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DOUBLE FORTIFIED SALT (DFS)

**Background**

Iodine and iron deficiencies are commonly reported micronutrient deficiencies around the world. A deficiency in either micronutrient is associated with adverse health outcomes, poor cognitive development and decreased work capacity\(^1\). India faces a high burden of anaemia, and accounts for a large part of the global gap in the adequate iron status of populations. In India today, 53 percent of women age 15-49 years and 58.5 percent of children under 5 years of age are anaemic.\(^2\) There has been no significant reduction in anaemia over time, likely due to the low coverage of iron interventions. Conversely, India has made important progress to control Iodine Deficiency Disorders through salt iodization. As per the National Iodine and Salt Intake Survey (2014-15), adequately iodized salt (≥15 ppm) is available in 78 percent of households in India.

Double Fortified Salt (DFS) is an innovative and cost-effective way to use a single, ubiquitous food vehicle to deliver both iron and iodine to vulnerable populations.

**Salt as a vehicle for delivery of iron and iodine:**

An essential ingredient for food preparation, salt has an unmatched distribution platform with a uniform uptake amongst all income groups, including the poorest. Salt consumption is not affected by seasonal availability, and salt is consumed daily in small and regular quantities, making it an attractive vehicle for fortification. **The use of encapsulated Ferrous Fumarate (EFF)-DFS before, during and after cooking does not change the organoleptic properties of food.** Additionally, if the regional or national patterns of salt consumption or micronutrient deficiencies change, it is possible to adjust the levels of both iron and iodine at the production point.

Nutrition International (formerly the Micronutrient Initiative) and the University of Toronto joined forces more than 20 years ago to develop DFS, using EFF as a source of iron. EFF-DFS is essentially indistinguishable from the standard iodized salt and retains the nutrients in a stable and bioavailable form, as neither the iron nor the iodine interacts with each other or with the salt through production,
shipping, storage and cooking. When the salt is ingested along with food, the microencapsulation is mostly stable through the upper digestive tract and mainly available in the small intestine to maximize absorption and bioavailability of both iron and iodine.

**Government approval:**
In December 2014, the Food Safety Standards Authority of India (FSSAI) approved the alternative formulation of DFS through the use of EFF as source of iron. Prior to EFF formulation, FSSAI had approved the formulation of DFS with ferrous sulphate, which was developed by the National Institute of Nutrition, Hyderabad. In addition to approving the formulations for production of DFS, in 2018 FSSAI published the standards for fortification of DFS with minimum and maximum levels of fortification with iron and iodine.

The EFF-DFS production process is an “open source technology” which means any salt manufacturer can produce EFF-DFS following the production process below.

**Ingredient specifications:**
The specifications of the premix are:

- Ferrous fumarate: The iron source.

- Hydroxy propyl methyl cellulose (HPMC; INS No. 464): A water-soluble polymer, based on chemically modified cellulose. It is a functional food ingredient that is widely used as a binder during agglomeration. It is included in Table 3 of the CODEX general standard for food additives.

- Sodium hexametaphosphate (SHMP): A stabilizer for iron and a good chelating agent. Its primary role is to bind water, thus limiting the migration of iron and iodine ions. It is a common ingredient in food, often used as an emulsifying, stabilizing and thickening agent in products such as cured meat, infant formula, ice cream and cheese. Its use is permitted by the Code of Federal Regulations, US Food and Drug Administration.

- Titanium dioxide (TiO2; INS No. 171): A white colour masking agent. It is a food ingredient used as a white pigment in processed foods. In the premix,
it is used to add a white coating to the particles. It is included in the CODEX general standard for food additives.

- Soy stearine: The main component for encapsulation. It is solid, fully hydrogenated, refined soybean oil and a common food ingredient. It is water insoluble and acts as a water barrier, thus preventing interaction with the outside environment. In salt, soy stearine may be used up to a maximum level of Good Manufacturing Practices, as per CODEX standard 192-1995, under Food Category 12.1.1.

<table>
<thead>
<tr>
<th>COMPOSITION OF THE PREMIX USED TO GENERATE EFF-DFS COMPOUND</th>
<th>COMPOSITION (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agglomeration process</strong></td>
<td></td>
</tr>
<tr>
<td>Ferrous fumarate</td>
<td>46.8</td>
</tr>
<tr>
<td>Hydroxy propyl methyl cellulose</td>
<td>5.0</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>14.9</td>
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<tr>
<td>Sodium hexametaphosphate</td>
<td>3.3</td>
</tr>
<tr>
<td><strong>Encapsulation process</strong></td>
<td></td>
</tr>
<tr>
<td>Soy stearine</td>
<td>24.0</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>6.0</td>
</tr>
</tbody>
</table>

**Production process**

There are two components to the process technology in developing the premix (Figure 1):

1. Agglomeration (the granulation process): Binding, stabilizing, and colour masking ingredients are used to produce the agglomerated granules that include iron. The granulation process consists of fluidizing a weighed quantity of ferrous fumarate with warm air. The fluidized ferrous fumarate particles are then bottom-sprayed with a granulating solution consisting of water, HPMC, SHMP and TiO$_2$. The particles in the premix must have a particle size similar to that of salt grains to prevent segregation.

2. Encapsulation (the coating process): Microencapsulation technology is used to enclose the agglomerated ferrous fumarate granules, thus preventing reactions between the encapsulated material (iron) and the surrounding environment. The coating is made of a suspension of TiO$_2$ in a hot melt of soy stearine.
The EFF-DFS formulation requires only 98 percent NaCl. Therefore, EFF-DFS can be produced using almost all kinds of raw salt produced across the four major salt producing states in India (Gujarat, Rajasthan, Tamil Nadu and Andhra Pradesh).

**Organoleptic, acceptability and efficacy studies**

According to a study by Nutrition International (NI) in 2007, 85 percent of the consumers in Madhya Pradesh were willing to shift from regular iodized salt to EFF-DFS consumption and were willing to pay the additional cost of INR 2 per kilogram because of the understanding that EFF-DFS provides vital ingredients to fight diseases. In 2007, Khanna et al. investigated the acceptability of the EFF-DFS formulation in comparison to iodized salt and other experimental formulations in a three-month household consumption study. The study reported acceptability of all salt, though iodized salt was considered “best choice” due to its familiarity. Follow up sensory trials reported no major differences in food preparation and taste. However, the results of the study suggested further improvements in the colour, texture and overall appearance of EFF-DFS. These suggestions were addressed through various technological advancements and presently, **EFF-DFS is indistinguishable in taste, colour and smell from regular iodized salt.**

Efficacy studies using EFF-DFS have shown an improvement in iron status, and reduction in the prevalence of anaemia and iron deficiency among children in elementary schools. A study done among women of reproductive age consuming DFS in a community setting in India reported an improvement in cognitive function and a reduction in iron deficiency anaemia. In another efficacy study conducted amongst 212 women working as tea pickers in the Darjeeling district, it was demonstrated that after 9 months, the participants receiving DFS showed significant improvements compared with controls in haemoglobin (+2.4 g/L), ferritin (+0.13 log10 μg/L), soluble transferrin receptor (-0.59 mg/L), and body iron.
(+1.43 mg/kg), with change in status analyzed by general linear models controlling for baseline values. This study demonstrated that DFS is an efficacious approach to improving iron status and should be further evaluated for effectiveness in the general population.9

Cost
On a unit basis, the incremental production cost of adding iron to iodized salt is approximately INR 2-3 per kilogram, which is affordable for the majority of the population.

Scaling up production
The annual requirement of edible iodized salt is 6 million metric tons. However, the present EFF-DFS installed production capacity is only 10 percent of the total requirement. The increase in demand for this innovation will lead to an increased production capacity, which in turn will eventually reduce the production cost. The additional flow-through cost of EFF-DFS to the consumer would depend on the desired profit margin, or if via public systems, any subsidies.

Nutrition International’s support to promotion and scale-up of DFS in India
NI’s efforts to promote and scale up DFS in India started in 2004 with installation of DFS production facility support to the Tamil Nadu Salt Corporation (TNSC), a public sector undertaking company. The state government of Tamil Nadu procured the DFS produced by TNSC and used it in the preparation of hot cooked meals served under the Mid-Day Meal (MDM) Scheme (a school feeding program in India). An estimated 3.6 million schoolchildren in Tamil Nadu benefitted from this initiative.

In Madhya Pradesh, NI is currently supporting the state government in introducing DFS through the public distribution system (PDS) to reduce the prevalence of anaemia among women of reproductive age in 89 tribal blocks across 20 districts. An estimated 2.5 million women of reproductive age will benefit from this intervention.

NI is also supporting the state government of Gujarat to introduce DFS into Integrated Child Development Services (ICDS) programming across all 33 districts of the state. This initiative is expected to benefit 3.2 million beneficiaries across the state.
Moving forward, NI will continue to support the central and state governments in introducing DFS through public sector programs, including ICDS for preschool-aged children, adolescent girls, pregnant women and lactating mothers, MDM for schoolchildren, and PDS for people living below poverty line.

**Recommendations**

In India, the preference for staple foods depends on the geography; 65 percent of the population consumes rice and 35 percent consumes wheat flour. These geographical preferences do not apply to iodized salt/EFF-DFS. Salt is an inelastic commodity with sustained consumption throughout the year across all socio-economic backgrounds within India’s population; this makes salt an excellent vehicle for fortification. The four major salt producing states in India (Andhra Pradesh, Gujarat, Rajasthan and Tamil Nadu) have the capacity to produce EFF-DFS for the entire country, which will make national scale-up more effective. An estimated average salt consumption of 10g per person per day of EFF-DFS will provide 100 percent of the daily iodine requirement and approximately 30 percent of the daily dietary iron requirement. The consumption of EFF-DFS on a regular basis will address both the challenges of iron deficiency anaemia and iodine deficiency disorders, thus reducing the health burden and economic costs related to illness.

Based on the above, NI recommends that EFF-DFS be included in all social safety net programs addressing the dual deficiency of iron and iodine across the country.


8. Wenger M, Murray-Kolb LE, Nevins JEH, Venkatramanan S, Reinhart GA, Wesley A and Haas JD. Consumption of a Double-Fortified salt Affects Perceptual, Attentional, and Mnemonic Functioning in Women in a Randomized Controlled Trial in India. JNutr 2017; doi: 10.3945/jn.117.251587


18. Wenger M, Murray-Kolb LE, Nevins JEH, Venkatramanan S, Reinhart GA, Wesley A and Haas JD. Consumption of a Double-Fortified salt Affects Perceptual, Attentional, and Mnemonic Functioning in Women in a Randomized Controlled Trial in India. JNutr 2017; doi: 10.3945/jn.117.251587