
Science 3: Predicting technical feasibility and cost for programmatic viability

Vehicle	[Vit. A] (mg/kg)	Relative Cost (US$/MT)	If veh. price (US$/kg)	% Price	Dil. Factor (vehicle/vit.A)
Oil	15	3.92	1.00	0.4 %	20,000-34,000
Wheat flour	3	2.97	0.5	0.6 %	20,000
Sugar	15	15.71	0.50	3.1 %	1,000 x 5
Salt	60	58.23	0.30	19.4 %	1,000
MSG	1,400	1,362.57	5.00	27.3 %	40

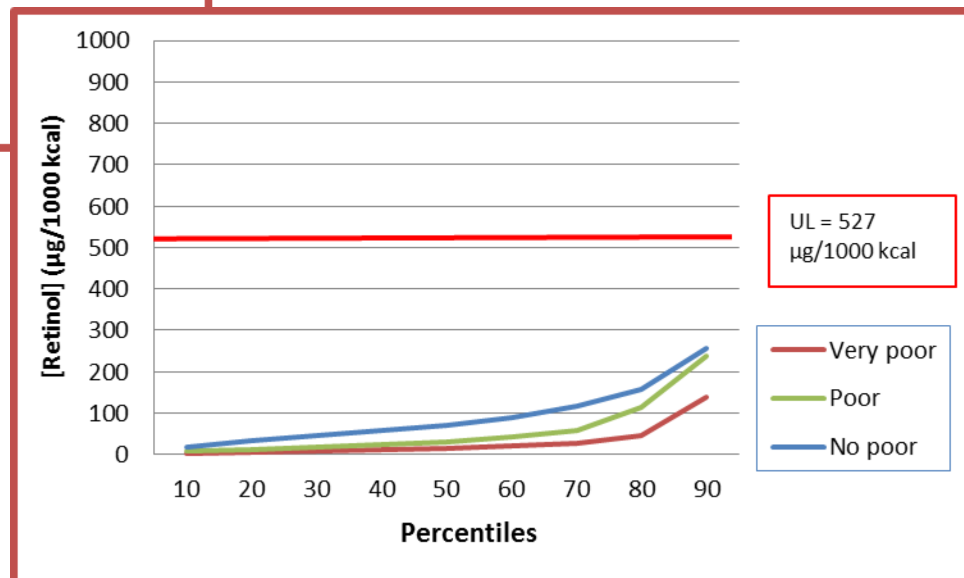
Note: Total annual cost for all cases, excepting oil –that is slightly lower-, is similar. Fortifying rice through dusting is similar to wheat flour, and through extrusion/coating cost is going to be $10-20/MT (2-3 % of the price) when dilution factors are 1:200 and 1:100, respectively.

Design 1: Determining "adequacy" and "safety" of vitamin A in the absence of fortified sugar on children 2-4 y, Guatemala-2006

Dietary "adequacy" (density)

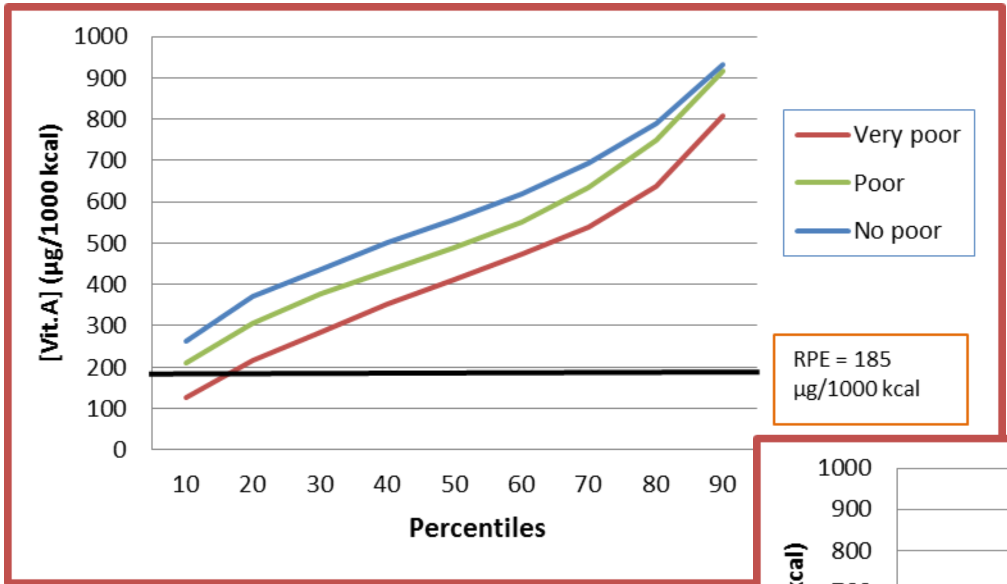


"Safety" of retinol (density)



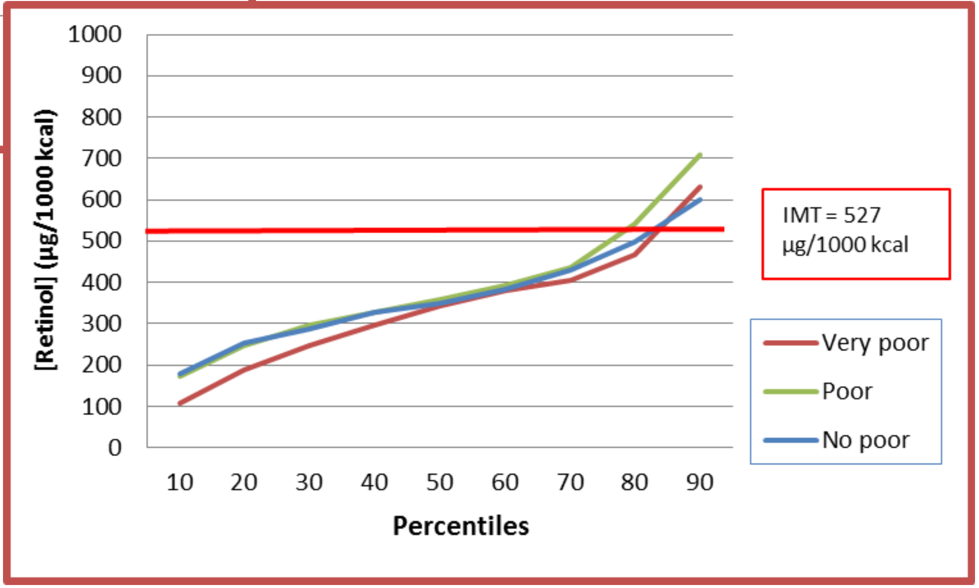
Source : Menchú *et al.* (INCAP). ENCOVI-2006 Household survey, Guatemala; 2013**.**

Design 2: Assessing "adequacy" and "safety" of vitamin A in the presence of fortified sugar with vit. A (9 mg/kg) on children 2-4 y, Guatemala



Dietary "adequacy" (density)

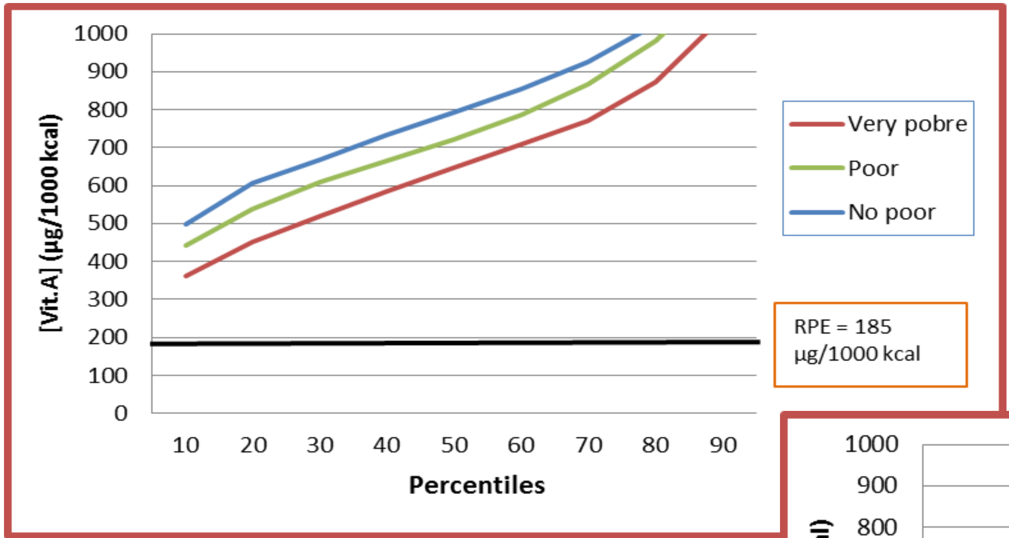
"Safety" of retinol (density)



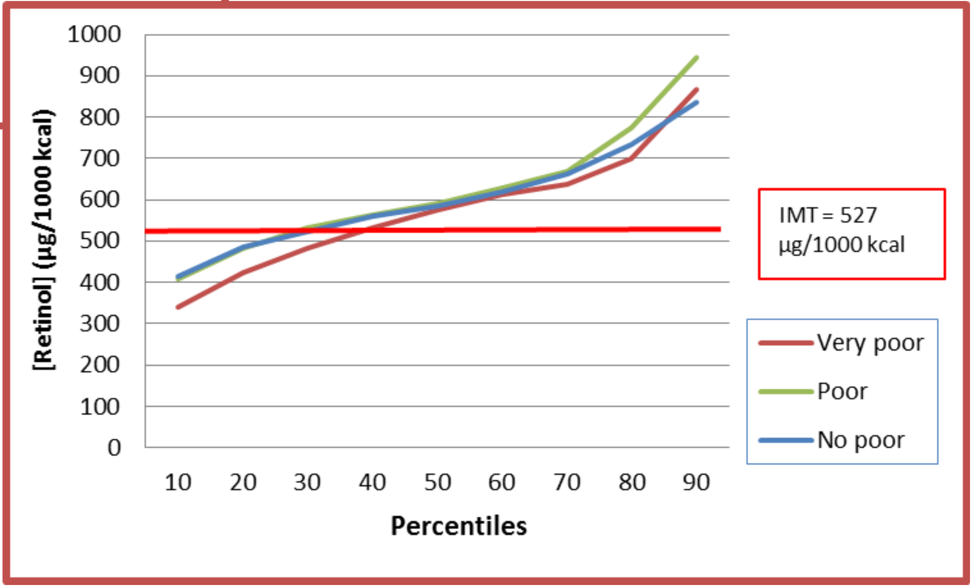
Source : Menchú *et al.* (INCAP). ENCOVI-2006 Household survey, Guatemala; 2013.

Design 3: Modeling "adequacy" and "safety" if adding vit. A supplements on children 2-4 y; unnecessary in Guatemala.

Dietary adequacy (density)

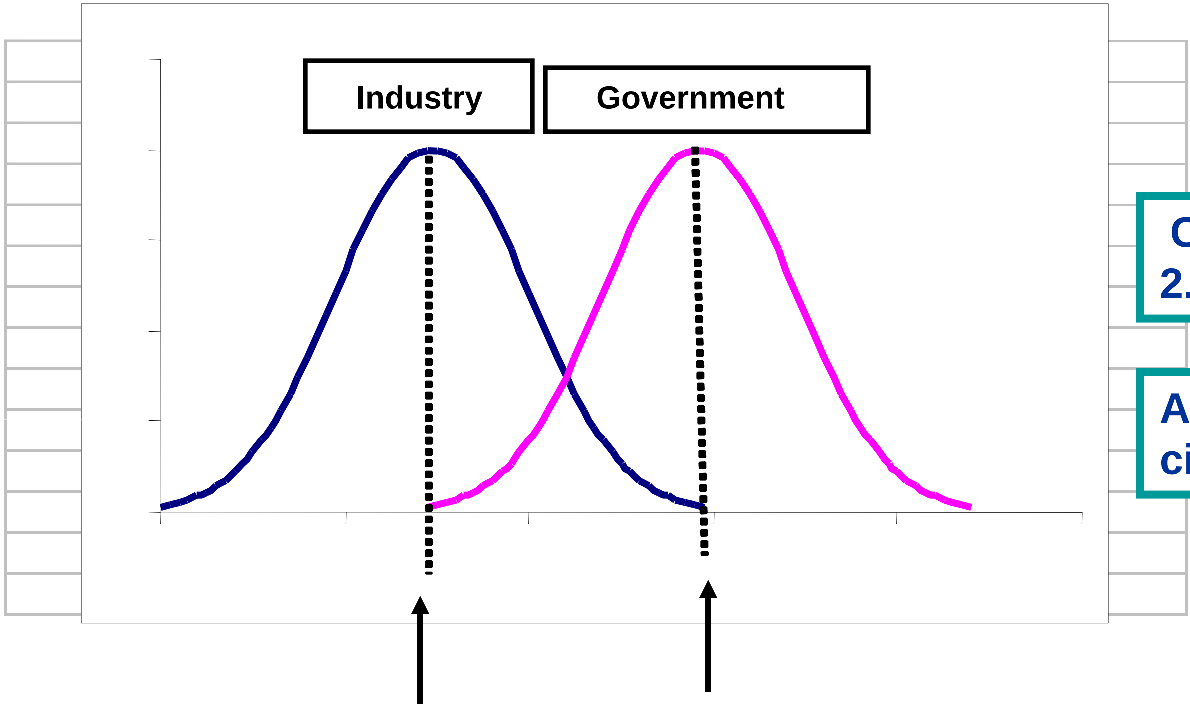


Safety of retinol (density)



Source : Menchú *et al.* (INCAP). ENCOVI-2006 Household survey, Guatemala; 2013.

Standards 1: The use of the "minimum" content is failing: Conflict in Chile between government and industry -2007



Regulation : 2.0-2.4 mg/kg.

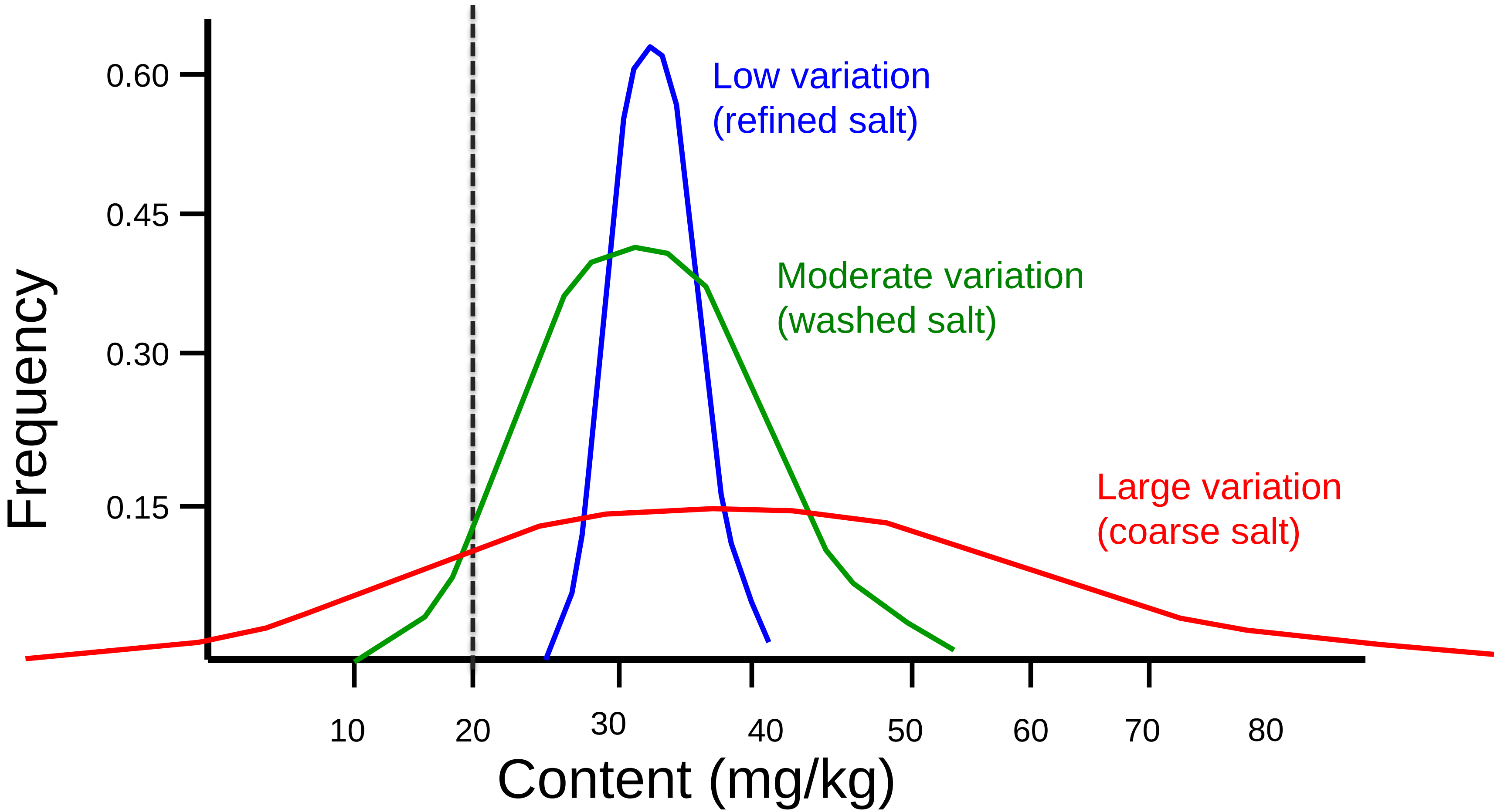
Country average: 2.0 mg/kg

Average in capital city: 7.1 mg/kg

Industry: Mean
Govrnmt: Mínimum

Govrnmt: Mean

Standards 2: Situation of the iodized salt in Mexico-2013; Regulation 30 ± 10 mg I/kg



Note: And this is using 50 g of salt in solution. What would be the situation using 1 g of salt or less, and which is common in household surveys for estimating "adequately" iodized salt?

Standards 3: Iodine content in different types of salt in México-2013 (Regulation: 30 ± 10 mg/kg)

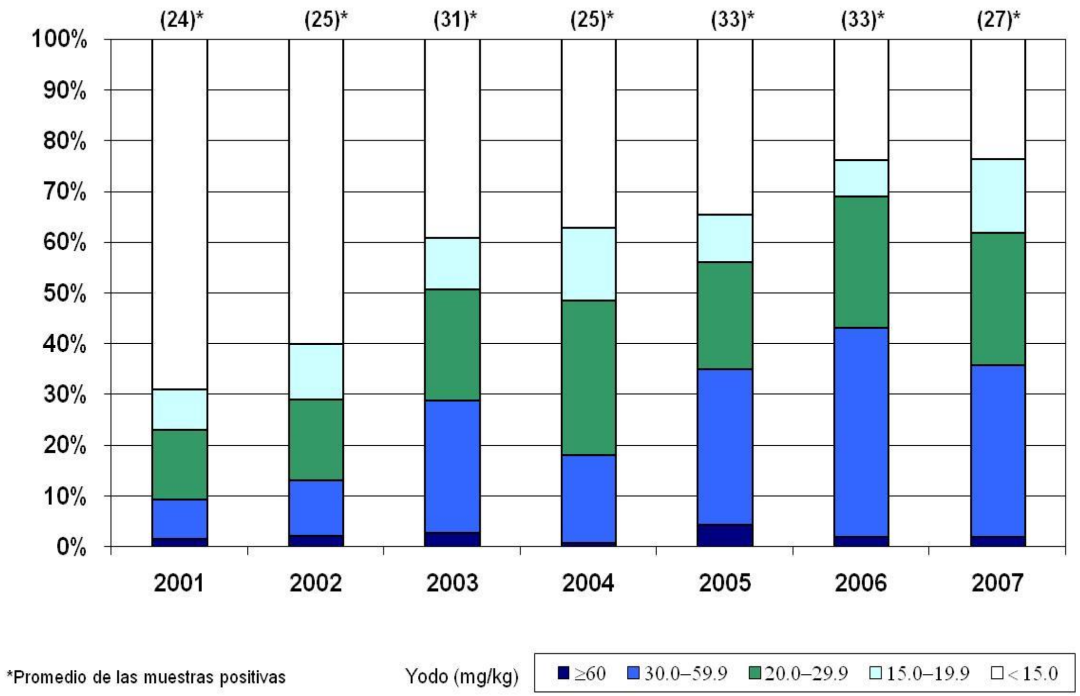
Parameter	Coarse salt	Coarse salt*	Washed salt	Washed salt*	Refined salt	Refined salt*
n	32	6	42	8	20	4
Median (mg/kg)	23.8	40.4	29.7	29.7	33.7	34.0
Mean (mg I/kg)	39.9	41.3	30.9	30.8	33.9	33.9
S.D. (mg I/kg)	46.5	31.0	10.0	6.5	2.9	0.6
C.V. (%)	116.4%	75.0 %	32.4 %	20.7 %	7.6 %	1.7 %
% samples < 20 mg I/kg	33.4 %	24.6 %	13.8 %	4.6 %	0.0 %	0.0 %
% samples < 15 mg I/kg	29.6 %	19.8 %	5.6 %	4.6 %	0.0 %	0.0 %

* Results using composite samples, made with the combination of 5 single samples.

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

Production and Enforcement: Surveillance system of iodized salt in Guatemala

National Mean: 7.2 | 10.0 | 18.1 | 15.7 | 21.4 | 24.7 | 20.5



Guatemala Regulation: 20-60 mg I/kg

2010 (only positive samples)

[I] (mg/kg)	% samples
< 5.0	12 %
< 15.0	28 %
15.0-19.9	10 %
20.0 – 29.9	23 %
30 – 59.9	37 %
≥ 60.0	2 %
Average	25.3 mg/kg
Standard Dev.	17.2 mg/kg
C.V.	68.1 %

- **Methodology:** 300 public schools randomly selected; 20 students per school, one sample per child = 6,000 samples analyzed by a qualitative test. Quantitative determination: 600 samples.
- **Cost:** $30,000/year or less, and it also includes sugar and wheat flour samples.

Monitoring consumption: Impact depends on the additional intake

Amount consumed x [Nutrient] = Additional intake

NUTRIENT BIOEFFICACY → [BIOAVAILABILITY & BIOCONVERSION]

FUNCTIONAL (Physiology changes)

CLINICAL (Tissues, organs)

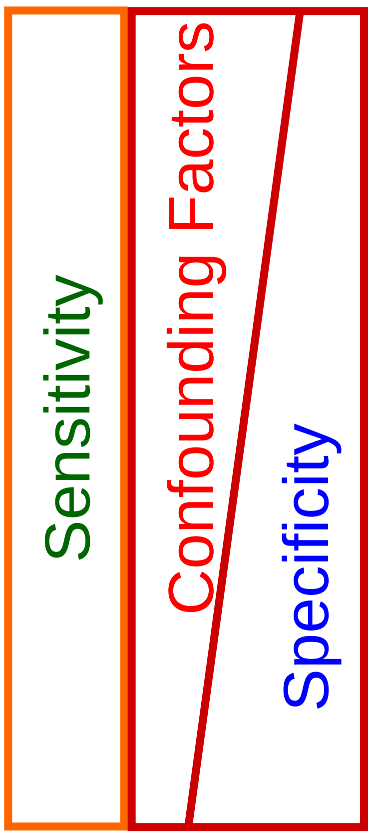
STATUS (Metabolic biomarkers)

EXPOSURE (Biomarkers of intake)

Basal bio-form → **Additional bio-form** → Total bio-form

Impact requires: Need + Additional micronutrient intake + Coverage

Evaluating impact: Micronutrient indicators for assessing need and impact



	Folate	Vit. A	Iron
FUNCTIONAL (Physiology changes)	-	Night blindness	IQ, endurance
CLINICAL (Tissues, organs)	NTD, Anemia	Anemia	Anemia
STATUS (Metabolic biomarkers)	RBC-folate	Serum retinol	Serum-Ferritin Soluble-TfR
EXPOSURE (Biomarkers of intake)	Serum-folate	Breast-milk retinol	-

What of these are being used?

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Conclusions-1

1. Experimental efficacy does not ensure program effectiveness (“copy and paste” is not a valid approach).
2. An effective program should comply with three conditions:
   a) Safe: Low risk of adverse effects for those who eat the food vehicle in large amounts;
   b) Efficacious: Supply significant amounts of micronutrient to those at need to correct the nutrient gap; and
   c) Efficient (sustainable): Low cost and with little dependence on external resources.
3. Permanence of the programs requires demonstrating and periodically documenting their performance and population impact.

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Conclusions-2

4. Although mass-fortification has low cost, when implemented through centralized and reasonable developed food industries, some investment for the programmatic components is still needed.
5. An effective food fortification program requires:
   a) Appropriate design to fit conditions of each context;
   b) Probably consideration of more than one fortification vehicle;
   c) Logical and sensible standards that reflect the reality of the fortification process;
   d) Introduction of a reliable and permanent enforcement system; and
   e) Implementation of consumption monitoring, and performance and effectiveness evaluation from the beginning of the program.

Conclusions-3

6. Food industry may transfer the cost of fortification into the price of the product, but the public sector needs to identify the source of additional funds for strengthening:
   a) Standards/regulation enactment;
   b) Enforcement at factories, importation sites, retail stores;
   c) Monitoring at households;
   d) Evaluation of program performance and effectiveness.
7. Efficient and sustainable programs are depending on local human resources and national commitment rather than on external financial aid, which would be better aimed for training, motivation, and support organization.

Intervention is:

- Biological justifiable
- Technically feasible
- Economically viable
- Programmatically controllable

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Biologically justifiable:

- There is a confirmed nutrient gap in the target population
- Fortification vehicle has good coverage and consumed in suitable amounts
- The additional micronutrient intake contributes substantially to reduce the nutrient gap (i.e. moves a large proportion of the population above the EAR values)
- Highest new intake is below the UL values for most individuals of the population

Technically feasible:

- Fortification takes place in centralized and reasonably developed factories
- Amount of fortificant is compatible with production practices (i.e. high dilution factors, no segregation, acceptable stability)
- Sensorial properties of the vehicle remain unchanged

Economically viable:

- Price increase due to fortification is low enough and always compatible with the usual trade practices of the fortification vehicle
- Possibility to finance the cost of the fortificant and the fortification process is real (transfer to the food price, or someone subsidized the cost)

Programmatically controllable:

- Real feasibility to establish a reliable and permanent enforcement system exists
- Periodical assessment of the program performance and effectiveness is possible

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Impact in individuals depends on the additional micronutrient intake, and not on the fortified vehicle

Vehicle	Daily ration (g/day)	[Vit. A] (mg/kg)	Additional intake vit. A (µg/d)	% EAR	Impact: Change in serum retinol (µmol/L)
Wheat flour	70	3	212	66 %	0.94 → 1.06
Oil	23	15	339	106 %	0.92 → 1.01
Sugar	22	15	337	105 %	0.72 → 1.06
Salt	7	60	420	131 %	0.88 → 1.14
MSG	0.25	1400	336	105 %	0.67 → 0.92

Deduction: As impact depends on the additional intake of the nutrient and not on the fortification vehicle, there are different alternatives to deliver the needed micronutrients and the usefulness of those depends on the local context.

Common fortification vehicles for mass-fortification

- Wheat and maize flours (refined)
- Rice
- Oils (better if saturated)
- Vegetable fats (margarine, e.g.)
- Sugar
- Salt

- Widely consumed
- Accessible and used by the target population
- Processed by formal factories
- Easy to control

But… they are also the type of foods whose intake must be reduced to avoid NCD

- Carbohydrates, fats
- Foods with high glycemic index
- Fructose, alcohol, trans-fatty acids, branched a.a.
- Sodium (common salt), cholesterol

- Overweight and obesity
- Diabetes
- Metabolic syndrome
- Cardiovascular diseases

Conclusion: Mass-food fortification uses those foods as vehicles of fortification, but it does not mean that also promotes increment in their consumption; it only takes advantage that they are widely consumed. Therefore, social-marketing practices must be carefully designed.