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Wellstart International
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TRIP REPORT

AUTHOR: Dr. Chessa Lutter, Applied Research Advisor, Wellstart International
Dr. Kim Hooper, Senior Scientist, Hazardous Materials Laboratory, California
Environmental Protection Agency

WHERE: Kazakhstan

WHEN: Dr. Lutter, February 13 - 26, 1994
Dr. Hooper, February 13 - March 8, 1994

BACKGROUND

Wellstart International's Expanded Promotion of Breastfeeding (EPB) Program began working in the Central Asian region of the Newly Independent States in response to a request by the USAID Office of Health to organize a seminar on maternal and child health¹. During this conference representatives from the Ministries of Health of Kazakhstan, Kyrgyzstan, Turkmenistan, Uzbekistan, and Tajikistan identified widespread concern about breast milk contamination and insufficient milk as a serious obstacle to the promotion of optimal breastfeeding practices. In September 1993, 15 representatives from these countries attended a month-long lactation management education (LME) course at Wellstart's Corporate Headquarters in San Diego, California. In response to concerns about breast milk contamination and insufficient milk Wellstart EPB submitted a proposal for applied quantitative and qualitative research on the following topics: 1) breast milk contamination; 2) insufficient milk; and 3) maternal and health provider perceptions, attitudes, and beliefs surrounding breast milk contamination and insufficient milk, as well as other cultural factors bearing on infant feeding practices. USAID R&D Health provided an OYB transfer, PIO/t # 936-5966-3692800, for \$250,000 and USAID Almaty granted concurrence, State #387850, to carry out an applied research program over an 18-month period in Kazakhstan.

The initial research planning visit was undertaken by Dr. Chessa Lutter, Wellstart EPB's Applied Research Advisor and consultant Dr. Nicholas Hooper, Senior Scientist, Hazardous Materials Laboratory, California Environmental Protection Agency, from February 13 to March 8, 1994. During this visit,

¹See "Maternal and Child Health Seminar: Summary Report, Central Asian Regional Seminar", Almaty, Kazakhstan, January 11-14, 1993. USAID.

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USAID Almaty requested a detailed workplan and budget for the research program. In addition, a proposal and budget for as yet unfunded follow-up program activities was requested.²

OBJECTIVES OF THIS TRIP

The overall objective of this trip was to initiate on-the-ground planning for and to launch the 18-month quantitative and qualitative applied research program on breast milk contamination and insufficient milk. The specific objectives are outlined as follows: 1) review in-country laboratories for analyzing contaminants according to international standards and protocol; 2) collect samples of breast milk and cows milk for transport to the U.S. for a pilot contaminants study; and 3) suggest in-country sources for contaminants found in samples.

The contaminants research is being conducted in two phases. Phase I was completed during this trip.

OUTCOMES

1. Review of in-country laboratories

Phase I: Measuring Levels of Selected Chlorinated Contaminants (SCCs, PCBs, PCDDs, PCDFs and chlorinated insecticides)

In Kazakhstan, analyses of samples of air, water, soil, foodstuffs or human fluids/tissues for SCCs are the responsibility of a number of Ministries and their laboratories, which are listed below. We visited these laboratories and reviewed their capacities to: analyze (including minimum detection limits) samples for the chlorinated insecticides; perform trace contaminant analyses on individual congeners of the chlorinated complex mixtures (e.g. PCBs, toxaphene, PCDDs or PCDFs); achieve goals of standard QA/QC.

The laboratories reviewed were:

- a) Ministry of Health (MOH) Sanitation and Epidemiology Laboratory (water, soil, food);
- b) MOH Nutrition Institute Lab of Food Quality Control (water, foodstuffs, human fluids, breast milk);
- c) MOH Republic Research Center for Maternity and Child Care Biochemical Lab (non-chlorinated, human blood, breast milk);
- d) Ministry of Agriculture Agrochem Research Center (water, soil, plants);
- e) Cabinet of Ministers Standards Committee Kazcertico (water, soil, foodstuffs);

²A budget for expanding these activities to other republics in the Central Asian region was also requested. However, this cannot be completed without further country-specific information.

- f) Cabinet of Ministers Institute of Meteorology (sediments from air, water, soil);
- g) Ministry of Food, Republican Center for Food Quality Control: Tagam, a joint stock company (water, food);
- h) MOH Uzbekistan Research Institute of Pediatrics, Nutrition Laboratory (breast milk);
- i) Ministry of Geology, Ecohydrochem Geo (air, soil, water). (A MOH laboratory in Tashkent, Uzbekistan that was reviewed performed analyses for SCCs in breast milk.)

Please see Annex 2 for characteristics of in-country laboratories that analyze for selected chlorinated contaminants (SCCs).

Phase II: Measuring Levels of Heavy Metals and Radionuclides

Laboratories and in-country experts experienced in the analysis of heavy metal and radionuclide contaminants have been identified but have not been fully contacted: Dr. M. Ilynshchenko, Rare Elements Chair, Research Institute in Chemistry, and Dr. Irina Tazhibaeva, Chair, Research Institute for Theoretical and Experimental Physics at the Kazakhstan National State University; and with the Ministry of Health Dr. Kamil Sadikov, Chief, Central Research Laboratory of the Medical Institute; Dr. Granofsky, MOH Republic Center of Hygiene and Epidemiology Lab; Dr. B. N. Arkadjevich, Department of Hygiene for Infants and Children; and Dr. Royald Nishi, Institute of Industrial Hygiene and Occupational Health, Ust-Kamenogorsk.

2. Collection of breast milk

a. Collaborating institutions and overall research plan

Collaborating in-country institutions for the collection of breast milk were the Ministry of Health (MOH) and the Institute of Nutrition. Although the original objective of this trip was to collect samples for a pilot study, because of the excellent cooperation received from the Ministry of Health and advance preparation by Dr. Hooper, it was possible to complete data collection for the first phase of a two-phase study on breast milk contamination. Pending additional funding, the focus of this first phase is organic chlorinated contaminants, which is of concern in South Kazakhstan and the Aral and Caspian sea regions, because of industrial development and agricultural practices. Pending additional funding, the focus of the second phase will be heavy metals and radionuclides, which is of concern in the North of Kazakhstan because of mining activities, industrial development, and its previous role as the center for Soviet nuclear testing. These sites were discussed and reviewed for accuracy and completeness with MOH officials, participants in the training session, and other health, laboratory, and environmental officials Drs. Lutter and Hooper contacted during their trip.

b. Research protocol and training

The WHO/EURO protocol, "Levels of PCBs, PCDDs, PCDFs in human milk: Protocol for second round of exposure studies" was used to collect data for the first phase of the study. (A copy of this protocol and the Russian translation is provided in Annex 3.) The use of this protocol ensures that the results provided by this research will be comparable to existing international data currently being compiled by WHO/EURO. Two survey instruments were used: 1) an exposure assessment questionnaire (adapted

from the WHO protocol for use in Kazakhstan); and 2) an infant feeding questionnaire. (English and Russian copies of both questionnaires are provided in Annex 4.)

All participants signed a letter of informed consent, which was provided by the MOH. A letter of consent provided by Wellstart International was used as a basis for the MOH letter. This was a new concept for the MOH team. Informing mothers, educating them about the issues explored in the research, guiding them to informed personal choice, and assisting health officials to define their own responsibility for educating women and allowing them to choose was a remarkable example of democratization in action. English and Russian copies of the letter of informed consent are provided in Annex 4.

Twelve professionals from the MOH and Institute of Nutrition were trained in use of the protocol. The training was conducted by Drs. Lutter and Hooper at the Maternity House #3 in Almaty on February 17 and took approximately 4 hours to complete. The outline used for the training and list of participants is provided in Annex 5.

c. Clinic selection

The protocol was carried out in two clinics in Almaty, and 1 clinic in each of the following regions: Shymkent Oblast; Zhitisay District, Shymkent Oblast; Kyrov District, Shymkent Oblast; Qyzlorda Oblast; Aral District, Qyzlorda Oblast,; and Atyrau Oblast. Selection of sites was based on assessment of agricultural and industrial development and probable pathways of disbursement of target contaminants. For example, clinics in the Shymkent Oblast were selected because this area is the major cotton growing region of Kazakhstan and because of the wide use of chemical fertilizers and pesticides typically used in cotton production. Clinics in the Qyzlorda Oblast were selected because of their proximity to the Aral Sea, which is believed to be a site of major environmental damage. Detailed information about in-country sources of contamination is provided under number 3 in this report.

d. Sample collection and sampling procedures

The protocol was completed and breast milk samples (average amount 70 ml) for 8-15 women at each clinic. The protocol specifies that samples be taken from women breastfeeding their first infant and that the infant be between 2 and 8 weeks of age. Because of concern about the extent to which the women recruited by health officials to participate in the study were representative of all women who fit the selection criteria, a standardized sampling procedure was initiated during the course of data collection. Health officials were requested to provide a list of all first born infants born between the dates that corresponded to an age of 2 to 8 weeks at the time of data collection. Mothers were then randomly selected from this list to participate in the study.

At each site a sample of commonly used milk, food, and/or oil were obtained for analysis of target contaminants. Environmental samples (e.g. soil) were also obtained. Samples were frozen and transported to the Hazardous Materials Laboratory of the California Environmental Protection Agency, one of 19 laboratories certified by WHO for the analysis of PCBs, PCDDs, and PCDFs.

e. Field work outside Almaty

Data collection outside of Almaty was conducted by a five person team: Drs. Lutter and Hooper, Dr. Tamara Chuvakova (Chief Neonatologist for Kazakhstan and Wellstart Associate, Dr. Gulnara Semanova

(Chief of the Laboratory, Institute of Nutrition and Wellstart Associate, and Mrs. Antonina Solovyova, (Interpreter). Wellstart provided per diem to local members of the team and paid for transportation costs. The team traveled by train and plane. Logistical support was provided by local health officials. MOH officials in Almaty provided a letter addressed to each clinic describing the research and requesting their participation and cooperation. They also notified each clinic by phone to inform them of the study in advance.

f. Laboratory analytic plan

The analysis will be conducted in two stages. In Stage I, two to three pooled samples per clinic will be analyzed. In Stage II, individual samples will be analyzed.

Although not originally identified as an objective of this part of the study, because of concern about maternal malnutrition and insufficient milk, the samples will also be analyzed for macro and micronutrient content. Possible target nutrients for the analysis are lactose, fat, protein, vitamin A, vitamin C, and folate.

g. Breastfeeding practices in Kazakhstan: Preliminary results

Preliminary results from the infant feeding data are reported in Annex 6.

3. In-country sources of contaminants

a. Phase I: Selected Chlorinated Contaminants

The target contaminants in Phase I are the large chlorinated non-biodegradable lipophilic compounds (PCBs, PCDDs, PCDFs and chlorinated insecticides) which have been found as contaminants in breast milk in other countries. These molecules typically accumulate in the body fat of animals in the environment and are passed on to humans through the ingestion of fish, meat and dairy products.

The selection of clinics, from which breast milk samples were collected for Phase I, was based upon considerations of this contamination pathway, on the population demographics (50% of Kazakhstanis dwell in cities), and on the likely geographical distribution of target chlorinated contaminants (agriculture and fish-consuming regions) in Kazakhstan.

The sampling strategy targeted three populations: one from large urban centers (Almaty, Shymkent, Qyzylorda) to broadly represent urban populations with/without industrial exposures to PCBs, PCDDs and PCDFs; and two rural populations with potentially high exposures including those living in regions where cotton is grown and those in regions of high fish consumption.

The South Kazakhstan-Uzbekistan area is the fourth largest cotton-growing region in the world. Historically, chlorinated insecticides have had major applications on cotton. Therefore, clinics were selected in two villages in cotton-growing agricultural regions of South Kazakhstan (Djetisay and Kirov villages).

The two rivers which traverse, irrigate and receive run-off from this cotton region are the Syr Daryu in Uzbekistan/Kazakhstan and the Amu Daryu in Uzbekistan. Both rivers are major input sources for the Aral Sea. Fish taken from these waterways or the inland sea are likely to contain chlorinated insecticides

and may serve as sources of human exposure if used as food for humans or livestock. Clinics were selected in regions where fish consumption is high including the town of Aral'sk on the Aral Sea, and Atyrau on the Ural River and Caspian Sea. In addition, fish consumption is moderate (for a Moslem culture) in the cities of Shymkent and Qyzylorda, both on the Syr Darya.

b. Phase II: Heavy Metal and Radionuclide Contaminants

Priority sampling sites have been tentatively identified based upon their mining activities (coal and non-ferrous metals -- chromium, beryllium, copper, zinc), nuclear or coal-fired power plants, or chemical synthesis plants (phosphorous, mercury). They include: Ustkamenagorsk (Zyranovsk, Leninogorsk, Zaysan); Karaganda (Temirtau, Saran, Dolinka, Ekibastuz); Aktyubinsk (Khromtau); Pavlodar; Aqtau; and Petropavlovsk.

In-country experts will aid in selecting sites with potential for high exposures as well as the potential for general background exposures.

4. Integration with other planned research activities

Demographic and Health Survey (DHS): With the widespread concern about maternal nutritional status and insufficient milk, it would be extremely useful for the planned DHS study to include a module on maternal nutritional status and the collection of maternal blood samples. This will be the only opportunity to collect nationally representative data on these important topics. Care should also be taken to over-sample children under two years of age so as to have an adequate sample to thoroughly analyze breastfeeding and weaning practices. It is also important to include infants under three months of age in the sample. Wellstart has held a coordination meeting with Dr. Almoz Sharmanov about this survey and has suggested changes and additions to DHS II, the questionnaire, to ensure that results can be directly used for programmatic action.

WHO/EUROPE: This WHO protocol specifies that subjects should be nonpregnant, non-lactating women. Thus, there is no overlap between this research study, and the proposed Wellstart research.

UNICEF: The proposal by Dr. Scrimshaw includes an assessment of maternal nutritional status and infant feeding practices. Wellstart has held a coordination meeting with Dr. Scrimshaw to ensure that there is no duplication of research efforts and that all protocols and results are shared.

London School of Tropical Medicine and Hygiene: Wellstart has been in contact with the London School of Tropical Medicine and Hygiene and has suggested the addition of several questions to their survey so that questions related to maternal perceptions of insufficient milk could be explored. Wellstart will continue to seek collaboration with Dr. Ismail to ensure no duplication of effort on these topics.

LESSONS LEARNED

There are broad public health and environmental implications for monitoring breast milk for contaminants. Breast milk is a non-invasive method of sampling human adipose tissue for the presence of harmful contaminants and provides comprehensive information on environmental conditions. It also provides information on adult body burdens of contaminants. The monitoring of breast milk for contaminants is relevant for general environmental monitoring, overall public health education and safety, as well as for specific concerns related to family planning, maternal health, and infant health.

Environmental Protection

Kazakhstan is justifiably concerned about the nature and extent of environmental contamination in their country and the effects of this contamination on human health and ecological stability. Public anxiety includes fears of contamination with radioactivity, pesticides, and heavy metals.

Informal contacts with USAID contractors for environmental programs indicate that current efforts are focussed on increasing the volume and quality of existing drinking water supplies through large scale engineering projects that involve the construction of delivery and purification facilities. Few resources are devoted at this time to examining presence and levels of the environmental xenobiotics mentioned above. USAID support of this breast milk study nicely complements this engineering work by offering a unique opportunity to monitor the occurrence and levels of xenobiotics in human tissues. Biologic monitoring for xenobiotics in breast milk is a non-invasive means of sampling human adipose tissue for the presence of harmful contaminants and provides comprehensive information on the effects of environmental conditions on humans. Breast milk, unlike other human bodily fluids is willingly given. The enthusiastic response of the MOH and young mothers in Kazakhstan to this work attests to this reality. The monitoring of breast milk for contaminants is relevant to general environmental monitoring and to overall public health and safety, in addition to the specific concerns related to family planning, maternal health, and infant health.

Democratization, Privatization, and Public Health

The breast milk study is unique, providing an opportunity to further the democratization of health care. Originally inspired by comments from in-country professionals and the public, conduct of this research has galvanized the interest, participation, and support of: the population of young, first-time mothers in the initial stages of breastfeeding; of regional and local medical providers in clinics and hospitals; and of major governmental health institutions.

Population

In the absence of valid and reliable data it is not possible to estimate the contribution that breastfeeding may currently make to birth spacing. However, the researchers found that mothers' milk production appears to be good and reported practices seemed adequate during the first eight weeks. If these impressions are confirmed, we may find that breastfeeding is a key element in birth spacing. Interest in breastfeeding among mothers and health personnel is very strong and positive. Breastfeeding promotion may be a very good entry point to introduce mothers to birth spacing and other approaches to family planning.

Promotion of Optimal Breastfeeding Practices

Consumer goods, infant formulas, vaccines, and contraceptives are in short supply. Breastfeeding is an efficient response to this situation because it provides the optimal form of infant nutrition and because of its immunological and contraceptive effects. Addressing concerns about breast milk contamination and insufficient milk is an important first step in setting the stage for a comprehensive program of breastfeeding promotion.

RECOMMENDATIONS & FOLLOW-UP

1. Qualitative Research

Qualitative research on infant feeding practices, breast milk contamination, and insufficient milk by Wellstart staff Dr. Carol Baume and consultant Dr. Laurie Krieger has been completed. This research provides important information on perceived insufficient milk, infant feeding practices, and maternal and health worker beliefs about contaminants essential for future programmatic actions.

2. Phase II of Breast milk Contaminants Study

Pending additional funding, this study will focus on collection of samples for analysis of heavy metal and radionuclide contamination in Northern Kazakhstan in November 1994. Results from Phase I would be disseminated at the time that data for Phase II would be collected.

Phase II may include collection of samples for analysis of PCBs, PCDDs, PCDFs and chlorinated insecticides from two additional sites in Kazakhstan in the southern cotton-growing region which includes one rayon with eight State Farms on the Kazakhstan-Uzbekistan border, a fishing village (inaccessible during winter months) of Hambash on the Aral Sea where fish consumption remains very high. In addition, collection sites and analytic laboratories have been identified in Uzbekistan. For minimal additional cost, samples could be collected from the areas likely to be sites of high exposure to chlorinated insecticides, since these areas border Kazakhstan.

3. In-Country Laboratory Capacity

The long-term goal of building in-country analytic laboratory capacity is best served by providing training to selected Kazakhstan scientists in U.S. analytic laboratories. Given resource limitations, maximum public health impact will not be gained from large investments in new equipment but from training of scientific personnel in 6-month sabbaticals in U.S. labs and the subsequent purchasing of equipment up-grades (far cheaper and as effective). Equipment up-grades could cost as little as U.S. \$15,000 for some labs. To develop in-country capabilities, this recommendation should be considered a priority.

4. Training

Wellstart consultant, Cheryl Wickham, will be conducting a training session in EPI INFO and data analysis with the Ministry of Health and Institute of Nutrition using Phase I data.

5. Dissemination and proposed follow-up activities have been proposed in the "Workplan and Budget for 18-Month Applied Research Program and Follow-up Activities in Kazakhstan."

Formal proposals to complete the breast milk contamination study and initiate a national breastfeeding program are forthcoming.

ANNEXES

1. List of Contacts
2. Capacities of In-Country Laboratories to Analyze for Selected Chlorinated Chemicals (SCCs)
3. WHO/EURO Protocol (English and Russian Translation)
4. Questionnaires and Letter of Informed Consent
5. Outline for Training Session on Sample Procurement and Participant List
6. Breastfeeding Practices in Kazakhstan: Preliminary Results

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ANNEX 1

List of Contacts

MINISTRY OF HEALTH

Dr. Marat Ashirovich, Chief, South Kazakhstan
Dr. Sophia Ayupova
Dr. Tamara Chuvakova
Dr. Anver Maimakov, Deputy Chief, South Kazakhstan
Dr. Tamara Paltusheva

INSTITUTE OF NUTRITION

Dr. Turegeldy Sharmanov, Director
Dr. Shamil Tazhibayev, Deputy Director
Dr. Gulnara Semenova

CITY HOSPITAL OF KZYLYORDA

Dr. Mukhtar Beisov, Head Doctor
Dr. Azima Ibraeva, Chief Pediatrician

CHILDREN'S HOSPITAL AND OUT-PATIENT CLINIC #2, SHYMKENT

Dr. Farida Urazova, Chief Doctor

REGIONAL HOSPITAL OF DZHETYSAI

Dr. Amangheldy Issabekov, Chief Doctor

REGIONAL HOSPITAL AND OUT-PATIENT CLINIC, KIROV R.

Dr. Baymakhan Balghinbaev, Chief Doctor
Dr. Rosa Bakeyeva, Deputy Chief Doctor

LABORATORY ASSESSMENT

Maydan Spataeo, Chief Physician, Ministry of Health
Tyrageldy Sharmanov, Director, Ministry of Health/Nutrition Institute
Nina Kayupova, Director, Ministry of Health/Center for Maternity and Child Care
Mark Elperin, Director, Ministry of Agriculture
Neshenko Anatolyi, Director, The Cabinet of Ministers/Standards Committee
Sagen Duisenov, Director, Cabinet of Ministers/Institute of Meteorology
Lydia Chepurina, Director, Ministry of Food
Tyrsubek Kubekov, Director, Ministry of Geology
Khasan Butaev, Director, Ministry of Health (Uzbekistan)

OTHER CONTACTS

Ms. Antonina Solovyova, Interpreter
Dr. M. Sharipkanova, Deputy Director, National Maternity and Child Health Center
Ms. Marilynn Schmidt, USAID/Almaty
Ms. Patricia Buckles, USAID/Almaty
Dr. Susan Welsby, Wellstart Consultant
Dr. S.K. Bhattarai, UNICEF/Almaty
Dr. W.D. Conch, Chevron International Oil Company/Almaty

ANNEX 2

Capacities of In-country laboratories to analyze for selected chlorinated chemicals (SCCs)

Capacities of In-Country Laboratories to
Analyze for Selected Chlorinated Chemicals
(SCCs)

The names, addresses, major personnel, equipment, analytes, matrices and basic supplies for in-country SCC laboratories are summarized in Table 1.

Some summary points;

- o Many laboratories in Kazakhstan are equipped to analyze for the chlorinated pesticides and total PCBs.
- o All require outside funding to undertake these analyses.
- o Only the Nutrition Institute laboratory has experience in the work-up of human breast milk samples.
- o All the laboratories analyze for SCCs using packed-column gas chromatography systems; none use capillary columns.
- o A number of the GCs are equipped with two electron capture detectors (ECD). These machines could be modified so that they could identify analytes more quickly and efficiently. The modification consists of adapting the plumbing for two columns, enabling them to run samples simultaneously on two columns (non-polar vs polar column packing).
- o To improve resolution and decrease likelihood of background interference when analyzing for SCCs, GCs in laboratories could be retro-fitted to be able to use capillary columns (30-60 m) about \$3-4K per machine.
- o A dual ECD GCs could be retrofitted with two capillary columns as follows:
 - 1) install split/splitless injection system;
 - 2) correct pneumatic plumbing;
 - 3) install mass flow controller to control the low flow rates needed for capillary columns;
 - 4) obtain the carrier gas (He2 or H2);
 - 5) plumb for make-up gas (N2) to flow to detector;
 - 6) install capillary columns (30 or 60 M).

- o The mass detection limit (DL) for SCCs on packed columns is about 50-100 pgms. The DL for SCCs on capillary columns 1-10 pgms.
- o None of laboratories are equipped with GC/MS. Thus, they are not equipped to analyze for PCDDs and PCDFs, or for congener-specific PCBs.
- o QA/QC for laboratories was not explicit. Written data standards are needed.
- o Depending upon the volume of samples to be analyzed, data processing resources could be upgraded.
- o All the laboratories are staffed with trained and experienced personnel. During the Soviet era, these personnel benefited from interacting with scientists from other Soviet countries on a yearly basis at annual scientific meetings. With the Soviet break-up, this scientific infrastructure has been lost, and the meetings and contacts have not occurred for several years. Staff morale and scientific competence is affected by this loss of contact. A scientific infrastructure needs to be re-built, so that scientists have the opportunity to keep pace with the rapidly changing world of science.
- o A program is needed to up-date the analytical training of selected scientific personnel. This could be accomplished through 1-year traineeships in US laboratories. Trainees would return to their Kazakhstan laboratories carrying retrofit kits to upgrade their GCs. Returnees would train other lab personnel and upgrade the GCs to carry dual ECDs and capillary columns. Training personnel is the most cost-effective way to build in-country capacity for monitoring breast milk contaminants. Greater public health benefit would accrue from a training program than from expensive new equipment purchases, given resource constraints. Central Asian Republics would greatly benefit if USAID should fund such a training/equipment-upgrade program.

Lab	Institution Laboratory, Address Phone Number	Director Lab Chief Phone number
1	Ministry of Health Sanitation and Epidemiology Laboratory 24 Aunzov Str Almaty 480008 KZ 53-00-55	Chief Physician Maydan Spataeo 43-26-55 Deputy Chief Physician Rufina Ivanova 42-04-61 Deputy Chief Physician Valery Krasnikov 53-05-88 Lab Chief Lydia Kletman 53-00-55 Operator Valery Tsukerman 42-62-97

2	Ministry of Health Nutrition Institution Lab of Food Quality Control 66 Klotchkov Str. Almaty, 480008, KZ 42-26-40 42-43-12	Director Tyrageloy Sharmanov 42-26-40 Lab Chief Stanislav Piotrovsky 42-26-40
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3	Ministry of Health The Republican Research Center for Maternity and Child Care Bio-Chemical Lab 125 Lenin Ave Almaty 480020 KZ 64-68-04	Director Nina Kayupova 64-67-40 Lab Chief Amngeldy Nasyrov 64-68-07
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4	Ministry of Agriculture Agro-Chem Research Center Mamy Kaskelen Region KZ 21-29-72	Director Mark Elpenn 21-29-72 Lab Chief Elvira Chavar 21-29-72
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Lab	Institution Laboratory, Address Phone Number	Director Lab Chief Phone number
5	The Cabinet of Ministers Standards Committee, KazCertico 83 Altynsarin Str Almaty 480035 KZ 21-45-67	Director Neshenko Anatoly 21-45-67 21-27-63 Lab Chief Ludmila Kuznetsova 21-45-67 Olga Latypova 21-45-67 Tatyana Privalova 21-45-67 Leonid Pelifosov 21-45-67

6	Cabinet of Ministers Institute of Meteorology 32 Abai Ave Almaty 480072 KZ 69-64-17	Director Sagen Duisenov 62-39-80 Chief, Environment Control Edward Pozdnyak 69-54-73 69-64-17
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7	Ministry of Food Republican Center for Food Quality Control Laboratory of Food Quality Control Tagan (Joint-Stock Company) 92 Internationalnaya Str Almaty 480012 KZ 63-94-94	Director Lydia Chepurina 63-94-94 62-18-94 Lab Chief Batims Isabekova 62-25-24
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8	Ministry of Geology EccoHydroChem:Geo 68/74 Abai Ave Almaty 480008 KZ 42-15-86 42-74-27	Director Tyrsyubek Kubekov 42-15-86 42-54-36 Chief of Lab Sofia Abyazova 42-74-27
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9	Ministry of Health (Uzbekistan) Research Institute of Pediatrics Nutrition Laboratory 3 Second Str Chimbae Tallant, UZ (3712) 29-45-05	Director Khasan Butaev (3712) 29-45-05 (work) 67-85-11 (home)
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Lab	Gas Chromatography					Detectors			Columns: Packing Materials				
	Name	Model	Country	Year	Run	EC	TE	FID	SE-30	OV1	OV17	Chrom5	Cap
1	Tsret	106	Russia	1980	+	+	+	+	+	+	+	+	-
	Tsret	550	Russia	1987	+	+	+	+	+	+	+	+	-
	Kristall	2000	Russia	1991	+	+	+	+	+	+	+	+	+
	LHM	80	Russia	1986	+	+	-	-	+	+	+	+	-
2	Varian	3700	Russia	1978	+	+	-	-	-	OV101	-	-	-
	Tsret	50	Russia	1991	+	+	-	-	-	-	-	-	-
3	Chromo	5	Czech	1985	+	-	+	-	-	-	-	+	-
4	Tsret	500	Russia	1990	+	+	-	-	+	-	+	+	+
	Tsret	100M	Russia	1989	+	-	-	+	+	-	-	-	-
	Paiunikum		UK	1970	+	+	-	-	+	-	-	-	-
5	Chromo	370	Russia	1986	+	+	-	+	+	-	+	-	+
6	Tsret	550	Russia	1991	+	+	+	+	+	-	-	-	-
	Tsret	1006	Russia	1991	-	-	-	-	-	-	-	-	-
	Tsret	106	Russia	1985	+	+	+	-	+	-	-	-	-
7	Varian	3700	Russia	1988	+	+	+	-	-	OV210	-	-	-
8	Tsret	550	Russia	1990	+	+	+	-	+	+	+	+	+
	Tsret	550	Russia	1990	+	-	+	-	+	+	+	+	+
	LXM	8	Russia	1978	+	-	+	-	+	-	-	+	+
	Chromo	5	Czech	1980	+	-	+	-	+	-	-	-	+
9	Chromo	1106	Ukraine	1985	+	+	-	-	+	-	+	-	+

Lab	Chlorinated Chemicals						Matrices					Stnds	Carrier Gas				
	DDT	Hep	HCH	Lin	PCB	Dxn	A	W	S	F	H		He	N ₂	Ar	H ₂ O	filter
1	+	+	+	+	+	-	-	+	+	+	-	KZ	-	+	+	-	-
	+	+	+	+	+	-	-	+	+	+	-	KZ	-	+	+	-	-
	+	+	+	+	+	-	-	+	+	+	-	KZ	-	+	+	-	-
	+	+	+	+	+	-	-	+	+	+	-	KZ	-	+	+	-	-
2	+	+	+	+	+	-	-	+	-	+	+	KZ	-	-	+	-	+
	+	+	+	+	+	-	-	+	-	+	+	KZ	-	-	+	-	+
3	-	-	-	-	-	-	-	-	-	-	+	Fatty A	-	+	-	-	-
4	+	+	-	+	-	-	-	+	+	-	A/P	US/Czech	-	-	+	-	-
	-	-	-	-	-	-	-	+	+	-	A/P	US/Czech	+	-	+	-	-
	+	+	-	+	-	-	-	+	+	-	A/P	US/Czech	-	-	+	-	+
5	+	+	+	+	-	-	-	+	+	+	-	KZ	-	+	-	+	-
6	+	-	+	-	-	-	+	+	+	-	-	KZ	-	+	-	-	-
	-	-	-	-	-	-	-	+	+	+	-	KZ	-	-	-	-	-
	+	-	+	-	-	-	+	+	+	-	-	KZ	-	+	-	-	-
7	+	+	-	+	-	-	-	+	-	+	-	KZ	-	+	+	-	+
8	-	-	-	+	-	-	-	+	+	-	-	KZ	-	-	+	-	+
	-	-	-	-	-	-	-	+	+	-	-	KZ	-	-	+	-	+
	-	-	-	+	-	-	+	+	-	-	-	KZ	-	-	+	-	+
	-	-	-	-	-	-	-	+	+	-	-	KZ	-	-	+	-	+
9	+	-	+	-	+	+	-	-	-	-	+	KZ	-	+	-	-	-

ANNEX 3

WHO/EURO Protocol (English and Russian translation)



World Health Organization
Regional Office for Europe

Levels of PCBs, PCDDs and PCDFs in human milk

Protocol for second round
of exposure studies

May 1992

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1. Introduction

Chlorinated hydrocarbons such as polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) are globally distributed in the environment and people are exposed inadvertently to them from numerous sources, of which foodstuffs are the most important. These compounds are lipid-soluble, poorly eliminated and are therefore accumulated and stored in human adipose tissues. They can pass through the placenta causing exposure of the foetus, and their existence in human milk exposes infants during the lactating period.

Since the first findings of these chemicals in human milk were published, the WHO Regional Office for Europe (WHO/EURO) has been coordinating a programme in collaboration with other international organizations and national institutions aimed to evaluate the possible health risks especially in infants and to control and prevent environmental exposure. In 1987, based on available research data on exposure levels and on toxicity and health effects, an expert group invited by WHO/EURO made an assessment of the health risks in infants associated with contamination of human milk. They concluded that at the levels generally found in human milk, a safety margin exists, although rather limited, and taking into account the many proven and universally accepted advantages of breastfeeding for the developing infant, it was strongly recommended to encourage and promote breastfeeding under all circumstances.

Since the database utilized for this first health risk assessment in infants was rather limited, WHO/EURO has developed several projects to produce more reliable data as a basis to improve this assessment. These include the exposure studies on levels of these chemicals in human milk, the first round of which took place in 1987-88. These studies have produced new exposure data from different areas, and in many countries represented the first data of its kind.

In order to improve the reliability and comparability of analytical data from different laboratories, WHO/EURO has also been coordinating interlaboratory quality control studies. The second round of the studies which included analysis of human milk and blood, was completed in 1989 with partici-

gation of 19 laboratories, and a consultation to evaluate the results and qualify the laboratories was held in 1990. This was the first time laboratories have been qualified to perform these analyses.

In 1990 WHO/EURO also organized an expert consultation to evaluate the feasibility of epidemiological studies on adverse health effects in infants. Another consultation reviewed the available research data and established a tolerable daily intake (TDI) from food of 2,3,7,8-tetraCDD, which is the congener on which most of the research data is based. This was the first time that a TDI had been set for this compound. The consultation recommended that in order to improve this assessment, new exposure data should be collected on other PCDD and PCDF congeners as well as on PCBs and other toxic halogenated compounds to which people are exposed either from the environment or through food. Scientific data on toxicity and kinetics of these chemicals is also needed.

The third round of the interlaboratory quality control studies, which has been expanded to include cows' milk and fish in addition to human milk and blood, is taking place in 1991-92. A list of laboratories qualified through that round to analyse for PCDDs, PCDFs and PCBs (including the potentially more toxic planar PCBs), will be available in autumn 1992. The second round of the exposure studies, for which the present protocol has been prepared, will also collect data on levels of the planar PCBs. This round is being planned and coordinated by a coordinating committee established by WHO/EURO.

Both the quality control and exposure studies are closely linked to the European component of the UNEP/FAO/WHO GEMS/food programme and data emanating from these studies will be utilized by that programme.

WHO/EURO urges all countries to participate in the second round of exposure studies in order to produce more reliable exposure data for risk assessment, to obtain a good overview of exposure levels and trends in different areas of the Region, and to identify any specific populations for further follow-up.

2. Aims of study

The planned study has the following main aims:

- to produce more reliable and comparable data on levels of PCBs, PCDDs and PCDFs in human milk for further improvement of health risk assessment in infants
- to determine trends in exposure levels in the countries and areas already studied during the first round of the studies during the period 1986-88, for the evaluation of applied risk management measures
- to provide a better overview of exposure levels in various countries and geographical areas
- to improve exposure data by including planar PCBs in the study, in addition to PCDD, PCDF and other PCB congeners
- to identify highly exposed local populations for immediate risk management actions, including epidemiological follow-up studies
- to promote, if necessary, additional national studies to be closely linked with the present studies through use of the same protocol.

In view of the costs, this study has been designed to serve as a descriptive study and does not therefore aim to obtain information on interactions between dietary intake and exposure levels of PCBs, PCDDs and PCDFs.

3. General principles

The guidelines set out in this protocol should be followed by each country participating in the study. The protocol used in the first round of the studies has been slightly modified by the coordinating committee. However, as few changes as possible have been introduced to ensure that the data collected can be compared with those from the first round, thus providing information on trends in the various areas.

Only data submitted through the national coordinators will be accepted by WHO/EURO for inclusion in the study.

4. Organization of study

4.1 Type of samples Since this protocol has been developed to give comparable results with those from the first round of the studies, pooled milk samples should again be used. If individual samples were used in the first round, such samples may again be used and the average of the individual results should be reported.

4.2 Number of samples/
sampling locations Milk from well-defined groups of mothers living in at least two areas with different exposure levels should be collected and pooled. At least two different groups from each country should be included in the study, e.g. expected high exposure group and low exposure group (highly polluted/unpolluted areas). Those countries which participated in the first round of the studies must collect samples from exactly the same locations as in the first round for purposes of comparison.

Additional areas with potentially high exposure levels are recommended to be included. Such highly polluted areas could be found in the vicinity of incinerators, pulp and paper industries and metal industries, as well as areas where the population has a high fish consumption. A careful description of the selected areas, e.g. regarding habitation, pollution sites, and industry, is very important. Each milk pool should contain milk from at least 10 mothers.

- 4.3 Selection of donors
- Donors should be primiparae.
 - Both mother and child should be apparently healthy, and the pregnancy should have been normal.
 - The mother should be breastfeeding one child only (i.e. no twins).
 - Mothers who have resided outside the area for more than 6 months during the last 5 years should be excluded.
 - Only mothers who are exclusively breastfeeding should be included.

In order to be able to determine trends in exposure levels, it is very important that the profile of the donating mothers is

similar to the group of mothers from the first round of the studies. To ensure this, the national coordinators should examine the questionnaires from the first round and base the selection of mothers for the present study on those results. In the case that such questionnaires are not available since this is the first time that the study is being carried out in the country, the mothers can be selected randomly with the above reservations. In all cases, however, the attached questionnaire should be used.

4.4 Methods for collecting, storing and transporting of samples

Breastfeeding mothers living in areas of different expected levels of exposure should be recruited at or from contact places (maternal and/or child clinics). They should be included only after having received both verbal and written information and given written consent. Individual interviews should be carried out using the attached questionnaire (see also 4.5 below). Mothers should be given a carefully decontaminated bottle for the milk sample and instructed on how to collect the milk. They should also be given a copy of the attached detailed instructions for sampling, storing and transporting of milk samples (Annex 1). Sampling should be carried out between 2 weeks and 2 months after delivery.

When pooled samples are used, at least 50 ml of milk must be collected from each mother. When individual milk samples are used in the studies, the collected amount depends on the demands of the analytical procedure, but a minimum of 350 ml is recommended. The portions collected during each feeding should be added to the collecting bottle and stored in the home freezer until the total volume has been collected (in a thick-walled 100 ml glass bottle with a teflon-lined screw cap). Subsamples should be homogenized (shaking for 10 min.) before pooling.

4.5 Questionnaire

The attached questionnaire (Annex 2) should be used as the basis for the interview with the donating mother (see 4.3 and 4.4 above) and its completion is compulsory.

The completed individual questionnaires should be sent to WHO/EURO for possible additional use within this study. They will also be important in identification of similar groups for an eventual third round of the studies, to ensure reliable results for determination of exposure trends. The summary of

the questionnaires for each pool (form sent separately to the national coordinators) should be completed by the coordinators and returned to WHO/EURO together with the individual questionnaires and exposure results.

4.6 Pooling Pooling should be done on volume basis by using 50 ml of collected milk from each mother.

4.7 Analysis The pooled milk samples should be analysed for three groups of compounds, i.e. normal PCBs, dioxin-like PCBs, and PCDDs/PCDFs. Annex 3 lists the individual congeners of each group of chemicals which should be analysed for and reported as a minimum requirement. Reporting forms are sent separately to the national coordinators.

Only those laboratories which have been qualified through the second or third rounds of the WHO/EURO interlaboratory quality control studies may be used to perform the analyses of the collected milk samples. The list of laboratories qualified through the second round of studies is attached as Annex 4. A list of those which qualify through the ongoing third round will be made available to the national coordinators in autumn 1992.

To assist those countries which need qualified analytical service, WHO/EURO will negotiate with those qualified laboratories included on the attached list, in order to select, for each group of compounds, a laboratory which will carry out analyses of samples from those countries.

The results should be calculated both on whole milk and milk fat basis. The fat content of the milk pool should be determined by the analysing laboratory using their own method. Furthermore, a sample of each pool should be sent to the reference laboratory selected by the Coordinating Committee for fat analysis in order to improve the reliability of results. Results should be reported to WHO/EURO using the reporting forms developed by the Coordinating Committee and sent separately to the national coordinators.

Shipping of the samples to the selected analytical laboratory should be carried out strictly in accordance with the attached instructions (Annex 1) in order not to damage the samples. The remaining milk should be stored deep-frozen for further analysis.

5. Ethics The results of this study are expected to strengthen the factual basis for constructive debate on the benefits and risks of breastfeeding.

6. Costs Each country is responsible for the costs of sample collection, shipping and analysis, and makes payments for analysis direct to the analysing laboratory. The costs of further statistical analysis of the exposure data and data gathered through the questionnaire, the costs of meetings of the coordinating committee and the consultation to evaluate the results, as well as publication costs, will be covered from other sources.

7. Coordination of study The WHO Regional Office for Europe will coordinate this study and has for this purpose established a coordinating committee with the following membership:

Professor Ulf Ahlborg, National Institute of Environmental Medicine, Stockholm, Sweden (toxicologist)

Ms Patricia Christensen, WHO/EURO (programme assistant)

Professor Ferdinand Haschke, University of Vienna, Vienna, Austria (paediatrician)

Dr Martin Nygren, FOA Research Establishment, Umea, Sweden (analytical chemist)

Dr Erkki Yrjänheikki, National Board of Labour Protection, Tampere, Finland (overall coordinator on behalf of WHO/EURO)

All results from participating countries will be collected and summarized by WHO/EURO in accordance with the decisions of the coordinating committee. Any WHO/EURO publications will be cleared by the national coordinators, however, each country is free to publish its own results.

Annex 1

Instructions for sampling, storing and transporting of samples

- The breast pump needs to be provided free of contamination. The mothers themselves should do no more than rinse the pump container with water and, if desired, boil it to avoid contamination from soap. However, since this can lead to bacterial contamination, care must be taken that the mothers do not use these pumps for private use, collecting milk for consumption by the baby without the pump first having been washed and sterilized.
 - The collecting bottle needs to be provided free of contamination. It needs to be thoroughly washed, rinsed and given a final acetone rinse before delivery to each mother. The mothers are not to do anything to these bottles.
 - The bottle should preferably be made of Pyrex glass, the cap should either have Teflon lining or be made of polyethylene.
 - The bottle with collected milk should be kept in the home freezer until the total amount from the mother has been collected, i.e. the portions collected during each feeding should be added to that bottle. Once frozen the milk should not be allowed to thaw.
 - No other vessel is to be used for collecting milk. Mothers must not use cups or other bottles they may have at home. Should they prefer to use manual lactation, the milk needs to be collected directly into the furnished bottle or in the collecting container that comes with the pumps.
 - The breast and hands should be kept as clean as possible, yet soap should be avoided as much as possible. When necessary to use soap, the breasts and hands should be thoroughly rinsed.
 - Should it be necessary to use ointments on the nipples because of soreness or tenderness, this should be done outside of sampling time and the ointment removed prior to sampling.
 - The ideal method to reduce problems of contamination from both soap and ointments is to provide the mothers with soap for personal hygiene and for dishwashing that has already been tested for possible contamination and found to be free thereof. The same holds true for ointments that can be used on the breast.
 - When sending the samples for analysis the package should be marked clearly "human milk samples", and the receiving institution should be notified giving precise details of delivery (airwaybill no., time, parcel number, etc.)
-
-

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World Health Organization
Regional Office for Europe

QUESTIONNAIRE

to mothers donating breast milk for analysis
of PCBs, PCDDs and PCDFs

CONFIDENTIAL!

1. Sample identification code:	2. Samples collected from DDMMYY				to DDMMYY				3. Date completed: DDMMYY									
4. Mother's age in years:	5. Mother's height in cm:				6. Mother's weight before pregnancy in kgs:				7. Mother's weight just prior to delivery in kgs:									
8. Area of residence during last 5 years:												urban	<input type="checkbox"/>	suburban	<input type="checkbox"/>	rural	<input type="checkbox"/>	
9. Previous area of residence: Years												<input type="checkbox"/>	urban	<input type="checkbox"/>	suburban	<input type="checkbox"/>	rural	<input type="checkbox"/>
and before: Years												<input type="checkbox"/>	urban	<input type="checkbox"/>	suburban	<input type="checkbox"/>	rural	<input type="checkbox"/>
10. Child's age in weeks at start of sampling:			11. Child's sex:			12. Child's weight at birth in grammes:			13. Child's weight at time of sampling in grammes:									
			boy <input type="checkbox"/> girl <input type="checkbox"/>															
14. Mother's dietary habits:												mixed diet	<input type="checkbox"/>	vegetarian, but with milk and eggs	<input type="checkbox"/>	strictly vegetarian	<input type="checkbox"/>	
other <input type="checkbox"/> give details: _____																		
15. Has the mother changed dietary habits markedly since the start of pregnancy?												no	<input type="checkbox"/>	yes	<input type="checkbox"/>			
if yes, state how: _____																		
16. How often, on average, does she eat fish and other seafood, including cold fish?												never	<input type="checkbox"/>	less than once a week	<input type="checkbox"/>	once a week	<input type="checkbox"/>	
twice a week <input type="checkbox"/> more than twice a week <input type="checkbox"/>																		
if twice a week or more, state the species she consumes most often: _____																		

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consume milk and milk products? never twice or less a week

more than twice a week but not every day every day

Fat content: low-fat (0.5-1.9%) medium-fat (2.0-2.9%) high-fat (3.0% or more)

Consumption per day: less than 250 ml a day 250-499 ml a day 500 ml or more a day

18. How often, on average, does she consume cheese? never twice or less a week

more than twice a week, but not every day every day

Fat content: low-fat high-fat

19. How often, on average, does she eat beef? never less than once a week once a week

twice a week more than twice a week

20. Current smoking habits: Non-smoker (has never smoked) Ex-smoker Smoker

if smoker, what does she smoke? Cigarettes Cigars/ceruttes Pipe

if cigarettes, how many per day? if cigars/ceruttes, how many per day?

21. Present type of work: _____

22. Present workplace: urban suburban rural

23. Duration in years: _____

24. Previous types of work: _____

25. Previous workplaces: urban suburban rural

26. Durations in years: _____

urban suburban rural

27. Kinds of medicine taken during sampling period:

28. Questionnaire completed by: (TYPE NAME) _____ Date: _____ Signature: _____

Annex 3

List of individual congeners of PCBs, PCDDs
and PCDFs to be analysed

Normal PCBs

IUPAC No. 23
IUPAC No. 52
IUPAC No. 101
IUPAC No. 138
IUPAC No. 153
IUPAC No. 180

Dioxin like PCBs

IUPAC No. 77
IUPAC No. 105
IUPAC No. 118
IUPAC No. 126
IUPAC No. 169

PCDDs

2,3,7,8-TCDD
1,2,3,7,8-PeCDD
1,2,3,6,7,8-HxCDD
1,2,3,4,7,8-HxCDD
1,2,3,7,8,9-HxCDD
1,2,3,4,6,7,8-HpCDD
1,2,3,4,6,7,8,9-OCDD

PCDFs

2,3,7,8-TCDF
1,2,3,7,8-PeCDF
2,3,4,7,8-PeCDF
1,2,3,6,7,8-HxCDF
1,2,3,4,7,8-HxCDF
1,2,3,7,8,9-HxCDF
2,3,4,6,7,8-HxCDF
1,2,3,4,6,7,8-HpCDF
1,2,3,4,7,8,9-HpCDF
1,2,3,4,6,7,8,9-OCDF

Annex 4

Laboratories qualified for analysis through
second round of WHO/EURO interlaboratory
quality control studies on levels of PCBs,
PCDDs and PCDFs in human milk and blood

(showing responsible persons - listed in alphabetical
order of countries)

A. Laboratories qualified
for analysis of PCBs in
human milk

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in human milk

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Всемирная организация
здравоохранения
Европейское региональное
отделение

УРОВНИ СОДЕРЖАНИЯ
ПХБ, ПХЦД и ПХДФ
В ЧЕЛОВЕЧЕСКОМ МОЛОКЕ

Протокол второго раунда
исследований по воздействию

Май 1992 г.

Настоящий документ является протокольным переводом документа ВОЗ/ЕВРО и
используется с ее разрешения.

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ПРИЛОЖЕНИЕ 1: Инструкции по отбору проб, хранению и транспортировке проб

ПРИЛОЖЕНИЕ 2: Анкета для матерей-доноров грудного молока на анализ на ПХБ, ПХЦД и ПХЦФ

ПРИЛОЖЕНИЕ 3: Перечень подлежащих анализу индивидуальных аналогов ПХБ, ПХЦД и ПХЦФ

ПРИЛОЖЕНИЕ 4: Перечень лабораторий, аттестованных для проведения анализа на ПХБ, ПХЦД и ПХЦФ в рамках второго раунда межлабораторных исследований по контролю качества ВОЗ/ЕВРО по уровням содержания ПХБ, ПХЦД и ПХЦФ в человеческом грудном молоке и крови

1. ВВЕДЕНИЕ

Хлорированные углеводороды, такие как полихлорированные бифенилы (ПХБ), полихлорированные дибензо-п-диоксины (ПХЦД) и полихлорированные дибензофураны (ПХЦФ) повсеместно распространены в окружающей среде, а люди неизбежно подвержены их воздействию из многочисленных источников, важнейшими из которых являются продукты питания. Эти вещества растворимы в жидкостях, трудно уничтожимы и, следовательно, накапливаются и откладываются в жировых тканях человека. Они могут проникать через плаценту, оказывая воздействие на плод, а их присутствие в человеческом грудном молоке подвергает их воздействию новорожденных в период грудного кормления.

С тех пор как впервые были опубликованы исследования о содержании этих веществ в человеческом грудном молоке, Европейское региональное отделение ВОЗ (ВОЗ/ЕВРО) занимается координацией программы в сотрудничестве с другими международными организациями и национальными институтами, направленной на выявление потенциального риска для здоровья, особенно для здоровья грудных детей, а также для контроля и предотвращения воздействия этих веществ на окружающую среду. В 1987 г. на основе имеющихся данных исследований уровней воздействия, а также токсичности и влияния на здоровье, приглашенная ВОЗ/ЕВРО группа экспертов провела оценку риска для здоровья грудных детей, связанного с загрязнением грудного молока. Они сделали вывод, что при обычных уровнях содержания этих веществ в грудном молоке существует определенный, хотя и ограниченный запас безопасности, и учитывая многочисленные доказанные и повсеместно признанные преимущества грудного вскармливания растущего младенца, было настоятельно рекомендовано поощрять грудное вскармливание и содействовать ему при всех обстоятельствах.

Так как база данных, использованная в ходе этой первой оценки риска для здоровья грудных детей, была достаточно ограниченной, ВОЗ/ЕВРО разработала ряд проектов с целью получения более надежных данных в качестве основы совершенствования такой оценки. Они включают исследования по воздействию на уровни содержания этих веществ в человеческом грудном молоке, первый раунд которых состоялся в 1987-88 гг. В результате этих исследований были получены новые данные о воздействии из различных регионов, причем во многих странах они представляли собой первые данные такого рода.

Для совершенствования надежности и сопоставимости аналитических данных из различных лабораторий ВОЗ/ЕВРО также координирует межлабораторные исследования по контролю качества. Второй раунд этих исследований, который включал анализ человеческого грудного молока и крови, был завершен в 1989 году при участии 19 лабораторий, а консультации по оценке результатов и аттестации лабораторий прошли

в 1990 году. Тогда впервые лаборатории были аттестованы по проведению таких анализов.

В 1990 году ВОЗ/ЕВРО также организовала консультации экспертов по оценке целесообразности эпидемиологических исследований в области отрицательного риска для здоровья грудных детей. В рамках других консультаций были проанализированы имеющиеся исследовательские данные, и была установлена норма предельно допустимого ежедневного потребления (ДЕП) из пищи 2,3,7,8-тетраХЦД, на котором основаны большинство исследовательских данных. Тогда впервые была установлена норма ДЕП по этому веществу. В рамках консультаций было рекомендовано, что для совершенствования этой оценки необходимо собрать новые данные по воздействию других однородных ПХЦД и ПХЦФ, а также ПХБ и других токсичных галогенированных составов, воздействию которых подвергаются люди либо через окружающую среду, либо через пищу. Кроме того, необходимы научные данные о токсичности и кинетике этих веществ.

Третий раунд межлабораторных исследований в области контроля качества, который был расширен и включал работы по коровьему молоку и рыбе, кроме человеческого грудного молока и крови, проходит в 1991-92гг. Перечень лабораторий, аттестованных в ходе этого раунда для проведения анализов по ПХЦД, ПХЦФ и ПХБ (включая потенциально более токсичные линейные ПХБ), будет опубликован осенью 1992 года. Второй раунд исследований воздействия, в рамках которого подготовлен настоящий протокол, также осуществит сбор данных по уровням содержания линейных ПХБ. Этот раунд планируется и координируется координационным комитетом, созданным ВОЗ/ЕВРО.

Исследования по контролю качества и по воздействию тесно связаны с европейским компонентом продовольственной программы ЮНЕП/ФАО/ВОЗ/ГЕМС, и полученные в результате этих исследований данные будут использованы в этой программе.

ВОЗ/ЕВРО призывает все страны принять участие во втором раунде исследований по воздействию для получения более надежных данных о воздействии для проведения оценки риска, для получения обзорных данных по уровням воздействия и тенденциям в различных областях Региона, а также для выявления конкретных групп населения для последующих исследований.

2. ЦЕЛИ ИССЛЕДОВАНИЯ

Запланированное исследование ставит перед собой следующие основные цели:

- * сбор более надежных и сопоставимых данных по уровням ПХБ, ПХЦД и ПХЦФ в человеческом грудном молоке для дальнейшего совершенствования оценки риска для здоровья младенца

- * определение тенденций в уровнях воздействия в странах и районах, изученных в ходе первого раунда исследований в период 1986-88 гг., для оценки практических мер управления риском
- * получение более полной картины, характеризующей уровни воздействия в различных странах и географических районах
- * совершенствование данных по воздействию путем включения в исследование линейных ПХБ, в дополнение к ПХЦД, ПХЦФ и других однородных ПХБ
- * выявление местных популяций с высокой степенью воздействия для принятия немедленных мер управления риском, включая последующие эпидемиологические исследования
- * поощрение при необходимости дополнительных национальных исследований, которые должны быть тесно связаны с нынешними исследованиями и должны использовать тот же протокол.

По соображениям стоимости данное исследование носит дескриптивный характер и, следовательно, не нацелено на выявление информации о взаимосвязи между приемом пищи и уровнями воздействия ПХБ, ПХЦД и ПХЦФ.

3. ОБЩИЕ ПРИНЦИПЫ

Изложенные в настоящем протоколе основные направления должны выполняться всеми принимающими участие в исследовании странами. Координационный комитет несколько изменил протокол, использованный в первом раунде исследований. Однако минимальное количество изменений было внесено для обеспечения сопоставимости данных, собранных в ходе этого раунда, с данными первого раунда, тем самым представляя информацию о тенденциях в различных районах.

ВОЗ/ЕВРО будет принимать для включения в исследования только те данные, которые представляются через национальных координаторов.

4. ОРГАНИЗАЦИЯ ИССЛЕДОВАНИЯ

4.1 Виды проб

Так как разработанный протокол предназначен для получения результатов, сопоставимых с данными первого раунда исследований, необходимо использовать пробы молокофонда. Если в первом раунде использовались индивидуальные пробы, они могут использоваться повторно, а в отчет должны включаться средние показатели по индивидуальным результатам.

4.2 Число проб/места сбора проб

Следует осуществлять сбор и создавать фонд молока, взятого у четко разграниченных групп матерей, проживающих по крайней мере в двух районах с различными уровнями воздействия. В исследование следует включать по крайней мере две различных группы от каждой страны: например, группа с ожидаемым высоким уровнем воздействия и группа с низким уровнем воздействия (районы высокого загрязнения/незагрязненные районы). Страны, которые участвовали в первом раунде исследований должны для сопоставления предоставить пробы из абсолютно тех же мест, что и в рамках первого раунда.

Рекомендуется включать дополнительные районы с потенциально высокими уровнями воздействия. Такие сильно загрязненные районы можно обнаружить вблизи пунктов сжигания отходов, мануфактурных фабрик и металлургических заводов, а также в местах высокого потребления населением рыбных продуктов питания. Чрезвычайно важно представлять подробное описание выбранных районов, например, в том, что касается населения, источников загрязнения и промышленных объектов. Каждый молокофонд должен содержать молоко по крайней мере от десяти матерей.

4.3 Отбор доноров

- * Доноры должны быть первороженницами.
- * Мать и ребенок должны быть в общем здоровыми, а беременность должна была протекать нормально.
- * Мать должна кормить грудью только одного ребенка (т.е. не близнецов).
- * Следует исключить матерей, проживавших за пределами обследуемого района более шести месяцев за последние пять лет.
- * Следует включать только тех матерей, которые осуществляют исключительно грудное вскармливание.

Для того, чтобы иметь возможность выявить тенденции в уровнях воздействия, чрезвычайно важно, чтобы характеристика матерей-доноров была сходна с характеристикой групп матерей из первого раунда исследований. Для обеспечения этого национальные координаторы должны проанализировать анкеты из первого раунда и основывать отбор матерей для настоящего исследования на их результатах. Если такие анкеты отсутствуют в связи с тем, что подобное исследование проводится в стране впервые, матерей можно отбирать методом случайной выборки, учитывая выше упомянутые условия. Однако во всех случаях следует использовать прилагаемую анкету.

4.4 Методы сбора, хранения и транспортировки проб

Кормящие грудью матери, проживающие в районах с различными ожидаемыми уровнями воздействия, должны набираться в пунктах контакта или через такие пункты (клиники матери и/или ребенка). Они могут быть включены только при получении ими устной и письменной информации и с их согласия в письменной форме. Индивидуальные собеседования должны проводиться с использованием прилагаемой анкеты (см. также п. 4.5 ниже). Матери должны получить дезинфицированную бутылку для сдачи пробы молока и проинструктированы о том, как собирать молоко. Они также должны получить экземпляр прилагаемых детальных инструкций отбора проб, хранения и транспортировки молока (Приложение 1). Отбор проб должен осуществляться в период от 2 недель до 2 месяцев после родов.

Когда используются пробы молокофонда, от каждой матери следует собрать, как минимум, 50 мл молока. Когда в исследованиях используются индивидуальные пробы молока, собранное количество зависит от потребной аналитической процедуры. Однако рекомендуется собирать, как минимум, 350 мл. Собранные в ходе каждого кормления порции должны добавляться в сборную бутылку и храниться в домашнем морозильнике до достижения полного объема (бутылка со стенками из толстого стекла объемом 100 мл с завинчивающейся пробкой с тефлоновым покрытием). Подпробы должны быть гомогенизированы (методом взбалтывания в течении десяти минут) перед замораживанием.

4.5 Анкета

Прилагаемая анкета (Приложение 2) должна браться за основу при проведении интервью с матерью-донором (см. п. 4.3 и п. 4.4 выше), заполнение анкеты носит обязательный характер.

Заполненные индивидуальные анкеты должны направляться в ВОЗ/ЕВРО для возможного дальнейшего использования в ходе исследования. Они также будут играть важную роль при определении аналогичных групп для последующего третьего раунда исследований, для обеспечения надежных результатов выявления тенденций воздействия. Сводные данные по анкетам каждого молокофонда (форма направляется отдельно национальным координаторам), составляются координаторами и возвращаются в ВОЗ/ЕВРО вместе с индивидуальными анкетами и результатами воздействиями.

4.6 Формирование молокофондов

Молокофонды должны формироваться по объему в 50 мл собранного молока от каждой матери.

4.7 Анализ

Собравшие в молокофонд пробы следует подвергать анализу на наличие трех групп составов, т.е. нормальных ПХБ, диоксиноподобных ПХБ и ПХДЦ/ПХДФ. В Приложении 3 приводится список индивидуальных представителей каждой группы химических веществ, на которые следует проводить анализ и данные о которых, как минимум, должны включаться в отчет. Формы отчетности рассылаются отдельно национальным координаторам.

Для анализа собранных проб молока могут использоваться только те лаборатории, которые прошли аттестацию в ходе второго или третьего раунда исследований ВОЗ/ЕВРО по межлабораторному контролю качества. Перечень аттестованных в ходе второго раунда исследований лабораторий приводится в Приложении 4. Перечень лабораторий, аттестуемых в рамках проходящего третьего раунда, будет представлен национальным координаторам осенью 1992 г.

Для содействия странам, нуждающимся в квалифицированных аналитических услугах, ВОЗ/ЕВРО проведет переговоры с включенными в прилагаемый перечень аттестованными лабораториями с целью отбора по каждой группе составов той лаборатории, которая будет проводить анализ проб из этих стран.

Расчет результатов должен производиться на основе цельного молока и молочного жира. Жировое содержание молокофонда должно определяться анализирующей лабораторией с использованием собственных методов. Далее, для совершенствования надежности получаемых результатов проба от каждого молокофонда должна направляться в отобранную Координационным Комитетом справочную лабораторию для анализа на жировое содержание. Результаты должны сообщаться в ВОЗ/ЕВРО с использованием форм отчетности, разработанных Координационным Комитетом и рассылаемых отдельно национальным координаторам.

Пересылка проб в отобранные аналитические лаборатории должна проводиться в строгом соответствии с прилагаемыми инструкциями (Приложение 1), чтобы не повредить пробы. Остатки молока следует продолжать хранить в сильно замороженном состоянии для последующих анализов.

5. ЭТИКА

Ожидается, что результаты настоящего исследования укрепят фактуальную основу для конструктивных споров о положительных сторонах и риске грудного вскармливания.

6. ЗАТРАТЫ

Каждая страна несет ответственность за затраты, связанные со сбором проб, их перевозкой и анализом, и оплачивает расходы по анализу непосредственно

анализирующим лабораториям. Стоимость дальнейшего статистического анализа данных по воздействию и данных, собранных посредством анкет, расходы на проведение встреч координационного комитета и консультаций по оценке результатов, а также расходы на публикации будут покрываться из других источников.

7. КООРДИНАЦИЯ ИССЛЕДОВАНИЯ

Региональное европейское отделение ВОЗ будет координировать это исследование и с этой целью создало координационный комитет в следующем составе:

Профессор Ульф Алберг, Национальный Институт Экологической Медицины, Стокгольм, Швеция (токсиколог)

Г-жа Патриция Кристенсен, ВОЗ/ЕВРО (помощник по проведению программы)

Профессор Фердинанд Хашке, Венский университет, Вена, Австрия (педиатор)

Д-р Мартин Нюгрэн, Исследовательский Центр FOA, Урнеа, Швеция (химик-аналитик)

Д-р Эрки Ирьянхейкки, Национальный Совет по защите Труда, Тампере, Финляндия (общий координатор от ВОЗ/ЕВРО)

Все результаты стран-участниц будут собраны и обобщены ВОЗ/ЕВРО в соответствии с решениями координационного комитета. Все публикации ВОЗ/ЕВРО будут визироваться национальными координаторами, хотя каждая страна может публиковать собственные результаты.

ПРИЛОЖЕНИЕ 1

Инструкции по отбору проб, хранению и транспортировке проб

- * Молокоотсасыватель должен предоставляться в дезинфицированном виде, чтобы самой матери было необходимо лишь промыть контейнер молокоотсасывателя водой и, при желании, вскипятить его во избежание от загрязнения мылом. Однако, так как это может привести к бактериальному заражению, следует убедиться в том, чтобы матери не использовали эти молокоотсасыватели в личных целях, например, для сцеживания молока для последующего кормления младенца без предварительного промывания и стерилизации молокоотсасывателя.
- * Сборная бутылка должна предоставляться в дезинфицированном виде. Перед передачей каждой матери она тщательно промывается, ополаскивается водой и ацетоном. Матери не должны ничего делать с этими бутылками.
- * Желательно, чтобы бутылка была сделана из боросиликатного стекла, а пробка имела либо тефлоновое покрытие, либо была сделана из полиэтилена.
- * Бутылка с собранным молоком должна храниться в домашнем морозильнике до тех пор, пока мать не соберет необходимое количество, т.е. порции, сцеженные после каждого кормления, должны добавляться в бутылку. После замораживания молоко не должно оттаивать.
- * Для сбора молока не следует использовать никакие иные сосуды. Матери не должны использовать чашки или другие бутылки, которые могут быть у них дома. Если они предпочитают мануальную лактацию, молоко следует сцеживать непосредственно в предоставленную бутылку или в сборный контейнер, поступающий в комплекте с молокоотсасывателем.
- * Грудь и руки должны быть максимально чистыми, однако, следует, по возможности, избегать мыла. При необходимости воспользоваться мылом грудь и руки следует тщательно ополоснуть.
- * При необходимости использования мазей на сосках вследствие раздражения на них или их размягчения не рекомендуется делать это во время взятия проб, и к моменту сцеживания мази должны быть сняты.
- * Идеальным методом снятия проблемы заражения от банного мыла и мазей является предоставление матерям для личной гигиены и мойки посуды такого мыла, которое было подвергнуто анализу на возможное заражение с выявлением отрицательного результата. То же самое распространяется на мази, используемые для обработки сосков.

* При отправке проб на анализ следует четко маркировать упаковку: "пробы человеческого грудного молока", и уведомлять адресата с указанием точных деталей доставки (номер накладной, время, номер посылки, и т.д.)



ПРИЛОЖЕНИЕ 2:

Анкета для матерей-доноров грудного молока
на анализ на ПКБ, ПКЦ и ПКДФ

World Health Organization
Regional Office for Europe

CONFIDENTIAL!

1. Sample identification code:	2. Samples collected from DDMMYY to DDMMYY		3. Date completed: DDMMYY
	<input type="text"/>	<input type="text"/>	<input type="text"/>

4. Mother's age in years:	5. Mother's height in cm:	6. Mother's weight before pregnancy in kgs:	7. Mother's weight just prior to delivery in kgs:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

8. Area of residence during last 5 years: urban suburban rural

9. Previous area of residence: Years urban suburban rural
and before: Years urban suburban rural

10. Child's age in weeks at start of sampling:	11. Child's sex: boy <input type="checkbox"/> girl <input type="checkbox"/>	12. Child's weight at birth in grammes:	13. Child's weight at time of sampling in grammes:
<input type="text"/>		<input type="text"/>	<input type="text"/>

14. Mother's dietary habits: mixed diet vegetarian, but with milk and eggs strictly vegetarian
other give details: _____

15. Has the mother changed dietary habits markedly since the start of pregnancy? no yes
if yes, state how: _____

16. How often, on average, does she eat fish and other seafood, including cold fish? never less than once a week once a week
twice a week more than twice a week
if twice a week or more, state the species she consumes most often: _____

How often does she, on average, consume milk and milk products?

never

twice or less a week

more than twice a week, but not every day

every day

Fat content:

low-fat (0.5-1.9%)

medium-fat (2.0-2.9%)

high-fat (3.0% or more)

Consumption per day:

less than 250 ml a day

250-499 ml a day

500 ml or more a day

18. How often, on average, does she consume cheese?

never

twice or less a week

more than twice a week, but not every day

every day

Fat content:

low-fat

high-fat

19. How often, on average, does she eat beef?

never

less than once a week

once a week

twice a week

more than twice a week

20. Current smoking habits:

Non-smoker (has never smoked)

Ex-smoker

Smoker

if smoker, what does she smoke?

Cigarettes

Cigars/ceruttes

Pipe

if cigarettes, how many per day?

if cigars/ceruttes, how many per day?

21. Present type of work:

22. Present workplaces: urban suburban rural

23. Duration in years:

24. Previous types of work:

25. Previous workplaces: urban suburban rural

25. Durations in years:

urban suburban rural

27. Kinds of medicine taken during sampling period:

28. Questionnaire completed by: (TYPE NAME)

Date:

Signature:

ПРИЛОЖЕНИЕ 3

Перечень отдельных аналогов ПХБ,
ПХЦ и ПХФ для анализа

Normal PCBs

IUPAC No. 28
IUPAC No. 52
IUPAC No. 101
IUPAC No. 133
IUPAC No. 153
IUPAC No. 180

Dioxin like PCBs

IUPAC No. 77
IUPAC No. 105
IUPAC No. 118
IUPAC No. 126
IUPAC No. 169

PCDDs

2,3,7,8-TCDD
1,2,3,7,8-PeCDD
1,2,3,6,7,8-HxCDD
1,2,3,4,7,8-HxCDD
1,2,3,7,8,9-HxCDD
1,2,3,4,6,7,8-HeCDD
1,2,3,4,5,7,8,9-CCDD

PCDFs

2,3,7,8-TCDF
1,2,3,7,8-PeCDF
2,3,4,7,8-PeCDF
1,2,3,6,7,8-HxCDF
1,2,3,4,7,8-HxCDF
1,2,3,7,8,9-HxCDF
2,3,4,6,7,8-HxCDF
1,2,3,4,5,7,8-HeCDF
1,2,3,4,7,8,9-HeCDF
1,2,3,4,5,7,8,9-CCDF

ПРИЛОЖЕНИЕ 4

Лаборатории, аттестованные для проведения анализов в рамках второго раунда межлабораторных исследований ВОЗ/ЕВРО по контролю качества по уровням ПХБ, ПХЦД и ПХЦФ в человеческом грудном молоке и крови

(С указанием ответственных лиц - в алфавитном порядке по странам)

Лаборатории, аттестованные для проведения анализов на ПХБ в человеческом грудном молоке

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ANNEX 4

**Questionnaires and Letter
of Informed Consent**

Анкета Вопросов для Матерей Дающих Собственное Молоко для Анализа

Сотрудничающие С Всемирной Организацией Здравоохранения

Wellstart International

Научный Центр Региональных Проблем Питания

Конфиденциально!

1. Номера Отождествления образца:	2. Место собрания образцов:																																																																																																																																												
3. ДАТА собранных образцов до (дд мм гг) после (дд мм гг) □□ □□ 94 □□ □□ 94	4. Возраст матери (лет):																																																																																																																																												
7. Вес матери до беременности (килограммов):	5. Сколько лет образования матери:																																																																																																																																												
8. Вес матери едва до рождения младенца (кг) - НАСТОЯЩИЙ ВЕС (кг)	6. Рост матери (сантиметров):																																																																																																																																												
9. Это первый младенец матери, и она кормит его своим молоком? да <input type="checkbox"/> нет <input type="checkbox"/>																																																																																																																																													
10. Пол младенца: сын <input type="checkbox"/> дочь <input type="checkbox"/>	11. Вес родившегося младенца (килограммов):																																																																																																																																												
12. Во время образца, ДАТА РОЖДЕНИЯ МЛАДЕНЦА _____ и вес _____ граммов):																																																																																																																																													
13. Место проживания матери за последние 20 лет: числа (месяц и год) с _____ до _____ близко: к промышленности <input type="checkbox"/> к фермам <input type="checkbox"/> ни к тому, ни к другому <input type="checkbox"/> с _____ до _____ близко: к промышленности <input type="checkbox"/> к фермам <input type="checkbox"/> ни к тому, ни к другому <input type="checkbox"/> с _____ до _____ близко: к промышленности <input type="checkbox"/> к фермам <input type="checkbox"/> ни к тому, ни к другому <input type="checkbox"/> с _____ до _____ близко: к промышленности <input type="checkbox"/> к фермам <input type="checkbox"/> ни к тому, ни к другому <input type="checkbox"/> с _____ до _____ близко: к промышленности <input type="checkbox"/> к фермам <input type="checkbox"/> ни к тому, ни к другому <input type="checkbox"/>																																																																																																																																													
14. Занятия матери за последние 10 лет: числа (год) место промышленность с _____ до _____ : _____ с _____ до _____ : _____ с _____ до _____ : _____ с _____ до _____ : _____	15. Занятия отца младенца за последние 10 лет: числа (год) место промышленность с _____ до _____ : _____ с _____ до _____ : _____ с _____ до _____ : _____ с _____ до _____ : _____																																																																																																																																												
16. Диета матери: (укажите частоту знаком в нужной клетке)																																																																																																																																													
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Infant Feeding Questionnaire

1. Do you nurse your baby on a fixed schedule or whenever the baby wants to nurse (on demand)?
 schedule on-demand
2. How many times did you breastfeed your baby yesterday during daylight hours? times
3. How many times did you breastfeed your baby last night between sunset and sunrise? times
4. At any time yesterday or last night was your baby given any of the following:
 - Unboiled water? yes no Boiled water? yes no
 - Sugar water? yes no
 - Juice? yes no
 - Tea? yes no
 - Baby formula? yes no What brand? _____
 - Fresh milk? yes no What kind? (cow's, etc.) _____
 - Kefir? yes no
 - Pasteurized or powdered milk? yes no
 - Other liquids? What? _____
 - Any solid or mushy food? What? _____
5. How many times last week did you give your baby the following:

Frequency

0 1-2 3-6 every day

- Unboiled water?
- Sugar water?
- Juice?
- Tea?
- Baby formula?
- Fresh milk?
- Kefir?
- Pasteurized or
- Powdered milk?
- Other liquids?
- Solid food or
- Mushy foods?

6. Did your baby drink anything from a bottle with a nipple yesterday or last evening?



WELLSTART
INTERNATIONALSM

February 8, 1994

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Dear Madam:

WELLSTART International and the Research Institute on Regional Nutrition Problems in Almaty are conducting a study on breastmilk.

We are studying the contents of your breast milk and other infant foods to help mothers and doctors understand what babies eat. To conduct these studies we are asking mothers at this and other clinics to donate samples of their breastmilk for our analyses. If you participate in this study there will be no risk to you or your baby.

To participate in this study, we request that you provide approximately 15 ml of breast milk and respond to a short set of questions. Your answers to these questions will be confidential.

Attached is some information about breastfeeding that you may take with you.

If you are willing to participate, please sign your name below.

Name

Date

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FAX: (619) 294-7787

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FIELD OFFICES
Cameroon
Rwanda



WHO Collaborating Center on
Breastfeeding Promotion and
Protection, with Particular Emphasis
on Lactation Management Education

КАЗАҚСТАН РЕСПУБЛИКАСЫНЫҢ
ДЕНСАУЛЫҚ САҚТАУ
МИНИСТРЛІГІ



МИНИСТЕРСТВО
ЗДРАВООХРАНЕНИЯ
РЕСПУБЛИКИ КАЗАХСТАН

480003, Алматы қаласы, З. Аблайхан даңғылы, 63-й
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Р/с № 121626 областного управления
Нацгосбанка Республики Казахстан, код банка 109

№ _____
На № _____ от _____

У В А Ж А Е М А Я М А М А !

Министерство здравоохранения Республики Казахстан совместно с "ВЕЛСТАРТ Интернешнл" (США) Научным центром региональных проблем питания г. Алматы проводят исследование грудного молока.

Молоко исследуется на содержание различных веществ, чтобы помочь кормящим матерям и врачам лучше понять состав питания новорожденных. Для успешного проведения исследований мы просим Вас предоставить образцы грудного молока для выполнения наших анализов. Участие в данном исследовании не связано с каким-либо риском для Вас и Вашего ребенка.

С целью участия в исследовании мы просили бы Вас любезно предоставить нам приблизительно около 50 мл грудного молока и ответить на вопросы краткой анкеты. Конфиденциальность Ваших ответов гарантируется.

Ниже дается информация о грудном вскармливании, которую Вы можете взять с собой.

Если Вы желаете принять участие в исследовании, просим написать внизу Вашу фамилию.

Фамилия

Дата

ANNEX 5

**Outline for Training Session on Sample
Procurement and Participant List**

TRAINING SESSION ON SAMPLE PROCUREMENT FOR STUDY ON BREASTMILK SAFETY

- I. Objectives for Training: By the end of the training session participants will be able to:
 - Understand the study objectives and methodology
 - Understand procedure for obtaining breast milk samples
 - Successfully completed role-playing session of sample procurement

- II. Background
 - A. MCH Conference
 1. Contaminants paper-conclusion that data are not available to support or refute widespread beliefs of breast milk contamination.
 2. Identified concern about breast milk contamination by Central Asian Health Officials at conference
 - B. LME Training
 - C. Collaborating institutions: Ministry of Health, Research Institute on Regional Nutrition Problems, Wellstart International. Technical support for sample procurement and analysis by the Hazardous Materials Laboratory of the State of California, a WHO certified laboratory for analysis of organic contaminants in breast milk. Dr. Hooper part of planning team.
 - D. Objectives
 1. To document the presence and level of organic contaminants in breastmilk and breastmilk substitutes
 2. To make a recommendation on the safety of breastmilk for infants.
 - E. Methodology: WHO protocol, "Levels of PCBs, PCDDs, and PCDFs in human milk: Protocol for second round of exposure studies
 - F. Analysis Samples will be analyzed in Dr. Hooper's laboratory in California

- III. Sample procurement
 - A. Overview of binder contents and collection containers etc
 - B. Review of procedure

- IV. A. Issues to highlight
 1. Importance of cleanliness so as not to contaminate sample. Wash and dry nipple, placement of cap of collection jar while milk is being expressed
 2. Importance of accurate record keeping, e.g. logging of subjects to ensure identity of sample.
 3. Storage of sample in freezer until pick-up

- IV. Role playing
 - A. Physician/midwife/nurse and mother in front of group (Gulnara and MOH representative)
 - B. Break into small groups to practice with representatives from clinics and Research Institute and MOH collecting the samples and others who will not be involved in data collection playing the mothers

Present at the Breastmilk Contamination Research Study Training Session
conducted by Drs. Chessa Lutter and Kim Hooper, ~~Friday~~ 18th February

Thursday

1. Nadezda Alexseevna, Chief Midwife
2. Anna Fedorovna, Chief Midwife
3. Almagul Ahatovna, Clinical Studies, Neonatology Department, Advanced Medical School.
4. Larissa Oktashevna, Chief of the Premature Baby Department
5. Asia Abdrachimovna, Scientific Worker at the Institute of Pediatrics
6. Nazigul Kayratovna, Scientific worker, Institute of Nutrition
7. Orungul Kanafeevna, Scientific worker Institute of Nutrition
8. Sergei Victorovich, Chief of the Laboratory, Institute of Nutrition
9. Tamara Chuvakova, Chief Neonotologist, MOH and Advanced Medical School
10. Gulnara Semenova, Chief of the Laboratory, Institute of Nutrition
11. Shamil Tashibayev, Deputy Director of the Institute of Nutrition and Chief of Breastfeeding Training Center at the Advanced Medical School, Doctor of Medical Science, Professor
12. Olga Chekmedova, Assistant at the Neonatology Department, Advanced Medical School.

ANNEX 6

Breastfeeding Practices in Kazakhstan: Preliminary Results

BREASTFEEDING PRACTICES IN KAZAKHSTAN: PRELIMINARY RESULTS

June 13, 1994

Introduction

Wellstart International in collaboration with the Ministry of Health and the WHO Collaborating Center on Regional Nutrition Problems is conducting a study to address concerns about breastmilk contamination. This study consists of two phases: Phase I focuses on selected chlorinated contaminants and chlorinated insecticides and was conducted in Central and Southern Kazakhstan in February and March 1994. Pending additional funding, Phase II will focus on heavy metals and radionuclides and will be conducted in Northern Kazakhstan. Technical and laboratory support is being provided by the California Hazardous Materials Laboratory. As part of this study, information on maternal and infant diet and nutritional status are being obtained. This report summarizes infant feeding results from Phase I.

Population and Methods

Phase I data were collected in nine clinics in six different areas: Almaty (three clinics), Shymkent, Djetisay, Kirov, Qyzylorda, Aralsk, and Atyrau (Figure 1). Clinic selection was based on assessment of agricultural and industrial development and the likely geographical distribution of target chlorinated contaminants.

The WHO/EURO protocol entitled "Levels of PCBs, PCDDs, and PCDFs in human milk: Protocol for second round of exposure studies" was adapted for use in Kazakhstan. This protocol specifies that subjects should be apparently healthy women breastfeeding for the first time and that infants should be between the ages of two and eight weeks of age. Thus, except for one subject who had not breastfed her first child and was now breastfeeding her second child, all other subjects were primiparous. Copies of the exposure assessment and infant feeding questionnaires in English and Russian are attached (Appendix 1).

To determine infant feeding practices, mothers were asked the following questions:

- "What did you give your infant to eat or drink yesterday?"
- "During the past week, how many times did you give your infant the following items to eat or drink?"

For each question, mothers were read the following list of liquids/foods: water, boiled water, sugar water, juice, tea, fresh milk, kefir, other liquids, formula, solid/mushy food. Mothers were also asked about infant feeding schedules, nursing frequency, and bottle use.

Anthropometric measures are based on maternal reports as scales and measuring boards were not available in the rooms where the questionnaires were administered. Mothers were asked to report their height, current weight, prepregnant weight, and weight at term. These measures were used to calculate weight gain during pregnancy, postpartum weight changes, and body mass index (BMI). Mothers were also asked to report infant birthweight and current weight. Reported birthweight was used to calculate the incidence of low birth weight (LBW). Mothers were also asked to report how many times per week they consumed a number of common meats, cooking oils, dairy products, and vegetables.

At each clinic, health personnel were asked to recruit 10 to 15 women who met the selection criteria. They were urged to recruit women who reflected the age, ethnic, and educational level of the clinic population.

Results

Breastmilk samples were collected and risk assessment questionnaires were completed on 97 women of whom 67% were ethnic Kazakh, 27% were ethnic Russian and the remainder were of German, Uzbek or other ethnic origin (Table 1). Infant feeding questionnaires were completed on a subset of 81 of these women.

The maternal and infant characteristics of the subjects are described in Table 2. The young age of the subjects (22.4 years) reflects the selection criterion that women should be breastfeeding for the first time and that the infant being breastfed should be between two and eight weeks of age. The mean educational level was 12.3 years of completed schooling: 58% of women had at least a high school education. The mean reported values for prepregnant weight, weight at term, and current weight were 56.9 kg, 66.5 kg, and 58.5 kg, respectively. The mean value of reported maternal height is 162.7 cm. Using these measures, weight gain during pregnancy was calculated to be 7.3 kg; women on average were calculated to be 2.2 kg heavier now than they were prior to pregnancy. Body mass index ($\text{weight}/\text{height}^2$), which is widely accepted as a summary measure of nutritional status was calculated as 21.4. The mean birthweight was 3,282 g; only 9% were of low birthweight (<2500 g). The current mean weight was 4247 g.

The most common infant feeding practice, as based on 24-hour maternal recall, was the use of boiled water (Table 3). Although only one woman reported giving unboiled water to her infant, boiled water was given by 73% of women. Sugar water, juice, and tea were also given by 14%, 18%, and 14% of women, respectively. Nearly 14% also gave their infants dill water, apple juice, or an "other" liquid. Infant formula was less frequently provided; only 7.4% of women reported this practice. However, 51% reported using a bottle. Infants were breastfed frequently (on average 7.2 times during the day and 2.4 times at night) and 70% of mothers reported breastfeeding "on-demand."

Infant feeding categories, summarized in Table 4, show the prevalence of exclusive breastfeeding (defined as breastmilk as the sole source of infant liquid/food) to be only 19%. The prevalence of full breastfeeding (defined as breastmilk and water) was 38%. Breastfeeding with water, tea, and juice is common among women with young infants: nearly 70% of women followed this practice. In contrast, use of other milks (infant formula, tinned or fresh milk) is rare: only 9% of women used these milks.

Women who were exclusively breastfeeding were asked about their planned "first food." Of the 17 women for whom data are available, seven replied "don't know," four replied "formula," three replied "kefir," and three replied "juice or vegetable puree."

Discussion

Inferences about infant feeding practices should be interpreted in light of the three main selection criteria:

- 1) Currently breastfeeding for the first time.

Because breastfeeding was a criterion for entry to the study, the proportion of women who initiate breastfeeding cannot be determined. It should be noted, however, that with the exception of one woman

who did not breastfeed her first infant and was currently breastfeeding her second, all subjects were primiparae.

2) Infants between two and eight weeks of age.

Because only very young infants were in the study, information is not available about how infants older than eight weeks are fed. This is of concern, for example, because although use of infant formula is not common in this group, it may be far more common among older infants. It also means we cannot draw conclusions about optimal breastfeeding - i.e., exclusive breastfeeding for 4-6 months.

3) Women and infants should be "apparently healthy."

Because of this selection criterion, anthropometric measures are also biased toward healthy women and infants. Although breastfeeding practices in this study are far from optimal, it is likely that they are even less optimal among women and infants who are not considered "healthy."

The results on infant feeding practices indicate that some, though not all, practices recommended by the Ministry of Health of the former Soviet Union are followed. For example, although the recommendations state that infants should be breastfed according to a fixed schedule (intervals of 3.5 hours during the day and 6.5 hours during the night), only 30.5% of women followed this recommendation. The vast majority (70%) breastfed "on-demand." In contrast, most women introduced water, teas, and juice at a very early age in keeping with recommendations to introduce fruit and vegetable juice at month one.

The recommendations summarized in the book, "Feeding of Children in the First Year of Life: Methodological Recommendations" (Ministry of Health of the USSR, Moscow, 1982), are the infant feeding guidelines currently available in clinics visited during this study. They contrast sharply with current WHO recommendations of providing only breastmilk for the first four to six months of life.

Although just over half of the women reported using a bottle, three-quarters reported providing boiled water, which indicates that other feeding methods in addition to bottles were used. It would be useful to know what these methods are. Infant feeding advice and information is urgently needed throughout the health system, as evidenced by the fact that 7 out of 17 women who were currently exclusively breastfeeding replied "don't know" when asked about their planned "first food."

Conclusions

Preliminary results from the infant feeding data from Phase I of the Breastmilk Contamination Study reveal the following:

- Breastfeeding practices are far from optimal. Even among very young infants, exclusive breastfeeding is not widely practiced. Most mothers of young infants are giving water, teas or juice.
- Bottle use is widespread: 50% of infants of infants between the ages of two and eight weeks receive a bottle.
- Use of infant formula is not widespread among very young infants.
- Current infant feeding information available in the clinics is very outdated and not in keeping with current international recommendations.

A national breastfeeding campaign is urgently needed to build upon the positive aspects of breastfeeding in Kazakhstan as well as to improve those practices that are less than optimal. The positive practices include the high initiation rates and large proportion of women who are breastfeeding on demand. Practices that are less than optimal include the early introduction of water, teas, and juice and widespread bottle use.

Table 1

Sample distribution by site: Preliminary results from Phase I

City	Infant feeding questionnaire (n)	Breastmilk sample and risk assessment questionnaire (n)	Kazah (n)	Russian (n)	Other (n)
Almaty	14	23	4	16	3
Aralsk	12	13	13		
Atyrau	18	18	11	7	
Shymkent	10	15	13	1	1
Dzhetyysay	11	11	9	1	1
Kryov R.	5	5	5		
Kzyl-orda	11	11	10		1
Total n	81	97	65	25	5
%			67%	27%	5%

07/28/94

K:\CHESSA\INFANT.T1

Table 2

Maternal and infant characteristics:
Preliminary results from Phase I¹

	$\bar{x} \pm \text{s.d.}$	Range
<u>Maternal</u>		
Age (years) ²	22.4 \pm 3.8	15 - 34
Education (years)	12.3 \pm 2.0	8 - 19
Height (cm) ³	162.7 \pm 6.1	150-182
Prepregnant weight (kg)	58.5 \pm 8.0	41 - 95
Weight at term (kg)	67.2 \pm 8.7	50 - 95
Current weight (kg)	56.8 \pm 8.3	40 - 80
Body mass index	21.4 \pm 2.6	
Pregnancy weight gain (kg)	7.3 \pm 6.5	
Post-partum weight change	2.2 \pm 5.6	
<u>Infant</u>		
Birthweight (g)	3282 \pm 645	1300 - 6000
Low birthweight (%)	9.3	
Current weight (g)	4247 \pm 832	1600 - 5900

¹n=97, infants are between 2 and 8 weeks of age.

²Mean \pm SD (range)

³Anthropometric measures based on maternal report.

Table 3

Infant Feeding in previous 24-hours:

Preliminary results from Phase I

<u>Foods/liquids given:</u>	<u>%</u>	<u>n</u>
Water ¹	1.2	(1)
Boiled water	71.6	(58)
Sugar water	13.6	(11)
Juice	17.3	(14)
Tea	13.6	(11)
Fresh milk	1.2	(1)
Kefir	0	(0)
Other liquids ²	7.4	(6)
Formula ³	7.4	(6)
Tin milk	0	(0)
Solid/mushy food	3.7	(3)
(None excl BF)		
<u>Breastfeeding schedule:</u>		
On demand	69.5	(57)
Fixed schedule	30.5	(25)
<u>Bottle use:</u>	50.0	(41)
<u>Breastfeeding frequency:</u>	<u>\bar{x} + s.d.</u>	<u>Range</u>
Day ⁴	7.2±2.4	(0 - 9)
Night	2.8±1.6	(2 - 20)

¹% (n), total n=81 infants between 2 and 8 weeks of age.

²Includes apple juice (n=1) and dill water (n=5).

³Brand names are Babylac (n=1), unspecified Chinese brand (n=1), Forlact (n=2), and Snow Brand (n=2).

⁴Mean±SD (range).

Table 4

Infant feeding categories:
Preliminary results from Phase I

<u>Infant feeding category¹</u>	<u>%</u>	<u>n</u>
Exclusive breastfeeding ²	18.5	(15)
Full breastfeeding	38.3	(31)
Breastfeeding with water, tea	53.1	(43)
Breastfeeding with water, tea, juice	69.1	(56)
Breastfeeding with other milks	8.6	(7)
Breastfeeding with solids	3.7	(3)

¹Infant feeding category definitions (categories are not mutually exclusive):

Exclusive breastfeeding=Breastmilk only.

Full breastfeeding=Breastmilk and plain or boiled water only.

Breastfeeding with water, tea=Breastmilk with water, sugar water, and/or tea only.

Breastfeeding with water, tea, juice=Breastmilk with water, tea, and/or juice only.

Breastfeeding with other milks=Breastmilk with other milks with or without water, tea, and/or juice.

Breastfeeding with solids=Breastmilk with solids, with or without water, tea, juice, and/or other milks.

²% (n), total n=81 infants between 2 and 8 weeks of age.