Bulgaria

During the 1950s, extensive surveys by Academician Pentchev demonstrated that the inhabitants in many areas of Bulgaria had severe iodine deficiency disorders, including goiter and cretinism (1). The early epidemiological findings were followed by a Government decision in 1958 to mandate the supply of only iodized household salt (20mg iodine/kg, using KI) in the affected regions, combined with free supplies to pregnant and lactating women and 6-18 year old children of KI supplements once weekly. Follow-up surveys among schoolchildren confirmed a significant reduction in goitre prevalence among schoolchildren from 56% initially to 31% in 1964 and 12% in 1974.

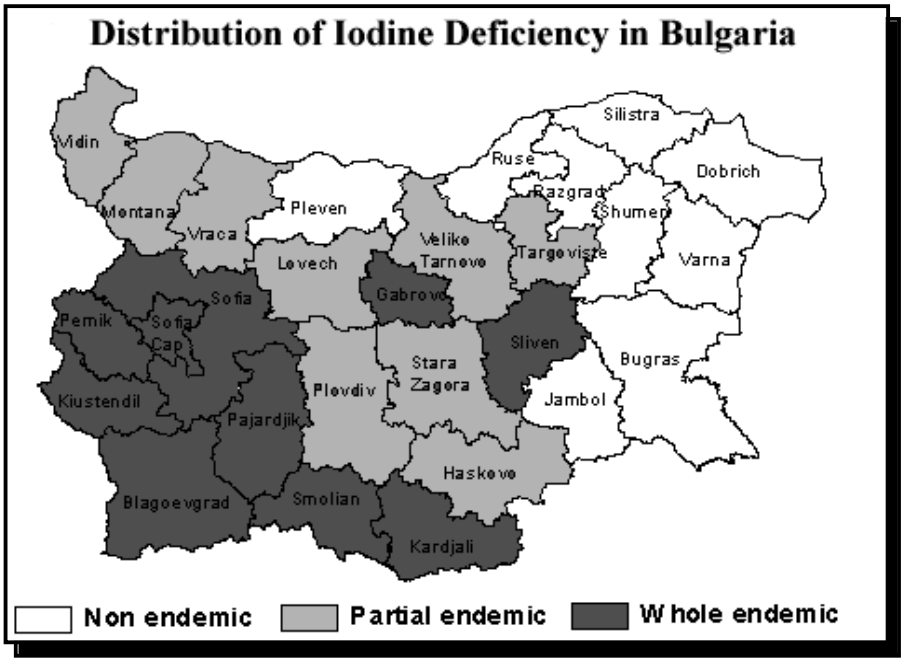

Figure 1: Endemic areas identified in 1950s, mapped according to present regions

Waning political attention and lack of permanent follow-through on the Government decision were among the causes for the re-emergence of the signs and symptoms of iodine deficiency by 1990, when the goiter prevalence in school children was found to have risen to 23%. Consequent small exploratory studies during the period of significant political turmoil until 1994 showed the persistence of moderate to severe iodine deficiency in the defined endemic areas (Figure 1).

The introduction of a free-market economy was accompanied by a reorientation of the IDD policy and in 1994, the Council of Ministers and the Chief State Sanitary Inspector issued decrees that introduced the following key program characteristics:

- Creation of a National Inter-Agency Commission under the Council of Ministers as the apex body for overall coordination and policy advice on IDD elimination
- Prohibition of the sale of non-iodized salt on the entire territory of Bulgaria
- Setting the national iodization standard at 28-55mg/kg KIO_3 (17-33mg iodine/kg) by subsequent amendment, dated 1 July 1996

- Assignment of authority for salt inspection and enforcement to the State Health Control System, i.e., the 28 Regional Inspectorates for Protection and Control of Public Health
- Establishment of laboratory capacity for population monitoring at the National Centre for Public Health Protection and for food control at the Central Veterinary Institute
- Mandating periodic population surveys for tracking the disappearance of IDD by assessments of goiter, urinary iodine, neonatal TSH and other relevant population indicators.

A nation-wide survey in 1996 (2) employed for the first time a combination of assessments of UI levels and goiter grading among 8,445 schoolchildren in 10 regions, with over-sampling in the previously defined endemic areas. In the defined endemic areas, 77.6% of the children were reportedly receiving iodine tablets. Overall, the median UI was 111µg/L, with no significant difference between endemic and other regions. The goiter rate was 28.6% in endemic areas.

From 1998 onward, the various measures and practical procedures under the national USI program have been continuously enhanced and perfected, and complemented by small-scale special interest studies at regular intervals. During 2001, the Council of Ministers issued an Ordinance for mandatory iodization of all the salt for households, public catering and food processing industries. The Ordinance also stipulated KIO_3 as the single permitted fortificant, and it improved upon the definition, authority and enforcement details for salt labelling and salt inspection. The KIO_3 titration in salt was made uniform, technicians in all the regional Inspectorates for Public Health were trained, and external QA of the salt titration procedure was introduced under responsibility of the National Centre for Hygiene, Medical Ecology and Nutrition. Reports of salt iodine inspections by the regional Inspectorates showed a consistent improvement of the proportion of salt within the mandated range of 28-55ppm KIO_3 from 56% in 1995/96, via 67% in 1997/99 and 77% in 2000/02, to 86% in 2003/04. The number of salt samples inspected each year in Bulgarian market outlets and food industries varied around 4,000.

By 2005, all the laboratories of the 28 regional Inspectorates were participating in QA assessments by the National Centre for Public Health Protection in Sofia. The iodine laboratory was a recognized QA service laboratory for the region as part of the CDC-supported IRLI laboratory network. The results of blind QA samples provided on regular basis by CDC showed that the laboratory performed consistently within the acceptable range. The Health Promotion/Education Section of each Inspectorate conducted regularly planned education sessions among professionals in the health care system (GPs and nurses), teachers and other concerned groups, and food industry employees. A range of information materials (leaflets, magazines, etc) were distributed systematically in schools, GP offices, clinics etc, and the Inspectorate staff provided the press with regular pertinent information.

The total market of salt for human consumption (table salt, food industry salt and salt for catering) in 2005 was estimated at 40,000MT/yr. The standard presentation to consumers is in 1kg polythene bags, which state clearly that the salt is iodized. ±90% of national salt market is served by one local producer (Tchernomorski Solnitzy in Burgas) and two large import firms located along the Black Sea. All the 3 companies import iodized and non-iodized salt from Israel, France, Tunisia, Ukraine and Belarus, and they have together sufficient capacity to meet the national market needs. Salt is sold partly under the own brands of the producer/importers, and ± half the total market supply of iodized salt appears to be

imported as such. The companies consider the iodization range of 28-55mg/kg KIO_3 comfortably wide and easy to meet. The single producer uses spray iodization by a UNICEF-donated machine of max 10,000MT/y, but actual production varies around ±4,000MT as evidenced by purchases of KIO_3.

As detailed above, a comprehensive system for monitoring of the iodate content of salt has been put in place and increasingly perfected by government and salt industry since 1994. The three salt companies understand the system well and support it loyally. During iodization, companies perform iodine content titrations 4x/day. They issue certificates with the final products leaving their facilities. As to imports of iodized salt, the regional Inspectorate laboratory inspects and releases the consignments on a shipment-by-shipment basis. The producer/importer's laboratories are checked by the Inspectorate at least once a month. Products found to be seriously outside of specification are not allowed to be sold or may have to be called back (removed) from the market. The Inspectorates perform regular testing of salt quality in the market, including checks on inventory turnover although shelf life is not a big issue with iodate and the market turnover on average lasts less than a Quarter. In case salt samples upon inspection are found outside of specification, the Inspectorate in Burgas handles the matter of notifying and follow-up decisions with the producer/importers. At household level, a national survey in 2003 showed that 90.4% of households used salt with 25mg iodate/kg (15mg iodine) or more.

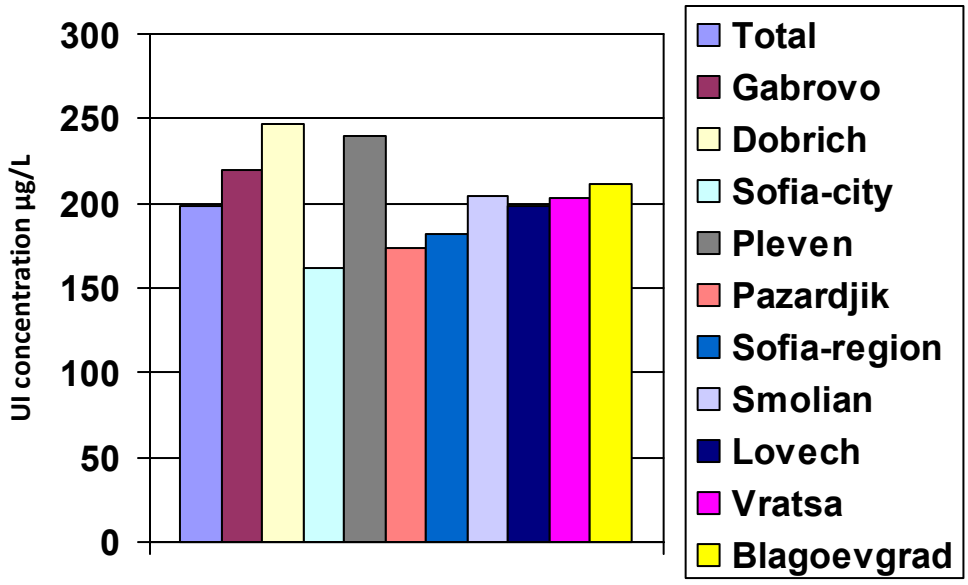

Figure 2: UI concentrations in school children by region, Bulgaria, 2003

To assess the iodine situation, a national survey in 2003 (3) collected data among 7-11y old school children and pregnant women (2nd and 3rd trimester) in 10 regions of Bulgaria – 8 regions with previous endemic goiter and 2 (Pleven and Dobrich) without. Figure 2 shows the median UI levels of the school children in each region – All are comfortably above 100µg/L and, not surprisingly, the UI levels were highest in children from the previously non-endemic regions Pleven and Dobrich. Only 4.3% of the children had enlarged thyroid volume (BSA-reference) by ultrasound. The same survey also obtained urine samples of pregnant women, except in Sofia city and region. Overall, the median UI in the pregnant women (Figure 3) was 165µg/L, with variations between 148 (Pleven) and 220µg/L (Lovech)

regions. The UI levels among women who reported taking iodine supplements (median 170µg/L) were not statistically different from those who did not (164µg/L). Taking the body weights obtained from these women into account, an estimated iodine intake of 248µg/d (95% CI: 231-264) was obtained, exactly equal to the RDA of 250µg/d proposed by IOM and ICCIDD/UNICEF/WHO.

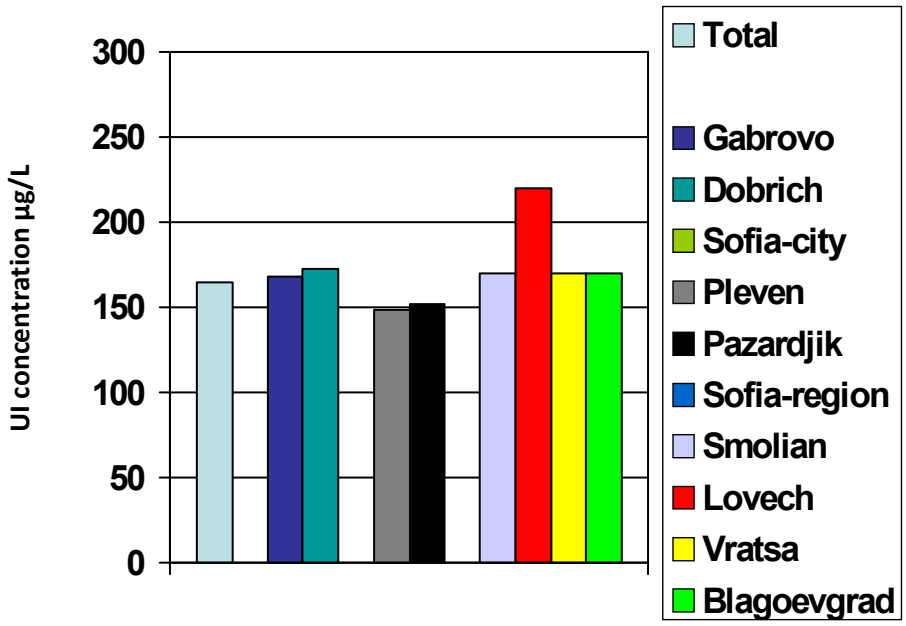

Figure 3: UI concentrations in pregnant women by region, Bulgaria, 2003

Systematic newborn screening for congenital hypothyroidism (CH) was introduced in Bulgaria in 1994 with >70,000 newborns/y being examined presently. The screening is routinely established with strong central support by the University Children's Hospital in Sofia. Results of TSH assays by Delphia method on heel prick samples are entered in a database, linked with data on residence, day of blood sampling (>70% at day 3-5 after delivery) and clinical data. The laboratory participates in external QA exchanges with the Deutsche Gesellschaft für Klinische Chemie. Recall rates for CH diagnosis have been steadily falling in recent years, from 1.8% initially to <0.1% in 2004 (±68,000 newborns tested). The system is very well organized and is useful for comprehensive monitoring of signs of insufficient iodine nutrition. A publication in 2005 (4) shows that the proportion of TSH>5mU/L has steadily decreased from 9.6% in 2000 to 3.6% in 2004.

A team nominated by the Network for Sustained Elimination of Iodine Deficiency visited Bulgaria in April-May 2005 for a comprehensive external review, including the situation of program leadership and surveillance. The team examined available data, information and reports, and collected information during visits and meetings with the range of partners collaborating in the USI strategy, including salt producers and importers, and food industries (bread, dairy products, canning), 4 regional Inspectorates, the TSH newborn screening center and the laboratory of the National Center for Health Promotion. In the report (5), the experts conclude that the USI strategy has succeeded in overcoming serious iodine deficiency disorders of the past in Bulgaria and that iodine indicators among children indicate optimum

iodine status. The experts recommended that the policy of free provision of iodine tablets (ant-strumin) can be discontinued given the low apparent coverage and negligible effect on UI values among pregnant women. The further improve on strategy effectiveness, the range for iodization may be improved to 35-55mg KIO_3 per kg salt. The final advice by the team was that the oversight of the USI strategy should become integrated with a newly formed set-up under the Food Law and Food Safety Council. USI achievement in Bulgaria was acknowledged in May 2007 (Figure 4), and an award ceremony took place later in the same year at the Ministry of Health (Figure 5) with all the key partners and national press in attendance.

May 2007

The Network for Sustained Elimination of Iodine Deficiency, the International Council for Control of Iodine Deficiency Disorders (ICCIDD), the United Nations Children's Fund (UNICEF), and the World Health Organization (WHO), hereby acknowledge the request of the Ministry of Health of Bulgaria for external evaluation of Bulgaria's Universal Salt Iodization (USI) and Iodine Deficiency Disorders (IDD) elimination program. In response to this request, we have the privilege herewith to recognize the achievement of the elimination of iodine deficiency through universal salt iodization in Bulgaria.

The achievement of the elimination of iodine deficiency is clearly described in the document entitled "Review of Progress toward Sustained Optimal Iodine Nutrition in Bulgaria" (van de Haar, van Ingen, Laurberg 2005), and we endorse the conclusions and the recommendations made in that report.

We are confident that the government of Bulgaria will sustain the elimination of iodine deficiencies. As noted in the report, continuous monitoring and surveillance will be crucial components in sustaining this remarkable achievement. The continuing operation of the National IDD Consultative Committee is another crucial component in sustaining Bulgaria's success. We note that the National IDD Consultative Committee could be enhanced if the salt industry were to be included in its membership.

We wish to congratulate the Government of Bulgaria for its success in achieving universal salt iodization and the elimination of iodine deficiency disorders as a public health problem. In achieving and sustaining the elimination of iodine deficiencies, the Government of Bulgaria is protecting the health and well-being of children and the entire population of Bulgaria for generations to come.

Alan Court
Chair
Network for Sustained Elimination of Iodine Deficiency

Gerard Burrow
Chair
International Council for Control of Iodine Deficiency Disorders

Maria Calivis
Regional Director
CEE/CIS United Nations Children's Fund

Marc Danzon
Regional Director
Regional Office for Europe World Health Organization

Figure 4: Letter of acknowledgment by the Network for Sustained Elimination of Iodine Deficiency

Figure 5: Award Ceremony at the Ministry of Health

During 2005, the Government of Bulgaria endorsed a National Food and Nutrition Action Plan, 2005-2010, which specifically stated as one of the sub-objectives: “Maintain sustainable adequate iodine intake”. The plan document outlines the responsibilities of various partners in Government and industry in a spectrum of actions including assessments and monitoring, QA of production and salt supply inspections, formal education, maintenance of awareness and annual reporting of progress.

Participation of national officers in UNICEF-supported regional meetings:

- Conference on Elimination of Iodine Deficiency Disorders (IDD) in Central Eastern Europe, the Commonwealth of Independent States, and Baltic States, 3-6 September 1997, Munich, Germany
- Regional Salt Producers’ Meeting, 29 September – 1 October, 1999 Kiev, Ukraine
- Workshop on Strengthening Strategies for the Elimination of Micronutrient Malnutrition. Ankara, Turkey, 13-17 September 2004
- Workshop on Strengthening of Laboratory Capacity and Iodine Status Assessments for Monitoring of Sustained IDD Elimination through USI in the CEE/CIS Region. Istanbul, Turkey, 18-19 May 2006

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