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NATIONAL DIARRHEAL DISEASE

PROGRAM PLAN: MALI

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TECHNOLOGIES FOR PRIMARY HEALTH CARE (PRITECH) PROJECT

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I. EXECUTIVE SUMMARY

The Malian Ministry of Public Health and Social Affairs (MOPHSA) has reviewed and approved a PRITECH proposal outlining the initial phases of a national program to reduce child mortality caused by diarrheal disease. The PRITECH proposal covers a three year period, 1985 to 1988, with donor financing provided by UNICEF, WHO and AID/PRITECH. Full implementation of the national program may require seven to ten years, and will depend upon donor financing for the subsequent phases. USAID is prepared to consider providing follow-on financing as part of future health programs.

PRITECH proposes four program components which fit within the Malian diarrheal disease program plan developed with WHO assistance. The four components are: (1) training of health workers to establish ORT in the health system; (2) promotion of ORT in the community; (3) local production and distribution of ORS packets, initially through health facilities and later through sales by commercial outlets; and (4) education of mothers to use ORT effectively, with ORS packets and sugar-salt solutions prepared in the home. There is a large gap between the furthest extension of rural health services and community health needs; coverage of health services in rural areas may be as low as 5 percent. The program activities with the health workers and through health service facilities are an essential first step but will have modest results. The program purpose is to establish ORT as the principal means of treating diarrheal disease in the health system,

and to begin a course of action which can feasibly, over time, establish ORT as a common practice in Malian households. As soon as possible, distribution of ORS packets should move beyond the health system into commercial channels. Radio broadcasts will be an important means of educating communities and getting information to mothers. Existing rural development programs, such as the literacy campaign, will be enlisted in the promotion and education effort, organized region by region.

PRITECH proposes to hire a full-time expatriate representative to help administer the program under the direction of PRITECH's Regional Officer based in Dakar. PRITECH will also provide up to twelve months of short-term technical assistance, and funding for educational materials and program evaluation. UNICEF and WHO will finance training and promotion costs as well as the equipment and supplies to produce ORS packets. Program implementation is scheduled to begin in June 1985.

II. BACKGROUND

A. General Indicators of Development

During more than two decades of independence, Mali's potential economic development has been frustrated by weak incentives for agricultural production, reliance on inefficient public sector enterprises, low rainfall causing drought and human disaster, and frequently unfavorable terms of trade for agricultural exports. Its mineral wealth cannot be exploited without investment in transportation infrastructure. Only 10% of the roads are paved, not even enough to link the regional capitals spread across Mali's 1,400 kilometer breadth. The USAID Country Development Strategy Statement refers to the "seamless web of political, technical, and structural constraints". As a result, Mali remains one of the poorest countries in Africa and the world, despite adequate cultivable land, irrigation potential and an enterprising population. Mali is struggling to keep ahead of Chad, Somalia, and Ethiopia. Large numbers of workers seek employment where economic opportunity is better: Ivory Coast, Senegal, and France.

For those who remain, deprivation is broadly shared. Half the rural population lives in absolute poverty with annual incomes of less than \$60 per capita including subsistence production. Nevertheless, almost all the population participates in the cash economy from sales of agricultural products; USAID staff guesstimate that 70-80% of the population pay cash for more than 10% of family consumption and a universally applied national tax. The society is basically egalitarian. The current regime has been in power for

more than fifteen years, despite economic problems and evidence of mismanagement, and without high levels of apparent repression. The overall social situation is relatively stable in the face of an inefficient economy and an ineffective government. Family ties and solidarity are cited as mitigating the effects of income disparity.

The economy has been handicapped by a burdensome public payroll, steadily contributing to budget and balance of payment deficits. By the end of the 1970s, more than 70% of the national budget was allocated to salaries and educational scholarships. According to a recent IMF study, Mali spends 80% more than expected on government wages given its income level and economic structure; in comparison, neighboring Niger which also relies heavily on the public sector spends 10% less than expected. Mali has been trapped by a policy of hiring all available secondary school graduates. Even so, government services are unable to reach out to the 10,000 villages in the country; services barely reach the 300 or so towns at the arrondissement level.

One of the most far-reaching government programs has been the national literacy campaign, which has been active in 3,500 villages and plans to reach 2,000 more during the next five years. The literacy program task is formidable; adult literacy rates were only 10% when measured in 1976. Although Mali devotes 30% of its national budget to education, primary school enrollment has only reached 28%, with female enrollment far below that average. To facilitate the task, national languages are being used instead of French. Bambara, a lingua franca understood by about 80% of the

population and a first language for half the population, reinforces national cohesion. The single national radio broadcast is reportedly received throughout the nation and in virtually every village; as an indicator of its reach, it is used to deliver messages to individuals in remote areas. Batteries are carried by the far-flung and well-established commercial networks which are part of the regional tradition.

Rural development programs have left a pattern of spotty, varied, intense effort without national coherence or sustained support. Donors, seeking regional opportunities or responding to regional needs, have balkanized rural development services in the hope of producing replicable demonstrations. During the seventies, integrated and complicated rural development projects grappled with the dearth of governmental infrastructure at the local level and the plethora of human needs. These programs had limited success and were difficult to sustain given the increasingly severe constraints on governmental resources.

Encouraged by the IMF and the donors, the government has begun taking pragmatic steps to give the economy a more sound basis. Reducing recurrent public sector costs, including subsidies, recovering costs of services and broadening the role of the private sector have become important new themes of government policy. The functions of public enterprises are being assessed; management and operations are being revamped. The national pharmacy, for example, has been relatively well managed and profit producing; with financing from the World Bank, more drugs and a range of essential generically - named drugs appropriate

for the public health system will be sold by the national pharmacy through both wholesale and retail outlets.

B. Health Indicators

A recent USAID planning paper on health, population, and nutrition summarizes basic facts as follows:

"In terms of the current health situation, nutritional status and population growth, Mali ranks among the worst countries: an infant mortality rate of around 160 per thousand live births (as high as 200/1000 according to some statistics), a child survival rate of 550 out of 1000 live births (i.e., about half of the children born alive die before the age of 15), a maternal mortality rate of about 15 per 1000 births, a life expectancy of about 43 years, a daily per capita caloric intake of about 80% of the requirement, and an annual population growth of 2.7%."

Malaria is endemic in the populous southern half of the country; almost a third of all infant and early childhood mortality may be attributed to this disease. Upper and lower respiratory tract infections come next in incidence according to most studies. Diarrheal diseases are especially fatal among children under three years of age. Cholera is endemic in the whole Niger river basin, especially in the delta area. Malaria, respiratory tract infections and diarrhea when combined with an underlying chronic malnutrition account for about half of all deaths among children under age 5.

Since broadly reliable demographic and epidemiologic data do not exist, the above statements must be based on extrapolations from sporadic surveys. For example, as an indicator of the poor nutritional status, an ad hoc survey done in 1982 at the pediatric ward of the Gabriel Toure hospital in Bamako showed that half of all hospitalized children on the day of the survey had clinical signs of marasmus and/or kwashiorkor (severe third degree

malnutrition). For the year 1980 in the pediatric ward, diarrhea was the second most frequent cause of death, after malaria; 11% of patients hospitalized for diarrhea died. At MCH centers in Bamako during 1980-82, the prevalence of diarrhea among children in attendance was typically about 25%.

The medical center at Kolokani, a town about 50 kilometers north of Bamako, recorded 28% incidence of diarrhea in 1981 with mortality of about 3%. For infants under one year, the mortality rate for patients with diarrhea was about 6%. In West Mali, in the area of the World Bank health project with a history of scant medical services, diarrhea is cited as the second most frequent cause of infant deaths, 14% of infant deaths.

Based upon a review of these findings, a WHO-led team concluded in September 1983 that diarrhea is a crucial public health problem in Mali; and that a national program to combat diarrhea must be established.

C. Historical Evolution of the Health System*

Most of the medical services in Mali are run by the Ministry of Public Health and Social Affairs (MOPHSA). An organization chart is presented in Annex 1. Regional and district medical officers have discretionary authority over health programs and budgets. The central government is responsible for planning, statistics, the coordination of health services, training, technical operating procedures, administration of external aid, the operation of hospitals, and enforcement of public health laws.

* This section draws on a November 1983 World Bank assessment of Mali's health sector.

To implement national health policy, the MOPHSA is attempting to develop a pyramidal health system down to the subdistrict level. The system comprises 12 national, regional and secondary hospitals (up from 3 in 1960) with a total of 2,500 beds; 46 district health centers (19 in 1960); 52 MCH facilities (none in 1960); and 382 subdistrict centers (138 in 1960). Despite poor conditions, hospital utilization is high; patients bypass the lower level facilities and go directly to hospitals for even minor ailments because the lower level facilities are often unable to provide even a basic level of care.

Many district health centers are merely old dispensaries that were upgraded in name after the 1977 administrative decentralization which created a greater number of districts and subdistricts. Each of Mali's districts now has a health center staffed by one or two doctors. Each subdistrict health center is staffed by a qualified or auxiliary nurse. Maternity and MCH facilities are staffed by a midwife; numerous rural maternities built by local residents are staffed by young women who received on-the-job training at a Government maternity.

Each regional system serves a population averaging one million, but due to difficult road conditions and long distances, in most of Mali the district health center must function as a self-contained health system and be capable of carrying out emergency surgery and most types of basic care. The district center staff are also responsible for providing technical support to the subcenters and village health workers, although the lack of vehicles and operating budget makes this more theoretical

than real. The lack of medical equipment and drugs and generally poor support leaves many young doctors discouraged after a year's service. Although the Government's promotion of village-level primary health care requires a credible health center and subcenter support system, in less developed regions, such as western Mali, the support system is functionally ill-equipped to meet the challenge.

Throughout Mali, effective medical coverage of the population is estimated at 15-20% maximum, with coverage as low as 5% in the western and northern regions. To improve medical coverage and strengthen maternal and child care and family planning services, the Government experimented with several village health programs whose results are being taken into account in expanding services.

1. Health Manpower

The main categories of health manpower are physicians, nurses and midwives. In addition, community based health field workers, functional literacy workers and traditional birth attendants are used for health related activities. MOPHSA employs over 4,300 health professionals and paraprofessionals, of whom 234 are doctors and surgeons, 1,996 are nurses, and 268 are midwives. Using World Health Organization norms, the Government has established specific targets for ratios of health personnel to population. Current health manpower production falls short of these requirements. Health personnel (physicians, nurses and allied health personnel) are currently trained at four different health professional training schools. But, in view of severe budgetary constraints and actual absorptive capacity, the government

is not likely to increase production rates for the foreseeable future. The government is more immediately concerned with improving the quality of basic and inservice training, and redressing the distribution currently skewed in favor of cities and large towns. New physicians are assigned to two years' mandatory service in rural areas, and other health personnel are assigned as a matter of priority to health development projects in rural areas.

Efforts to retain skilled personnel in rural areas are frustrated by poor working conditions and professional isolation. In 1981, the Ministry with assistance from USAID conducted a manpower training needs survey in three districts of western Mali. The majority of respondents complained about a lack of materials, drugs and transport. Forty-six percent did not know who was their immediate supervisor: they could only name the physician/medical officer as their head. Ninety-seven percent had no educational/information journals or materials. Eighty-five percent of the nursing and paramedical staff had never received inservice training. Training was requested in all key areas including supervision, pedagogical techniques required for communicating with patients and training village health workers.

The Government has attempted to draw on inter-sectoral resources, notably in the area of rural development, water supplies, and education in order to complement the activities of MOPHSA. Agriculture development projects have operated in Mali on the assumption that farmers respond better to extension efforts and participate more actively in marketing, credit and input

upply activities if at least a nucleus of villagers has attained a minimal level of functional literacy and numeracy in their own languages. Functional literacy components have therefore been included in rural development projects in southern and western Mali. To date, 3,500 out of about 10,000 villages in Mali have benefited from functional literacy campaigns. Health education has been successfully introduced into post-literacy teaching materials. The Government plans (with support from a proposed IDA education project) to extend literacy actions to 2,000 new villages over the next five years, principally through existing Rural Development Operations (ODRs).

The literacy network and agricultural extension agents are the only Government supported personnel who are legitimately present, active and influential at the village level. Continuing efforts are needed to draw on their ability and willingness to assist in organizing village level health care, health education and hygiene.

2. Pharmaceutical Distribution

Soon after independence, drugs were imported mainly through MOPHSA and distributed through its health facilities free of charge. Due to deteriorating finances and management problems, MOPHSA could not meet the fast growing demand for drugs. It became heavily indebted to foreign suppliers and came to rely on French Government grants to supply drugs while debts were paid off. Meanwhile, the Government authorized the Ministry of State Enterprises to create a parastatal Pharmacie Populaire du Mali (PPM) to import drugs for the commercial sector.

The MOPHSA has had no drug budget for several years and has effectively ceased the regular distribution of drugs. (It continues to pass out donated stocks on an ad hoc basis.) Meanwhile, the PPM has become a profitable enterprise with an extensive distribution network consisting of 93 directly managed wholesale/retail outlets and 443 affiliated retail outlets.

Aware that its own system was failing to support national primary health care objectives, the Government undertook a study of the pharmaceutical sector. One outcome of the study was a proposed structural reform: first, responsibility for drug procurement and distribution from MOPHSA was entrusted to PPM with its wholesale/retail network extending into every circle in Mali. Second, MOPHSA would strengthen its capability to coordinate and oversee drug policy, monitor drug utilization and needs and inform prescribers and the public. Third, local production and research would be grouped under the Office Malien de Pharmacie (OMP). As a MOPHSA affiliate, OMP would take charge of the existing intravenous solution manufacturing plant, the Institute of Traditional Medicine and the new essential drug factory. Under this arrangement, it is envisioned that PPM will assure distribution of essential drugs to the level of each circle. MOPHSA clinical facilities will pay for the stock that they pick up at PPM outlets, either by means of local credit accounts based on the MOPHSA operating budget or with cash provided from revenue generation schemes. The implementation of these structural reforms will be effected through a World Bank financed project

that is expected to get underway in the near future (estimated twelve to eighteen months).

In sum, the situation concerning distribution of ORS is as follows: At the moment, MOPHSA has no regular supply of essential drugs at its health facilities. Patients may, however, obtain prescriptions and purchase them from the nearest PPM outlet. Under the proposed reforms, mechanisms are scheduled to be put in place whereby each facility will obtain stocks of drugs from PPM outlets.

3. Health Sector Financing

Total expenditures in Mali for 1981 were estimated to be about 16.7 billion MF (US\$22.4 million) of which approximately 54% was private expenditure, mainly on drugs. MOPHSA's public expenditure accounted for about 30% of the total, and foreign assistance for the remaining 16%. This corresponds to a total per capita expenditure of about 2,300 MF (or US\$3.08).

Due to a steady deterioration in Mali's public finances, the recurrent budget for health has decreased from about a 9% share of the national budget in 1972 to about 6% at present. This is equivalent to about 0.75% of GDP. At the same time, MOPHSA has continued to absorb new graduates of the medical and nursing schools, which has meant that the ratio of personnel to material has been rising with a concomitant reduction in the productivity of each individual worker. Personnel account for between 60-75% of expenditure since 1976. Public recurrent expenditure in real terms declined from about 981 MF per capita in 1972 to 793 in 1981.

The bulk of recurrent expenditure benefits the urban areas since a disproportionate percentage of health personnel as well as drug distribution outlets are concentrated in Bamako and the regional capitals. An analysis of expenditure in three districts in the First Region (western Mali), which reflects the situation of other rural areas, demonstrates this unequal distribution. Some 7% of Mali's population lives there, yet only 2.4% of higher level health professionals are assigned there, and only 1.3% of the Pharmacie Populaire's sales are made in the zone. The recurrent costs in this area, primarily for personnel, are about 150 MF per capita; it is likely that total recurrent expenditures there do not exceed 200 MF, which is roughly one-fourth of the national per capita public health expenditure of about 800 MF.

4. Donor Assistance*

Between 1975 and 1981, average annual foreign donor assistance was about equal to the MOH budget. In 1981 the U.S. was the second largest donor in health; however, the U.S. slipped to fifth place in 1983, after the FED (European Community), FAC (French), GTZ (German) and Switzerland. Estimates for 1984 put it in eighth place after the Italians, UNICEF and the World Bank.

a) Donors other than the US: The World Bank project, (project KBK), an IDA loan of approximately 17 million US dollars spread over 7 years, will construct and equip three regional hospitals and about 36 dispensaries and health posts in the first region, notably in Kita, Bafoulabe and Kenieba. For this support a

* This section draws from the December 1984 USAID/Mali Background and Planning Paper on Health, Population and Nutrition.

planning unit has been created in the MOH. The project will also assist the national pharmacy (PPM) with about 3 million dollars to establish a revolving fund. The World Bank project is now in its 5th year of design, but apart from the planning unit, not much has happened yet. The orderly furnishing and equipping of so many centers as well as the training of Malians in its proper use will be a real challenge. Another major component of the project will be a water and sanitation program for the same region.

The Franco-Belgian MSF, (Medecins sans Frontieres) financed by FED, provides about 17 physicians and nurses for practically the whole north of Mali. They run nutrition/feeding centers and mobile teams trying to cope with famine, measles, meningitis, cholera - all at once.

The French provide technical assistance but also important commodities to the medical school and the teaching hospital.

The Germans, through GTZ, assist in the national schistosomiasis program. In addition, they finance a basic health service, formerly in the Dogon area and now in the Selingue area, where the construction of dams has brought a sharp increase in schistosomiasis.

The Swiss run a medical team in the southern Sikasso area, a kind of Village Health Worker program, but mainly focusing on local midwives. It also assists the MOH with training programs for nurses and doctors.

The Japanese have planned to contribute miscellaneous medical equipment to all fixed facilities in Mali.

UNICEF has now become a major commodity contributor. It also fund its own two Swedish and one Norwegian medical teams in the Timbuktu, Gao and Dire area. The Italians, through WHO and

UNICEF, are still designing a 5 million US dollar health/nutrition project, probably in the Segou region. Its main components will be immunization, oral rehydration and nutrition.

The World Health Organization (WHO) makes contributions in the form of technical assistance as well as scholarships and conference financing. A nutrition program operates in the Sikasso area and is part of a two-country project involving Niger. In addition, WHO is involved in a joint applied research project with USAID through SHDS (Strengthening Health Delivery Systems) to provide training for personnel from West African Institutions. The other important group which is rarely mentioned in official documents is the communist countries, especially Russia and the Republic of China. The Russians provide about 25 doctors to Mali, mostly to the Gabriel Toure and Segou Hospitals. The Chinese have a major surgical team in Kati, about 10 miles north of Bamako. Their other main contribution is the above-mentioned pharmaceutical factory.

In addition, there is the whole range of the, largely unknown, Non-Governmental Organizations (NGOs): the Dutch volunteers, running a rudimentary immunization program in the Sikasso region, the French volunteers in the San hospital, the British Save the Children Fund in Douentza, Care Deutschland with a (controversial) polio immunization program, and Foster Parents International in Banamba just to mention a few. These groups, although small

in budget terms, can be very effective and often are the only ones who provide health services in rural areas. PRITECH has established liaison with a coordinating committee for NGOs, primarily European Organizations.

b) Current U.S. assistance: The U.S., in 1984, contributed to two bilateral, two regional and several centrally funded projects in Mali. The "Koro project" is a remnant of the former Rural Health Development Services Project. Its redesign provides the renovation of the health center in Koro and the rural dispensary in Toroli as well as the construction of two new dispensaries in Madougou and Koporo-ne. They will be completely furnished and equipped according to a masterplan already established for the World Bank project. Existing Village Health Worker Teams (VHWT) will be retained. Immunization of children under two against tuberculosis, measles, whooping cough, diphtheria, tetanus and polio as well as tetanus prophylaxis given to pregnant women (mainly for prevention of neonatal tetanus) is envisaged at the fixed center in Loro and through its mobile team. The team will also assume the role of VHW supervision in order to save transportation costs and pool scarce manpower. The regional vaccine storage center in Mopti will receive some basic coldchain equipment and office supplies, and the central depot in Bamako will be given a refrigerator-mounted vehicle.

Whether actual immunization will start before project termination (June 30, 1985) will depend upon the timeliness of construction and arrival of the UNICEF ordered equipment.

Although, apart from the immunization program; few additional recurrent costs will be added, maintenance of the program will still require outside financial help, hopefully by other foreign donors. Discussions with other donors indicate some interest in continuing these services in Koro.

Two other bilateral projects exist in Douentza and Yelimane; both are for well construction. The two implementing agencies are CARE/Mali and Operations Puits, respectively. The latter one has been beset by numerous problems and may be terminated prematurely in 1985.

The emergency drought situation and the cholera epidemic are likely to preoccupy the Mission's health office well into mid-1985. A recently published report from a USAID/Embassy/OPAM (GRM's agricultural production office) field trip survey clearly indicates the existence of a famine area just 250 kilometers north of Bamako. Recently, public awareness has increased in Europe and the U.S. Tens of thousands of tons of food are now being planned for shipment into Mali and freely distributed. The U.S. alone will contribute about 70,000 tons in FY 1985, which will be distributed through various governmental and non-governmental channels. At the request of the Ministry of Health a cholera investigation by two CDC (Center for Disease Control, Atlanta) medical epidemiologists was carried out between November 10 and December 6, 1984. In addition to the usual epidemiological surveys of attack rates, mortality rates, clinical severity and susceptibility to various chemoprophylaxes and chemotherapies, the team improved cholera laboratory facilities in Bamako. They

also established similar facilities in each health centre of the Segou region and in the "heartland" of cholera, the Niger delta around Niafunke. Additionally, in conjunction with WHO and UNICEF a two day workshop was held in Segou. About 30 physicians, nurses, sanitarians and lab technicians received technical instructions and materials, such as oral rehydration salts, infusions and laboratory equipment. Detailed recommendations were given to the government, which, to some extent, led to a revision of its strategy, for example, the abandonment of immunization and mass chemoprophylaxis in favor of active surveillance and oral rehydration therapy.

Three years ago AID spearheaded an effort to establish two oral rehydration units in Bamako and organized a Sahel regional workshop in December 1983, in which delegates from almost all of the Sahelian health ministries participated. A ten-point action program (the "Bamako Declaration") was drawn up. In addition, hundreds of French copies of an OR manual, based upon this Malian experience, have been widely distributed.

Oral rehydration will also, along with family planning and immunization, have a place in the design of the new MCH/FP project.

The above clearly shows that, although basic commodities will be provided, the major thrust in U.S. assistance will be technology transfer, training, policy making, and institution building.

As for the Manantali Resettlement Project in western Mali, the U.S. will contribute approximately \$400,000, mainly for construction of two rural dispensaries, one maternity ward and

one PPM outlet. In addition, a schistosomiasis, malaria and nutrition survey will assess the impact of newly irrigated areas on the health of the population.

D. Historical Evolution of Diarrheal Disease Treatment

In 1979, the government established a national commission for diarrheal disease. In 1980, a simple action plan was developed which featured education about sanitation to prevent diarrhea and ORT, using the simple sugar-salt solution, to treat diarrhea.

In 1981, the Ministry prepared a national program plan for diarrheal disease. The objective was to reduce diarrheal mortality rates among children under 5 years of age from 25% to 10% of child deaths over five year period. The program strategy was based on the following priorities:

- to improve nutrition for children;
- to provide potable water;
- to improve hygiene in the environment;
- to establish standard methods of ORT in hospitals, health centers and among paramedical personnel;
- to inform mothers how to recognize dehydration and to seek treatment at health centers.

The most serious constraints to carrying out the strategy were seen as cultural attitudes in the population, requiring a long period of education and encouragement to change behavior. Program activities were recommended extending down to the village level and including ORT.

In September 1983, a WHO consultant, Prof. Kashala Tumba Diong, working in collaboration with Malian experts on childhood disease,

prepared a plan of operation for the national diarrheal disease program. The reports findings on the incidence of diarrhea and mortality rates are discussed in Section II B above. The program proposed four components operating at each level from the national to the community: committee structures to administer the program, oral rehydration units (ORUs) established in health facilities, training of health workers, and supply/distribution of ORS packets. In addition, a national communications campaign would inform mothers about how to use the sugar-salt solution. Some research was recommended for funding by WHO. This plan of operation has not been implemented. Senior Ministry officials think the administrative committee structure was too complex and too cumbersome. There has been no funding provided as yet for the ORUs or the training. UNICEF has been providing ORS packets recently for the cholera epidemic. Over 400,000 packets have been distributed to all 7 Regions of the country by the MOH Division of Epidemiology but, since systematic training of health staff in ORT has not occurred, it is unclear to what extent the packets are being used. The MOH in Mali does have a commitment to the diffusion of ORT nationwide. This is evidenced by the development of a national program plan, the establishment of OR units in Bamako, and the training of some health workers in ORT in the context of donor-funded projects in Koro, Mopti, Segou and Kayes Regions. However, up till now, the MOH has not been able to decide on a functional administrative structure for the program. Since the program, as conceived, covered several areas (water, hygiene, nutrition, etc.), responsibility for its execution was unclear. This meant that detailed implementation plans were never developed and donors were not approached for special funding for ORT.

III. ANALYSIS OF CONSTRAINTS

A. General Development Constraints

Mali lacks the infrastructure needed by a national diarrheal disease program to make contact with families and to persuade mothers to use ORT effectively. There are not even enough paved roads to link the major towns. Although the national radio broadcast reaches most of the country, we are not sure that every village has a receiver. Most mothers won't have frequent opportunity to listen. There is no existing public organizational structure reaching from the center to the villages which can sustain an ORT program, other than the health system. Communities do not have traditional organizations which can readily be harnessed to an ORT program. Families and especially mothers in rural areas are almost universally illiterate. In Mali, it seems like an unbridgeable gap from Bamako to the village.

The rural development programs of donors are coping with this gap by launching regional programs: often restricted to two or three of the country's 46 "Cercles,"* compartmentalized and usually requiring intensive effort. The trend is towards simpler programs with limited objectives that avoid recurrent costs that cannot be met by the Malians or the donors. Donors have to consider the trade-offs between reaching the more distant areas most in need and the accessibility of projects for management and supervision.

* A "Cercle" is an administrative division, covering approximately 100,000 people. Each of the 7 Regions of the country has 6 or

The government is not able to extend its services much further because the budget is already overstretched. Any new village level activities are likely to depend upon supplementary financing from donors: for rural development programs in limited areas, for brief efforts with specific objectives such as the literacy campaign, or for emergency programs such as the drought relief in the north. The constraint on the national budget has become an incentive to seek alternatives to public sector financing of goods and services: cost recovery through fees for public services; profitable sales by public enterprises such as the national pharmacy; reductions of subsidies; as well as more opportunity for private enterprise, such as private medical care. The shift in policy and the openness to financial reforms will create opportunities to suggest alternatives to relying completely on the health system to carry out an ORT program. Nevertheless, the gap to be bridged in getting to the villages is broad; any new national program will take time, persistence and ingenuity.

B. Health Sector Constraints

The coverage of the rural population by health services is very low. Unlike neighboring Niger, there is no functioning cadre of village health workers. Where village health workers exist, there has been no system of supervision or referral in operation. The World Bank health assessment estimates coverage at 15-20% nationally. Since almost 10% of the population lives in Bamako or its environs where health services are concentrated, it is possible that only 5-10% of health needs are provided in rural areas. Anecdotal reports from ministry staff tend to confirm

this conclusion. It is clear that people don't have much confidence in services at the peripheral levels; the effective demand for services is low. Peripheral health facilities have little to offer. Nevertheless, even at 5-10% coverage in rural areas, a population of 360,000 to 720,000 is being reached, including perhaps 70,000 to 140,000 children under 5 years of age.

An important obstacle to any new health service program is the fragmented organization of the MOPHSA. There are four major directorates with somewhat overlapping powers and all with some responsibilities for health services. Below the Minister, there is no single administrative force able to direct people, resources and plans into focussed action. Nevertheless, the Director of Health Services is pushing for a pragmatic, operational program for ORT; his support and leadership could be crucial. Within the Directorate for Health Services, the division for family health is responsible for ORT programs; it is overburdened, especially with donor programs concerned with maternal-child health. It is difficult to sustain leadership and direction for any particular program. A bright spot is the unit in family health responsible for education and communications programs; leadership and commitment within this unit is at a high level.

As noted in the background section, the MOPHSA does not currently have the capacity to assure a steady supply of ORS. This is true both from the point of view of financing the supply and from the point of view of distributing it.

C. Diarrheal Disease Control

Only a small segment of the population could be reached directly by the public health services with information, demonstrations or treatment with ORT. Only a small segment of the population could receive or purchase ORS packets through public sector distribution systems. Any change in these facts is unlikely to occur in the next few years. The coverage and influence of radio messages on mothers behavior is uncertain. The opportunity and effectiveness of the private sector to inform mothers or distribute ORS packets is unknown. In this situation, PRITECH's program objectives need to be realistically modest.

IV. STRATEGIC OPTIONS FOR THE NATIONAL DIARRHEAL DISEASE PROGRAM

The government plan for the National Program and the WHO-led team's operational plan establish the 0-5 age groups as the target for a program strategy that features:

- establishment of ORT as the preferred treatment for diarrhea in the health system (unless severe dehydration requires intra-venous therapy)
- promotion of sugar-salt solution for use in the home
- use of health workers and the mass media to inform mothers about ORT.

The PRITECH team has taken the program target and these elements of a program strategy as givens, and as a starting point for considering what steps might best promote the effective use of ORT within the next three years and beyond.

The key strategic questions for the PRITECH team have been the following:

- How heavily to rely on the health system as a means to reach mothers? How far down in the health system to provide training and to push the program?
- Whether packets should be imported or produced in Mali?
- What logistics system(s) to rely on for packet distribution?
- How to incorporate and to connect with the variety of rural development programs, health services programs, cooperatives and other community organizations, PVOs, and relief programs, all of which are operating on a fragmented and often isolated basis?
- Where will the leadership and administrative direction for the programs arise?

The team has planned the program in conformance with WHO guidelines for ORT treatment, specifically that mothers would use sugar-salt solution in the home at the onset of diarrhea, and seek packets of ORS and treatment at a health facility if diarrhea persists and dehydration occurs.

V. PROGRAM DESCRIPTION

A. Goal

To reduce child mortality, under age 5, which is caused by diarrheal disease in Mali.

B. Purpose

To establish ORT as the principle means of treating diarrheal disease in the health system, and to begin a course of action which can feasibly, over time, establish ORT as a common practice in Malian households. The time period for the PRITECH program is three years; completion of the course of action initiated by PRITECH may take seven to ten years and will require further donor assistance.

C. Program

The Directors and senior officers of MOPHSA, convened by the chief of the Minister's Cabinet, reviewed and approved the following program strategy with estimated budgets on February 25, 1985. Also participating in the session were representatives of WHO and UNICEF. The program strategy was presented by PRITECH, based on joint staff work with the Directorate for Health Services.

Within the framework of the Ministry National Program for Diarrheal Disease prepared in 1981 and the Operational Plan for that program prepared in December 1983, PRITECH proposes a program to reach mothers and families with ORT. The program has four parts:

1. Training of health personnel at three levels: the seven regions, the 46 circles, and the approximately 300 arrondissements throughout the country. Health personnel will be trained to:

- a) administer GRT effectively,
 - b) inform the public about ORT and educate mothers to use ORT effectively, and
 - c) train and supervise subordinate health personnel who will perform a) and b) above.
2. Informing the public about ORT, using existing political/ community organizations to reach opinion leaders at all levels. Health personnel will coordinate with local extension workers to organize the inclusion of information sessions on ORT into the meetings at regional, circle, arrondissement and, whenever possible, village levels of the following local groups: Development Councils and Committees (grouping government representatives and community leaders), party structures (Women's Unions, Youth Unions, etc.), cooperative groups, etc.

Where village health workers are functioning or other community workers are functioning or other community workers are present at village level, funds will be made available for short training sessions to be organized by arrondissement health staff and local extension workers. The structure of rural development programs varies widely throughout the country, but these will be requested to participate in all cases. Literacy workers and school teachers will be especially important as opinion leaders, and will be given educational materials on ORT.

These efforts to create a favorable climate for the understanding and acceptance of ORT will be supplemented

and spread by direct radio broadcasts, with brief messages directed at families and mothers.

3. Mass communications for mothers about ORT, using radio broadcasts, posters, and printed pictorial instructions. Radio broadcasting will be repeated over a period of several months. In the first phase, mothers will be instructed to prepare sugar-salt solution in the home. Later, when packets are available, mothers will be instructed how to acquire and to use packets. Training of health workers will be scheduled to precede the radio broadcasts, so all sources of information for mothers will have a standard message.
4. Distribution of ORS packets. In the first phase, roughly one-half million packets will be available for free distribution by health personnel. Distribution will occur prior to or at the time of training. In the second phase, in about one year to eighteen months, packets can be produced locally at the Malian Pharmaceutical Factory and distributed for sale through the National Pharmacy system of outlets. If the government does not produce packets, they will have to request imported packets from UNICEF. PRITECH will assist with studies to determine the feasibility of marketing ORS packets through other commercial distribution systems. If feasible, commercial sales beyond the pharmacy system could begin prior to the completion of the PRITECH project.

<u>D. Outputs and Indicators</u>	<u>Means of Validation</u>
1. <u>Training of health personnel</u>	
--health workers trained in ORT	--participation of workers in seminars/workshops
--health facilities using ORT	--MOPHSA Reporting System; spot surveys by project staff
2. <u>Promotion of ORT</u>	
--studies of mothers present beliefs/practices	--report
--education materials for health workers and mothers	--materials designed, tested and reproduced
--radio broadcasts	--number of broadcasts; spot surveys to assess coverage
--community awareness	--inclusion of ORT in meeting of community organizations; spot checks by project staff
	--data on sales and packet use
3. <u>Supply of ORS</u>	
--Phase One: free packets available from health workers and used for patients	--MOPHSA records, surveys of sentinel circles
--Phase Two: packets produced in Mali and distributed/sold through PPM and commercial channels	--production and sales data

--Phase Three: commercial
distribution outside
drug system

--feasibility study

--completion of report

--commercial sales

--agreements with
distribution agents

4. Effective use of ORT

--patients receiving ORT
at health facilities and
reduced use of other
methods of treatment

--MOPHSA reporting system;
spot surveys by project
staff

--patients arriving at sentinel
centers dehydrated

--patients arriving at centers
having already started ORT

--mothers using ORS at home

--sample surveys at end
of 2nd and 3rd years

--sugar/salt solution

--ORS packets

E. Financial Plan

The Malians will provide the existing resources of MOHPSA and radio broadcast time. The incremental costs of the program will be financed by WHO, UNICEF and AID/PRITECH. WHO funds are to be provided through the regional office in Brazzaville. UNICEF funds will be allocated from the country program for Mali. PRITECH funds will be provided by Africa/SWA. The tentative budget presented below will be refined in the course of preparing annual implementation plans. Budget estimates are for a three year program, from June 1985 to June 1988. The budget does not include packets already supplied by UNICEF.

Donor:	<u>WHO</u>	<u>UNICEF</u>	<u>AID/PRITECH</u>	<u>TOTAL</u>
<u>Activity</u>				
Training	52,000*			52,000
Promotion	90,000*			90,000
Follow-up and Supervision		30,000		30,000
Education Materials		1,000	62,000	63,000
Packet Production		45,000		45,000
Vehicle for Supervision			22,500	22,500
PRITECH Coordinator			90,000	90,000
Technical Assistance			125,500	125,500
Evaluation		<u>22,500</u>		<u>22,500</u>
	<u>142,000</u>	<u>98,500</u>	<u>300,000</u>	<u>540,500</u>

The availability of funds from WHO has not been confirmed. PRITECH is asking UNICEF to be ready to provide funds for training and promotion, if necessary. The source of these funds needs to be determined and confirmed before proceeding with any implementation actions.

* A portion of this amount, for the National Seminar and for training in one region, will be allocated from a joint WHO/UNICEF nutrition project. If WHO is unable to provide any of these funds, UNICEF will be requested to increase their contribution.

VI. FEASIBILITY

A. Economic/Financial Feasibility

The project will use the existing resources of MOPHSA: staff, organization and facilities. The staff has been designated to develop the promotion and education materials; they are already engaged in the effort. Staff will be identified and assigned to organize the seminars and the workshops and to supervise the program. MOPHSA assures that radio broadcast time can be provided as part of the existing health education programming on the national station. None of these costs are incremental to the routine budget. We are assuming that participation of other development programs and organizations will not involve additional incremental costs.

The special costs of the program - for education materials and programs, and for the training sessions and workshops - are of a one-time nature. All these one-time incremental costs are being handled by AID/PRITECH, WHO and UNICEF. UNICEF will also fund the incremental costs of supervision visits during the course of the project. There will be ten supervision visits by MOPHSA and project staffs to each region, a total of 70 visits.

The recurrent costs of providing packets will be covered by the sales of packets through the national pharmacy system. The national pharmacy has demonstrated that it operates at a profit. More extensive distribution would also be on a commercial sales basis.

B. Management/Administrative Feasibility

The Malian leadership for the program is not adequately defined. Tentatively, the head of family health programs has been designated to direct the diarrheal disease programs. It is not clear whether this will be a permanent arrangement. In the meantime, the Director of Public Health has been directly involved in decisions about how to organize the program. This arrangement is satisfactory, beneficial in fact, in the short run. The administrative arrangements will need to be more clearly defined before the program begins. We have a commitment from the Director of Public Health that the necessary leadership will be provided.

C. Socio-Cultural Feasibility

The cultural responses to ORT in Mali have not as yet been analysed. Since there have been several experiences with ORT both in urban and rural areas (see page 21), a preliminary study of the responses of both mothers and health staff should provide useful information for initial program orientation. Some insights will also emerge during the testing of educational materials. The project staff will be alert to problems during the spot surveys, as part of program supervision. The best indicators of problems will be the evaluation surveys at the end of the second and third years. All these information sources will be used to modify the program appropriately.

VII. IMPLEMENTATION PLAN

A. Schedule (see page 37)

The program will be implemented over a three year period; the implementation schedule assumes program approval in April and the start of program activities in June 1985.

Health workers will be trained country-wide at the arrondissement level, spreading out from the center to the seven regions to the 46 circles or districts, and then to the more than 300 arrondissements or subdistricts. Selectively, where health workers are active beyond the arrondissement, community health workers and village representatives will be informed about ORT. Even if only 5 to 10 percent of the rural population is being reached by the health system, health workers and community leaders will be important supporters, to give mothers confidence to try ORT. At the regional conferences, a training strategy will be devised for each of the seven regions to involve any existing system of community services, such as the literacy program, rural development programs, or the feeding programs in the north. The educational materials will be ready by the first quarter of 1986, when training begins at the circles and arrondissements. All of the regions will be involved by the first quarter of 1986, and the circle level conferences will be completed by the third quarter of 1986.

As explained below, the UNICEF sachets now in Mali will be made available to health workers in conjunction with the promotion and training activities. Distribution will be quite limited until the sale of locally produced sachets begins in the third quarter of 1986. We are assuming rapid start-up of ORS production; if UNICEF

procurement of the packaging machine is delayed, the distribution schedule may be pushed back. There should be enough lead time to order more imported packets through UNICEF, if funding is available by the end of the third quarter of 1985.

We expect that most mothers in Mali will hear about ORS from radio broadcasts, directly or indirectly through family and freinds. The initial radio broadcasts will promote homemade sugar-salt solution, beginning in the second quarter of 1986. Radio promotion of sachets will await supply and distribution of sachets through the pharmacy system.

INTRODUCTION OF ORT: ACTIVITIES MID 1985 - MID 1988

	1985		1986				1987				1988	
	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr	1st Qtr	2nd Qtr
1. National Conference for Instructors	XXX											
2. Regional Conferences		XXX	XXX									
3. Preparation of Educational Materials	XXX	XXX	XX									
4. Circle Conferences			X	XXX	XXX							
5. Promotion at Arrondissement Level			X	XXX								
6. Radio Promotion of Sugar-salt Solution				XXX	XXX	---	---					
7. Set up of Sachet Production		XXX	XXX	XX								
8. Local Production of Sachets				XX	XXX							
9. Free distribution of Sachets by Public Health Workers, etc.	XXX	XXX	XX-	---								
10. Sale of Sachets by Pharmacie Populaire du Mali (PPM) System					XXX							
11. Sale of Sachets by Other Commercial Outlets										XXX	XXX	XXX
12. Radio Promotion of Sachets					XXX							
13. Evaluation of Distribution and Availability of Sachets		XXX				XXX					XXX	
14. Evaluation of Mass Education and Promotion Campaign				XXX	XX		XXX				XXX	

B. Promotion/Educational Activities, and Training Activities

The following detailed implementation plan and budgets were developed with the staff of the Directorate of Health Services:

1. Training and Awareness Raising Activities at all Levels

Type and Level of Activity	Persons To Be Trained or Sensitized	Trainers	Main Objectives of Activity	Est. Cost
a) Training of Program Trainers, National level (6 days)	<p>A national team which will be responsible for training at the regional level and follow-up of training activities at the peripheral level. (9 persons)</p> <p>Members of the health region training teams. (14 persons)</p> <p>Teachers of the national schools of social health training. (5 persons)</p>	<p>Malian consultants WITH ORT experience.</p> <p>WHO/UNICEF representative(s)</p> <p>USAID/PRITECH representative(s)</p>	<p>Review the principles and relative to OPT.</p> <p>Study in depth what activities must be carried out in order to ensure that ORT is used by health facilities and by mothers in Mali.</p> <p>Study educational materials which need to be used for training at the regional level and at the "Cercle" level (WHO modules, etc.).</p>	CFA.F. 872,500
b) Training at the regional level (4 days in each region)	<p>2 or 3 staff representatives of each social health "Cercle" (15-20 per region)</p> <p>Social health personnel at the regional level (5 per region)</p>	<p>Regional trainers who participated in the national seminar</p> <p>2 or 3 members of the national team</p>	<p>Review the principles and the practices relative to ORT.</p> <p>Determine what are the training and awareness-raising activities to be carried out at the "Cercle" level.</p>	CFA.F. 7,185,500

Type and Level of Activity	Persons To Be Trained or Sensitized	Trainers	Main Objectives of Activity	Est. Cost
c) Awareness-raising at the regional level (1 day)	Regional authority representatives of Technical Services and democratic organizations	Regional trainers	Inform the participants of the importance of ORT and of its use by mothers. Discuss training and awareness raising activities which must be carried out in the region	(to be carried out at the time of the regular meetings of the popular organizations)
d) Training at the level of each "cercle" (2 three day sessions per cercle).	1 or 2 members of health staff of each "Arrondissement" (10-15 persons). Social health staff of the "Cercle". (5 persons)	"Cercle" trainers who participated to the regional seminar. 1 or 2 members of the Regional Team.	Review the principles and the practice relative to ORT at the levels involved. Determine what are the training and awareness-raising activities to be carried out at the Arrondissement level.	CFA.F. 15,272,000
e) Awareness raising at the "Cercle" level. (1 day)	Cercles authorities, representing Technical Services.	"Cercle" trainers	Inform participants of the importance of ORT and of its use by mothers. Discuss awareness raising activities to be carried out at the "Cercle" and Arrondissement level.	(to be carried out at the time of the regular meetings of the popular organizations).
f) Awareness raising at the level of each Arrondissement	Arrondissement authorities, representing Technical Services and Democratic organizations.	Arrondissement health personnel. Members of the "Cercle" Social health team.	Inform participants about ORT. Discuss the potential means by which mothers could be encouraged to use ORT.	(to be carried out at the time of the regular meetings of the popular organizations).

Type and Level of Activity	Persons To Be Trained or Sensitized	Trainers	Main Objectives of Activity	Est. Cost
g) Visits for activity planning and follow-up at the regional and "Cercle" levels (10 visits per region during a three-year period).				CFA.F 13,300,000
h) Extension work at the sector level (2 days in some sectors)	Community health workers. Village representatives	Arrondissement health personnel. Arrondissement and sector extension workers.	Inform participants of the importance of ORT	CFA.F. 40,670,000 (pour 10 sectors per cercle)

2. Educational Materials

Type of Material	Purpose	Content	Quantity	Est. Prices
a) Small poster	Memory aid to be distributed to all mothers after the explanation	Illustrations of how to prepare the water sugar salt solution and of ORS packets	500,000	CFA.F 12,000,000
b) Booklet (in the various national languages)	Educational guide to be used by all individuals who may have to carry out training activities with the population (health, education, literacy and extension personnel).	Key illustrated messages concerning: <ul style="list-style-type: none"> ° the danger of diarrhoea (loss of water) ° the use of ORT at the first stool. ° the feeding of the diarrheal child. ° the prevention measures. 	20,000	CFA.F 8,200,000
c) Large posters	Visual reminder to be placed in all the health facilities, schools and public places	Preparation of salt-sugar solution for diarrhoea Preparation of ORS packets for diarrhoea (in a second phase)	30,000	CFA.F 6,600,600

Type of Material	Purpose	Content	Quantity	Est. Prices
d) Flannelographs	Pictures to be used to accompany the booklet during the group training sessions in health facilities.	Same pictures as in the booklet	2,000 sets	CFA.F 950,000
e) WHO Training modules (superior level)	Materials to be distributed during the "Cercle" seminars	Management of diarrhoea Training activities planning and follow-up at the grass-root level.	310 sets	
f) WHO Booklet "Treatment of diarrhea and utilization of ORS"	Materials to be distributed during the "Cercle" seminars	Management of diarrhoea using ORT	1,500	
g) Radio spot	Mass dissemination of ORT	Repetition of booklet message preparation of salt-sugar solution at first and in a second phase of the packets.	3 or 4 short spots repeated over several months	
h) Illustrated labels for local production of packets.	Reminder for the mothers of how to mix the packets correctly	Illustrated instructions (the same pictures as on the small poster)	Depending on local productions	4 CFA.F per unit

C. Production of ORS Packets

UNICEF is taking responsibility for procurement of the equipment and supplies needed to produce packets locally, based upon the PRITECH feasibility study presented in Annex 2. Implementation arrangements were discussed with UNICEF; there do not appear to be any important foreseeable problems. PRITECH staff will consult regularly with UNICEF to monitor implementation according to the program schedule.

D. Distribution of ORS Packets

Estimation of needs will evolve with the three phases of the distribution plan. Evaluation of ORS consumption in each phase will provide the starting point for forecasting the supply requirements for the following phase.

Phase One: To launch the first phase, initial estimates will be based on assumptions about the coverage of the MOPHSA's health care facilities, Mali's demographic profile and the prevalence of diarrheal disease.

Coverage of ORS packets: The World Bank has estimated current health care coverage in the three pilot circles of the upcoming Primary Health Care Project at 5% of the population. It further estimates (hopes) that the range of intervention contemplated under the Project will increase coverage to a maximum of 45% (World Bank, Staff Appraisal, Mali Primary Health Care Project).

Population: The regional training programs will use children under 5 years of age as the target population for the ORT project. Mali's population in 1985 is taken to be 8,015,000 with children of that age group comprising 18.4% (Dr. Vincent Vicary, FAC, "Elements de Demographie Medicale").

Prevalence: Seven episodes of diarrheal disease annually for the target population.

Course of therapy: Two one-litre packets of ORS per episode (WHO's standard norm of treatment).

On the basis of these assumptions, ORS supply requirements for twelve months would be calculated as (% health services

coverage x total population)

X target population % x (number of diarrhea episodes per
year x units of ORS)

OR (.05 x 8,015,000) x .184 x (7 x 2) = 1,032,332 packets

Because, however, staff training at the circle and arrondissement levels will take place at a roughly constant rate throughout the first year of the project, only 50% of this quantity or 516,000 packets will be required for the first phase of the distribution plan. This works out at an average of 11,217, say 11,200 for each of 46 circles. (For purposes of comparison, the maximum coverage estimate of 45% would generate a first phase ORS supply requirement of 4,645,000 packets, all other assumptions remaining the same.)

UNICEF ORS packets come 50 to the carton, each carton measuring 9.5 x 12 x 37 centimeters and weighing about 2.1 kilograms. The "average" circle allotment of 11,200 packets would require 224 cartons which quantity of stock would occupy 1 cubic meter and weigh 470 kilograms.

For purposes of effecting the first phase distribution, the project will take advantage of ORS stocks already present in Mail. These total an estimated \pm 800,000 packets including about 500,000 managed by MOPHSA's Division of Epidemiology and about 300,000 at UNICEF.

The estimated need of 516,000 packets works out to an average 73,700 per region. This represents 6.5 cubic meters of stock weighing 3100 kilograms to be transported to each region during the course of the first phase. It is planned to distribute these

stocks at or before the regional training seminars in accordance with their populations and the amount of time remaining in the interim before start up of regular distribution through PPM (larger stocks for regions participating in the earliest training seminars, smaller stocks for those participating in the later ones).

The vehicular resources available for accomplishing this task include a two ton truck at the Division of Epidemiology, a ten ton truck at OMP and a ten ton truck at the Division d'Hygiene. Because this distribution is essential to Project Start up and because it is a one time activity, the Project will provide budgetary support for gasoline and driver's per diems to assure that it is carried out in a timely and well coordinated manner. Concerning transport from the regional to the circle level, this will be handled by the individual circles. Most circles have land rover type vehicles that makes periodic visits to the regional bureaus (if only to pick up salaries). The precise arrangements for dividing the stock between reserves at the regional level and working stocks at the circle level will be worked out on a region by region basis at the time of the seminars.

Finally, during this initial phase, a representative sample of circles will be selected as sentinels for purposes of monitoring the actual dispensing of ORS in health centers and dispensaries. This information will be used as part of the basis for estimating needs for the second phase of the distribution plan.

Second Phase: During this phase, ORS, either locally manufactured or imported, will be distributed for sale to the

MOPHSA's health care facilities and to the public through the PPM's network of wholesale/retail outlets and affiliated retail outlets. Forecasts of needs for this phase will await evaluation of ORS consumption at health facilities during the first phase and a current assessment of the potential for direct sales to the public at PPM's retail outlets.

At an appropriate point during the second phase a marketing study will be carried out to determine the potential and the costs of widespread commercial marketing of ORS. Together with consumption data from health facilities and sales data from PPM outlets, this study will form the basis for forecasting needs during the third phase of the distribution plan.

Third Phase: If the information collected during the second phase so warrants, during the third and final phase of the distribution plan, ORS will be distributed through both the PPM and other commercial channels. The latter would include appropriate parastatal and private enterprises.

E. Technical Assistance and Program Management

The PRITECH Mali representative will coordinate program activities with MOPHSA staff and UNICEF, under the supervision of the PRITECH Regional Officer based in Dakar. The representative should be hired as soon as possible after the program is approved. The PRITECH planning team interviewed four qualified expatriate candidates currently resident in Mali. We believe hiring of the representative can be accomplished by June 1985, if the program is approved in April.

A first action for the representative and the Regional Officer will be development of the first year work plan which will be used to plan and monitor program activities. Requirements for short term assistance will be determined at that time. Tentatively, we estimate the following needs: production/distribution experts, 2 months; education materials specialist, 4 months; training specialist, 3 months; and evaluation specialists, 3 months.

VIII. EVALUATION PLAN

A. ORT Training and Promotion

Section V D, Outputs, outlines the indicators of program achievement for training and promotion; these indicators will be monitored by PRITECH and MOPHSA staff in the course of implementation. Spot surveys, direct observation at field sites by project staff using standard report forms, will be accomplished as project staff travel throughout the country. The real test of the training, promotion and education activities will be the prevalence of effective use of ORT in health facilities and homes. At the end of the second and third years of the program, PRITECH will organize sample surveys in cooperation with UNICEF and MOPHSA to determine whether mothers are beginning to use ORT effectively.

B. ORS Supply Evaluation Plan

Phase One

The interim between ORT Project start up and the commencement of regular PPM/MOPHSA supply operations is assumed to be twelve to eighteen months. During this period, the Project will not set up an ORT distribution system; rather it will arrange for a one time stock of ORS for the 46 circles to see them through until the regular supply system begins to function. Accordingly, supply evaluation for the first phase will not concern itself with system operations and will focus solely on the question of the quantity of ORS being dispensed for patients at the circle and arrondissement health facilities.

Once health center and dispensary based personnel in a circle have been trained in ORT, one could expect the quantity

of ORS dispensed for patients to average 11 packets per 1,000 people per month over the course of a year, based on the assumptions used for estimating needs. Assumptions have their limitations, however, and no region or circle is precisely average so that this figure cannot be taken as an absolute criteria on which to evaluate whether or not training has been effective or ORS is being dispensed and used as it should be. Comparing monthly figures on ORS dispensed from a representative sample of circles would be useful, however, for determining what future supply requirements are likely to be given a set of assumptions about coverage, disease prevalence and staff training and ORS utilization. Within the sample, where any circle's figures for ORS dispensed are conspicuously above or below the norm, further investigation will be undertaken to determine the reasons for these variations.

Accordingly a representative sample of circles (4 to 7) will be selected for monitoring the quantities of ORS dispensed. Care will be taken to balance the sample to include urban/rural and geographical variations. A simple format will be developed in collaboration with MOPHSA counterparts for collecting information on drugs dispensed at each health facility and forwarding it to the circle health center. This information will be aggregated at each circle in the sample on a monthly basis. It may then be used along with other performance evaluation indicators to estimate future ORS needs and evaluate program effectiveness.

Phase Two

Once the PPM/MOPHSA supply connection is established, evaluation from the "supply system perspective" will expand its focus to include both quantities of drugs dispensed and the quality of system operations. The precise arrangements for the PPM/MOPHSA relationship and for intra circle drug distribution will be worked in the coming year as part of the World Bank financed pharmaceutical reform project. In general, however, evaluation during the second distribution phase will cover the following points:

- availability of ORS at PPM outlets
- availability of ORS at MOPHSA health facilities
- appropriateness of storage and distribution arrangements
- quantities of ORS dispensed for patients at MOPHSA health facilities
- quantities of ORS sold to MOPHSA facilities and sold directly to the public
- value of ORS sales

Phase Three

A final or "expanded market" phase is contemplated if distribution and sales of ORS through the PPM/MOPHSA networks can be managed effectively. This would encompass social marketing and possible distribution through additional private and/or parastatal commercial channels. Ultimately, evaluation of marketing activities will be based on the volume and value of sales. The details of evaluation for the final phase of distribution will have to await the formulation of the specific strategies and objectives for expansion of ORS sales.

IX. FURTHER ANALYSIS REQUIRED

The major unresolved issue for the program is how to move beyond the limits of the MOPHSA system of facilities and the PPM outlets.

Commercial Distribution Alternatives

With a view to assuring the widest possible distribution of ORS a brief appraisal of commercial distribution alternatives was made. It appears that adequate wholesale/retail networks do exist to permit expanding the distribution of ORS well beyond the reach of the public sector health system if adequate demand can be created. The following alternatives have been considered:

1. Pharmacy Populaire du Mali

As noted in the background section, this profit making parastatal enterprise has an extensive distribution network consisting of 93 "officines" or directly managed wholesale/retail outlets and 443 "depots agrees" or affiliated retail outlets. One hundred fifty five or 35% of the depots are privately owned, typically by former MOPHSA employees, and the rest are managed by communal or cooperative organizations. Officines are located in every circle in the country and the depots expand this reach down to every arrondissement. Typically, these depots resupply themselves from the officines on a cash and carry basis according to need. The PPM resupplies officines from its central stores once every three months. This connection is direct from central to circle level without regional or intermediate storage facilities.

2. Other State Run Enterprises

We visited the SONATEM which has the state monopoly on cigarettes and matches to obtain an idea of the distribution structure of other state run enterprises. The SONATEM has wholesale outlets in every circle in the country. Through this network it sells its products to independent local wholesalers and retailers located at distance from the outlets. Both PPM and SONATEM are able to manage direct distribution of their products down to circle level wholesale outlets. But where PPM relies on its system of depots agrees to expand its reach beyond the circle level, the SONATEM relies on local trading networks to accomplish the same thing. For purposes of expanding the distribution of ORS, it is SONATEM's wholesale clients rather than its formal distribution system that appear to be of interest.

3. Private Commercial Enterprises

Saacha Dialo is a privately owned manufacturer and distributor of household products such as bleach, vinegar, and plastic utensils. This firm undertakes no direct distribution from its central plant and sales room in Bamako. Rather, it relies on trade agents located in every regional capital except Tombouctou and Gao to come in, buy stock, and redistribute it through local trade networks in their respective zones of operations. To help its agents cover their own distribution costs the firm provides a remise of 2% given in kind at the end of the year. Saacha Dialo has no agents and achieves no widespread distribution in the northern part of the country, that is Tombouctou and Gao. This is due to the high costs of distributing goods in these regions and

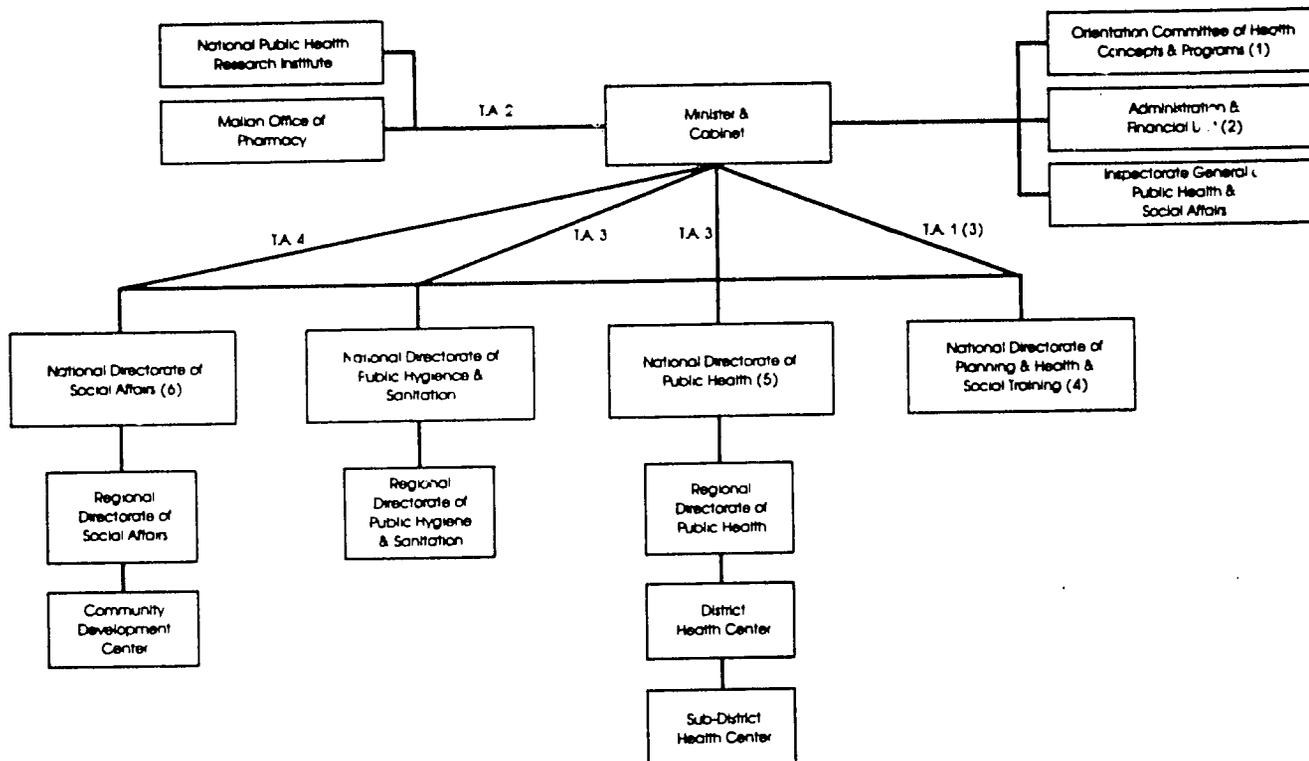
competition from cheaper products seeping in from Algeria and Niger.

The organizations visited are taken as proxies for the other organizations of their respective segments of the commercial sector. Further study will be required to determine whether or not they fairly represent the general state of affairs. If they do, further study will also be required to determine how to best exploit the different sector segments for distributing ORT. At first glance, however, the setting for commercial distribution appears to be a promising one.

ANNEXES

MALI

Organization Chart of the Ministry of Public Health and Social Affairs



- Notes:
- (1) Orientation Committee of Health Concepts & Programs (COCES) is an ad hoc consultative health commission.
 - (2) The Administrative & Financial Unit (CAF) is a branch of the Ministry of Finance & Commerce and is responsible for managing the MOPHSA's personnel, equipment, materials & Finances.
 - (3) TA 1, 2, 3 and 4 refer to the four existing technical advisors to the Minister.
 - (4) The National Directorate of Planning & Health & Social Training supervises the Secondary School of Health & the Nursing School at Point "G".
 - (5) The National & Regional Directorates of Public Health supervise 3 national hospitals & 9 regional & secondary hospitals, respectively.
 - (6) The National Directorate of Social Affairs also supervises the National Center for Community Development.

Source: MOPHSA

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LOCAL PRODUCTION OF ORS SACHETS IN MALI

I. Introduction and Summary

The PRITECH team has assessed the feasibility of local production of oral rehydration salts in sachets. Local production of ORS using trisodium citrate packaged in polyethylene film appears to be feasible on technical grounds and advantageous on financial grounds:

- In Mali's relatively arid climate, the citrate formulation should have a shelf life that is longer than the time the product would have to spend in a well managed distribution system
- The capital costs of setting up a production facility are relatively modest
- The product could be produced for only two thirds the current cost of imported ORS

This annex includes an analysis of the technical and financial factors bearing on this decision, a production plan, a summary of the necessary inputs from donors interested in supporting local production and an implementation schedule.

II. Technical Feasibilitya. Formula and packaging costs

Analyses and actual experience in many developing countries have shown that it is nearly impossible to produce the WHO-UNICEF "standard" ORS sachet at a cost close to that of the current market price from large-scale factories of US\$0.05 (FOB Europe). The major difficulties in matching this low cost elsewhere are the high delivered cost of the laminated aluminum-polyethylene-polyester packaging material when purchased in relatively small

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quantities, the high cost of shipping the glucose and other chemicals, and the high amortization cost of a new production facility and automatic equipment for producing sachets if it is not used at near full capacity.

In 1984, however, this situation was somewhat changed by the approval by WHO for the substitution of trisodium citrate for sodium bicarbonate in the ORS formula, resulting in a product that promises to be far more stable (yielding a longer storage life) under the influence of high temperature and humidity.

Under humid conditions, the citrate ORS package requires less protection from moisture than the bicarbonate ORS, but aluminum laminate packaging is still recommended by WHO for citrate ORS to have comparable stability. WHO now states unequivocally¹ only that a laminate with a thinner aluminum foil layer will provide a storage life equivalent (4 years) to the "standard" ORS product under humid conditions. The cost of this type of material is only slightly less than the "standard" foil recommended, and only compensates for the higher cost of the citrate, so economically no benefit is seen.

Under dry storage conditions, on the other hand, accelerated

¹ W.H.O. (Revised) Guidelines for O.R.S. Production, to be issued in 1985.

² Siewert, M. and Gnekow, H. - The Stability of Glucose-Electrolyte Mixtures (Oral Rehydration Salts) used for The Treatment of Diarrhea Diseases. Pharmazeutische Zeitung, 128, 22.2 (June 1983) (in German).

laboratory trials² strongly suggest that citrate ORS packaged in inexpensive polyethylene sachets are at least as stable as bicarbonate ORS packaged in aluminum, and may even be more stable than the same citrate ORS packed in aluminum foil. These studies also indicate that citrate ORS in polyethylene can provide acceptable product stability under humid storage conditions. The effect in this case is not the caramelization and solidification seen when the bicarbonate is subjected to dry, hot storage, but is a moderate hardening which is partially reversible when the sachet dries out.

The implications of these results for ORS production and distribution in Mali are significant. Even in the most tropical region, Sikasso, the daily mean relative humidity never exceeds 80%, and remains below 60% about half the year (Fig. 2). The humid period also corresponds with a period of low daily mean temperatures, with the likely effect of mitigating the deterioration due to the humidity. The humid season is followed by a long dry period when stored sachets which have absorbed moisture would dry out, leaving the sachet contents caked but easily crushed and soluble. However, it would not be prudent to assume more than a 2 year storage life under field conditions until further experience with citrate ORS is amassed. A properly managed distribution system should in any case move sachets through to end users in a much shorter time (See Table 4 for estimates of distribution system pass-through times).

The implications of this climatic pattern for production in Bamako are equally benign. Daily average humidity in Bamako

(Fig. 1) exceeds the recommended level for ORS (bicarbonate) production during only four months of the year, and again corresponds with a period of relatively low daily maximum temperatures. This greatly reduces the requirements for climatic control of the production facility and reduces problems with deterioration of stored raw materials.

Being able to justify the use of polyethylene film (which is manufactured locally) in place of aluminum foil laminate has the effect of saving from one to two cents (5-10 FCFA) in the production cost per sachet, and also affords rather greater freedom in the content and format of the printed ORT instructions inserted in the sachets. This savings can be had even if the ORS is packaged in two layers of polyethylene film, as has been recommended in some countries.

b. Scale and technology of production

The number of sachets required annually for Mali is not likely to exceed 1 million per year, by any realistic estimate of what can be achieved through a national program. At this production level, semi-automatic equipment for sachet filling and sealing is clearly preferred over more complex and expensive automatic equipment. A production line using this kind of equipment would be used at close to maximum capacity, and greatly reduce operating costs associated with maintenance and climate control. Another benefit is the opportunity to cost-effectively employ several more workers than required with automatic equipment. Estimation of the cost savings associated with lower depreciation and maintenance costs is somewhat

difficult, but the net saving may be in the vicinity of one cent (5 FCFA) per sachet.

c. Production facility

Given the above favorable conditions in Mali for potential low-cost, moderate scale production, it is satisfying to be able to identify an existing facility having both the technical capacity and the interest in producing ORS sachets. The Usine Malienne de Produits Pharmaceutiques (UMPP) in Bamako was established under an assistance project by the People's Republic of China with an initial investment of 2.1 billion CFA, and began production of a modest range of tablets, injectables, pommades, and syrups in 1983. Although there have been serious administrative problems which resulted in a recent extended cessation of production, the UMPP resumed operation in October 1984. The 1985 production plan, which anticipates 22 essential drugs having a total wholesale value in the order of 2 billion CFA, appears to be well underway.

The UMPP has been recently transferred from the Ministry of Health to the Ministry for the Guidance of State Enterprises. There are 27 Chinese technicians working among 126 Malian employees. Phasing out of these technicians is expected to occur by 1987. Although it is difficult to know exactly how management decisions are now made, the general administrative structure appears to be largely Malian, so it may be supposed that the Chinese now function mainly as technical advisors.

The present interest by the UMPP in producing ORS seems to derive from the wish to add profitable essential drugs to the product line and to lower overall production costs by utilizing

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unused space in the tablet production area. The high probability of donor financing of investment costs can be presumed to be an important factor in selecting among alternate products for increasing utilization and sales, but the question of relative profitability is far from straightforward. Items produced by UMPP cannot be imported by the Pharmacie Populaire Malienne (PPM) and the UMPP is allowed a fixed profit margin of 11% for all items produced, so both the market and the profit margins of the UMPP are protected. However, the UMPP seems willing to produce ORS sachets despite the prospect of relatively small total profit; assuming sales of 1 million sachets, profit would be roughly equal to that from their smallest volume tableted product (Table 1).

The UMPP is in many respects perfectly suited for ORS production. Personnel with several years experience in the preparation and handling of dry powder ingredients (including anhydrous glucose, used in intravenous solutions) are in place and working under Malian pharmacists and production supervisors. A suitable space in the tableting area will be made available and renovated for sachet production. Procurement mechanisms exist which appear to work efficiently, although there have been serious cash-flow problems in the past. Raw material storage space is limited, but could be adequate if glucose is received quarterly and the stores rearranged. A well-equipped quality control laboratory exists and is staffed by trained personnel. Much of the more costly equipment needed is already installed and is underutilized: tray drier, milling/sieving machines, a large floor scale, moisture balance, dessicator,

and precision balances. A well-equipped maintenance workshop is staffed by technicians capable of dealing with any problems in the type of equipment suggested. While not all good manufacturing practices are observed, production generally appears to be carried out under hygienic conditions, and a lot control system functions. There is no quarantine as such, but the finished goods store is spacious and orderly.

d. Alternative Production Site

There is a laboratory at the Office Malienne de Pharmacie (O.M.P.) which is engaged in production of traditional medicines and galenicals, and which has also expressed an interest in producing ORS as an initial step towards full-scale production at the U.M.P.P. Current production consists of rather small numbers of sachets of partially processed plant material. Polyethylene pouches are filled by hand and sealed with a simple commercial heat-sealer. An analytical laboratory contains most of the instruments needed for quality control of ORS production, but the space available for raw materials storage, batch production and sachet production is very limited.

III. Proposed Production Plan

Product Description: UMPP "Mali ORS" (Citrate Formula)

For a sachet which makes 1 liter of solution, 27.9 grams of ORS mixture (W.H.O. modified formula) is sealed in an inner bag of the smallest possible size (approximately 60 X 90 mm) of 0.04 mm thick polyethylene. This bag and the instructional leaflet are sealed together in a slightly larger outer bag of 0.05 mm thick polyethylene. Date and batch numbers are stamped on the leaflet. Finished sachets are packed in polyethylene

bags or cartons of 50 and these are enclosed in a banded master carton containing 1,000 sachets.

The production activities needed to produce the above will follow closely those described in the WHO guidelines for ORS production. These can be simplified to a practical production protocol by taking local and specific factors into account. Further changes and simplifications may be expected to be implemented over time in response to experience with materials from different suppliers, seasonal climate effects on product life, and different ways of scheduling and organizing production. The flexibility of the suggested semi-automatic equipment and the technical resources of the UMPP should permit rapid adaptation to alternative methods of production.

The basic steps and additional requirements are:

1. Materials procurement, inspection and storage.

Judging from the ability to procure good quality anhydrous glucose of French origin at low cost (6 FF/kg delivered to factory), the UMPP has an efficient procurement system which can make favorable shipping arrangements. Storage space for raw materials will be rather overburdened unless procurement and storage are managed carefully. The existing storage area of 225 m² would be barely adequate even if empty for storing materials for a million sachets, and it is at least half full at present. The store is not palletized so the full volume is inefficiently used. Either additional storage space must be found, or the existing space used more efficiently. A practical solution would be to order glucose supplies (which comprise the greatest part of the volume) in lots of 5 to 10 tons quarterly

or semiannually, and to use palletized storage. Storage can be denser still if the glucose is supplied in 50-kg sacks. Roquette Freres is a satisfactory French source of food-grade glucose and the price should be no higher than that now paid for pharmaceutical grade in drums. The storage problem should be studied by UMPP and equipment for palletization should be provided if necessary (see Table 2 for a tentative list of required equipment).

The comprehensive laboratory assays of incoming raw materials demanded in the WHO Production Guidelines can be dispensed with if it is the factory's policy to rely on lot analysis documents which may be requested from reputable suppliers. If procurement is done through or on the basis of recommendations of UNICEF, there should be little grounds to require laboratory control at the UMPP.

2. Batch mixing. Materials for one to two days production are brought to the batch preparation area and moisture contents are checked with a moisture balance. Materials should only be dried if they are so moist that subsequent production steps will be rendered difficult. This should not be necessary often, and may be minimized by curtailing batch production during the humid season. This seems to be a practical and low-cost option.

Glucose should generally be found free of lumps and foreign objects, but the other chemicals may require milling and sieving. Existing equipment at U.M.P.P. will serve adequately.

The 50-kg glucose sack forms the basis of ORS batch production. Net weight should be adjusted to 50 kg \pm 100 g and the contents emptied into a mixer along with the other batch ingredients which have been weighed and double-checked by two workers and a supervisor. A floor scale suitable for weighing the glucose already exists in the production area, but a precision table scale for measuring the smaller quantities of chemicals is needed. One plough type and one double-cone type mixer, each of 50 kg capacity are already in place, but a more appropriate 200 liter drum-hoop mixer should be provided. The plough-type mixer should be useful for breaking up lumped powders.

The 69 kg batch is mixed for a period determined by trial to achieve complete mixing, probably around thirty minutes. Contents of the mixer are transferred to smaller airtight containers, identified by lot number, and sampled for sodium, potassium and moisture content. The batch may be accepted or rejected and reprocessed if not up to standard. A flame photometer should be provided so an assay of the critical sodium and potassium ions can be done quickly and reliably. (Bottled gas for the photometer is available locally.)

A batch for 2,500 sachets or roughly a half day's filling/sealing should take no more than one hour to prepare if no drying is needed.

3. Sachet preparation. Considerable cost savings can be achieved by forming 3-sided empty sachets from a continuous roll of polyethylene sheath. A local factory makes this material at low cost, but it is not clear that they can produce as narrow a sheath as might be desirable. The alternatives would be use

of a wider, shorter sachet of around 100 x 70 mm, or importation of rolls of narrow (65 and 70 mm) sheaths. If the latter can be imported exempt of duty, the price should be about the same as that quoted by the local factory. In any case, it should be quite easy to use a range of sizes of polyethylene with the equipment proposed.

Empty sachets can be prepared on two impulse film-welding machines equipped with cutters. At a production rate of 50 bags/minute (total from both machines), the 2 million pouches required would occupy three operators four months (assuming 24 days/month, 7 hours/day). The labor cost and depreciation of the machines would add around 0.5 CFA to the material cost of 1.7 CFA per (double bag) sachet. This should be compared with a cost of US\$8,000 per million double sachets (US\$0.008 = 4 CFA) for preformed sachets shipped from Europe to East Africa. Assuming lower shipping costs to Mali, a cost savings factor of two, or 1.5 CFA is still likely if sachets are formed locally.

A year's supply of empty sachets could be produced during the three or four humid months, leaving the dry months for a filling-sealing operation using the same two heat-sealers. This should completely minimize the risk and inconvenience of humidity in the production area and may even eliminate the need for air-conditioning.

4. Sachet filling, sealing, and inner packing.

Mixed ORS powder is transferred from the closed drums to the hopper of the table-mounted semi-automatic auger-type dosing machine. Inner sachets are opened and moved under the auger

feeder and the machine is operated. The operator hands the filled bag to the first thermosealer operator who makes the top seal. At the same time, outer bags are being opened, leaflets stamped, and leaflets and inner bag inserted into outer bags, which are handed to and sealed by the second thermosealer operator. Finished sachets are counted in 50s into cartons, which are sent to the final cartoning station where 20 inner cartons are packed into master cartons of 1,000 ORS sachets. Note: A saving of weight and 1 to 2 CFA per sachet might be achieved by using heavy gauge opaque polyethylene bags instead of the inner cartons. If tightly wrapped and sealed this would provide good mechanical protection and superior moisture protection compared with cardboard boxes.

5. Quality Control. Sachets are sampled at 10-minute intervals during filling and checked on a precision balance to see if the weight of the contents is within specified limits, and the filling machine readjusted if necessary. Visual inspection will detect any sealing problems. A number of sachets from each run should also be checked for sodium, potassium, and moisture content.

6. Production scheduling. While there are several possible ways to schedule production so the target of 1 million sachets per year is met, the following annual calendar allows for cessation of filling during the rainy season while permitting a high annual utilization of capacity (assume 24 workdays/month, 7 hours/day). (See figures 3 and 4).

Annual Production Calendar

Months	Activities	Rates	Output
July to Oct (= 672 hours)	bag production from rolls	25 bags/minute on each of 2 machines	2,000,000 empty bags
Nov to June (= 1,344 hours)	batch mixing	2 - 3 day	400 batches
	filling/sealing	fill-12.5/min seal#1-12.5/min insert-12.5/min seal#2-12.5/min	1,000,000 finished sachets
		cartoning- 1 per 4 min/ outer carton- 1 per 80 minutes	1,000 cartons of 1,000 sachets each

IV. Production Cost Calculations

A. Direct Costs

1. Materials. Materials used in ORS production are the glucose and other salts, leaflets, packaging film, and inner and master cartons.

Material	Quantity Per 1,000,000 Sachets	Unit Cost (est. CIF)	Cost Per Million*
Anhydrous glucose crystalline, foodgrade	20,000 kg	\$0.60/kg (France)	\$12,000
Potassium Chloride, BP	1,500 kg	\$1.20/kg	\$ 1,800
Sodium Chloride, BP	3,500 kg	\$0.40/kg	\$ 1,400
Trisodium Citrate	2,900 kg	\$1.50/kg	\$ 4,350
Polyethylene 0.04mm in 65 mm wide rolls	480 kg	1,000 CFA/kg	480,000 CFA
Polyethylene 0.05mm in 70 mm wide rolls	783 kg	1,000 CFA/kg	783,000 CFA
Inner carton approx 250x200x100	20,000	75 CFA	1,500,000 CFA
Outer carton approx 400x500x500	1,000	500 CFA	500,000 CFA
Instruction Leaflet	1,000,000	4 CFA	4,000,000 CFA
TOTAL MATERIALS			\$19,550+7,263,000 CFA or \$20,580+7,330,000 CFA adjusted for waste

* US\$1 = 450 CFA

Cost in CFA when locally available.

Item costs do not include an extra 5% waste allowance.

2. Direct labor. Labor costs can be simply calculated from the proposed production schedule:

Activity	Personnel Required	Equivalent Man-months*	1 yr Production Cost (CFA) **
Bag production (4 months)	3 workers	12	220,800
	1/2 supervisor	2	100,000
Batch mixing (2.2 hrs/day for 8 months)	2 workers	5	92,000
	1 supervisor	2.5	
Filling/sealing (8 months)	8 workers	64	1,177,600
	1 supervisor	8	400,000
Cartoning	1 worker	8	147,000
			2,137,000 CFA

* 168 hours = 1 man-month

** Workers' salary = 18,400 CFA/month

Supervisors salary = 50,000 CFA/month

3. Other direct costs. Other costs such as incidental labor and electricity are nearly negligible and have not been estimated.

B. Indirect Costs

1. Amortization of plant and equipment.

Amortization costs for the initial investment in the UMPP are apportioned equally among the four production lines.

The annual burden on the tablet line is 32,500,000 CFA.

(See Table 1). An assumed ORS production value of 25,000,000 CFA represents 5.5% of the total tablet line production value, which corresponds to an amortization share is 178,750 CFA per annum.

Amortization for replacement of the additional equipment needed can be crudely calculated by using the same 16 year period as used for the original plant and dividing it into an expected new investment of \$25,000 or 11,250,000 CFA for an annual rate of 703,000 CFA.

2. Administrative overhead. Information on administrative costs and how they are apportioned was not made available, but a crude estimate can be made. Assuming 30 administrative staff at average salary of 600,000 CFA, administrative salaries total 18,000,000 CFA. Estimating another 10,000,000 CFA for indirect utilities, supplies, etc., and dividing by a total annual production value of 2 billion CFA suggest an overhead burden of around 1.5 percent. (The cost of the Chinese advisors has not been considered here.) If apportioned by production value, this would represent 375,000 CFA for ORS sachet production.

Table 3 lists all estimated ORS production cost components.

TABLE 3

ORS Estimated Production Costs
(based on production of 1,000,000 per year)

	Cost per Year	Rounded Cost Per Sachet
Direct Costs		
a. Chemicals	9,260,500 CFA	9.26 CFA
b. Packaging film	1,329,000 CFA	1.33 CFA ¹
c. Cartons	2,000,000 CFA	2.00 CFA ²
d. Instruction Leaflets ³	<u>4,000,000 CFA</u>	<u>4.00 CFA</u>
TOTAL MATERIALS	16,589,500 CFA	16.59 CFA
e. Labor	<u>2,137,600 CFA</u>	<u>2.14 CFA</u>
TOTAL DIRECT COSTS	18,727,100 CFA	18.73 CFA
Indirect Costs		
f. Amortization of existing plant	179,000 CFA	0.18 CFA
g. Amortization of incremental investment	703,000 CFA	0.70 CFA
h. Administrative overhead	<u>375,000 CFA</u>	<u>0.38 CFA</u>
TOTAL INDIRECT COSTS	1,257,000 CFA	1.26 CFA
Total Production Cost		19.99 CFA
+ Allowable Profit (11.11%)		<u>2.22 CFA</u>
Ex-factory cost		22.21 CFA
<hr/>		
+ 25% PPM Markup		<u>5.55 CFA</u>
Retail Sales Price		27.76 CFA

1 Unit Cost would increase by 1-2 CFA if empty sachets are imported.

2 Unit Cost would decrease by 1 CFA if cartons are replaced by opaque 0.10 mm polyethylene bags.

3 One-color printing, double page single side.

4 Excluding initial stock of raw materials.

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The predicted cost of production, 20 CFA, resulting in a cost of 22 CFA to the distributor (PPM) and a final retail sales price of 28 CFA, appears to be low enough to make local production attractive on economic grounds. This low cost is made possible in part by the rather low estimates made for the delivered cost of the chemical ingredients, which is based on information given by U.M.P.P. for the latest price paid for French origin anhydrous glucose, of 6.00 FF/kg. It must be presumed that shipping costs are kept low through favorable arrangements of some type, but even if the estimates are too low by 50%, this would have the effect of increasing production cost by only 5 CFA. Since fixed costs are low (mostly depreciation and amortization) even if production levels are much lower than expected, production costs should not increase by more than 3 or 4 CFA if materials can still be procured in economical amounts. The most pessimistic set of assumptions might yield an ex-factory cost of 30 CFA, and even then such cost-saving options as using printed sachets instead of an inserted leaflet, a single polyethylene pouch, or bags instead of inner cartons, would allow the cost to be reduced. All this must be seen in the perspective of the probable cost of importing standard sachets, likely around US\$0.05 ex-factory plus \$0.02 for shipping, equivalent to 33 CFA (at US\$1 = 450 CFA).

V. REQUIRED INVESTMENT FOR ORS PRODUCTION AT UMPP

A tentative list of production equipment needed and estimated costs is given in Table 2. This list should be the object of further discussion since several items shown may be

considered optional, and it may be prudent to add a third thermosealing unit when production approaches the maximum level of 1 million per year. An air conditioner for the present milling-mixing room may be judged necessary, although since this is a rather large room it may not be practical to consider this. In any event, the investment in plant modification, furnishings, and equipment is unlikely to be less than \$20,000 or more than \$30,000 (9 million CFA to 13.5 million CFA).

An initial supply of raw materials is usually considered to be part of the capital investment, and amortization of this amount or the short term rate interest paid to finance it, is normally considered a production cost component. Since initial materials are likely to be provided by a donor agency, this was excluded from Table 3, while amortization of the equipment, to be donated or not, was included since allowance for its depreciation and eventual replacement must be made. Even if raw materials for a substantial period of production are donated, the UMPP should be encouraged to calculate its selling price as if it had actually purchased the materials rather than according to a subsidized lower cost. Provided the donor agrees with this policy, the benefit thus realized could be used as a cushion for future materials purchases.

VI. DECISION FACTORS AND IMPLEMENTATION

A. The pros and cons of local ORS production may be summarized as follows:

In Favor:

1. Lower cost compared with imported ORS. (22 CFA vs 33 CFA)

2. Possibility of using instructional leaflets printed according to local needs.
3. Profit to UMPP of up to 2.2 million CFA per year.
4. Wages of 2.2 million CFA per year paid in wages to 6 - 8 additional workers.
5. Availability of a fresh product for the distribution system, as compared to imported sachets which may already be as much as one year old on arrival in Mali.
6. Creating a vested interest in the U.M.P.P. for encouraging the promotion of ORS in Mali.
7. Building local capacity for sachet production of future ORS products (e.g., starch-based)

Against:

1. Possibility of using the available space at UMPP for a more profitable essential drug.
 2. Possibility that sales of ORS will be much lower than expected, resulting in slightly higher unit cost and lower total profits.
 3. Greater dependence on imported supplies, in that five or six different items must be procured rather than one.
 4. Risk that extrapolation of the laboratory trials that demonstrated high stability of citrate ORS in polyethylene may not be justified and that actual storage life may be significantly less than the imported standard sachets.
- B. If, after full consideration of these factors, the decision is made to start local production at UMPP, the following basic actions will be necessary:

1. Review of feasibility, production plans, and equipment specifications by WHO-UNICEF ORS production expert.
2. Order production equipment to be imported.
3. Begin renovation of production area at UMPP.
4. Procure locally available furnishings.
5. Order initial raw material stock (with glucose delivered in lots according to available storage space.) The quality of locally-made polyethylene sheath should be evaluated and a decision made about sachet size. Importation of polyethylene sheath or finished empty bags is an option which should be exercised as soon as possible if it is necessary.
6. Once the production room is available and equipment arrives in Mali, installation of equipment should proceed and production trials started as soon as raw materials are available.

Implementation should proceed according to the schedule shown below:

Activity	CY 1985				CY 1986			
	I	II	III	IV	I	II	III	IV
1. Production decision taken & investment funds committed	X							
2. WHO reviews technical plan.	XXXX							
3. Equipment & materials procurement.			XXXXXXXXXXXX		X-X-X-X-X			
4. Renovate production room and stores area			XXXXX					
5. Resolve polyethylene question	X	X						
6. Installation & training					X-X-X-X-X		XXXXX	
7. Begin production							X-X-X-XXXXX	

Depending primarily on the time required for equipment and material procurement, production can be expected to start not before mid-1986 and not later than the end of 1986.

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TABLE 1

Value of U.M.P.P. Tablet Production (1985 Production Plan)

<u>Tablets</u>	<u>Quantity</u>	<u>Ex-Factory Unit Price</u>	<u>Total</u>
Chloroquine 0.1g	30,000,000	11 MF	330,000,000 MF
Aspirin 0.5g	35,000,000	10 MF	350,000,000 MF
Sulfaguanidine 0.5g	4,000,000	11 MF	44,000,000 MF
A.P.C. 0.4g	4,000,000	10 MF	76,000,000 MF
Sulfamethoxypyridazine 0.5g	2,000,000	27 MF	54,000,000 MF
Chloramphenicol 250mg	800,000	34 MF	27,200,000 MF
Oxytetracycline 250mg	1,200,000	25 MF	<u>30,000,000 MF</u>
		TOTAL	911,200,000 MF
		or	455,600,000 CFA

If ORS cost = 25 CFA, then 1,000,000 = 25,000,000 CFA = 5.5%
of total tablet production

Initial investment = 4.2 billion MF or 2,100,000,000 CFA

Total annual amortization = 130,000,000 CFA (16 years straight-
line depreciation)

Total tablet line amortization - 32,500,000 CFA (1/4 of total value)

$$\begin{array}{r} \\ \times 5.5\% \\ \hline 178,750 \end{array}$$
 CFA or 0.18 CFA/sachet

New equipment amortization

\$25,000 = 12,500,000 CFA - 16 years = 781,000 CFA/yr
 or 0.78 CFA/sachet

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TABLE 2

Production Equipment Needed at U.M.P.P.
for 1,000,000 CRS

Required Article	Remarks	Estimated Cost FOB	
		US\$	FCFA
Air conditioner for filling room	29,000 BTU	1,000	(450,000)
Floor Scale	20 kg. max. graduated by 20 gm.	1,500	(675,000)
Mixer, 200 liters	Drum-hoop type incl. extra drums and spare parts	5,200	(2,340,000)
Auger doser		5,400	(2,430,000)
Thermosealing machine (2)	Impulse type, with cutter	4,600	(2,070,000)
Flame Photometer		800	(360,000)
*Wooden Pallets (40)	Pharma Standard	640	(288,000)
*Hand Pallet Truck	2,000 kg capacity	720	(324,000)
*Pallet Stacker	800 kg. capacity, 2.4 meter height	1,700	(765,000)
*Pallet Racks		1,000	(450,000)
Hygrometer	Direct-Reading	250	(120,000)
Shipping		3,000	(1,500,000)
Modifications to Production Area			500,000
Tables, chairs, shelves			500,000
Totals		\$25,810 imports	100,000 CFA local costs

*desirable but not absolutely necessary = \$4,060.

TABLE 4

Distribution Pipeline Analysis

A complete supply system design would include specific assumptions about order interval, order size and maximum/minimum stock levels for different points in the distribution system (health facility, PPM office at circle level, PPM's central depot). These assumptions would determine the amount of time that ORS would spend in depots and on shelves between the time it is dispensed for patients. Because ORS has a limited shelf life it is necessary to know how long it will take for packets to pass through the system in order to determine the optimum packaging mode and formula composition. For the PPM system, the precise details of distribution system design will be worked out under the World Bank/MOPHSA Pharmaceutical Reform Project. On the basis of what is now known, however, it is quite feasible to construct the pipeline model shown below and thereby estimate the maximum amount of time that locally produced ORS would spend on the shelf as 20 months. This is a highly conservative estimate, made for the purpose of demonstrating the practicality of the proposed packaging/formula composition, the estimated shelf life of which is 24 months.

(continuation of Table 4)

<u>Structure</u>	<u>Activity</u>	<u>Length of time</u>	
Foreign Suppliers	Preparation of order raw materials	1 month	> 9 months may lapse before raw materials enter the distribution system as finished ORS
	International Transport	6 months	>
Customs	Port clearing	2 months	>
Factory	Manufacturing	Current	4 months required to produce initial stock for the system, then current production will keep it topped off.
PPM depot	Safety stock	6 months	>
	Working stock	3 months	>
	(Quarterly deliveries)		> maximum of 17 months from the time ORS enters system until it is dispensed for patients
PPM circle Level outlets	Safety stock	3 months	>
	Working stock	3 months	>
	(Monthly deliveries)		>
MOPHSA Health Facilities	Safety stock	1 month	>
	Working stock	1 month	>
	(Daily dispensing)		



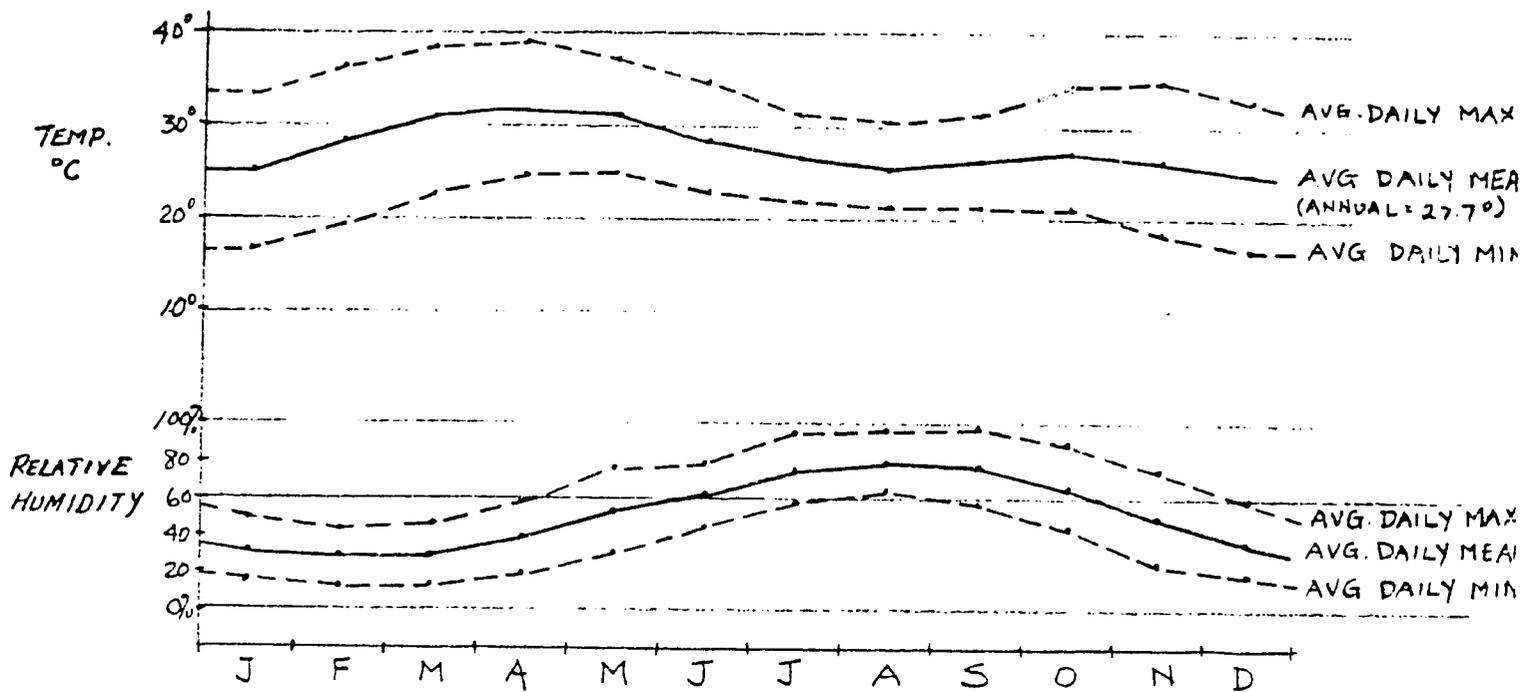


FIG. 1 - BAMAKO: ANNUAL TEMPERATURE AND HUMIDITY RANGES (PERIOD 1951-80)

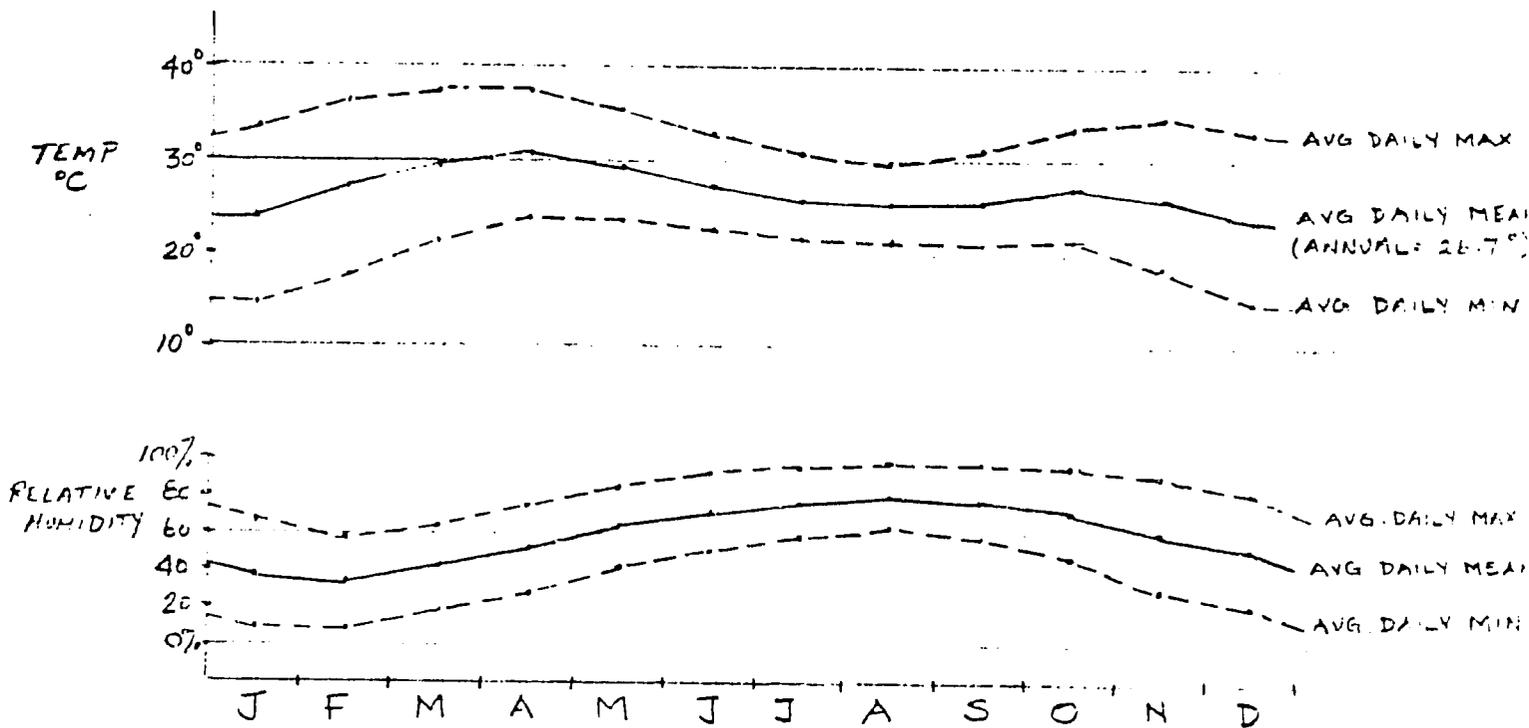
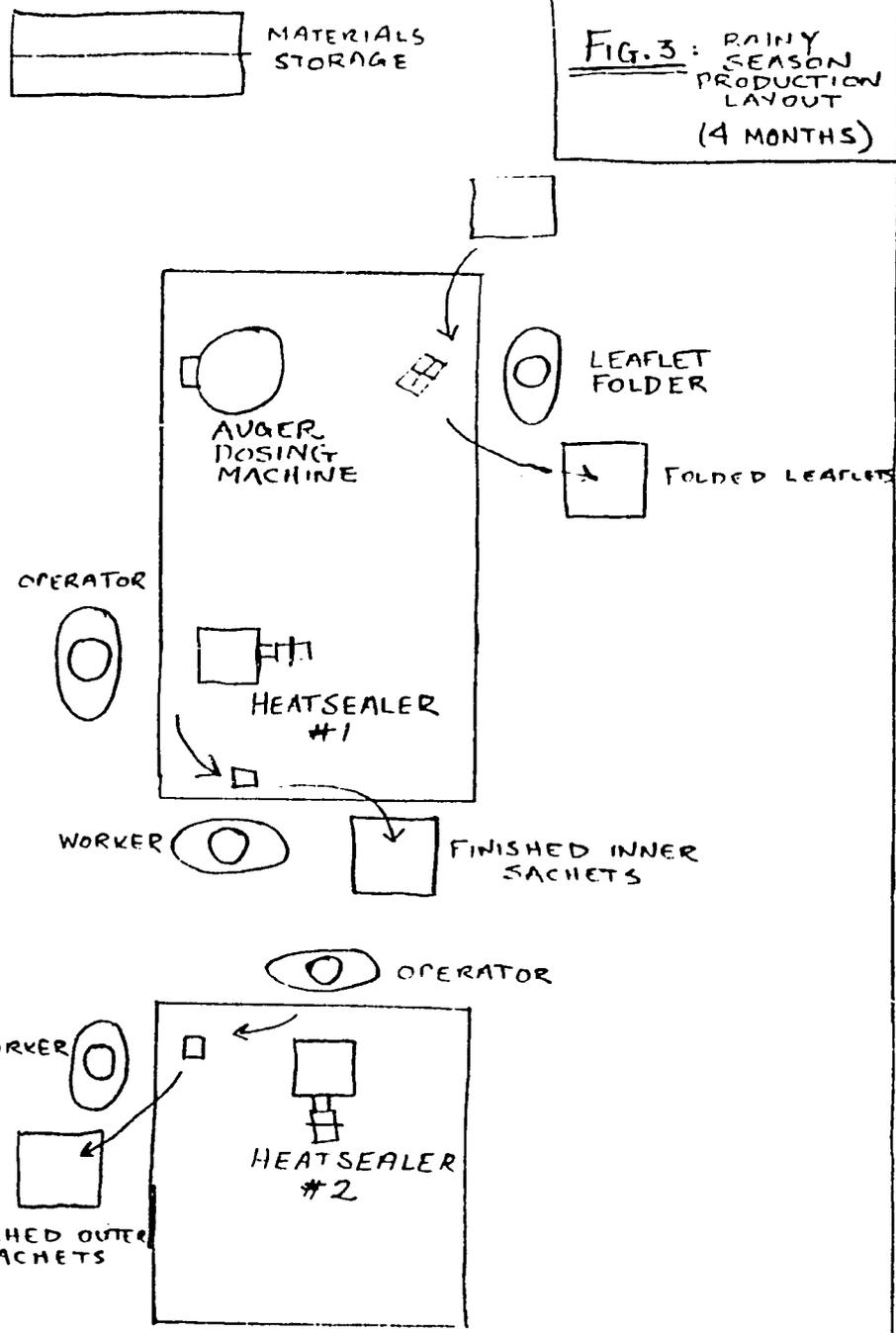


FIG. 2 - SIKASSO: ANNUAL TEMPERATURE AND HUMIDITY RANGES (PERIOD 1951-80)

APPROX. 5.00 SCALE □ = 10 X 10 CM

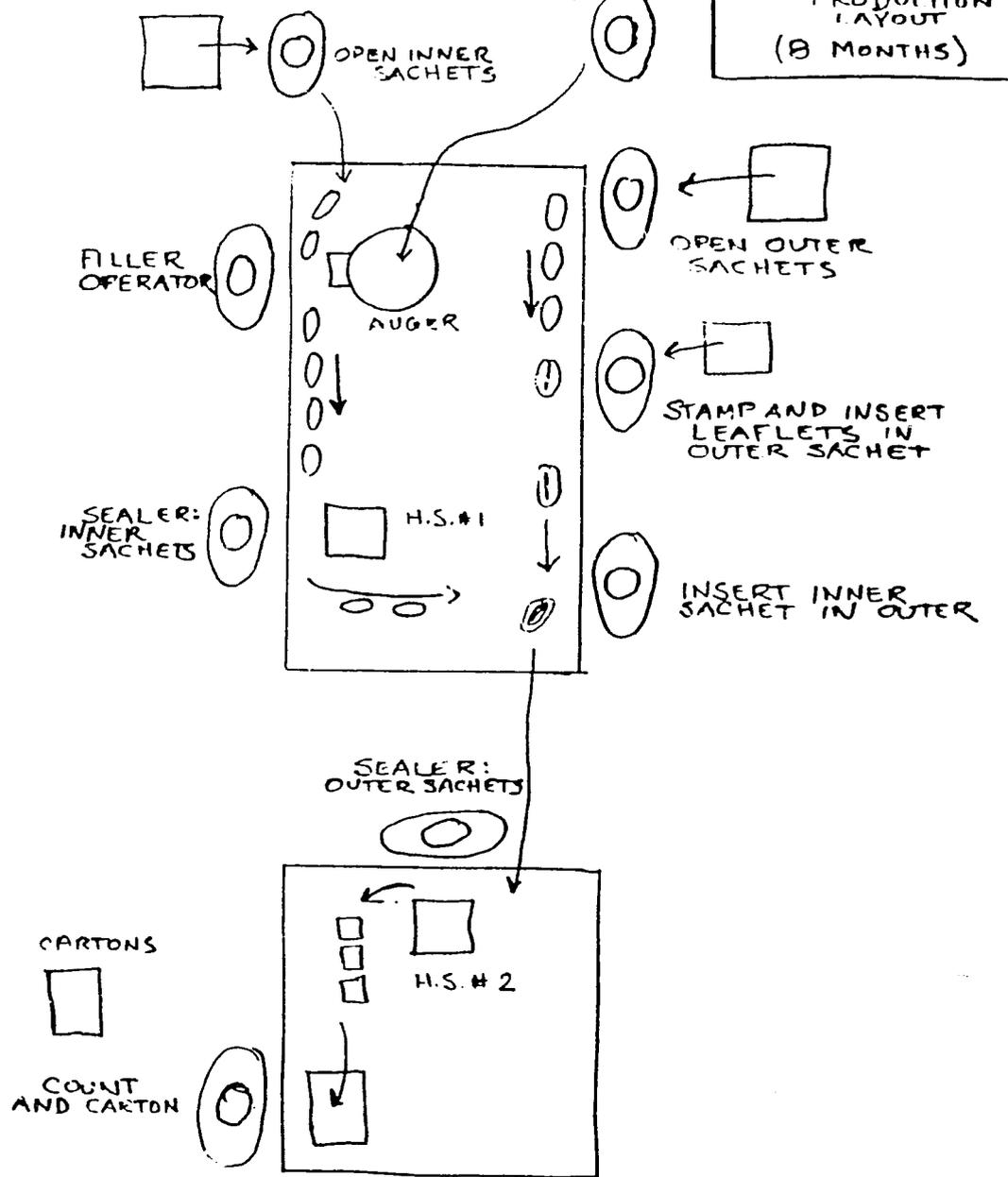
FIG. 3: RAINY SEASON PRODUCTION LAYOUT (4 MONTHS)



MATERIALS

ORS MIX
SUPERVISOR

FIG. 4: DRY SEASON PRODUCTION LAYOUT (8 MONTHS)



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