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Rationale for the Importance of Revising the Strategy for Monitoring the Use of Iodised Salt in Armenia

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Introduction

There is growing international recognition that most of the total salt intake comes from processed foods (70–80%); therefore, such commercially manufactured foods with iodized salt in their recipes are the main source of dietary iodine among consumers [2-4, 6, 7, 9, 10, 13, 14, 16, 17]. In Armenia, a recent comparative assessment of sources of dietary salt showed that the total contribution of processed foods to the total average salt intake (9,8 g/day) amounts to 61,3% [1]. Given this evidence, there is a common understanding locally that salt used for food processing might represent the main share of all food-grade salt consumed, ensuring a significant intake of iodine. Hence, efforts are needed to enforce the provision for all food grade salt to be adequately iodized and used in the production of processed foods, to achieve and sustain optimal iodine status among all population groups of the country [2].

Universal salt iodization (USI) in Armenia is mandated through the Republic of Armenia (RA) government decree No 353-N of 12.02.2004, which prohibits the production and imports of non-iodized edible salt and its use in relevant commercially processed foods. A year later, a national survey showed that 97,2% of household salt samples contained more than 15 mg iodine)kg of salt, and the median urinary iodine concentration (mUIC) among 8-10 years old children was at the WHO-recommended upper limit. Therefore, the national

regulation was modified, calling for a reduction in iodine content in salt to $40 \pm 15 \text{ mg/kg}$ [12].

The success in attaining the goal of elimination of iodine deficiency in Armenia was acknowledged in 2006 by the Network for Sustained Elimination of Iodine Deficiency - a certificate was granted [16]. A follow-up national iodine survey, conducted in 2016-2017, confirmed that the country's population has adequate iodine nutrition and is protected against iodine deficiency [8].

Until 2017, the risk-based audits conducted by the national Food Safety Inspection Body (FSIB) did not envisage inspections of iodine content of salt used in food manufacturing. The USI component for inspections and enforcement of the use of iodized salt in processed foods was established through a Joint Order (829-A and 74-A, March 2016) of the Ministries of Health and Agriculture (currently, Economy). Throughout 2017 and 2018, the FSIB monitored the iodine content of both locally produced and imported salt in retail markets, catering facilities and processed food production facilities. At that time, the iodine content in almost 10% of \approx 300 samples of food-grade salt collected from points of import, retail markets, public catering facilities, and processed food production sites were classified as not within the national standard of 25 - 55 mg)kg iodine content (here-in referred to as "outside standard"). However, the FSIB reports did not specify whether the deviations in salt iodine content were below or above the national standard. Such analyses would help identify remaining challenges and inform adjustments to the national salt iodization program [15].

This study was undertaken to specify salt iodine levels using international classifications to categorize salt as non-iodized, inadequately iodized, adequately iodized, and excessively iodized (18), so as to guide programmatic decision making among the relevant public and private sector stakeholders of the national USI program in Armenia. Quantitative data on salt iodine content determined by FSIB Laboratory Services Center (LSC) were assessed in conjunction with programmatically relevant criteria such as source of salt (imported versus domestically produced) and salt supply chains (salt in retail outlets, salt used in catering facilities, and salt used by food industry).

Material and Methods

The LSC has been routinely determining iodine levels in food-grade salt, using a validated quantitative assessment tool - iodometric titration (GOST R 51575). In this study, the LSC data on iodine levels in salt were extracted from the form N1 (annex to the March 2016 Joint Order referred to above) for the period of 2021-2023. From a total of 1,916 salt samples tested during those 3 years, 1,392 were collected by FSIB inspectors from retail outlets, catering and food manufacturing organizations across Armenia, and 524 were sampled from imported batches at border control points. The results, classified in LSC form

N1 as "outside of standard" i.e., outside range of 25 - 55 mg/kg (98% of those - below the range), were summarized as absolute numbers and proportions - by year of monitoring, source of salt and its supply chain.

Quantitative (exact) iodine concentrations in salt samples classified as "outside standard" for 2022 and 2023 were extracted from the LSC laboratory 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), per international guidelines [18]. Those guidelines also define salt with iodine concentration ≥15 mg/kg as adequately iodized (at the household level) [18]. Thus, we applied the results of the quantitative tests of salt iodine content to assess the public health implications of the quality of iodized salt consumed by the population as household salt vs. salt in commercial foods [1, 2].

Results and Discussion

As summarized in Table 1, the highest number of salt samples, collected for iodine testing during 2021-2023, were from retail markets (753), followed by border control points (524), commercial catering facilities (345), and processed food manufacturing entities (294). Overall, there was a substantial increase in the proportion of salt samples within the domestic supply chain that were found to be outside standard over the 3 years. Although the total number of salt samples that were classified as outside standard at the border posts was much fewer, as a whole, there was a substantial increase in the proportion of such samples, as well.

Table 1 Trends in the number and proportions of food-grade salt samples tested vs. found to have iodine content "outside standard" across the main edible salt supply chains: 2021-2023.

Year	Retail		Public catering		Food industry		Cumulative summary of domestic supply chain		Border control point (Imported salt)		
	Total	Outside Stan- dard	Total	Outside stan- dard	Total	Outside stan- dard	Total	Outside stan- dard	Total	Outside stan- dard	
	(N)									(N)	
2021	224	11	123	3	128	2	475	16	172	4	
								(3.4%)		(2,3%)	
2022	222	21	147	14	126	18	495	53	217	1	
								(10.7		(0.5%)	
								%)			
2023	307	107	75	17	40	8	422	132	135	7	
								(31.3		(5,2%)	
								%)			
Total	753	139	345	34	294	28	1392	201	524	12	

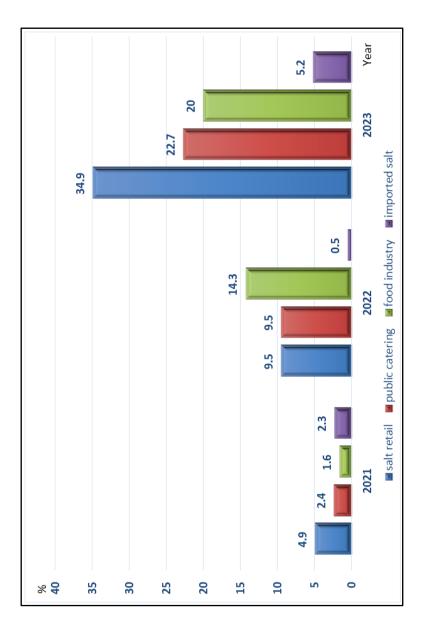


Figure. Proportional distribution of salt classified as "outside standard" by supply chain.

Percentages (proportions) of non-standard salt samples for the above four areas are reflected in the figure, which demonstrates the picture of significant increase of "outside standard" samples in the country, compared to samples from imported salt batches. This may indicate production of inadequately iodized salt or inappropriate local conditions of salt packaging)re-packaging or storage and salt delivery to the population.

WHO recommends [18] salt iodization to be universal, defined as iodization of all food grade salt, including salt used in food production (adequately iodized salt to be consumed by >90% of households). The National USI program aims to deliver the fortification of salt with iodine within acceptable dosage range to ensure both efficacy and safety of the fortification process. However, the increasing proportions of salt samples with "outside standard" iodine content (below and above 25 - 55 mg)kg) indicate deviation from USI strategy. It is generally assumed that the iodine requirements of all population groups are covered in settings where USI is effective and sustained [5, 17, 18].

Regular consumption of salt with low iodine content (below national standard) may result in insufficient iodine intake, whereas such consumption of salt with excess iodine concentration increases the risk of excess iodine intake (including potential adverse effects on normal thyroid function). The term "outside standard" hides the direction and magnitude of deviation of dietary iodine intake from the recommended range. It also does not help to guide the relevant enforcement authorities or the national salt producer and importers as to the relevant measures to take to improve the USI program performance.

To better understand the situation with regard to the actual iodine content of salt across the above supply chains, we analyzed the LSC laboratory records (2022-2023) on levels of iodine in salt samples collected from domestic supply sources. Of a total of 185 non-standard salt samples tested by the LSC during the above 2-year period, the vast majority (182 samples) were classified as below the national standard for iodine content (i.e., <25 mg/kg), while the iodine content of only 3 samples was found to be above the upper limit of the standard (>55 mg/kg).

Data on the levels of iodine in the salt samples were also used to assess the proportions of salt samples categorized as non-iodized (<5mg/kg iodine content), inadequately iodized (5–14.9 mg/kg), adequately iodized, (15–40 mg/kg) and or over-iodized (>40mg/kg), using the World Health Organization (WHO) guidance related to the quality of iodized salt at the household level (Table 2). That guidance is based on the assumption that at an average per capita salt consumption level of 10 g/day, salt containing 15 to 40 mg/kg iodine concentration would provide 150 µg of iodine per person per day [18].

Table 2 Categories of iodine levels in food-grade salt from domestic supply chain (retail, catering and food industry) for 2022 and 2023 based on international recommendations.

Year	Salt samples classified as outside	Ranges of iodine levels in domestic dietary salt								
	standard based on national standard of 25 - 55 mg/kg		odine ng/kg)	Inadequate (5–14.9 mg/kg)		Adequate (15–40 mg/kg)		Excess (> 40 mg/kg)		
	(N)	N	%	N	%	N	%	N	%	
2022	53	17	32.1	7	13.2	28	52.8	1	1.9	
2023	132	37	28.0	7	5.3	86	65.1	2	1.5	
Total	185	54	29.2	14	7.6	114	61.6	3	1.6	

^{*}Data source: LSC laboratory records.

It is also well established that about 61% of edible salt consumed in Armenia comes from processed foods. Bread is the basic component of the diet (main staple food) and a key source of dietary salt among the population of the country. The average per capita salt intake from bread is a rather high (3,75 g/d which comprises about 38,3% of salt obtained from PFs and discretionary household salt) [1]. Furthermore, as a major dietary source of iodine in the diet of Armenians, bread provides approximately 40% of the recommended daily intake (RDI) of iodine, which is equal to the share of iodine provided through consumption of household iodized salt. Overall, about three-quarters of daily iodine intake is attributed to iodized household salt and bread containing iodized salt [2]. Notwithstanding the importance of PFs in iodine nutrition, the regulatory monitoring is more focused on the salt supply through retail outlets and salt imports.

Regulatory monitoring, led by the FSIB, is essential toward assuring that iodized salt marketed across the country meets the national standard. That Agency holds producers and suppliers of iodized salt and target iodized salt containing processed foods, accountable for marketing underfortified salt. The last national population survey carried out in Armenia in 2016 found that 98% of households used **adequately iodized** salt [8]. However, based on this study, it is quite concerning that 132 of 422 domestic salt samples (31,3%) tested by the FSIB laboratory in 2023, were classified as **outside standard**. According to international classification, 28% of the above 132 samples fell into category of **non-iodized**, and 5,3% were categorized as **inadequately iodized**. The findings suggest that there may have been some deterioration in the population coverage

of adequately iodized dietary salt in Armenia since 2016. If true, this may have also negatively affected the population's iodine status.

The enforcement mechanism of the FSIB regulatory monitoring system is called upon to ensure compliance of iodized salt with the national standard. Enforcement for effective and sustainable implementation of the USI strategy should be based on a cooperative working relationship between food control and public health agencies, together with transparent engagement of salt producers and importers, as well as food producers and other relevant stakeholders.

To conclude, recent data on the rates of not adequately iodized salt samples (against the national standard) indicate the need for appropriate follow up with the "iodized salt sector" to ensure that problems related to production and imports of quality iodized salt is addressed, and for tighter regulatory monitoring to ensure good compliance with the quality standard, to optimal iodine nutrition among the population. Quantitative information on direction and magnitude of noncompliance has to be provided to differentiate lower-quality iodized or non-iodized from adequately iodized (>15 mg/kg) applying international classifications to consider relevant regulatory measures. Complementary information is needed on the source of salt (domestic vs. imported) and supply)distribution chains to concentrate the focus of regulatory monitoring on major sources, e.g., among processed food producers (such as bread) to ensure effectiveness of the national salt iodization program.

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Обоснование пересмотра стратегии мониторинга использования йодированной соли в Армении

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Преобладающая доля пищевой соли (70–80%) потребляется через промышленно обработанные продукты питания. Поэтому готовые продукты, приготовленные с использованием йодированной соли, становятся для потребителей основным источником йода.

Результаты мониторинга уровней йода в 2021-2023 гг. показывают, что в исследованных образцах соли на этапах импорта, производства и оборота поваренной соли в Армении фиксируется определенное увеличение количества образцов, не соответствующих стандарту (25÷55 мг/кг). В форме нормативного мониторинга они представлены в обобщенном виде как отклонения от нормы ("outside standard"). Мы подвергли эти отклонения количественной классификации по четырем международно признанным категориям — на нейодированные, недостаточно йодированные, достаточно йодированные и чрезмерно йодированные. Это позволяет оценить эффективность процесса обогащения, которая нарушается, если количество йода в соли меньше нормы, и безопасность, которая нарушается, если оно больше нормы. Считается, что адекватно йодированная соль, содержащая > 15 мг/кг йода, потребляемая обычно 10 г в

день, обеспечит потребление взрослыми 150 мкг йода (т. е. может быть использована для достижения ожидаемой цели).

Соответствие йодированной соли национальному стандарту необходимо для обеспечения оптимального йодного питания населения. Необходимо представить направление и величину количественного расхождения от стандарта, чтобы отличить низкокачественную йодированную или нейодированную соль от адекватно йодированной соли и применить дифференцированные подходы нормативного мониторинга.

Рекомендуется собрать дополнительную информацию об источниках поставки соли (внутреннем производстве и импорте) и цепочках распределения в стране и снабжения населения, а нормативный мониторинг сосредоточить на ключевых источниках соли, таких как хлеб, обеспечивая эффективное правоприменение.

Հայաստանում յոդացված աղի օգտագործման մոնիթորինգի ռազմավարության վերանայման հիմքերը

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Կերակրի աղի գերակշիռ մասը (70–80%) սպառվում է արդյունաբերական եղանակով պատրաստված սննդամթերքի միջոցով։ Ուստի յոդացված աղով պատրաստված սնունդը սպառողների համար դառնում է յոդի հիմնական աղբյուր։

Յոդի մակարդակների մոնիթորինգի՝ 2021-2023 թթ. արդյունքները ցույց են տալիս, որ Հայաստանում կերակրի աղի ներմուծման, արտադրության ու շրջանառության փուլերում հետազոտված աղի նմուշներում արձանագրվում է լոդի ստանդարտին (25÷55 մգ/կգ) չհամապատասխանող նմուշների թվի որոշակի աձ։ Նորմատիվալին մոնիթորինգի համապատասխան ձևում դրանք ներկայացվում են ընդհանրացված տեսքով, որպես շեղում նորմից ("outside standard")։ Մենք շեղումները ենթարկել ենք քանակական դասակարգման, րստ միջազգայնորեն ընդունված չորս կատեգորիաների՝ չլոդացված, ոչ համարժեք լոդացված, համարժեք լոդացված և չափազանց լոդացված, որը հնարավորություն է տալիս գնահատելու հարստացման գործընթացի արդյունավետությունը, որը վտանգված է, եթե լոդի քանակն աղում նորմից պակաս է, և անվտանգությունը, որը վտանգված է, եթե այն նորմից ավելի է։ Ենթադրվում է, որ համարժեքորեն յոդացված աղր > 15 մգ/կգ յոդ պարունակելու և սովորականի նման օրական 10 գ սպառելու պարագալում մեծահասակներին կապահովի 150 մկգ լոդով (ալսինքն, կարող է ծառալել նախատեսված նպատակին)։

Յոդացված աղի համապատասխանությունն ազգային ծրագրի ստանդարտին էական նշանակություն ունի բնակչության օպտիմալ յոդային սնուցումն ապահովելու համար։ Անհրաժեշտ է ներկայացնել քանակական անհամապատասխանության ուղղությունը և մեծությունը՝ ցածր որակի յոդացված կամ չյոդացված աղը համարժեքորեն յոդացված աղից տարբերելու համար, և կիրառել նորմատիվային մոնիթորինգի տարբերակված մոտեցումներ։

Առաջարկվում է հավաքել լրացուցիչ տեղեկություններ աղի աղբյուրի (երկրում արտադրված և ներմուծված) և մատակարարման)բաշխման շղթաների վերաբերյալ և նորմատիվային մոնիթորինգը կենտրոնացնել աղի հիմնական աղբյուրների վրա, ինչպիսին, օրինակ, հացն է՝ ապահովելով կիրարկման արդյունավետությունը։

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