DEC-fortified salt for the elimination of lymphatic filariasis:

A manual for program managers

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Introduction and Purpose

This manual is intended to supplement the information provided in the WHO Program Managers' Guidelines, "Preparing and Implementing a National Plan to Eliminate Lymphatic Filariasis in Countries Where Onchocerciasis is Not Co-Endemic" (WHO/CDS/CPE/CEE/2000.15). This manual on diethylcarbamazine (DEC)-fortified salt is written specifically for DEC-fortified salt programs and although it includes some of the information presented in the Program Managers' Guidelines, both manuals should be referred to when designing an overall Lymphatic Filariasis (LF) elimination program.

The selection of the most appropriate strategy to eliminate the transmission of lymphatic filariasis, whether it is mass drug administration (MDA) of DEC-fortified salt, annual single-dose albendazole and either DEC or ivermectin tablets, or a combination of strategies, depends on a number of factors. Past experience with other public health programs - namely salt fortification efforts or mass treatment campaigns for polio, vitamin A, or de-worming - can help predict the success of a lymphatic filariasis campaign. Countries with the capacity to conduct mass distribution campaigns regularly and successfully may find that the infrastructure is already in place to conduct an annual single-dose MDA of DEC or ivermectin plus albendazole. Similarly, countries with successful national salt iodization interventions are likely to find a DEC-fortified salt program relatively easy to incorporate into their existing salt fortification program.

The manual is divided into two main sections. The first section covers the process of deciding whether a DEC-fortified salt program is an appropriate strategy to select and the second section deals with the implementation of a DEC-fortified salt program. Appendices are included to provide detailed information on certain topics.

Part 1. The Decision to Use DEC-Fortified Salt

Common table or cooking salt fortified with diethylcarbamazine (DEC) is an effective, safe tool for eliminating lymphatic filariasis (LF), and already has a proven public health record. Before its use is selected by program managers as an appropriate strategy for a national program to eliminate LF, however, certain specific questions must be addressed. These include the following:

- Is Onchocerciasis or Loiasis co-endemic with LF? *(If the answer is yes*, THEN DEC, EITHER AS AN ANNUAL TREATMENT OR IN FORTIFIED SALT, IS CURRENTLY **NOT** RECOMMENDED)
- Does the country have a successful salt iodization program?
- Are the filariasis endemic areas of the country clearly defined?
- Does the government adequately support filariasis elimination and the use of DEC-fortified salt?
- Do political leaders, the medical establishment, public health program managers, and salt industry representatives agree that a DEC-fortified salt intervention is appropriate?
- Does the ability to generate demand and awareness for DEC-fortified salt at the community level exist?
- Does the salt industry have regular and known distribution patterns, and is the industry well organized in general?
- Is the salt distribution such that it would be possible to ensure that DEC-fortified salt reaches the at-risk populations?
- Can the monitoring system ensure adequate DEC content during salt production and can it also measure household coverage?
- If a tablet mass drug administration (MDA) program is being considered, is there adequate experience with such a program to project high coverage rates?
- If a tablet MDA program has been implemented, has coverage been adequate to ensure elimination, or has there been difficulty maintaining high coverage year after year?

This manual is designed to help guide program managers in answering the above questions and to provide guidance for implementing a DEC-fortified salt program.

1.1 Safety and Efficacy of DEC-Fortified Salt

Diethylcarbamazine (DEC) was studied as a filaricidal agent as early as 1947 and the concept of fortifying salt with DEC was introduced by Hawking in Brazil in 1967. Early studies found that DEC powder can be added to table salt without changing the taste, color or consistency of the salt. It is extremely heat stable and it is still effective after normal cooking procedures. Salt can be fortified with both iodine and DEC, using traditional spray iodization processes, without compromising their effects.

Adverse reactions to DEC are primarily a result of the death of microfilariae and adult worms, and not a reaction to DEC itself. While DEC tablets often cause acute adverse reactions in people with high filarial loads and/or adult worms, DEC-fortified salt much less frequently causes adverse reactions because it is ingested at a lower dose.

In addition, DEC has low toxicity and does not accumulate in the body. In people with bancroftian filariasis, there have been few reported side effects due to DEC-fortified salt, and there has been no report of adverse reactions in pregnant women. Mild and transient localized reactions (and dying adult worms) have accompanied use of DEC-fortified salt in persons infected with brugian filariasis.

For more information, see articles by Hawking and Marquez (1967), Gelband (1994), and Houston (2000), listed in the References section.

1.2 A Comparison of DEC-Fortified Salt Use and DEC-Based Annual Single-Dose Treatment Methods for Eliminating Lymphatic Filariasis

Both methods of DEC administration (*i.e.,* in the form of fortified salt or annual tablet distribution) work by clearing microfilariae from the bloodstream of infected individuals. DEC (or ivermectin in countries where onchocerciasis or loiasis is co-endemic) is administered annually as a single dose, along with a single dose of albendazole.[1] The two standard treatment regimens for lymphatic filariasis in areas *without* co-endemic onchocerciasis and loiasis are presented in the following table:

Table 1. WHO Treatment Regimen for Lymphatic Filariasis in Areas *Without* Co-Endemic Onchocerciasis or Loiasis

Drug Regimen	Dose	Duration
DEC-fortified salt	0.2% to 0.4 % weight for weight of DEC to salt	DEC-fortified salt substituted for regular salt for 6-12 months (this timeframe may be extended)
DEC plus albendazole annual single dose	400 mg (albendazole) 6 mg/kg body weight (DEC)	annual single dose for 4-6 years annual single dose for 4-6 years

It should also be possible to utilize a combination of both mass drug administration (MDA) with annual single-dose DEC plus albendazole and MDA using DEC-fortified salt. For example, DEC-fortified salt could be used in selected target areas where the salt supply is easily controlled, while annual single-dose tablet administration could be carried out in areas where good coverage is relatively easily achieved. Furthermore, sequential implementation of annual single-dose DEC plus albendazole tablets followed or preceded by DEC-fortified salt would be another potential strategy, as would DEC-fortified salt plus an annual single dose of albendazole.

[1] Albendazole enhances the effect of microfilarial clearance and also works against intestinal helminth infections (hookworm, ascaris, enterobius and trichuris) which are common in lymphatic filariasis endemic communities.

Considerations in Deciding Between Treatment Strategies

The following table compares important factors to be considered in deciding between the use of DEC-fortified salt and annual single-dose DEC plus albendazole tablets.

Table 2. Factors in Comparing LF Elimination Strategies

	MDA (DEC-fortified salt)	MDA (annual DEC plus albendazole tablets)
Preparation period	May need a long preparation period to get started.	Relatively quicker to get started.
Infrastructure	Existing salt iodization infrastructure can be used.	Infrastructure developed for other mass distribution interventions can be used.
Legal and political considerations	May require review of food law to permit addition of pharmaceutical to food product.	May require political advocacy for acceptance of repeated annual distribution to entire at-risk populations
Personnel	Requires initial staff effort to work with salt producers, then continuous effort for monitoring.	Requires significant staff effort to prepare for and manage distribution for short periods every year.
Coverage and monitoring	Once DEC salt is in the regular salt distribution system, coverage is estimated by household salt use surveys and simple salt tests. If other sources of salt are available, a good social marketing program is crucial to achieve high coverage rates.	High coverage rates have to be achieved each year to interrupt transmission. Coverage may decline due to adverse effects. Coverage can be estimated by recorded tablet receipt or tablet consumption surveys.
Side effects	Because of very low daily doses, negligible, if any, adverse reactions.	Adverse reactions common in a fraction of the population. These may be significant enough to reduce coverage for subsequent distributions.
Sustainability	One year's use of DEC salt may be sufficient. Once DEC salt is accepted, coverage is likely to remain stable.	Requires repeated high levels of effort for the 4 to 6 years of annual drug distribution. Side effects or 'community fatigue' may reduce coverage for subsequent rounds.
Efficacy	Gradual (over 3 months) but persistent reduction of microfilaria density and prevalence (similar to mass tablet distribution); appears to sterilize adult worms. Probably prevents re-infection for the period of use.	Rapid and persistent reduction of microfilaria density and prevalence; kills proportion of adult worms. Likely to have shorter prophylactic period for re-infection.
Effects on intestinal helminths	Minimal effects on intestinal helminth infections.	Dual regimen with albendazole reduces intestinal helminths.
Community acceptance	Health education efforts needed to ensure acceptability by community, mostly at beginning	Health education efforts needed to promote campaign and ensure adequate coverage, continuous effort required for each distribution

	of the program.	round.
Control of program	Mostly outside of the health sector.	Mostly within the health sector.
Costs	If salt is distributed through the regular salt distribution/market channels, no operational costs except for fortification process.	Program has to meet operational costs to distribute drugs every year.

1.3 Geographic Distribution of Lymphatic Filariasis and Use of DEC-Fortified Salt

The pattern of lymphatic filariasis infection in a given country will greatly influence the kind of intervention that can be implemented. The distribution pattern of infection will affect the cost and effectiveness of different interventions. Therefore, before any informed decision can be made regarding a strategy using DEC-fortified salt, the target area must be mapped for lymphatic filariasis endemic communities and a salt analysis and cost analysis performed.

Guidelines for classifying areas of countries as LF transmission present, or LF transmission absent, are available in the Program Managers' Guidelines. Most countries will have already completed the mapping process before deciding on which MDA strategy is most appropriate.

In countries with a limited number of circumscribed endemic areas, MDA using tablets may be most efficient. In countries with larger, more dispersed populations affected, or with endemic urban areas, DEC-fortified salt may be more efficient, or may be important as an adjunct intervention.

1.4 Salt Situation Analysis

What is a Salt Situation Analysis?

A salt situation analysis assesses production capacity, quality, importation, cost, and packaging as well as other characteristics of the salt industry. This information can then be used to decide if the salt industry is adequately organized to implement a DEC-fortification program. In particular, the salt situation analysis should include:

- Information on salt production, distribution, and salt iodization including the methods used and location and number of producers or importers.
- Salt distribution from production to wholesale to retail shops to households, including differences in border areas.
- Salt pricing, traditional use patterns, and consumer preferences.
- Packaging and labeling practices.
- The level of government involvement in the salt industry, including price control or subsidies, import restrictions, and regulations.

- Issues of consumer sensitivities regarding salt, additives to salt, price and package size, and salt quality.

Appendix 4.1 provides a brief guide for conducting a salt situation analysis. Reference information on salt production and fortification is included in Appendix 4.2. These appendices may be useful in preparing for meetings with salt producers and others while conducting the salt analysis.

Using Information from a Salt Iodization Program

If a salt situation analysis has been performed for the salt iodization program, the information should be available from the Ministry of Health (MoH), UNICEF or those implementing the salt iodization program. A notable difference between the DEC-fortified salt program and an iodization program is the fact that salt iodization is commonly mandated by law and is universal. Thus for the iodization program, the entire country is covered, so salt distribution patterns are not very relevant. While this may be true for a DEC-fortified salt program in some instances, salt distribution may be limited to targeted areas in other instances, and the sources of salt for those areas need to be identified.

In addition, salt iodization programs are designed to be ongoing, since iodine deficiency needs to be continuously addressed. In contrast, DEC-fortified salt programs may only need to be implemented for a few years, thus making sustainability issues less critical.

Using Information from Salt Distribution Patterns

Understanding the patterns of salt distribution to populations inhabiting filariasis endemic areas is essential before launching a DEC-fortified salt program. A salt situation analysis can help clarify the best method of distributing fortified salt.

Making DEC-fortified salt available to endemic communities can happen in several different ways:

- The most common method is likely to be similar to the way salt iodization became established in most countries. The government can work with donors to ensure the capacity among major producers to produce DEC-fortified salt and to subsidize the DEC itself. In addition, the government can work with the salt industry to generate demand in endemic areas, allowing market forces to ensure availability. The government's role is thus to support enhancing production capacity and to help build demand, while allowing the normal salt production and distribution channels to ensure availability of DEC-fortified salt.

- In instances where there are fewer distinct LF endemic areas, the government can contract with the main producers supplying those areas to produce batches of

DEC-fortified salt for the endemic communities, and assure that the salt is available through the normal industry distribution channels.

- Where the salt industry is not well organized and LF is restricted to a small number of communities, the government can work with local merchants to establish more localized community-based fortification.

Using Information from the Salt Situation Analysis

The information from the salt situation analysis will help determine whether a DEC-fortified salt program is feasible. Circumstances that facilitate a DEC-fortified salt intervention include the following:

- A successful salt iodization program consisting of modern iodization equipment, a good working relationship with the government, and the majority of the salt production done by 2-3 large producers.
- A strong monitoring system, as part of the iodization program, at both the level of production (conducted by the producer) and at the wholesale, retail and consumer levels (conducted by the government). The monitoring results should show that the consumer consistently receives salt that contains adequate iodine and that iodised salt is consumed by more than 80% of households.
- Labelling indicating salt is iodized, and packaging capacity (ideally producing 1 kg or smaller packages).
- The ability to work efficiently and effectively with the government to define and meet appropriate food and drug regulatory requirements for fortifying salt with DEC.
- Favourable views of both salt iodization and DEC-salt fortification in LF endemic regions by the political and clinical health establishments, without *inappropriate* fears that a DEC-fortified salt program might be dangerous.
- Government or donor agency support for the additional costs to producers for adding DEC to salt. Methods to do this include providing or subsidizing the DEC fortificant and providing both technical support and capitalization costs if needed.

While the above circumstances describe the ideal situation for using DEC-fortified salt, they are not required to implement a successful program. However, if the situation varies widely from the above, implementation of a DEC-fortified salt program may be more challenging to put into practice, and therefore a less attractive choice, than an annual single-dose tablet program.

1.4 Cost Analysis

What is a Cost Analysis?

A cost analysis identifies all relevant costs associated with an intervention, such as DEC-fortified salt or DEC-tablet distribution. In the case of the lymphatic filariasis elimination program the cost analysis is a useful tool to:

- Understand costs associated with different strategies (*e.g.*, DEC-fortified salt, mass distribution of tablets of DEC /albendazole, or a combination of these)
- Help plan the implementation of the selected strategy

For example, based on disease distribution patterns and salt production methods, a cost analysis for one country may indicate that an intervention with DEC-fortified salt is only cost efficient when applied to the entire population, while for a different country a targeted approach with DEC-fortified salt may be as cost efficient. Since data on coverage achieved with DEC-fortified salt may not be available, some consideration needs to be given to the likelihood of achieving adequate coverage to eliminate transmission with MDA using DEC-fortified salt or MDA using tablets, and the implications for overall program costs.

The cost analysis can be a useful tool in approaching decision makers such as government officials, donors and salt producers to help generate acceptance and support for the intervention.

What Costs Are Included in the Analysis?

A cost analysis will need to be performed for each strategy that is being considered. Therefore, if alternative strategies include DEC-fortified salt and/or mass treatment with albendazole and DEC tablets, costs for each intervention will need to be calculated.

When conducting a cost analysis all significant costs will need to be considered, from capitalization costs (cost of retooling, costs for equipment specific to DEC addition, costs for setting up new labeling, etc.), additional manufacturing costs, and overall program costs (including DEC-fortified salt promotional efforts, monitoring, additional staffing or laboratory equipment). Additionally, who is paying for the costs – the government, the salt producers, the consumers, donors – should be noted.

Detailed guidelines for performing a cost analysis are available on the Emory LFSC website, in the Resources section, at www.filariasis.us.

Part 2. Implementing a DEC-Fortified Salt Program

Once the decision to implement a DEC-fortified salt program has been made, a new set of decisions arise. The program manager will need to choose whether to use a universal or targeted distribution strategy; he or she will have to determine the best approach to involve salt producers and educate the public about the program; staff capacity will need to be developed; and methods for monitoring the program will have to be designed and implemented.

This section provides information on the key objectives and activities that should be considered in establishing a DEC-fortified salt program, either as the primary intervention or as an adjunct intervention to support a MDA tablet program.

2.1 The DEC-Fortified Salt Program as Part of the Global Programme to Eliminate Lymphatic Filariasis

All national DEC-fortified salt programs are part of the Global Programme to Eliminate Lymphatic Filariasis. While the Global Programme has set the goal of achieving global elimination of LF by 2020, each country will have to set its own national goals, objectives and targets and select the most appropriate intervention strategy.

The following are suggested guidelines for potential objectives of programs based on DEC-fortified salt distribution:

Set final objectives:

- DEC-fortified salt available in the market for 100% of the target population for 1-3 years by <insert year>
- Household use of DEC-fortified salt reaching 95% in all target areas

Set intermediate objectives:

- Mapping the distribution of LF for all implementation units completed by <insert date>
- 25% of implementation units with DEC-fortified salt in the marketplace, initiated as a pilot, by <as early as possible>
- 100% of target implementation units with DEC-fortified salt available in the marketplace by <as early as possible>
- Monitor DEC content of salt and household consumption in target implementation units

Set immediate objectives:

- Identify the distribution of LF though the national mapping efforts
- Include DEC-fortified salt distribution as a potential strategy in the National PELF Strategic plan
- Obtain results of earlier salt analysis or conduct new salt situation analysis

- Establish a national technical advisory group (which should include salt industry representatives and those involved with salt iodization, along with those directly involved in the efforts to eliminate LF) to develop a national strategy
- Review current government policies to ensure that national policies exist that will allow, or that can be adapted to permit, salt fortification with DEC
- Establish working relationship with salt producers, and consider establishing a Salt Board to help with coordination among salt producers/importers
- Order DEC for fortification or DEC-fortified salt for distribution
- Develop training materials
- Train all involved health personnel within first year
- Assess consumer preferences and develop IEC/marketing strategy and necessary materials for promoting DEC-fortified salt
- Establish monitoring and evaluation plan including QC at production level, and household surveys to ascertain coverage

2.2 The Role of the Program Manager and Team in a DEC-Fortified Salt Program

Each national DEC-fortified salt program will have different staffing needs based on the size and scope of the program, as well as the opportunity to coordinate activities with complementary programs and share staff and information. All will need an enthusiastic, competent national program manager.

Given that the actual fortification process will be managed by the salt producers, a primary role of the national team will be to identify the producers supplying endemic areas, and to work with them to develop a mechanism whereby they can produce sufficient quantities of DEC-fortified salt to meet the need of the target population.

Another key role of the national program team is the development of a comprehensive health education and social marketing plan to increase awareness of LF and to generate demand for DEC-fortified salt within the endemic areas. The health education component may be conducted by the Ministry of Health's national health education unit, but it will require significant technical assistance and coordination from the national program team. While individual producers or importers will have their own brand to market, the government will also have a role in promoting all DEC-fortified salt as a preventive measure against LF. This marketing effort may be best contracted to a professional advertising agency that can develop the most effective messages to increase demand for DEC-fortified salt.

Monitoring and evaluation is another crucial component for the success of the program. As part of this effort, the program team will need to document coverage. Information collected in sentinel sites will be critical to understanding whether transmission is being

eliminated, but coverage surveys also will be important to determine whether household use of DEC-fortified salt is high in all endemic areas.

2.3 Choosing a Universal or Targeted Distribution Strategy

One of the first decisions that needs to be made in developing a DEC-fortified salt program is whether to fortify all of the salt in a country, including in areas that are not endemic for LF. There are advantages and drawbacks associated with both universal and targeted fortification. The best approach will depend on the disease distribution, salt production and distribution patterns, and costs attached to each strategy.

The salt situation analysis and the map of endemic areas are vital in determining which strategy is appropriate. It should be noted that there is not a great deal of well-documented information on this topic. While DEC-fortified salt has been vital to success in China and other areas of Asia, careful documentation of the steps for choosing the ideal approach is not available.

Table 3. Differences between Universal Distribution and Targeted Distribution

	Universal	**Targeted**
Cost	Less expensive when majority of population requires treatment because less effort is involved. May be more expensive if most individuals do not live in endemic areas because of unnecessary treatment, though cost per individual is low.	May be more expensive if it requires more interaction with small local producers who usually have higher production costs. But may be cost-effective if the endemic areas and its population are small in comparison to the rest of the country, or if few producers supply most communities.
Coverage	May help achieve high coverage but includes individuals in non-endemic areas.	May achieve high coverage in targeted areas but may miss some of the population of other endemic areas.
Production	Easier when there are a few large producers.	More difficult as producers may require two separate production lines, or different distribution from normal. Easier when there are numerous local producers or clear distribution lines between producers.
Distribution	Easy to manage.	More difficult. Important that non- fortified salt is not distributed in targeted areas (may be especially difficult if DEC-fortified salt is more expensive).

The decision between a universal strategy and targeted strategy will depend on a number of factors and will vary from country to country. However, in general the following conditions or criteria should exist for the selected strategy:

Criteria Favorable for Universal Distribution Strategy

- The majority of the population lives in an endemic area.
- The endemic area of the country is widespread and not easily defined.
- Salt is produced by a limited number of producers who distribute throughout the country.

Criteria Favorable for Targeted Distribution Strategy

- The population living in the endemic areas represents a small fraction of the total population.
- The endemic areas are isolated and easily defined.
- The source of salt for the endemic areas is easily identified, and can involve a small number of producers.
- High prevalence in urban areas where annual single-dose mass drug administration is logistically difficult.
- Price of DEC-fortified salt can be subsidized to offset costs for producers and prevent consumers from buying cheaper non-DEC-fortified salt.

2.4 Promoting the Program with Salt Producers, Importers and Distributors

Salt producers are essential to the program, and much of the time of the program manager will be devoted to developing and maintaining a close working relationship with the salt producers.

The salt producers will handle most of the technical work directly related to producing and distributing DEC-fortified salt. However, it is important that the program manager have a basic understanding of the mechanics of salt production, the salt fortification process, and related issues such as the laws and regulations governing salt fortification.

Appendix 4.2 provides detailed background information on the production and fortification of salt. More information on salt production can also be found on the Salt Institute's website, at www.saltinstitute.org.

The first contact with the salt producers will most likely be made during the salt analysis. Promotion of the idea of a DEC-fortified salt program should begin at that point, although the main focus of the contact will be gathering information for the salt analysis. For countries with salt iodization programs, the promotion of the DEC-fortified salt program will most likely be easier than in countries without previous experience with fortified salt.

Common concerns that are likely to be raised include the additional production costs of adding DEC (especially if the salt is not fortified with iodine or fluoride), the cost of purchasing DEC, the logistics involved in procuring DEC, packaging costs (if different from current practices), costs related to labeling DEC-fortified salt, and concerns about the potential for decrease in demand. These concerns about increasing costs are valid,

and need to be addressed to ensure full cooperation of the salt industry. The costs may be passed on to consumers if costs are small and unlikely to affect the consumption pattern of salt and if all salt available in the country is fortified. Otherwise, the government may choose to subsidize the cost of fortifying the salt as part of its health budget. Since a DEC-fortified salt program for LF is not expected to last many years, such a subsidy does not imply a long-term drain on limited government funds.

How to Gain Agreement

Salt producers will be most willing to fortify salt with DEC if one or more of the following conditions pertain:

- Fortification is required by the government for imported and/or locally produced salt.
- There is some potential for increased sales stemming from effective marketing of DEC-fortified salt by the LF program.
- The opportunity to "do good" is not offset by costs of the fortification process that decrease profits.

For most programs, the government will not require the fortification of salt with DEC and the program manager will have to interest the salt producers using the marketing and consumer relations approach.

Subsidies

A subsidy may be a useful tool with which to support the salt producers in implementing a fortification program. A number of different types of subsidies can be considered, including:

- Reduced or eliminated import tariffs (if salt is imported)
- Tax breaks for salt producers (if salt is produced domestically)
- Free provision of DEC for fortification
- Support for start-up costs, such as new equipment needed for fortification
- Shared costs of marketing for generic DEC-fortified salt (for example, media campaign, packaging, etc.)
- Direct cash payment to producers
- Reduced (subsidized) prices for consumers through other means

Obviously, great care must be taken not to provide too much or too little by way of subsidies, and the program manager must have written pre-approval by the appropriate office that will be providing the subsidy (i.e., the Ministry of Finance) before offering a subsidy to producers.

2.5 Logistics of DEC-Fortified Salt

Given the limited experience with DEC-fortified salt programs, many of the logistical approaches are still being developed. And like so many other issues, the logistics will vary among programs depending on the local situation.

Legal issues

While promoting the concept of a DEC-fortified salt intervention, program managers must understand the legal environment in which this intervention will be permitted. With salt iodization, iodine is seen as both a nutrient and a natural component of salt, sea salt in particular. As such, it is managed as a food product, and the laws and regulations pertaining to salt iodization are manageable. Furthermore, most countries make iodization required by law.

For DEC, the laws and regulations that apply are less clear. Even though DEC is a pharmaceutical, in this case it is being treated as a fortificant or food product. Laws relating to pharmaceuticals often include more stringent quality assurance measures, more specific import and export regulations, and distribution only through approved medical channels. These may be obstacles to implementing a DEC-fortified salt program, since such a program cannot be managed within the health infrastructure—but rather capitalizes on the existing salt trade. Thus it is critical that program managers open a dialogue with the local Food and Drug Administration (FDA) and other agencies to determine (a) what laws and regulations apply; (b) what needs to be done to modify these to permit a DEC-fortified salt program; and (c) what political backing is needed to make these changes. In some instances this may be a simple matter of having the Minister of Health endorse the intervention, and gain acceptance in the Cabinet for this process. The FDA can then accept a provision within their regulations to permit the DEC-fortified salt intervention—a process that avoids the time-consuming process of changing a law or even a regulation. Since creating the permissive regulatory environment takes time and political commitment, the process should be started as soon as a DEC-fortified salt intervention is being considered.

Calculating DEC Starting Material Requirement

First, the program team will need to determine the proper concentration of DEC to fortify salt. A consumption survey to assess household use of fortified salt may have been done in preparation for salt iodization. However, if not previously completed, a survey is probably not necessary, as studies in many countries have shown a range of 5-15 grams/person/day. Fortification of salt with from 0.1% to 0.6% DEC weight for weight (w/w) has been shown to be safe, with the usual recommendation of 0.2-0.4% w/w. DEC has a wide safety margin, with much higher doses (6 mg/kg body weight) being used for tablet MDA than could ever be achieved with fortification.

Producers and importers have the best understanding of the ebb and flow of the salt market. Based on their ordering patterns, the amount of DEC required for fortification is based simply on the concentration recommended by the government. Producers can then calculate the amount of DEC they require over a production period. The program manager's first step, therefore, will be to work with the salt producers to calculate the amount of DEC starting material required to fortify the number of tons of salt expected to be produced for consumption in the target area. The methods to determine the amount of DEC required differ somewhat for a universal distribution strategy and targeted distribution strategy.

For a universal distribution strategy

This method is much simpler than for a targeted strategy. Since consumption patterns are not expected to change with the addition of DEC, the salt producers' current production estimates for the country can be used to determine the number of tons of salt that will require fortification. Salt used for human consumption should be fortified, differentiating this from salt for industrial use, including industrial food production such as salting fish, or production of bakery goods. Similarly, it will be necessary to differentiate products for the domestic and export markets.

For a targeted distribution strategy

If the salt producers produce salt only for distribution in the targeted area, then the same method employed for the universal strategy can be used, i.e. the producers' production estimates determine the number of tons of salt that will require fortification for the targeted areas. Distribution to these areas may be somewhat fluid, and a salt producer will have to assist with a review of distribution and sales records to determine the number of tons of salt that will be produced for the targeted area. If these records are not available, the demand can be estimated by using the following formula:

Tons of salt required = (total population of target area) x (yearly per capita consumption of salt)

Total population of target area = all children and adults

Yearly per capita salt consumption = 3.65 kg (10 grams per day x 365 days)

See Appendix 4.2 for further calculations regarding the amount of DEC required per ton of salt.

Production of DEC-Fortified Salt

Salt production is done using a variety of methods, including crystallizing salt from pans in which sea water is allowed to concentrate. Regardless of the production method, salt is usually processed before any fortification occurs. This process may include washing, crushing or sorting to differentiate salt of different crystal sizes, drying, and adding anti-caking agents.

Fortification, whether with iodine, fluoride or DEC, can be done using different methods—usually a wet or dry method, using continuous or batch processing. The wet and dry methods differ with regard to their effectiveness for different fortificants. The wet method consists of spraying fortificant on at a fixed rate as processed salt moves through the production line. While it is relatively simple to use this method for adding potassium iodate, it is more complicated to add DEC since DEC is less soluble and may require more water. The dry method consists of mixing the correct proportions of salt and the fortificant with one of a variety of mixers. However, if a dry method is used, there may be some settling of DEC, depending on salt crystal size and DEC particle size. Decisions regarding the method used for DEC fortification will depend on the current production facilities and methods used by the producers, the cost for upgrading equipment, and the ease by which DEC can be added to the existing fortification processes for iodine. Producers may need some additional technical assistance in determining the best method for DEC fortification.

Appendix 4.2 contains more information on fortification and processing methods.

Procurement, Storage and Distribution of DEC

It is expected that in most cases the salt producers will be responsible for procuring the DEC starting material from approved suppliers and that the material will be sent directly to the production plant for storage and use. However, technical and logistical support by the program manager will be essential in facilitating the processing of the order and ensuring that the order is placed in a timely manner and the shipment is received without delay. Procurement may also be facilitated by the government or WHO, for logistic or tax reasons.

See the Program Managers' Guidelines for more information on drug procurement and storage.

Appendix 4.5 provides contact information on pharmaceutical companies approved by WHO to supply DEC to salt fortification programs.

Customs

Clearance

DEC either will enter the country as the pure substrate, as a pre-mix with salt or as imported DEC-fortified salt. Each country will have regulations regarding the clearance of pharmaceuticals through customs, and the program manager will have to be familiar with the regulations. Coordination with the salt producers is essential to ensure that there are no problems with clearance that could delay production or reduce the producers' commitment to the project. It is important that the program manager hold several discussions with the National Food and Drug Administration to determine the laws regarding DEC, and whether DEC that is used in salt can be considered a food additive.

In such a case, clearance procedures may be greatly simplified. Furthermore, the clearance process for imported DEC-fortified salt will involve monitoring to ensure that the shipment complies with government standards.

Duty Tax

To reduce the extra costs to the salt producers of fortifying salt with DEC, programs may consider requesting that the Ministry of Finance allow the DEC or DEC-fortified salt to pass customs duty-free or at a reduced rate. Managers should also explore procuring DEC through donor or other government mechanisms that limit duty liabilities.

Packaging and Labeling of DEC-Fortified Salt

Packaging

Packaging is usually (and optimally) done at the point of production. Ideally, the packaging for DEC-fortified salt will not need to be significantly altered from the usual practices currently accepted by consumers. However, DEC may settle in the coarser salt used commonly in many countries, causing a variation in DEC content in salt used at the household level. Therefore, DEC-fortified salt should ideally be packaged in 1 kg or smaller labeled consumer packages.

Consumer packages may be grouped in 25-50 kg heavy-gauge plastic bags for distribution to wholesalers and retailers. If the salt is improperly or poorly packaged, there may be iodine losses and uneven distribution of DEC within larger bags.

Labeling

Each package of DEC-fortified salt will need to be clearly labeled as containing DEC. Producers will need to be given the government requirements for labeling. The program manager will need to ensure that the label meets government requirements, if any, regarding additives to food. Discussions with the National Food and Drug Administration need to resolve issues of labeling for importation or production as well as those pertaining to labeling at the point of sale. This is critical in instances where retailers are in the habit of re-packaging, since labeling at this point becomes impractical.

2.6 Health Education

The key to a successful DEC-fortified salt program will be engaging the consumer through a comprehensive information, education and communication (IEC) campaign. This involves two specific components. First, it will be important to build awareness about lymphatic filariasis itself, including the mode of transmission, and the fact that the disease can be eliminated for future generations. Second, it will be crucial to build demand for DEC-fortified salt.

Initially, it will be important to gather information on existing knowledge and practices regarding LF itself and regarding salt use. This might include:

- Establishing groups who understand LF and DEC-fortified salt (including developing a fact sheet for health workers)
- Gaining understanding of consumer issues, through techniques like focus groups and knowledge, attitude, practices and behavior (KAP) surveys, such as
  - Traditional salt use patterns
  - How much price elasticity there is (how much more consumers might be willing to pay for a fortified product)
- Researching and developing messages to encourage consumers to buy DEC-fortified salt
- Identifying target groups most likely to influence consumer awareness and behavior with respect to use of DEC-fortified salt

Taking the time, perhaps up a year, to develop and distribute health messages about the need for and upcoming availability of DEC-fortified salt will ensure the necessary demand to reach target coverage rates. To reach the consumer, the IEC campaign will need to target shopkeepers, community leaders, and others who will influence the consumption patterns of consumers.

DEC-fortified salt will be sold in the market often in competition with other salt. While awareness of lymphatic filariasis and of the availability of DEC-fortified salt will help consumers understand the need to use DEC-fortified salt, it may also be important to develop a more specific marketing campaign, using modern advertising techniques. While each company selling salt may advertise their brand, capitalizing on the added value of DEC, the government should partner with suppliers by initiating a generic marketing campaign.

2.7 Quality Assurance

In order to ensure that the DEC-fortified salt contains an acceptable level of DEC a systematic method of internal and external monitoring needs to be established.

Building on Salt Iodization Monitoring

Most of the testing for DEC will be based on measurements of the amount of DEC in salt using quantitative or qualitative methods. However, in some instances, levels of iodine can be helpful, if a combined premix is used such that the ratio of DEC to iodine remains fixed.

DEC-fortified salt programs can benefit from salt iodization efforts in countries where those efforts are well established, since both producers and government labs are used to monitoring procedures. Iodization programs use two methods to determine the iodine content of salt. Titration, used primarily by large producers, is the mainstay of quality control efforts and most countries have adequate laboratory facilities to perform a quantitative analysis of iodine content in salt using titration methods. A second and

simpler method to assess iodine content in salt is to use a stabilized starch solution, now commercially available as a 'salt test kit'. This method involves placing one or two drops of solution on a few grams of salt, and observing the intensity of color change. When there is a fixed ratio pre-mix used, these methods may be helpful in monitoring DEC-salt programs.

Further information on these iodine methods can be found in the document "Monitoring Universal Salt Iodization Programs" mentioned in the reference section.

Internal Monitoring

Internal monitoring refers to the quality control procedures done by the producer, and is the mainstay of DEC-fortified salt quality assurance. Each producer will be given the specifications the DEC-fortified salt is required to meet. The producers will conduct internal monitoring and quality control to ensure that the level of DEC in the salt meets the required standards. Often the program will assist producers with establishment of appropriate laboratory techniques to measure DEC in salt. This can be done in conjunction with training for the government laboratory to ensure that quality assurance methods are standardized.

Producers with the capacity for fortification usually have sampling procedures in place to monitor the quality of their product. Sampling for DEC testing can follow the procedures used for salt iodization. Producers also need to establish control limits, that is, the ability of the equipment to produce a product with a concentration of fortificant within certain acceptable limits. Internal monitoring then determines if batches remain within those control limits.

Laboratory assessment should be done using the high performance liquid chromatography (HPLC) or spectrophotometric methods, with qualitative testing used as an adjunct measure. The gold standard for assessing DEC in salt is the HPLC method. This method is costly, however, and may be difficult for both producer and government labs alike. The spectrophotometric method is less costly and compares favorably to the HPLC method. This spectrophotometric method is likely to be the method most commonly used for both producers and government labs.

There is also a field method for qualitative assessment of the presence of DEC in salt, analogous to the salt test kit for iodine. Since salt will never contain DEC in the absence of fortification, demonstration of the presence of DEC is very useful. Both the Food and Drug Administration (FDA) inspectors and the producers may use this qualitative method to provide rapid monitoring to ensure that DEC is present. This method may also be very useful for household coverage surveys to determine the proportion of households using DEC salt.

More information on laboratory analysis of DEC in salt can be found in Appendix 4.3.

External Monitoring

External monitoring refers to the monitoring done by the government to ensure that the product meets government standards. The FDA of each country program should conduct external monitoring to confirm that the producers are meeting the required standards. The program manager should work with the FDA laboratory staff to ensure that there is adequate capacity and equipment to perform DEC-fortified salt analyses, using the same (and standardized) methods used in the producer laboratory, or the more exact HPLC method. External monitoring involves periodic sampling from wholesale and retail sites, and is often difficult due to limitations in government inspection staff and budget.

2.8 Monitoring and Evaluation

Monitoring Household Coverage

At the household level, monitoring by the Ministry of Health will consist of three primary questions:

1. What percentage of target households has DEC-fortified salt?
2. How is the DEC-fortified salt used? (e.g., as a replacement to regular salt, for certain foods only, for certain family members only, etc.)
3. Does the DEC-fortified salt used in the household contain the recommended amount of DEC?

To answer these questions, coverage surveys will have to be implemented. Sentinel sites cannot be considered adequately representative of the general population to provide accurate coverage estimates, and representative survey methods are recommended. Coverage information can be determined through a number of representative methods including:

- **Inclusion of household salt testing as part of survey done for other purposes**
  Any survey that is designed to collect information from household members, in a representative selection of households, may easily be able to add salt questions and testing of the salt used in that household. Thus it may be possible to include salt testing in national demographic surveys, nutrition surveys or even agricultural surveys. Certainly any micronutrient survey that is testing salt for iodine content can be used.

- **Special household surveys in endemic districts**
  In small communities, it may not be difficult to randomly select households to sample, and to estimate coverage by checking the label and testing the salt for iodine or DEC. In larger endemic areas, cluster survey methods may be more appropriate. In most instances, an exact coverage estimate will be desired initially

and lot quality assurance sampling (LQAS) may not be useful for estimating coverage. However, as the program develops, it may be possible to classify geographic areas as meeting a criterion of a certain coverage level by LQAS methods.

- **School surveys**
  Schools can also be used to sample household salt. School children can be asked to bring in a sample of salt from home (including the label or description of the label), and the salt can be tested in school. Schools can be selected randomly from within the endemic area, and the school children asked to bring in samples can also selected randomly. The main risks with school sampling are a) that school attendance may not be high, causing bias in coverage estimates; and b) children may not bring the salt, or may bring salt that is not what is usually used, or may trade with other children.

In most instances, specific household salt cluster surveys will provide the most reliable estimate of DEC-fortified salt use. These should follow the standard EPI cluster survey model, and should be used to gather additional information on consumer awareness of LF, concerns about the DEC-fortified salt program, potential adverse effects, and other information.

Appendix 4.4 contains further information on sampling methods, including a sample questionnaire.

Monitoring Impact

The primary measure of effectiveness will be the reduction of microfilaremia, using data from the sentinel sites. The Program Managers' Guidelines detail the general recommendations for monitoring progress by periodic review of impact indicators. Along with the process indicators (such as coverage estimation), these impact measures will be essential for assessing progress toward elimination goals.

Measurement of microfilaremia is the indicator of choice for measuring impact, since it declines after both mass treatment and DEC-fortified salt consumption, and since it is directly associated with transmission. Other impact measures, including detection of infection in the vector and the use of ICT antigen assessment in different age cohorts, might also prove to be of value. All such input indicators should be measured at sentinel sites where repeated measures can compare data with subsequent data.

Further detail on the general program recommendations for monitoring progress toward LF elimination can be found in the Program Managers' Guidelines.

2.9 Budgeting the Program

The Program Managers' Guidelines provide details on budgeting for LF Elimination Programs, but there are some costs specific to DEC-fortified salt programs that need to be considered. These can be divided into:

- Costs related to production and distribution, including quality assurance
- Costs related to building consumer demand for DEC-fortified salt
- Costs related to monitoring

Costs Related to Production

Consumers are very sensitive to the price of salt. If all costs for production are passed to the producer, the producer will pass these to the consumer, and the consumer may decide not to use DEC-fortified salt because of its higher cost. Since it is in the interest of the program to limit production costs so that the price of DEC-fortified salt remains the same as non-DEC-fortified salt, the government may want to assist with some of these productions costs. These might include:

- Costs for equipment needed to add DEC-fortification capacity to the existing production line
- Costs for establishing a quality control capacity to assess DEC-fortified salt
- Direct costs for the DEC fortificant (ideally paid for by other donors)
- Costs related to new packaging and labeling measures
- Costs related to any changes in normal distribution patterns, particularly those in 'targeted distribution' areas
- Costs related to building support among producers, importers, wholesalers and retailers, including meetings, establishment of a Salt Board, training, etc.
- Costs for other quality assurance measures, including establishment of capacity for assessing DEC in salt at the Food and Drug Administration laboratory

Table 4. Estimated Equipment Costs

Item	Requirement	Cost
Medium fortification unit (5 tons/hour)	None if already installed for salt iodization. One or more needed for large producers, depending on size of endemic area	$5000-$7000 per unit
Community cement-mixer type fortification unit	One per community (capacity is about 250-400 kg/day)	$1000 per unit
Spectrophotometric laboratory equipment for analysis of DEC in salt	One for central government lab and for each separate salt industry lab	$4000-$7000 per lab depending on equipment needed
Addition of DEC fortification unit to existing production line	Dry mix or wet mix equipment depending on existing production methods, for each major producer	$2000-$4000 depending on production facility
Salt field test kits (thymol) for DEC	Adequate supply for community	(not currently commercially

	level use and/or producers	available—easily produced in national laboratory)
Salt field test kits (stabilized starch) for iodine	Adequate supply for community level use and/or producers	$0.50-$2.00 per test kit—through UNICEF
DEC (in bulk)	Adequate supply for salt for endemic areas (a community of 4000-5000 people will require approximately 50 kg DEC per year)	$10-20 per kg depending on source; likely to be supplied by WHO or other partner

Costs Related to Building Demand

All LF programs will have costs associated with increasing awareness of LF as a disease and for building demand for the chosen intervention. For DEC-fortified salt programs this is critical, since consumer demand for DEC-fortified salt is the single most important element in the program. Consumers need to understand the disease itself, and the possibility of LF affecting their children in the future. In addition, they need to understand the DEC-fortified salt intervention so there is not misinformation about the fortification process and what it is trying to achieve. With proper IEC/marketing efforts, demand should be high, since LF is a frightening disease that leaves a strong impression in affected communities, and since consumers do not notice any change in salt that is fortified with DEC. The IEC/marketing costs overlap with similar costs for a MDA tablet program, and include:

- Costs for determining current awareness and behaviors related to LF
- Costs related to implementing an awareness campaign to increase awareness and understanding about LF
- Costs related to determining current practices regarding salt use
- Costs related to developing a marketing strategy for DEC-fortified salt, including building support among key stakeholders, completing training for different advocacy groups, and implementing the IEC/marketing strategy
- Costs for development and testing of a logo to identify DEC-fortified salt
- Costs for assessing consumer response to a DEC-fortified salt intervention program (perhaps in a pilot area at first)
- Costs for maintaining a marketing strategy to ensure continued use over the intervention period
- Costs for gaining continued support among key stakeholders including donors; salt producers, importers, wholesalers, and retailers; and health professionals

Costs Related to Monitoring

The costs associated with the monitoring recommendations in the Program Managers' Guidelines will be similar for MDA tablet and DEC-fortified salt programs. However, assessing coverage will differ slightly. DEC-fortified salt programs will rely on representative surveys to assess household use of DEC-fortified salt. Some of the monitoring costs associated with a DEC-fortified salt program will include:

- Costs for assessing household use of DEC-fortified salt through coverage surveys or other mechanisms
- Costs for field test kits to assess DEC presence in salt
- Costs for reviewing quality assurance issues, and ensuring ongoing capacity at different laboratories
- Costs for addressing difficulties or inconsistencies with DEC-fortified salt levels at different points from production to consumption, should these arise
- Costs, similar to MDA programs, for monitoring impact, and the effect on transmission

Part 3. References

The following references provide additional information specifically relevant to DEC-fortified salt programs:

Sullivan K, Houston R, Gorstein J, Cervinskas J, 1995. Monitoring universal salt iodization programmes. *UNICEF/PAMM/MI/ICCIDD/WHO.*

This document provides detailed information used in establishing salt iodization programs. Sections include:

- Salt situation analysis
- Legal issue review (for iodine only)
- Cluster survey methods
- LQAS methods
- Monitoring, including forms

At: http://www.micronutrient.org/Salt_CD/4.0_useful/4.1_fulltext/pdfs/4.1.2.pdf

World Health Organization, 2000. Preparing and Implementing a National Plan to Eliminate Lymphatic Filariasis, WHO/CDS/CPE/CEE/2000.15

This document should be available to all LF Program Managers, and provides a comprehensive review of establishing an LF program. The manual does not provide detailed information on DEC-fortified salt programs. The sections include:

- Overall program development
- WHO recommendations for doses for mass pill distribution
- Establishing sentinel sites for baseline and other monitoring
- Reference material

At www.filariasis.org in the Information Resources – Documents – Scientists section.

Houston, R. Salt fortified with diethylcarbamazine (DEC) as an effective intervention for lymphatic filariasis, with lessons learned from salt iodization programmes. Parasitology, Vol 121, Supplement, 2000.

Historic review of DEC salt studies from 1967

At www.filariasis.net in the Library – Antiparasitic Drugs section.

Meyrowitsch DW, Simonsen PE, 1998. Long-term effect of mass diethylcarbamazine chemotherapy on bancroftian filariasis: results at four years after start of treatment. *Trans Royal Soc Trop Med Hyg 92:* 98-103.

Summary of controlled trial comparing DEC salt with mass drug administration of various doses, including graphs of decline in microfilaremia prevalence and density.

Other Sources of Interest

Articles available on www.filariasis.net

Fan PC. (1990) Eradication of bancroftian filariasis by diethylcarbamazine-medicated common salt on Little Kinmen (Liehyu district), Kinmen (Quemoy) Islands, Republic of China. *Ann Trop Med Parasitol.* 84(1):25-33.

Fan PC, Peng HW, and CC Chen. (1995) Follow-up investigations on clinical manifestations after filariasis eradication by diethylcarbamazine medicated common salt on Kinmen (Quemoy) Islands, Republic of China. *J Trop Med Hyg*. 98(6):461-4.

Freeman AR, Lammie PJ, Houston R, et al. (2001) A community-based trial for the control of lymphatic filariasis and iodine deficiency using salt fortified with diethylcarbamazine and iodine. *Am J Trop Med Hyg* 65(6):865-71.

Gelband H. (1994) Diethylcarbamazine salt in the control of lymphatic filariasis. *Am J Trop Med Hyg*. 50(6):655-62.

Houston R, Lapointe M, Lammie P, Freeman A, and D Addiss. (2003) The role of salt in global elimination of lymphatic filariasis.

Lui J, Chen Z, Huang X, and Z Tu. (1992) Mass treatment of filariasis using DEC-medicated salt. *J Trop Med Hyg*. 95(2):132-5.

Other Articles

Ottesen EA, Duke BO, Karam M, and K Behbehani. (1997) Strategies and tools for the control/elimination of lymphatic filariasis. *Bull World Health Organ*. 75:491-503. (on www.filariasis.org in Information Resources – Documents – Scientists section)

Hawking F and RJ Marquez. (1967) Control of bancroftian filariasis by cooking salt medicated with diethylcarbamazine. *Bull World Health Organ.* 41:405-414.

Part 4. Appendices

Appendix 4.1 Conducting a Salt Situation Analysis

Gathering Existing Information

The first step in performing a salt situation analysis is to gather existing information. This should involve discussions with UNICEF to determine whether such an analysis has already been completed and to review the experience with salt iodization. There may be adequate information available on current salt distribution patterns and on current fortification to make further inquiry unnecessary. These discussions also will help identify key producers who have been active in the iodization effort.

Domestic Salt Production

It will be important to open a dialogue with the key producers, even if these producers do not necessarily supply salt to all the endemic areas. The larger producers, particularly those involved with salt iodization, will have reviewed market issues on packaging, price and the most efficient distribution channels. In addition, if they are iodizing salt, they will have information on fortification technology and can help determine how difficult it would be to include DEC for some production batches. It may be useful to meet with several key producers in different parts of the country to determine what the existing situation is with regard to current production of fortified (iodized) salt, and the capacity of the industry to respond to DEC-fortified salt needs.

Foreign Salt Production

The situation is different for countries that do not produce salt, but import it from other countries. In some instances, the law requires that imported salt be iodized. In other instances, raw salt is imported and iodized in country. These situations pose different constraints to production of DEC-fortified salt. If the fortification is done out of the country, it will be necessary to work both with the key salt importers and the foreign producers to produce a double-fortified product. If fortification is done in country, it will be easier to work with the companies (or government agency) responsible for this fortification.

Information on Production

First, it will be important to identify where fortification can take place to ensure DEC-fortified salt availability to endemic communities. While iodization usually occurs just prior to packaging at the production site, in some instances iodization is done at a more centralized site which iodizes salt produced by many smaller producers. In reviewing the salt production situation in the country, it is important to know whether most at-risk communities use salt produced by larger facilities that currently iodize salt, or whether there are at-risk communities that use salt produced by local merchants that may not iodize the salt. In the former situation, it should not be difficult to substitute a DEC/iodate pre-mix for the currently used iodate pre-mix. In the latter situation, it may

be difficult to change the customary habits of the at-risk communities--that of using locally produced salt which may be sold as small quantities from an open container, and not packaged.

Second, it will be helpful to review the techniques currently used for iodization, including whether a dry or wet mix method is used, what iodine compound is used, and whether there are other stabilizers or de-caking additives. Since DEC is very stable, and shown to be compatible with iodine, these issues are not likely to prevent production of DEC-fortified salt, but may influence the method used. For example, if the producer is using a wet mix method, a larger amount of water will probably be necessary to get the proper concentration of DEC, and this may affect either the speed of the mixing unit or the size of the spray nozzle. Having an understanding of the current iodization methods will be useful, as these details will need to be worked out for each production site.

Third, it will be essential to understand how the salt industry is organized. In some instances, salt production is government controlled. The government may control maximum salt price in the marketplace, creating a situation that alters the way that DEC-fortified salt is introduced and making subsidies easier to implement. Alternatively, salt production may be competitive, but the government may impose restrictions on imports, through import tariffs. If this situation changes over time, allowing imported salt to capture more of the market share, the fortification program will have to adapt. In other instances, salt production may be fully independent free market. All of this may affect the ability to work with producers to ensure availability of DEC-fortified salt to endemic communities.

Consumer Issues

While it is not important to know all the details of production for a DEC-fortified salt intervention, it is important to understand what is being provided in response to consumer preferences, and how this affects the potential for fortification. Traditional consumer preferences may influence the balance between more refined (and costly) salt and more traditional coarser salt. Salt iodization has tended to shift production toward a more refined product, since moisture content, crystal size and packaging all influence the stability of iodine in salt.

DEC is, if anything, more stable than iodine, and thus some of the concerns about packaging and storage for salt iodization are less critical for DEC-fortified salt. Salt that is managed properly for iodine (avoiding long storage periods or exposure to sun and rain) will be acceptable for DEC. While there is some concern about DEC settling in coarser moist salt (as is true for iodine), this can be overcome by packaging in small consumer packs (0.5 – 1 kg). Packaging and labeling are important also, because it will be important to distinguish DEC-fortified salt from salt containing only iodine.

Cultural practices in regards to salt usage are important to explore. Salt that is coarser and not completely clean may be traditionally washed at home, and this practice may

rinse most of the fortificant out prior to consumption. Even salt that is clean may be used in households in such a way that fortificants are lost. With iodine, there was some concern about storage in open containers near the stove, a practice that might increase iodine losses. Luckily the stability of DEC makes these practices less concerning, but washing does pose a risk of loss of effectiveness. Traditional use patterns may also need exploring. In some cultures, special salt may be used for certain things, and a fortified product may not be acceptable. Some cultures may have special needs (such a pickling) which may be perceived (correctly or incorrectly) as requiring normal unfortified salt. These practices may limit the actual consumption of DEC-fortified salt. The situation analysis should attempt to understand these traditional practices to determine if they might influence the effectiveness of a DEC-fortified salt intervention.

Salt Distribution and Pricing

Since all human populations have used salt for centuries, salt trade routes have a very colorful history--disruptions in these trade routes have influenced a multitude of historic events. Thus existing distribution patterns may have historic underpinnings or may simply reflect current demand and transport costs. Understanding the normal distribution patterns, particularly for iodized salt, is important in understanding the logistical difficulties in getting DEC-fortified salt to the endemic areas.

Wholesalers may play an important role in salt distribution, with the bulk of salt from major producers going to a number of warehouses for onward distribution to retailers. In some instances these distribution patterns, including distribution to retailers, are very stable. In such cases it is possible to identify both the wholesalers and producers supplying each endemic community quite easily, allowing a logistically simple system into which to add DEC-fortified salt. In other cases the distribution, even to and from wholesalers, is more reactive to individual retailer demands, which might vary dramatically from one production season to the next. In this case, there may be many wholesalers (and thus multiple producers) supplying a given endemic community and this could make supply of DEC-fortified salt logistically more difficult. Clearly this situation becomes even more complex if a portion of the salt used in the country is imported. Part of the salt situation analysis should thus review in depth the distribution pattern from wholesale to retail outlets, focusing on endemic areas.

It may also be possible to work directly with retailers. Depending on the number of endemic communities, this may involve substantially more human resources. However, if a larger producer has the capacity to produce DEC-fortified salt for a given set of communities, and if demand is created, retailers should not have difficulty ordering DEC-fortified salt to meet that need. Understanding transport costs and the pricing structure will be helpful in determining to what degree subsidization may be necessary for a DEC-fortified salt intervention.

It should be noted that the ultimate goal for most national salt iodization programs is to have demand for iodized salt support the costs for iodization. This will ensure

sustainability for the effort, allowing countries to move away from any subsidization necessary from the government or donor agencies. Currently UNICEF supplies much of the potassium iodate needed for salt iodization. With DEC-fortified salt the situation is different in that sustainability is of less concern. An effective DEC-fortified salt program, covering all endemic areas, may only need to be in effect for a few years. Thus the subsidy that may be necessary to ensure adequate DEC-fortified salt use may easily be justifiable on the basis of the savings incurred with elimination of filariasis.

Monitoring and Regulation

The situation analysis should also review what is currently being done to monitor the salt iodization program. A DEC-fortified salt intervention also will need to be monitored, and it may be possible to combine monitoring efforts. Monitoring should be done by producers as part of the production process. In addition, there should be some 'external' monitoring done by the government to ensure safety and quality. The situation analysis should review this system, including review of the laboratories in place and the sampling methods. More information on monitoring is provided in Section 2.8 in this manual.

The legislation and regulations pertaining to salt iodization may be interesting to review prior to implementing a DEC-fortified salt intervention. In many countries it took several years and a great deal of advocacy to get the political system to pass legislation either allowing or mandating salt iodization. It also took time to develop the implementing regulations. Iodine is usually considered a food additive (since it is a necessary part of the human diet) and thus food laws are used. DEC may be considered a pharmaceutical, and the laws governing addition of a medication to a food product may differ. In developing a government policy for DEC-fortified salt, it will be helpful to understand the process that may have been completed for salt iodization, as well as reviewing the pertinent laws governing medications in food.

Summary: Information to Review

A salt situation analysis in preparation for implementing a DEC-fortified salt program should review the following:

- Historical information and UNICEF documents on salt production and distribution, and salt iodization
- Salt production, processing, and distribution; the location of larger producers; whether salt is imported; and iodization methods
- Salt distribution from production to wholesalers to retailers
- Salt pricing, traditional use patterns, and consumer issues
- Government involvement in the salt industry, from price control, import restrictions, to role in iodization
- Monitoring, laboratory issues, legislation and the regulatory environment

Appendix 4.2 Brief Overview of Salt Production and Fortification Methods

Salt

Salt is a white crystalline compound of chlorine and sodium ions held firmly in a regular cubic structure. Salt has a characteristic taste, is used primarily to enhance the flavor of foods, and is essential for the regulation of ionic concentrations in the body. Numerous surveys have found that the per capita consumption of salt in household food is remarkably constant among countries and cultures, leading to its usefulness as a vehicle for micronutrients and additives.

The production and distribution of salt as a commodity has occurred for thousands of years. Today salt is manufactured using the following methods:

- *Solar or thermal evaporation of seawater*. The sea is a reservoir of trillions of tons of salt and more than seventy-five countries in the world have solar salt facilities.
- *Mining of underground salt deposits*. The salt is obtained by either the traditional method of manual or mechanical excavation or by solution mining that uses hot water to dissolve the salt underground into "brine" which is then evaporated into salt at the surface.
- *Mining of surface deposits of salt*. This can have varied degrees of sophistication.

Food consumption accounts for only 25% of total salt use, and direct household salt consumption a fraction of that. Most of the salt manufactured today goes toward industrial use as an important raw material in the chemical process industry and the deicing of roads.

Salt Manufacturing Process

Salt for household consumption is processed from crude or raw salt using a number of methods. This results in a product that varies considerably in sophistication depending on the country and the market. At the high end, salt is packed in fancy containers with spouts and dispensing mechanisms with free-flowing salt of extreme whiteness and regular particle size. In the medium range, salt is packed in plastic sacs of varying weight and the salt is white to off-white in color with varying levels of granulometry and humidity. At the low end, salt is marketed in bricks or coarse particle size of brown or yellow color and may only be 60% to 80% pure with a high humidity level of 3% to 5%. *The fortification of coarse or brick salt or salt with a level of humidity greater than 2% and particle size greater than ¼ inch is not recommended.*

Crude salt is converted to table grade through three main methods, all of which can be used with fortification:

1. The Evaporative Refining of Salt

This method, usually employed in large-scale operations, is the most technologically advanced method of salt processing and produces salt of the highest quality. The production costs are high and the method requires relatively large amounts of energy. This method involves dissolving the raw or crude salt in water, purifying the resulting brine both physically and chemically and then evaporating the water and crystallizing the salt contained in the solution. The salt is of very high purity, regular particle size and extreme whiteness. This process is shown diagrammatically below.

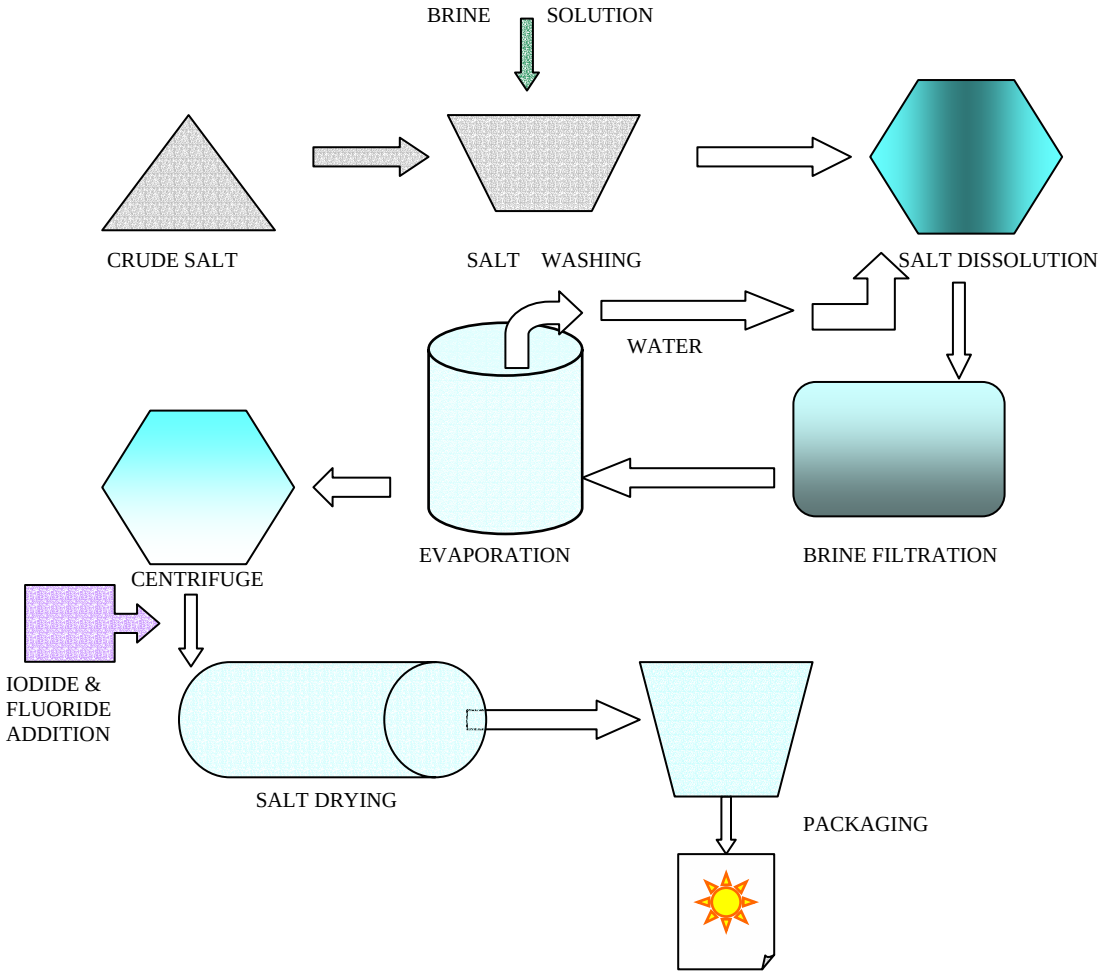

Fig 1: Salt Evaporative Refining Process

2. The Hydro-Refining Process (Wash, Mill and Dry Process)

This method is a less-expensive process for producing salt of reasonable quality. Crude salt is milled to reduce the particle size, washed free of dirt and most other physical impurities, and then dried to produce free flowing crystals. The salt has good particle size and color characteristics. Fortification of the salt with iodine, fluoride or DEC may take place either just prior to or after drying. The process is shown below.

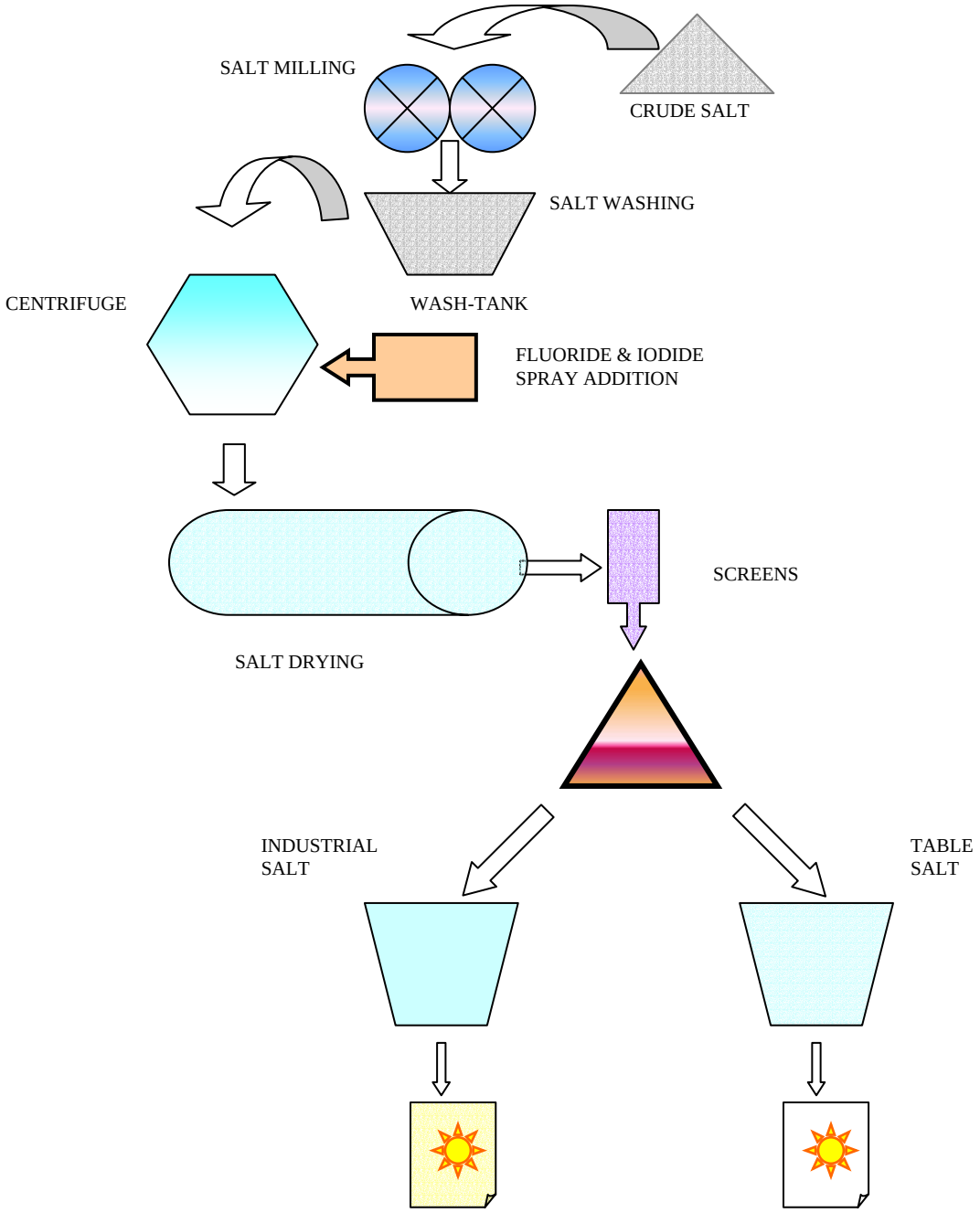

Fig. 2 Hydro-Refining Process

3. The Mill and Package Process

This method is the least technologically sophisticated process and results in salt of the lowest quality and greatest variability. In this process the salt is simply milled to reduce its particle size then packaged. Some variations of the process employ drying of the salt to reduce humidity. Depending on the salt quality, fortification may not be appropriate. If fortification is used, the additives are usually added prior to milling. The process is represented diagrammatically below.

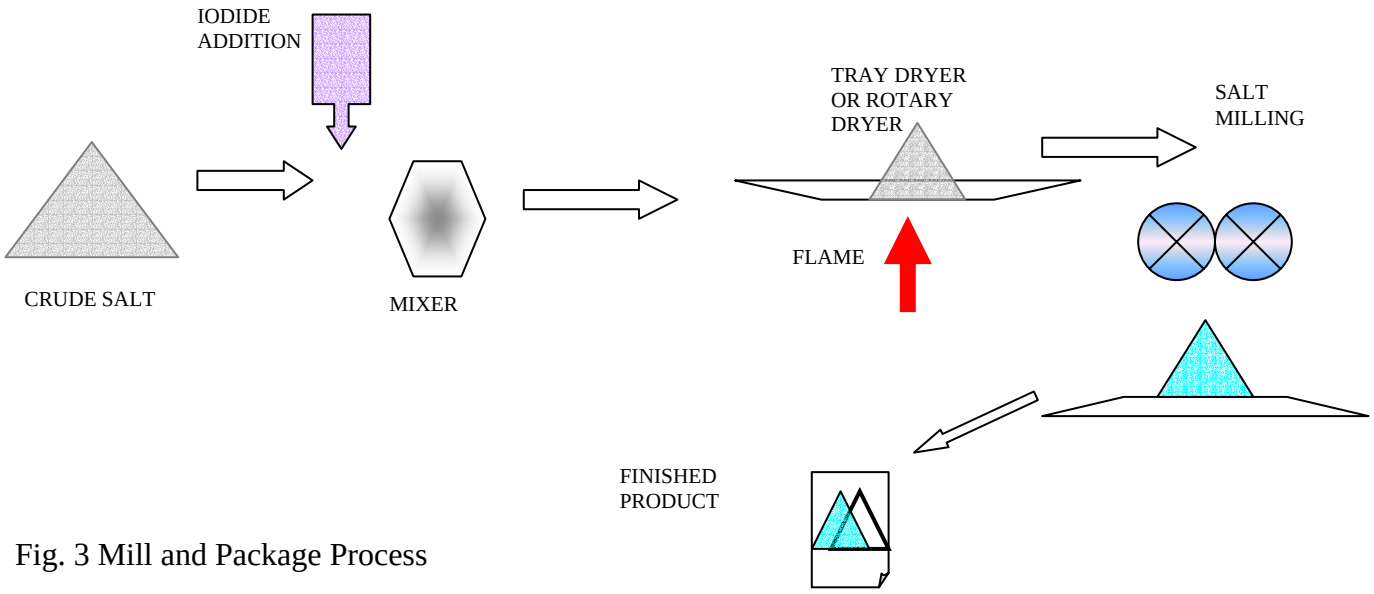

Fig. 3 Mill and Package Process

Summary of Methods

The quality of table salt varies widely due to the various methods used in production. The following table displays the expected range of values of the quality parameters of salt from the three methods described above.

Table 5. Quality Parameters of Salt from Three Processing Methods

DESCRIPTION	Evaporative Refining	Hydro-refining	Mill -Package
NaCl	99.8	99.25	90-95
Moisture	0.001	0.25	0.5-6
Water Insolubles	0.005	0.15	2-7
Calcium	0.01	0.05	0.1

Magnesium	0.05	0.10	1.0
Sulfate	0.04	0.20	1.0
Iron	0.0005	0.06	-
Color	Extreme white	White, off-white	Varies

Given the range of quality, it is critical to assess the salt available on the local market to determine whether it is appropriate for fortification, especially with respect to humidity and the degree of insoluble impurities. Salt of borderline quality may have to undergo more processing in order to be successfully fortified. If the salt is already being fortified with iodide and fluoride this indicates that the salt quality is such that DEC fortification may be incorporated into the existing fortification program.

Salt Fortification Process

The recognition of salt as a nearly ideal vehicle for fortification has seen the increased and proposed use of salt to transport a host of micro-nutrients, such as iodine, fluoride and iron, and medicaments, such as DEC, to prevent and cure a variety of ailments. Salt has a number of properties that make it ideal for fortification including:

- Salt is consumed universally by all persons, regardless of race, class or social standing.
- Salt is consumed in nearly the same average proportion per person regardless of geographical area or cultural differences.
- Salt is inexpensive, in most places the lowest cost item on the shopping list.
- Salt is physically and chemically stable and does not react with a variety of other chemicals.

The addition of fortificants to salt is achieved by two basic methods, the dry and the wet methods.

Dry Method

This involves the dry mixing of the correct proportions of salt and the desired forticant. A variety of mixers may be used, such as screw and paddle mixers, rotary mixers, drum mixers and inverted cone mixers.

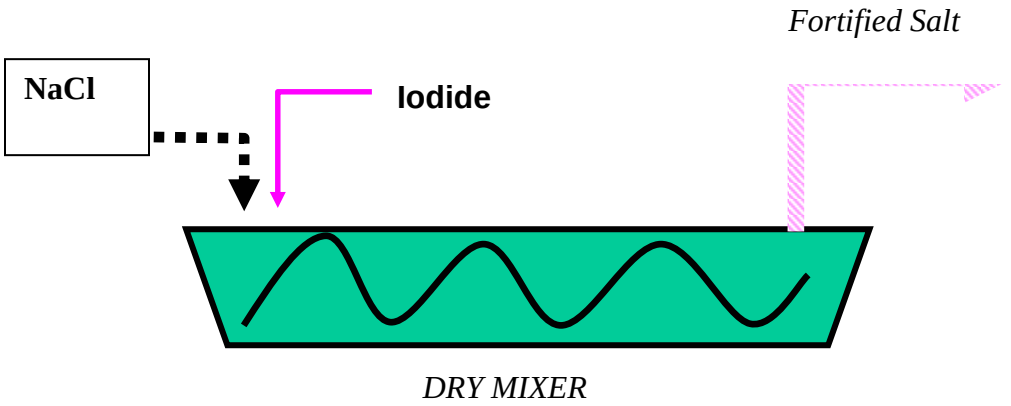

Fig. 4 Dry Method of Salt Fortification

The advantage of the dry method is that it may be scaled to very small production quantities. In addition the equipment required is relatively inexpensive and readily available. There are no complex control mechanisms and accurate dosage may be achieved by the proper weighing of the ingredients, the use of a premix, and sufficient mixing times.

The table below shows the quantities of salt, potassium iodate, potassium fluoride and DEC required to mix 1 ton of salt to produce a finished fortified salt product of specifications 50ppm I, 200ppm F, and 0.3% DEC.

Table 6. Formula for One Ton of Fortified Salt

NaCl (salt)	*KIO_3 (iodate)*	*KF (fluoride)*	*DEC*
997 kg	84.0 g	610.5 g	3,000 g
Target Conc.	50ppm I	200ppm F	0.3% DEC

Table 6 demonstrates a very important point. For a triple fortified salt, such as shown above, the desired final concentration of the fortificants means that considerably more DEC will be added than either KIO_3 or KF. The weight ratio of DEC to KIO_3 is more than thirty to one. This adds to the complexity of the fortification process, as care has to be taken to ensure the proper homogeneity of a mixture with such a wide variation in the quantities to be mixed.

One way to reduce these problems is to use a premix. This is simply an intermediate mixture of the ingredients so that the final desired mixture is achieved in two stages instead of one, ensuring better homogeneity.

The following combination of weights, listed in Table 7, is used to make 1 ton of a premix to be used 10 kilos at a time to make the final triple fortified salt with specifications identical to the one in Table 8. The total of all the ingredients weights, i.e. NaCl, KIO_3, KF and DEC, add up to 1000 kilos (1 ton).

Table 7. Formula for One Ton of Fortified Premix

NaCl (salt)	*KIO_3 (iodate)*	*KF (fluoride)*	*DEC*
630.6 kg	8400 g	61,050 g	300,000 g
Target Conc.	5000ppm I	20000ppm F	30% DEC

Now the premix has 100 times the concentration that is required in the fortified salt. To obtain the correct level of concentration in the fortified salt product requires mixing 1 weight premix to 99 weights unfortified salt. For example, to produce 1 ton of triple fortified salt (with 50ppm iodate, 200ppm fluoride, and 0.3% DEC) requires 10 kilos of premix and 990 kilos of unfortified salt.

Wet Method

The wet method involves making a wet solution of the forticant ingredients. This solution is sprayed at a controlled rate to a set flow rate of unfortified salt. The salt is then mixed well to ensure distribution of the fortification solution throughout the salt. The wet method is more amenable to large-scale continuous, mechanized production processes. Control of the finished concentrations is usually very good if all systems involved in the wet method are properly coordinated.

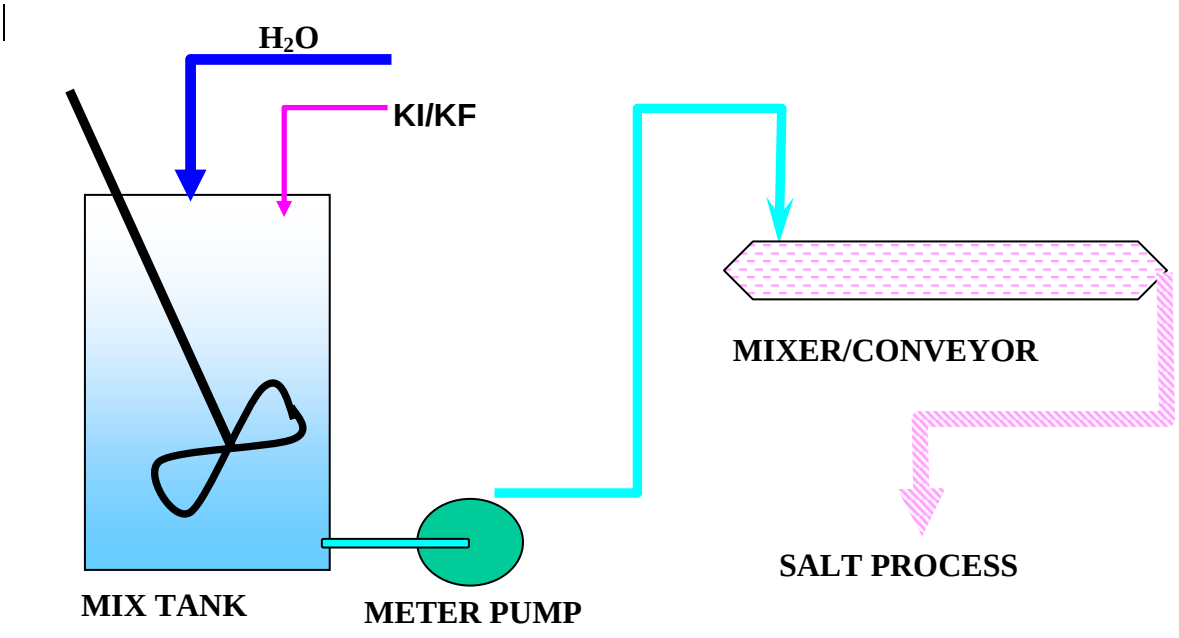

Fig. 5 Wet Method of Salt Fortification

Limitations to Proper Fortification

To be effective, salt fortified with DEC or any other fortificant should be uniformly covered with the fortificant and the level of fortification must remain stable for a reasonable period of time from production to consumption. The primary factor that can adversely affect the quality of fortified salt is the difference in particle size between DEC and salt and this can occur in both the dry and wet mixing methods.

Dry Method

In dry mixing, the situation is illustrated by two figures. The first figure represents appropriate relative particle sizes. During the dry mixing process this size difference produces a product in which the ingredients are loosely attached to each other and are in the correct weight proportion for homogeneity.

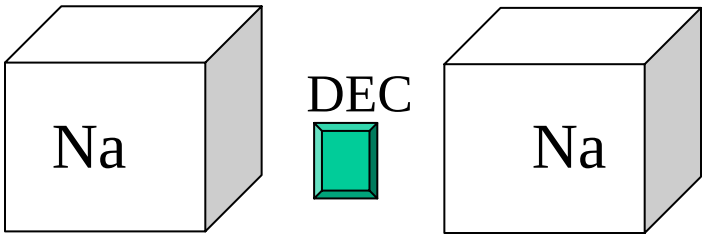

Fig. 6 Appropriate Relative Particle Sizes

The second figure illustrates a situation in which homogeneity cannot be attained or maintained for the desired fortificant concentration because the difference in particle size is too great.

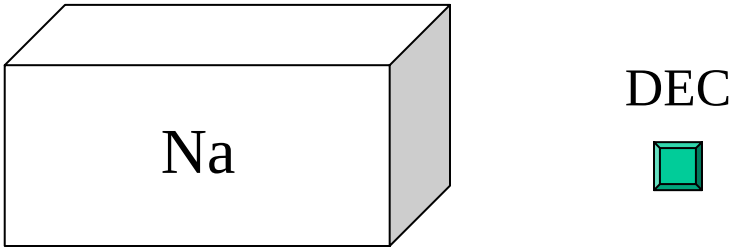

Fig. 7 Unsuitable Relative Particle Sizes

Although it is difficult to say with great precision what the size limits for proper fortification are, in general only salt of a fine to medium grade particle size is expected to be successfully fortified by the dry method with DEC.

Wet Method

The same holds true for the wet method. Given that smaller spheres have a larger surface area per unit mass than larger particles, the concentration of fortificant on smaller particles is larger per unit mass than on larger particles. Therefore, to achieve consistency of concentration the salt particles should be of a fairly consistent size.

Analysis of DEC

DEC in salt can be assessed using high performance liquid chromatography (HPLC) or spectrophotometric methods. The HPLC method is complex and costly, but the spectrophotometic method is feasible at production facilities. More information about these methods can be found in Appendix 4.3. However, quality assurance of the DEC content may be augmented with a non-analysis approach.

Essentially this requires that the DEC fortification process is performed correctly from the start. For both the dry and wet methods, the key to proper fortification is to ensure that the required proportion of fortificants to salt is maintained to a high degree of accuracy and precision, requiring accurate weighing out or measurement of flows of fortificants, fortification solutions and salt. This can be achieved in most cases.

In the case of the dry method, a simple batch record sheet as shown below is obligatory for proper quality assurance. The analysis of this sheet by supervision and monitoring authorities on a regular basis is essential.

ABC SALT FACTORY

Salt Dosing Batch Report.

Date……

Technician…….

Supervisor……

Target Finished Salt
50 ppm Iodide
0.3 % DEC

Batch #	Time	Weight of Salt (kg)	Weight of DEC (gm)	Weight of KIO3 (gm)	Calc Ratio		Iodine Analysis
					DEC/ Salt	KIO3/Salt	I
Target		996.9	3,000	84.0	3.001.	.0843	50 ppm

Comments……
……
……

Signed……

Fig. 8 Sample Salt Production Quality Control Report

Operational Aspects

Every effort must be made to make the dosing process as convenient as possible to the salt producers and technicians who perform and monitor the fortification process. This will ensure sustainability of the fortification operation and consistency of desired results. Remember, it is an unspoken rule in plant operations that "what gives problems doesn't get done". It is essential to listen to the needs and recommendations of the salt producers as they are most knowledgeable about the production process.

The personnel requirements for a fortification operation will vary depending on the plant sophistication and level of existing technology and process. For small-scale operations an additional person may be required to prepare the equipment each day, weigh out the ingredients, and record the batch processing. This person also could be required to take and label samples and perform iodine analyses. Additionally, he or she would be responsible for cleaning any equipment at the end of the shift and preparing for the next day's operation.

Appendix 4.3 Synopsis of Laboratory Methods for Analysis of DEC-Fortified Salt

Information on HPLC Methods

For more information on HPLC methods of analysis, please see the following article:

> Mathew N and M Kalyanasundraram. (2001) A high performance liquid chromatographic method for the estimation of DEC content in medicated salt samples. *Acta Tropica*. 80(2):97-102.

It is available on PubMed at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=PubMed.

Standard Protocol for Spectrophotometric Assays of Diethylcarbamazine (DEC) in Table Salt

Production of high quality DEC-fortified salt requires routine testing of different batches of the finished product at the level of the producer as well as at the Ministry of Health (MoH). At the producers' level, DEC levels in the fortified salt should be measured quantitatively at least once per day, using the adaptation of the Saker-Solomons Test described below. Qualitative testing of DEC, using 0.1% bromthymol blue, should be carried out more frequently.

The adaptation of Saker-Solomons test is based upon the extraction of DEC from an aqueous salt solution into chloroform containing organic soluble tetrabromophenolphthalein ethyl ester (TBPEE). The extraction of the DEC effects a change in pH of the chloroform-TBPEE solution causing color change in the (lower) layer from yellow-green to purple-red. The intensity of the purple-red color is proportional to the concentration of the DEC.

A) Preparation of reagents
   1. pH=8 phosphate buffer:
      Dilute 162.0 g of $K_2HPO_4 \cdot 3H_2O$ and 12.0 g of K_2HPO_4 to 500 ml with water.
   2. 0.025% TBPEE solution:
      Dissolve 25 mg of tetrabromophenolphthalein ethyl ester (available from Eastman Organic Chemicals, Rochester, NY, USA) in 100 ml of chloroform in a 125-mL Erlenmeyer flask. Shake the chloroform solution with 10 ml of 2N HCl. After the phases are allowed to completely separate, draw off as much as possible of the aqueous HCl phase with a disposable Pasteur pipette (it should be possible to remove all but 1 or 2 ml of the aqueous layer). Store the TBPEE-in-chloroform solution under an added 10 ml of pH=8 phosphate buffer. Prepare new stock solution weekly.

B) Preparation of the standards (0.1- 1.0% diethylcarbamazine citrate)

1. Weigh out DEC and salt as specified below and add them to labeled 200 ml volumetric flasks.

	DEC	Salt	DEC Concentration
Flask A	0 mg	10 g	0 %
Flask B	10 mg	10 g	0.1%
Flask C	25 mg	10 g	0.25%
Flask D	50 mg	10 g	0.5%
Flask E	100 mg	10 g	1.0%

2. Add distilled water to the line for each flask.

C) Preparation of unknowns

1. Weigh out 10 g of the salt samples to be tested and add each to a labeled 200 ml volumetric flask.
2. Add distilled water to the line for each flask.

D) Performance of the assay

1. Add into a round bottom, screw-capped tube
   a) 2 ml of 0.025% tetrabromophenolphthalein ethyl ester
   b) 1 ml of 1.5 M aqueous phosphate buffer, pH= 8
   c) 1 ml of DEC assay solution (see below)
2. Cap the tubes and rotate them 20 times by hand.
3. Allow the tubes to stand for 1 hour
4. Measure % transmittance at 565 nm
5. Convert % transmittance measurements to absorbance
6. Plot results for standards and compare absorbance of unknowns to standard curve

Use of the DEC-Fortified Salt Field Test Kit

There is a simple qualitative test for DEC in salt that uses a color change reaction. This test kit is not commercially available, and has not been fully validated to determine the exact content of DEC that it is capable of detecting. Since normal salt contains no DEC, a positive reaction to the test is indicative that DEC is present. The test kit will not determine whether there is too much DEC; therefore, this analysis would still need to be done by spectrophotometry or HPLC methods.

The test kit has not been formulated with stabilizers, and thus should be made up just prior to use, i.e. immediately before a household survey. The solution is a simple solution as follows: 0.1% bromthymol blue (weight for weight) in distilled water.

Appendix 4.4 DEC-Fortified Salt Household Coverage Survey Methodology

Overview

DEC-fortified salt programs will only be successful if there is adequate use of DEC-fortified salt in most households in endemic areas. A population-based, representative survey method will provide an accurate coverage estimate, and DEC-fortified salt programs rely on these as the means to determine the likelihood of program success.

The purpose of a population-based survey is to provide a coverage estimate that is statistically likely to be representative of the population sampled. The estimate does not depend on data aggregated from different distribution sites, and is thus not as subject to missing data, mathematical errors, or difficulties with estimating an accurate denominator from census figures. The sampling methods outlined here are virtually the same as those for a mass drug administration (MDA) program, except that a selection of households (not individuals) is made, and only one respondent from each household is questioned.

For MDA programs, coverage denotes the proportion of individuals having been dosed. For DEC-fortified salt programs, it is very likely that all members of a household will use the same salt, and thus coverage is based on the proportion of households in which DEC-fortified salt is being used.

Ideally, to get a representative sample of households in a given implementation unit (usually a district), all households should be listed, and a sample of these households selected at random. Since this usually is not possible, the best compromise is to ensure random selection of smaller areas within the implementation unit, and randomly select households from within these smaller areas. In order to do this, a smaller geographic area needs to be defined—and usually this represents a village, ward, locality or other administrative division of the district. To simplify analysis, the selection of these smaller units is done proportionate to population so that more populated areas are weighted accordingly. Thus the first step in this sampling methodology is to ensure random selection of sub-units within the IU from which a cluster of households will be selected.

Once these smaller sub-units have been selected, it is important to ensure that every household within the sub-unit has an equal likelihood of being selected for the survey. There are a variety of methods used to ensure this likelihood. The simplest is to randomly select a ‘starting household’ and then select contiguous households until the desired number of households has been selected. This is, in fact, selection of a cluster of households within the sub-unit. For some sub-units, it will be necessary to divide the sub-unit into a manageable size from which the households can be numbered, allowing selection of a ‘starting household’. This subdivision is also done using random selection techniques.

Finally, an individual within a household needs to be selected to serve as the respondent most likely to know what salt is being used in the household.

Methods

Selection of Implementation Units

The survey is done at the level of the implementation unit (IU), usually the district or administrative equivalent. Approximately 20% of all IUs should be surveyed. The districts to be surveyed can be purposively selected, in order to review IUs where the program is going well, and those in which there may be some difficulties.

The coverage estimate is representative of the IU being surveyed. While it is possible to sample individual IUs and combine results for a national estimate, this raises costs and complexity, and should only be undertaken with expert statistical advice.

Selection of Areas from which Clusters of Individuals will be Selected

For this protocol, within the selected survey area, 30 sub-units need to be selected. From each of these, a cluster of households will be selected. The ideal sub-unit is an administrative unit for which population figures are available. The sub-unit may be a village, a statistical enumeration area (used for census determination), a ward, or a locality.

These 30 sub-units must be selected randomly from among all sub-units within the IU. In addition, since different areas will have different populations, the areas need to be weighted to take these population differences into consideration. By weighting during selection, it is not necessary to weight the results during the analysis.

A step-by-step example of population proportionate sampling is given below. In order to do this method of sampling, the following are required:

- A clear definition of the sub-unit within the IU, including the ability to define its geographic boundaries when doing field data collection.
- A complete listing of all the sub-units within the IU, ensuring that no populated areas in the IU are excluded.
- Estimated population figures for each sub-unit.

Training of survey workers should emphasize the importance of adhering to random selection principles. Once a sub-unit or starting household is selected, it should be included in the sample. Substitutions invalidate random selection and easily lead to erroneous results. Attention to the quality of sampling methods both for areas and for households within these areas is critical to avoid questions and concern about data accuracy once results are tabulated.

Selection of Households Within A Sub-Unit

Once the 30 sub-units of the IU have been identified, enumerators will need to sample a cluster of households from each of those areas. For this protocol, 30 households will be selected from each, resulting in an overall sample size for the survey of 900 households.

In making the selection, all households must have an equal chance of being included in the survey. In practical terms, this is usually done by using methods to randomly select a 'starting household'. Only households that are occupied (currently serving as a residence, even though the inhabitants may be away) are considered in the sampling.

Ideally, households should be selected at random from a list of all households in the sub-unit. However, this is usually not possible, since such a list is not usually available. An alternative is to map all the households within the sub-unit, and maps may be available due to the work of other programs, such as the polio eradication effort. However, it is costly to create maps for the survey, and, if maps aren't available, alternative methods are recommended. If the sub-unit selected is so large that it is difficult to identify a starting household, it should be further divided. First divide the sub-unit into manageable areas with approximately the same number of households and then select one randomly. Continue by selecting the starting household within that area.

The most important issue is to have a practical mechanism that allows a 'starting household' to be selected at random, with all households in the area having an equal chance of being selected.

In order of preference, the following selection methods are recommended:

1) *Randomly select a starting household from a list of all households in the sub-unit.*

In this ideal but unlikely situation, perform a random selection of one household from the full list by selecting a random number between 1 and the total number of households listed. This defines the 'starting household'. Beginning with this household, sample consecutive households as noted in the section "Selection of the Cluster of Households" below.

2) *Randomly select a starting household from a map of all households in the sub-unit. The map should ideally be updated with a resident of the area who knows about recent changes.*

Maps may exist from recent DHS surveys, NIDs (immunization campaigns) or census activities. The map can be used to number all households and list them. From this listing, it is possible to again perform a random selection of 1 household to serve as the 'starting household'. Since consecutive households are sampled from this starting household, it will not matter if a few households are not on the list. However, if the map is grossly inaccurate, it should not be used.

3) *Divide the sub-unit into smaller units such as quadrants, and following random selection of one of these, develop a list of households within the smaller unit and randomly select the starting household.*

Step 1: Identify a central point within the sub-unit through consultation with a village leader.

Step 2: Visually divide the sub-unit into a smaller number of units (such as quadrants), each with roughly the same number of households.

Step 3: Randomly select one of these smaller units for household sampling.

Step 4: Number all the households in the selected smaller unit, and by selecting a random number between 1 and the total number of households, select the starting household. If the smaller unit or quadrant proves to be too large to number all households, it can be divided again into smaller areas with roughly the same number of households, repeating the process until a starting household can be randomly selected.

4) Randomly select a direction of travel, and after counting all households in that direction of travel, randomly select a starting household.

Step 1: Identify a central point within the sub-unit through consultation with a village leader.

Step 2: Spin a pen or bottle to randomly select a direction of travel from the central point If there are no households in that direction, change the direction clockwise until the first house in encountered. This becomes the new direction.

Step 3: Number all households that fall within this direction of travel from the central point to the boundary of the sub-unit. It is important to stick as closely as possible to the actual line of the direction of travel.

Step 4: Randomly select a number between 1 and the total number of households along the direction of travel, and use this as the starting household.

<u>Selection of the Cluster of Households Within the Sub-Unit</u>

Once the starting household has been selected, data are collected from one respondent in each of a 'cluster' of households closest to the starting household. Care should be taken in selecting the most appropriate respondent:

- The respondent should be someone who currently lives in the household.
- The respondent should be the person who does the majority of the food purchasing for the family, and thus is most likely to purchase the salt used by the household.

Once data have been collected from the respondent in the starting household, the next nearest household is selected, and data collected from the respondent in that household. This process continues until data have been collected from respondents in 30 households.

To select the next nearest household following the randomly selected starting household, the house whose entrance is nearest when exiting the starting household is chosen. If there is a path between the starting household and the next nearest household, and if the

path is to the right, that path is taken, and the nearest household along that path is selected. The next nearest household is selected in the same way, until 30 households have been included.

While the sub-unit selection and household selection are the same as for MDA programs, the questionnaire instrument will differ, and the enumerators will also be collecting salt samples for testing. When there are joint programs, with DEC-fortified salt used as an adjunct intervention following MDA program implementation, coverage surveys should be able to ascertain coverage for both programs. In this case, questions on receipt of a dose are asked of every family member, preferably before asking questions about household salt use. Dosing is determined for all individuals in the household, while salt use is determined primarily for the overall household, since in most instances salt is purchased for the household and used in cooking as well as table salt. While there may be some concerns about within-household use of salt, the most important indicator is the proportion of households using DEC-fortified salt.

Analysis

Currently, the recommendation for reporting MDA coverage is to report the total individuals dosed divided by the total population of the endemic areas. For DEC-fortified salt coverage surveys, the coverage estimate is based on the total number of households in which the respondent states that the household uses DEC-fortified salt, divided by the total number of households sampled.

It may be useful to enter the data into a spreadsheet or database to make sub-analyses easier, and to manage multiple coverage surveys over time. If additional questions are asked of individuals within households, such as knowledge, awareness, behavior or practice questions, computerization will be necessary, and this information may be valuable to review over time.

Population Proportionate Sampling Example

STEP 1: List all sub-units within the area or IU to be surveyed

Within the selected IU, make a complete list of all the sub-units from which the cluster of households will be selected. The list does not need to be in any particular order, but must include all the sub-units within the IU.

STEP 2: List the population for each sub-unit

In a column next to the name of the sub-unit, list its estimated population. The source of the population figure is not critical as long as the same source is used for each area. Usually census figures (with correction if the census is old) are used.

STEP 3: Calculate the cumulative population for the list of sub-units

In a 3rd column, successively add the population for each sub-unit, providing a cumulative population figure for the whole survey area. This can be done using a computer spreadsheet.

STEP 4: Calculate the sampling interval

To calculate the sampling interval, divide the total population for the IU by 30 (the total number of sub-units to be selected).

STEP 5: Randomly select the starting point

Using a random number table, select a number between 1 and the sampling interval, and record this in a 4th column.

STEP 6: Calculate populations from which to select subsequent sub-units

Add the sampling interval to the starting point, and record in the 4th column. Continue to add the sampling interval successively until the total population for the area is reached or exceeded.

STEP 6: Select remaining sub-units

Using the figures in the 4th column, determine if a sub-unit is to be included in the survey as follows: If the first random number (between 1 and the sampling interval) recorded in the 4th column includes the population of the first sub-unit listed (in the 3rd column), then that sub-unit is selected as the first of the 30 sub-units to be selected. If the random number is larger, then the first sub-unit in which the cumulative population includes this random number is selected as the first sub-unit.

Using the next number in the 4th column, determine the next sub-unit that is included in that number, and continue making selections until all 30 sub-units are selected. In some instances, a sub-unit will have a large population, and it is possible that it will be selected more than once. The table below shows an example of selection of areas using PPS methods.

Table 8. Example of Selecting Sub-Units Using PPS Methods

1	*2*	*3*	*4*	*5*	*6*
Sub-unit (village, ward)	**Population**	**Cumulative Population**	**Sub-Units selected**	**Random start plus sampling interval**	**Sampling interval calculations**
					Total population=37741 Total number of areas=30 Sampling interval = **1258** (37741/30)
1	480	480			
2	555	1035	1	718	
3	657	1692			
4	489	2181	1	1976	
5	367	2548			
6	456	3004			
7	1299	4303	1	3234	Random start = random number between 1 and 1258 For this example = **718**
8	345	4648	1	4492	
9	333	4981			
10	777	5758	1	5750	
11	888	6646			
12	675	7321	1	7008	
13	324	7645			
14	865	8510	1	8266	
15	567	9077			
16	756	9833	1	9524	
17	1234	11067	1	10782	
18	3465	14532	2	12040	
				13298	
19	567	15099	1	14556	
20	878	15977	1	15814	
21	898	16875			
22	909	17784	1	17072	
23	345	18129			
24	345	18474	1	18330	
25	556	19030			
26	675	19705	1	19588	
27	564	20269			
28	867	21136	1	20846	
29	933	22069			
30	967	23036	1	22104	
31	876	23912	1	23362	
32	347	24259			
33	879	25138	1	24620	
34	1266	26404	1	25878	
35	1244	27648	1	27136	

36	2134	29782	2	28394	
				29652	
37	467	30249			
38	234	30483			
39	266	30749			
40	188	30937	1	30910	
41	399	31336			
42	789	32125			
43	987	33112	1	32168	
44	867	33979	1	33426	
45	856	34835	1	34684	
46	745	35580			
47	679	36259	1	35942	
48	346	36605			
49	457	37062			
50	679	37741	1	37200	
			30		

Sample Questionnaire for Use with DEC-Fortified Salt
Household Coverage Surveys

Questionnaire and Enumerator Guidelines

Draft: January 20, 2004

Household identification *This provides basic information on the households selected*

District_____ Implementation Unit_____ Date: [___]/[____]/[____]
dd / mm / yyyy

Ward/Locality_____ Cluster number_____

Type of community: 1) Urban [___]
2) Rural

(Based on regional or district classification)

Name of head of household_____

1) Who usually purchases household staples like sugar or salt? [___]
   a) Mother
   b) Father
   c) Sibling
   d) Relative or maid
   e) Neighbor

(This question identifies the most likely respondent, the best person to answer the questions about household salt use.)

Address questions to the identified person if possible.

2) Respondent: [___]
   a) Mother
   b) Father
   c) Sibling
   d) Relative or maid
   e) Neighbor

3) Respondent education [___]
   a) No formal education
   b) Primary school
   c) Secondary school
   d) College/university

4) Respondent marital status [___]
   a) Single

b) Married
c) Divorced
d) Widowed
e) Separated

5) Number of children under 5 years old living in household: [___]
(Determine the number of children 6-59 months old living in household)

6) Total number of people living in household: [___]
(Include those having lived or planning to live for at least 1 month in the household.)

7) Before today, had you heard about lymphatic filariasis *(use local term)*? [___]
a) Yes
b) No

If no, go to question 13. If yes, continue with question 8.

8) What did you hear about it?
a) Causes 'bigfoot' [___]
b) Causes hydrocele [___]
c) Can affect children [___]
d) Spread by mosquitoes [___]
e) Other_____ [___]
f) Don't know [___]
(This question is designed to determine whether the respondent understands some aspects of lymphatic filariasis. Check all responses that the respondent mentions on their own. Do not prompt for responses.)

9) Where did you hear about LF?
a) Mass media (radio or tv) [___]
b) Print media (poster, leaflet, calendar) [___]
c) Health worker [___]
d) Neighbor or friend [___]
e) Community group member [___]
f) Other_____ [___]
(For this question, check all responses that the respondent mentions on their own. Do not prompt for responses.)

10) Were you happy with the information that you got? [___]
a) Yes
b) No
(This question tries to determine if the contact with the person was positive or the information from a poster was interesting and informative)

11) Do you think that LF infection can be prevented? *(Do not prompt)* [___]
a) Yes

b) No

12) If so, what can be done to prevent LF?
- a) Be dosed during MDA [___]
- b) Use DEC-fortified salt [___]
- c) Take traditional medicine [___]
- d) Apply topical remedy [___]
- e) Perform religious or other ceremony [___]
- f) Other_____ [___]

(For this question, check all responses that the respondent mentions on their own. Do not prompt.)

13) Do you have salt in the house today? [___]
- a) Yes
- b) No

If no, go to question 17.

If yes, ask the following: Can we see the salt that you are currently using for cooking and as table salt? Please show us all the types of salt you are using.

(Look at each type of salt, observing packaging, labeling, package size. If there is more than one type, ask questions about each.)

14) <u>Enumerator: If yes, describe the salt by checking the characteristic for each type</u>

	type 1	*type 2*	*type 3*
a) Iodized salt	[ ]	[ ]	[ ]
b) DEC-fortified salt (also iodized)	[ ]	[ ]	[ ]
c) Labeled non-fortified salt	[ ]	[ ]	[ ]
d) Unlabeled package	[ ]	[ ]	[ ]

15) How long ago did you buy this salt? *(Ask of each type)*

	type 1	*type 2*	*type 3*
a) < 7days	[ ]	[ ]	[ ]
b) 7 - 14 days	[ ]	[ ]	[ ]
c) > 14 days	[ ]	[ ]	[ ]

	type 1	*type 2*	*type 3*
16) Which is the type of salt you usually buy?	[ ]	[ ]	[ ]

17) If there is no salt in the household today, what type of salt do you usually buy? [___]
- a) Iodized salt
- b) DEC-fortified salt (also iodized)
- c) Labeled non-fortified salt

d) Unlabeled small package
e) Do not know

18) Do you normally buy salt in its original package, or in smaller repacked unlabeled plastic bags? [___]
a) Original package
b) Repacked unlabelled plastic bag

19) Have you ever heard of DEC-fortified salt? [___]
a) Yes
b) No

20) Have you used DEC-fortified salt in the past? [___]
a) Yes
b) No

21) If you are currently using, or have used DEC-fortified salt, how do you use it? *(Please read answers and check all that apply.)*
a) As a replacement for regular table salt [___]
b) As a replacement for regular cooking salt [___]
c) For certain foods only [___]
d) For certain family members only [___]

22) If you are currently using, or have used DEC-fortified salt, have you noticed any difference from using non-fortified salt?
a) Different taste or smell [___]
b) Different cooking characteristics [___]
c) Gave confidence that others wouldn't get LF [___]
d) Caused adverse side effect [___]
e) No differences noted [___]

(If household has salt in the house today, collect a small sample for analysis. Check below if sample was collected)

23) Sample was collected from this household [___]
a) Yes
b) No

24) Please note whether the sample is labeled?
a) Labeled as fortified with DEC and iodine [___]
b) Labeled but not fortified [___]
c) No label [___]
d) Home package or not packaged [___]

25) Do you intend to have your family use DEC-fortified salt in the future? [___]
    a) Yes
    b) No

(Thank the respondent, ask if there are any questions, label the salt sample and replace it if necessary.)

Appendix 4.5 Contact List for DEC Suppliers

PRE-QUALIFIED DIETHYLCARBAMAZINE CITRATE (DEC)
ACTIVE PHARMACEUTICAL INGREDIENT (API) MANUFACTURER
AS OF 1 NOVEMBER 2002

1. Syntholab Chemicals & Research

Administrative Office: 20/30 Shamaldas Gandhi Marg (Princess Street)
Mulchand Mansion,1st floor, Room Number 2,
Mumbai 400 002 INDIA
Telephone/FAX: 91 22 2205 5577 or 91 22 2208 8484 or 91 22 5635 7640
E-mail: syntholab@vsnl.com or syntholab@vsnl.net

- Mr. Sharad Shah's (partner) mobile phone: 98 200 71 727

Appendix 4.6 Checklist/Timeline for DEC-Fortified Salt Programs

YEAR ONE

_____ Update results of previous salt situation analysis OR complete a salt situation analysis, including holding meetings with importers, completing a retail market survey and identifying target producers.

_____ Convene a National Task Force.

_____ Complete a program workplan and budget.

_____ Assess current staff training needs and identify additional staff needs.

_____ Complete mapping in regions not previously tested.

YEAR TWO

_____ Build partnerships with salt importers and producers.

_____ Establish regulations on the fortification of salt by the producer as well as on the import and sale of DEC-fortified salt on the local market.

_____ Train and equip salt producers to fortify salt with DEC and iodine.

- _____ Orient producers/importers regarding LF and DEC-fortified salt.
- _____ Review equipment needs.
- _____ Review cost differential for packaging.
- _____ Establish packaging and labeling protocol, including development of a new label.
- _____ Identify DEC source, procure DEC and establish shipping strategy.
- _____ Initiate pilot production runs with QC.

_____ Establish a quality control laboratory to monitor DEC and iodine levels in fortified salt.

- _____ Establish sampling protocol for production and FDA.
- _____ Conduct combined lab training for producers and FDA.
- _____ Review lab capacity at FDA and producers, including equipment and reagent needs, etc.

_____ Develop IEC strategy to increase community awareness and to support morbidity component.

- _____ Implement a KAP survey regarding LF.
- _____ Initiate focus group discussions.
- _____ Identify health care personnel advocates and educate them re: LF and DEC-fortified salt.

_____ Produce educational materials for IEC strategy, including an advocacy fact sheet and a press kit.

_____ Train and mobilize community level advocates.

_____ Initiate mass media campaign for LF awareness and disability program awareness.

_____ Develop a marketing strategy to build demand for DEC-fortified salt, including the production of materials and messages.

_____ Conduct morbidity surveillance in conjunction with community mobilization effort.

_____ Train community health workers and other providers in the basic treatment of lymphedema.

_____ Establish community-level treatment and support groups for persons with lymphedema of the leg.

_____ Establish sentinel sites, collect baseline data on microfilaremia and antigenemia, prevalence and intensity of intestinal worm infections, and perform an entomological assessment.

YEAR THREE

_____ **Implement DEC-fortified salt strategy.**

_____ Monitor the distribution of fortified salt.

_____ Implement quality assurance testing at producers and FDA.

_____ Define coverage sampling strategy and evaluate drug coverage at the household level 6 months after program launch.

_____ Collect microfilaremia and antigenemia data at sentinel site to monitor progress one year after launch.

_____ Continue other programmatic activities, including lymphedema treatment, hydrocele repair and health education.

YEAR FOUR

_____ Monitor drug coverage and compliance, including a KAP survey.

_____ Identify spot check sites and implement surveys, collecting data on microfilaremia and antigenemia.

_____ Introduce training in lymphedema management into health curricula.

_____ Continue other programmatic activities, including lymphedema treatment, hydrocele repair and health education.

YEAR FIVE

_____ Monitor program in sentinel sites (full epidemiological assessments) and assess whether transmission has been interrupted, using entomological measures and by collecting blood from children less than 5 years of age and testing it for filarial antigen.

_____ Determine future need for fortified-salt distribution based on results of transmission assessment.