



# PILOT IMPLEMENTATION OF USI FORTIMAS METHODOLOGY

UUP NATIONAL INSTITUTE

FOR ASSESSMENT AND TRACKING EFFECTIVE COVERAGE OF THE NATIONAL SALT IODIZATION PROGRAM AND IODINE STATUS OF PREGNANT WOMEN IN THE REPUBLIC OF ARMENIA

# **TECHNICAL REPORT**

YEREVAN - APRIL 2024

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Pilot implementation of USI FORTIMAS Methodology for Assessment and Tracking Effective Coverage of the National Salt lodization Program and iodine status of pregnant women in the Republic of Armenia

#### ABSTRACT

To enable public and private sector stakeholders of the national salt iodization program in Armenia to be able to confirm high population coverage of well iodized salt and the associated adequate iodine status of the population systematically and at a substantially lower cost than typical population-based representative surveys, the IGN supported the "pilot" implementation of the FORTIMAS (Fortification Monitoring and Surveillance) methodology, adapted to tracking "effective coverage" of iodized salt, in Armenia. Primary analysis of non-probabilistic data showed high (92%) household coverage of adequately iodized salt and optimum (175.3  $\mu g/L$ ) median urinary iodine concentration among 1<sup>st</sup> trimester pregnant women, across purposively selected sentinel sites. Secondary analysis of data on production, imports and distribution of iodized salt indicated consistently high expected and assessed population coverage of iodized salt during the past decade. The prevalence of neonatal TSH levels above 5 mUI/L (an indicator of iodine status among pregnant women) over past 12 years was less than 3% with a general trend of decreasing from 2.35% in 2017 to 1.39% in 2023.

The cost of implementation of the FORTIMAS approach as an initial round of "annual" iodized salt program monitoring and surveillance in Armenia, was only a fraction of that of a typical nationally representative salt iodization/population iodine status survey. Furthermore, because the overall framework of a potential "Armenia FORTIMAS System" has been developed under this project, it may be estimated that about 10 annual rounds of salt iodization program monitoring and surveillance may be carried out in Armenia int the future, at about the same cost as one nationally representative salt iodization program survey.

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# *Abbreviations and acronyms* In alphabetical order:

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ASP – Avan Salt Plant
ANC - antenatal care
CJSC - closed joint-stock company
DHS Demographic and Health Survey
FSIB - Food Safety Inspection Body of the Republic of Armenia
ICCIDD International Council for Control of Iodine Deficiency Disorders
IDD – Iodine Deficiency Disorders
IGN – Iodine Global Network
MC – Medical Centre
MoESCS – Ministry of Education, Science, Culture and Sport of the Republic of Armenia.
MoH - Ministry of Health of the Republic of Armenia
mUIC - median urinary iodine concentration
M&S - Monitoring and Surveillance
NCP - Neonatal Screening Program (at Arabkir MC)
NIH - National Institute of Health
NCDC - National Centre for Disease Control and Prevention
NWG - National Working Group
TSH – Thyroid-Stimulating Hormone
USI – Universal Salt Iodization
UNICEF - United Nations Children's Fund
WHO – World Health Organization

### I. Introduction

Located in the South Caucasus, Armenia was historically affected by endemic goiter that was virtually eliminated in early 1970s as part of effective salt iodization strategy in the USSR. Iodine deficiency returned in 1991 when Armenia became independent after dissolution of the Soviet Union [1]. However, starting from 1999, production of iodized salt was resumed by sole national salt producer, Avan Salt Plant (ASP). By 1998, about 70% of households were using iodized salt. A Demographic and Health Survey (DHS) carried out in Armenia in 2000, found that although use of iodized salt at the household level had increased to 84% in the country overall with substantial variation by regions [2, 3]. In 2004, the government passed decree No. 353-N making production and importation of iodized salt mandatory as well as its use at household level and for food processing. More recently, in 2016, regulatory inspection and enforcement of the use of iodized salt in Armenia was established through a Joint Order (829-A and 74-A) of the Ministries of Health and Agriculture (currently, Economy) [4].

A national survey was conducted in Armenia in 2005 showing that 97.2% of households were using iodized salt while median urinary iodine concentration (UIC) among 8 to 10 years old children was slightly above  $300\mu g/L$ , most likely due to a relatively high level ( $50 \pm 10 \text{ mg/kg}$ ) of iodine content in salt [5]. Subsequently, this was reduced to  $40 \pm 15 \text{ mg/kg}$ . The most recent survey (2016), confirmed that the country's population has adequate iodine nutrition with median UIC of  $242\mu g/L$  in school-age children and  $226 \mu g/L$  in pregnant women [6].

Armenia's 2016 STEPS Survey [7] found a mean salt intake of 9.8 g/day in adults (11 g/day for men and 8.4 g/day for women) based on sodium excretion measured in 24 hours urine samples. In a spin-off of the 2016 Iodine Survey, sodium was measured in spot urine samples of adult women and, based on urinary Na/Creatinine ratios, average sodium intake was calculated at 5.5 g/day, equivalent to salt consumption of 13.9 g/day. Finally, the Global Fortification Data Exchange [8] provides an estimate of salt intake for the country at 12.5 g/day. The modeling conducted in 2019 using IGN Guidance allowed to estimate the contribution of most important processed foods and household salt to iodine intake among the Armenian population. Mean per capita daily salt intake from household salt and major salt-containing foods is 10.6 g, of which 4.0 g originates from household salt, 4.3 g from bread and 2.3 g from all other key salt containing foods combined [9].

From a public health perspective, the WHO recommends that national surveys of household coverage of iodized salt and population iodine status be carried out every 3-5 years. However, the high cost of such surveys is a significant barrier to their regular implementation [10]. Experience has shown that it is unrealistic to expect ongoing external (or internal) funding every few years to support costly statistically representative national surveys of iodized salt coverage and/or population iodine status. Therefore, the Iodine Global Network<sup>1</sup> (IGN) has supported the adaptation of the FORTIMAS methodology as a much less costly salt iodization program

<sup>&</sup>lt;sup>1</sup> - https://ign.org/; accessed 6 March 2024.

monitoring and surveillance approach that countries could implement to track the status of their salt iodization programs, without much external funding support.

To enable public and private sector stakeholders of the national salt iodization program in Armenia to be able to confirm high population coverage of well iodized salt and the associated adequate iodine status of the population systematically and at a substantially lower cost than typical population-based representative surveys, the IGN supported the "pilot" implementation of the FORTIMAS<sup>2</sup> (Fortification Monitoring and Surveillance) methodology, adapted to tracking "effective coverage" of iodized salt, in Armenia.

**Objectives.** The primary objective of this project was to assess the feasibility/acceptability of the recently developed IGN methodology for monitoring and surveillance (M&S) of national iodization programmes, using sentinel site data collection (referred to as USI FORTIMAS), that could be implemented as a less complex and costly data collection approach for assessing and tracking the national USI programmes in a timely manner. The secondary objective of the study was to update older population survey data (2016) in order to assess the current nutritional (iodine) status of the population and the coverage of adequately iodized salt, to help inform national USI implementation in Armenia.

**Expected outcomes.** There were two expected outcomes of the pilot:

- Findings and conclusions from national implementation of the new IGN methodology in Armenia are generalized and feasibility/acceptability of USI FORTIMAS is evaluated (including usability, clarity of instructions and examples, appropriateness of content, assessment of resources needed for implementation); and, ultimately, its regular implementation for the monitoring and surveillance of national iodization programmes is recommended.
- The national salt iodization strategy in Armenia is strengthened to achieve/sustain optimal iodine nutrition through salt iodization, using current data/information on the coverage of iodized salt and nutritional (iodine) status of the population.

## 2. Materials and Methods

Based on the FORTIMAS approach, this study included secondary analysis of data on domestic production and imports of iodized salt (to estimate the "expected" population coverage of **quality** iodized salt). Data/information was provided by Avan Salt Plant, and the relevant government authorities - the Ministry of Economy and the Food Safety Inspection Body (FSIB) of the Republic of Armenia. That information is then "triangulated" with primary data on household coverage of adequately iodized **salt** (containing >15 mg/kg iodine [10]) and iodine status among 1st trimester pregnant women, collected using **sentinel site**<sup>3</sup> and purposive (non-probabilistic) data collection

<sup>&</sup>lt;sup>2</sup>- https://www.smarterfutures.net/fortimas; accessed 6 March 2024.

<sup>&</sup>lt;sup>3</sup> - "Sentinel site" refers to a community (a large town or a district) within a region, purposively selected, based on its "expected" rate of population coverage of (adequately) iodized salt, where household salt samples and urine samples of (1st trimester) pregnant women could be feasibly collected for testing to "confirm" adequate (or inadequate) rate of household coverage of adequately iodized salt and median urinary iodine concentration among pregnant women.

methods, as well as findings of annual trends in neonatal TSH levels provided by the Neonatal Screening Program (NSP) .

Indicators deemed needed and feasible, to assess and track quality, coverage, and impact of a national salt iodization program are summarized below in Table 1.

**Table 1.** Indicators as deemed needed and feasible, to assess and track quality, coverage, and impact of a national salt iodization program in the Republic of Armenia

Row	Indicator Category		Indicator (in rank order)	Data Type	Measure
Quality &		1	Annual quantity of domestic <b>quality</b> iodized salt	Program level	MT
1	Quantity of lodized Salt	2	Annual quantity of imported <b>quality</b> iodized salt	Program level	MT
		4	Annual quantity of domestic and imported iodized salt marketed	Program level	MT
		1	Annual "expected" population coverage of quality iodized salt <sup>a</sup>	Program level	%
2	Coverage of Iodized Salt	<b>2</b> -a	Prevalence of households that use (any) iodized salt	Population level	%
	2-	2-b	Average iodine content of household iodized salt, in and across, all sentinel sites	Population level	mg/Kg (or ppm)
3	Impact	1-a	Median urinary iodine concentration (mUIC) (among 1 <sup>st</sup> trimester pregnant women)	Population level	μg/L
4	ImpactMedian neonatal TSH concentration <3mIU/L and/or <3% prevalence of elevated (>5mIU/L) neonatal TSH concentration <sup>b</sup>		Population level		

<sup>a)</sup> - Includes population coverage of total iodized salt available for household use as well as for domestic production of target processed food(s).

<sup>b)-</sup> Applies in countries where (essentially) all newborns are screened/tested for congenital hypothyroidism

### **2.1 Indicators of the salt iodization process**

**Monitoring of iodized salt quality.** The Laboratory Services Centre (LSC) of the FSIB routinely determines iodine levels in food-grade salt<sup>4</sup> collected by its inspectors from commercial markets and processed food production facilities, to identify food-grade salt with iodine concentration "outside standard" of  $40 \pm 15$  mg/kg. For this study, data were extracted from FSIB form N1 (annex to Joint Order 829-A and 74-A, March 2016) for calendar years 2021 through 2023. From a total of 1,916 salt samples tested, 1,392 had been collected from selected retail outlets, food

<sup>&</sup>lt;sup>4</sup> Using iodometric titration as the official laboratory method per GOST R 5157.

catering facilities, and processed food production businesses across Armenia. Another 524 samples were collected from imported batches of salt at border control points over the same three-year period. Quantitative data on iodine concentrations in a total of 185 such salt samples identified by the FSIB/in 2022 and 2023, were extracted from the FSIB/LSC records and categorized as "non-iodized" (<5mg/kg); "inadequately iodized" (5-14.9 mg/kg); "adequately iodized" (15-40 mg/kg); and "over-iodized" (>40mg/kg), based on their iodine levels, per international guidelines which also define household salt with iodine concentration  $\ge15 mg/kg$  as adequately iodized [10].

**Monitoring of expected annual population coverage of iodized salt.** The design of the nonprobabilistic FORTIMAS data collection approach to assess the coverage of iodized salt and iodine status of 1<sup>st</sup> trimester pregnant women in Armenia included the calculation of expected annual population coverage of iodized salt in the country based on:

- Total annual quantity of iodized salt available in the country for use by households, commercial food catering businesses (e.g., public restaurants and canteens), and processed food production facilities (e.g., bakeries, snack food producers, etc.).
- Estimated average per capita salt consumption of 12.5 g/day<sup>5</sup>.
- Annual population size of the country<sup>6</sup>.
- Data on quantities of production and imports of adequately iodized salt were provided by the Avan Salt Plant and the Ministry of Economy of the Republic of Armenia, respectively.

**Monitoring household coverage of adequately iodized salt.** To estimate the overall household coverage of iodized salt in the country in 2023, 30 students from one secondary school (identified by the Ministry of ESCS) in each of 7 sentinel sites (total -210 students) were selected to bring 30 – 40 g of table/kitchen salt from their homes (herein referred to as household salt). Three sentinel sites were located in the capital city Yerevan and 4 in each of the following regions: Armavir, Ararat, Kotayk and Shirak. Each student was provided a small zip-lock plastic bag labelled with the predesignated identification codes of the selected school (i.e., data collection point). Upon collection of the household salt samples, the relevant information was recorded in a special form, which together with salt samples, were transported to the Salt Testing Laboratory of the ASP for quantitative measurement of iodine content by iodometric titration (GOST R 51575). In addition, a copy of the household salt collection form was kept at the "FORTMAS Central Office" in the National Institute of Health in Yerevan.

**Monitoring of use (coverage) of iodized salt in bakeries.** Two typical<sup>7</sup> bakeries producing "ordinary" (European style) bread and lavash (Armenian flat bread) were selected within each of the 7 sentinel sites (14 bakeries total) and the catchment area of the selected schools. One sample of salt was collected from each of the bakeries and transported to the designated Laboratory Services Center (LSC) of the FSIB for subsequent iodine analysis using iodometric titration (GOST R 51575). Salt content in bread (finished product) was calculated from the baker's recipe (BR) dividing salt concentration in dough to the commonly applied index 1.25 [11, 12]. Using information on daily per capita consumption of bread, average salt content in bread and iodine

<sup>&</sup>lt;sup>5</sup> Global Fortification Data Exchange (GFDx) - <u>https://fortificationdata.org/country-fortification-dashboard/?alpha3\_code=ARM&lang=en;</u> accessed 10 March 2024.

<sup>&</sup>lt;sup>6</sup> Source: <u>https://www.macrotrends.net/global-metrics/countries/ARM/armenia/population</u>; accessed 5 March 2024.

<sup>&</sup>lt;sup>7</sup> - "Typical" refers to bakeries where most of the families within the catchment area of each sentinel school purchase bread and bread products (relatively large ones).

content of iodized salt, the average daily iodine intake from iodized salt in commercially baked bread was estimated.

#### 2.2. Indicators of impact (iodine status)

**Urinary iodine concentration (UIC).** On average, every month hundreds of pregnant women (PW) in their 1<sup>st</sup> trimester visit antenatal health centers (ANC) in Armenia. These visits are free of charge and include examination by the obstetrician and collection of blood and urine samples for routine laboratory analysis. As part of this project, the additional task of medical personnel in the selected sentinel ANC was to complete a brief form and aliquot a small volume of urine (about 5 ml) in a separate labeled vial, freeze and ship it to the National Institute of Health (NIH) in Yerevan.

To assess iodine status in 1<sup>st</sup> trimester PW, urine samples of 280 subjects were collected in 7 sentinel ANC: 105 samples from 3 clinics in Yerevan, 44 samples from each clinic in Armavir, Ararat and Kotayk regions, and 43 samples from clinic in Shirak region (Table 2). Once collection of urine samples was completed, they were transferred to the "I"MUNO" laboratory in Tbilisi, Georgia where they were assayed for iodine concentration, under supervision of Dr. Nelly Barnabishvili, by Sandell-Kolthoff method with spectrophotometric detection and expressed in  $\mu g/L$  (micrograms per liter).

Region	1 <sup>st</sup> trimester pregnant women (N)
Yerevan	105
Armavir	44
Ararat	44
Kotayk	44
Shirak	43
Total	280

**Table 2.** Number of pregnant women recruitedfor urinary iodine testing

**Neonatal thyroid stimulating hormone (TSH) levels**. Adequate thyroid function is important during pregnancy as maternal thyroxin greatly influences neurodevelopment of the fetus. Neonatal hypothyroidism screening tests measure the serum level of TSH. Elevated TSH in a newborn may indicate congenital hypothyroidism, or it may be a transient elevation due to inadequate maternal iodine status during pregnancy. The prevalence of neonates with elevated TSH levels is therefore a valuable indicator of the severity of iodine deficiency in a given population. The increase in the number of neonates with moderately elevated TSH concentrations (above 5 mlU/l whole blood) is proportional to the degree of iodine deficiency during pregnancy. When a sensitive TSH assay is

used on samples collected three to four days after birth, a <3% frequency of TSH values >5 mlU/l indicates iodine sufficiency in a population [10].

In 2005, the Ministry of Health of Armenia instituted a neonatal congenital hypothyroidism screening program. It was expanded by 2012 to include all maternity clinics and hospitals in the country, accounting for nearly 100% of births in the country. The Neonatal Hypothyroidism Screening Program (NHSP) at Arabkir Medical Center (MC) measures neonatal TSH via dried blood-spot sample on filter paper obtained from heel-prick of newborns. Each card includes the name of the maternity clinic, the sex of the child, date of birth of the infant, date of screening of the infant, duration of pregnancy, birth weight, and address of the mother. The samples are obtained by maternity ward clinicians throughout the country and sent to the central laboratory at Arabkir MC where they are analyzed for TSH level via fluoroimmunometry using DELFIA Neonatal TSH kit [13].

From 2017 through 2023, 255,108 neonatal TSH screening tests were performed by Arabkir Medical Center. Records with TSH values greater than 15mIU/L were removed. Tests in which the blood spot was not obtained between 2 and 5 days of life were also excluded, as were records of potentially premature infants (defined as less than 2500g at birth, or less than 37-week gestation, or where either the birth weight or gestational age were missing) [13]. After eliminating these influences on neonatal TSH level, an accurate and reliable dataset of 185,989 (from 2017 through 2023) was used to determine the mean and median neonatal TSH levels as indirect annual assessment of iodine status of pregnant women in Armenia (**Table 3**).

Year	Total number of screening tests	Number of screening tests used for analysis	Mean TSH level (mIU/L)	Median TSH level (mIU/L)
2017	37,722	26,653	1,755	1,380
2918	36,464	25,833	1,777	1,380
2019	35,981	26,051	1,580	1,150
2020	36,477	27,035	1,506	1,120
2021	36,217	26,939	1,465	1,090
2022	35,597	26,516	1,458	1,080
2023	36,650	26,962	1,482	1.160

 Table 3. Neonatal TSH screening data from 2017 to 2023.

### 3. Results and discussion

#### 3.1. Salt situation in Armenia

The Avan Salt Plant (ASP) was the primary supplier of edible salt in Armenia prior to 2018 (Annex 1). Thereafter a decreasing share of domestically produced iodized salt has been offset by increased iodized salt imports (Table 4, Figure 1). Besides fine (free flowing) iodized salt, ASP produced around 6,000 tons of lump rock salt (5-10 kg blocks) annually for animal consumption, out of which  $\approx$ 1,400 tons were further ground as non-iodized salt for processed foods (mainly of

artisanal soft cheese) that are exempt of requirement to use iodized salt. According to data from the Ministry of Economy, the total amount of imported iodized salt (mainly from Iran) increased from 4,400 tons in 2018 to 7,500 tons in 2023 (Figure 1). Export of salt from Armenia is small (less than 200 tons annually), and iodized salt constitutes up to 25% of that amount [4, 9].

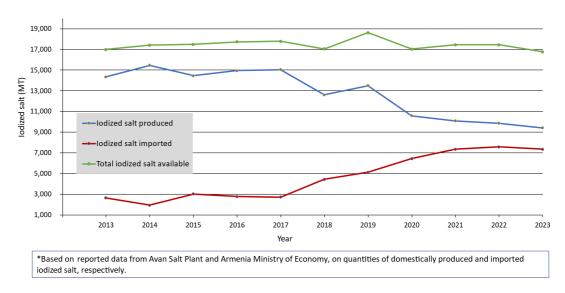
Table 4. Annual volumes of salt supply in Armenia, 2019-2023 (production, imports, and exports)

INICATOR	Supply volumes (MT) by years				
	2019	2020	2021	2022	2023
<b>a.</b> Total amount of salt produced in	24,975.2	28,158.2	32,685.7	22,888.0	20,387.9
the country					
<b>b.</b> Amount of <b>iodized</b> food-grade salt	13,487.3	10,578.8	10,085.4	9,873.2	9,415.3
produced in the country					
c. Amount of iodized food-grade salt	5,124.6	6,450.2	7,356.9	7,578.5	7,347.8
imported into the country					
<b>d.</b> Amount of iodized food-grade salt	73.7	3.6	11.4	15.8	12.6
exported from the country					
e. Amount of iodized food-grade salt	18,538.2	17,025.4	17,430.9	17,435.9	16,750.5
supplied to the population					
f. Amounts of non-iodized "extra"	396.4	576.2	513.8	703.1	696.5
food- grade salt supplied by ASP					
g. Total amount of food-grade salt,					
iodized and non-iodized, consumed	18,934.6	17,601.6	17,944.7	18,139.0	17,447.0

a, c, d – data from Ministry of Economy; b, f – data from Avan Salt Plant;

e – supply according to the formula (e = b + c - d); and total g = e + f

**Figure 1.** Trends in annual quantities of domestic vs. imported vs. total iodized\* salt available in Armenia from 2013 to 2023.

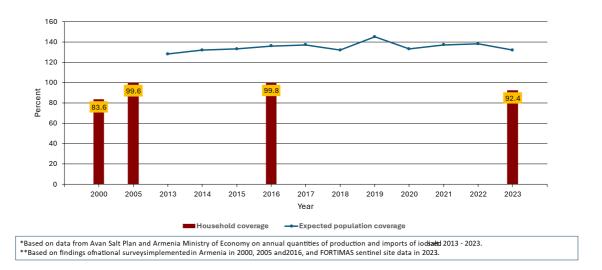


The annual amounts of salt consumed in the country in most recent years have averaged around 18,000 tons, almost entirely in iodized form. However, it is estimated that a small share (up to 4%) of edible salt used in households and by food processors may be non-iodized.

#### 3.2. Expected annual rate of population coverage of iodized salt in Armenia

While the decrease of iodized salt domestic production has been offset by its increased imports, the annual rate of <u>expected population coverage</u> of iodized salt has remained stable over the same time period (Figure 2). It should be noted that the consistently higher than 100% "expected" population coverage of iodized salt in Armenia over time may, in part, be due to an actual higher per capita intake of salt than 12.5 g/day or some inaccuracies in annual iodized salt production and imports data, as well as unknown levels of losses of salt.

**Figure 2.** Trends in annual rates of <u>expected population coverage</u>\* vs. <u>assessed</u> <u>household coverage</u>\*\* of iodized salt in Armenia: 2000 through 2023.



#### 3.3. Household coverage of iodized salt in the country

Household salt samples (210 in total) were tested for iodine content within 8 to 14 days of collection. As shown in Table 5, 12 salt samples (5.6%) were non-iodized, and out of those, 11 were from Shirak region (city of Gumry). However, only 1 of the 199 household salt samples from the other 6 sentinel sites was found to contain no iodine. Further assessment of the source of non-iodized salt marketed in Gumry city may be warranted.

Salt iodine level (mg/kg)	Salt samples (N)	Prevalence (%)
0.0	12	5.7
10 - 14.9	4	2.0
<u>&gt;</u> 15	194	92.4
Total samples tested	210	100.0

**Table 5.** Ranges of iodine level in household salt inArmenia in 2023.

Excluding those 12 salt samples, only 2% of all the remaining household salt samples from the 7 sentinel sites contained <15 mg/kg iodine, while over 92% were found to be adequately iodized (containing >15 mg/kg iodine) (Table 5). Furthermore, among the 198 salt samples found to be

iodized, a mean iodine concentration of 32.8 mg/kg was within the national standard of 40  $\pm$  15 mg/kg.

Using the categories of salt falling "within" vs. "outside" the national iodization standard (from 25 to 55 mg/kg), nearly 23% of the household salt samples from the sentinel sites fell "outside standard" (Table 6). Furthermore, among the "outside standard" salt samples, only 1% contained >55 mg/kg iodine, while about 17% contained <25 mg/kg iodine. In comparison, a recent analysis of data on iodine content of salt samples collected from various market sources in Armenia and tested by the FSIB in 2023, found that the iodine content of about 31% of those salt samples fell "outside standard" [14].

Salt iodine level	Salt samples (N)	Prevalence (%)
Outside standard	48	22.9
Within standard	162	77.1
Total samples tested	210	100.0

**Table 6.** The proportion of household salt sampleswith iodine content "outside standard" \*. Armenia, 2023.

\*Defined as salt with 25 to 55 mg/kg iodine content.

Given the findings of complementary information that indicate consistently high <u>expected</u> <u>population</u> coverage of iodized salt, and <u>assessed household</u> coverage via statistically representative surveys, during the past decade (Figure 2), finding of about 92% household coverage of adequately iodized salt in Armenia in 2023, using the FORTIMAS methodology, appears to be quite reliable. The learning is particularly important because the cost of this approach as an initial round of "annual" iodized salt program monitoring and surveillance in Armenia, was only a fraction of that of a typical nationally representative salt iodization/population iodine status survey. Furthermore, because the overall framework of a potential "Armenia FORTIMAS System" has been developed under this project, it may be estimated that about 10 annual rounds of salt iodization program monitoring and surveillance may be carried out in the country in the future, at about the same cost as one nationally representative salt iodization program survey.

#### 3.4. Assessment of the use of iodized salt in commercial bakeries

In 2022, people in Armenia consumed a total of 8.09 kg bread per month or 266 g per day [15]. The consumption of "ordinary" breads, including popular premium wheat breads, "naan", white or brown loafs, baguettes, etc. was 6.99 kg/month and lavash (Armenian flat bread) - 1.1 kg/month. The ratio of consumption of these two main categories of bread (86.4% and 13.6%) allowed for calculation of weighted average of iodized salt content of 1.4 g in 100g of bread. Based on daily consumption of bread in Armenia (266 g/day) and the average concentration of salt in bread (1.4%), the average daily salt intake from bread is 3.72 g or about 37.2% of the total average daily consumption of salt by the population of the country.

Iodine content in salt samples collected in 14 bakeries from the seven sentinel sites are presented in Table 7. Only one out of 14 sentinel bakeries used non-iodized salt while the other 13 used

adequately iodized salt with iodine content within the range of the national standard (25 - 55 mg/kg). Median iodine content of bakery salt was 37.0 mg/kg (95% CI 33.82  $\div$  42.18).

Sentinel site (administrative	Code of	Code of	Bakery salt iodine content,
territory – district or marz)	sentinel	Sentinel bakery	mg/kg
	school		
1. Yerevan, community Nor	1.	1a.	39.1
Nork		1b.	37.0
2. Yerevan, community	2.	2a.	31.7
Erebuni		2b.	31.7
3. Yerevan, community	3.	3a.	43.3
Malatia-Sebastia		3b.	37.0
4. Armavir marz, city of	4.	4a.	29.6
Echmiadzin		4b.	45.4
5. Kotayk marz, city of	5.	5a.	34.9
Abovyan		5b.	34.9
6. Shirak marz, city of	6.	6a.	43.3
Gyumri		6b.	0 (no iodine)
7. Ararat marz, city of	7.	7a.	32.7
Ararat		7b.	53.9

**Table 7.** Iodine levels in salt used for bread baking in sentinel bakeries.

Mean 38.0 ± 6.86; Median - 37.0 mg/kg

The results of this study confirm that bread products commonly consumed in Armenia remain the major source of salt in the diet and on average provide 61.2% of Recommended Nutrient Intake for iodine.

#### 3.5. Median urinary iodine concentration (mUIC) among 1st trimester pregnant women.

Urinary iodine concentration (UIC) is the main impact indicator reflecting iodine status of the surveyed population. Based on such analysis of urine samples of 280 1st trimester subjects, median UIC (mUIC) among pregnant women nationwide was 175.3  $\mu$ g/L (range 26.8 – 600.4  $\mu$ g/L) (Figure 3), confirming adequate iodine status (mUIC within the 150-250  $\mu$ g/L range) in the population group most sensitive to insufficient iodine intake [10].

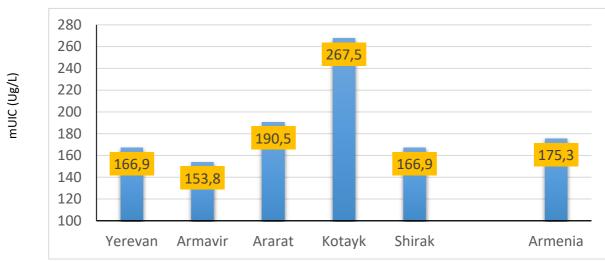


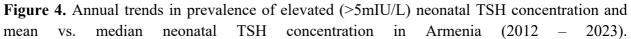
Figure 3. Median UIC in pregnant women nationally and by regions of Armenia

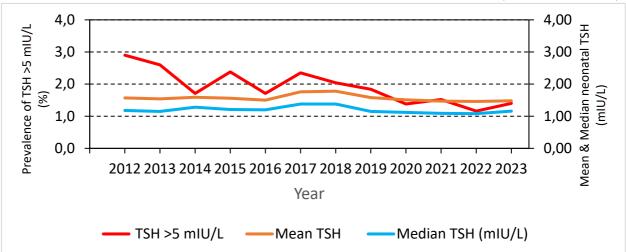
Regions

Median UIC across the selected regions of Armenia (data from 3 sentinel sites in Yerevan were pooled) are presented in Figure 3 to illustrate the generally adequate iodine status among 1<sup>st</sup> trimester pregnant women across the country. The differences in mUIC levels between the regions are likely due to random fluctuations in urinary iodine excretion manifested by insufficient samples sizes to estimate mUIC at the sub-geographic level.

#### 3.6. Neonatal TSH concentration

Another impact indicator of universal salt iodization – less than 3% prevalence of elevated (over 5 mUI/L) neonatal TSH concentration [10] also points to sustained adequate iodine nutrition of Armenia population. Over the past 12 years the prevalence of elevated TSH level was less than 3% with a general trend of decreasing from 2.35% in 2017 to 1.39% in 2023, while the mean and median TSH levels remained stable between 1.00 and 2.00 mIU/L (Figure 4).





### 4. Conclusions and Recommendations

Recognizing the profound interest and need of the health authorities, management and partners of the national salt iodization program in Armenia to confirm high population coverage of well iodized salt and the associated adequate iodine status of the population systematically and at a substantially lower cost, than typical population-based representative surveys, the IGN supported the "pilot" implementation of the FORTIMAS (Fortification Monitoring and Surveillance) methodology, adapted to track the coverage and impact of the national salt iodization program in Armenia.

The project was implemented with active and essential engagement of public and private sector stakeholders (main partners) of the salt iodization programme in the country, such as Ministries of Economy (MoE) and Education, Science, Culture and Sport (MoESCS) of the Republic of Armenia, Food Safety Inspection Body (FSIB), Neonatal Screening Program and Avan Salt Plant (ASP). Facilitating its successful implementation, the FSIB provided quantitative data on iodine levels in salt samples from all supply chains monitored by the agency; initiated relevant revision

of its reporting tool (Form N 1 in Joint Order 829-A and 74-A of 2016), requested technical assistance from the USI FORTIMAS Office of the NIH toward development of its "risk-based audit plans" for future salt inspections, including more focus towards monitoring of salt used in food industry with special focus on bakeries because of bread being a major staple food in the country.

The Ministry of Economy initiated review of its data collection forms to provide disaggregated data on total annual volumes of domestically produced and imported iodized and non-iodized dietary salt. Given the above efforts, it should be assumed that the FORTIMAS approach has apparently helped the partners to better appreciate how their data and information relate to public health and nutrition in the country.

The ASP, a strong historical partner of the national USI program, further exhibited its partnership by offering its laboratory and technical capacity by testing iodine content of household salt samples collected through the schools across the seven sentinel sites.

Findings from primary analysis of non-probabilistic data showed high (92%) household coverage of iodized salt and adequate (175.3  $\mu$ g/L) median UIC among 1st trimester pregnant women, across purposively selected sentinel sites. Secondary analysis of data on production and imports of iodized salt also indicated consistently high expected and assessed population coverage of iodized salt during the past decade. The prevalence of neonatal TSH levels above 5 mUI/L (an indicator of iodine status among pregnant women) over the past 12 years was less than 3% with a general trend of decreasing from 2.35% in 2017 to 1.39% in 2023. It is obvious, that sustained adequacy of iodine status in a population is achieved as the population in Armenia is able to consume quality "dietary iodized salt", i.e., household iodized salt and iodized salt containing processed foods.

The cost of implementation of the FORTIMAS approach as an initial round of "annual" iodized salt program monitoring and surveillance in Armenia was only a fraction of that of a typical nationally representative salt iodization/population iodine status survey. Furthermore, because the overall framework of a potential "Armenia FORTIMAS System" has been developed under this project, it may be estimated that about 10 annual rounds of salt iodization program monitoring and surveillance may be carried out in Armenia in the future, at about the same cost as one nationally representative salt iodization program survey.

In general, the pilot implementation of the FORTIMAS approach allowed for an "overall" assessment of the status of the national salt iodization program in Armenia where the last national population iodine status survey was carried out in 2016. The exercise helped to positively assess the feasibility and utility of the FORTIMAS methodology as a much less costly approach that Armenia should continue implementing to track the status of the national salt iodization program without much external funding support.

In this study, urine samples were transferred to Tbilisi, Georgia where their iodine concentrations were assayed by the "I"MUNO" laboratory under supervision of Dr. Nelly Barnabishvili., who demonstrated extremely kind and professional attitude towards this important part of the project in Armenia. The transportation of samples to Tbilisi however added to complexity and the cost of

the activity. In addition, the procedures of transportation, including customs clearance were "not easy" to overcome. Expecting regular implementation of the activity, there must be a feasible solution for this challenge. A feasibility study for creation of a national laboratory for regular UI determination was planned in 2005 and the need to strengthen the system for assessment of iodine nutrition was recalled in the government decree No 40 of 2014. However, a specialized laboratory to carry out regular UI assays is still absent.

In a view of potential introduction and, possibly, regular implementation of USI FORTIMAS methodology in Armenia, it is strongly recommended, that the Ministry of Health in cooperation with the main government stakeholders – FSIB and Ministry of Economy re-establish, support and coordinate the work of an Intersectoral (Multidisciplinary) Working Group (IWG) to ensure on-going, systematic and regular collection, analysis and interpretation of secondary, as well as primary, data to assess the status of the USI program over time (preferably on annual basis), as exemplified by this pilot project. The repeat annual collection and analysis of data on the indicators summarized in this report should be quite feasible because data on annual quantities of domestic and imported iodized salt, FSIB quality monitoring, and neonatal TSH are available through the relevant organizations in the country.

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Salt source and type	Production/supply in MT:					
	by years					
	2013	2014	2015	2016	2017	2018
Salt produced by ASP, total <u>A1. «Extra» iodized, including:</u> - packed, 1 kg brick-shaped in poly-	30786 <u>14347</u>	29792 <u>15389</u>	27392 <u>14372</u>	32249 <u>14821</u>	32550 <u>14799</u>	22583 <u>12415</u>
<ul><li>propylene packages;</li><li>packed in 25 kg polyethylene</li><li>bags;</li></ul>	12092 2255	12735 2654	11953 2419	11786 3035	11982 2817	9885 2530
A2. «Extra» non-iodized, manufact. (25 kg polyethylene bags);	-	67,2	90,6	131,3	144,4	203,6
<b>A3.</b> 2nd grade rock salt, grinding N 2, <b>iodized</b> , 0,9 kg polypropylene packages:	295	294	306	303	252	199
<b>A4</b> . 2nd grade rock salt, grinding N 2, <b>non-iodized</b> , for manufacturing purposes:	-	-	-	76	93	125
B. "Technical" Grinding N3						
(in industry, for melting road ice, for cleaning boiler filters, etc.):	9 786	7 227	6 602	11 394	12 358	5 963
	6 358	6 815	6 021	5 524	4 905	3 677
C. Fodder rock salt (used in animal husbandry), including: selective rock salt	5 905	6 375	5 606	5 211	4 634	3 576
D. Imported iodized salt	2638	1952	3021	2771	2732	4433
(in brackets – non-iodized)	(n/a)	(n/a)	(0)	(90 MT)		
E. The total volume of iodized salt produced and imported (E = A1+ A3+D)	17280	17635	17699	17895	17783	17047

# Production and import of iodized and non-iodized food-grade salt in Armenia, 2013-2018