Final Draft
20 May 2005

Review of Progress towards Sustained Optimal Iodine Nutrition in Bulgaria

26 April – 5 May 2005

REPUBLIC OF BULGARIA

Report by a team of experts on behalf of the

Network for Sustained Elimination of Iodine Deficiency

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I. INTRODUCTION

This is a report of findings by a team of experts on the progress in Bulgaria toward the national goal of sustainable elimination of iodine deficiency disorders (IDD). The first part of the report consists of sections covering the history and the present situation as appraised by the team. Next, the team's conclusions and recommendations follow.

As described in more detail later, the major conclusions of the team are:

- **Thanks to a dedicated strategy of iodizing all the table salt and all the salt used in the food processing industries, Bulgaria has succeeded in eliminating iodine deficiency and iodine deficiency disorders**

- **To prevent the return of iodine deficiency in Bulgaria, the present USI strategy should be continued, with regular actions established as a behavioural norm in the organizations that support and execute the national IDD elimination policy**

The team visited Bulgaria on behalf of the Network for Sustained Elimination of Iodine Deficiency from 26 April till 5 May 2005 to review records and documentation, and to hold interviews and discussions with people in government, academia, salt industry and food processing industry, the media and consumer organizations concerned with meeting the national goal. The agenda of work by the team was coordinated by Dr Tzveta Timcheva, consultant of the Ministry of Health, together with the UNICEF, UNDP and WHO offices in Bulgaria. Annex 1 gives the details of the team member's schedules.

In anticipation of the review, the Bulgarian MOH prepared a detailed report, which in the team's view presented a truthful and accurate history and situation analysis. Therefore, the MOH report is appended as an integral part of this report (Annex 2).

A list of key publications on IDD elimination in Bulgaria is given in Annex 3.

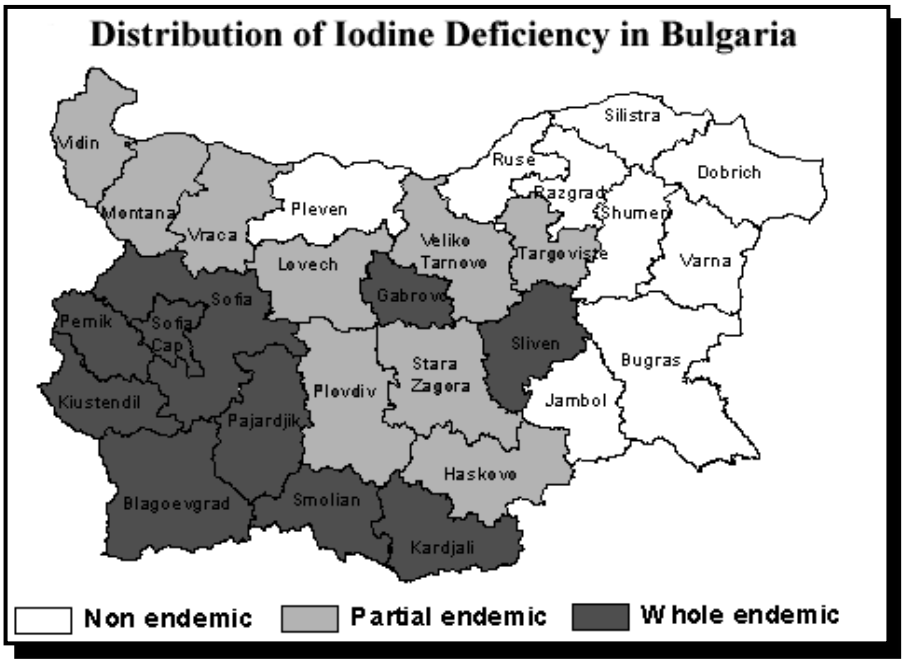
II. HISTORICAL DEVELOPMENTS

During the 1950s, extensive surveys were conducted by Academician Pentchev among >1million 7-18 yr-old children in 48 municipalities together with numerous analyses of soil and water samples. The surveys revealed:

- Low iodine intake with severely affected "endemic goitre" areas, encompassing 42% of the present population
- In the endemic areas, 64% of schoolchildren had goitre (26% had a large goitre)
- Around 6,000 of the inhabitants of endemic areas were affected by cretinism with mental and physical deficiencies.

The results of these early surveys clearly demonstrated that the inhabitants of sizable areas in Bulgaria had severe iodine deficiency and their consequences, and that many inhabitants of other parts of the country were less severely affected (Figure 1).

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

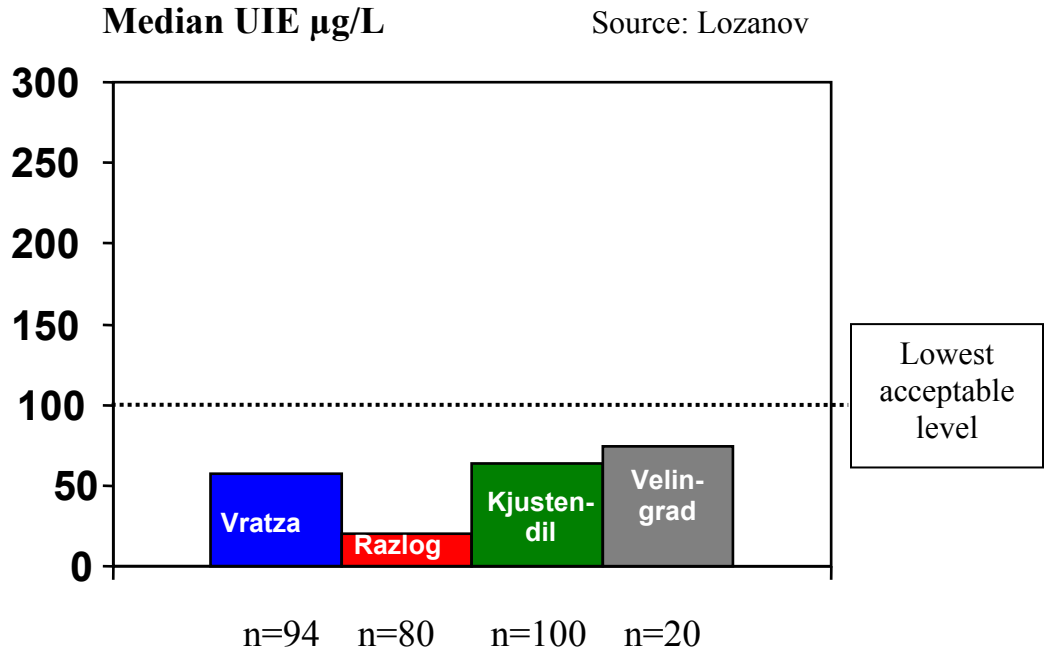


The original surveys focused on the presence of goitre and manifest cretinism. From our present knowledge of the consequences of low iodine intake, the team infers that the full spectrum of IDD was present in a considerable part of Bulgaria, including also an unnecessary and preventable high incidence and prevalence of thyroid diseases in the population. Prevention of these disorders by itself may make the IDD elimination program cost-effective. However, the more significant consequences are a general tendency to low mental and intellectual performance caused by insufficient brain development in the foetus and young infant, as well as a series of reproductive failure complications that affect the pregnant women.

These early epidemiological findings were followed by a Government decision in 1958 to mandate the supply by salt industry of only iodized household salt (KI, 20ppm I) in the affected (endemic) regions, combined with additional free supplies to pregnant and lactating women and 6-18 year old children of 1mg KI supplements once weekly. Follow-up surveys among schoolchildren in these areas confirmed a significant reduction in total goitre prevalence (TGP) among schoolchildren from 56% initially to 31% in 1964 and 12% in 1974.

Waning political interest and lack of proper follow-through were among the reasons for a re-emergence of the signs and symptoms of iodine deficiency by 1990, when the TGP among schoolchildren was found to have risen to 23%. Consequent small exploratory studies during the period of significant political turmoil until 1994 (Figure 2) illustrated that moderate-severe iodine deficiency persisted or had re-emerged in selected areas.

Figure 2:
Urinary iodine in pilot studies of schoolchildren, 1991-1994



The introduction of a free-market economy was accompanied by a Government decision to reorient the IDD elimination policy. In 1994 the Council of Ministers and the Chief State Sanitary Inspector issued decrees that introduced the following key programme characteristics:

- Creation of a National Inter-Agency Commission under the Council of Ministers as the apex body for overall coordination of national policy
- Prohibition of the sale of non-iodized household salt on the entire territory
- Setting the national standard for household salt at 28-55ppm KIO_3 (16.6-32.6ppm I) (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 (RIPCPH) (formerly Hygiene-epidemiological Inspectorates)
- 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 goitre, urinary iodine, neonatal TSH and other relevant population indicators.

A nation-wide IDD survey in 1996 (results presented in 1997; fully reported in 1998) employed for the first time in Bulgaria a combination of assessments of urinary iodine concentration (UIC) and goitre presence in schoolchildren. The total sample size was 8,445 with over-sampling in the previously endemic regions. Of the children in endemic areas, 77.6% were reportedly receiving iodine tablets. Overall, the TGP was 28.6%, including 3.5% of children with goitres greater than grade Ia (palpable, but not visible with the neck in extended position). The median UIC among a systematic sub-sample of 1,028 children was 111µg/L, with no significant difference between the endemic (107µg/L) and non-endemic (120µg/L) regions.

From 1998 onward, the various measures and practical procedures under the national effort to eliminate IDD have been continuously enhanced and perfected and small-scale special interest studies were conducted at regular intervals.

In 2001, the Council of Ministers issued an Ordinance to further improve upon the requirements on the composition and supply of salt for nutritional purposes. This included the mandatory iodization of all the salt for household use and for 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 (in consumer markets and food industries). The method for KIO_3 assays in salt was standardized, technicians in all the regional RIPCPH's were trained, and QA of the salt assays performed in the RIPCPH's was initiated by the National Centre for Hygiene, Medical Ecology and Nutrition (now named National Centre for Public Health Promotion).

Reports of salt iodine inspections by the RIPCPH system in Bulgaria show a steady and consistent improvement of the proportion of edible salt falling 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 varies around 4,000.

The laboratories of the RIPCPH system are participating in external QA assessments by the National Centre for Public Health Protection (formerly National Centre for Hygiene, Medical Ecology and Nutrition) in Sofia. The iodine laboratory of this national centre is a recognized QA service laboratory for the region as part of the CDC-supported IRLI

laboratory network[1]. In turn, CDC regularly provides the laboratory in Bulgaria with blind QA samples, the results of have consistently been found to be within the acceptable range.

The Health Promotion/Education Section of each RIPCPH conducts regular and planned education workshops among professionals in the health care system (GPs and nurses), teachers and other concerned groups, including food industry. A range of communication materials (leaflets, magazines, etc) for consumers are distributed systematically through schools, GP offices, clinics etc. The RIPCPH's provide the press with regular information on IDD and USI.

[1] (see http://www.cdc.gov/nccdphp/dnpa/immpact/global/irli_network.htm).

III. THE PRESENT SITUATION

a. National Salt Supply and Iodization Status

1. National iodized salt market

The total market of edible salt for human consumption (table salt, salt used by the food industry and salt used by the catering industry) is estimated at 40,000ton/yr, which equals 15gram/person/day. Having visited more than 10 shops, no non-iodized salt was found in any retail shop by the team. The standard presentation to consumers is in 1kg polythene bags, which state clearly that the salt is iodized. Shop prices hover around 0.30Lev/kg.

The national market is almost completely covered by one local producer and two large importers, all located along the Black Sea coast. All three firms import iodized and non-iodized salt from various countries (Israel, France, Tunisia, Ukraine, Belarus) and each has its own iodization capacity. Salt is sold to other distributors/re-packers, wholesalers and retailers, partly under the own brands of the producer/importers.

The current market shares are estimated as follows:

Promar	40 %
Tchernomorsky Solnitzy	40 %
Kanotrans	10 %
Other small importers	10 %

The total iodization capacity of the three above firms is estimated at 40,000ton/yr. All firms also import salt iodized according to the Bulgarian standard. Roughly half the total market supply of iodized salt appears to be imported as such. As a result it can be stated that there is ample supply of iodized salt, even if one of the above players were to discontinue business.

The companies visited (representing ~80% of the supply) consider the present iodization range (28-55ppm KIO_3) comfortably wide and easy to meet.

2. Local salt production

Bulgaria has 1 local (solar) salt producer – Tchernomorski Solnitzy in Burgas, which was visited. The plant produces 70-80,000t/yr of salt and has recently changed ownership. The new owners have plans for modernization and extension of the actual production and also a plan for a completely new facility for drying/grinding/sieving plus iodization and packaging nearer the actual harvesting area. The plant can be accessed by ship (± 3,000t) and narrow gauged railcars of 4t each. Access by road is virtually impossible for trucks.

Iodization is carried out by the spray mix method using a recently UNICEF-donated machine of up to 10,000t/y capacity, backed up by 2 effectively obsolete machines. The

actual production of iodized salt has been around 4,000t/yr over the last few years as evidenced by KIO_3 purchases.

3. Salt quality assurance and monitoring

A comprehensive system for monitoring of the iodine (iodate) content of salt has been put in place and increasingly perfected by government and salt industry partners since 1994. The team had the opportunity to investigate this system at producer/importer level as well as at the level of market outlets and food industry. The team found the system to be robust and well executed.

The producer/importers understand the system well and support it loyally.

(a) QC at production/importation level

During iodization, companies perform 4x/day iodine (iodate) content tests by titration. They issue certificates with the final products leaving their facilities. Without this certificate it is impossible to sell or purchase salt. For importation of iodized salt by the three firms, the regional RIPCPH laboratory tests and releases the product on a shipment-by-shipment basis. The producer/importer's laboratories are checked by RIPCPH at least 1x/month. All samples are double-tested by the government laboratory. When the test results obtained by the producers and the Government differ, the results by the RIPCPH laboratory are accepted as final.

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. For this, the producer/importers have a crude tracking system in place. Further details are given in Annex 2.

(b) QC at wholesale/retail level

The government laboratories perform regular testing of salt quality in the market (see above). This includes checks on inventory turnover although shelf life is not a big issue with iodate and on average lasts less than a Quarter. In case salt samples upon inspection are found out of specification, the Burgas RIPCPH handles the matter of notifying and follow-up decisions with the producer/importers. Details are given in Annex 2.

(c) QC at household level

The National Survey of 2003 demonstrated that >95% of households use salt with >15ppm iodine.

b. Status on Iodine Intake and IDD in Bulgaria

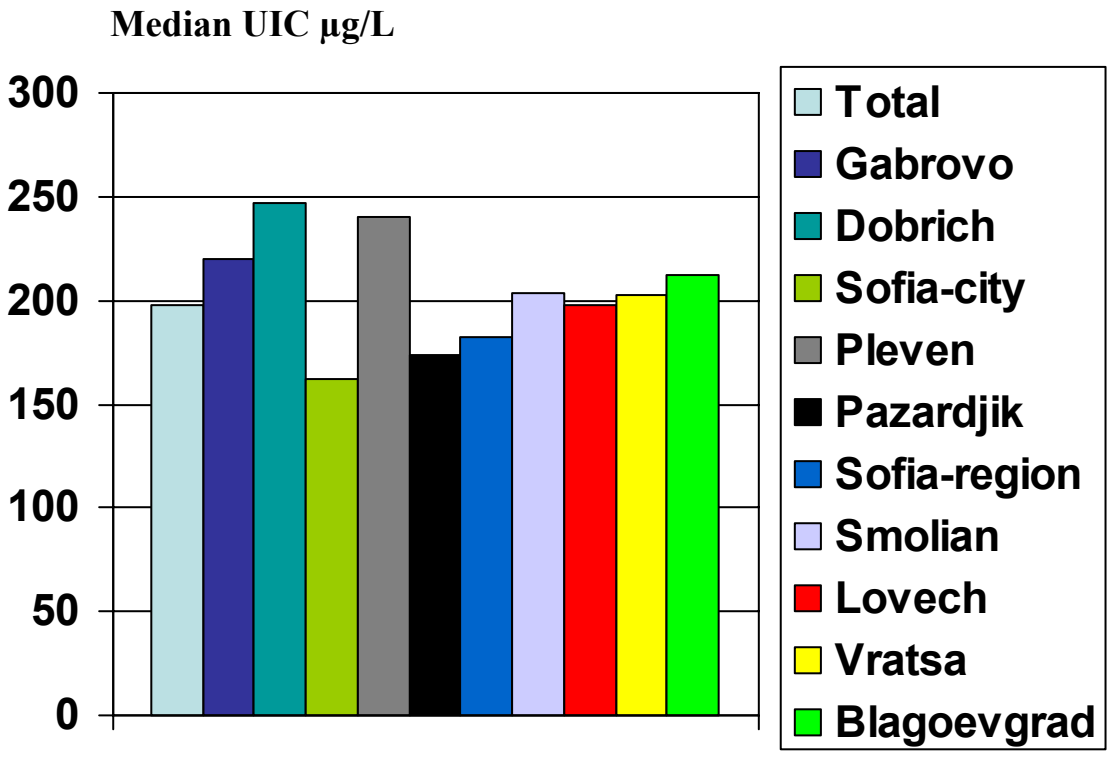
Based on the extensive documentation provided by MOH (Annex 2) and further analysis of the 2003 national survey database in collaboration with the National Committee, the team evaluated the evidence of progress toward IDD elimination in Bulgaria, proceeding in two steps: Evidence that iodine deficiency had been alleviated, and evidence that IDD has been reduced below the public health significance level.

1. Evidence of the disappearance of iodine deficiency

Using ICCIDD/UNICEF/WHO guidelines on the interpretation of urinary iodine among schoolchildren, the results of the national survey in 2003 (Fig 3) demonstrate adequate iodine intake in Bulgaria.

In the 2003 survey, the UIC of 809 schoolchildren aged 7-11 years were examined in a total of 10 regions – 2 non-endemic as judged from previous studies (Dobrich, Pleven), 3 partly endemic (Pazardjik, Lovech, Vratsa) and 5 previously endemic. Schoolchildren were identified from enrolment lists after random selection of schools in the regions. The schoolchild median UIC by region varies around 200µg/L with slight variation among different regions. Notably, compared to other regions UIC was relatively low in Sofia city and Sofia region, which is in concurrence with a small-scale study among pregnant women in Sofia in 2001.

Figure 3:
Urinary iodine concentration in schoolchildren by region;
Bulgarian National Survey, Spring 2003.



In none of the regions was the iodine intake among schoolchildren insufficient (median UIC <100µg/L), and in none of the regions were median intakes indicating "excessive" (median UIC >300µg/L). As might be expected, the highest median UIC values were observed in previously non-endemic regions. The prevalence of UIC<50µg/L for the total sample, 0.8%, was below 20%, thus fulfilling another of the recommended criteria.

2. Evaluation of the disappearance of iodine deficiency disorders

(a) School children

Well aware of the fact that it may take time before goitres have entirely regressed after the iodine intake of the population is restored, the team discussed the available data on the goitre assessments in schoolchildren with the Bulgarian national committee and experts who had conducted the 2003 survey.

Approx. 4,000 children had undergone palpation of the thyroid gland by experts from the regions involved in assessing children for the presence of goitre. Systematically, every 10th child had also the thyroid size estimated by ultrasound examination. The report noted that 520 (13%) of children had grade1goitre and 24 (0.4 %) grade2 by clinical examination according to the recent ICCIDD/UNICEF/WHO classification, whereas only 4.3% had an enlarged thyroid gland by ultrasound measurement. As the results of the clinical examination suggested that IDD had not yet been eliminated, the team found it important to evaluate these results in more detail.

In collaboration with the Bulgarian national committee who had conducted the 2003 survey, the original database was used to compare results of goitre palpation and thyroid ultrasound examination in the individual children who had both examinations performed. Out of a total of 365 children, 307 had the clinical goitre score 0 (no goitre) and 57 children had been scored 1 (a goitre that can be felt but not seen). On none of the 24 children in the 2003 survey with grade2 goitre was ultrasound examination performed.

In our analysis (see table below) thyroid volume was identical in the children scored to have no goitre (grade0) and children judged to have a palpable but not visible goitre (grade1). Moreover, there was no association between goitre grade and thyroid volume when data were adjusted for age, sex, region, height and weight in the analyses (data not shown).

Ultrasonography	Clinical Goitre grade 0	Clinical Goitre grade 1
N	306	57
Thyroid volume (ml) Median	3.57	3.65
P25-75	2.60 - 4.48	2.57 - 5.00
P5-95	1.07 - 5.80	1.25 - 8.10
Range	0.30 - 12.0	0.54 - 9.96

These results indicate that in the 2003 survey, goitre grade1 was not to be regarded as an accurate measurement sign of IDD, but merely was related to other factors such as for

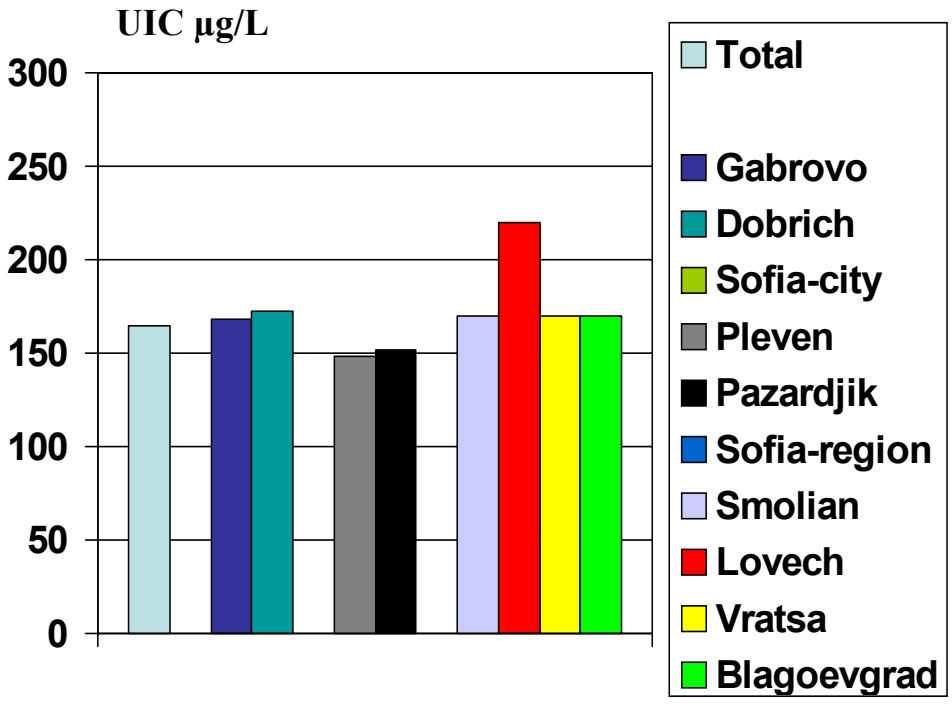
example the general structure of the neck. The team concludes that the clinical grade1 goitres of the 2003 survey should not be considered accurate enough for evaluating the current absence or presence of IDD.

In 2003, the goitre prevalence as evaluated from ultrasound estimation was 4.3% and the occurrence of visible goitre 0.4%. Both are below 5%. Thus, the team is of the opinion that in Bulgaria, IDD has been reduced below the level of public health importance.

Finally, it should be remembered also that the 2003 survey significantly over-sampled children in previously endemic areas. Therefore, the true national goitre prevalence among schoolchildren was lower than the estimates given in the 2003 report.

(b) Pregnant women

Figure 4:
Urinary iodine concentration in pregnant women by region;
Bulgarian National Survey, Spring 2003.



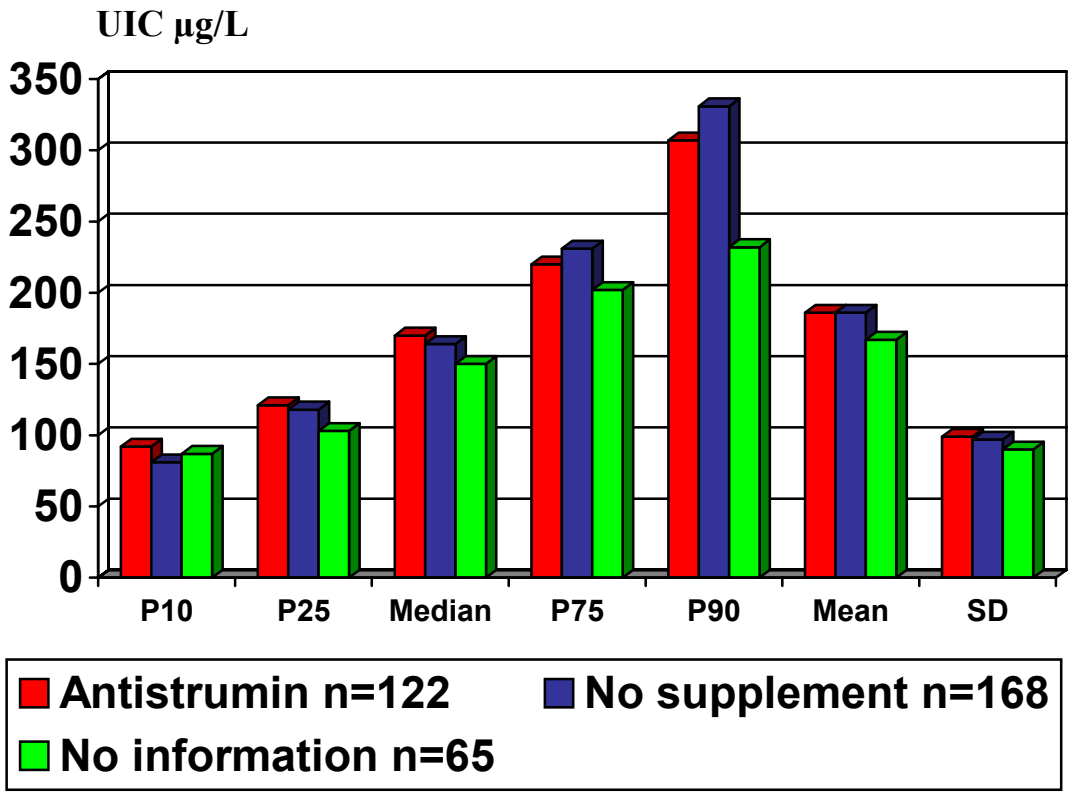
Pregnancy is a most vulnerable period with regard to the risks associated with iodine deficiency. The nutritional iodine requirement during pregnancy increases considerably due to a significant need for increased thyroid hormone synthesis.

The above-mentioned 2003 national survey also included a sub-sample of pregnant women aged 26±5y in their 2nd half of pregnancy from the same regions where children were sampled, except Sofia city and Sofia region. As was the case with schoolchildren,

also the pregnant women were over-sampled in the previously endemic regions. The thyroid size was examined by ultrasound and of 355 women the UIC was determined. Overall, the median UIC was 165µg/L (Figure 4). The regional UIC medians among pregnant women were sizably lower than those found among schoolchildren. Also, compared to schoolchildren the region-wise UIC medians among pregnant women were more variable and ranged between 148 (Pleven) and 220µg/L (Lovech).

In addition, the database on pregnant women included a code for the usage of KI tablets ("Antistrumin"), which according to current policy is supplied to pregnant women in the formerly endemic areas without charge. The 2003 report mentions that up to 50% of women of these regions reported using KI tablets. In collaboration with the Bulgarian national committee who had conducted the 2003 survey, the original database was re-analyzed to compare the UIC distribution parameters between women reporting the use - or not- of KI tablets. The median UIC among women recorded as using supplements was 170µg/L and among non-users the median was 164µg/L. Among women in previously non-endemic areas (code absent), a median UIC of 150µg/L was found. Figure 5 shows that the three distributions are very similar and not different statistically.

Figure 5:
UIC of pregnant women reportedly using KI tablets and those not using KI tablets
Bulgaria National Survey, 2003



Assuming that the codes in the database accurately reflect the use of KI tablets, this analysis would indicate that the policy of KI tablet supplementation does not lead to a meaningful improvement of the iodine nutrition status among the reported users.

(c) Newborns

Systematic screening of newborns for congenital hypothyroidism (CH) has been ongoing in Bulgaria since 1994 with >700,000 newborns examined since the start. The screening is routinely established throughout the country, with a strong central support effort by the University Children's Hospital in Sofia. Nearly 300 CH cases have been identified and treated through the system, making it very cost-effective.

Results of TSH assay 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 some clinical data. The laboratory participates in external sample 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 may be useful for comprehensive monitoring of signs of insufficient iodine nutrition. More information is needed, however, of the effect on TSH results from the current use in some delivery institutions of iodine-containing disinfectants.

c. Likelihood of sustained IDD elimination

The team used the list of criteria recommended by the 1999 ICCIDD/UNICEF/WHO expert panel for a judgment on the likelihood that the success of IDD elimination through USI in Bulgaria will be permanent. Annex 2 has more details on the technical criteria that have been met or surpassed in Bulgaria. This section focuses on the team's considerations of operational and programmatic significance.

1. An effective, functional national body (council or committee) responsible to the Government for the national programme for the elimination of IDD (this council should be multidisciplinary, involving the relevant fields of nutrition, medicine, education, the salt industry, the media, and consumers, with a Chairman appointed by the Minister of Health).
   - In accordance with Ministerial order, a National IDD Consultative Committee, chaired by the National Endocrinology Adviser who is appointed by the Minister, advises the Council of Ministers in Bulgaria. Although the Committee's members cover various disciplines, it does not include representation of the salt industry. The Committee meets at various intervals to review annual reports and discuss survey/special study findings, and advise accordingly to the Council
   - In preparation to joining the EU, Bulgaria has enacted a National Food Law and instituted a Food Safety Council, chaired by the Deputy Minister of Health and with representation of all sectors involved, including the Bulgarian Association of Food Manufacturers. The new Food Law includes all the ordinances that mandate

USI (previously enacted). The Council is obligated to meet every 2 to 3 months, and authorized to recommend changes on food and nutrition issues

- A draft Food and Nutrition Action Plan developed with assistance from WHO is under consideration by the Council of Ministers. It includes actions for continued review of progress toward IDD elimination through USI. Upon acceptance of the FNAP, the Ministry of Health is planning to integrate the IDD Consultative Committee into the new Food Safety Council structure.

Team's opinion: Criterion is largely met.

2. Evidence of political commitment to universal salt iodization and the elimination of IDD.
   - National legislation and regulations are adequate
   - Government leadership is evident, with a budget for necessary public efforts
   - There is a cost-effective, functional system of follow-up, which includes all essential partner contributions.

Team's opinion: Criterion is met.

3. Appointment of a responsible executive officer for the IDD elimination programme.
   - Oversight management is included in the job description of a Senior Officer in the Directorate Protection and Control of Public Health, Ministry of Health.

Team's opinion: Criterion is met.

4. Legislation or regulations on universal salt iodization (while ideally regulations should cover both human and agricultural salt, if the latter is not covered this does not necessarily preclude a country from being certified as IDD-free).
   - The law and regulations apply to all consumer (edible) salt and food industry (food-grade) salt and prohibits the sales of non-iodized salt nation-wide.

Team's opinion: Criterion is met.

5. Commitment to assessment and re-assessment of progress in the elimination of IDD, with access to laboratories able to provide accurate data on salt and urinary iodine.
   - Legislation/regulation specifically address the requirement for regular surveys, studies and monitoring based on routine inspections
   - Reporting on progress toward IDD elimination through USI is part of the annual reports by the Ministry of Health. Oversight and review of progress is part of the mandate of the Food Safety Council (and IDD Consultative Committee)
   - The iodine laboratory at the National Centre for Public Health Protection is part of the ILRI world-wide laboratory network

Team's opinion: Criterion is met.

6. A programme of public education and social mobilization on the importance of IDD and the consumption of iodized salt.
   - The Health Education/Promotion Section in each of the 28 RIPCPH's execute a well-planned, continued effort to educate stakeholders (including continued education of professional groups) and the public

- IDD/USI is part of the regular curriculums in primary/secondary school and in postgraduate training of nutritionists and endocrinologists
- Salt industry puts information on the packaging of consumer salt.

Team's opinion: Criterion is largely met.

7. Regular data on salt iodine at the factory, retail and household levels.
   - Salt industry (producer/importers) perform QA of supplies, evidenced by certification
   - RIPCPH Burgas regularly performs inspections at national import/production
   - RIPCPH's continuously monitor the market outlets and food industries country-wide
   - Lab performance in RIPCPH's is periodically checked and up-graded as needed

Team's opinion: Criterion is met.

8. Regular laboratory data on urinary iodine in school-aged children, with appropriate sampling for higher risk areas.
   - National surveys have been performed at periodic intervals (every 5 years), interspersed with special interest studies, with appropriate recent interest in iodine nutrition among pregnant women
   - The national survey dates less than 2 years ago and included school-aged children and pregnant women with over-sampling in previously endemic areas

Team's opinion: Criterion is met.

9. Cooperation from the salt industry in maintenance of quality control.
   - Procedures and capacity for quality assuring the supplies of iodized salt by the importers/producer are adequate
   - Salt industry fully understands and supports the national policy

Team's opinion: Criterion is met.

10. A database for recording of results or regular monitoring procedures, particularly for salt iodine, urinary iodine, and if available, neonatal TSH, with mandatory public reporting.
    - The RIPCPH's report quarterly to MOH on the results of salt inspections. MOH is developing more efficient methods and software for consolidation and analysis
    - Reporting of progress in IDD elimination through USI is part of the annual MOH report
    - Press articles and other media reporting takes place coincidentally to other events

Team's opinion: Criterion is largely met.

IV. CONCLUSIONS AND RECOMMENDATIONS

a. Conclusions

The team concludes that Bulgaria has succeeded in tackling a historically significant and severe IDD problem by bringing the dietary iodine intake in the population within the generally acceptable range. ***Bulgaria has eliminated iodine deficiency.***

Underlying this success is a well-organized and conscientiously applied universal salt iodization strategy that adds a small and regular amount of iodine to the common diet of the population by the iodization of all household (edible) and food industry (food-grade) salt. ***The USI strategy in Bulgaria is effective and should be sustainable.***

Based on the results and further analysis of recent national survey data, and on a review of ongoing activities and existing documentation, the team also concludes that at present IDD has fallen below public health significance. ***IDD has been eliminated in Bulgaria.***

Bulgaria has reached the first stage of the national goal of sustained IDD elimination.

This success can endure into the future only by permanent execution of the current USI strategy, based on actions that are established as habitual norms in the organizations involved. The existing systems are perfectly adequate to achieve this in principle when they are properly maintained.

The extensive documentation of the historically severe IDD situation during the 1950s is a stark illustration of the consequences facing Bulgaria in case of future failure.

b. Recommendations

In making recommendations, the team remains cognizant of the conclusions spelled out in the section above. Thus, it is most important to recognize first that persistence of the current efforts can sustain IDD elimination in Bulgaria.

Nevertheless, there always is room for improvement. Thus, the recommendations below are offered with a view to improve efficiency, save costs, reduce the likelihood of future failure and sharpen the focus in impact assessments of the national IDD elimination policy.

1. Focus on pregnant women as most meaningful and informative group

On basis of the 2003 survey, UIC levels among pregnant women were sufficient but barely reached above the recommended minimum for this group. In contrast, the median UIC levels among schoolchildren of the same regions were distributed nicely around the recommended mid-range for their group. Any unforeseen future reduction in the general dietary iodine supply or consumption in the population will therefore first and foremost

affect pregnant women, i.e. the subgroup upon which iodine deficiency has the most significant damaging impact.

The team suspects, but no evidence (data) is available to support this, that women in Bulgaria when pregnant may reduce their intake of salt added at the table and during cooking. In future population monitoring, therefore, the team recommends focusing on the iodine status among pregnant women, optimally before the 20th week.

2. Discontinue the policy of KI tablet distribution to pregnant women

Upon further analysis of data from the 2003 survey, no evidence was found in support of the expectation that providing KI tablets makes a meaningful contribution to improving the UIC among pregnant women who reported using the tablets. Moreover, supplement coverage data in Bulgaria indicate that in practice, the policy is not reaching the level that may ensure adequate protection. In contrast, the evidence shows that USI as practiced in Bulgaria does reach all segments of society in Bulgaria with a small amount of additional iodine via the common food intake and thereby improves the iodine nutrition status of all.

The team recommends discontinuation of the public policy to provide pregnant women in formerly endemic areas with KI tablets. This leaves the practice intact that medical care providers such as GPs and Obs/Gyn specialists may decide that pregnant women in their practice should have iodine supplements prescribed.

This recommendation should be seen in direct connection to the next recommendation.

3. Adopt an improvement of the range of mandated salt iodine levels

In view of the barely sufficient iodine nutrition status among pregnant women, and with the UIC levels among schoolchildren comfortably in the mid-range, it would be prudent from a public health viewpoint to introduce a small increase in the dietary iodine supply by raising the mandated iodization levels of salt, including the food-grade salt supplied to processed food sources such as bread and dairy products.

Relative to worldwide experience of iodization practices in modern salt industries, the range of salt iodine levels mandated in Bulgaria is comfortably wide. Upon consultation, 2 of the major salt industries (~80% of the national market) confirmed having the ability to achieve a narrower range.

Thus, the team recommends that the national authorities should consider mandating a slightly narrower range for salt iodine levels through an increase of the lower mandated level while leaving the upper level intact. Tentatively, 35-55ppm as KIO_3 is suggested.

Given the presently prevailing practice in food inspection and industry supplies, the salt manufacturers will continue targeting the salt iodine levels in the centre of the mandated range. Thus, all other things remaining equal, adoption of this adjusted range would

increase the dietary iodine supply from salt iodization to the average consumer by 8% (from 26.6 to 29.6ppm iodine at market level).

Introduction of an improved mandated range requires consultation with salt industry and coordination in RIPCPH's.

4. Effectuate the current plans for improved national oversight

The team encourages the Ministry of Health to swiftly effectuate the planned integration of the (former) IDD Consultative Committee structure into the new set-up under the Food Law and Food Safety Council. This has the advantage of a more balanced participation and input of all partner organizations concerned in the national IDD elimination efforts.

To provide up-to-date information to the Food Safety Council, the team also recommends that MOH should put in place a more immediate analysis method and reporting routine on basis of the quarterly salt iodine results received from the RIPCPH's. In today's electronic age, it is relatively easy to establish PC-based data software handling that can grow into a national database encompassing the range of data and information required for effective oversight.

5. Consider using the neonatal TSH data for regular population monitoring

Bulgaria has an efficient and well-functioning system for neonatal TSH screening, based on virtually all newborns in the country and aimed at the identification of infants requiring treatment for congenital hypothyroidism. In view of ICCIDD/UNICEF/WHO considerations, the team recommends that the neonatal TSH screening system should be explored for its usefulness as a timely and encompassing data source to monitor trends in IDD and population iodine nutrition status.

The team noted that iodine-containing disinfectants are still being used in Bulgaria during institutional delivery of newborns, which is known to affect the thyroid hormone status of the mother and newborn. This practice should be discontinued. Alternative safe and effective disinfectants are amply available.

c. Research Directions

In addition to the recommendations on the direction of future policy, the team noted a few concerns that may be addressed by research.

1. Do pregnant women change their food consumption during pregnancy?

While the UIC levels of the 2003 survey indicate that pregnant women in all regions covered by the sample have sufficient iodine intake, the survey excluded women from Sofia-city and Sofia-region. In the 2001 study of pregnant women in Sofia, UIC levels were far below recommended. As described before, the team is concerned therefore that women in Bulgaria may change their dietary habits when pregnant.

The team recommends that a future research effort specifically should address the question whether women, when finding out that they are pregnant, change their salt consumption habits. The findings among pregnant women in 2001 would indicate that this research should preferably take place in Sofia-city/region. The research methods should pay special attention to the relationships among attitudes, knowledge and practices, and the influence that health care providers and health education may have on habitual dietary practices during pregnancy.

2. Ecological relationships with newborn TSH data

To examine the reliability and usefulness of using the Bulgarian neonatal TSH database as a source for timely monitoring of IDD trends in the population, the team recommends an ecological analysis of the spring 2003 TSH data compared with the schoolchild UIC data from the 2003 survey classified by region.

3. Proportional contributions of USI via household and food industry salt

It will be important for future policy-making to study in a few typical population groups and situations how much of the additional iodine from USI is reaching the consumption of the population through household salt *vis-à-vis* various industrially processed food items. A simple lithium-tagging method is available to "spike" iodized salt and obtain these proportions in a few typical groups. Having this information available will facilitate future adjustment, if and when needed, of the mandated salt iodine levels in case the discretionary salt consumption decreases due to health policy to reduce the dietary sodium intake.

Key people encountered during the visit

Ministry of Health
Dr. Lyubomir Koumanov – Deputy Minister and Chief State Sanitary Inspector
Dr. Snejana Altankova – Director of Directorate "Protection & Control of Public Health"
Dr. Tzveta Timtcheva – Consultant, Director National Program for IDD Elimination
Dr. Masha Gavrailova – Head of Department "Public Health Protection"
Dr. Svetlana Spassova – Head of Department "Non Communicable Diseases"
Dr. Georgi Uzunov – Senior Expert, National IDD Focal Point

Regional Inspectorates for Protection & Control of Public Health – Blagoevgrad
Dr. Slavka Paskaleva – Deputy Director
Mrs. Rositza Dimitrova – Director of Directorate "Laboratory analyses"
Mrs. Jordanka Ignatova – Chemist
Mrs. Rositza Kondeva – Laboratory Technician
Dr. Ivan Temelkov – Head of Department "Control of Food and Food Facilities"
Dr. Emil Dimitrov – Head of Department "Protection of Public Health"

Regional Inspectorates for Protection & Control of Public Health – Pazardjik
Dr. Fani Petrova – Director
Dr. Zoya Shosheva – Director of Directorate "State Health Control"

Regional Inspectorates for Protection and Control of Public Health – Plovdiv
Dr. Ani Engilian – Director
Dr. Vanya Tancheva – Director of Directorate "Laboratory analyses"
Dr. Vladimira Stefanova – Head of Department "Control of Food and Food Facilities"
Dr. Simeon Pavlov – Director of Directorate "Protection of Public Health"

Regional Inspectorates for Protection and Control of Public Health – Burgas
Dr. Svetla Stancheva – Head of Department "Control of Food and Food Facilities"

Capital Regional Inspectorates for Protection and Control of Public Health
Dr. Mihail Popov – Deputy Director
Dr. Violeta Demireva – Director of Directorate "Protection of Public Health"
Mrs. StoyankaArnaudova – Chemist
Dr. Rumyana Jordanova – Head of Department "Specialized Health Control"
Dr. Anna Gerova – Head of Department "Operative Health Control"
Dr. Svetlana Kiryakova – Head of Department "Health Promotion", IDD regional coordinator

Neonatal Screening Laboratory, Pediatrics Hospital
Dr Iva Stoeva – Chief Pediatric Endocrinologist and Head, Laboratory

Branch Chamber of the Industrial Bread Producers and Confectionaries in Bulgaria, Sofia
Dipl. Eng. Ivan K. Ivanov – Vice-President

Dairy producer "Lacrima" JSK, Pazardjik
Mr. Goran Gerdjikov – Executive Director
Mrs. Miglena Doycheva – Chief Technologist

Tchernomorski Solnitzi Salt Company, Burgas
Mr Georgi Nocolov – CEO and co-owner
Mrs Margarita Invancheva – Technical Manager
Mrs Maria Gardjeva – Marketing Manager

Promar Salt Company, Burgas
Mr Peter Vichev – Managing Director

University Clinic of Thyroid and Diseases of Metabolism
Assoc. Prof. Dr. Anna-Maria Borisova – Head of the Clinic and National Consultant on Endocrinology
Dr. Rusanka Kovatcheva – Ultrasonografist
Prof. Bojan Lozanov – Head of the Section of Thyroidology

National Center for Public Health Promotion
Department of Medical Ecology and Nutrition
Assoc. Prof. Blagoj Jordanov – Head, Laboratory of Nutrition
Mrs Evelina Atzeva, Biochemist
Mrs Anna Ananieva, Lab Technician
Mrs Kamelia Stoeva, Lab Technician
Department and Laboratory of Food Chemistry
Assoc. Prof. Roumen Tsanev – Head, Department of Food Chemistry

UNICEF office in Bulgaria
Mr Octavian Bivol, Representative
Ms Jetchka Karaslavova, Communications Officer
Mr Dinko Draganov, Project Assistant

WHO Country Office in Bulgaria
Ms Emilia Tontcheva, Liaison Officer

ANNEX 1

PROGRAM OF THE INTERNATIONAL TEAM FOR EVALUATION OF IDD POLICY IN BULGARIA				
Date	**Hour**	**Frits van der Haar**	**Peter Laurberg**	**Jan van Ingen**
		ACTIVITY		
26 April TUE		Arrival and meeting with Mr. Octavian Bivol (UNICEF Rep) and Ms Emilia Toncheva (WHO Rep) at UNICEF office		
27 April WED	**09.00 – 10.30**	Meeting with Dr. Snejana Altankova – Director of Directorate Protection and Control of Public Health – MoH		
	10.30-12.30	Meeting with Chair and Co-chair of IDD Consultative Committee Prof Bojan Lozanov and Dr Tzveta Timtcheva - MoH		
	14.00 – 16.00	Visit to the Federation of Industrial bread producers and confectioners and meeting with the executive director – Mr. Boris Inchev		
28 April THU	**08.30**	**Departure to Blagoevgrad**		
	10.00-12.00	Visit to RIPCPH – Blagoevgrad, meeting with Director Dr. Lena Pavlova and familiarizing with the monitoring and health promotion work in the field of IDD		
	12.30	**Departure to Sofia and lunch on the way**		

Date	Hour	Frits van der Haar	Peter Laurberg	Jan van Ingen
28 April THU	**14.00-16.00**	Visit to RIPCPH – Sofia, meeting with Director Dr. Georgi Kostov and familiarizing with the monitoring and health promotion work in the field of IDD	**Arrival and accommodation**	
29 April FRI	**08.30-11.00**	Visit to Neonatal TSH Screening Laboratory, Paediatrics Hospital, meeting with Dr. Iva Stoeva, chief		
	11.30-13.30	Visit to National Centre for Public Health Protection's – laboratories for ioduria and for quality control		
30 April SAT	**Holiday**	Lunch meeting and discussion with Prof. Bojan Lozanov (on behalf of Bulgarian National Committee) on details and findings of the national survey, 2003		
1 May SUN	**Easter**	Team review of data and key findings of national survey, 2003. First draft on points of attention and inventory for additional data analysis		**Arrival and accommodation**
2 May MON	**Easter 14.00**	Team inventory of issues for assessments during field visits		**Departure to Burgas**
3 May TUE	**08.00**	**Departure to Pazardjik**		
	08.30 -10.30			Visit to Tchernomorski Solnitzi salt plant, meeting WITH executive director Mr. Tzvyatko Tzvetkov and familiarizing with the work
	10.00 - 12.00	Visit to dairy industrial facility "Lacrima" , meeting the executive director and familiarizing with the practice of iodized salt use in dairy products		

Date	Hour	Frits van der Haar	Peter Laurberg	Jan van Ingen
3 May TUE	**11.00 - 13.00**			Visit to RIPCPH - Burgas, meeting with Director Dr. Svetla Stancheva and familiarizing with the monitoring and health promotion work in the field of IDD
	12.00	**Departure to Plovdiv**		Visit to Promar Salt Import Company - meeting with the executive director Mr. Velko Chankov and familiarizing with organization and realization of salt import
	14.00-16.00	Visit to RIPCPH - Plovdiv, meeting with Director Dr. Ani Engilian and familiarizing with the monitoring and IDD health promotion work		
	16.00	Departure to Sofia		Departure to Sofia
4 May WED	**09.00 - 10.00**	Meeting with National endocrinology advisor - Ass. Prof. Dr. Ana-Maria Borisova		Visits to typical selection of market outlets in Sofia for finding non-iodized salt on sale for household purchase
	10.30 -11.30	Meeting with Deputy Minister of Health and Chief State Sanitary Inspector Dr Lubomir Koumanov		
	11.30 - 12.30	Public statement of findings and press conference		

RIPCPH - Regional Inspectorate for Protection and Control of Public Health

ANNEX 2

Note:

Annex 2 consists of the report prepared by MOH in anticipation of the present review, and it is provided as a separate MS Word electronic file to preserve its integrity.

The file is named <IDD Situation in Bulgaria.doc>

ANNEX 3

Scientific publications on progress toward Sustained Elimination of IDD in Bulgaria

Penchev, Ivan et al. Endemic Goitre in Bulgaria. Sofia, 1961

Timtcheva T, Zlatarov I. Bulgarian table salt market and IDD prevention strategy. In Geertman GM, Editor. 8th World Salt Symposium Vol 2: 1071-1076. Amsterdam, Elsevier, 2000

Ivanova L, Lozanov B, Timtcheva T, Vukov M, Boeva B. Urinary iodine in IDD monitoring in Bulgaria. In: Geertman RM, Editor. 8th World Salt Symposium Vol 2, 1249-1250. Amsterdam, Elsevier, 2000

Lozanov B. Control of iodine deficiency in Bulgaria towards the 21st century. Endocrinologia Vol 6 (3); 41-42, 2001

Ivanova L, Lozanov B, Timtcheva Zv. IDD status in Bulgaria. 28th Annual Meeting of the European Thyroid Association; Satellite meeting of West-Central Europe ICCIDD. Goteborg, Sweden, 7 September 2002

Ivanova LB, Ivanova RB, Dimitrov PS, Kovatcheva RD, Lozanov BS. Urinary iodine concentration and thyroid volume in schoolchildren of Sofia: Evaluation of effectiveness of salt iodization. C Eur J Occup Envrironm Med Vol 8 (4); 263-269, 2002

Ivanova RB, Kirilov G, Ivanova LB, Lozanov BS. Evaluation of thyroid status in pregnant women under supplementation with iodized table salt. Endocrinologia Vol 8 (1); 34-39, 2003

Lozanov B, Ivanova L, Kovacheva R, Ivanova RB, Timtcheva Z, Vukov M. Iodine status and goitre prevalence in Bulgaria: Current epidemiologic studies. 29th Annual Meeting of the European Thyroid Association. Edinburgh, UK, 18-22 October 2003

Ivanova L, Timtcheva Tz, Lozanov B, Ivanova R, Vasileva B, Hubaveshki S. Ioduria in the monitoring of IDD preventive strategies adequacy in Bulgaria. 29th Annual Meeting of the European Thyroid Association. Satellite meeting of West-Central Europe ICCIDD. Edinburgh, UK, 18 October 2003

Lozanov BS, Ivanova L, Timcheva Z, Vukov M. Eradication of iodine deficiency disorders in Bulgaria: Results of the national representative survey on the iodine status and the endemic goitre – 2003. Endocrinologia Vol 9 (3); 146-156, 2004

Lozanov B, Ivanova L, Kovatcheva R, Ivanova I, Borissova A.-M, Timcheva Z. Eradication of iodine deficiency disorders in Bulgaria (Abstract). Balkan Congress of Endocrinology (Bucharest, October 2005). Advance copy